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**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| IN RE INTEGRA LIFESCIENCES HOLDINGS CORPORATION SECURITIES LITIGATION | Case No.: 3:23-cv-20321-MAS-TJB<br><br>**CONSOLIDATED AMENDED CLASS ACTION COMPLAINT**<br><br>**JURY TRIAL DEMANDED** |

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Lead Plaintiffs San Antonio Fire and Police Pension Fund, Pembroke Pines Firefighters & Police Officers Pension Fund, City of Birmingham Retirement and Relief System, and Operating Engineers Construction Industry and Miscellaneous Pension Fund (collectively, "Lead Plaintiffs"), by and through their undersigned counsel, bring this action for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a), and Securities and Exchange Commission ("SEC") Rule 10b-5, 17 C.F.R. § 240.10b-5, against Integra LifeSciences Holdings Corporation ("Integra" or the "Company") and certain of its officers (collectively, "Defendants"). Lead Plaintiffs bring these claims on behalf of all persons or entities that purchased or otherwise acquired shares of Integra common stock between March 11, 2019 and July 28, 2024, inclusive (the "Class Period"), and were damaged thereby.

Lead Plaintiffs allege the following upon personal knowledge as to themselves and their own acts, and upon information and belief as to all other matters. Lead Plaintiffs' information and belief as to allegations concerning matters other than themselves and their own acts are based upon, among other things, the investigation of Lead Plaintiffs and their counsel, which includes, without limitation: (a) review and analysis of public filings made by Integra with the SEC; (b) review and analysis of press releases and other publications disseminated by Defendants and other parties; (c) review of news articles, shareholder communications, conference calls, and postings on Integra's website concerning Defendants' public statements; (d) interviews with former Integra employees and those of its vendors; (e) review and analysis of pleadings and other filings in or related to litigation against Integra, including *Krause v. Integra LifeSciences Corp.*, No. 0:24-cv-04339-LMP-ECW (D. Minn., filed Dec. 4, 2024) and *Myers v. Integra LifeSciences Corp.*, No. 1:24-cv-12461-FDS (D. Mass., filed Sept. 25, 2024) (the "Whistleblower Actions"); (f) consultation with industry and financial experts; (g) documents published by the U.S. Food and

Drug Administration ("FDA") and produced by the FDA in response to Freedom of Information Act ("FOIA") requests concerning extracellular bovine matrix ("EBM") products; (h) research reports by securities and financial analysts concerning Integra; (i) data reflecting Integra's stock price; and (j) review of other publicly available information concerning the Company, its manufacturing operations, regulatory compliance, and the Individual Defendants (defined below).

Lead Plaintiffs' investigation into the factual allegations contained in this complaint is continuing, and many of the relevant facts are known only by Defendants or are exclusively within their custody or control. Lead Plaintiffs believe that substantial additional evidentiary support will exist for the allegations in this complaint after a reasonable opportunity for discovery.

## I. INTRODUCTION

1. Integra manufactures surgical and wound care medical devices, and the Company's most lucrative product is regenerative surgical tissue or "biologic mesh." This case arises from Defendants' misrepresentations and fraudulent scheme to avoid incurring the substantial costs necessary to fix Integra's systemic, serious, and recurring violations of current Good Manufacturing Practices ("cGMP"), which are foundational FDA regulations governing product quality and patient safety in connection with the manufacture of the Company's biologic mesh. As has now become clear from the Whistleblower Actions filed by, *inter alia*, the Company's former Chief Quality Officer, Defendants' deliberate scheme to flout costly cGMPs was perpetuated by key members of Integra's "Executive Leadership Team," including its former Chief Executive Officer, and current Chief Legal Officer, Chief Compliance Officer, and President of the Tissue Technologies division.

2. For Integra, manufacturing these sterile, implantable devices in compliance with cGMPs was especially critical because, as products derived from bovine (cow) skins, they are particularly susceptible to bacterial and fungal contamination. Knowing that cGMP compliance

was key to Integra's ability to exploit this booming market, Defendants repeatedly assured investors that the Company "adheres to good manufacturing practices" and touted Integra's "numerous mechanisms and processes embedded within [its] business operations to protect and ensure product quality" and "compliance with all regulatory requirements."

3. When, at the start of the Class Period, FDA investigators found numerous cGMP violations at Integra's critical manufacturing facility located in Boston (the "Boston Facility")—its exclusive site for manufacturing biologic mesh—Defendants reassured investors that the Company undertook "significant efforts to remediate the observations," "that work is now complete," and "there are no patient safety issues here." And, facing increasing pressure to keep producing these lucrative products at a high pace, Defendants repeatedly confirmed that the FDA's findings did not preclude the Boston Facility from "running normal capacity," and even assured investors they were running the Boston Facility at ***overcapacity*** to produce enough "safety stock" to satisfy surging, pent-up demand for these products.

4. Throughout the Class Period, Defendants operated the Boston Facility knowing that it was at all times violating the same cGMP regulations. Notwithstanding, Defendants repeatedly assured investors that Integra was successfully remediating the serious deficiencies flagged by the FDA at the Boston Facility, was committed to cGMPs and established industry standards for quality assurance, and had built ample safety stock of marketable biologic mesh manufacturing at the Boston Facility.

5. Defendants' reassuring statements to investors were utterly and intentionally false. In truth, Defendants ***prevented*** remediation of the systemic and severe cGMP deviations the FDA had repeatedly flagged since its 2019 Warning Letter. Far from timely and adequately fixing these basic contamination issues that posed potentially life-threatening risks to patients, Defendants, in

a ***concerted effort*** to boost profits and avoid costly manufacturing stoppages, blocked any remediation that entailed significant cost or delay. Indeed, Defendants refused to implement numerous, specific corrective and preventive actions recommended made by employees, external auditors, and consultants alike. Instead, Integra instituted superficial "band aid" fixes, ignored complaints of cGMP violations, and silenced dissent. As one former Integra employee who witnessed and reported blatant cGMP departures at the Boston Facility for three years stated, Integra was "***the worst microbiological pharmaceutical company I ever worked at***." Another former Integra employee with a Ph.D. and extensive background in bacterial endotoxins was so disgusted by the Company's callous disregard of cGMP that he left Integra after only eight months and forfeited a lucrative signing bonus because he believed if he stayed, he would have ended up "***in jail or hell***."

6. Multiple sources confirm that, contradicting their statements to investors, Defendants knew that the pervasive cGMP violations at the Boston Facility were not being adequately addressed. Indeed, the corroborating accounts of ***twenty*** former Integra employees with percipient knowledge confirm that management and the executive leadership team held regular meetings during which the Boston Facility's cGMP deficiencies and ongoing FDA inspections were discussed regularly, yet no meaningful effort was made to remediate them, and ***no timeline milestone was ever met***.

7. These accounts were strikingly consistent and, together with two Whistleblower Actions pending in federal district courts, give rise to a strong scienter inference that Defendants intentionally defrauded investors when discussing the state of Integra's remediation efforts and the timetable for Integra's resumption of ordinary distribution of biologic mesh from the Boston Facility. A former Integra executive with national reach who participated in the executive

leadership's monthly and quarterly meetings described how, at these regular meetings, the heads of the Quality and Regulatory departments gave presentations about the Boston Facility's cGMP deficiencies to the Individual Defendants, including extensive reporting to Defendant Davis, the executive responsible for the Company's Tissue Technologies business. Yet, the Individual Defendants "***kicked [remediation] to the curb***" because they had resolved to do the "***least amount possible with the least amount of money***" to keep the Boston Facility in production and protect the "***very high-margin***" products manufactured there. Another former Integra executive who participated in these monthly meetings confirmed that the Boston Facility's cGMP deficiencies were routinely discussed and "***got a lot of attention right to the top***." Yet another former employee recounted that despite having "***a flashlight on [the Boston Facility] at all times,***" Defendants refused to perform any meaningful remediation because they had "***gotten away with this for this long.***" A senior R&D executive confirmed that, notwithstanding Defendants wholly positive statements to investors regarding their significant efforts and "enhanced rigor" at remediation, the Company came as close to the line on cGMP compliance because it was "***cheap***," adding that once the Company decided in 2021 to relocate operations from the Boston Facility to a new site, remediating the Boston Facility became a "***non-issue***."

8. Defendants' deliberate scheme to deceive investors and the FDA was anchored at the highest level of the Company. The Company's Executive Leadership Team purposefully kept the Quality Department in the dark about internal whistleblower reports concerning quality and safety issues at the Boston Facility and the Company's other manufacturing sites. Indeed, in violation of established Company policy and FDA requirements, the Company's former Chief Executive Officers ("CEO"), former Chief Legal Officer ("CLO"), Chief Compliance Officer ("CCO"), and other C-level officers and Executive Vice Presidents ("EVP") took deliberate and

closely-coordinated steps to sideline the Company's top Quality officials from being informed of internal complaints concerning critical contamination that impacted virtually ***all*** biologic mesh produced at the Boston Facility. Defendants' deliberate removal of the Quality Department from investigating internal whistleblower reports extended across the Company's manufacturing sites.

9. Remarkably, Defendants prevented Susan Krause ("Krause"), the Company's former Corporate Vice President and Chief Quality Officer, from being informed of and allowed to participate in the investigation of internal employee complaints concerning quality issues that directly impacted patient safety. Thus, in November 2022, Krause—***the Company's top official responsible for product quality***—belatedly became aware that Defendant Redondo, Integra's CCO, swiftly closed one such complaint made on an anonymous employee whistleblower hotline for "insufficient information," without even informing Krause. Immediately, Krause halted manufacturing at the Boston Facility and brought the issue to the attention of the FDA. Significantly, the internal whistleblower's complaint concerned potential contamination of ***37 lots*** of product—an extremely high number given the limited number of EBM products manufactured at the Boston Facility. However, rather than taking such complaints and the associated risk to patient lives and the Company's long-term viability seriously, Defendants retaliated against Krause and attempted to block her from complying with FDA directives.

10. Indeed, throughout the Class Period, Defendants, including then-CEO Jan De Witte ("De Witte"), then-CLO Eric Schwartz ("Schwartz"), and CCO Redondo interfered with Krause's repeated attempts to remediate the Boston Facility and comply with FDA directives, pressured her to put contaminated product back on the market, and demanded that she participate in unlawful and deceitful conduct directed at investors and the FDA. For example, while manufacturing at the Boston Facility was suspended in May 2023, De Witte instructed Krause to knowingly import

adulterated product, illegally relabel it for sale in the United States, and sell it into the national market. In addition, in March 2024, after Integra received yet another whistleblower report on its employee hotline concerning critical quality and safety issues, Integra leadership shared "few details about the information in the complaint" with Krause and told an employee on her Quality Department who was involved in the investigation to "not share any information about the report" with Krause. After Krause demanded and received over 100 pages of documents from "Integra leadership" that had previously been withheld from her, she confirmed "***over 40 quality issues that directly impacted patient safety***" and "***conclusive evidence of misconduct***," including "***falsification of records.***"

11. Ultimately, Defendants' deeply-rooted scheme to evade costly remediation and production stoppages was brought to an end when Krause and Thomas Myers, the Company's former Senior Director, Site Head of Quality Operations at the Boston Facility ("Myers"), rebuffed Defendants' intimidation, pressure tactics, and illegal directives and ensured that Defendants' scheme would be brought to the FDA's attention. These facts are set forth in remarkable detail in two wrongful termination lawsuits brought by Krause and Myers, the Company's two former senior-most officials responsible for quality at the Boston Facility. These Whistleblower Actions reveal how Krause and Myers exited Integra under extreme duress in the spring of 2024 as the wheels were coming off Defendants' scheme to bring production at the Boston Facility back online on an accelerated timetable that blatantly flouted any concern for cGMP compliance, product quality, or patient safety.

12. In the first Whistleblower Action, Krause asserts that Defendant De Witte and other senior executives "***actively engage[d] in a concerted effort to downplay quality control issues, avoid FDA regulations, and risk patient safety in violation of multiple applicable laws and***

***regulations***." Krause's complaint describes how this concerted misconduct permeated Integra's senior leadership and was part of an entrenched and toxic culture where the Company only implemented critical quality measures "***to the extent that it did not affect profit***." Krause's wrongful termination complaint demonstrates that, during her nearly three-year tenure as Integra's Chief Quality Officer (June 2021 to March 2024), Defendants De Witte, Schwartz, Redondo, and other senior leadership "***undermined her efforts to ensure safety and compliance at every turn***." Krause describes how Defendants "***repeatedly pressured***" her to disregard significant and potentially dangerous quality issues at the Boston Facility, and demanded that she provide information to the FDA that "***would have been false and required her to commit fraud***." When Krause refused, she was forced to resign on March 10, 2024. Amazingly, Krause specified at least three instances where she brought her concerns to members of the Company's Board of Directors, including the Chairman, who ***admitted*** they knew of Defendants' deceit but condoned it to prevent "***even more***" retaliation against Krause and other high-level employees who earnestly sought to bring the Company into compliance.

13. In the second Whistleblower Action, Myers similarly asserts that after reporting serious concerns regarding the manufacture, production, and distribution of contaminated product at the Boston Facility to Defendants in March 2024, Integra fired him. Myers' wrongful termination complaint describes how, exactly two-weeks after Krause's forced resignation, Integra fired Myers "effective immediately," after he: (1) implored Defendants that the Company's resumption of manufacturing at the Boston Facility "***needed to immediately shut down***" due to extensive, ongoing endotoxin contamination, but the Company's ***"senior leadership"*** refused to do so, and instead "***accelerated***" the manufacturing timetable; (2) disregarded senior leadership's directive to allow the manufacture of product known to be riddled with contamination to continue

using an unlawful, unethical, and dangerous "***cutting around***" process that Integra had surreptitiously employed for years; and (3) forced the issues to a head when he personally "***ordered the shutdown of manufacturing***" at the Boston Facility and notified the FDA's external compliance auditor. Importantly, Myers's actions "***ensur[ed] that the FDA would also be notified and Integra would not be able to bring the contaminated Products to market***."

14. These new, explosive allegations by the two former employees tasked with ensuring quality and safe manufacturing at the Boston Facility, confirm that Defendants' reassuring statements to investors about the Company's remediation efforts, quality assurance and cGMP compliance, and operating capacity at the Boston Facility were not only materially false and misleading, but made with fraudulent intent. As FDA investigators, the Whistleblower Actions, multiple internal whistleblower complaints, and many of the Company's own former employees from multiple levels and sites across the Company (including additional accounts corroborating the Whistleblower Actions' core allegations relevant to this case) all warned Defendants prior to and throughout the Class Period, the crucial Boston Facility was rife with pervasive, systemic, and serious violations of fundamental cGMPs in the same quality systems that Defendants specifically touted to investors. These egregious cGMP violations exposed the Company's products to heightened risks of deadly endotoxin contamination, exposed patients to life-threating illness, and exposed Integra to a host of even more dire consequences. Integra's failure to adequately monitor, control, and test for dangerous bacterial and fungal growth at the Boston Facility led to severe regulatory sanctions, crippling business disruptions, a massive "global recall" of all products manufactured out of the Boston Facility ***for more than five years***, and ultimately its complete shutdown.

15. These facts were gradually revealed to investors through a series of partially corrective disclosures at the end of the Class Period, which caused Integra's stock price to collapse, falling nearly 67% from its Class Period high and wiping out nearly $4 billion in shareholder value.

16. Integra's shareholders have been significantly harmed by Defendants' fraud. This action seeks redress on their behalf.

## II. JURISDICTION AND VENUE

17. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

18. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

19. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b), Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Integra maintains its headquarters in Princeton, New Jersey, which is situated in this District, conducts substantial business in this District, and many of the acts and transactions alleged herein, including the dissemination of materially false and misleading statements, occurred in substantial part in this District.

20. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchanges.

## III. PARTIES

### A. Lead Plaintiffs

21. Lead Plaintiff San Antonio Fire and Police Pension Fund ("San Antonio") was established in 1919 and provides comprehensive retirement, death and disability benefits for the

City of San Antonio's approximately 7,789 police officers, firefighters, retirees, beneficiaries and disabled. It manages roughly $4.2 billion in total assets as of December 31, 2024. As reflected in the certification previously filed with the Court, San Antonio purchased Integra common stock during the Class Period and suffered damages as a result of the federal securities laws violations and false and/or misleading statements and/or material omissions alleged herein.

22. Lead Plaintiff Pembroke Pines Firefighters & Police Officers Pension Fund ("Pembroke Pines") is a pension plan that administers retirement, disability, and death benefits for Pembroke Pines, Florida's police officers and firefighters. Pembroke Pines manages over $998 million in assets that it invests for the welfare of its members and their families. As reflected in the certification previously filed with the Court, Pembroke Pines purchased Integra common stock during the Class Period and suffered damages as a result of the federal securities laws violations and false and/or misleading statements and/or material omissions alleged herein.

23. Lead Plaintiff City of Birmingham Retirement and Relief System ("Birmingham") is a public pension system organized for current and former employees of the City of Birmingham, Alabama. Birmingham manages approximately $1 billion in assets for the benefit of its approximately 7,000 active and retired participants. As reflected in the certification previously filed with the Court, Birmingham purchased Integra common stock during the Class Period and suffered damages as a result of the federal securities laws violations and false and/or misleading statements and/or material omissions alleged herein.

24. Lead Plaintiff Operating Engineers Construction Industry and Miscellaneous Pension Fund ("Operating Engineers") is a retirement fund administered for the benefit of operating engineers and their dependents and beneficiaries in Western Pennsylvania and Eastern Ohio. Operating Engineers manages approximately $1.7 billion in assets for the benefit of its

approximately 17,000 active and retired participants and their beneficiaries. As reflected in the certification previously filed with the Court, Operating Engineers purchased Integra common stock during the Class Period and suffered damages as a result of the federal securities laws violations and false and/or misleading statements and/or material omissions alleged herein.

**B. Defendants**

25. Defendant Integra is a Delaware corporation headquartered in Princeton, New Jersey. The Company manufactures and distributes medical devices used in the fields of neurosurgery, and reconstructive and general surgery. As such, Integra is subject to extensive regulation by the FDA, and foreign regulatory agencies. The Company's shares trade on the NASDAQ under the ticker symbol "IART."

26. Defendant Jan D. De Witte has served as Integra's Chief Executive Officer and a director since December 2021. On February 28, 2024, shortly after Integra disclosed that it was suspending all manufacturing activities at the Boston Facility and recalling all products manufactured there for the preceding five years to address serious and longstanding regulatory compliance deficiencies repeatedly cited by the FDA, Integra issued a press release announcing De Witte's "intent to retire" as President and CEO by the end of 2024. The release stated that De Witte's departure from Integra was part of a "Leadership Transition Plan" and that a search for a successor to De Witte was underway. Integra's Chairman, Stuart Essig, was appointed as Executive Chairman, "effective immediately."

27. Defendant Peter J. Arduini ("Arduini") served as Integra's Chief Executive Officer and a director from January 3, 2012 to December 1, 2021. Before transitioning to CEO, Arduini served as the President and Chief Operating Officer ("COO") at Integra from October of 2010 to December of 2011.

28. Defendant Eric I. Schwartz served as Integra's Executive Vice President and Chief Legal Officer from November 12, 2018 to May 26, 2025. As the Company's CLO, Schwartz was responsible for the global legal, compliance, regulatory affairs, and corporate development functions. Prior to that, he served as General Counsel to a medical device company focused on spinal implants, and before that, as general counsel and assistant general counsel, respectively, of two other medical device businesses.

29. Defendant Glenn G. Coleman ("Coleman") served as Integra's COO from June 24, 2019 to September 23, 2022. As COO, Defendant Coleman was responsible for overseeing Integra operations and a majority of Integra's talent force, including manufacturing and quality. Prior to that, Coleman served as the Company's Corporate Vice President and Chief Financial Officer from May 2, 2014 to June 24, 2019.

30. Defendant Tracy Redondo has served as Integra's Vice President and CCO from May 2021 to the present. As CCO, Redondo is charged with enforcing compliance for the entire Company, including addressing all important compliance issues by discovering and resolving non-compliance operational issues to implement optimal corrective solutions aligning with relevant laws & regulations, and facilitating with audit finding remediations by training staff on best corrective measures. Redondo has been employed with Integra since June 2009.

31. Defendant Carrie L. Anderson ("Anderson") served as Integra's Executive Vice President and Chief Financial Officer ("CFO") from June 24, 2019 to February 2, 2023.

32. Defendant Robert T. Davis, Jr. ("Davis") is, and at all relevant times was, Integra's Executive Vice President and President of the Tissue Technologies division. He began his current role in March of 2020 and has also served as Corporate Vice President and President of the Orthopedics and Tissue Technologies division since December 2016. As Executive Vice President

and President of the Tissue Technologies division, Defendant Davis is responsible for the management of the division's regenerative tissue products. Defendant Davis's responsibilities include leadership of sales, commercial operations, regulatory affairs, quality assurance, manufacturing services and repair, and business development of the regenerative tissue portfolio of products. He previously served as Corporate Vice President and President of the Specialty Surgical Solutions division from November 2014 to November 2016. Before that, Davis served as the President of Integra's Neurosurgery Division from July 2012 to November 2014.

33. Defendant Lea Knight ("Knight") has served as Integra's Executive Vice President and Chief Financial Officer since June 2023. Before that, she served as the executive vice president of business finance for Booz Allen Hamilton.

34. Defendant Steve Leonard ("Leonard") has served as Integra's Vice President, Global Operations and Supply Chain since August 2020. Prior to that, Defendant Leonard also served as Senior Vice President Operations from May 2019 to August 2020.

35. According to Integra's SEC filings, including its most recent Proxy Statement to shareholders filed April 4, 2025, the Company's CEO "functions as our chief risk officer" and "is supported in this role by both our Chief Legal Officer and our Chief Compliance Officer, who reports to our Chief Legal Officer." As chief risk officer, Integra's CEO is responsible for, *inter alia*, ensuring "management provides periodic updates to the Board or Board committees regarding risks in many areas," including "legal, governance, legislative [], general compliance (including sales and marketing compliance), quality, regulatory, … operations and sales." "Both formal reports and less formal communications between the Board and our President and Chief Executive Officer derive from a continual flow of communication throughout the Company regarding risk and compliance."

36. Thus, during the Class Period, Defendants De Witte, Schwartz, Redondo, and their predecessors were the top officers at the Company responsible for overseeing, managing, and ensuring "a continual flow of communications throughout the Company regarding risk and compliance." Their decision to remove the Company's Chief Quality Officer from key processes for managing risk, and indeed instructing her to falsify risk levels for certain manufacturing sites, was antithetical to their essential purpose as the Company's senior risk team, and rendered their statements to investors materially false and misleading. Additionally, their conduct operated as a scheme to deceive investors regarding the true risk profile of the Company's biologic mesh manufacturing and marketing business.

37. Defendants Anderson, Arduini, Coleman, Davis, De Witte, Knight, Leonard, Redondo, and Schwartz are collectively referred to herein as the "Individual Defendants." The Individual Defendants, because of their positions with Integra, possessed the power and authority to control the contents of the Company's reports filed with the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, i.e., the market. Each of the Individual Defendants was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material, non-public information available to them, each of the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false and misleading statements pleaded herein.

## IV. PROCEDURAL BACKGROUND

38. Lead Plaintiffs file this Consolidated Amended Class Action Complaint ("AC") in response to the Court's determination in its June 30, 2025 Memorandum Opinion granting Defendants' Motion to Dismiss the Consolidated Class Action Complaint (the "CAC") (ECF No. 83) (the "Opinion"). The Opinion determined Lead Plaintiffs had adequately established that "Defendants clearly knew about the cGMP violations throughout the Class Period," but that the statements provided by fifteen former Integra employees ("FE") "do not plead with adequate detail facts that allow the Court to infer intent. It is not enough for Defendants to know about the violations—they must have acted with 'the intent to deceive, manipulate, or defraud' at the time the allegedly false or misleading statements were made." *Id.* at 27.

39. To address the Court's determination in the Opinion, the AC adds detailed factual allegations from the Whistleblower Actions, two wrongful termination lawsuits filed against Integra after the filing of the CAC by two of the Company's most senior officials responsible for quality control at the Boston Facility.

40. The AC also adds corroborating information sourced from numerous additional high-level former employees who worked at the Boston Facility and have firsthand, percipient knowledge of the facts and occurrences at issue in the Whistleblower Actions. Indeed, to the extent the AC relies in part on allegations from the Whistleblower Actions, Lead Plaintiffs undertook an extensive and thorough independent investigation of each of those facts alleged herein, including, *inter alia*, directly and personally confirmed the truthfulness and accuracy of the Whistleblower Actions in calls between counsel for plaintiffs in those actions and counsel for Lead Plaintiffs, and corroborating those allegations through interviews with former Integra employees before and after the filing of the Whistleblower Actions, and other facts learned throughout Lead Plaintiffs' investigation.

41. As alleged further below, Lead Plaintiffs' investigation since the CAC has uncovered additional facts confirming scienter for the Defendants named herein. These facts include directives by Defendant De Witte, Integra's former CEO, Defendant Schultz, Integra's former CLO, and other members of Integra's executive leadership: (1) routinely pressuring and instructing Krause, Myers, and other employees to provide false and deceptive information to the FDA and Integra's external compliance auditor; (2) routinely blocking Krause, the Company's top officer responsible for Quality, from timely receiving and investigating internal reports of safety and quality issues at the Boston Facility as well as the Company's other manufacturing sites; (3) routinely refusing to implement specific recommendations made internally and by outside consultants and auditors to timely and effectively remediate the cGMP violations repeatedly flagged by the FDA since the beginning of the Class Period; and (4) routinely silencing dissent, including firing or forcing the resignations of Krause, Myers, and many other high-level quality, safety, and compliance personnel who genuinely sought to address the pervasive and serious problems at the Boston Facility. These and other detailed facts uncovered in Lead Plaintiffs' investigation show that Defendants pursued a concerted, Companywide directive to prioritize profits and manufacturing output above patient safety, product quality, and regulatory compliance, while knowingly deceiving investors and the FDA when repeatedly speaking on these same topics.

42. The AC also (a) adds factual allegations explaining why Defendants' alleged misstatements where knowingly false or misleading when made; (b) supplements the scheme liability claims asserted under Section 10(b) of the Exchange Act and SEC Rule 10b-5(a) and (c) with the conduct alleged in the Whistleblower Actions and corroborated by other former Integra employees interviewed during Lead Plaintiffs' investigation; (c) otherwise clarifies the

intentionally misleading nature of Defendants' challenged statements, as alleged herein; (d) adds Schultz and Redondo as Defendants; and (e) removes Jeffrey A. Mosebrook as a Defendant.

## V. OVERVIEW OF DEFENDANTS' FRAUD

### A. Integra Acquires A Highly Profitable Biologic Mesh Portfolio Manufactured At A Legacy Boston Facility.

43. Founded in 1989, Integra is a medical device and technology company that develops and manufactures surgical instruments and regenerative tissue technologies.

44. In 2015, Integra sought to boost its revenue and profit growth by acquiring TEI, then an emerging producer of biologic mesh products used mainly for tissue reconstruction. The deal was designed to expand the reconstructive surgery and regenerative wound care portions of Integra's Tissue Technologies division—in particular, by acquiring the ability to produce TEI's popular and higher margin SurgiMend and PriMatrix EBM[1] devices. Indeed, in a press release announcing the closing of the TEI acquisition, Integra declared that the addition of the SurgiMend and PriMatrix EBM products created "a significant opportunity to build our platform and fuel a robust pipeline of regenerative products to accelerate Integra's overall growth." Integra further stated that it expected the acquisition "to be immediately accretive to our adjusted EBITDA and operating margins," with enormous gross margins of "about 80%."

45. As part of the acquisition, Integra assumed the lease of the Boston Facility, the exclusive manufacturing center for SurgiMend and PriMatrix. Located in South Boston, the Boston Facility was a converted, eighty-year-old school with a fragmented layout and antiquated equipment and infrastructure that presented numerous challenges to quality manufacturing.

[1] The Company's biologic mesh portfolio consists of collagen-based extracellular bovine matrix ("EBM"), a biodegradable, biologic mesh created from layers of fetal cattle skin tissue, which is then heavily processed to prepare, sterilize, and store the cattle dermis for subsequent implantation into the human body while still maintaining its structural integrity and bioactivity.

46. After the TEI acquisition and throughout the Class Period, Integra increasingly promoted its biologic mesh portfolio to investors as key to the Company's top- and bottom-line growth—in particular, the SurgiMend and PriMatrix brands. Integra invited leading plastic and reconstructive surgeons to investor events, such as Integra's Analyst/Investor Day in May 2021, where one such surgeon stated that, having used SurgiMend for over 11 years, "[t]here are really no other source materials" that "compete with" SurgiMend.

47. From the outset of the Class Period, investors were focused on the Company's ability to manufacture enough product to meet the strong demand for Integra's highly profitable biologic mesh devices, which boasted extraordinary profit margins of over 80%. For example, in 2019, Credit Suisse analysts reported that demand for PriMatrix and SurgiMend "remain[s] strong," and that Integra was "investing in expanding its manufacturing capacity for these products." Morgan Stanley likewise noted during the Class Period that "EBM is a high margin product," underscoring that "an impact to sales would [] have an outsized impact on earnings."

### B. Integra's Biologic Mesh Business Is Subject To The FDA's cGMP Regulations.

#### 1. cGMP Compliance Is Central To Integra's Business.

48. Integra is required to comply with FDA regulations governing the manufacture of medical drugs and devices, called cGMP. Integra's business, reputation, and ability to manufacture and sell its medical devices depended on its strict compliance with cGMP.

49. Device manufacturers must certify compliance with cGMP when seeking approval for new uses of their devices and must maintain compliance in order to continue to manufacture, market and sell them. Under federal law, medical devices are subject to the "adulteration provisions" of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") under Section 501, codified in 21 U.S. Code § 351. Under these regulations, a device is "deemed to be adulterated,"

i.e., out of compliance with federal law, if "the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable [cGMP] requirements." 21 C.F.R. § 351(h).

50. The FDA principally relies on these process-based regulations because it cannot test all finished devices in the United States. The FDA mitigates this risk by requiring that every product be manufactured in accordance with validated procedures. Underscoring the importance of validation, cGMP requires medical device manufacturers to validate each step in their manufacturing process, and to ensure they manufacture each of their products in the exact same validated manner. Any device manufactured using a non-validated procedure will be deemed "adulterated" by the FDA.

51. cGMP standards require device manufacturers to establish strong quality management systems and robust operating procedures, validate all testing procedures, control environmental conditions, prevent contamination, and detect and correct all quality deviations. These requirements are codified, in part, at 21 C.F.R. Pt. 820, § 820.70, *et seq*., and in additional guidance issued by the FDA. The regulations are designed "to ensure that finished devices will be safe and effective and otherwise in compliance with the [FD&C Act]." 21 C.F.R. § 820.1(a).

52. A core component of cGMP is that device manufacturers must develop a Corrective and Preventive Action ("CAPA") framework, a quality management system used to identify and rectify defects in manufacturing to ensure they do not recur. These requirements are codified in 21 C.F.R. § 820.100. As FDA guidance explains, the agency views CAPA as "[o]ne of the most important quality system elements" and "essential in dealing effectively with product and quality problems, preventing their recurrence, and preventing or minimizing device failures."

53. The FDA must also necessarily rely on testing and quality control data generated and furnished by regulated companies in making important public health decisions. Accordingly, "data integrity" requirements are a key element of the FDA's cGMP regulations. The FDA's data integrity requirements are designed to ensure that testing data is complete, consistent, accurate, and free from potential manipulation. The FDA insists on rigorous data integrity requirements because data integrity is essential to ensure that test data is neither lost nor manipulated and, therefore, that medical devices are safe and effective. As FDA guidance explains, "[d]ata integrity is critical throughout the [cGMP] data life cycle, including in the creation, modification, processing, maintenance, archival, retrieval, transmission, and disposition of data after the record's retention period ends."

54. The FDA's core cGMP requirement of data integrity prohibits "testing into compliance," which refers to the improper practice of successively re-testing products or manufacturing components that have failed analytical testing and inspection until passing results are obtained, without investigating the root causes of, or even reporting, the failing results. The FDA has long warned manufacturers that "testing into compliance" is a particularly serious violation of cGMP regulations and the scientific standards essential to ensuring consumer safety.

**2. FDA Enforcement Of cGMP Requirements And Violations.**

55. The FDA conducts periodic inspections of device manufacturing facilities to enforce compliance with cGMP requirements. At the conclusion of an inspection, the FDA holds a close-out meeting with company management and shares its observations, including any violations discovered during the inspection. If violations are discovered, the FDA will privately provide the manufacturer with a form entitled "Inspectional Observations," known as an FDA Form 483. The FDA will issue these Forms 483 "when an investigator[] has observed any conditions that in their judgment may constitute violations of the [FD&C Act]." 21 U.S.C. §

374(b). The "Observations" documented in Forms 483 "are made when in the investigator's judgment, conditions or practices observed would indicate that any … device … has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health."

56. Under FDA guidance, a Form 483 is "issued to the most responsible person available at the close of the inspection," with a copy "sent to the top management of the firm." The FDA will also prepare an Establishment Inspection Report ("EIR") providing the manufacturer with more detail on the inspectional observations in the Form 483.

57. Generally, the FDA does not publish or announce the issuance of Forms 483 or EIRs. The company receiving a Form 483 has an obligation to respond to the FDA's observations within 15 business days with a root cause analysis, impact assessment, and a set of corrective and preventive actions (CAPAs).

58. In cases where the FDA believes the manufacturer has failed to take adequate corrective and preventive action in response to a Form 483, the FDA may also issue a warning letter to a device manufacturer. Unlike Forms 483, the FDA regularly publishes warning letters on its website shortly after they are privately issued to the manufacturer.

59. Companies that violate cGMP requirements face severe sanctions from the FDA. If the FDA discovers serious, pervasive, and repeat cGMP violations, the FDA may order the company to take extensive remedial action that could require the company to cease operations in whole or in part, institute product recalls,[2] and implement expensive, time-consuming corrective

[2] Under FDA regulations, a manufacturer may characterize a product recall as "voluntary" as long as it promptly agrees to the FDA's recall recommendation. *See* 21 C.F.R. §7.46. Manufacturers who refuse the FDA's recommendation to self-initiate may be subjected to a mandatory recall and a host of severe regulatory repercussions. The FDA may remove a violative product from the

measures—just like those Integra was directed, and ultimately failed, to implement at its Boston Facility. Regaining the FDA's trust and remediating cGMP violations is invariably a difficult, time-consuming, and expensive process. Thus, a failure to adhere to cGMP requirements can have serious, potentially crippling effects on a company's ability to continue operations. Accordingly, given their critical importance to the Company's operations and the severe ramification of FDA enforcement, Integra's cGMP compliance is highly material to investors.

### C. Prior To The Class Period, The FDA Cited Integra For Severe And Pervasive cGMP Violations At The Boston Facility.

60. After the TEI acquisition and leading up to the Class Period, Integra investors were keenly focused on the Company's cGMP compliance at the Boston Facility, given its status as the exclusive manufacturing site for the Company's high-growth, high-margin biologic mesh portfolio. This focus intensified under increasing FDA scrutiny, including the agency's observations of widespread violations of fundamental cGMP at the Boston Facility. To quell investor concern, Defendants concealed and misrepresented Integra's compliance with cGMP at the Boston Facility throughout the Class Period, while minimizing the significance of any regulatory scrutiny.

#### 1. 2018 FDA Inspection.

61. In the fall of 2018, the FDA conducted a seven-day inspection of the Boston Facility, in which investigators discovered widespread and potentially dangerous violations of core cGMP requirements for preventing toxic bacterial contamination of its surgical tissue reconstruction products. The FDA detailed these findings in the 2018 Form 483 privately issued

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marketplace by withdrawing product approvals, seizing offending items, obtaining an injunction against sale or commencing criminal prosecutions or civil and criminal contempt charges, or imposing civil money penalties against the manufacturer. *See* 21 U.S.C. §§ 331(a)-(c); 21 U.S.C. § 333; 21 C.F.R. §800.55(i).

to Integra on November 2, 2018. The FDA further detailed these findings in a lengthy EIR privately issued to Integra on November 28, 2018 (the "2018 EIR," and together with the 2018 Form 483, the "2018 Inspection Reports"). As detailed below, the 2018 Inspection Reports cited Integra for gross deficiencies in its contamination controls, environmental controls, process validation controls, and CAPA controls relating to the Company's manufacturing of EBM products. Indeed, leaving no doubt that these were serious regulatory violations, the FDA subsequently cited them in a Warning Letter that the agency issued to Integra, as discussed below.

62. ***Contamination Control Violations***. At the Boston Facility, the FDA found serious and pervasive violations of the requirement to maintain adequate contamination controls—one of the most critical cGMPs to the manufacture of Integra's EBM products. Specifically, the FDA found that Integra was failing, on multiple critical levels, to test its supposedly sterile surgical tissue regeneration products for dangerous endotoxins, including wholly failing to test the water used to manufacture its products for bacteria. Indeed, the FDA found that Integra was violating seven different categories of cGMP relating to contamination control in myriad ways.

63. Remarkably, the FDA reviewed 35 EBM surgical device lots manufactured at the Boston Facility and found that ***a staggering 43%*** of those products initially failed endotoxin contamination testing because the testing returned "invalid assay" results, but that the products were repeatedly retested "with no documented justification" until they passed inspection. Significantly, the FDA further found that Integra never bothered to investigate ***why*** 43% of its products were failing critical contamination testing. These violations were particularly serious. Not only did they implicate Integra's highest margin products and directly affect patient safety, but the sheer rate of failures and retesting until a passing result was achieved demonstrated that either Integra's contamination testing system as a whole was deeply flawed or the Company was

actually committing data fraud by "testing into compliance." Either way, the implication of these findings was clear: Integra needed to revamp its entire contamination testing process from the ground up before it could safely manufacture products at the Boston Facility. Indeed, as a result of these gross, systemic failures, the FDA concluded that Integra "failed to mitigate the risk of bacterial endotoxin contamination" in the manufacturing of its EBM devices.

64. ***Environmental Control Violations***. The FDA's 2018 inspection further uncovered a host of sources of potential product contamination that could "reasonably be ***expected***" to cause product contamination at the Boston Facility. Among other things, the FDA found that Integra had failed to actually clean the Boston Facility's "Clean Rooms"[3] by appropriately disinfecting them—a fundamental cGMP requirement and one of the most important tools in combating contamination and maintaining quality and safety in the manufacturing of EBM devices. Moreover, Integra had failed to put in place proper monitoring and testing to determine whether these "Clean Rooms" were actually appropriately sterilized in the first place, or whether dangerous bacteria was present at specified levels. The FDA continued to cite systemic issues with Integra's process for monitoring contamination, again, making clear that not only would remediation require an overhaul of the Company's product testing process, but its entire system for monitoring contamination at the Boston Facility, as well. The FDA concluded that "[Integra's] ***manufacturing areas design is inadequate to prevent cross-contamination***" and "the firm ***failed to adequately establish procedures to control bacterial endotoxin contamination***."

[3] A "clean room" or "cleanroom" is used in the medical device manufacturing industry to manufacture products in an aseptic (sterile) or controlled environment. It is one of the most important tools in combating contamination and maintaining safety and quality in medical device manufacturing.

65. ***Process Validation Control Violations***. The FDA also found widespread violations of cGMP requirements to validate quality and safety testing processes. Again, the FDA found that these violations posed a particular danger to patients because Integra "failed to re-validate processes ***critical to quality*** or pose ***high risk*** to manufacture of EBM medical devices." And, again, many of the violations related directly to the risk of dangerous contamination of Integra's supposedly sterile surgical devices, including failure to validate testing for the sterility of both the Company's surgical products and the Boston Facility. Once again, the violations were pervasive—the FDA found violations of nine different categories of cGMP relating to safety testing validation—and further indicated that a broad overhaul to the Company's manufacturing processes would be required to remediate the issues.

66. ***CAPA Control Violations***. The FDA also found that Integra was violating cGMPs requiring the Company to properly investigate and correct known product safety and quality failures, including failures specifically related to contamination. For instance, Integra knew that its air quality control systems in the Boston Facility were inadequate to detect contamination with dangerous bacteria, and yet the Company failed to address the problem ***for an entire year***. The FDA highlighted that Integra continued to sell supposedly sterile surgical devices to patients despite knowing for an entire year that "there is no assurance that environmental sample analyses [conducted during that period] provided reliable results."

67. As another example, the FDA noted that a defect in Integra's manufacturing process caused significant tearing in EBM components—this defect was identified in 73% of the products inspected. Integra claimed it implemented a "fix," but the defect persisted. Rather than implement further remedial measures, as required by cGMP, Integra simply (and falsely) marked the issue as resolved. The FDA specifically stated that there was no legitimate reason for Integra to continue

to ignore the problem; instead, the FDA explained the Company's failure to address this defect "***was driven by a business decision***."

68. Not only did the FDA find pervasive and "repeated CAPA system deficiencies," it highlighted that, in prior inspections, it had already cited Integra for "[p]revious CAPA issues for deficiencies related to lack of timely execution and implementation." These pervasive violations clearly put Integra on notice that not only did the Company require an overhaul of its manufacturing processes, it needed to completely revamp its process for identifying safety and quality failures, remediating them, and ensuring that the remediation was effective. Yet, Integra continuously failed to address these issues and, as discussed below, concealed and then misrepresented them to investors.

* * *

69. In addition to presenting the above findings to Integra in the 2018 Inspection Reports, the FDA also discussed them with Integra management at a close-out meeting on November 2, 2018. The meeting was attended by several senior Integra executives, including the Company's Vice President of Quality Engineering and its Senior Manager of Quality Assurance, who was also Integra's "Management Representative" to the FDA, and who participated in the inspection, and received the 2018 Inspection Reports on Integra's behalf. In addition, the 2018 EIR states that Integra directed the FDA to send all related correspondence ***directly to Defendant Arduini***.

70. Significantly, Integra's Senior Director of Quality Assurance, John Giantsidis, sent the FDA correspondence following its 2018 inspection, in which he privately acknowledged that Integra management understood "the significance of the issues raised by FDA during the recent inspection" and admitted that "several of [the Company's] processes would benefit from control

improvements." Giantsidis's letters made clear that Integra's executive management had been apprised of the FDA's findings, writing that "Integra management has conducted a thorough review and evaluation of the FDA 483 Observations." Giantsidis reported to Integra's Vice President of Global Quality who, in turn, reported directly to Defendant Arduini.

**2. 2019 FDA Warning Letter.**

71. On March 6, 2019, mere days before the start of the Class Period, the FDA privately issued Integra the 2019 Warning Letter addressed to Defendant Arduini, later published on the FDA's website on March 19, 2019. The 2019 Warning Letter repeated the FDA's same scathing observations detailed in the 2018 Inspection Reports and further warned Integra that it was not taking sufficient action to correct those violations and prevent their reoccurrence.

72. The FDA's issuance of the 2019 Warning Letter was significant. The FDA issues such letters only "for violations of ***regulatory significance***, *i.e.*, those that ***may actually lead to an enforcement action*** if the documented violations are not promptly and adequately corrected."

73. The 2019 Warning Letter warned Integra that the "deficiencies observed during [the FDA's 2018] inspection ***are significant*** and ***demonstrate a systemic failure of your firm's quality systems***." The FDA notified Integra that its remedial measures were "***not adequate to address the [observed] violations***," and deemed the devices manufactured at the Boston Facility "adulterated." As a result, the FDA demanded that Integra "take prompt action to correct the violations addressed in [the 2019 Warning Letter]," and warned that "***[f]ailure to promptly correct these violations may result in regulatory action*** being initiated by the FDA without further notice."

* * *

74. Defendants received the 2019 Warning Letter on March 6, 2019. Knowing the FDA would publish the 2019 Warning Letter in short order, Defendants disclosed the 2019

Warning Letter to investors on March 11, 2019 (barely a week before the FDA's publication on March 19, 2019). But Defendants immediately downplayed the systemic cGMP violations documented by the FDA, assuring investors that the Company was effectively remediating the violations and doing so would not have a material impact on the Company's operations or financial performance. In truth, however, Defendants exploited the fact that the FDA's regulatory framework is primarily grounded in self-regulation. Because manufacturers have wide leeway to develop compliant practices and corrective actions specific to their product, Defendants chose to delay or avoid implementing costly or disruptive CAPAs and undertaking necessary remediation efforts, which would both erode the extremely high margins of Integra's EBM products and require at least a temporary closure of the Boston Facility and all manufacturing of product at that plant. Rather than sink costs into an old, small, dilapidated, and disjointed facility, Integra management instead secretly directed their efforts at searching for a new, state-of-the-art replacement plant for its EBM products.

### D. Throughout The Class Period, Defendants Falsely Assured Investors That They Were Remediating The Boston Facility, Complying With cGMP Regulations, And Would Continue Manufacturing Its Biologic Mesh Products At Capacity.

75. Despite the fact that the FDA explicitly demanded in the 2019 Warning Letter that Integra "take prompt action to correct" the widespread deficiencies at the Boston Facility or face "regulatory action … without further notice," Defendants were well aware that Integra had ***not*** undertaken any meaningful efforts to remediate these critical issues. To the contrary, Defendants minimized and concealed the impact of the FDA's findings on Integra's capacity to continue manufacturing EBM devices at the Boston Facility. Defendants recognized the 2019 Warning Letter had potentially disastrous implications for SurgiMend, PriMatrix, and the other high-demand, high-margin EBM devices manufactured at the Boston Facility, upon which the Company

relied to grow its revenues and boost its profits. Accordingly, even as the FDA continually warned Integra regarding the repeat and worsening cGMP violations at the Boston Facility, Defendants made a series of false statements assuring investors that they were successfully remediating the Boston Facility, complying with cGMP, and would continue manufacturing SurgiMend and PriMatrix at capacity at the Boston Facility. Crediting these statements, analysts reaffirmed the Boston Facility's remediation progress and its capacity to continue manufacturing SurgiMend and PriMatrix to meet existing and future demand.

76. ***First***, Defendants repeatedly told investors that Integra's remediation in response to the 2019 Warning Letter was proceeding as planned, and that Integra had successfully addressed the serious violations of fundamental cGMPs identified by the FDA at the Boston Facility—even as the FDA found additional, worsening deficiencies at the Boston Facility during the Class Period.

77. For example, on the first day of the Class Period, March 11, 2019—just five days after the Company received the FDA's 2019 Warning Letter—Integra filed a Current Report with the SEC on Form 8-K assuring investors that the Company had already undertaken meaningful actions to remediate the issues discussed in the Letter, would continue to doing so, and that the remediation would be financially inconsequential. Specifically, the Form 8-K stated that "since the conclusion of the [FDA] inspection, ***[Integra] has undertaken significant efforts to remediate the observations and continues to do so***." Additionally, Defendants downplayed the magnitude of the issues flagged by the FDA, emphasizing in the Form 8-K that the 2019 Warning Letter "***does not restrict the Company's ability to manufacture or ship products or require the recall of any products***," and underscoring that the violations were purportedly so insignificant and easy to fix that Integra "***does not expect to incur material incremental expense for remediation activities***."

78. Thereafter, Defendants continued to silence any concern regarding the 2019 Warning Letter and its potential impacts to the Company. For example, in early 2020, as demand for SurgiMend and PriMatrix increased, Defendants continued to assure investors that the Company was successfully remediating the deficiencies identified in the 2019 Warning Letter and that there were no impediments to Integra's ability to capitalize on the increasing demand for its lucrative EBM products. For instance, during Integra's February 19, 2020, Q4 earnings call, Defendant Coleman proclaimed that Integra had successfully undertaken "***quality remediation efforts throughout 2019***" underscored that Integra intended to complete those remediation efforts "***in the short term and then get the warning letter lifted in 2020***," and emphasized that "***there are no patient safety issues***" with those products.

79. Defendants made similar statements at multiple investor conferences, including assurances that the remediation work had been successfully completed, the Boston Facility was producing EBM devices that presented no issues to quality or patient safety, and that there was no cause for concern regarding the Company's cGMP compliance. For example, on May 20, 2021 at Integra's 2021 Virtual Investor Day, Defendant Coleman stated that "work" remediating the Boston Facility "***is now complete***," providing the Company with "***a manufacturing footprint that's … able to produce quality products***." Coleman emphasized that: "***The key takeaway here is we've strengthened our quality operating mechanisms and reduced quality risk with enhanced rigor and this has led to better FDA inspection results***."

80. Moreover, not only did Defendants continuously assure investors that meaningful remediation had been completed, and that the Boston Facility was producing safe and high-quality products, Defendants went out of their way to assure investors that the remediation would be financially immaterial. Indeed, in every quarterly report on Form 10-Q that the Company filed

with the SEC between April 29, 2019 and November 2, 2021, Defendants told investors that Integra "***does not expect to incur material incremental expense for remediation activities***."

81. On February 24, 2022, Defendants disclosed in Integra's 2021 Annual Report that the FDA had initiated an inspection of the Boston Facility in October 2021 and issued a Form 483 at the conclusion of the inspection in November 2021. However, throughout the remainder of the Class Period, Defendants continued to assuage any concern regarding the FDA's observations, falsely assuring investors that all issues identified by the FDA were actively being remediated. For example, during an April 26, 2023 earnings call, Defendant De Witte stated that "***we've been working for the past couple of years to upgrade our Boston facility based on FDA observations in 2018 and 2021***," and that the Company "***had an audit early in March that confirms we're on the right track with our execution***." Similarly, on July 27, 2023, Defendant De Witte again assured investors that "***we have no specific indications of any product complaints related to high endotoxin levels***," that "***[p]atient safety is non-negotiable for us***," and that Defendants were "***highly focused on our remediation efforts***" and "***fully expect[ed] to complete the remediation***" in short order. Defendants repeated similar assurances to investors during subsequent investor conferences and SEC filings in 2023 and 2024.

82. Defendants' representations were utterly false and misleading. Contrary to Defendants' repeated representations to investors, senior management was deliberately ***not*** undertaking meaningful efforts to address the pervasive cGMP departures at the Boston Facility, choosing instead to institute superficial fixes rather than incur the significant efforts and costs necessary to adequately remediate the numerous deficiencies observed by the FDA. Lead Plaintiffs' investigation (discussed below) has confirmed that, rather than sink resources into the Boston Facility, management decided no later than 2021 to abandon any meaningful or costly

improvements to remediate the Boston Facility and to shift all production of EBM products to a different facility.

83. ***Second***, Defendants made a host of statements to investors throughout the Class Period touting Integra's cGMP compliance, including its internal mechanisms and processes to protect and ensure product quality for consumers, as well as the Company's "significant" investments in quality.

84. For example, on September 30, 2022, the Company disseminated to investors its inaugural Environmental, Social and Governance Report for 2021 ("2021 ESG Report"), which highlighted Integra's deep commitment to producing high quality and safe medical devices that were fully compliant with cGMP—and, indeed, met "all regulatory requirements." Specifically, Integra's 2021 ESG Report represented that Integra had "***numerous mechanisms and processes embedded within [its] business operations to protect and ensure product quality, continuously improve the effectiveness of our quality management system, and ensure compliance with all regulatory requirements***." The 2021 ESG Report unequivocally represented that Integra "***adheres to good manufacturing practices (GMPs), [and] quality system regulations (QSRs)***."

85. On August 17, 2023, Defendants issued a similar Environmental, Social and Governance Report for 2022 ("2022 ESG Report") that went even further, assuring investors that Integra's continually improved its quality systems to ensure its medical devices met the very highest and most current cGMP. Specifically, the 2022 ESG Report stated that "***product safety and quality are paramount***" to Integra, and thus the Company "***continuously improves our Quality Management System (QMS) to meet the highest and most current quality standards***."

86. Defendants issued similar statements assuring investors of Integra's commitment to cGMP compliance during multiple conference calls with analysts and investors—including

statements touting "significant investments" at the Boston Facility specifically. For example, on May 4, 2023, at Integra's Analyst/Investor Day, Integra's Vice President, Global Operations and Supply Chain, Defendant Leonard stated: "Last year and this year, ***we made significant investments in quality across all of our manufacturing sites with a focus on accelerating our quality project in Boston*** involving testing, infrastructure, and physical layout changes."

87. These representations were also utterly false and misleading. Contrary to Defendants' statements touting Integra's cGMP compliance, and assuring investors the Company was making "significant investments in quality[,]" Defendants knew Integra's Boston Facility was rife with pervasive, systemic, and long-standing violations of fundamental cGMPs, including in the same "quality management systems" Defendants specifically touted to investors. Indeed, as discussed further above and below, both prior to and during the Class Period, Defendants received numerous warnings of Integra's widespread and serious cGMP failures, including a whistleblower complaint, warnings from multiple Integra employees from different levels across the Company, and scathing private reports from the FDA citing Integra for serious, repeat cGMP and data integrity violations, including widespread efforts to evade mandatory product quality testing and standards by "testing into compliance," falsifying reports, and failing to perform required analyses. And, as discussed below at §IV.E.2, while Defendants disclosed in the Company's 2021 Form 10-K that Integra had received the 2021 Form 483 concerning the Boston Facility, Defendants never disclosed the scathing content of the 2021 Form 483 describing myriad observations of significant cGMP deviations, and instead issued the wholly positive 2021 and 2022 ESG Reports that told investors precisely the opposite: Integra "adheres" to cGMP and other regulations, and, moreover, continually improves its systems to "meet the highest and most current quality standards."

88. ***Third***, Defendants repeatedly told investors throughout the Class Period that the FDA's observations and findings would not impact the Company's ability to manufacture EBM products at the Boston Facility at capacity.

89. For example, during Integra's February 19, 2020 earnings call, Defendant Coleman highlighted that the Company had made "changes … to the actual physical [Boston] facility" after the Company "went through an FDA audit" specifically designed to "***get [the Company] 50% more capacity as [it] enter[s] 2020***."

90. Defendants further assured investors that demand for its biologic mesh products was so great that, despite the outbreak of the COVID-19 pandemic in early 2020, and unlike virtually all the Company's other manufacturing facilities, the Boston Facility continued to operate during the COVID lockdown at full capacity—indeed, its personnel were working overtime shifts and the Company was making capital investments at the Boston Facility to support pent-up demand for Integra's EBM devices. For example, Defendant Anderson, Integra's then-CFO, stated during Integra's May 7, 2020 1Q earnings call that sales of "***SurgiMend increased double digits***" and attributed that growth to the "***increase in supply coming from the capital investments we [] initiated last year at our Boston [Facility].***" During this call, Defendant Coleman also told investors that the Boston Facility was "***building safety stock***" and investors should expect "***double-digit growth***" for SurgiMend and PriMatrix products to continue since the Company would "***have plenty of safety stock to support***" pent-up demand once COVID-19 lockdowns subsided.

91. These statements were highly material to investors, as the Company's portfolio of EBM devices was among Integra's fastest growing and highest margin products. Indeed, during the Class Period, Defendants repeatedly boasted about the extraordinarily high-margin EBM products manufactured at the Boston Facility and their critical importance to the Company's future

growth prospects. For example, on October 28, 2020, in discussing SurgiMend and PriMatrix, Defendant Coleman highlighted the fact that "***these are very high margin products for us, 80%-plus. So we're well positioned not just to capitalize on the top-line, but also to drive higher gross margins going forward***." Similarly, Defendants also boasted about the purported improvements that they had made to the Boston Facility itself, and that the Boston Facility would fuel the Company's growth for years to come. For example, on May 20, 2021, Defendants emphasized that the Company had made investments in its "core" Boston Facility as well as two other plants, which they expected to deliver "***the greatest growth [] over the next 5 years***."

92. Accordingly, any production decreases or pauses to address cGMP deficiencies at the Boston Facility would negatively impact the Company's revenue growth and, even more so, its bottom line. Furthermore, any production decreases or pauses to address cGMP deviations related to dangerous bacterial contamination risked customer loss and serious reputational harm.

93. Moreover, while assuring investors that the FDA's observations and findings would not impact the Boston Facility's ability to manufacture at capacity, Defendants repeatedly told investors that the issues flagged by the FDA would not require the recall of any EBM products. For example, at the beginning of the Class Period, on March 11, 2019, Defendants filed a current report with the SEC on Form 8-K, which stated that the 2019 Warning Letter "***does not restrict the Company's ability to manufacture or ship products or require the recall of any products.***" Likewise, Integra's 2021 Annual Report, filed with the SEC on Form 10-K on February 24, 2022, stated that neither the 2019 Warning Letter nor the 2021 Form 483 restrict the Company's "***ability to manufacture or ship products or require the recall of any products***."

94. Defendants' statements about Integra's ability to maintain production volumes and meet demand for its lucrative SurgiMend and PriMatrix products were materially misleading,

because, as further discussed below, unbeknownst to investors, Defendants were only able to build up safety stock by skirting cGMP regulations and deliberately failing to undertake meaningful remediation at the Boston Facility. Defendants' focus on quantity at the expense of quality was unsustainable, and ultimately Integra was forced to suspend all manufacturing activities at the Boston Facility in order to prevent the release of adulterated products and recall all products manufactured there for the preceding five plus years.

95. Analysts and investors credited Defendants' statements that Integra was devoting substantial efforts and resources to, and had already made substantial progress on, remediating the manufacturing and quality control deficiencies the FDA identified at the Boston Facility, and that the Boston Facility's capacity for manufacturing would not be impacted by any production stoppage or recall. In a March 2019 report for instance, Piper Jaffray told investors not to be "overly concerned" about the 2019 Warning Letter because the Company had "emphasized that there were no safety issues associated with the products" and management assured they would "have the issue resolved within about six months" in the third quarter of 2019. Credit Suisse also published a report echoing Defendants' statements that the 2019 Warning Letter was "not triggered by any safety issues or recalls," "sales of products from the facility should not be affected, and any costs related to remediation are not expected to be material." Morgan Stanley issued a report the same day underscoring that although "EBM is a high margin product and an impact to sales would [] have an outsized impact on earnings," the financial impact of remediating the Boston Facility's compliance deficiencies "is likely minimal" given "no needed recalls, and limited operational impacts."

96. Moreover, analysts continued to rely on Defendants' reassuring statements even after the announcement of the production stoppage and product recall at the Boston Facility. In an

April 2023 report issued after the announcement of the production stoppage at the Boston Facility, Wells Fargo analysts reported that "Mgmt indicated that the backlog is immaterial given ample inventory on hand." And in May 2023, Raymond James issued a report crediting Defendants' representations that "the [Boston Facility] is back up and running to start 2024," while BTIG analysts likewise credited management's assurances that "there are no more 'big shoes' to drop."

97. As investors would eventually come to learn, however, the Company's utter disregard for cGMP and prioritization of production and profits over safety and quality ultimately necessitated shipping holds of key products across the Company's manufacturing sites. The shipping holds were instituted as part of a "compliance master plan" Defendants ***admitted*** was implemented at the FDA's behest. Essentially, by the end of the Class Period, the FDA grew so tired of Integra's empty promises of cGMP compliance and remediation of the Boston Facility, and shipment of over five years of product that was prone to dangerous bacterial contamination, that it took the extraordinary step of expanding its scrutiny of Integra's cGMP compliance across the entire organization.

### E. In Truth, Integra's Boston Facility Was Rife With Systemic, Severe, And Continuing cGMP Violations That Defendants Knew—And Were Repeatedly Told By The FDA And Senior Quality Officers—Were Not Being Cured.

98. Unbeknownst to investors, throughout the Class Period the Boston Facility remained rife with the same severe and systematic violations of cGMP requirements designed to prevent contamination of the Company's supposedly sterile surgical products the FDA had identified in its 2018 inspection and 2019 Warning Letter. Integra understood that adequate remediation would require lengthy closure of the Boston Facility, the Company's exclusive site for manufacturing EBM products, and the implementation of time-consuming and costly remedial measures, as investors learned at the end of the Class Period. Facing market pressure to sustain and increase production of its highly-lucrative EBM products, and having already invested

substantially to construct new manufacturing facilities, Integra failed to remediate these critical violations, deceiving both investors and the FDA. Defendants' scheme to prioritize profits over safety is confirmed by the accounts of multiple former employees from all levels and across the organization with first-hand knowledge of the significant issues at the Boston Facility, who consistently describe how Defendants received numerous warnings of Integra's widespread and serious cGMP violations, yet failed to undertake any meaningful remediation to address the issues. Instead, these former employees describe how Defendants implemented "band aid" fixes or undertook no remediation at all, brazenly believing that they could "sweep the issues under the rug" and "r[u]n out the clock before the FDA nabbed them." That the recurring, systemic cGMP violations remained unaddressed throughout the Class Period—and Defendants' knowledge thereof—is further demonstrated by a steady stream of private correspondence and meetings among Defendants and the FDA regarding these exact same issues. These realities are further confirmed by the Whistleblower Actions. In short, Defendants pursued a Company-wide directive to prioritize profits and manufacturing output above patient safety, while telling investors precisely the opposite.

**1. Former Employees Confirm That Following The 2019 Warning Letter, Defendants Intentionally Failed To Overhaul Integra's Quality Systems Resulting In Continued cGMP Violations At The Boston Facility Through 2021 Because Compliance Would Be Too Complex, Costly, And Disruptive To Manufacturing.**

99. As detailed above, the FDA's 2018 inspection revealed widespread and severe violations of core cGMP requirements for preventing toxic contamination of Integra's tissue reconstruction products. The FDA's 2019 Warning Letter put Defendants on notice that this "systemic failure of [the Company's] quality systems" required a complete overhaul of the Company's controls and manufacturing processes to adequately remediate the violations.

100. Yet, as Defendants knew even before the Class Period began, the total overhaul of the Company's quality systems the FDA warned was required could not be achieved without causing a protracted shutdown of the Company's manufacturing operations, including at the Boston Facility where Integra's most lucrative, highest margin products were made. Faced with increasing pressure to maintain production levels the Company deemed critical to its financial performance, Defendants pursued a deliberate strategy to forego the remediation overhaul the FDA warned was required, instead opting to sacrifice quality and safety compliance to avoid incurring a disruption of manufacturing at all costs.

**a. Defendants Knew That The Boston Facility's Poor Design, Fragmented Layout, And Aging Infrastructure Presented Major Obstacles To Remediation, But Intentionally Did Not Implement The Necessary Remediation.**

101. As multiple former employees reported to Lead Plaintiffs, and the Company's two former highest-ranking officers responsible for quality at the Boston Facility recently confirmed in the Whistleblower Actions, the Boston Facility presented unique obstacles to remediation due to its aged infrastructure, fragmented manufacturing layout, and deficient processes. However, rather than meaningfully address these serious issues, the Individual Defendants and other senior Integra executives engaged in a concerted effort to downplay quality control issues, avoid FDA regulations, and risk patient safety as part of a deliberate effort to prioritize profits and avoid manufacturing stoppages at all costs. Defendants' actions violated basic quality and safety standards, presented serious risks to patient safety, and ultimately resulted in a Company-wide stoppage of all manufacturing to implement a "compliance master plan" overseen by the Board of Directors.

102. For example, FE 1,[4] Integra's former Chief Scientific Officer from February 2014 through October 2021,[5] described how the Boston Facility's age and layout presented obstacles to remediation that were discussed at the highest levels of the Company, but were too complex and costly to properly fix and would have required debilitating manufacturing stoppages. As FE 1 explained, the Boston Facility was a four-story warehouse on the south side of Boston that was between 50 to 100-years-old. He likened the situation to "***buying an old farmhouse that has lead pipes, and you have to change all piping, all the walls and rebuild it,***" fixing all the issues becomes a "***money pit***."

103. For example, he explained that installing proper water handling systems and air handling systems would have been not only costly, but taken years to perform. As a result, Integra was forced to implement "***a million Band Aids***." Given the building's haphazard layout, its old age, and the necessity to consider the uses of other tenants before remodeling could be done, FE 1 explained that attempting to continue producing product while remediating all of the issues at the Boston Facility ***"was like changing tires on a car going 60 miles an hour."***

104. FE 1 also confirmed that these issues were discussed with Integra's senior management and executive leadership, including Defendants Arduini, Coleman and Anderson, during monthly review meetings, in which Integra's quality and regulatory teams led presentations on the operations of each facility, including the Boston Facility. These meetings, which occurred each month until at least FE 1's departure from the Company in October 2021 if not after, were

[4] Former Integra employees are referred to herein as Former Employee ("FE #") and are all referenced herein in the masculine form to maintain their confidentiality.

[5] As Chief Science Officer, FE 1 oversaw medical affairs and clinical operations for the development of new product. In that capacity, he often worked with the Quality Assurance department for the Boston Facility (which was acquired during his tenure), including when adverse events occurred at the plant.

attended by the Company's executive leadership, as well as the head for every function such as operations, manufacturing, quality, and regulatory, and management from each facility, including the Boston Facility. During these meetings, members from the quality and regulatory teams presented on each Integra facility, whether they had any adverse events, and the status of any FDA inspections, and progress of any remedial work. The presentation decks for these meetings were sent to all participants in advance.

105. FE 1 explained that the Boston Facility was a regular topic of discussion at the monthly meetings, including the FDA's inspections of the Boston Facility. He explained that, "whether it was remodeling, production, or supplies, ***there was no month that Boston was Scot-free***." FE 1 recounted that the Company extensively discussed proposals to move production away from the Boston Facility because "it was an old facility where they were always fixing something, and they needed to tear it down and build it up." However, the Company decided against pursuing these proposals because of the disruption they would have caused to the Company's ability to manufacture the high-margin EBM products produced exclusively at the Boston Facility.

106. FE 2,[6] Integra's former Vice President, Head of Strategic Initiatives & Business Development from October 2014 until January 2019, similarly described that, unlike the Company's other more modern facilities, the Boston Facility was situated in an old building that was multiple stories, had old machines and relied on elevator access to move materials from one part of the Facility to others during the manufacturing process. FE 2 explained that, upon the Company's acquisition of the Boston Facility from TEI, Integra's executive management,

[6] FE 2 headed strategic initiatives and business development for the Company's Tissue Technologies segment. He also helped support corporate development activity, acquisitions, and divestitures. He was the lead divisional person working closely with Integra's corporate leadership.

including Defendants Arduini, Coleman, and Davis as well as Company executive Mark Augusti, held monthly management meetings where the Boston Facility's manufacturing operations, including remediation needs and related costs, were regularly discussed. FE 2 recounted that, during these monthly meetings, the Company explored transferring manufacturing operations from the Boston Facility to a different Company facility, but did not carry out the proposal (until years later) because it was deemed too disruptive to the Company's manufacturing operations.

107. FE 3,[7] Integra's former National Director Integrated Delivery Networks East, also confirmed that the Company's senior and executive management, including each of the Individual Defendants, "knew about all the issues" at the Boston Facility from the time of the TEI acquisition in 2015 until the FDA "nabbed" Integra and shut down the plant shortly after his departure in the spring of 2023. First, FE 3 explained that Integra management acquired all of TEI's paperwork for the Boston Facility as part of the acquisition, and they knew during and after the acquisition that there were many things that needed to be fixed at the Boston Facility—including issues that made the Facility prone to high levels of endotoxin contamination. He stated that the Boston Facility was a very old plant, and that even though the Company had plenty of time to remediate the issues, they would have been very costly to fix. He also stated that the key problem was with endotoxins and explained that in the medical device industry "***endotoxin is a very bad word and something that the clinicians do not want to hear***." FE 3 explained that Integra's entire strategy was built on price increases, and the Company never seemed to spend money on Research and

[7] FE 3 served as a National Director Integrated Delivery Networks ("IDNs") East, Enterprise Corporate Contracting Group from before the TEI acquisition in 2014 until he quit in February 2023. FE 3 reported to Integra's Vice President of Enterprise Sales and was responsible for executive level contracting and strategic planning across a diverse multi-specialty product portfolio in neurosurgery, surgical instruments, and regenerative medicine to IDN/Group Purchasing Organizations ("GPO") corporate client group.

Development or fixing issues. According to FE 3, in dealing with issues at the Boston Facility, everything was like a "***short-term band aid***" rather than looking at a long-term strategy. He recalled that everything was "quarter-to-quarter" and when it came to addressing the issues at the Boston Facility, while "***there was a lot of knowledge about processes and improvements that could have been fixed way before the FDA pulled the plug***," senior management's approach was to do the "***least amount possible with the least amount of money.***" He added, "***this was a huge issue and that is why it didn't get addressed***."

108. Second, FE 3 confirmed that the C-suite and senior management knew about the significant cGMP deviations and endotoxin issues at the Boston Facility because these issues were regularly discussed at monthly and quarterly meetings with executive and senior management. FE 3 personally attended these routine meetings with upper management, which were held virtually via Teams and in-person. Other than during the COVID lockdown when the meetings were done virtually, many of the senior leaders were expected to attend in-person. FE 3 confirmed that CEO De Witte, the CFO, COO, Robert Davis, and Steven Leonard each attended these regular monthly and quarterly meetings, which occurred throughout his tenure at Integra.

109. FE 3 described that during these cross-functional meetings, each business function presented, usually with a Power Point presentation. FE 3 explained that the purpose of meetings was to have each of the functional areas, including Quality and Regulatory, report on different projects and other line items such as remediation. With respect to Quality and Regulatory reports on the Boston Facility, he added, "yes, everyone knew that this one was a problem." For example, FE 3 further explained that the remediation issues at the Boston Facility rolled up to a senior leadership function which presented them at the executive level meetings. Defendant Robert Davis was the SVP of Tissue Technologies, and those functions would have been reported by him. FE

3 recalled how during these regular meetings, the C-Suite was provided with updates on the cGMP issues at the Boston Facility, including the lack of progress made on remediation. FE 3 repeatedly described how "***this issue and many other issues seemed to be dealt with by the C-Suite with apathy***."

110. FE 3 stated that executive "apathy" towards the quality and compliance issues at the Boston Facility started from the time of Integra's 2015 acquisition of TEI and continued during his entire tenure at Integra, including following the 2019 Warning Letter, during the FDA's 2021 inspection, and up until his departure in February 2023. FE 3 said that the C-Suite was presented with proposals and had the knowledge on how to fix the issues at the Boston Facility, yet the executives were "***very apathetic***." For example, they would say that things needed to be fixed, and they had a remediation plan, yet nothing would get fixed. He stated that there was at least a five-year span after the acquisition where these issues could and should have been addressed. FE 3 explained that, when they received the 2019 Warning Letter and critical endotoxin contamination issues were disclosed, it started to affect the Company monetarily because Integra started to lose share with those segments. However, FE 3 explained that SurgiMend and the other EBM products manufactured at the Boston Facility were very profitable products, and senior management did not want to undertake expensive remediation in order to protect the high margins.

111. FE 3 confirmed that everything that was flagged by the FDA in the 2019 Warning Letter and throughout his tenure at Integra was reported on at these regularly monthly and quarterly meetings. Rather than addressing the issues, including recurring deviations from cGMP, "***there was a lot of kicking things to the curb***" and executive management "***knew this was happening but they didn't do shit.***" FE 3 reiterated that despite the C-Suite's knowledge of the extensive cGMP issues and need to develop a long-term strategy for remediation of the Boston Facility,

"***There was no progress or accountability and focus to remediate them. They first said that the remediation was going to be six months, then a year, then 18 months, and it was still not fixed***." FE 3 confirmed he attended multiple meetings with Defendant De Witte, Integra's CEO, where these issues with the Boston Facility were discussed; as a result, De Witte was "***of course***" aware of all of the issues; and added that "***the problem that has always existed at Integra is a lack of accountability all the way to the top***."

112. FE 3 again confirmed that everything that was flagged by the FDA in the 2019 Warning Letter, and throughout his tenure was reported on at these monthly and quarterly meetings. He added that because of these regular monthly and quarterly meetings, "***there is zero way that the C-Suite was not aware of these issues.***" FE 3 reiterated: "***They all knew what was happening. Before that FDA Warning Letter came in 2019, they knew about the problems in Boston for five years and they ran the clock out before the FDA nabbed them***."

113. FE 4,[8] a former Site Quality Director at Integra from January 2021 until March 2022, also confirmed that the Company's senior and executive leadership closely monitored quality control issues at the Boston Facility. FE 4 explained that the Site Quality Director of each facility, including the Boston Facility, was required to attend monthly meetings held by the Company's senior quality leaders, including Maria Cianciotto, Integra's former VP of Quality for Operations from 2018 until December 2021, followed by Annette Boland, Integra's former VP of Global Product Quality from January 2022 until September 2023. At these meetings, Site Directors presented their monthly quality metrics, which included reporting on any quality control issues relating to contamination, and in particular endotoxin contamination issues. Site Directors

[8] FE 4 served as a Site Quality Director at Integra from January 2021 until March 2022, and was responsible for overseeing quality issues at the Company's Toronto facility.

were required to present detailed information on their quality metrics, including the status of all CAPAs and Non-Conformance or "NC" Reports opened in response to quality control incidents, as well as report any changes in their facility's manufacturing controls or their continuous improvement plans.

114. FE 4 reported that quality issues at the Boston Facility were regularly discussed at these monthly meetings. He recalled that the Boston Facility was "a very important site to the Company," but was "in trouble" due to prior FDA inspections and had "a lot of associated risks." FE 4 recalled that, as also reported by FE 1 and FE 2, the Boston Facility's "fragmented" manufacturing layout contributed to its quality control issues, and "everyone was aware that Boston had challenges." As part of the Company's reporting processes, FE 4 explained that the quality control issues reported to Integra's senior quality leaders each month were in turn reported up to Integra's executive leadership, including Integra's Chief Quality Officer and the Individual Defendants. FE 4 explained that "the Boston site got a lot of attention right to the top" and "***there's no way they didn't know that the facility was behind on CAPAs and NCs***."

**b. cGMP Violations Persisted Due To The Company's Deliberate Failure To Remediate Following The 2019 Warning Letter.**

115. As explained below, after Defendants received the 2019 Warning Letter, cGMP violations persisted from 2019 through 2021 due to the Company's deliberate decision to forego the overhaul of its quality systems the FDA warned was required, in-line with a corporate directive to prioritize profits over product quality, patient safety, and regulatory compliance.

116. For example, FE 5,[9] a former Integra employee who worked at the Boston Facility from November 2020 through June 2023 first as a Quality Control Analyst and later as a Quality

[9] FE 5 was employed by Integra to work in the Boston Facility as a QC Analyst from November 2020 to September 2021, a QA Specialist I from September 2021 to April 2022, and a QA

Assurance Specialist, was primarily responsible for water testing, conductivity testing, and bioburden testing, but also participated in clean room environmental monitoring. FE 5 explained that, despite the Boston Facility's persistent compliance deficiencies, Integra did not dig deep enough into the root causes of the nonconformances and endotoxin contamination issues experienced at the Boston Facility, stating: "That was something that the Company did not want to do. ***They wanted to sweep the surface level stuff under the rug and let it all fester***." FE 5 further described how there were a number of things that he wanted to change with respect to quality at the Boston Facility, but none of those projects progressed due to Integra's relentless emphasis on "***profits over quality***," which he explained "***ultimately came from the top***." During FE 5's tenure, Boston Facility Plant Manager Edward Callahan held daily production meetings at 1:00 p.m. during which everything was discussed from manufacturing to the release of product and in great detail. FE 5 routinely attended these meetings and explained that Edward Callahan very heavily implied production quantity over quality and always asked why they could not get certain products out the door. Specifically, he recalled that "during these production reviews, Callahan would keep pushing and pushing for the lots to be approved. It didn't matter if we had to delay testing because we needed new reagents or one failed testing and we had to scrap the lot and remake it. He never liked to hear that." He said Callahan "***got a lot of pressure from corporate to churn out more lots***," particularly because the Boston Facility manufactured EBM products that were in high demand and had high profit margins. As a result, many cGMP violations that existed during and even before FE 5 was employed by the Company were never remediated, but instead simply "***swept under the rug***."

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Specialist II from April 2022 to June 2023, at which point he voluntarily left the Company. FE 5 reported to Senior QC Manager Bernard Braun.

117. FE 6,[10] a former Manufacturing Technician at the Boston Facility from December 2019 until December 2020 and Team Leader from December 2020 until December 2022, likewise confirmed that cGMP were not followed at the Boston Facility after the Company's receipt of the 2019 Warning Letter, including failing to sanitize the Boston Facility's sterile manufacturing rooms and greatly increasing the risk of exposure to bacterial contamination. FE 6 recounted repeated issues where the Company's procedures to thaw frozen bovine skins used to manufacture EBM devices violated cGMP. For example, FE 6 recalled that employees routinely left bags of frozen skins to thaw in the basement of the Boston Facility. By allowing the product to thaw in an unmonitored way, there was no way for the Company to ensure that the finished product could be produced, or perform, to specifications later in the manufacturing chain or in the field.

118. FE 7,[11] a Quality Control Analyst at the Boston Facility from September 2020 until November 2020, confirmed that the rampant cGMP violations remained un-remediated well into 2020. FE 7 explained that he was responsible for running clean room testing for the air, surfaces and floors. He explained that the Boston Facility had serious violations of cGMP in its air and surface testing that occurred in the period leading up to his arrival. The Company had a "***huge backlog***" in documentation for validating their testing and training records. FE 7 explained that unlike any manufacturing facility he had ever worked in, at Integra "nothing was electronic and everything was on paper," relying on a piecemeal record-keeping system in which employees would "manually write down" results from air testing equipment to undergo further review and analysis. FE 7 was surprised that Integra had no electronic system, and that it was "a pie in the

[10] FE 6 was employed by Integra to work in the Boston Facility from January 2019 until he was terminated in December 2022 after reporting non-compliance with cGMPs. As Team Leader, he was responsible for reporting cGMP violations to the Boston Facility's management.
[11] FE 7 departed the Company in November 2020 due to its inadequate COVID safety protocols.

sky dream to get a new electronic system." FE 7 also described that the Boston Facility had frequent issues where "testing equipment was old and tests had to be repeated." He explained that, despite this recurring issue, "Quality Control didn't want to validate new equipment because it's a lengthy process," which was deemed unacceptable because it required manufacturing to pause while the validations were performed. Underscoring the Company's refusal to tolerate even the most minimal disruptions of the pace of production, FE 7 specifically recalled that "Production would get upset because they had to pause their work for 30 minutes to an hour to allow QC to finish their work." FE 7 also described that, under the Company's testing protocols, materials were checked "on a priority basis versus age of material basis," i.e., based on how urgently Production demanded the material rather than quality or safety needs associated with aging materials.

119. Troublingly, the Company's own internal documents reflected that the Company had failed to close out the FDA's findings from the 2018 inspection. FE 8, Integra's Quality Assurance and Regulatory Affairs Consultant at the Company's Cincinnati facility from March 2020 to December 2021 and then a Quality Assurance and Regulatory Affairs Consultant at the Boston Facility from December 2021 to May 2022,[12] explained that none of the FDA's findings from the 2018 inspection were closed out when FE 8 arrived at the Boston plant in 2021 and was tasked with responding to them. Because the Company had not properly maintained any of the documentation needed to respond to the FDA, FE 8 was forced to look through the Boston Facility for documents in people's desk drawers, file cabinets, and closets.

[12] At the Cincinnati facility, FE 8 wrote procedures and processes for quality validations for surgical validations. At the Boston Facility, FE 8 handled the Company's responses and corrective actions in response to the 2018 and 2021 FDA findings because the FDA was not satisfied with the Company's responses and corrective actions to the 2018 findings.

120. Even when Integra hired quality control personnel as part of its purported remediation efforts, the Company egregiously failed to make changes to remediate the cGMP violations these specialists were supposedly hired to fix. For example, in July 2021, Integra hired—for the first time in the Boston Facility's history, a "Continuous Improvement Specialist," FE 9.[13] Once on site, FE 9 quickly discovered that he would be the only person handling continuous improvement for the entire severely neglected Boston Facility, as Integra failed to staff any team to support the new role. FE 9 recounted that the Boston Facility suffered from continual noncompliance with important CAPAs that the Company assured the FDA it was implementing. As FE 9 described it, there were an extremely large number of CAPAs at the Boston Facility throughout his tenure at the Company and, in terms of implementation and execution, "***[t]hey were no way near close to where they should have been with the CAPAs***." FE 9 stated that he found it "***shocking***" that it took so long for Integra to work on the CAPAs, which never were fully addressed during his tenure at the Company. FE 9 explained that, as can be expected when a company's CAPA systems are ineffective, endotoxin contamination was discovered by the FDA in product samples produced at the Boston Facility.

**c. The cGMP Violations At The Boston Facility Resulted From Company-Wide Deficiencies In Integra's Controls That Defendants Ignored, Downplayed, And Blocked Efforts To Fix.**

121. Multiple other former employees confirmed that the Company's failure to carry out the necessary overhaul of its quality systems was not isolated to the Boston Facility. As the FDA made clear in the 2019 Warning Letter—and as Defendants understood—the deficiencies in Integra's contamination and testing processes were systemic, presenting a Company-wide issue.

[13] FE 9 served as a Continuous Improvement Specialist for the Company in Boston, Massachusetts from July 2021 until May 2023. FE 9 was part of the team tasked with remediating non-compliant manufacturing practices and systems flagged by the FDA from as far back as 2019. He reported to the General Manager of the Boston Facility.

Indeed, as detailed below, multiple former employees reported that the same issues with the Company's core quality and safety assurance processes at the Boston Facility affected the Company's other manufacturing facilities. And as with the Boston Facility, Defendants knew about these widespread deficiencies but ignored them, swept them under the rug, and blocked efforts to address them. As FE 8, who worked in Quality Assurance and Regulatory Affairs at both the Boston Facility and Cincinnati facility, explained, Integra "always went for the lowest budget option," and the Company's practice of "squeezing" profits instead of remediating issues at the Boston Facility "was the biggest risk to public health."

122. FE 10,[14] a former Buyer at Integra's Mansfield Facility, where brain surgery equipment was manufactured, witnessed the impact of the Company's systemically deficient quality systems. For example, FE 10 saw cranial access kits with rusty drill bits. Seeing the consistent poor quality of the devices the Company manufactured, FE 10 told his personal doctor "***if he ever needed to operate on him to never use an Integra product.***" FE 10 also saw kits manufactured at the Mansfield Facility that were equipped with expired morphine. FE 10 noted that, based on his discussions with other Integra employees, the Boston Facility was as bad as the Mansfield Facility. He explained that these issues were driven by the Company's pressure to prioritize manufacturing output at all costs, adding: "If someone said that we can't do this or this is not right, there was a quiet conversation that we needed to do it this way to get the product out the door. ***They could have cared less what they were shipping out as long as it went out the door.***" FE 10 also stated that the pressure to cut corners was "***absolutely***" coming from corporate,

[14] FE 10 served as a Buyer at Integra's manufacturing plant in Mansfield, Massachusetts ("Mansfield Facility") from November 2020 to December 2022 and reported to the Senior Materials Manager. The Mansfield Facility manufactures surgical instruments used in neurosurgery for the Codman Specialty Surgical division including intracranial access kits and forceps.

and that management at the plant level were "***complete soldiers***" to "***what they were being told from the top***." He explained that prioritization of profits over cGMP compliance was truly a Company-wide issue, reiterating "***it was whatever it took to make the shipment and the dollar. They didn't care***."

123. Other former employees reported similar issues at the Company's manufacturing plant in Plainsboro, New Jersey. For example, FE 11[15] served as a Microbiologist Technician for Integra's plant in Plainsboro, New Jersey (the "Plainsboro Facility") where he described the Standard Operating Procedures and FDA guidelines as rarely, if ever, being followed by his team. FE 11 was responsible for manufacturing collagen which required the utmost cleanliness to maintain the required sterile environment for its production. Ventilated suits were a mandatory uniform for the Microbiologist Technicians at the Plainsboro Facility and the manufacturing rooms where the collagen was made were kept sealed. However, the Quality Assurance ("QA") department, which was tasked with preventing microbes from infiltrating the rooms' aseptic environment, did not regulate the technicians' entry or exit from the sealed rooms. Just as the 2018 inspection of the Boston Facility by the FDA revealed personnel walking freely between non-classified rooms and Clean Rooms, the same disregard for the sterility of Clean Rooms reigned at the Plainsboro Facility. FE 11 explained, "***QA was responsible for testing us for contaminants such as fungus and other contaminants on our suits and gloves, but people weren't doing that, they were just walking out without conducting the proper protocol.***" FE 11 explained that these issues were not confined to Plainsboro, and instead traced back to the

[15] FE 11 served as a Microbiologist Technician from October 2020 to September 2021 at the Integra manufacturing facility in Plainsboro, New Jersey. He worked in a team of 8 or 9 employees who were responsible for producing collagen to distribute.

Company's leadership "cutting corners." He added, "management should have ensured QA was in place doing their job, but no one did anything about it."

124. FE 12,[16] a former Sterilization and Microbiology Subject Matter Expert for Integra from August 2020 until April 2022, confirmed that the Company's quality systems suffered from major deficiencies in its process validation controls. FE 12, tasked with a project to review and update the Company's quality control processes for manufacturing metal and plastic implants in the orthopedic division, explained that the Company "***was not continuously staying up to date with their standards***." For example, FE 12 explained that every time regulatory standards governing a particular medical device changed, the manufacturer company is required not only to apply the new standard going forward, but to re-examine its prior validation procedures to identify any potential gaps with the new standard and determine potential instances of nonconforming results. He discovered that Integra was not performing this retroactive assessment as required, and even where it applied the new standard going forward, lacked a formalized process for ensuring it was appropriately implemented. Specifically, the Company asked FE 12 to change the dates of validation for the Company's sterilization and microbiology validations from 2014, when the validation was first conducted, to 2020, when the new regulatory standards were updated. FE 12 described this as "***insane***." Further, the Company relied on an "antiquated repository system" for tracking its documents to ensure that testing procedures were appropriately validated according to current standards.

[16] FE 12 served as a Sterilization and Microbiology Subject Matter Expert for Integra from August 2020 until April 2022. FE 12 worked out the Company's Austin, Texas office and worked closely with Integra's regulatory division to update its quality control procedures to meet changes in governing regulatory standards.

**2. In 2021, The FDA Discovered—And Privately Warned Defendants—That The Boston Facility Remained Rife With cGMP Violations.**

125. Confirming the accounts of these former employees that the Boston Facility remained rife with cGMP violations after the 2019 Warning Letter, the FDA conducted an extensive inspection of the Boston Facility in 2021 and issued detailed findings concerning the Facility's significant, recurring deviations from cGMP.

126. In the fall of 2021, the FDA conducted a nine-day inspection of the Boston Facility, in which investigators discovered continuing cGMP violations, showing the Company had not in fact corrected the systemic violations of core cGMP requirements for preventing toxic contamination of its surgical products discovered by the FDA in 2018. The FDA detailed its findings from the 2021 inspection in the 2021 Form 483 privately issued to Integra on November 12, 2021. As detailed below, the 2021 Form 483 cited Integra for gross deficiencies in its environmental controls and process validation controls that the Company had failed to remediate between 2018 and November 2021.

127. ***Environmental Control Violations*.** In 2018, Integra was cited for "fail[ing] to establish alert and action levels for surface viable floor sites during routine environmental monitoring," exposing the sterile devices manufactured in the Clean Rooms to contamination from dangerous bacterial and fungal growth. In its February 28, 2019 letter to the FDA, the Company told the FDA it implemented a CAPA to set the required "alert and action levels" for the Clean Rooms, which they assured would remediate the issue by April 2019. Yet in the 2021 inspection FDA investigators discovered that ***Integra had not actually implemented this change***, finding that the Company ***still had "failed to establish alert and action specifications*** for fungal organisms identified during routine clean room environmental monitoring." The FDA also noted repeated data integrity violations, as had also been discovered in the 2018 inspection, finding that when

testing the Clean Rooms for fungal contamination, Integra documented the results as "passing" under its acceptance criteria, ***even where*** "***fungal growth results were recorded***" ***as*** "***[t]oo numerous to count.***"

128. The FDA even found that Integra was systemically failing to perform certain required testing entirely, finding fungal contamination "testing was not performed in November [2020] due to lack of resources in QC team" and "***sampling for all sampling sites was not performed for all weeks in September of 2020***." The FDA also discovered that the Company failed to take corrective action when fungal contamination was discovered, noting ***42*** "***Fungal Growth Recovery Incidents had occurred***" ***in the Clean Rooms*** with no investigation or corrective action.

129. ***Process Validation Control Violations.*** The 2021 Form 483 states that Integra again failed to adequately establish "procedures for monitoring and control of process parameters for a validated process" and also failed to validate "process[es] whose results cannot be fully verified by subsequent inspection." In 2018, FDA investigators noted that the Company's bacterial endotoxin testing processes were deficient because Integra "failed to use the medical device with the largest surface area as 'worst case' sampling for [its] bacterial endotoxin verification study." In its February 28, 2019 letter to the FDA, the Company told the FDA it remediated this violation by implementing a CAPA that "include[d] updated test method instructions for bacterial endotoxin testing on finished, sterile devices." Yet during the 2021 inspection, FDA investigators discovered that ***Integra had not actually implemented this change***, finding that "the devices used for [Integra's testing] qualification were … not representative of larger sizes manufactured."

* * *

130. The FDA privately issued the 2021 Form 483 documenting the above findings to Integra's Management Representative Edward J. Callahan, Plant Manager of the Boston Facility, who reported to Barbara McAlleer, Senior VP of Quality Assurance for Tissue Technologies, who reported to John Mooradian, CVP of Global Operations, who reported to Defendant Arduini. Additionally, upon information and belief, the FDA discussed the findings from the 2021 inspection with Integra management at a close-out meeting on or about November 12, 2021.

131. The FDA did not publicly disclose the 2021 Form 483. While Integra disclosed its receipt of the 2021 Form 483 months later in its 2021 Form 10-K, it provided only a generic description that lacked any explanation of the repeated, pervasive, and serious departures from cGMP observed by the FDA. To the contrary, Integra's boilerplate disclosures downplayed the impact of the 2021 Form 483, and Defendants thereafter continued to mislead investors regarding Integra's supposed adherence to strict quality control measures and rigorous and robust quality assurance processes. Moreover, the Company soon issued its inaugural 2021 ESG Report that told investors precisely the opposite of the scathing observations detailed in the 2021 Form 483, proclaiming that Integra "adheres to good manufacturing practices (GMPs), [and] quality system regulations (QSRs)," coupled with wholly positive descriptions of the Company's purported "numerous mechanisms and processes embedded within [its] business operations to … ensure compliance with all regulatory requirements." Defendants doubled down the next year, proclaiming in the 2022 ESG Report that "product safety and quality are paramount" to Integra, and thus the Company "continuously improves" its systems "to meet the highest and most current quality standards." Again, these statements were precisely the opposite of myriad observations of egregious cGMP deviations contained in the 2021 Form 483.

132. Following the Company's receipt of the 2021 Form 483, Defendants continued in their failure to take meaningful action to carry out the overhaul of Integra's quality systems required to remediate the violations. Once again, numerous former Integra employees describe how from 2022 through the end of the Class Period, Defendants never undertook any meaningful remediation at the Boston Facility.

133. For example, FE 13,[17] who served as Integra's Director of Medical Communications from March 2022 until October 2022, described that cGMP violations relating to endotoxin contamination remained rampant at the Boston Facility after the 2021 inspection and were known to the Company's executive leadership, including the Individual Defendants. FE 13, who has a Ph.D. along with an extensive background in bacterial endotoxins, described how, during a 2022 audit of the Boston Facility by an outside auditor inspecting the Facility for international device approvals,[18] "the Quality team was discussing ways of steering the auditor away from their endotoxin issues." FE 13 confirmed that pressure to conceal the endotoxin issue from the auditor came directly from management.

134. FE 13 explained that the Company was "absolutely not doing enough to remediate their violations of good manufacturing practices." Instead, they were "slapping band aids on these issues." For example, "the Company made a number of superficial changes" in response to the FDA's findings and "were trying to push this off as not being a systemic problem." But, FE 13 explained, "having endotoxins regularly getting into their products" ***was*** a systemic problem,

[17] FE 13 served as Integra's Director of Medical Communications from March 2022 until October 2022. He reported to Head of Global Medical Affairs Sandra Berriman, who reported up two levels to Defendant De Witte.

[18] Under the FDA's Medical Device Single Audit Program ("MDSAP"), device manufacturers can use a MDSAP recognized Auditing Organization to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program.

which the Company never adequately investigated to identify and correct the root cause, as cGMP requires.

135. FE 13 confirmed that "endotoxin contamination in the Boston facility was a company-wide, known issue in February 2022 because I distinctly remember having conversations about endotoxins and where it was coming from during my interview process." Specifically, he explained that his supervisor, Head of Global Medical Affairs Sandra Berriman, was "well aware" of the issues and reported directly to both senior executive Michael McBreen and Defendant Davis, who both reported to Defendant De Witte. As FE 13 recounted, "Berriman knew and there was no way that Bob Davis did not know, and if Davis knew so did Jan De Witte." It was a "well-known issue," and "it would be highly unlikely that these issues were not known at the top." FE 13 described SurgiMend as Integra's "***golden child***," and "***front-runner***" product, and reiterated that it was "very unlikely management didn't know of the issues" at the Boston Facility because management had "***a flashlight on it at all times***."

136. FE 13 further explained how the Company retaliated against employees who reported compliance issues, even after the issues were brought to the attention of Human Resources and upper management. FE 13 described how, despite the Company's purported mantra of "see something, say something," management pressured supervisors not to report deviations in cGMP or implement appropriate corrective measures because they were "***going to be costly***," and retaliated against those who did flag concerns, including himself. For example, after discovering his manager attempted to get him "fired" for reporting issues with a quality control contractor, FE 13 raised these concerns directly with Defendant Davis, who "swore that Compliance and Legal was looking into it." However, one month later FE 13 spoke with Compliance and Legal and they

indicated that they had never heard about it, with FE 13 adding that "***they are a bunch of liars, up and down the company***."

137. FE 13 explained that unlike others who stayed at the Company, he was not able to "rationalize" Integra's profit-first, safety-second practices, where the Company's "M.O." has been to do the least amount of work with the FDA and other notified bodies, and "***worry about it after the fact***." When asked why Integra chose to flout regulatory requirements rather than simply complying, FE 13 reiterated that it was a matter of cost and resources. He said if they wanted to do it the right way, they needed to bring in more resources which would cost more money, commenting "***the culture was that we have gotten away with this for this long***." FE 13 eventually left Integra after only eight months, forfeiting his $20,000 sign-on bonus, because he was unwilling to be complicit in Integra's profit over safety scheme—and declared that if he had stayed he would have ended up "***in jail or hell***."

138. Like FE 13, FE 5 also confirmed that instead of taking necessary corrective measures the Company absolutely sought to run out the clock with the FDA and commented, "***it was Integra's culture to sweep issues under the rug and say that they will get to them later.***" He provided the following example of something that he worked on to improve only to have it "***swept under the rug***" once the proposed fix was determined to be too costly. Each of the skins manufactured at the Boston Facility had individual identification numbers and all that data was maintained on an outdated Microsoft Access database. The Access database had data going back to 2003 and the underlying software had last been updated in 2016. Accordingly, FE 5 raised concerns "***numerous times***" about this database with his supervisors because the system was incredibly slow, kept crashing, and he was concerned that they could lose all that data. However, FE 5 lamented that his concerns fell on deaf ears because of the high cost and time it would take

to replace the software, adding: "***Anything that cost money to improve their processes they just kept pushing it off***."

139. FE 5 indicated that he had discussions with Krause, Integra's Chief Quality Officer, about replacing their Access database and other suggestions that he had to improve quality controls at the Boston Facility. Krause told FE 5 that these corrective measures had to wait until after the FDA investigation, however, the Company would never actually look into the issues. FE 5 added that ***Krause was always trying to get things changed and improved***, but was always having to "***shoo[]us away and brush[] everything off***," explaining that "***management wanted to hit times and get product out rather than address systemic issues***."

140. FE 5 confirmed that Integra's leadership ***definitely*** put profits over quality. He explained that the Boston Facility manufactured a product that was in high demand and high margin, and that the practice of elevating "profit over quality" came from the top and not from the technicians working in the plant, since the lower-level employees had no incentive to fudge test results. FE 5 also described how during most of his tenure at the Company, the Boston Facility did not even have a Quality Director, adding that short staffing was always discussed. Making matters worse, FE 5 noted there were many involuntary turnovers at the Boston Facility. For example, FE 5 described how Integra fired (1) the Plant Manager, Edward Callahan, in October 2022; (2) the Manufacturing Manager, Robert McGrath, in February 2023; and (3) FE 5's own manager, Bernard "Bernie" Braun after he was "raising the same concerns" as FE 5 and "pushing for a lot" of changes. FE 5 emphasized that Braun's firing was "***unwarranted***."

141. FE 14[19] also reported that the Company's quality systems at the Boston Facility remained grossly deficient and greatly increased risk of bacterial contamination in its manufacturing of supposedly sterile devices. FE 14 served as the Inventory Control Lead for the Boston Facility from June 2022 to July 2023. FE 14 recounted multiple incidents in which Integra refused to enforce compliance requirements in order to continue the pace of its manufacturing operations. For example, while performing his review of product inventory, he found a batch of bovine skins that were stored not in the Clean Room as required, but rather ***in a storage room in the basement*** of the building, which violated cGMP because the storage room was not temperature-controlled or regulated by an air handling system, and the product was being touched by human hands—both of which increased the risk of bacterial endotoxin contamination. He recalled, "***there were times when product came out of the clean room and then went back into the clean room. I raised this to my supervisor because I thought it was a huge compliance issue.***" But Integra failed to make any changes in response to FE 14's reports.

142. FE 14 expressed shock that this issue was not addressed, noting that the storage room basement was "***literally called the rat room***" by employees at the Boston Facility because it was previously a vivarium that was never decommissioned for use in medical device manufacturing. FE 14 stated that it "***it didn't take a genius to know***" that moving material from the rat room to the clean room "***was a huge violation***." FE 14 confirmed that this "***huge gap in GMP***" that presented a clear risk of cross-contamination was never addressed during his entire tenure at the Company.

[19] FE 14 worked for Integra's Boston Facility from June 2022 until July 2023 as an Inventory Control Lead. He was responsible for inventory control and ensured that the Boston Facility's records matched their physical inventory for auditing and inventory control processes within the Facility and at an offsite location where the Company also kept frozen products. He reported to the Boston Facility's Supply Chain Manager.

143. Despite the FDA's 2021 Form 483 citing Integra for inadequate procedures to prevent cross-contamination of the Clean Rooms, FE 14 specifically confirmed that he never witnessed any CAPA instituted to address the cross-contamination issue from movement of materials in-and-out of the Clean Room. Moreover, FE 14 stated that he did not witness and was not aware of any training on CAPAs for any personnel at the Boston Facility, whether in his department or otherwise. He added, "when I started at the Company, I knew about the FDA Warning Letter, but I did not get the sense that it was serious and there were ***no meetings or formal training on how they were going to address these issues***."

144. FE 14 also explained how he frequently reported cGMP violations and quality issues to his manager Alina Herombli, who reported directly to Defendant Leonard. FE 14 stated that Defendant Leonard considered the Boston Facility "his baby," and in turn visited the facility five or six times per year, during which Defendant Leonard witnessed the state of the Boston Facility's deficient manufacturing processes. FE 14 recalled that when the Company came under pressure to initiate the product recall announced in April 2023, Defendant Leonard pushed back against the idea.

145. FE 6 also recounted a repeated issue with technicians from the first shift failing to retrieve frozen bovine skins to initiate the thawing process in time for the second shift to begin their manufacturing work. To avoid disrupting the pace of manufacturing operations, the skins were received and quick-thawed in a large water bucket. This increased exposure to potential bacterial endotoxin contamination because both the water and the bucket were outside of the approved manufacturing process, which were clear violations of cGMP. Even after raising these issues to management, Integra failed to take any action and instead "***swept things under the rug***."

146. Indeed, when FE 6 suggested that Integra management install surveillance cameras in key manufacturing areas where cGMP violations were occurring, he was told that Integra "***did not want the FDA to find anything on these cameras***" and instead purposefully installed cameras in the hallways of the Boston Facility, but not in the Clean Rooms or other work areas where EBM products were made. FE 6 declared that Integra was "***the worst microbiological pharmaceutical company I ever worked at.***"

147. FE 8 further explained that Integra was using a "low budget," disreputable provider to perform critical ethylene oxide sterilization of their tissue products, even after the 2021 inspection occurred. FE 8 explained that Integra used the same "local guy" that had handled sterilization for TEI and who ran a "low budget" operation. When the sterilizer overheated, the temperature was out of proper parameters, and the "local guy" stood out in the yard with a hose to cool the sterilizer off. However, instead of trying to find a new sterilization available with prepackaged validation, the Company continued to use his services during the last six to eight months of FE 8's tenure—approximately the end of 2021 through May 2022—for sterilization work at the Boston Facility. These problems with the Company's sterilization processes were well-known at the executive level, as FE 8 noted, as they were raised in a meeting at the end of 2021 with directors, senior management, and a member of the Board of Directors.

148. Rather than take meaningful steps to remediate the cGMP violations outlined in the FDA's 2021 findings, Integra put on a "dog and pony" show for the third-party auditor they hired to "appease" the FDA, and with whom FE 8 was tasked with interfacing. For example, when FE 8 recommended a more robust design control or revalidation of a product, management rejected his proposals because they would have cost more in the short-term, and then the Company would not be able to meet market demand for their tissue products, including SurgiMend and PriMatrix.

FE 8 even raised this issue to Susan Krause, Integra's then-Chief Quality Officer, during the 2021 inspection, when he sat next to Krause in the backroom while the FDA's audit took place. As a result, when FE 8 gave the Company's messaging to the third-party auditor, the third-party auditor was frustrated with Integra's responses and told them the Company's proposed solutions would not work. FE 8 explained that Integra's practice of not implementing long-term solutions was part of the Company's ***short-term mindset on meeting their quarterly earnings and bonus targets***.

### 3. In 2022, A Company Whistleblower Reported The Risk Of Dangerous Endotoxin Contamination At The Boston Facility Resulting From Core cGMP Violations.

149. In October 2022, Defendants privately received yet another stark warning concerning the ongoing cGMP deficiencies, quality system problems, and risk of dangerous endotoxin contamination at the Boston Facility after an employee lodged a whistleblower complaint. Specifically, on October 20, 2022, and as later described in the FDA's 2023 Warning Letter, an Integra employee called the Company's compliance hotline and brought to light "quality issues" in "manufacturing areas" related to Integra's "inspection process, bacterial endotoxin testing, bovine hide/skin thickness measurements, and control of sterilized devices" to Integra's compliance team.

150. Faced with an employee complaint to an official Company hotline, Integra was required to launch an internal investigation at the Boston Facility. The Company's Senior Quality Engineer in the Boston Facility led the investigation that followed the whistleblower complaint. The Company's compliance team identified at least 37 lots of product impacted by quality issues during the investigation. On December 14, 2022, the team initiated a distribution hold on the product in the 37 adulterated lots. The Company simultaneously implemented a hold on the production of any new product out of the Boston Facility because of the large quantity of adulterated product.

151. On January 11, 2023, Defendants were forced to expand the manufacturing hold to cover the manufacturing of any in-process products at various stages of the manufacturing process, including fleshing, freeze drying, testing for cutting/thickness, and endotoxin testing. This work-in-progress inventory was further quarantined internally.

152. The October 2022 whistleblower complaint triggered the FDA's for-cause inspection beginning on March 1, 2023. By March 13, 2023, the production and distribution of any and all products manufactured at the Boston Facility—regardless of stage—had to be placed on hold. By that point, the Boston Facility was "in a worst-case position," and at the end of the internal investigation, a product recall was the only remaining path.

153. As detailed below, during the 2023 inspection, the FDA issued findings that corroborated the whistleblower's complaint and discovered that Defendants had abjectly failed to remediate the "systemic" cGMP deficient quality systems identified in the 2018 Form 483, 2019 Warning Letter and the 2021 Form 483 that they had repeatedly claimed to have fixed. Indeed, despite the fact that the FDA issued serial correspondence specifically informing senior management of the widespread, egregious, and recurring cGMP deficiencies at the Boston Facility, and received regular internal reports (at least monthly and quarterly) reinforcing the FDA's citations, Defendants never disclosed the internal whistleblower to investors, and instead repeatedly assured investors that "patient safety is non-negotiable for us," "product safety and quality safety are paramount," and that the Company had "numerous mechanisms and processes embedded in [its] operations" that it "continuously improves" to ensure adherence to cGMP and all other FDA regulations.

**4. In 2023, FDA Inspectors Corroborated The Whistleblower Complaint And Discovered Defendants' Abject Failure To Remediate The cGMP Violations At The Boston Facility.**

154. Between March 1, 2023 and May 17, 2023, the FDA conducted a 10-week inspection of the Boston Facility, in which investigators confirmed systemic, continuing violations of fundamental cGMP at the Boston Facility. The FDA detailed its findings from the 2023 inspection in a Form 483 privately issued to Integra on May 17, 2023 (the "2023 Form 483"). The 2023 Form 483 also describes a host of additional, egregious cGMP violations, all of which were a direct result of the Integra's systemic, Company-wide lapses in compliance and contributed directly to the quality and safety issues culminating in the product recall announced in April 2023. As detailed below, these violations included systemic and continuing deficiencies in the Company's contamination and process validation controls, product non-conformance controls, and CAPA controls, demonstrating that Defendants prior assurances to investors were utterly false.

155. ***Contamination Control and Process Validation Control Violations***. In 2023, FDA investigators discovered Integra was still failing to adequately detect and prevent contamination of its products from dangerous bacterial endotoxins. The FDA described seven ways in which Integra's endotoxin testing procedures remained in violation of cGMP requirements, many of which tied directly back to the 2018 inspection. For example, in 2018 the FDA warned Integra that its endotoxin testing procedure, QCP-055, "failed to monitor or control potential bacterial endotoxin contamination." Contrary to Integra's written assurance to the FDA that it effectively reformed QCP-055, the FDA discovered that Integra again "failed to include critical steps [in its endotoxin testing procedures] and their procedure, QCP-055, was inadequate." This failure to remediate QCP-055 resulted directly in contamination issues reported by the whistleblower in 2022.

156. The FDA's findings also revealed a serious lack of data integrity and failure to document important events had also persisted at the Boston Facility from at least 2018 through 2023, finding that the Company had egregiously continued its practice of disregarding negative test results by giving a passing grade to products that should not have passed, and re-testing non-passing products repeatedly until they eventually cleared screening tests, each clear violations of cGMP.

157. Yet even more egregiously, in addition to failing to properly test for endotoxin contamination as the whistleblower reported and the FDA corroborated, Integra allowed dozens of lots of product exposed to endotoxin contamination to be released into the market without any adequate investigation or corrective action—the exact events compliance with cGMP is designed to prevent

158. ***Product Non-Conformance Control Violations***. As the FDA documented in the 2023 Form 483, Integra "***failed to contain nonconforming product and adequately investigate Out of Specification ('OOS') bioburden and bacterial endotoxin results***,"[20] even when its testing data showed that "nonconforming material did not meet microbiological quality and cleanliness product requirements." The FDA describes three incidents ***prior*** to the whistleblower complaint in which Integra management "approved and released" lots of finished products even though "the bacterial endotoxin result … exceed[ed] their acceptance criteria." In these incidents, the Company generated Non-Conformance ("NC") Reports that went to Integra management notifying them of the non-conformance issues, yet management still approved the lots for release

[20] Bioburden refers to the total number of viable microorganisms present in or on a product or surface, including both pathogenic and non-pathogenic microorganisms, providing a general indication of microbial contamination.

anyway with "no hold or quarantine was implemented for potentially impacted devices," and no "adequate risk based assessment."

159. As a result of these multiple failures to prevent potentially contaminated products from being released into commercial distribution, the FDA concluded that Integra systemically "failed to review … trending results for product bioburden and bacterial endotoxin contamination," thus "releasing product exceeding bacterial endotoxins specifications."

160. ***CAPA Control Violations***. During the 2023 inspection, FDA investigators determined that, despite Integra's repeated assurances since the 2018 inspection that they had implemented a cGMP-compliant CAPA system, "[p]rocedures for corrective and preventative action have not been established." The FDA noted that this failure constituted "a repeated observation" from its prior inspections and found that Integra's CAPA control violations resulted in multiple ***additional*** cGMP violations committed in its handling of the October 20, 2022 whistleblower complaint. For example, FDA investigators noted that, when it received the whistleblower complaint, Integra "failed to implement a CAPA to identify the actions needed to correct and prevent recurrence of nonconformances in the three areas of processing identified in the [whistleblower] complaint." As a result, as noted above, Integra continued to approve products from the impacted lots for release for an additional two months into December 2022.

161. The FDA noted that, even when Integra belatedly issued a product hold in December 2022, it only applied the hold to specific lots identified by the whistleblower, rather than, as required to be cGMP-compliant, all other potentially impacted "lots manufactured during the same time frame."

162. Additionally, the FDA found that, in response to the whistleblower complaint, Integra violated CAPA controls by "fail[ing] to adequately investigate the potential health impact

of the internal complaint." Inexplicably, Integra did not even perform this health impact evaluation ("HHE") until April 12, 2023, ***nearly six months after receiving the whistleblower complaint***. And when Integra did belatedly perform the HHE, Integra improperly omitted multiple patient infection complaints from its review. As the FDA's July 17, 2023 warning letter would later reveal, Integra's flawed HHE performed in April 2023 "concluded a field action"—*i.e.*, a product recall—"was not recommended" at that time, preventing Integra from initiating the recall until over a month later in response to FDA intervention.

* * *

163. On May 17, 2023, the FDA privately issued the 2023 Form 483 documenting the above findings to Integra's Management Representative Kenneth W. Allen. Additionally, upon information and belief, the FDA discussed the findings from the 2023 inspection with Integra management at a close-out meeting on or about May 17, 2023.

164. In response to the 2023 Form 483, Integra addressed the FDA's scathing findings in a letter privately sent to the FDA on June 8, 2023, signed by Susan Krause, Integra's Chief Quality Officer. The letter copied, among others, Defendant De Witte.

165. Integra's June 8, 2023 letter admitted that, contrary to its prior representations, the Company had "revealed areas requiring additional attention and improvement" and "acknowledge[d] the need to adjust [the Company's] previously established remediation plans." The Company also claimed to have implemented a number of additional remediation measures that it assured the FDA would "complete the remediation activities identified prior to the [2023 inspection]."

166. Underscoring the severity of Integra's continued remediation failures and its cGMP violations, the FDA sent Integra another warning letter following its review of the Company's

June 8, 2023 correspondence. On July 17, 2023, the FDA privately sent Integra a warning letter (the "2023 Warning Letter"), later published on the FDA's website on August 15, 2023. The 2023 Warning Letter—addressed to Defendant De Witte, copying Susan Krause, Integra's Chief Quality Officer—chastised Integra for the Boston Facility's systemic, pervasive, and never-remediated cGMP violations, including by highlighting that Integra still had not "identified all necessary corrective actions to demonstrate that your quality system will ensure controls are in place to prevent the release of non-conforming product[s]" and noting that many of the problems identified during the FDA's 2023 investigation were ***repeat "deficienc[ies] from [the FDA's] 2019 Warning Letter to this facility***." Consequently, the FDA concluded the Boston Facility's products were "adulterated."

167. Given Integra's serial refusal to bring the Boston Facility back into compliance with cGMP, the FDA made the following assertions in the 2023 Warning Letter:

- "We remain concerned that your quality system will be capable of identifying similar OOS errors when you resume operations and will prevent the release of non-conforming products."
- "In response to this Warning Letter, you will need to provide evidence that an effective and sustainable CAPA system will be implemented at your firm."
- "In response to this Warning Letter, you will need to provide evidence that you have reviewed all your operations to ensure that you have validated processes in place."
- "In response to this Warning Letter, you should provide confirmation that all proposed corrective actions are appropriate and effective."

168. Significantly, in the 2023 Warning Letter, the FDA also concluded that, although Integra had recalled all products manufactured by the Boston Facility since March 1, 2018 and agreed not to distribute any product made by the Boston Facility unless or until the "site is operating in substantial conformity with Quality System regulation[,]" the remediation efforts Integra had proposed still were "not adequate" for the FDA. Accordingly, the 2023 Warning Letter

made clear that self-regulation was no longer an acceptable option for Integra. Instead, the 2023 Warning Letter informed Integra that it must obtain a "***certification by an outside expert consultant*** that he/she has conducted an audit of your establishment's manufacturing and quality assurance systems relative to [cGMP] requirements," submit the consultant's report to the FDA and also submit to the FDA a "certification by your establishment's Chief Executive Officer [] that he or she has received the consultant's report and that your establishment has initiated or completed all corrections called for in the report."

169. In sum, given the far-reaching, systemic, and recurring violations of fundamental cGMPs documented by the FDA in its Forms 483, EIRs, and Warning Letters from 2018 to 2023, the FDA clearly determined that bringing the Boston Facility into compliance was no small feat, but likely would require many years' worth of remediation efforts, including attendant costs and production delays. Indeed, the FDA demanded to receive initial certifications from the consultant and Integra by "March 31, 2024" and all subsequent certifications between "March 31, 2025 and March 31, 2026[,]"—effectively concluding that it would take Integra ***at least three years*** to establish to the FDA that it had successfully remediated the Boston Facility.

### 5. Following The 2023 Warning Letter, Defendants Still Intentionally Failed To Take Steps Necessary To Remediate The Boston Facility And Continued To Manufacture Severely Contaminated Product.

170. The message to Defendants after the FDA's 2023 inspection and its issuance of the 2023 Form 483 and Warning Letter rang loud and clear; Integra would not be permitted to resume production of its lucrative biological mesh products unless and until an independent expert consultant confirmed all cGMP violations at the Boston Facility were, in fact, successfully remediated. Yet, even after receiving the 2023 Warning Letter, the Company failed to correct cGMP violations through the end of the Class Period before ultimately admitting the Boston

Facility was unsalvageable and manufacturing of tis EBM products would be relocated to a different facility.

171. For example, FE 16,[21] hired as a Compliance Specialist at Integra, described how CAPA progress was stalled and violations that were documented from as far back as 2018 still existed in May 2023 when he began to work at the Boston Facility. FE 16 explained the history; when Integra acquired TEI, no cleaning regulations were in place or instituted at the plant and Standard Operating Procedures ("SOP") were not followed. This longstanding culture of noncompliance FE 16 observed when he started working at the Boston Facility grew worse during his tenure at Integra, including due to the Boston Facility's dilapidated condition and inappropriate infrastructure. For example, due to the age of the Boston Facility, there was preexisting microbial contamination in the water system, presenting an extreme difficulty to remediating the Facility's water contamination issues.

172. FE 15[22] served as a Manufacturing Process Engineer for the Boston Facility starting in November 2023. His areas of focus were the Clean Room and sterilization processes and he was responsible for monitoring a crew that used specialized machines in those areas. After FE 15 joined Integra, he was assigned to the Clean Room in December 2023 to do process runs. In January 2024, his team began cleaning and checking validations. In the second week of February 2024, the team started a full process. In March 2024, the Company's external auditor (which

[21] FE 16 served as a Compliance Specialist from May 2023 until January 2024 at Integra's Boston Facility. He worked with Integra's Compliance Quality Assurance department and was responsible for managing the Company's paper-based quality system in response to the FDA's 2023 Warning Letter that resulted in a production shutdown. He reported to Senior Compliance Specialist, Matthew Thorton.

[22] FE 15 served as a Manufacturing Process Engineer for Integra in the Boston Facility from November 2023 to July 2024. FE 15 was responsible for analyzing the cleaning procedures and CAPAs at the Boston Facility.

Integra was required to retain by the FDA) visited the Boston Facility and stopped the process. As discussed below, the external auditor, Greenleaf, did so after being explicitly told by Myers, the Company's former Senior Director, Site Head of Quality Operations at the Boston Facility, of continued widespread contamination of EBM products manufactured there. Myers was summarily fired, along with the Company's former Chief Quality Officer, for failing to follow senior executives' instructions to lie to Greenleaf and implement an unlawful scheme to distribute contaminated EBM product in violation of multiple laws, regulations, and standard industry practices. *See infra* §V.E.7.b.

173. According to FE 15, progress on remediating the long-existing CAPAs never materialized. For example, FE 15 recalled that his team began working to validate the refrigerators in the Clean Room, however, the refrigerators had condensation building up inside of them. As a work-around, his team put pieces of insulating tape in the places where there was condensation in order to reduce it, however, he feared the tape would fall off and the team would not be able to record accurate validations when using probes. He reported this non-compliant refrigerator condition to his manager who escalated it to upper management, but there was no change. FE 15 explained that out of four refrigerators, three would not pass validation because of the condensation that was forming inside them, which was not tied to a purified water system, increasing the risk of bacterial endotoxin development. FE 15 summarized that, despite his team consistently flagging these kinds of cGMP violations and compliance failures, the Company simply was not going to make the necessary improvements.

174. Ultimately, FE 15 explained, "***the Company decided to stop all production in Boston because nothing was improving. It is true, I have not seen anything improve the nine months that I was there.***" As for the Company motto of "***say something if you see something***",

FE 15 pointed out that in reality, if you said something, your reports were not taken seriously and you were "***labeled a problem***."

**6. Unbeknownst To Investors, Defendants Recognized That The Boston Facility Was Not Being Properly Remediated And Decided To Relocate Manufacturing Of The Company's EBM Devices To A New Facility In Braintree, But Refused To Stop Manufacturing Operations At Boston.**

175. As explained above, Defendants were aware prior to the Class Period that the Boston Facility's outdated machines, dilapidated infrastructure, and increasingly obsolete design and layout could not be effectively remediated without a protracted shutdown that would result in lost sales and significant costs. Thus, Integra's management made a strategic decision no later than 2021 to abandon any meaningful or costly improvements to remediate the Boston Facility, even though doing so came at the expense of patient safety and product quality. Integra would instead focus its efforts on relocating to a larger, state-of-the-art facility that would be "PMA-ready" and able to yield substantially higher levels of product.[23] As FE 17, Integra's former Director New Product Research and Development, Regenerative Tissue Technologies from its acquisition of TEI in 2015 through his resignation in September 2022, confirmed, once the Company decided to move to Braintree, timely and meaningfully remediating the Boston Facility became a "***non-issue***."

176. However, in its public disclosures, Integra only disclosed the possibility of relocating manufacturing of EBM devices away from the Boston Facility in May 2023 as part of its "long-range growth plans," and, as discussed below, repeatedly told investors during the Class Period that EBM manufacturing would continue at the Boston Facility while concealing that the

[23] "PMA" refers to a medical device manufacturer's submission of an application to the FDA for pre-market approval for a new indication. The PMA process entails a multi-step review that the FDA uses to determine if a medical device is safe and effective for its proposed use. During the Class Period, Integra submitted a PMA for SurgiMend's use in post-mastectomy breast reconstruction that, if approved, was forecasted to significantly grow SurgiMend sales.

EBM products manufactured there were rife with dangerous and potentially life-threatening bacterial endotoxin contamination, which could not be distributed unless the Company's employees followed Defendants' instructions to lie to the FDA and its external auditors.

177. FE 9 corroborated this timeline, recalling that within his first few months of working for Integra upper management began talking about moving the EBM manufacturing processes from South Boston to Braintree, Massachusetts for a newer, larger plant with less limitations. Braintree was going to offer open concept manufacturing, which FE 9 recalled was explained to him and all other employees at the Boston Facility during a "town-style meeting" at some point during the summer of 2021. During that meeting, a representative from executive management described to the employees at the Boston Facility the Company's plan to relocate all manufacturing operations for the EBM devices produced at the Boston plant to a new facility in Braintree. As FE 9 explained, given the worsening condition of the Boston Facility and the failure to make progress on critical CAPAs, moving to a new location was ***"not a last-minute idea."***

178. The strategic decision to relocate was also the product of extensive private planning and negotiations with local town officials in the nearby town of Braintree, Massachusetts. On April 5, 2022, Kevin Breeden, then Integra's Senior Vice President of Operations, attended a meeting of the Braintree Town Council's Ways & Means Committee and informed the committee that Integra's Board of Directors had approved relocating the Company's Boston manufacturing operations to a new, larger, and state-of-the-art facility about 20 minutes south of Boston in the Town of Braintree (the "Braintree Facility"). Mr. Breedon was joined at the meeting by a "relocation team" that included Nicole Taub, Braintree's Chief of Staff and Town Solicitor; Ed Spellman, Braintree's Director of Municipal Finance; Margaret LaForest of the Massachusetts Office of Business Development; and Brandon Pyers and Carl Nerlich of Deloitte Consulting.

179. Breeden stated in his presentation to the Ways & Means Committee that the Company had instituted a search for a larger and more modern facility for the manufacture of its collagen-based EBM products. With approval of the Integra Board secured, Breeden told the Council Committee Members that construction of the new facility would be complete in the fourth quarter of 2023 with occupancy at the end of 2024 and full production at the end of 2025 into 2026. Integra underscored its commitment to the relocation, negotiating a 25-year lease consisting of an initial 15-year lease with two 5-year renewals, and agreeing to staff the plant with highly trained individuals.

180. Thus, unbeknownst to Integra investors, management had already decided to abandon ship at the Boston Facility as early as the spring of 2021 (and potentially beforehand) and refocus efforts on relocating production of all the Company's EBM products to an entirely new plant. Also unbeknownst to Integra investors, management refused to stop production at the Boston Facility despite knowing that the high-margin EBM products manufactured there were rife with dangerous and potentially life-threatening bacterial endotoxin contamination, and instructed its Quality Department to lie to the FDA and the Company's external auditor to avoid costly delays in production, destruction of freshly produced contaminated product, and a prolonged shutdown of the Boston Facility.

181. These well-considered, long-term plans to shift production for EBM devices away from the Boston Facility, while continuing to manufacture contaminated product at Boston, were key parts of Defendants' deliberate decision and fraudulent scheme to forgo the remediation overhaul the FDA repeatedly warned Integra was required. Defendants' investment of resources and expenses into its anticipated move to Braintree subjected the Company to considerable costs, but were deemed preferable to incurring the much greater costs to the Company's operations and

prolonged shutdown of the Company's lucrative EBM business that would result from having to perform the required remediation of the obsolete Boston Facility.

182. In short, while the Company's plans to open the Braintree Facility could have been done in conjunction with remediation of the Boston Facility (*see* Opinion at 37), in fact, numerous former employees confirm that no such effort to remediation the Boston Facility was made. Instead, once Defendants decided to relocate EBM manufacturing to the Braintree facility, remediation of the obsolete Boston Facility became a "non-issue."

### 7. Integra's Two-Highest Ranking Officials Responsible For Quality At The Boston Facility Confirm That Defendants Lied To Investors And Intentionally Refused To Remediate The Boston Facility In A Scheme To Boost Short-Term Profits And Avoid Costly Manufacturing Stoppages.

183. Defendants' deliberate scheme to boost profits by not implementing legally required and critically important quality and safety remediation at the Boston Facility, as well as its other manufacturing sites was further confirmed and amplified in bombshell Whistleblower Actions filed by Integra's former two most-senior officials responsible for quality at the Boston Facility. The veracity of the factual allegations in these Whistleblower Actions, filed by Krause, Integra's former Corporate Vice President and Chief Quality Officer, and Myers, Integra's former Senior Director, Site Head of Quality Operations (Boston), was confirmed by Lead Plaintiffs' counsel with Krause's and Myers' respective counsel of record.[24]

#### a. Integra's Former Chief Quality Officer Confirms Defendants' Fraud.

184. After years of receiving warning after warning that the Boston Facility was repeatedly violating the same basic cGMP regulations that were pervasive at the beginning of the

[24] Krause's counsel further confirmed in a July 1, 2025 article published by *The Minnesota Star Tribune* that "[t]o be clear, all of the allegations in Ms. Krause's detailed complaint are true and accurate."

Class Period, and with a critical FDA follow-up investigation set to occur within months, Integra recruited Krause in mid-2021 to become the Company's Corporate Vice President and Chief Quality Officer. As Chief Quality Officer, Krause assumed leadership of a 600-person Quality Department overseeing the quality of 25,000 different products manufactured at over a dozen sites, and reported directly to Integra's CEO. Krause served as Integra's Chief Quality Officer from June 21, 2021 to March 11, 2024.

185. Krause brought significant experience to Integra's Executive Leadership Team. Krause had more than 30 years of global leadership experience in quality, compliance, design assurance, supplier quality, operations, and manufacturing engineering. Among her many high-level positions in the industry, she served for nearly 4 years as the Vice President, Global Quality, Compliance and Risk, for Molex, a manufacturer of medical, automotive and consumer products. At Molex, Krause's responsibilities covered 75 manufacturing sites and approximately 45,000 employees. Prior to Molex, Krause served in multiple high-level quality positions at Medtronic, one of the world's largest medical device companies. During her nearly decade of service at Medtronic, Krause's leadership positions in the area of quality included Quality Program Director, Quality Engineering Director, Global Quality Engineering Director, and ultimately nearly three years as Corporate Quality Integration Director, working from Medtronic's corporate headquarters. Krause's extensive experience also included ten years at Boston Scientific, another leading global medical device company.

186. For years, Integra held out Krause's hire as a "key accomplishment" for the Company and Krause as integral part of the Company's Executive Leadership Team. For example, the Company's 2023 Investor Day conference on May 4, 2023, included a presentation with a slide titled "Key Accomplishments Since 2021 Investor Day," one of which was the addition of "key

executive talent." Of the six executives named in the slide, Krause's hire as Chief Quality Officer was first. The same presentation included a slide titled "World-class Leadership Team Focused on Execution" that included a headshot of Krause alongside the Company's other top executives, including Defendants De Witte (CEO), Davis (President Tissue Technologies), Leonard (CVP Global Operations & Supply Chain), and Schwartz (CLO). During the conference, De Witte told investors "I'm very proud of our executive leadership team," specifically mentioning Krause as a recent addition to the "ELT" who brought "new skills and leadership in line with our market expansion, innovation, and business efficiency objectives." De Witte emphasized that, with Krause's hire, Integra had a "terrific leadership team" that was "highly accomplished in running complex operations." The Company's 2022 ESG Report similarly identified and pictured Krause as part of Integra's "World-Class Leadership Team," proclaiming that "Integra's executive leadership team cultivates a high-performance culture and drives our commitment to excellence and execution."

187. On December 6, 2024, Krause filed a wrongful termination complaint in Minnesota federal court for illegal, discriminatory, and retaliatory treatment by Integra after she was forced to resign for, *inter alia*, refusing Defendants' "demand that she provide false information to the FDA."[25] Krause's complaint details how for years she personally witnessed Defendants De Witte and Schwartz "actively engage in a concerted effort to downplay quality-control issues, avoid Food and Drug Administration (FDA) regulations and risk patient safety in violation of multiple applicable laws and regulations." This longstanding, consistent, and systemic refusal to address critical quality issues was "well-known by senior leadership and the Board of Directors at Integra

[25] Krause's action against Integra was originally commenced in Minnesota state court on November 8, 2024. After Integra removed the case to federal court, on July 11, 2025, the U.S. Court for the District of Minnesota denied Integra's motion to transfer the case to the District of New Jersey.

who, throughout the Class Period, took "no significant steps to address these serious issues." Instead, Defendants, including De Witte, Schwartz, and other top Integra's executives, consistently refused to implement specific recommendations for quality improvement and remediation at the Boston Facility, circumvented established Company practices and FDA regulations so that Krause would not be informed of internal complaints and was blocked from participating in ensuing investigations, and repeatedly pressured and issued explicit directives to Krause to lie to the FDA regarding quality, remediation, and manufacturing at the Boston Facility.

188. Shortly after assuming her position as Integra's Chief Quality Officer in June 2021, she was informed that Integra was expecting an FDA inspection of its Boston Facility within 90 days. Krause quickly learned that Integra had not even come close to addressing the issues the FDA flagged in the 2019 Warning Letter. Indeed, after inspecting the Boston Facility over a two-week period spanning October 28 to November 12, 2021, the FDA promptly issued adverse findings and ordered a "regulatory meeting" with Integra "due to the seriousness of these repeat findings." The regulatory meeting was held on January 26, 2022. At the meeting, the FDA required Integra to "develop a solid remediation plan or it would be issued further action in the form of a warning letter or consent decree."

189. However, rather than devote meaningful Company resources to develop the required remediation plan, Krause describes a series of events in which Defendants De Witte, Schwartz, and other senior Integra executives repeatedly ***interfered*** with Krause's efforts to develop a "solid remediation plan." Indeed, during Senior Management Team meetings held in Florida beginning March 5, 2022, De Witte and Schwartz criticized Krause so severely about her

activities[26] that she was forced to seek medical attention at a Miami emergency room for "dangerously highly blood pressure." Their verbal abuse was so severe that Krause required medical treatment after returning to her home in Minnesota.

190. Months later, Defendants knowingly instructed Krause to put critical devices used in brain surgery back on the market despite known risks to patient safety and in violation of FDA regulations. Specifically, in August 2022, following an FDA-mandated recall of Cerelink[27] due to repeated malfunctions during brain surgeries, De Witte "***repeatedly pressured***" Krause to put the product back on the market despite "***the clear risk to patient safety***" and "***before the attempted resolution of that malfunction was proven effective***." After Krause refused to accede to De Witte's pressure and continued to work to confirm Cerelink was safe, she experienced "constant verbal abuse and hostility from Mr. De Witte."

191. Defendants further undermined Krause's ability to effectively perform her duties as the Company's top Quality officer by circumventing established Company policy and FDA regulations to conceal internal complaints from Krause that concerned quality or safety issues. Indeed, Integra's Policy for Managing Internal Reports (WWCP-040), which applies to all internal reports submitted to the internal employee hotline that alleges issues or practices affecting product quality, design, processes/manufacturing, or post-market issues, provides that "the Chief Quality

[26] Details of this meeting and Defendants' other conduct thwarting Krause from developing the requisite "solid remediation plan" in response to the Fall 2021 inspections of the Boston Facility are redacted from the public version of Krausse's complaint. The redactions are due to a purported Confidentiality Agreement that Integra claims it required Krause to sign as a condition of her employment. *See Krause*, 0:24-cv-04339-LMP-ECW, Dkt. 36, at ¶12 ("Integra [made] it clear its offer of employment to Susan Krause [was] contingent upon her signing a Confidentiality Agreement[.]"). Significantly, Krause opposes sealing of any portion of her complaint and has declared under penalty of perjury that "I did not execute a Confidentiality Agreement with Integra at any time." *See id.*, Dkt. 31, at ¶3 (Krause declaration in opposition to continued sealing).

[27] Cerelink is a medical device used to monitor intracranial pressure during brain surgery.

Officer [i.e., Krause] will be notified of quality-related internal reports within ***24 hours*** of the Chief Compliance Officer becoming aware that the internal compliance report alleges a quality-related issue for prompt follow-up and investigation." Remarkably, Krause was informed of just ***one*** such internal report within the requisite 24-hour period during her nearly three-year tenure as Integra's Chief Quality Officer even though the Company received approximately ***90*** such reports during her tenure as the Company's highest ranking quality officer. And, even in that single instance, the full report was kept from Krause's view.

192. In one critically important example, on October 22, 2022, Integra circumvented its established Policy for Managing Internal Reports by failing to timely inform Krause of the Company's receipt of a complaint on an internal employee hotline (*i.e.*, the whistleblower complaint described *infra* at §5.e.3) alleging that sterile and non-sterile products were mixed at the Boston Facility and that site management had instructed employees to ignore the potential contamination. Company policy required Krause to be notified of the hotline complaint within 24 hours. She was not notified within 24 hours. Krause did not even learn of the existence of the hotline report until nearly a week after it was made, on October 28, 2022. Even then, she was told only that it "focused on an issue that Integra was already purportedly resolving." Less than three weeks later, on November 17, 2022, Defendant Redondo, Integra's CCO, closed the complaint citing "insufficient information," without informing Krause.

193. The Company's "investigation" into the internal complaint and abrupt determination to close it was led by Defendant Redondo and other senior executives, without Krause's involvement. Significantly, neither Redondo, the CCO, nor anyone else in the Company notified Krause of the complaint within the requisite 24-hour period, even though it was Krause's responsibility to investigate it. Indeed, the FDA requires "that the Chief Compliance Officer

disclose all information that is patient, product, or quality related to the Chief Quality Officer so that a patient impact analysis can be completed." After Krause learned that top executives were "***hiding***" information about the Complaint from her and blocking her from participating in its investigation, Krause again suffered high blood pressure and was hospitalized on November 27, 2022.

194. Moreover, Krause only learned of the Company's decision to close the whistleblower complaint because the whistleblower repeatedly ***put notes under the Boston Facility's manager's door***, concerned Integra closed the report without taking adequate steps to investigate it. Specifically, the hotline reporter "put[] notes under the Boston plant manager's door on December 5, 2022, December 14, 2022, and January 11, 2023." The first note alerted Krause that the internal complaint had been closed, and the third note cited "***37 different lot numbers***" with quality issues, an extremely high number given the relatively limited scale of the Boston Facility's operations and the handful of EBM products manufactured there.

195. Almost immediately after Krause learned of the critically important information provided by the hotline whistleblower – including a staggering number of Quality deficiencies at the Boston Facility – Krause put all new manufacturing at the Boston Facility on hold and brought the information in the complaint to the FDA's attention. Specifically, Krause ordered that all new manufacture of new products at the Boston Facility cease as of December 14, 2022. Yet, despite Krause's directive, Integra kept processing "work in progress manufacturing" at the Boston Facility until January 11, 2023, to avoid the risk it would have to throw away costly inventory by pausing production mid-manufacturing. Significantly, notwithstanding that the Company summarily closed its investigation into the hotline complaint without ever informing the FDA of its existence, on January 17, 2023, Krause notified the FDA that Integra had received the October

22, 2022 complaint and an investigation was immediately opened into the reported contamination and possible quality issues. The same day, Krause met with and notified the FDA via a Teams Meeting regarding action to ensure patient safety.

196. As a result of Krause's actions, the FDA conducted a "for cause" on-site inspection of the Boston Facility over a 2½ month period spanning March 1 to May 16, 2023, which revealed a host of critical cGMP violations. First, less than two weeks after the inspection began, the FDA identified an issue with the manner in which Integra measured the level of endotoxin in products manufactured at the Boston Facility. Second, on April 27, 2023, outside lab results revealed that certain products manufactured at the Boston Facility contained "unacceptably high concentrations of endotoxins," which can cause patients to suffer serious harms including high fever, sepsis, meningitis, or death. Notably, the outside lab results reflected endotoxin levels that were "***27 times higher than the levels detected by Integra's internal testing***," and were verified through a second test. Third, the investigation revealed that Integra had been informed of over ***80 customer complaints*** "in which patients reported high fevers, inflammation, revision surgical intervention, infection, and meningitis."

197. In addition to the Company's initial refusal to provide the October 22, 2022 internal whistleblower's complaint to Krause, allow her to participate in the investigation, and closure of the investigation in violation of Company procedures and FDA requirements, Krause further identified numerous additional instances in which the company sought to withhold critical adverse information concerning quality and safety issues from Krause and the FDA. For example, at the start of the investigation prompted by Krause's January 2023 notification to the FDA, the Lead FDA Auditor requested a copy of the transcript from the October 22, 2022 hotline complaint, "which must be provided by law." Defendants Schwartz and Redondo "refused to provide it."

Integra only complied after Krause stepped in and "escalated the matter" to Defendant De Witte, who reluctantly instructed Redondo to give Krause a copy of the transcript, otherwise Integra risked being written up for "Failure to Comply."

198. Similarly, Defendants pressured Krause to violate FDA regulations, including by directing Krause to distribute product produced at the Boston Facility, as well as the Company's other manufacturing sites, that was known to be contaminated and presented serious risks to patient health. For example, on or about April 27, 2023, Defendants criticized Krause for specific actions she took in response to serious quality and safety issues uncovered during the FDA's 2½ month on-site inspection in March-May 2023. In particular, De Witte and Schwartz "yelled at and verbally abused" Krause after the Company's Product Safety Board (of which Krause was a member) agreed to destroy the existing inventory of the products that caused the 80 customer complaints concerning patients who reported high fevers, inflammation, revision surgical intervention, infection, meningitis after receiving EBM implants manufactured at the Boston Facility. On a phone call, Krause told De Witte "***Believe me, I want to save these [products] just as much as you guys, but I don't want to break a regulation to do it***." De Witte responded rhetorically, "***Why not?***"

199. Three days later, on May 2, 2023, Defendants directed Krause to personally violate FDA regulations and applicable laws. Specifically, after Krause refused to allow Integra to ship inventory from the Company's distribution center in Europe to Boston and illegally relabel it for sale in the United States (given that the entire manufacturing process at the Boston Facility had been shut down), De Witte insisted that Krause "could load the printer equipment into the trunk of her car and drive them to Integra's manufacturing location in Mansfield, Massachusetts, to print

the labels, and then bring them back" to the Boston Facility for U.S. distribution. De Witte told Krause that "***no one would know***" of this illegal scheme.

200. Defendants De Witte and Schwartz repeatedly took other actions that interfered with Krause's ability to perform her duties and the Company's Chief Quality Officer, including demanding that Krause falsify critical information in internal documents, and concealing from Krause critical issues concerning product quality and patient safety. For example, De Witte demanded that Krause lower the risk assessment for multiple sites in a presentation to Integra's Board of Directors, even though Krause believed the sites were at high risk of receiving an FDA warning letter for noncompliance. When Krause attempted to push back on misleading changes, De Witte and Schwarz "***retaliated by threatening to withhold compensation from her***."

201. Similarly, in December 2023, after Integra's Product Safety Board issued a recall of Integra's cranial access kits because of an "extremely serious issue" involving improper sterilization, De Witte and Schwartz "***aggressively tried to override***" the recall decision – including an explicit threat by De Witte to Krause that he would "***withhold her bonus if the cranial access kits recall proceeded***." Likewise, on January 24, 2024, after Integra received another employee hotline complaint regarding quality issues, including falsification of records at the Company's site in Plainsboro, New Jersey, the Company provided Krauss with a "few details about the information in the complaint" and instructed an employee on Krause's quality team "***that she could not share any information about the investigation***" with Krause.

202. Significantly, Integra's Board of Directors admitted to Krause that it ***knew*** the Company's top executives lied to them about quality, safety, and compliance issues. This included deception involving quality, safety and compliance at the Boston Facility, as well as risk levels at the Company's other manufacturing sites. For example, after the FDA issued Integra the July 17,

2023 Warning Letter, Integra's Chairman had a one-on-one meeting with Krause "to discuss the Boston situation, CEO performance, and new product innovation and design." The following day, the Board "met and posed numerous questions" to Krause about the Boston remediation," and during another one-on-one meeting with another Board member, Krause was told that she "should not be concerned about all the questions from the Board regarding Boston and that ***the Board knew that she was not getting support from Mr. De Witte and Mr. Schwartz, and that they were going to address it***." Despite the Board's professed knowledge of the "Boston situation" and De Witte and Schwartz interference with remediation, the Board never took any significant steps to address these serious issues.

203. Similarly, on February 20, 2024, Krause met with a Board member to explain that the Integra executives were responsible for the deliberate falsification of a presentation for the following day's Board meeting. Krause told the Board member that De Witte and Schwartz "***forced changes to lower the risk level of the Boston manufacturing facility and other high risk manufacturing plants***." In response, the Board member admitted to Krause that Board of Directors "***was aware the CEO and CLO were lying***." Yet, when asked by Krause whether the Board wanted Krause to "change the slides to reflect the true risk," the Board member told Krause not to do so because the Board "***was concerned that the CEO and CLO would retaliate even more***" against Krause and one of her reports. Again, despite the Board's professed knowledge of the "***true risk***" of the Boston Facility and the Company's other manufacturing facilities, the Board never took any significant steps to address these serious issues.[28]

[28] The Board's knowledge that the Company's top executives were lying to them about critical product quality issues and manufacturing site risk levels included the Company's facility in Mansfield, Massachusetts. Prior to Integra's February 2024 Board meeting, Krause warned alerted a Board member about this issue, explaining that De Witte and Schwartz "forced inaccurate risk

204. The Board of Directors also "made no efforts to address the hostile and retaliatory environment" that De Witte's and Schwartz's created and directed at Krause, despite being repeatedly made aware of the misconduct. Indeed, Integra's Chief Human Resources Officer, Chantal Veillon, acknowledged to Krause during one of many meetings on this issue that in addition to Krause, "***other executives had raised the same type of concerns***" and "***that there was a known problem***."

205. Ultimately, after years of enduring intense criticism and overt interference with her responsibilities as Chief Quality Officer by the Company's top executive – including explicit and repeated instructions to lie to the FDA and violate federal regulations so that Integra could continue its lucrative EBM manufacturing and distribution activities without undertaking costly and time consuming remediation – Krause brought the issue to a head by threatening the Company with legal action. Krause's refusal to participate in Defendants' scheme resulted in her constructive termination.

206. Up until the time Krause was forced to resign, Defendants continued to instruct her to lie to the FDA. On March 7, 2024, the anonymous whistleblower who had filed the employee hotline complaint on January 24, 2024 made a report to the FDA because of concerns Integra was "not taking action to protect patient safety." The next day, March 8, 2024, Krause demanded that Integra share all information with her relating to the January 24, 2024 whistleblower report. In response, Krause received "over 100 pages of documents from Integra leadership that previously had not been shared with her, including pictures of employees at the Plainsboro site falsifying

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levels to be shown on the slides." In response, the Director told Krause "***not to correct the slides***" because the Board of Directors did not want De Witte and Schwartz "***to further retaliate***" against Krause and one of her direct reports. Notably, in the third quarter of 2024, after Krause's forced departure, Integra recalled ***22 products*** out of the Mansfield facility.

records and one employee destroying evidence." This information, previously withheld from Krause, confirmed "***over 40 quality issues that directly impacted patient safety***" and "***conclusive evidence of misconduct***," including "***falsification of records***." Remarkably, that same day, Defendant De Witte demanded Krause "sign and send a letter to the FDA" on March 12, 2024, stating "that the whistleblower's allegations were false." Krause refused. Krause did so because the statement De Witte demand she provide to the FDA "***would have been false and required her to commit fraud***." Krause "***communicated this directly***" to De Witte and Schwartz multiple times, yet they consistently "***pressured [Krause] to provide the FDA with false and deceptive information***."

207. In short, rather than listening to and allowing Krause to timely and adequately address the repeated CGMP violations flagged by the FDA at the Boston Facility as well as the Company's other manufacturing sites, Integra's top executives prevented Krause from addressing the problems, schemed to conceal internal complaints and investigations from being brought to Krause's attention as required by law and Company policy, and repeatedly instructed and pressured her to lie to the FDA and violate federal law. As a result, on March 11, 2024, Krause submitted her resignation letter to Integra due to the intolerable working conditions created by Integra's top executives, specifically citing the Company's "***demand that she provide false information to the FDA***."

**b. Integra's Former Senior Director, Site Head Quality Operations At The Boston Facility Confirms Defendants' Fraud.**

208. The damning facts detailed in Krause's Whistleblower Action are bolstered by the equally explosive facts included in Myers' Whistleblower Action. Indeed, while Krause was constructively terminated because she could no longer endure the Company's outright hostility, discrimination, and retaliation for reporting quality and safety issues at Boston Facility and refused

De Witte's directives to lie to the FDA, Myers was fired "effective immediately" just two weeks after Krause for personally ordering the shutdown of the Boston Facility, and personally notifying the FDA's external compliance auditor of the Company' resumption of unlawful manufacturing activities there. Myers' actions "***ensured that the FDA would also be notified and Integra would not be able to bring the contaminated Products to market***."

209. Like Krause, Myers was a highly experienced professional who was actively recruited by Integra under the false pretense that he would be permitted to meaningfully address the significant compliance, manufacturing, and legal issues relating to Integra's manufacture of EBM products at the Boston Facility. When he joined Integra, Myers had over thirty years of experience in the quality operations field, specifically within industrial manufacturing, biotechnology development, and the medical device and diagnostics industries. Integra recruited Myers from his role as senior director of commercial product quality at Siemens Healthineers, a global medical device company. Myers spent more than 5 years at Siemens Healthineers in positions of increasing responsibility in site operations, quality assurance and commercial product standards before joining Integra as the Boston facility's Senior Director, Site Head of Quality Operations. Myers served in that role from August 28, 2023 until his termination on March 26, 2024. Myers' functions focused on quality management, quality assurance engineering and management, research and development engineering, and manufacturing engineering and operations at the Boston Facility.

210. Myers was hired by Integra as the longstanding issues at the Boston Facility were coming to a head. In or about the summer of 2023, Integra began recruiting Myers to become its Senior Director, Site Head of Quality Operations at the Boston Facility. During the recruiting conversations, Integra told Myers that the Company had experienced "significant compliance,

manufacturing, and legal issues related to the manufacture of its EBM products at the Boston Facility, and that it planned to close the Boston Facility in 2025 and would move Myers, along with his colleagues, the Company's facility in nearby Braintree, Massachusetts. Accordingly, upon joining Integra, Myers was informed that (1) Integra had to issue a global recall to remove from the market all EBM products produced at the Boston Facility, due to a series of whistleblower complaints revealing that the products had been contaminated by bacterial endotoxin; (2) Integra was under investigation by the FDA, which had resulted in the FDA issuing the 2019 Warning Letter and the 2023 Warning Letter; and (3) Integra was the defendant in this instant securities fraud class action lawsuit.

211. Against this backdrop, "Integra leaders made it clear to Myers that, if he were hired he would be responsible for ensuring that Integra close all quality management systems compliance gaps identified by the FDA." Integra leaders "promised Myers that he would have the full back[ing] of Integra management in seeking to establish a culture of quality and compliance and that safety and adherence to industry principles and FDA rules would take precedence over realizing Integra's principal market goals" of ensuring the FDA's PMA of SurgiMend by the end of 2024, and the resumption of EBM product manufacturing at the Boston facility in November 2023 and commercial marketing in June 2024. None of these statements was true.

212. Indeed, less than three months after joining Integra, Myers told Integra's senior executives that the targeted November manufacturing restart at the Boston Facility "needed to be pushed back to properly address" concerns expressed by "several Integra employees" regarding the planned process for manufacturing EBM products at the Boston Facility. Myers's desire to ensure that Integra did not distribute contaminated product from the Boston Facility and avoid "life threatening risks" to patients were met with hostility by Integra's senior executives.

However, at a November 10, 2023 "senior leadership meeting," other senior leaders disagreed, and "***instead recommended accelerating the manufacturing timetable*** so that commercial manufacturing would commence in December 2023, more than six months ahead of the targeted June 2024 date. (Emphasis in original.) Myers did not stay silent but instead stated his increasing concern that "***Integra leadership was more interested in shipping product than patient safety***."

213. Defendants rejected Myers' concerns and resumed commercial manufacturing of EBM products at the Boston Facility on an accelerated timeline, beginning January 9, 2024. Integra leadership's blatant disregard of Myers' justified concerns quickly became an unmitigated disaster. Less than two months later, on February 26, 2024, contamination from a variety of biologic and unknown sources were discovered within virtually all – ***97%*** – of the freshly manufactured EBM sheets, or product batches, across all of Integra's EBM product lines, including SurgiMend, PriMatrix, TissueMend, and ReVize.

214. Significantly, Defendants' directive to resume manufacturing at the Boston Facility on an accelerated timeframe flouted FDA requirements, numerous cGMPs, and basic quality standards. As Myers explained, "rather than perform a thorough investigation and root cause analysis … as is required, Integra leadership instructed its employees" to (1) bypass mandatory FDA remediation requirements and industry standards that mandated Integra to produce a nonconformance report regarding the issue and to take corrective and preventive actions ("CAPA"); and (2) instead simply "cut the contamination out of the product." This directive by Integra leadership was "***in direct violation of one of the FDA warning letters requirements***" and posed severe danger to patients, as it is "***impossible to cut the contamination out of product sheets***" and the impossibility to validate such "***rework***." Accordingly, Myers insisted to Integra leadership "***that such rework was not viable because there was no possible way to guarantee that***

***such a process would remove all contamination***." Nevertheless, during a site leadership meeting, and over Myers's repeated protestations," Integra leadership continued to pressure Myers to allow "rework" of the product by cutting around the contaminated portions.

215. Moreover, Defendants attempted to manufacture a false justification for their directive to resume manufacture of EBM products despite knowing that virtually ***all*** newly manufactured product tested showed potentially deadly contamination. During a leadership meeting at the end of February 2024, "Integra leaders told Myers that a medical officer should be consulted to assess the true health risk to patients of the contamination," even though a medical health risk assessment "had already been documented that stipulated that ***no*** particulate contamination is permissible." Defendant Leonard told Myers he "felt good about" Defendants' scheme to find a "medical officer" to approve the Company's improper and unlawful "cut around" plan. However, Myers emphasized to Leonard that the cutting around the contamination "***was not an ethical or viable option***." Myers "***consistently maintained***" to Integra leadership that the newly manufactured EBM sheets "***must be destroyed***" and that the manufacturing process must be "***shut down until the root cause investigation was conclusive and all sources of contamination were corrected***." However, Integra did ***not*** destroy the freshly manufactured EBM sheets that testing revealed were riddled with contaminants. Instead, Integra's Vice President of Operations pressured Myers "***to find ways to use***" the contaminated products. On March 7, 2024, during an executive team meeting, Myers, joined by Krause, reiterated to Integra leadership that manufacturing of EBM products at the Boston Facility "***needed to immediately shut down***."

216. Additionally, Myers and Krause told Integra leadership that representatives of the FDA's external compliance auditor, Greenleaf, must be notified that testing in late February 2024 revealed that virtually all of the freshly manufactured EBM sheets at the Boston Facility were

contaminated, and rather than destroy the sheets as required, the Company planned to "cut around" the contamination and distribute the remaining portion for surgical implantation into patients. Once again, Defendants refused and instead pressured Myers to deceive GreenLeaf auditors by responding evasively to questions about whether the Company planned to rework contaminated product.

217. Appalled by Defendants' unlawful and unethical scheme to rework contaminated product in violation of basic quality standards and fundamental cGMPs, Myers then took matters into his own hands by personally ordering the shutdown of manufacturing at the Boston Facility, and personally notifying Greenleaf representatives of Integra's plan to "rework" contaminated product. Hence, Myers was pivotal in ending Defendants' fraud by "***ensur[ing] that the FDA would also be notified and Integra would not be able to bring the contaminated products to market***."

218. Specifically, on March 14, 2024, after a Greenleaf auditor directly asked Myers and other Integra leaders whether Integra had a process to allow rework of contaminated product, Myers told the Greenleaf auditor "***we will not rework the product***" and "***it was not feasible to rework biological products to remove microbial contamination.***" The next day, March 15, 2024, Greenleaf completed its audit. Significantly, Greenleaf 's audit report included "***twenty-five nonconformance findings, many of which concerned Integra's failed cleaning and contamination controls.***" The focus areas of the audit findings concerned the same cGMP violations that the FDA had repeatedly flagged to Integra since the start of the Class Period, including microbiological controls for bacterial endotoxin testing, water testing and manufacturing cleaning and contamination controls, as well as design controls, manufacturing processes, and complaint management processes.

219. After shutting down the Boston Facility and ensuring Defendants' scheme to continue the unlawful manufacture of EBM products at the Boston Facility would be brought to the FDA's attention, Myers continued to take action to ensure that his efforts would not be undone. During the week of March 18, 2024, Myers held two mandatory staff meetings in which he told the Quality Department "that they would come under intense pressure from Integra management to find any and all means to resume production and rework the contaminated product, but that they should respond with, 'no we have to do things right.'"

220. Remarkably, Defendants ***still*** attempted to pressure Myers into deceiving the FDA. On or about March 25, 2023, at an Integra senior leadership meeting, Integra's senior leadership "insisted that the sheets must be saved by reworking them" because destroying the sheets would be costly, would significantly set back the manufacturing process, would likely doom Integra's ability to receive PMA on Surgimend, and because De Witte and other Defendants had publicly committed to investors that the Boston Facility would resume distribution of EBM product by June 2024. Myers held firm, repeatedly insisting that the contaminated EBM sheets could not be reworked and that it "***all has to be scrapped***."

221. The very next day, March 26, 2024, ***"Myers was notified that his employment with Integra was being terminated effective immediately."***

**c. Former Integra Employees Corroborate, Specifically Confirm, And Provide Additional Details On Core Facts Underlying The Whistleblower Actions And Defendants' Fraudulent Scheme.**

222. Defendants' conduct, as set forth in the Whistleblower Actions, strongly supports Defendants' scienter. Krause's complaint details how Integra's top executive, Defendant De Witte repeatedly instructed her to lie to the FDA and violate federal laws and regulations so that the Company could continue producing and distributing its lucrative EBM products (and other medical devices) without undertaking costly remediation, without implementing costly production halts,

and without destroying EBM sheets that were known to be riddled with endotoxin contamination. Myers' complaint builds on the facts set forth in Krause's complaint, including Myers' similar refusal to "accede[] to Integra leadership's desire to violate state and federal laws and push [contaminated] product to market." Indeed, Myers explicitly alleges that Integra executives acted with a "conscious disregard for law" and with "malice and oppression."

223. Additional former employees specifically corroborated and amplified many of the facts set forth in the Whistleblower Actions. These former employees, Krause and Myers, and the twenty former employees identified herein collectively describe how Defendants directed and perpetuated a Companywide directive throughout the Class Period that prioritized profits and manufacturing output above patient safety, product quality, and regulatory compliance, while knowingly deceiving investors and the FDA.

224. For example, FE 18,[29] who reported to Krause and was a Senior Manager with responsibilities for compliance and quality at Integra beginning in Q3 2023 and ending in Q2 2024, reviewed the Whistleblower complaints and confirmed that Krause was "trying to keep Integra compliant with FDA regulations." FE 18 said that Integra's Boston facility was not an adequate location to produce sterile products.

225. FE 18 also corroborated and supplemented the allegations in Myers' Complaint. FE 18 indicated that Myers was an "extraordinary" Quality Director. FE 18 worked directly with Myers on several matters discussed in his Complaint, including the Greenleaf audit, and the particulate contamination CAPA.

[29] As a Senior Manager with responsibilities for compliance and quality at Integra, FE 18 was responsible for, among other things, managing the Quality Management System for the Tissue Technologies division, supporting remediation projects, managing external and internal audits, and content released to the FDA.

226. FE 18 stated that the Director of Operations and VP of Operations were "putting immense pressure" on Quality to resume manufacturing in Boston despite iron contamination on the products. FE 18 reported that iron contamination is a high-risk failure that could contribute to patient harm. With regard to the audit concerning contamination discussed in Myers's complaint, the auditor stated "if you didn't put a hold on manufacturing, we would have to notify the FDA to shut you down."

227. Given his own conclusions about the need to shut down the Boston facility and the statement from the auditor, FE 18 indicated that he was in alignment with Myers's assessment of severity of the situation in Boston in early 2024. FE 18 confirmed that he believed, as a Quality expert, that Myers "made the right choice." FE 18 also said that the Vice President of Operations and his Director put the Quality system under "undo duress" in their "attempt to bypass the CAPA protocols and release contaminated products."

228. FE 17,[30] Integra's former Director New Product Research and Development, Regenerative Tissue Technologies from its acquisition of TEI in 2015 through his resignation in September 2022, reviewed Krause's complaint and specifically confirmed its core allegation that Integra's approach to quality, safety, and compliance was to make improvements only when they did not affect profits. Before being interviewed as part of Lead Plaintiffs' ongoing investigation, FE 17 was provided with a copy of Krause's complaint and confirmed during the interview that

[30] FE 17 worked for TEI Biosciences at the Boston Facility from 2006 through its acquisition by Integra in July 2015 and remained employed by Integra at the Boston Facility until his resignation in September 2022. FE 17 spent a significant amount of time working with senior management, including the CLO, CQO, and CRO on new indications. Before joining TEI, FE 17 had years of fifteen years of relevant industry experience, including designing and carrying laboratory testing on new products at other medical device companies. FE 17 holds a Ph.D. in Molecular Biology from Princeton University, and has multiple post-doctoral fellowships, including at the University of Rochester School of Medicine and The John Hopkins University School of Medicine.

he had read it. During the interview, FE 17 was read paragraph 12 of Krause's complaint and confirmed its allegations that Integra and its senior executives were (i) only concerned about quality control, patient safety, and regulatory compliance to the extent that they did not affect profits; and (ii) engaged in a concerted effort to downplay quality control issues, avoid FDA regulations, and risk patient safety. FE 17 indicated that these allegations were consistent with his experience at Integra since it acquired TEI Biosciences in 2015.

229. Notably, FE 17 described how he personally warned Krause, within weeks of her joining the Company, that her efforts to reform the Quality department were likely to fail. FE 17 explained how within weeks after Krause joined Integra in June 2021, they had a one-on-one, off-site conversation in which he told Krause that her plans to increase Quality staffing, budgets, and address the issues at Boston would be rebuffed by management. FE 17 informed Krause that before her, there was a long history of turnover of high-quality SVPs and VPs in the Quality and Regulatory department who, like her, sought to genuinely address the issues at the Boston Facility but their suggestions were rejected. Krause replied to FE 17 by saying that he had a negative attitude. However, FE 17 noted, Krause became a convert before she quit.

230. FE 17 explained that Integra's overriding practice was to come as close to the line as it could when it came to quality, safety, and compliance so as not to impact profits. FE 17 described that after Integra acquired TEI, it immediately began testing the limits by only acting to address costly quality, safety, and compliance issues when there was serious regulatory risk. FE 17 emphasized this was an endemic practice at the Boston site as well as the Company's other manufacturing facilities; it was apparent immediately after Integra's acquisition of TEI and continued through his tenure at the Company. FE 17 advised that after Integra acquired TEI, he believed it was an entirely different company. FE 17 noted that many of his colleagues left Integra

shortly after the acquisition due to Integra's decisions elevating profits over quality and safety, and described an ensuing revolving door of very highly credentialed Quality and Regulatory employees, including VPs and SVP, who left Integra for the same reason. FE 17 noted that between the FDA Audit in 2018 and the next FDA Audit in 2021, the SVP of Quality had turned over three times, and R&D employees with 10 to 20 years of experience had left. FE 17 stated that whenever they replaced the Quality management team, the new team was always like, "Holy sh*t, you didn't tell me how bad it was." FE 17 himself resigned from Integra in September 2022 because of the problems at the Boston Facility and his refusal to lie to the FDA, adding that he and others were supposed to tell the FDA they were doing the right things and that he "could not do that."

231. FE 17 provided an example of the Company's pervasive practice for testing the limits in terms of quality, safety and compliance risks. Integra was conducting clinical studies, and had implanted titanium joints in patients' ankles. Every one of those titanium joints had shattered. The Company kept implanting these joints knowing that the reportability limit was 20 serious adverse events in a clinical trial. It decided to stop the trial only once the number reached 19. FE 17 added that this was an example of moving to the absolute limit of safety and regulatory risks, and only then stopping before eclipsing a threshold that would require them to report to the regulator.

232. FE 17 advised that after Integra came under continued scrutiny by the FDA for failing to address repeat deficiencies cited at the Boston Facility, the FDA told Integra it would no longer be able to rely on the 510(k) process for obtaining FDA clearance for marketing products produced at the Boston Facility, but would instead need to seek and obtain PMA before proceeding

with any new indications for EBM products manufactured at Boston.[31] Given the extremely high margins of these EMB products, Integra decided to proceed with a PMA for SurgiMend and attempt to skate by the FDA inspections in late 2021 not by meaningfully fixing the problems previously cited by the FDA, but instead making superficial changes while ignoring any known issues that the FDA did not specifically raise. This is when Krause was hired to help create the appearance of compliance, but who would be limited in her ability to truly remediate the Company's Quality issues.

233. FE 17 said that management's response was not to spend the resources necessary to meaningfully remediate the issues, but rather to address the issues superficially while hiring a series of VPs and SVPs with impeccable backgrounds to impress the FDA. FE 17 described management's plan was to placate the FDA by getting a new quality head, a leader in the field with a really great background. He explained that Krause was just this person, she was a very good Quality leader with an impeccable background and decades of experience.

234. FE 17 then discussed the Company's extremely guarded approach to dealing with inspections and answering the FDA's questions. He said that Integra had a history of findings with the FDA prior to the TEI acquisition. He indicated that the FDA would have a finding, and Integra would reply that the issue (finding) was fixed. The FDA would revisit them and find that the finding was not remediated. The FDA would discover the new coat of paint and tell Integra that this was their last chance to fix it. By the third finding, Integra still did not correct the issue.

[31] The FDA's "510(k)" process is known as a premarket notification and is less rigorous than the "Premarket Authorization" (PMA), which is required for products that are considered to be subject to greater risk in terms of either manufacturing, design, or use. *See* https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k; https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma.

235. FE 17 said that Integra's premise on quality was not to raise issues with the FDA. He noted that at one point he attended every audit with the FDA, every international customer, and market inspectors. During his first FDA audit with Integra, he was getting literally kicked under the table and being passed notes telling him that he should leave the meeting. He noted that senior executives were very much involved in controlling the FDA interactions, adding the Company wanted to control what they said, and this limited their response, and led to whistleblowers. According to FE 17, following that first meeting with the FDA, only a select group of people were allowed to reply to the FDA's questions.

236. FE 17 stated that if the FDA asked a specific question, Integra would imply that they were not withholding information. The FDA had to ask for a specific thing before Integra would produce it. He said that if the information the FDA requested was in a folder in the next room, Integra would ask to get back to the FDA the following day. FE 17 added that Integra's approach was to misdirect the FDA and delay providing it with information. questions.

237. FE 17 stated that about a week after the FDA's October/November 2022 inspections, management knew it had gone bad. In response, a slide deck was created for the C-Suite and filtered up to the Board of Director level describing how the Company promised to hire 60 people at the Boston Facility to address the issues flagged by the FDA. But the 60 person total included in the presentation was illusory. For example, FE 17 saw that his own name referred to in an Excel spreadsheet on which the figure was derived. His name was referenced as being on three separate teams. FE 17 also saw other individuals and teams that were double, and triple counted. FE 17 further noted that at the time the inaccurate and misleading presentation was drafted, Krause's recommendation to increase staffing had already been rejected.

238. Next, FE 17 confirmed that before and after Krause's hire, specific recommendations were made regarding how to effectively remediate the issues at the Boston Facility by his team, the Quality team, other departments, and even outside consultants. These recommendations were passed up the ladder but were not implemented due to cost or timing. FE 17 described several specific recommendations, all of which were designed to address the risks of serious and widespread bacterial endotoxin contamination at the Boston Facility.

239. First, FE 17 stated that when the FDA first came in 2018 its biggest findings concerned endotoxin contamination. The FDA did not think that Integra was properly testing for endotoxin contamination, and noted the Company was selling products 1,000 square centimeters in size, but the largest piece it tested was only 8x12 centimeters. The FDA wanted to know why Integra thought testing such a small piece was indicative of the possible contamination across the entirety of the larger piece from which the sample was taken. FE 17's team looked at that and said that the Quality team should have scaled that test up. He said that the recommendation was rejected and the premise going forward was how they needed to justify their process of testing just a small area. He said that they considered every possible option but did not come up with convincing arguments, which the FDA agreed were not convincing.

240. FE 17 said that they looked at it again and it was obvious that they could not take a piece of material 1,000 square centimeters and fit it into a test tube. The product also started off by one millimeter thick and then became four millimeters thick. Integra then brought in a number of industrial consultants and others within the testing industry. They all said that rather than do one test, the material would have to be cut up into twenty pieces and then do twenty tests – one test per piece. Management's reaction was that testing for endotoxin contamination was already expensive and reacted very negatively asking how they were going to be able to do twenty tests

on each unit. FE 17 explained that it became a matter of cost. Thus, Integra's management rejected both the R&D team's conclusion and the outside consultants' recommendations that Company's endotoxin tests needed to be vastly scaled up.

241. Second, FE 17 provided another example of how the Company tried to avoid properly testing for endotoxins by favoring cheaper, unscientific, and unreliable methods. Specifically, another idea floated was shaking the product and testing the juice from it. However, this was completely imprecise—by shaking the product there was no guarantee that they were getting 100% of endotoxins or 0%. Integra did some tests and found that shaking the product to test what came off was ineffective. To verify, the Company took purified endotoxin and poured it on the product. They then shook the product, and resulting tests of the juice did not return a positive result for endotoxins because the endotoxins adhere to the product like superglue.

242. FE 17's team proved that their work invalidated the Company's proposed method of testing under several scenarios. The following day Integra management met again, thanked R&D for their input, and said they would not be needing R&D any further. R&D was then dismissed from these discussions and as far as FE 17 knew management did not alter the tests. FE 17 added that once management knew they had a big problem, they did not want to hear from the people that also had awareness of the problem.

243. FE 17 stated that as of the time he left Integra in September 2022 because he refused to lie to the FDA, none of the recommendations he had been involved in had been implemented. He added that they even went through Quality files to see when the recommendations were made. He said that the files were missing from the filing cabinet where they had been stored. The Company either intentionally or negligently would lose the files. He emphasized that the Company

did everything it could to prevent the documentation of problems that could come back to bite them later.

244. FE 17 also corroborated and amplified specific facts and occurrences described in Krause's and Myers's complaints. First, FE 17 confirmed that there were executive meetings in early 2022 following the FDA's disastrous Fall 2021 inspections of the Boston Facility. Asked whether Integra's top executives blamed Krause for the failed inspection, FE 17 responded that it was not unusual at all for there to be a sacrificial lamb to blame the issues on and that the executive was siloed and harangued. In FE 17's experience, this seemed to be a tradition at the Company.

245. Second, FE 17 recalled having a one-on-one meeting with Defendant Davis in Spring 2022. Davis said to FE 17 that he has been with the Company for at least ten years. FE 17 told Davis that he was with the Company for over fifteen years. Davis then asked FE 17 what they were doing right and what were they doing wrong. FE 17 discussed with Davis that the Company had hired people with great backgrounds and big plans to fix issues at Boston, but they were not being implemented. FE 17 confirmed with Davis that the Company was "cheap" and was at that time paying for it.

246. Third, FE 17 confirmed his awareness of the Company's longstanding practice described in Myers's complaint, where the Company improperly and unethically engaged in "re-working" or "cutting around" contaminated portions of product sheets rather than throwing away the entire sheet. FE 17 confirmed that the Company had been employing this improper practice for years, as early as 2018. FE 17 confirmed that the practice was unsafe and improper because it is impossible to know where contamination ends.

247. FE 17 personally witnessed the cutting around approach being employed in mid-2020, during COVID. He recalled visiting the Boston Facility with a mask over his face while the

cutting was done and still not wanting to get close to see out of concern for his own safety. FE 17 confirmed that Integra management was aware that the process was a fundamental violation of basic safety, quality, and cGMP standards, but did it anyway because destroying entire sheets would be too costly. FE 17 explained that the only proper practice you can do in such a situation is to throw away the whole sheet. He described how after the cutting was done, the Company would discard the contaminated portion and destroy the illegal evidence. FE 17 noted that this was characteristic of the Company's approach to safety, quality, and compliance. FE 17 confirmed that to his knowledge, the improper cutting around practice described in Myers's complaint was still being done as of the time he left the Company.

248. Significantly, FE 17 described how once the Company decided to move to Braintree, timely and meaningfully remediating the Boston Facility became a "non-issue." Instead, Integra used the Boston Facility prototyping shop to develop processes for Braintree.

249. Finally, and importantly, FE 17 confirmed that based on his personal experience at the Company and his discussions with colleagues who remained at Integra after he left, nothing in Krause's complaint was false or inaccurate. FE 17 explained that the allegations were consistent with the accounts of several of his colleagues that he remained in contact with at Integra after he left the Company. FE 17 noted that after he left the Company, he continued to stay in regular contact with his former colleagues where they discussed the prevailing circumstances at Integra. FE 17 explained that since leaving Integra, he had regular monthly lunch meetings with director-level R&D and manufacturing employees who worked at the Boston Facility, and regular calls quarterly with employees at the Company's corporate headquarters in New Jersey. Based on these meetings and calls, FE 17 understood that nothing has changed since his departure.

250. Other former Integra employees similarly confirmed the veracity of facts included in Krause's complaint. Like FE 17, these former Integra employees confirm that Defendants' years-long scheme to prioritize profits and manufacturing output of product quality, patient safety, and regulatory compliance pre-dated Krause's arrival at the Company and were readily apparent as of the start of the Class Period.

251. Consistent with the allegations of Krause and Myers, FE 19, a Program Manager in Integra's New Product Launch group who worked out of Integra's corporate headquarters from Q4 2021 until Q4 2023 and was focused on Tissue Technologies, confirmed Integra's repeated refusal to remediate issues at the Boston facility.[32] While Integra employees were being told the FDA Form 483s concerning Boston were being addressed, FE 19 indicated that the efforts of Integra's leadership were not working, and continued to be ineffective at all times during his tenure.

252. FE 19 reported that high personnel turnover in Boston, particularly in the Quality group, resulted in a loss of institutional knowledge and prevented Integra from remediating the issues identified by the FDA, including chain of custody and other Quality documentation. Throughout FE 19's tenure, Integra remained unable to develop a system to remediate these Quality documentation and tracking issues.

253. This is consistent with similar accounts from FE 17 and others, described above. Integra's hiring of Krause—a very experienced Quality executive—is further confirmation of

32 FE 19 was responsible for new product launches in the Tissue Technologies division. These products included the Company's cellular matrix products, many of which were produced at Integra's Boston Facility. FE 19 reported to Cara Miller, Senior Director of Program Management, and who was actively working on remediation on the Boston Facility during FE 19's tenure at Integra. Miller reported to Tom Gilbert, General Manager of the Boston facility, and Gilbert reported to Defendant Davis. Miller discussed the Boston remediation project with FE 19.

Integra's inability to develop critical Quality assurance systems, Defendants' awareness of it, and that Defendants concealed this highly material fact when speaking to investors.

254. FE 19's awareness of the remediation failures in Boston was based on his conversations with his boss, Miller, and his participation in monthly New Product Launch (NPL) meetings, held to discuss strategy around all products in the Tissue Technologies division, including SurgiMend. The NPL meetings took place every month during FE 19's tenure at Integra. FE 19 indicated that they were routinely attended by Integra leadership, including Defendants Davis and Anderson, as well as Miller and Gilbert. Davis attended the meetings every month and Anderson attended approximately every other month. FE 19 and others prepared slides for each NPL meeting covering each product produced in Boston, including SurgiMend. The slides were distributed to all invitees to the NPL meetings, including Anderson and Davis. FE 19 understood that it was Defendant Davis's responsibility to keep Defendant De Witte updated on the remediation efforts in Boston, including the impact of the remediation failures on product deliverables related to SurgiMend.

255. The subject of remediation at the Boston facility was discussed at each of the NPL meetings, and it was noted that the remediation timelines and milestones were not met. During FE 19's tenure no progress was made in remediating the quality control issues identified in the FDA Form 483s concerning the Boston Facility. FE 19 reported that the remediation deadlines and timelines being delayed resulted in scheduling for product deliverables also being delayed. FE 19 also reported that even at the time of his departure from Integra in October 2023, the Company was not getting any closer to remediating the problems in Boston.

256. FE 19 was read Defendant De Witte's statement in April 2023 that Integra was on the right track with its execution of remediation of the Boston facility and noted that statement was

made after months of NPL meetings where it was discussed that Integra was, in fact, ***not*** achieving remediation milestones.

257. Similarly, FE 20 confirmed that Integra's failure to remediate the Boston Facility was well known to Integra's senior executives, including several of the Individual Defendants. FE 20 worked at Integra from 2012 through November 2023, serving in several executive capacities within the Operations function at the Company. In his Operations role from 2022 on, FE 20 had numerous meetings in which quality, compliance and regulatory issues were discussed. He also attended monthly business review meetings that senior executives, including Defendants Davis and Leonard, attended. FE 20 said that the content of these monthly business review meetings was reported up to the C-Suite executives.

258. FE 20 acknowledged that serious quality problems at the Boston Facility were well known within Integra and discussed openly at meetings, including the monthly business review meetings he attended. He had visited the Boston site multiple times and it was clear that it was not conducive to manufacturing medical devices up to FDA standards. The Company's efforts to remediate Boston were not serious – they were merely band aids to try and satisfy the FDA in the short term. He was aware that a Boston-based employee filed a complaint in 2022 that 37 lots of product had manufacturing and safety violations. This employee later left the Company.

259. FE 20 noted that from the time Integra acquired TEI, there were deficiencies with its products and production standards. FE 20 said that this was because Integra did not invest in infrastructure and equipment to bring it up to current standards, capital was only allocated if something catastrophic happened. He knew this from his own responsibilities where the Company was using legacy equipment at various facilities, including some that were 30 to 50 years old and not up to standard for current operations.

260. Consistent with Krause's and Myer's Whistleblower Actions, FE 20 stated that the lack of investment in quality and operations was a profit driven directive based on decisions from the Company's most senior leadership, including Defendant De Witte.

261. FE 20 had a couple of meetings with De Witte, and his focus was on profitability: cost containment and revenue. FE 20 said that this theme was reflected in the way the Company handled remediation in Boston. The pressure to drive profit reached its peak in 2022 – 2023 because the Company was not meeting the guidance it provided to investors.

262. FE 20's experience also corroborates that C-Suite executives at Integra put intense pressure on Krause and other Quality Department executives. For example, FE 20 recalled attending an annual leadership team meeting in January 2023 where he observed that Krause appeared to be stressed going over a presentation concerning remediation efforts at the Boston facility and that he later heard that Leonard had made comments about the presentation deck because he did not agree with its content. FE 20 said he was aware that Krause left that meeting before the presentation and Annette Boland and another Quality Assurance person presented on Boston instead.

263. Multiple other former Integra employees whose accounts are set forth above similarly confirmed the veracity of facts included in Krause's complaint, including Defendants' years-long scheme to prioritize profits and manufacturing output of product quality, patient safety, and regulatory compliance.

264. For example, FE 9, a Continuous Improvement Specialist at Integra from July of 2021 through May of 2023, stated that the Boston Facility was continually noncompliant with important CAPAs, which the Company assured the FDA it was implementing. FE 9 was the first and the only Continuous Improvement Specialist at the Boston Facility because Integra failed to

hire staff to support his role. As a result, FE 9 confirmed the Boston Facility's CAPAs were never fully addressed during his entire tenure at the Company.

265. In addition to refusing to implement recommendations and failing to support compliance staff, the Company actively looked for ways to circumvent quality control efforts. For example, FE 12, an Integra Sterilization and Microbiology Subject Matter Expert at Integra from August 2020 until April 2022, explained that when regulatory standards governing a particular medical device changed, the Company was required to apply the new standard going forward and re-examine its prior validation procedures. When standards changed in 2020, the Company made an "***insane***" ask, instructing him to changewithout any re-examinationthe Company's sterilization and microbiology validations from their original 2014 validation date to 2020, the date when new regulatory standards were adopted.

266. FE 8, a Quality Assurance and Regulatory Affairs Consultant at the Boston Facility from December 2021 to May 2022 similarly explained that every time he wanted to implement a solution at the Boston Facility the "consistent response" from top management was that they needed to "***find a way to do it without taking time or money***." Rather than take meaningful steps to remediate the cGMP violations outlined in the FDA's 2021 findings, FE 8 described how Integra put on a "dog and pony" show for the third-party auditor they hired to "appease" the FDA.

267. FE 13, a Ph.D. with an extensive background in bacterial endotoxins who served as Integra's Director of Medical Communications from March 2022 until October 2022, also described how, during a 2022 audit of the Boston Facility, "the Quality team was discussing ways of steering the auditor away from their endotoxin issues." FE 13 confirmed that pressure to conceal the endotoxin issue from the auditor came directly from management.

### F. The Truth Emerges

#### 1. April 26, 2023: Integra Disclosed That It Halted Production At The Boston Facility And Was Belatedly Taking Significant Steps To Promptly Bring The Facility Into Compliance.

268. On April 26, 2023, before the market opened, Integra issued a press release announcing its financial results for the first quarter of 2023. The Company shocked investors by disclosing that it had "***[p]aused production at the Boston manufacturing site in March while pulling forward quality system upgrades project into the first half of 2023.***" As a result of the production pause and increased expense of expediting the long-overdue quality systems upgrades, Integra announced lowered operating margins for the quarter and flat revenue growth projections.

269. That same morning, the Company held a conference call to discuss Integra's first quarter financial results. During that call, Defendant De Witte admitted that the Company had only recently decided to implement meaningful steps to promptly bring the Boston Facility into compliance with cGMP, stating that the "FDA Inspection in March [2023] reinforced the urgency of these quality system upgrades" and created a new "sense of urgency" to implement "a quality system that operates at a higher level." De Witte described Integra's new "8-week focused project," which required the pause of all manufacturing at the Boston Facility to allow Integra to "make the changes in process and physical layouts that are needed." As Mathieu Aussermeir, Integra's Vice President of Corporate Finance, Investor Relations & Treasurer, stated, this 8-week focused project resulted in "idle capacity," additional "project cost," and "impact" to full Company revenue.

270. However, as discussed above in §IV.D., Defendants continued to conceal the full relevant truth and prevented the further decline of Integra's stock price by continuing to make false statements and omit material facts about Integra's remediation progress and the Company's ability to meet customer demand for its EBM products. For example, on the same call, De Witte

downplayed the production pause and reassured investors that the Company was "on track" to "complet[e] related work at [its] Boston facility to upgrade [its] quality systems." Defendant De Witte represented that "an audit early in March [] confirms we're on the right track with our execution." Defendant De Witte further assured investors that the production pause would not have any disruptive impact on the Company's ability to meet customer demand for SurgiMend, stating that Integra had "elected to pause production" and was able to do so because it had "ample inventory in the system… to satisfy current customer demand." He stated, "we're going to be back up and running early June with the factory." Meanwhile, De Witte omitted the scathing observations of widespread, egregious, and recurring deviations from cGMPs detailed in the 2021 Form 483—needless to say how Integra could possibly remediate them all, ***in addition*** to the FDA's outstanding unpremeditated violations from the 2019 Warning Letter and its new observations during the March 2023 inspection, in just eight weeks.

271. As a result of these disclosures, the price of Integra shares fell $4.64 per share to close at $54.20 on April 26, 2023, a decline of nearly 8%.

272. Analysts immediately attributed the stock drop to the revenue impact from the production pause at the Boston Facility. For instance, Truist reported on April 27, 2023 that despite "better" first quarter growth, Integra shares "ended -7.9% yesterday (vs. S&P 500 -0.4%)" due to "mixed forward guidance resulting from a factory shutdown [of the Boston Facility]." Truist lowered its price target from $62 to $58, explaining "we think there could be further downside depending on the resolution of these items." Similarly, Raymond James reported that "the pull forward of the Boston facility upgrades" "adds new risks to the IART story," and concluded that the Company's "slower top-line growth profile supports a discount." The same day, BTIG analysts called Integra's anticipated step up in growth in the second half of 2023

"daunting," adding that the eight-week shutdown of the Boston Facility's manufacturing "put risk of timing on the table."

273. At the same time, analysts relied on Defendants' reassuring statements and remained optimistic that Integra would resolve the Boston Facility's issues in the short term and that the remediation efforts would not prevent the Company from achieving its full year 2023 guidance. For example, Wells Fargo analysts reported that "the pull forward of the Boston quality system upgrade" was "unexpected and weighed on the stock today," but maintained its full year 2023 earnings estimates, noting that "Mgmt indicated that the backlog is immaterial given ample inventory on hand." Oppenheimer issued a report the same day, noting that "[s]hares are under pressure" due to the disclosure of the production pause, but reiterated its outperform rating, noting that "Mgmt. characterized [this] as [a] short-term issue[]."

274. Then, after the market closed on April 26, 2023, Integra disclosed in its Form 10-Q for the first quarter of 2023 that it expected to receive an ***additional*** Form 483 from the FDA concerning the Boston Facility, disclosing that "[o]n March 1, 2023, the FDA commenced an inspection of the [Boston] facility, and [Integra] anticipate[s] that the FDA will issue an FDA Form 483 at the conclusion of this inspection."

275. Nevertheless, Defendants continued to quell investor concern regarding quality and safety issues at the Boston Facility with false statements indicating that significant and meaningful remediation efforts were underway. For example, on May 4, 2023, during Integra's annual Investor Day conference, Defendant Leonard stated that "***[l]ast year and this year, we made significant investments in quality across all of our manufacturing sites with a focus on accelerating our quality project in Boston involving testing, infrastructure, and physical layout***

***changes***." Leonard assured investors that Integra was "***on a path to reach world-class quality assurance across all manufacturing sites by this summer***."

276. By this point, however, Defendants clearly knew that Integra, in fact, had ***not*** taken any meaningful steps needed to improve quality assurance at the Boston plant and never had any intention of undertaking the extensive and costly remediation efforts necessary to salvage the archaic Boston Facility. Indeed, the fallout from the FDA's 2018 and 2021 inspections, including the agency's flagging of numerous, repeat, and egregious compliance deficiencies; the regular monthly and quarterly meetings attended by the Company's entire C-suite and other senior management which included regular updates on the serious issues at the Boston Facility; as well as the information revealed in the October 2022 internal whistleblower complaint that triggered the FDA's for-cause inspection in March 2023, indisputably put Defendants on notice that the Boston Facility remained plagued by numerous fundamental cGMP violations, many of which had persisted for at least five years and as of the time of these April 26 and May 4, 2023 statements still had not been remediated. Indeed, as Integra's senior management privately admitted to the FDA in correspondence dated mere weeks later, Defendants were well aware that the Boston Facility still had "multiple areas requiring additional attention and improvement." Moreover, as of this time Defendants also knew but failed to disclose that Integra had already made the decision to relocate its EBM manufacturing operations to a new state-of-the art facility in Braintree—a decision that would inevitably require a lengthy production halt if the FDA discovered violations requiring a pause in production or shutdown of the Boston Facility.

**2. May 23, 2023: Integra Announces A "Voluntary Global Recall" Of All Product Manufactured Out Of The Boston Facility For The Past Five Years.**

277. Defendants' scheme further unraveled when, less than one month after announcing their "8-week focus project" that purportedly would ***fully*** remediate the myriad, egregious, and

outstanding deficiencies Boston Facility, on May 23, 2023, Integra announced a "voluntary global recall" of all products manufactured at the Boston Facility at any point during the past ***five years***. Specifically, before markets opened that day, Integra blindsided investors by filing a Form 8-K with the SEC disclosing that the Company, "after consultation with the [FDA], initiated a voluntary global recall of all products manufactured in its [Boston Facility]" that were "distributed between March 1, 2018 and May 22, 2023." Integra explained that it "identified through an internal investigation process in its Boston facility deviations with endotoxin testing that may have resulted in the release of products with higher levels of endotoxins than permitted by the product specifications," and that it "decided to initiate the voluntary recall and extend the temporary halt of manufacturing at its Boston facility to implement additional detection and quality controls."

278. In connection with the recall, Integra sent all customers who received SurgiMend and PriMatrix products during the more than five-year period of the recall an "URGENT" notice informing them that an internal investigation uncovered higher levels of endotoxins in the SurgiMend and PriMatrix products that posed significant "Risks to Health," including inflammatory responses leading to fever and/or surgical intervention/revision surgery. Indeed, the recall notice stated that the Company had received 53 complaints that it deemed reportable to the FDA or European national authorities.

279. In this same Form 8-K, Integra also disclosed for the first time that the recall and continued manufacturing stoppage would have a significant impact on the profitability of the Company's Tissue Technologies segment. The Company downwardly revised its guidance for the second quarter of 2023 by 6% and slashed adjusted earnings per diluted share by 26%. The Company also disclosed that it expected to take a $22 million impairment charge at the end of the second quarter of 2023 for recalled inventory manufactured at the Boston Facility. The Company

estimated that its full-year revenue and adjusted EPS would be negatively impacted by approximately $60 million, or 5%, and $0.35, or 10%, respectively.

280. As a result of these disclosures, the price of Integra common stock declined by $10.24 per share, or 22.5%, from a closing price of $50.72 per share on May 22, 2023, to a closing price of $40.48 per share on May 23, 2023, on extraordinarily high trading volume. Given that no other Integra-specific news was announced that day, the Company's unanticipated disclosure of the 5-year product recall was the clear impetus for the sharp sell off.

281. Analysts were alarmed by the recall and questioned the veracity of Defendants' prior public statements. Morgan Stanley reported that the "recall and manufacturing stoppage will have the most significant impact on the higher-growth and higher-margin Tissue Technologies segment (35% of revenue)." Morgan Stanley also questioned whether management had actually undertaken the remediation efforts at the Boston Facility, stating that the recall "does not instill confidence that quality initiatives have taken form, particularly after commentary at the recent Analyst Day [ ] outlining significant investment in quality at the Boston facility."

282. Piper Sandler analysts reiterated their neutral recommendation, calling Integra's disclosures "surprising and concerning" and citing the "lack of catalysts to get shares moving from here," "given Tissue Tech is the most impacted unit of the business here and is expected to be a meaningful growth driver for the company." Likewise, a Bank of America report deemed the recall "the latest in a series of setbacks for key revenue growth drivers." Bank of America linked the recall directly to the systemic issues the FDA had repeatedly identified at the Boston Facility, explaining that the "Boston facility has [a] history of observations/deficiencies," "has been under a warning letter since March 2019," "was re-inspected [in November 2021] and had additional 483 observations," and "received more 483 observations last week which led to the recall."

283. Nevertheless, analysts continued to credit Defendants' statements that Integra was remedying the issues at the Boston Facility and would resume manufacturing in the near term. For example, Raymond James issued a report on May 23, 2023, relying on Defendants' representations that "the [Boston Facility] is back up and running to start 2024" and factored "revenue recovery across 2024" into its estimates. BTIG analysts were likewise optimistic, noting that while "the recall and 8-K leave us with bigger questions about mgmt. and the continued missteps that IART has gone through over the past year," they were reiterating their neutral rating based on management's assurances that "there are no more 'big shoes' to drop."

284. On July 26, 2023, Integra issued a press release announcing its financial results for the second quarter of 2023. In the press release, which was also filed with the SEC on Form 8-K, Integra disclosed that on July 17, 2023, as a result of the FDA's 2023 inspection of the Boston Facility, the FDA not only issued a new Notice of Inspectional Observations on Form 483 but also issued another warning letter. In doing so, Integra disclosed for the first time that the 2023 Warning Letter would prevent the Company from obtaining the PMA for SurgiMend's post-mastectomy indication, given that "premarket approval applications for Class III devices to which the quality system regulation violations are reasonably related will not be approved until the violations have been addressed."

285. As detailed above, the 2023 Warning Letter, which was consistent with what the 2018 Form 483 and 2021 Form 483 previously disclosed, concluded that Integra still had not "identified all the necessary corrective actions to demonstrate that your quality system will ensure controls are in place to prevent the release of non-conforming products," noting that many of the problems identified during the FDA's 2023 investigation were ***repeat "deficienc[ies] from [the FDA's] 2019 Warning Letter to this facility***."

286. That same day, the Company held a conference call with analysts and investors to discuss its second quarter 2023 financial results. During that call, Defendant De Witte revealed that the commercial relaunch of products made at the Boston Facility would not take place for ***at least another ten months***, until "***mid to late second quarter 2024***." De Witte further disclosed that for the second quarter of 2023, Integra "saw a negative impact of approximately $23 million from lost revenues and returns and a negative impact to adjusted EPS of roughly $0.20 associated with the recall." De Witte stated that, contrary to his earlier assurances that manufacturing at the Boston Facility would resume in June 2023, the Company had now adopted a remediation plan "to ***resume manufacturing by the end of the fourth quarter of this year [2023]***" and "***to initiate a commercial relaunch by the mid to late second quarter 2024***."

287. However, Defendants attempted to regain investors' confidence by telling investors that the production pause and recall of products made at the Boston Facility had no connection to patient safety issues, unequivocally stating that "***we have no specific indications of any product complaints related to high endotoxin levels***. ***Patient safety is non-negotiable for us***." De Witte also silenced any concern that the issues cited in the new Warning Letter could not be quickly addressed by the Company, and doubled down on Integra's commitment to relaunch production of its surgical mesh products from a remediated Boston Facility: "***I want to assure our customers and investors that we are highly focused on our remediation efforts, and we fully expect to complete the remediation and return these critical technologies to the market for our customers and their patients***." De Witte also emphasized that Integra's "***leadership[] [was] definitely fully engaged on the Boston execution***."

288. During the question and answer portion of the call, analysts pressed Defendants for details on the remediation efforts and timeline for the Boston Facility resuming production. In

response, Defendants reiterated that they were confident in the assumptions underlying the timeline and emphasized that the timeline even factored in "contingency… for unforeseen things that may happen." Defendant De Witte emphasized that Integra controlled the timeline for resuming manufacturing at the Boston Facility, stating that "[t]he FDA has confirmed that restarting manufacturing is done at our own decision… there's no… FDA audit involved in restarting manufacturing or restarting the shipping."

289. Analysts noted that Integra had shifted back the timeframes for resuming production at the Boston Facility, but accepted Defendants' representations that Integra was on track to meet their revised timelines for effectively remediating the cGMP issues at the Boston Facility. For instance, on July 28, 2023, Raymond James analysts issued a report noting that "[e]xpectations from May were that the issues [at the Boston Facility] would be cleaned up by the end of July, with the initial response to the FDA submitted in June," but "[a]n additional WL received last week extends the timeline through 2023, as the Form 483 requires an increased level of documentation (root cause analysis, validation, verification)." Raymond James underscored that the extended timeframe also accounted for "planned in-process external audits and the final audit… as well as the need to rebuild inventory," and emphasized that "[n]o FDA clearance is required to restart the facility, but IART will provide audit results to the FDA."

290. In light of the recall of all products manufactured at the Boston Facility over the previous five-plus years due to deviations from cGMP and the new 2023 Warning Letter, Defendants went out of the way to reassure investors that Integra complied with cGMPs and that its products met the highest quality standards. Thus, on August 17, 2023, the Company issued its 2022 ESG Report, assuring investors that Integra "***adheres to Good Manufacturing Practices (GMPs)***, ***[and] Quality System Regulations (QSRs)***," and "deliver[s] the highest-quality

products." The 2022 ESG Report underscored that "***product safety and quality are paramount,***" and the Company "***continuously improves our Quality Management System (QMS) to meet the highest and most current quality standards***."

291. During the 2023 Wells Fargo Securities Healthcare Conference on September 6, 2023, Defendants touted the significant progress Integra had made on remediating the Boston Facility and confirmed that Integra remained on track to resume production and distribution on the timelines disclosed during the Company's Q2 2023 earnings call. For instance, in response to an analyst question about the production pause and recall, Defendant Knight assured investors that "***the Boston remediation continues to progress well***" and Integra "***hired in the right technical expertise to support and drive building a remediation plan and executing against it… we are absolutely on the right path, that our timelines to get back into market are real***." Doubling down on De Witte's earlier statements about the Company's timeline for resuming production at the Boston Facility on the Q2 2023 earnings call, Defendant Knight assured investors that the Company would "***begin manufacturing again in the end of this year and that commercial distribution would resume somewhere in the mid to late Q2 2024 timeline***." She further assuaged investor concern, stating that the Company was undertaking "independent reviews … to let us know whether or not we were on pace," noting that "***that [the] first independent review and the observations coming out of it say we're still on track for that timeline***."

292. In the second half of 2023, Defendants continued to assure investors that the Boston Facility would resume manufacturing activities that year. During the Company's Q3 2023 earnings call on October 25, 2023, Defendant De Witte assured investors that "***our progress in addressing the Boston facility and returning to the market remains on track***," and continued to claim that "***the adequacy of [Integra's] remediation plan"*** was "confirm[ed]" by "[i]nterim

external reviews." De Witte represented that "the changes made so far… reflect ***significant steps made towards the resumption of manufacturing by the end of the fourth quarter 2023 and commercial distribution in mid- to late second quarter '24***" and reiterated that "***we are on track with our communicated timelines***."

293. Analysts continued to accept Defendants' representations that Integra was making progress on remediating the Boston Facility, and on track to resume manufacturing at the Boston Facility by the end of the fourth quarter of 2023. For example, Wells Fargo analysts issued a report on October 25, 2023, noting Integra's "progress in addressing the Boston facility" and reporting that "Boston restart timelines remain on track" with "good visibility." Raymond James analysts similarly reported that "[t]here were no changes to the Boston facility re-start[,]" "IART will start manufacturing [at that facility] by the end of 4Q23," and resume commercial distribution "by late 2Q24." JPM Securities similarly noted that the Boston "plant remediation remains on track, with the timelines previously communicated," and credited management's assurances that "interim external reviews have confirmed the adequacy of its remediation plan and the changes made so far, reflecting steps forward toward resumption of manufacturing by the end of 4Q23 and commercial distribution in mid- to late-2Q24."

### 3. February 28, 2024: Integra Announces The Sudden "Retirement" Of CEO De Witte And Additional Negative Impacts From The Recalls.

294. On February 28, 2024, Defendants' fraud was further revealed to the market when the Company issued a press releases disclosing the sudden "retirement" of De Witte after less than two years as the Company's CEO, disappointing financial results for the fourth quarter and full year 2023, and disappointing guidance for the first quarter and full year of 2024 that was well below analysts' expectations and due, in part, to continuing negative impacts from the recall and production stoppage at the Boston Facility. Specifically, before markets opened on February 28,

2024, Integra issued a press release disclosing a "leadership transition plan," including the abrupt "retirement" of De Witte due to "family requirements." In the press release, the Company stated that the Board of Directors had initiated a formal search for a replacement to De Witte and that Chairman Essig, the Company's former CEO and current Non-Executive Chairman, had been appointed as Executive Chairman.

295. Before markets opened on February 28, 2024, Integra also issued a press release reporting disappointing financial results for the fourth quarter and full year 2023. In the press release, the Company stated that 2023 earnings were negatively impacted by issues at the Boston plant, including (i) a 7.7% decline in adjusted EPS due to spending reductions, (ii) a 62% decline in GAAP net income, (iii) an 11.7% decline in adjusted net income due to product returns, unfavorable mix from the lost revenue and remediation costs, and (iv) a 24% decline in adjusted EBITDA margins due to the recall. The press release also announced disappointing guidance for the first quarter and full year of 2024, including an anticipated decline in revenues from 5.5% to 4.1% for the first quarter 2024, as well as reductions attributable to the cessation of any new orders for private label products manufactured at the Boston Facility.

296. During a conference call held during market hours to discuss the Company's financial performance and forecasts, the Company provided investors with an update on the progress of remediation at the Boston Facility. During the call, Defendant De Witte attempted to blunt the announcement of continuing adverse impacts from the cGMP deviations by providing a largely favorable update on the Boston Facility, stating: "We restarted the factory in November and in January, we successfully completed an initial external review following the factory restart, the dress rehearsal we referred to in earlier calls. We're now preparing for the external audit which will take place in March. Successful audit will allow us to start building finished good inventory

to resume distribution mid to late second quarter." However, De Witte admitted that Integra's "growth" and "achievements" in other areas continued to be "obscured by [the] Boston recall," in particular, the Company's forecasted gross margins. As Defendant Knight explained, the Company's forecasted gross margins were lowered because the higher gross margin EBM portfolio "will only be back in for 2024 for a portion of the year" and remediation costs will keep mounting "until we're fully up and running."

297. During the question and answer portion of the call, management admitted that the Boston Facility recall directly accounted for part of guidance reduction, noting that the planned reopening would be limited to SurgiMend and PriMatrix, and would not include any private label business, which accounted for approximately 20% of the Boston Facility's revenues. Indeed, Defendant Knight revealed that despite the Boston Facility's reopening, the Company had received no orders from its private label partners and the Company did not expect to have all products relaunched out of Boston until 2025. When an analyst asked Defendants for "more color" on the results of the dress rehearsal and questioned "why that gives you confidence on the resumption of sales starting in the second quarter," Defendant De Witte stated that the dress rehearsal gave the Company "confirmations" that it had performed the required remediation work, and yielded only "***limited observations on things that we could have improved***." He assured investors that the "***[s]uccessful audit will allow us to start building finished goods inventory to resume distribution mid- to late second quarter.***"

298. As a result of these disclosures, the price of Integra common stock declined by $5.60 per share, or 13.5%, from a closing price of $44.27 per share on February 27, 2024, to a closing price of $38.67 per share on February 28, 2024, on abnormally high trading volume. The Company's stock price continued to decline the following day, falling another $1.76 or 4.6% to

close at $36.91 on February 29, 2024, as the market continued to digest the news and multiple analysts cut their price targets for Integra shares. In total, Integra's stock price plunged by over $7.36, or more than 16%, over this two-day period.

299. Analysts easily connected the Company's disappointing results to De Witte's departure and lost business from private label brands. For instance, Raymond James issued reports stating that Integra's earnings guidance was "surpris[ing] … given commentary in late '23," and noting that Integra "lower[ed] the expected '24 Boston revenue contribution by ~$20M, and is only including a ~$9M benefit from SurgiMend/Primatrix, with no anticipated contribution from Private Label (~20% of Boston revenue historically)." J.P. Morgan similarly reported that it remained "cautious on Integra" in light of the "disappointing guide, as well as multiple moving pieces from the CEO transition and uncertainty around a recapture of lost Boston sales." Truist called the miss a "disappointment" and noted that "the cadence of these contributions [from the Boston Facility] (and how realistic they are) and how they factor into guidance is a key question."

#### 4. May 6, 2024: Integra Shutters The Boston Facility Through At Least The End Of 2024 And Refuses To Provide Any Timeline For Its Reopening.

300. On May 6, 2024, the market was stunned by additional disclosures regarding when (if ever) the Boston Facility would resume operations, and the attendant negative impacts on the Company's financial performance and growth prospects. On that date, before markets opened, Integra issued a press release announcing first quarter 2024 financial results and updated guidance. While the Company issued favorable results for the first quarter of 2024 and favorable guidance for the second quarter of 2024, it slashed the Company's full year adjusted EPS guidance from a range of $3.15 to $3.20 per share, to $3.01 to $3.11 per share, well below analysts' consensus estimate of $3.19 per share.

301. During the accompanying earnings call with investors, the Company provided a highly unfavorable update on the Boston Facility, which accounted for the reduced full-year guidance and cast a cloud over the amount and timing of any future growth tied to sales of SurgiMend and PriMatrix. Specifically, Defendant De Witte stated on the call that the external audit of the Boston Facility, which was required by the FDA as part of the process to address the 2023 Warning Letter and resume production, resulted in "more findings than we anticipated" and that "[b]ased on our preliminary assessment, we no longer expect to resume commercial distribution in 2024," effectively bringing the total shutdown time to over ***a year and a half***. As a result, the Company removed SurgiMend and PriMatrix entirely from its full year 2024 guidance. As De Witte stated on the call, "[f]or the full year, we are updating our adjusted EPS to be in the range of $3.01 to $3.11 per share, reflecting the delay of the relaunch of SurgiMend and PriMatrix."

302. Analysts were blindsided by the negative update on the Boston Facility. During the question and answer session following the Company's prepared remarks, the very first question was from a Wells Fargo analyst declaring the negative Boston news "came today as a surprise to a lot of people." The Wells Fargo analyst commented that it "sounds like you [Integra] don't expect to resume commercial distribution in 2024," and asked management to "share some additional details around what the results of the [external] audit revealed" and whether it meant management had to "revisit" their long-term plan. In response, De Witte provided scant details, stating only that "the final audit confirmed that there's more to be done," which the Company "acknowledge[s] and accept[s]." De Witte attempted to assuage investor concerns by pointing to "changes" the Company had made "to the operations and quality leadership and structure to ensure the right focus and capabilities is applied to Boston." De Witte's statement misleadingly implied

that to fix the deficiencies at the Boston Facility, Integra had to terminate its Chief Quality Officer (Krause) and Site Head of Quality Operations at the Boston Facility (Myers).

303. Numerous other analysts asked the Company for additional details regarding when the Boston Facility would reopen and when SurgiMend and PriMatrix would return to market. For example, during the call, an Oppenheimer analyst pressed De Witte for more information "about the next steps in Boston" and "the milestones that investors should be looking for as you go through the rest of the year?" Once again, De Witte was reticent to provide any concrete milestones, conceding that the Company was "still determining the work plan," and stating that milestones would be set after the Company finished "translating the observations from the latest audit." De Witte added that, while "at this point in time there's no specific milestones yet," "we know enough to come to the conclusion that we are pushing out the PriMatrix and SurgiMend's revenue for this year." Later, in response to a question from a Truist analyst, Defendant Knight reiterated that the Company would also not be providing any guidance on contributions from products made at the Boston Facility for any part of 2025.

304. As a result of the persistent, serious, and seemingly insurmountable issues at the Boston Facility, a Raymond James analyst asked if the Company had "started looking" at manufacturing SurgiMend and PriMatrix at another facility and, if so, "[h]ow long it would take to get up and running at a new facility or another facility." In response, De Witte assured that the Company was "not excluding any option" and "if there are options, we will take them into account." Defendant Knight added that the Company had been "building out capacity at another site in Boston called Braintree," which was among the options the Company was considering.

305. Additionally, management reiterated on the call that not only was the Company's earnings forecast negatively impacted by the complete removal of all revenues for SurgiMend and

PriMatrix for all of 2024—with no knowledge or expectations of when these important revenues would return—but also that the complete cessation of sales of SurgiMend and PriMatrix would negatively impact the Company's gross margins. As De Witte stated, "[i]n light of the ongoing remediation costs that we'll incur based on the Boston timeline," investors "should now think about gross margins that will be moderately down year-on-year versus 2023."

306. As a result of these disclosures, the price of Integra common stock declined by $5.75 per share, or 22.5%, from a closing price of $28.89 per share on May 3, 2024, to a closing price of $23.14 per share on May 6, 2024, the following trading day, on extremely high trading volume.

307. Multiple analysts issued negative reports on the Company after the May 6, 2024 disclosures. For example, J.P. Morgan issued a report on May 6, 2024 citing the Company's lowered full-year adjusted EPS guidance, which noted that with "Boston challenges taking far longer than expected and no clear timeline on a resolution, this represents a disappointing setback on top of an already challenging past few quarters for Integra, and we think it will take time for investors to get more constructive on the story." Raymond James also issued a report on May 6, 2024 emphasizing that the persistent issues at the Boston Facility remain "a focus (and drag) on the 2024 outlook." One month later, analysts *continued* to report on the uncertainty surrounding the Boston Facility and when and where Integra would resume production of its EBM devices. For example, Jefferies issued a report on June 6, 2024 partially titled, "Assessing Boston Options + Timelines," which underscored that "revenue contributions from IART's South Boston facility have been removed from the '24 guide and IART does not anticipate including revs in '25 either."

308. On May 14, 2024, Integra presented at the Bank of America Healthcare Conference 2024. In response to a question from a Bank of America analyst about when investors should

expect to receive new information about the Boston Facility, including an update on the timing for its reopening – "Like when will we know when we will know [about when it will reopen]" – Defendant Knight admitted that the difficulties remediating the deficiencies identified by the FDA were so severe that the Company was strongly considering moving manufacturing for the products from the Boston Facility to an entirely different site that was still under construction. Remarkably, after noting the "frustration and disappointment" the Company's investors had experienced based on the findings of the FDA's 2024 final audit, Defendant Knight acknowledged that the Company had been considering the move to Braintree ***for at least 18 months***. As Knight put it, "[do we] remediate the process and relaunch out of our existing South Boston location?" or "[d]o we remediate the process and launch directly out of a facility in Braintree, Massachusetts, which is the facility that we already had under construction because that was our long-term plan for the Boston portfolio" that "had been put into place about 18 months ago."

309. Defendant Knight also made clear that strategic decisions related to operations at the Boston Facility were being made at the highest levels of the Company. Specifically, during the Bank of America Conference, Knight emphasized that "planning for Boston is being led absolutely" by "management" and "the Board," adding that "across our management team, we are making the decision as to what the right pathway is" and "that decision is a management decision – "absolutely an internal management decision" – that "obviously does get reviewed with the Board." In response to a follow-up question from the Bank of America analyst whether, if manufacturing of products from the Boston Facility were moved to the Braintree Facility, "how close would that be to actual production," Knight refused to provide a "definitive answer" and remarked that: "What I can share though is our, from a time line perspective, our lease in South Boston site [i.e., the Boston Facility] is up in 2026." In other words, Defendant Knight conceded

that for at least the prior one and a half years, Integra management and the Board had actively considered moving all EBM manufacturing at the Boston Facility to a different site still under construction, all while the Company continued to receive repeated warnings from the FDA of significant cGMP violations at the plant but passively waited for the Boston Facility's lease to expire in 2026.

310. On July 15, 2024, Defendants' long-held plans for abandoning the Boston Facility were revealed to investors. On that date, Integra issued a press release titled, "Integra LifeSciences Provides Updated Plans for Its Manufacturing Facility in Braintree, Massachusetts." The release stated that the Company planned to wind down the Boston Facility and restart production of its PriMatrix and SurgiMend products at its new manufacturing site in Braintree, Massachusetts. According to the release, the Braintree Facility would be operational "in the first half of 2026" and the Boston Facility would be used only temporarily and on a limited basis "to support product and process development" at the new Braintree plant. Defendant Davis, Executive Vice President and President of Tissue Technologies, noted that "[g]iven the advantages of the Braintree facility and the challenges of the Boston facility, the decision to consolidate our efforts at our new Braintree location enables us to focus our resources in one location… while limiting execution risk." Put differently, Defendants essentially conceded that remediating the egregious cGMP violations at the Boston Facility would take a period of ***three years total*** from the initial production stoppage. Thus, Integra finally came clean that deficiencies at the Boston Facility were so pervasive, severe, and time-consuming and costly to remediate that it was preferable to shutter the plant completely and restart manufacturing of EBM devices at an entirely new plant, rather than attempt to remediate deficiencies at the Boston Facility that the FDA had been observing and warning Defendants about and Defendants had been promising they were remediating for over six years.

**5. July 29, 2024: Integra Discloses Systemic Compliance Deficiencies And Shipping Holds Across The Company.**

311. The full truth about the Company's compliance deficiencies was finally revealed on July 29, 2024. On that date, Integra stunned the market by disclosing that the persistent, pervasive, and significant compliance deficiencies that the FDA had been flagging for years at the Boston Facility were far more serious, and, in fact, permeated the entire Company.

312. On July 29, 2024, before markets opened, the Company issued a press release (filed on Form 8-K with the SEC), filed its Form 10-Q for Q2 2024, and held an accompanying earnings conference call with investors to announce the Company's financial results for the second quarter of 2024. In these documents and on this conference call, Defendants announced a "compliance master plan to address quality system and GMP compliance learnings" across the Company, which resulted in dramatically lower full year 2024 revenue and earnings guidance, lowered 2025 revenue and earnings guidance, and uncertain forecasts beyond.

313. To address the systemic compliance failures across the Company, management and a dedicated committee of the Board of Directors would be immediately undertaking costly preventive and corrective actions that would continue through 2024, 2025, and beyond. Significantly, the "compliance master plan" included a production pause across the Company's key product lines. Defendants admitted that these dramatic steps were taken based on the Company's interactions with regulators. Thus, the market learned that the FDA was so frustrated with the Company's utter failure to adequately remediate the persistent, pervasive, and significant cGMP failures at the Boston Facility after years of warnings that the FDA took the remarkable step of compelling Integra to undertake a sweeping Company-wide compliance overhaul with disastrous ramifications for Integra's business, financial performance, and outlook. This

stunningly unforeseen development caused Integra's stock price to plunge nearly 20% in a single day, on extraordinarily high trading volume.

314. The "compliance master plan" and accompanying shipping holds were disclosed in the Company's earnings release and Form 10-Q, and discussed further during the accompanying earnings call with analysts. Executive Chairman Essig delivered the Company's opening remarks on the call, revealing upfront that Integra had identified "a series of operational and quality system gaps" which made it "clear that ***there is a need to bolster our manufacturing quality compliance processes across the organization***." Essig sketched the counters of a new "compliance master plan" to "improv[e] our quality system and GMP compliance across our manufacturing and supply network," which would drive "increased spending in the second half of 2024 and lower revenue and EPS expectations for the year." Indeed, Essig described that "several shipping holds" put in place to address regulatory compliance issues had already had revenue impacts, and that planned investments associated with the compliance overhaul would occur beyond 2024 and continue throughout 2025. Essig frankly admitted that management was finally "giving these issues the attention they deserve," and emphasized that these efforts were needed "to support sustainable long-term growth."

315. Essig was followed by Defendant De Witte, who spoke specifically to the Company's plan to permanently shut down the Boston Facility and relocate all manufacturing for the Company EBM devices to "our new state-of-the-art manufacturing facility in Braintree, Massachusetts." De Witte stated that the Company was still constructing the Braintree Facility, which it did not expect to "operationalize" until the first half of 2026. De Witte conceded that the "limitations of the physical space" and unusual "layout" of the Boston Facility were additional reasons for the move to a "brand-new" plant.

316. During the call, CFO Knight detailed the significant financial impacts to Integra as a result of the new "compliance master plan." For full year 2024, Integra now forecasted reduced revenues "in the range of $1.609 billion to $1.629 billion" due to "the temporary shipping hold and supply back-orders," representing a reduction of approximately $90 million. The hit to earnings was even more substantial, with adjusted earnings per share in the range of $2.41 to $2.57 per share—a reduction "in the order of magnitude of about 80 basis points," according to Knight—due to the "temporary shipping hold as well as our planned increase in spending to support [the] compliance master plan." Knight conceded that the increased spending would impact both the second half of 2024 and 2025, but reiterated that it was necessary in order to "remain confident that our portfolio and commercial teams can generate sustainable growth over time."

317. During the analyst question and answer session that followed management's prepared remarks, analysts barraged management about the impetus for and impacts of the "compliance master plan." In response to a question from a Raymond James analyst, Knight stated that the emphasis of the compliance master plan "is exactly on quality management systems and GMP compliance," and that it "incorporated observations that we've gotten from regulatory authority along with our own internal assessments." A Citigroup analyst noted that she was "confused" as to why the Company had decided to implement the global compliance program and a broad-based shipping hold—"Were those things that the FDA asked you to do? Or were those things that you chose to do?" In response, Knight again conceded that they came about as "the result of observations that we've received, both internally as a result of internal assessment that we do across our network as well as regulatory authorities externally."

318. Analysts also questioned why it had taken so long to fix the issues at the Boston Facility. For example, a BTIG analyst pointedly asked, "Why has it taken … so long as it has to

resolve the issues? And why will it still take through the course of 2025 to resolve the issues?," noting that the Company's failure to get SurgiMend "back online" had "bedeviled investors for a while now with the quality issues." In response, Defendant De Witte explained that institution of the "compliance master plan" was driven by "the need to be more effective at standardizing our quality system across the company," which is why management decided "with our Board to launch this compliance master plan." As to the Company's manufacturing of SurgiMend and other EBM devices, De Witte frankly acknowledged that building the Braintree Facility with the plan to have that site ready in 2026 was "[a]ll … part of a long-term manufacturing strategy for SurgiMend and PriMatrix," as Defendants "knew [the Boston Facility] was never going to be big enough to deliver to the growth opportunities, specifically with our breast strategy and SurgiMend."

319. Finally, as to the severe financial repercussions of the compliance master plan, analysts peppered management with questions about the "supply disruptions" caused by the compliance master plan, how long the shipping hold would last, and how long revenues and margins would be negatively impacted. As to the supply disruptions, De Witte and Knight both acknowledged the disruptions but declined to provide specifics, unable to express anything more than hope that the disruptions would abate in 2025 and beyond. As to margins, Knight acknowledged that in addition to the significant "negative impact" on margins forecasted for 2024 and 2025, "beyond that … we do anticipate some level of maintenance costs from a gross margin perspective and the impact on gross margins as a result of those investments" but "I can't say specifically what that would be because were not providing 2026 guidance at this point."

320. As a result of these disclosures, the price of Integra common stock declined by $6.01 per share, or 21%, from a closing price of $31.43 per share on July 26, 2024, to a closing

price of $25.42 per share on July 29, 2024, the following trading day, on extremely high trading volume.

321. Following the call, numerous analysts slashed their ratings for Integra's stock and issued reports excoriating Integra management for their lack of transparency with investors. For instance, Morgan Stanley analysts issued a report titled "An Unexpected (And Deep) Cut," noting "[n]ew headwinds coupled with remediation investments drag the '24 outlook lower with repercussions extending into '25." Morgan Stanley lowered its estimates, explaining that the "deep earnings cut provides little visibility on IART's go-forward growth/profitability." J.P. Morgan analysts also lowered their guidance noting that "quality- and recall-related issues have taken far longer than anticipated to resolve," and "a significantly greater than expected disruption from the Boston [] facility," because "the company has chosen to move away from the Boston facility entirely." J.P. Morgan took a "cautious view on the company's ability to cleanly resolve these headwinds given a mixed track record seen so far." Truist analysts lowered their price target on Integra to $26 from $32, citing the Company's "big" guidance cut for the second half of the year while noting that there is too much uncertainty given the ongoing execution risk and a potentially prolonged share recapture situation with so many products off the market. Citigroup similarly cut its recommendations to sell from neutral, and reduced its price target from $30 to $23, citing the anticipated hit to revenue in third quarter 2024 from the shipping hold, and explaining, this is "not the news we wanted as Integra bumps along toward manufacturing resolution." BTIG downgraded Integra to sell from neutral, and cut its price target 13%, citing the ongoing quality issues and resultant shipping hold, which it anticipated would severely impact margins into 2025, excoriating management for "***a poor job of improving its operations but an even worse job communicating these issues and setting appropriate expectations***." Jefferies likewise lowered its price target,

noting that it "will be a long slog for IART to work through quality issues and recoup share in the market along with recovering credibility with investors."

### G. Post-Class Period Events Further Corroborate Defendants Pervasive Failure To Remediate Known Compliance Deficiencies.

322. Defendants' refusal to comply with cGMP requirements is further confirmed by additional quality issues that have continued to plague Integra's facilities after the Class Period. These issues, extending beyond the Boston site, to Integra's other facilities reflect a systemic failure to abide by critical quality and safety standards.

323. On January 6, 2025, Integra disclosed in a press release that on December 29, 2024, it had received yet another FDA warning letter "relate[d] to quality system issues identified during FDA inspections at three of the Company's facilities located in Mansfield, Massachusetts, Plainsboro, New Jersey, and Princeton, New Jersey." The warning letter stated that the FDA's inspections had revealed that certain of Integra's products that are used for wound care, soft tissue repair, and reconstruction surgery were "adulterated…in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation."

324. Then, on the February 25, 2025 earnings call, Defendant Knight disclosed that "$10 million of quality-related shipping holds" would be "carried over from 2024" in addition to "an incremental $8 million to $10 million in quality-related ship holds already identified in the first quarter as part of our Compliance Master Plan." She further stated that Integra would be assuming a $90-$120 million cushion for shipping holds "beyond what we know today." The disclosure of the shipping holds "***caught [analysts] off guard***." As analysts at JPMorgan noted, "the potential for new shipping holds and recent supply challenges in Private Label ***raise questions***."

325. Finally, on May 5, 2025, during its earnings call, Integra disclosed that it had identified additional ship holds for certain products and that, based on its assessment, Integra now expected "total ship holds for the year to be between $55 million and $70 million" instead of the $27 million that it had previously disclosed to investors. Integra also told investors that, while the Company was "working diligently to resolve all warning letter observations to the FDA satisfaction," "the organization has also revealed the need for more effective prioritization of our program at the enterprise level and a more disciplined approach to program management and execution." Analysts at Wells Fargo observed that "the impact from shipping holds makes it ***hard for us to get comfortable on the company being able to deliver product without seeing additional supply disruptions***," and analysts at BTIG remarked that "***investors are likely wary of these dynamics given shipping holds continue to plague IART***."

## VI. ADDITIONAL ALLEGATIONS OF SCIENTER

326. As alleged herein, numerous facts give rise to a strong inference that Defendants knew or recklessly disregarded that their statements and omissions were materially false and misleading when made concerning (i) Defendants' remediation efforts at the Boston Facility; (ii) quality assurance and compliance with cGMP in the manufacturing and production of SurgiMend, PriMatrix, and other EBM products; and (iii) the capacity for production of EBM products at the Boston Facility were materially false and misleading when made. In addition to the allegations set forth above, particularized facts evidencing Defendants' scienter include the following.

### A. Integra's Two-Highest Ranking Quality Officials For The Boston Facility, Confirm Defendants' Intent To Deceive Investors And The FDA.

327. In two wrongful retaliation lawsuits, Krause and Myers, the Company's former senior-most officials responsible for quality at the Boston Facility, confirm in remarkable detail that Integra's senior management intended to deceive investors and the FDA, directing and

perpetrating a culture of noncompliance in which serious quality and safety risks were "only addressed if they did not impact profits or present an immediate and significant regulatory risk. Indeed, instead of timely remediating fundamental, pervasive, and serious cGMP violations repeatedly cited by the FDA, the Individual Defendants, (1) lied to and deceived the FDA and external auditors, and directed employees to do the same, in connection with critical on-site inspections, to avoid having to destroy lucrative product and institute costly manufacturing and distribution stoppages; (2) circumvented established procedures for reporting quality, safety, and compliance issues to avoid detection by senior personnel tasked with ensuring quality for products manufactured at the Boston Facility; (3) terminated senior officials who refused to participate and blew the whistle on Defendants' fraud; and (4) deliberately refused to undertake the necessary overhaul of its quality, safety, and compliance systems at the Boston Facility, including specific recommendations presented to the Company's Board of Directors. These allegations establish the direct involvement of the Defendants in this Action, and their intent to deceive the FDA, and, in turn, conceal their intentional deception of the FDA from investors by making the numerous false statements described below.

328. As detailed above, on October 20, 2022, an employee whistleblower lodged an internal complaint through Integra's hotline about the serious quality system issues at the Boston Facility. Among other things, Krause confirmed that the whistleblower complaint alleged that sterile and non-sterile products were being mixed at the Boston Facility and that management had instructed employees to ignore any potential contamination.

329. More specifically, Krause confirmed that senior Integra executives handled the whistleblower's complaint without the involvement of Krause – the Company's senior-most official responsible for quality. Indeed, according to Krause, Integra's internal company policy

and FDA regulations mandated executive management's involvement: Both required that the Chief Compliance Officer notify the Chief Quality Officer (then Krause) of any quality-related internal reports, including the whistleblower complaint, within 24 hours of receipt. Despite this mandate, Krause waited more than a week before anyone alerted her about the complaint. Shortly thereafter, Krause confirmed that Integra's CCO, Tracy Redondo, closed the complaint but once again, failed to inform her that the complaint had been closed.

330. Nevertheless, even after Integra brushed aside the whistleblower's allegations, the whistleblower persisted in his warnings by "putting notes under the Boston plant manager's door on December 5, 2022, December 14, 2022, and January 11, 2023"—the last of which outlined "***37 different lot numbers***" with quality issues.

331. After learning of the whistleblower's allegations, on December 14, 2022, Krause put all new manufacturing at the Boston Facility on hold. But over her objection, Integra continued "work in progress" at the Boston Facility for almost a month. Integra's refusal to halt manufacturing at the Boston Facility led Krause to notify the FDA about the October 22, 2022 complaint, triggering a "for cause" on-site inspection that started on March 1, 2023.

332. Krause confirmed that when the FDA Auditor requested a copy of the transcript from the hotline complaint, Defendant Schwartz and Redondo "refused to provide it," only complying after Krause stepped in and "escalated the matter" to Defendant De Witte. Defendant De Witte then instructed Redondo to give Krause a copy of the transcript so she could turn it over to the FDA and Integra could avoid being written up for "Failure to Comply" – which could subject the Company to severe consequences, including orders to cease all manufacturing and commercial operations at the Boston Facility, recalls of products manufactured there, denial of Integra's PMA for SurgiMend's use in breast reconstruction, civil fines, and criminal prosecution.

333. The issues the FDA identified in its investigation at the Boston Facility included: (i) the manner in which Integra measured the level of endotoxins at the Boston Facility; (ii) lab results showing that certain products manufactured at the Boston Facility contained "unacceptably high concentrations of endotoxins," which can cause patients to suffer serious harms; and (iii) over ***80 customer complaints*** "in which patients reported high fevers, inflammation, revision surgical intervention, infection, and meningitis." Because of the seriousness of these issues, Integra's Product Safety Board agreed to destroy existing inventory of tainted products. When Krause expressed that she wished she could save the product but did not want to violate FDA regulations, Defendant De Witte responded, "***Why not?***"

334. Similarly, on May 2, 2023, after Krause refused to allow Integra to ship inventory from Europe to Boston and illegally relabel it for sale in the United States, Defendant De Witte pressured her to violate FDA regulations, insisting that she "could load the printer equipment into the trunk of her car and drive them to Integra's manufacturing location in Mansfield, Massachusetts, to print the labels, and then bring them back" to the Boston Facility for U.S. distribution and that this scheme would work because "***no one would know.***"

335. On January 24, 2024, another anonymous whistleblower made another complaint regarding quality issues in Plainsboro. Receiving no response to his complaint, the whistleblower made a report to the FDA on March 7, 2024 because of concerns Integra was "not taking action to protect patient safety." Defendant De Witte again demanded that Krause shirk regulations, requesting that she "sign and send a letter to the FDA" stating "that the whistleblower's allegations were false." In the face of Krause's refusal, Defendants De Witte and Schwarz "***pressured [Krause] to provide the FDA with false and deceptive information***." FE 18 corroborated that

Krause was put under extreme duress by Leonard to alter slides concerning remediation of the Boston Facility a meeting in 2023.

336. Defendants De Witte and Schwartz repeatedly made other demands that interfered with Krause's ability to perform her duties, including: (i) demanding that Krause lower the risk assessment for multiple sites in a presentation to Integra's Board, even though Krause believed the sites were at high risk of receiving an FDA warning letter for noncompliance; (ii) threatening to withhold Krause's bonus if she proceeded with the recall of Integra's cranial access kits; and (iii) verbally attacking Krause if she did not accede to their demands. Krause reported their conduct to Integra's Board on July 17, 2023, and February 20, 2024.

337. Myers' allegations corroborate Krause's account. Myers explained that, less than three months after joining Integra, in November 2023, Myers met with senior executives and informed them that the targeted November manufacturing restart at the Boston Facility "needed to be pushed back to properly address" concerns expressed by "several Integra employees" regarding he planned process for manufacturing EBM products at the Boston Facility. But like Krause, executives met Myers' warning with hostility and "instead recommended ***accelerating*** the manufacturing timetable."

338. In the face of Myers' warnings, Defendants resumed commercial manufacturing of EBM products at the Boston Facility on an accelerated timeline, beginning January 9, 2024. When just weeks later contamination was discovered within 97% of the freshly manufactured EBM sheets, across all of Integra's EBM product lines, Defendants continued to flout regulatory requirements, bypassing the investigations and root cause analysis required by the FDA. Myers warned Integra leadership that such a process would not ensure against contamination, but they

continued to pressure Myers to allow "rework" of the product by cutting around the contaminated portions.

339. Myers confirmed that Defendants attempted to manufacture a false justification for resuming manufacturing of EBM products despite the widespread and potentially deadly contamination. During a leadership teleconference at the end of February 2024, "Integra leaders told Myers that a medical officer should be consulted to assess the true health risk to patients of the contamination despite the fact that a medical health risk assessment had already been documented." According to Myers, approval from a medical professional meant that he would be forced to approve the release of the EBM products—regardless of any risk assessment that they had conducted.

340. Myers elevated these concerns to Krause and Defendant Leonard. Nevertheless, Leonard told Myers he "felt good about" their "cut around" plan. After Myers reiterated his concerns to Leonard, Integra's Senior Director of Operations, Ken Allen, sent Myers a text message "expressing anger for [Myers'] unwillingness to restart manufacturing and/or investigate ways to rework the contaminated product."

341. Myers continued to advise Integra leadership against the "cut around" plan, including during a March 7, 2024 executive team meeting when he and Krause told leadership that manufacturing of EBM products at the Boston Facility "needed to immediately shut down." Met with rejection once more, Myers ordered the shutdown of manufacturing and "ensured that the FDA would also be notified and Integra would not be able to bring the contaminated products to market." Shortly thereafter, he was fired, "effectively immediately."

342. The detailed and damning facts alleged in Krause's and Myer's Whistleblower Actions concerning a years-long, "concerted effort" by Integra's senior leadership – with the

knowledge of the Company's Board of Directors – to "downplay quality control issues," "avoid FDA regulations, and risk patient safety in violation of multiple applicable laws and regulations" strongly supports scienter.

**B. Numerous Additional Former Employees Confirm That Defendants Deliberately "Kicked To The Curb" Any Costly Or Meaningful Remediation, In A Deliberate Scheme To Prioritize Profit And Manufacturing Output Over Product Quality, Patient Safety, And cGMP Compliance.**

343. The consistent accounts of multiple former employees at all levels and across the organization—including employees who worked at the Boston Facility during the Class Period and who personally attended regular monthly and quarterly meetings with Integra's senior and executive management—confirm that the Individual Defendants intentionally deceived investors and the FDA as part of a deliberate scheme to prioritize profits and manufacturing output at all costs, even if it meant blatantly flouting product quality, patient safety, and cGMP compliance.

344. Numerous former employees confirm that Integra's violations of federal regulations and cGMP were pervasive and widely known inside of Integra, including by those at the very top of the Company. However, rather than undertake meaningful steps to remediate the pervasive, serious, and recurring cGMP deviations at the Boston Facility, Defendants refused to stop production or undertake other costly measures that would impact EBM device sales—which boasted "***80%-plus"*** profit margins and which Defendants ***"expect[ed] the greatest growth to come from over the next five years"***—as part of a Company-wide directive to prioritize profits over safety and quality. Integra senior management's actual knowledge, and access to information, concerning the rampant violations at the Boston Facility, and their deliberate efforts to avoid disruptions to production and other costly remediation in order to protect the growth and extraordinary profit margins of its EBM portfolio—including by retaliating against employees who complained of quality issues—strongly supports the Individual Defendants' scienter.

345. Preliminarily, the explosive facts set forth in Krause's and Myer's Whistleblower Actions leave no doubt that Defendants scheme to prioritize profits and production at all costs was intentionally pursued and directed by the Individual Defendants and other members of Integra executive leadership team, including Defendants De Witte, Schwartz, Davis, Leonard and Redondo.

346. Moreover, Krause's and Myers' accounts are confirmed and amplified by numerous other former Integra employees with firsthand knowledge of the scheme. These allegations based on accounts from FEs 17, 18, 19 and 20, are detailed above and make clear that the Individual Defendants sought to actively deceive and mislead investors and the FDA.

347. FE 17 specifically indicated that the core allegations in Krause's complaint concerning Integra's prioritization of profits over safety and quality, and making superficial changes to create an appearance of compliance. FE 17 noted that he personally warned Krause that her efforts to reform the Quality Department were doomed to failure. FE 17 noted that Krause was among several hires by Integra that were designed to create an appearance of dedication to compliance, but that there was no true commitment in terms of resources, investment or actual compliance. For example, FE 17 noted that following the FDA's 2022 inspections, the Company represented that it would hire 60 people to work on remediation at the Boston Facility, but that number was illusory.

348. FE 17 also reported that the Company sought to carefully control who could interact with and respond to questions from the FDA and also was not transparent or forthcoming with the FDA, but rather sought to conceal or delay providing information even if it was very specifically requested.

349. FE 19 similarly corroborated that Integra made no progress in actually remediating the problems at the Boston Facility, which was known by the Individual Defendants, specifically including Defendants Anderson and Davis, who were at monthly meetings where this was discussed. Defendant Davis was responsible for providing updates on the discussions at those meeting to Defendant De Witte. FE 19 specifically stated that Defendant De Witte's statement in April 2023 about Integra being on the right track in remediation of the Boston Facility was made after months of meetings where Davis and Anderson were present and where it was discussed that remediation milestones were ***not being achieved***.

350. FE 20 similarly corroborated Krause's and Myers's allegations that the Company prioritized profit over quality and that he personally observed that directive in meetings with Defendant De Witte. FE 20 also corroborated Krause's allegation that she was put under extreme duress to conform statements and presentation to the Defendants' preferred narratives.

351. FE 18 corroborated the allegations that Integra sought to conceal information from and mislead the FDA and the Company's auditor in connection with manufacturing holds mandated by Integra's failure to address cGMP issues in Boston that the FDA had identified. FE 18 also indicated that both Myers and Krause sought to bring the Company into compliance and made the right decisions.

352. FE 3 confirmed that the C-suite and senior management knew about the significant cGMP deviations and endotoxin issues at the Boston Facility, and lack of remediation, because these issues were discussed at regular monthly and quarterly meetings with executive and senior management. FE 3 personally attended these regular monthly and quarterly meetings, along with CEO De Witte, the CFO, COO, SVP of tissue technology, Robert Davis, and VP of Global Operations and Supply Chain, Steven Leonard. In fact, according to FE 3, Integra senior

management knew as early as the TEI acquisition that there were several systems that needed to be fixed at the Boston Facility—including issues that made the Facility prone to high levels of endotoxin contamination which would have been very costly to fix, but issues were routinely "kicked to the curb" to protect profits. The C-Suite had knowledge about processes and improvements that could have been implemented, but rather than address the endotoxin contamination and continual deviations from cGMP, Defendants knew or at least recklessly disregarded the fact that any remediation efforts implemented were not actually effectively progressing. FE 3 recalled, "there was no progress or accountability and focus to remediate. They first said that the remediation was going to be six months, then a year, then 18 months, and it was still not fixed." FE 3 underlined: "***They all knew what was happening. Before that FDA Warning Letter came in 2019, they knew about the problems in Boston for five years and they ran the clock out before the FDA nabbed them***."

353. As FE 3 explained, senior level management was "***apathetic***" because SurgiMend and other EBM products manufactured at the Boston Facility were very profitable, and senior management did not want to undertake expensive remediation in order to protect the high margins on the EBM products. According to FE 3, everything was "quarter-to-quarter" and when it came to addressing the issues at the Boston Facility, senior management's approach was to do the "***least amount possible with the least amount of money***." FE 13 similarly confirmed that the Company's "M.O." was to do the least amount of work with the FDA and other notified bodies, and "***worry about it after the fact***." Echoing FE 3's account, FE 13 stated that rather than proactively address extensive cGMP deviations at the Boston Facility and incur significant costs and resources, "***the culture was that we have gotten away with this for this long***."

354. FE 8, Integra's Quality Assurance and Regulatory Affairs Consultant at the Company's Cincinnati facility from March 2020 to December 2021 and then a Quality Assurance and Regulatory Affairs Consultant at the Boston Facility from December 2021 to May 2022, explained, consistent with FE 3's and FE 13's accounts, that the Company "***had no interest in fixing anything***" because the Company did not want to invest money in its fixes. Instead, Integra "***squeezed whatever they could***" out of the "acquired product," including SurgiMend and PriMatrix. FE 8 explained that every time he wanted to implement a solution, whether it was at the Boston Facility or the Cincinnati facility, the "consistent response" from top management was that they needed to "***find a way to do it without taking time or money***."

355. FE 1, Integra's former Chief Scientific Officer from February 2014 through October 2021, confirmed FE 3's recollection that the Company held monthly meetings led by the quality and regulatory teams during which Integra's quality and regulatory teams led presentations on the operations of each facility, including the Boston Facility. These meetings, which were held at the Company's headquarters, were attended by the Company's executive leadership, as well as the head for every function such as operations, manufacturing, quality, and regulatory, and management from each facility, including the Boston Facility. During these meetings, members from the quality and regulatory teams presented on each Integra facility, whether they had any adverse events, and the status of any FDA inspections, and progress of any remedial work. Slide decks were prepared for these meetings, and members from the quality and regulatory teams presented the data in them, while manufacturing from a specific plant or site would provide comment.

356. In addition, there was a distribution list for these meetings in which the slide decks were sent to everyone on the list serv, including senior management and the executive leadership

team. The senior leadership team included the highest levels of management, including the CEO and CFO, as well as business presidents. Specifically, FE 1 recalled that Defendants Arduini, Coleman, and Anderson were involved in the monthly meetings, as well as the head for every function such as operations, manufacturing, quality, and regulatory.

357. FE 1 confirmed that the Boston Facility was discussed regularly, including the FDA's inspections of the Boston Facility. He explained that, "whether it was remodeling, production, or supplies, ***there was no month that Boston was Scot-free***." FE 2 likewise confirmed that, upon the Company's acquisition of the Boston Facility from TEI, Integra's executive management, including Defendants Arduini, Coleman, and Davis as well as executive Mark Augusti, held monthly management meetings where the Boston Facility's manufacturing operations, including remediation needs and related costs, were regularly discussed.

358. FE 4, a former Site Quality Director at Integra from January 2021 until March 2022, further confirmed that the Company's senior and executive leadership closely monitored quality control issues at the Boston Facility. FE 4 explained that the site quality director of each facility, including the Boston Facility, was required to attend monthly meetings held by the Company's senior quality leaders, including Maria Cianciotto, Integra's former VP of Quality for Operations from 2018 until December 2021, and then Annette Boland, Integra's former VP of Global Product Quality from January 2022 until September 2023. At these meetings, site directors presented on their monthly quality metrics, which included reporting on any quality control issues relating to contamination, and endotoxin contamination issues. Site directors were required to present detailed information on their quality metrics, including the status of all CAPAs and Non-Conformance or "NC" Reports opened in response to quality control incidents, as well as reporting any changes in their facility's manufacturing controls or their continuous improvement plans.

359. FE 13 confirmed that "endotoxin contamination in the Boston facility was a company-wide, known issue in February 2022 because I distinctly remember having conversations about endotoxins and where it was coming from." Specifically, he explained that his supervisor Head of Global Medical Affairs Sandra Berriman, was "well aware" of the issues and reported directly to both senior executive Michael McBreen and Defendant Davis, who both reported to Defendant De Witte. As FE 13 recounted, "Berriman knew and there was no way that Bob Davis did not know, and if Davis knew so did Jan De Witte. ***It was a well-known issue*** ***and "it would be highly unlikely that these issues were not known at the top."*** FE 13 described SurgiMend as Integra's "***golden child***," and "***front-runner***" product, and reiterated that management had "***a flashlight on it at all times***."

360. Given the importance of its EBM products to the Company's growth and profitability, Integra enforced a Company-wide directive to prioritize profits over safety and quality compliance, as confirmed by former employees from multiple levels and different manufacturing facilities across the Company. For example, FE 5 complained that there were a number of things that he wanted to change with respect to quality at the Boston Facility, but none of those projects progressed due to Integra's relentless emphasis on "***profits over quality***," which he explained "***ultimately came from the top***." Other former employees reported the same in the Company's other facilities. For example, FE 10 described how the Company's Mansfield Facility was rife was cGMP violations due to the Company's directive to look the other way on bad compliance practices even when employees like FE 10 raised quality and safety issues and just "***get the product out the door***," FE 10 emphasized that the pressure to cut corners was "***absolutely***" coming from corporate, and that supervisors at the plant level were "***complete soldiers***" to "***what they were being told from the top***." FE 10 said this was true company-wide, and that executive

management "***could have cared less what they were shipping out as long as it went out the door***." FE 10 reiterated: "***It was whatever it took to make the shipment and the dollar. They didn't care***." FE 11 described similar issues at the Company's Plainsboro facility, explaining that executive management "***cut corners***" and "***should have ensured QA was in place doing their job, but no one did anything about it***."

361. As other former employee information confirms, the Company also retaliated against those who reported compliance issues with cGMP compliance. For example, FE 13 confirmed that the Company retaliated against employees who reported compliance issues to upper management. FE 13 explained that when he, a director, complained about noncompliance, he discovered his boss had approached Human Resources to inquire about timing his future termination.

362. Finally, FE 8 further explained that Integra chronically underreported complaints and adverse event reports—including for SurgiMend and PriMatrix—because the Company attributed adverse events to patient comorbidities. When Integra received a patient complaint concerning a device, the Company would code the complaint as part of its investigation. However, as Integra's third-party auditor pointed out to the Company, the Company did not file adverse events beyond the initial coding of the complaint when the patient possessed comorbidities. Rather, Integra would end the investigation and simply point to a patient's comorbidities to say that it could not be proven that the product caused the adverse event. In other words, if a patient was already injured prior to using this device, there was no way anyone could prove the patient got an infection from their product and, therefore, the Company would not file an adverse event report.

363. That Integra senior management—including Individual Defendants—had knowledge of and access to discussions surrounding the Boston Facility's failure to comply with cGMP and the FDA's audits documenting that noncompliance, deliberately refused to implement costly and time consuming remediation, retaliated against employees who complained about compliance deficiencies, and chose not to further investigate patient complaints concerning Integra's devices and instead attributed them to patient comorbidities, gives rise to a strong inference of scienter or, at minimum, severe recklessness.

### C. The FDA Repeatedly Told Defendants Of Systemic, Severe, And Recurring cGMP Violations At The Boston Facility.

364. The FDA's routine inspections and issuance of Forms 483, EIRs, and Warning Letters put each Defendant on notice—prior to and throughout the Class Period—that the Boston Facility was in violation of federal regulations and cGMPs, and was manufacturing SurgiMend, PriMatrix, and other EBM products in unsanitary conditions that were prone to bacterial endotoxin and fungal contamination. The Boston Facility received numerous Forms 483, EIRs, and Warning Letters, all with recurring and worsening identified deficiencies.

365. As alleged above, the FDA privately sent Integra a Form 483 in 2018 alleging numerous quality deficiencies in the Boston Facility that contradicted Defendants' public statements. Among other things, the 2018 Form 483 described how Integra's quality systems and manufacturing conditions were "not in conformity with the current good manufacturing practice requirements of the Quality System Regulation." The 2018 inspection found that the Boston Facility was rife with cGMP violations, including numerous deficiencies in Integra's contamination controls, environmental controls, process validation controls, and CAPA controls relating to the Company's manufacturing of biologic mesh products.

366. As alleged above, and as Defendants were aware, these cGMP violations were serious, widespread, and required immediate remediation. In addition to presenting the above findings to Integra in the 2018 Inspection Reports, the FDA also discussed them with Integra management at a close-out meeting on November 2, 2018, which was attended by senior members of Quality Assurance, including Brenda M. Romeo, Senior Manager of Quality Assurance, whose reporting line led to Defendant Arduini. Notably, as the 2018 EIR sets forth, Integra directed the FDA to send all related correspondence directly to Defendant Arduini.

367. On March 6, 2019, the FDA issued a warning letter to Integra, concluding that Integra's proposed remediation measures "***are not adequate to address the [cGMP] violations***," which the FDA determined "***demonstrate a systemic failure of your firm's quality systems***" and necessitated "***prompt action to correct the violations addressed in this letter***." Significantly, the 2019 Warning Letter was directly addressed to Defendant Arduini, and also copied Ms. Romeo.

368. Integra continued to receive clear warnings from the FDA that the Boston Facility was rife with serious cGMP failures. On November 12, 2021, after conducting an investigation, the FDA issued the 2021 Form 483. The 2021 Form 483 again cited Integra for continuing cGMP violations at the Boston Facility and showed that Defendants had neither corrected the prior cGMP violations discovered during the 2018 inspection, nor prevented similar cGMP violations from reoccurring. As detailed above, these included environmental control violations that Integra had assured the FDA would be remediated, as well as failure to establish alert and action levels to detect bacterial and fungal growth despite Integra's representation to the FDA that it had implemented a CAPA to address this violation. The 2021 Form 483 was privately issued to Integra's Management Representative Edward J. Callahan, Plant Manager of the Boston Facility, whose reporting line led to Defendant Arduini.

369. After the 2023 inspection, the FDA issued yet another Form 483 detailing systemic and repeat cGMP violations, which the Company had not remediated, and many of which dated back to the 2018 inspection. These violations included deficiencies in the Company's contamination and process validation controls, product non-conformance controls, and CAPA controls, including the Company's approval of dozens of adulterated lots for commercial release even after an internal whistleblower had raised concerns. The 2023 Form 483 was issued to Integra's Management Representative Kenneth W. Allen. In response, Integra sent a letter to the FDA signed by Susan Krause ("Krause"), Integra's Chief Quality Officer, and copying Defendant De Witte. Notably, the letter conceded that the Company had "multiple areas requiring additional attention and improvement" and "acknowledge[d] the need to adjust [the Company's] previously established remediation plans"— conceding that Defendants knew their remediation efforts were wholly deficient.

370. Finally, on July 17, 2023, the FDA sent Integra the 2023 Warning Letter, which was directly addressed to Defendant De Witte, copying Krause. The scathing letter chastised Integra for the Boston Plant's egregious never-remediated cGMP violations, including that Integra still had not "identified all the necessary corrective actions to demonstrate that your quality system will ensure controls are in place to prevent the release of non-conforming products," and noting that many of the problems identified during the FDA's 2023 investigation were ***repeat "deficienc[ies] from [the FDA's] 2019 Warning Letter to this facility***."

371. Moreover, as discussed above, the FDA directs all companies that receive a Form 483 to send the report "***to the top management of the firm***," i.e., Defendants Anderson, Arduini, Coleman, Davis, De Witte, Leonard, Knight, Redondo, and Schwartz.

372. The multitude, pervasiveness, and duration of the serious cGMP violations outlined in the Forms 483, EIRs, and Warning Letters, support a strong inference that all Defendants were aware of them or, at minimum, recklessly disregarded them. The FDA's consistent scrutiny, over years, of the continuous violations, contributes to a strong inference of the Individual Defendants' scienter.

### D. Defendants Refused Costly Remediation Of The Antiquated Boston Facility – It Became A "Non-Issue" – Because Integra Internally Decided To Relocate To A New "State-Of-The-Art" Facility.

373. Integra's refusal to make needed investments and upgrades of Boston Facility due to the costly and extensive disruptions to production that would result from remediation and Defendants' future plans to move to the Braintree Facility further supports an inference of Defendants' scienter.

374. Contrary to Defendants' assurances that the Company had "done a lot of things just around the manufacturing process there to build out more capability" at the Boston Facility and had "ma[d]e significant investments in that facility to support the growth plans over the next five years," Defendants never planned to complete the remediation process at the Boston Facility because doing so would entail massive disruptions in manufacturing just as Integra was attempting to become a leading provider in the surging and highly lucrative market for biologic mesh. As Integra ultimately acknowledged, the remediation required to address egregious and pervasive cGMP violations at the Boston Facility was so extensive that implementation would require a production stoppage for up to ***three years***—a time period that Defendants found untenable, as they sought to keep up production at the Boston Facility to show investors they were able to meet market demand.

375. On July 15, 2024, when Integra announced that it would be shifting manufacturing of PriMatrix and SurgiMend to the new Braintree Facility, the Company revealed that the

"difference in timing compared to restarting in our existing Boston facility" was ***minimal.*** As Defendant Davis stated, "[g]iven the advantages of the Braintree facility and the challenges of the Boston facility, the decision to consolidate our efforts at our new Braintree location enables us to focus our resources in one location. This represents a minimal difference in timing compared to restarting in our existing Boston facility, while limiting execution risk." In other words, remediation of the Boston Facility would take around the ***same time*** as the operationalization of the Braintree Facility—which was expected in the first half of 2026. Defendants conceded that remediating the egregious cGMP violations at the Boston Facility would take a period of ***three years total.***

376. The Company's refusal to tolerate any disruptions to production was further corroborated by former employees. FE 2 confirmed that, during monthly meetings with Integra's executive management, including Defendants Arduini, Coleman, and Davis, the Company explored transferring manufacturing operations from the Boston Facility to a different Company facility, but did not carry out the proposal because it was deemed too disruptive to the Company's manufacturing operations.

377. Moreover, Defendants never intended to complete remediation of the Boston Facility—nor invest the necessary resources and funds to address the Facility's pervasive quality standard issues—because they planned to move into a new facility.

378. As set forth above, Integra's Board of Directors officially approved moving ahead with the Braintree relocation on April 1, 2022—meaning that the Board and senior management were necessarily considering the relocation well before then. At the time, Integra's Senior Vice President for Plant Operations and Plant Optimization stated that the reason for the relocation was

that they were "going to outgrow" the Boston Facility and needed a "state-of-the-art" facility to move into.

379. Despite Defendants' intention to relocate to the Braintree facility, Defendants continued touting their remediation progress throughout the Class Period and misled investors to believe that production at the Boston Facility would not be disrupted. Even after the Company announced the recall in May 2023, Defendants continued to assure investors that remediation was well underway. On September 6, 2023, Defendant Knight assured investors that "the Boston remediation continues to progress well" and that the Company had "hired in the right technical expertise to support and drive building a remediation plan and executing against it … we are absolutely on the right path."

### E. Regulatory Compliance And Quality Control Were Critical To Integra's Business.

380. Integra's quality control processes and cGMP compliance were areas of significant regulatory scrutiny, which further supports an inference of Defendants' scienter. As noted in SEC filings during the Class Period, Integra's "products, development activities and manufacturing processes [were] subject to extensive and rigorous regulation by numerous government agencies, including the FDA and comparable foreign agencies." Defendants further touted Integra's "numerous mechanisms and processes embedded within our business operations to protect and ensure product quality, continuously improve the effectiveness of our quality management system, and ensure compliance with all regulatory requirements."

381. Because Integra is subject to strict regulatory control, Defendants were familiar, and had extensive experience, with the FDA's inspection and citation process. The FDA inspected Integra's facilities and inspectors reported regulatory violations to Integra's management. In particular, and as Integra knew, enforcement of cGMP requirements was a subject of outsized

concern at the FDA at the outset of the Class Period. As alleged above, the FDA has emphasized that companies that violate cGMP requirements face severe sanctions, including the bringing of a seizure, injunction, or even criminal case in court. Integra has acknowledged in SEC filings that if the FDA believes that a company is not in compliance with applicable regulations, the FDA "may issue a warning letter, institute proceedings to detain or seize products, issue a recall order, impose operating restrictions, enjoin future violations and assess civil penalties against that company, its officers or its employees and may recommend criminal prosecution to the U.S. Department of Justice." Moreover, given Integra's issuance of annual ESG Reports during the Class Period touting its ability "to protect and ensure product quality, continuously improve the effectiveness of our quality management system, and ensure compliance with all regulatory requirements," it belies common sense that the Company's top-level management, including the Individual Defendants, did not know of the long-standing, pervasive, and serious manufacturing, maintenance, and quality control deficiencies that plagued the Boston Facility.

382. The critical importance of regulatory compliance to Integra's business, and the personal experience that Integra's executives had with the FDA's inspection and citation process—which consistently resulted in findings of cGMP violations at the Boston Facility and the issuance of observations, findings, and warnings to the Company at its executives—supports the inference that Defendants' statements regarding Integra's compliance with cGMP regulations were at least recklessly false when made.

### F. Defendants Repeatedly Assured Investors That They Were Focused On And Actively Addressing The FDA's Warnings And Citations.

383. Throughout the Class Period, Defendants assured investors that Integra management was focused on and actively managing the Company's efforts to address the FDA's Forms 483 and Warning Letters, as well as the Company's remediation process. Specifically,

Defendants told investors that senior management was actively focused on the remediation efforts at the Boston Facility.

384. On February 19, 2020, after the FDA's 2018 inspection, Defendant Coleman assured investors that "***[w]e've been doing quality remediation efforts throughout 2019***." Then, on May 20, 2021, during the Company's 2021 Virtual Investor Day conference, Defendant Coleman stated that the Company "made investments in [its] core plants," including the Boston Facility, and told investors that the Company's "***work is now complete***" and that these investments equipped the Company with "***a manufacturing footprint that's … able to produce quality products and staffed with colleagues with deep expertise in manufacturing complex products***."

385. Defendants continued to tout their remediation process well into the Class Period, even as the FDA continued to issue warnings to the Company in 2021 and 2023, culminating in the May 2023 announcement of the recall of all tissue-related products made at the Boston Facility. For example, on April 26, 2023, when asked about the production pause at the Boston Facility by an analyst, Defendant De Witte assured, "***we've been working for the past couple of years to upgrade our Boston facility based on FDA observations in 2018 and 2021***," and that the Company "***had an audit early in March that confirms we're on the right track with our execution***." On July 27, 2023, during the Company's Q2 2023 earnings call, Defendant De Witte stated that Integra's "***leadership[] [was] definitely fully engaged on the Boston execution***."

386. Later, on May 14, 2024, at the Bank of America Healthcare Conference 2024, Defendant Knight made clear that "***planning for Boston is being led absolutely***" by "***management***" and "the Board," adding that "across our management team, we are making the decision as to what the right pathway is" and "***that decision is a management decision***" –

"***absolutely an internal management decision***" – that "obviously does get reviewed with the Board."

387. Yet, while Defendants were making these repeated assurances, the Boston Facility continued to possess serious quality deficiencies. Either Defendants possessed knowledge concerning Integra's purported remediation efforts, in which case they knew that the efforts were inadequate, or Defendants lacked the knowledge they claimed to have, in which case their statements on the subject were deliberately reckless.

### G. Defendants Repeatedly And Specifically Promoted The Importance Of The Boston Facility And Its High-Margin Biologic Mesh Products, Including After The Recall.

388. Given the importance of the Boston Facility and SurgiMend and PriMatrix to Integra, Defendants discussed one or both of those topics at virtually every earnings call and investor conference held during the Class Period. As alleged above, Defendants gave detailed responses to analysts' frequent questions about the Boston Facility, SurgiMend and PriMatrix inventory, and the remediation process after the recall was announced. That Defendants' misstatements concerned the specific subjects about which Defendants frequently communicated with investors during the Class Period, including in response to specific questions by analysts, supports, at minimum, an inference of deliberate recklessness.

## VII. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

389. During the Class Period, Defendants made materially false and misleading statements and omissions concerning the Company's: (i) remediation efforts at the Boston Facility; (ii) quality assurance and compliance with cGMP in the manufacturing and production of SurgiMend, PriMatrix, and other EBM products; and (iii) capacity for production of EBM products at the Boston Facility. Defendants' misstatements are set forth in full below, along with a summary

of the material facts that Defendants withheld from the public that rendered them materially false and misleading.

**A. Defendants' Materially False And Misleading Statements Concerning Defendants' Remediation Efforts At The Boston Facility.**

390. Throughout the Class Period, Defendants made false and misleading statements concerning Integra's remediation efforts at the Boston Facility. Each of these statements was materially false or misleading because Integra's cGMP violations at the Boston Facility were far more widespread and serious than Defendants admitted, and Defendants were not taking sufficient or any steps to remediate the violations. Defendants' statements, along with a summary of the facts rendering them false and misleading, are set forth chronologically below.

391. On March 11, 2019, Integra filed a Current Report on Form 8-K, which stated that "***since the conclusion of the [FDA] inspection, [Integra] has undertaken significant efforts to remediate the observations and continues to do so***."

392. The statement in ¶391 above was materially false and misleading and omitted material facts. It was misleading for Defendants to state that Integra had "undertaken significant efforts to remediate the observations and continues to do so" when Integra's cGMP violations were far more widespread and serious than Defendants admitted, and Defendants were not, in fact, taking sufficient or any steps to remediate the violations. For example, the 2021 Form 483 found systemic cGMP deficiencies in Integra's environmental controls, including violations from the 2018 inspection that Integra had explicitly assured the FDA it had implemented reforms to effectively remediate. Similarly, contrary to Integra's representations to the FDA, Integra did not remediate cGMP violations discovered in Integra's bacterial endotoxin testing procedures during the 2018 inspection, including Integra's failure to test the "largest surface area as 'worst case' sampling for [its] bacterial endotoxin verification study." As later revealed by the 2023 Warning

Letter, by 2023 Integra still had not "identified all the necessary corrective actions to demonstrate that your quality system will ensure controls are in place to prevent the release of non-conforming products," and many of the problems identified in the 2023 inspection were repeat "deficienc[ies] from [the FDA's] 2019 Warning Letter to this facility." Multiple former employees confirmed that, rather than remediate long-standing deficiencies at the Boston Facility, Defendants "always went for the lowest budget option" to avoid disrupting manufacturing at the Boston Facility, and the Company's practice of "squeezing" profits instead of remediating issues at the Boston Facility "was the biggest risk to public health."

393. On February 19, 2020, during the Company's Q4 2019 earnings call, Defendant Anderson stated that the Company had experienced "supply constraints" due to temporary measures that caused "limited production" at the Boston Facility. In response to an analyst question for more detail on these changes at the Boston Facility, Defendant Coleman assured investors: "You probably remember we went through an FDA audit. ***We've been doing quality remediation efforts throughout 2019. There are no patient safety issues here [at the Boston Facility]***."

394. The statements in ¶393 above were materially false and misleading and omitted material facts. It was misleading for Defendant Coleman to state that Integra had "been doing quality remediation efforts throughout 2019" and that "[t]here [were] no patient safety issues here" when Integra's cGMP violations were far more widespread and serious than Defendants admitted, and Defendants were not taking sufficient or any steps to remediate the violations. For example, the 2021 Form 483 found systemic cGMP deficiencies in Integra's environmental controls, including violations from the 2018 inspection that Integra had explicitly assured the FDA it had implemented reforms to effectively remediate. Similarly, contrary to Integra's representations to

the FDA, Integra did not remediate cGMP violations discovered in Integra's bacterial endotoxin testing procedures during the 2018 inspection, including Integra's failure to test the "largest surface area as 'worst case' sampling for [its] bacterial endotoxin verification study." As later revealed by the 2023 Warning Letter, by 2023 Integra still had not "identified all the necessary corrective actions to demonstrate that your quality system will ensure controls are in place to prevent the release of non-conforming products," and many of the problems identified in the 2023 inspection were repeat "deficienc[ies] from [the FDA's] 2019 Warning Letter to this facility." Multiple former employees, including Krause and Myers, confirmed that, rather than remediate long-standing deficiencies at the Boston Facility, Defendants "always went for the lowest budget option" to avoid disrupting manufacturing at the Boston Facility, and the Company's practice of "squeezing" profits instead of remediating issues at the Boston Facility "was the biggest risk to public health."

395. On May 20, 2021, during the Company's 2021 Virtual Investor Day conference, Defendant Coleman stated that the Company "***made investments in [its] core plants***," including the Boston Facility, and told investors that the Company's "***work is now complete***" and that these investments equipped the Company with "***a manufacturing footprint that's … able to produce quality products*** and staffed with colleagues with deep expertise in manufacturing complex products." Defendant Coleman also touted the Company's quality control procedures, stating: "The key takeaway here is ***we've strengthened our quality operating mechanisms*** and ***reduced quality risk with enhanced rigor and this has led to better FDA inspection results***."

396. The statements in ¶395 above were materially false and misleading and omitted material facts. It was misleading for Defendant Coleman to state that the Company had "made investments" in the Boston Facility and that the "work [is] now complete" and that these

investments equipped the Company with "a manufacturing footprint that's … able to produce quality products" when Integra's cGMP violations were far more widespread and serious than Defendants admitted, and Defendants were not taking sufficient or any steps to remediate the violations.

397. For example, the 2021 Form 483 found systemic cGMP deficiencies in Integra's environmental controls, including violations from the 2018 inspection that Integra had explicitly assured the FDA it had implemented reforms to effectively remediate. Similarly, contrary to Integra's representations to the FDA, Integra did not remediate cGMP violations discovered in Integra's bacterial endotoxin testing procedures during the 2018 inspection, including Integra's failure to test the "largest surface area as 'worst case' sampling for [its] bacterial endotoxin verification study." As later revealed by the 2023 Warning Letter, by 2023 Integra still had not "identified all the necessary corrective actions to demonstrate that your quality system will ensure controls are in place to prevent the release of non-conforming products," and many of the problems identified in the 2023 inspection were repeat "deficienc[ies] from [the FDA's] 2019 Warning Letter to this facility."

398. Further, far from having "strengthened" Integra's "quality operating mechanisms" and "reduc[ing] quality risk with enhanced rigor" leading to "better FDA inspection results," Integra's CAPA procedures specifically designed to correct and prevent cGMP violations and process validation controls were inadequate throughout the Class Period. Multiple former employees confirmed that, rather than remediate long-standing deficiencies at the Boston Facility, Defendants "always went for the lowest budget option" to avoid disrupting manufacturing at the Boston Facility, and the Company's practice of "squeezing" profits instead of remediating issues at the Boston Facility "was the biggest risk to public health."

399. On April 26, 2023, during the Company's Q1 2023 earnings call, Defendant De Witte stated, "***we've been working for the past couple of years to upgrade our Boston facility based on FDA observations in 2018 and 2021***." He continued, "as we are preparing to have SurgiMend PMA product there, ***the Boston site requires a quality system that operates at a higher level. So that's … a project that's been ongoing. We had an audit early in March that confirms we're on the right track with our execution***."

400. The statements in ¶399 above were materially false and misleading and omitted material facts. It was misleading for Defendant De Witte to state that the Company had "been working for the past couple of years to upgrade our Boston facility based on FDA observations in 2018 and 2021" in the Boston Facility and that the "an audit early in March" "confirm[ed]" the Company was "on the right track" with "execution" when Integra's cGMP violations were far more widespread and serious than Defendants admitted, and Defendants were not taking sufficient or any steps to remediate the violations.

401. For example, the 2021 Form 483 found systemic cGMP deficiencies in Integra's environmental controls, including violations from the 2018 inspection that Integra had explicitly assured the FDA it had implemented reforms to effectively remediate. Similarly, contrary to Integra's representations to the FDA, Integra did not remediate cGMP violations discovered in Integra's bacterial endotoxin testing procedures during the 2018 inspection, including Integra's failure to test the "largest surface area as 'worst case' sampling for [its] bacterial endotoxin verification study."

402. Far from being on "the right track with our execution" of the remediation, the FDA had just begun its 2023 for-cause inspection, which had been triggered by the October 2022 internal whistleblower complaint regarding adulterated lots. During this inspection, the FDA

would discover repeat "deficienc[ies] from [the FDA's] 2019 Warning Letter to this facility." The issues the FDA uncovered included issues with how Integra measured endotoxins in products and over 80 customer complaints "in which patients reported high fevers, inflammation, revision surgical intervention, infection, and meningitis." In addition, the day after Defendant De Witte made these statements, outside lab results revealed that certain products manufactured at the Boston Facility contained "unacceptably high concentrations of endotoxins" that were "***27 times higher than the levels detected by Integra's internal testing***."

403. As later revealed by the 2023 Warning Letter, by 2023 Integra still had not "identified all the necessary corrective actions to demonstrate that your quality system will ensure controls are in place to prevent the release of non-conforming products." Multiple former employees confirmed that, rather than remediate long-standing deficiencies at the Boston Facility, Defendants "always went for the lowest budget option" to avoid disrupting manufacturing at the Boston Facility, and the Company's practice of "squeezing" profits instead of remediating issues at the Boston Facility "was the biggest risk to public health."

404. On July 27, 2023, during the Company's Q2 2023 earnings call, Defendant De Witte assured investors that the production pause and recall of products made at the Boston Facility had no connection to patient safety issues: "***we have no specific indications of any product complaints related to high endotoxin levels***. ***Patient safety is non-negotiable for us***." During the call, Defendant De Witte stated that, contrary to his earlier assurances that manufacturing at the Boston Facility would resume in June 2023, the Company had now adopted a remediation plan "***to resume manufacturing by the end of the fourth quarter of this year [2023]***" and "***to initiate a commercial relaunch by the mid to late second quarter 2024***." He continued, "I want to assure our customers and investors that ***we are highly focused on our remediation efforts***, and ***we fully***

***expect to complete the remediation*** and return these critical technologies to the market for our customers and their patients."

405. The statements in ¶404 above were materially false and misleading and omitted material facts. It was misleading for Defendant De Witte to state that the Company had "we have no specific indications of any product complaints related to high endotoxin levels" and that the Company had adopted a remediation plan "to resume manufacturing by the end of the fourth quarter of [2023]" with a "commercial relaunch by the mid to late second quarter 2024" when Integra's cGMP violations were far more widespread and serious than Defendants admitted, and Defendants were not taking sufficient or any steps to remediate the violations.

406. For example, the 2021 Form 483 found systemic cGMP deficiencies in Integra's environmental controls, including violations from the 2018 inspection that Integra had explicitly assured the FDA it had implemented reforms to effectively remediate. Similarly, contrary to Integra's representations to the FDA, Integra did not remediate cGMP violations discovered in Integra's bacterial endotoxin testing procedures during the 2018 inspection, including Integra's failure to test the "largest surface area as 'worst case' sampling for [its] bacterial endotoxin verification study."

407. Far from being able to resume manufacturing and a commercial relaunch, the FDA had only recently concluded its 2023 for-cause inspection, during which it uncovered: (i) unacceptably high concentrations of endotoxins (more than ***27 times*** higher than Integra's internal testing levels); (ii) issues with how Integra measured endotoxins in products; and (iii) over 80 customer complaints "in which patients reported high fevers, inflammation, revision surgical intervention, infection, and meningitis."

408. In addition, the FDA had just sent Defendant De Witte the 2023 Warning Letter ***less than a week before***. The 2023 Warning Letter stated that the FDA had discovered repeat "deficienc[ies] from [the FDA's] 2019 Warning Letter to this facility," and further found that Integra still had not "identified all the necessary corrective actions to demonstrate that your quality system will ensure controls are in place to prevent the release of non-conforming products."

409. Multiple former employees confirmed that, rather than remediate long-standing deficiencies at the Boston Facility, Defendants "always went for the lowest budget option" to avoid disrupting manufacturing at the Boston Facility, and the Company's practice of "squeezing" profits instead of remediating issues at the Boston Facility "was the biggest risk to public health."

410. It was also misleading for Defendant De Witte to state that Defendants were "highly focused on our remediation efforts" and "fully expect[ed] to complete the remediation" when Defendants never intended to remediate the Boston Facility because, as later admitted, Defendants "knew [the Boston Facility] was never going to be big enough to deliver to the growth opportunities, specifically with our breast strategy and SurgiMend." Further, rather than complete the remediation of the Boston Facility, Defendants had already decided to relocate manufacturing activities away from the Boston Facility to a new site in Braintree as early as 2021.

411. On September 6, 2023, Defendant Knight attended the Wells Fargo Securities Healthcare Conference 2023 on behalf of Integra. In response to an analyst question about the production pause and recall, Defendant Knight assured investors that the "***Boston remediation continues to progress well***" and Integra "hired in the right technical expertise to support and drive building a remediation plan and executing against it … ***we are absolutely on the right path, that our timelines to get back into market are real***." Doubling down on De Witte's earlier statements about the Company's timeline for resuming production at the Boston Facility on the Q2 2023

earnings call, Defendant Knight assured investors that the Company would "***begin manufacturing again in the end of this year and that commercial distribution would resume somewhere in the mid to late Q2 2024 timeline***." As back-up, she added that the Company underwent "independent reviews … to let us know whether or not we were on pace," and "that first independent review and the observations coming out of it say ***we're still on track for that timeline***."

412. The statements in ¶411 above were materially false and misleading and omitted material facts. It was misleading for Defendant Knight to state that "the Boston remediation continues to progress well" and that "we are absolutely on the right path, that our timelines to get back into market are real" when Integra's cGMP violations were far more widespread and serious than Defendants admitted, and Defendants were not taking sufficient or any steps to remediate the violations.

413. For example, the 2021 Form 483 found systemic cGMP deficiencies in Integra's environmental controls, including violations from the 2018 inspection that Integra had explicitly assured the FDA it had implemented reforms to effectively remediate. Similarly, contrary to Integra's representations to the FDA, Integra did not remediate cGMP violations discovered in Integra's bacterial endotoxin testing procedures during the 2018 inspection, including Integra's failure to test the "largest surface area as 'worst case' sampling for [its] bacterial endotoxin verification study."

414. Far from being able to resume manufacturing and a commercial relaunch, the FDA's 2023 for-cause inspection had uncovered: (i) unacceptably high concentrations of endotoxins (more than ***27 times*** higher than Integra's internal testing levels); (ii) issues with how Integra measured endotoxins in products; and (iii) over 80 customer complaints "in which patients reported high fevers, inflammation, revision surgical intervention, infection, and meningitis."

415. In addition, the 2023 Warning Letter revealed that the FDA had discovered repeat "deficienc[ies] from [the FDA's] 2019 Warning Letter to this facility," and further found that Integra still had not "identified all the necessary corrective actions to demonstrate that your quality system will ensure controls are in place to prevent the release of non-conforming products."

416. Multiple former employees, including Krause and Myers, confirmed that, rather than remediate long-standing deficiencies at the Boston Facility, Defendants "always went for the lowest budget option" to avoid disrupting manufacturing at the Boston Facility, and the Company's practice of "squeezing" profits instead of remediating issues at the Boston Facility "was the biggest risk to public health."

417. Further, rather than "progress" with remediation of the Boston Facility, Defendants had already decided to relocate manufacturing activities away from the Boston Facility to a new site in Braintree as early as 2021. Finally, as the Company would later admit, there remained "a series of operational and quality system gaps" at the Boston Facility, which would force the Company to implement a global compliance program "to bolster our manufacturing quality compliance processes across the organization."

418. On October 25, 2023, during the Company's Q3 2023 earnings call, Defendant De Witte assured investors that "***our progress in addressing the Boston facility and returning to the market remains on track.*** Interim external reviews ***confirm the adequacy of our remediation plan*** and the changes made so far and they ***reflect significant steps made towards the resumption of manufacturing by the end of the fourth quarter 2023 and commercial distribution in mid- to late second quarter '24.***" He added, "***we are on track with our communicated timelines***."

419. The statements in ¶418 above were materially false and misleading and omitted material facts. It was misleading for Defendant De Witte to state that the Company had "our

progress in addressing the Boston facility and returning to the market remains on track" and that "significant steps" had been "made towards" resuming manufacturing and commercial distribution when Integra's cGMP violations were far more widespread and serious than Defendants admitted, and Defendants were not taking sufficient or any steps to remediate the violations.

420. For example, the 2021 Form 483 found systemic cGMP deficiencies in Integra's environmental controls, including violations from the 2018 inspection that Integra had explicitly assured the FDA it had implemented reforms to effectively remediate. Similarly, contrary to Integra's representations to the FDA, Integra did not remediate cGMP violations discovered in Integra's bacterial endotoxin testing procedures during the 2018 inspection, including Integra's failure to test the "largest surface area as 'worst case' sampling for [its] bacterial endotoxin verification study."

421. Far from being able to resume manufacturing and a commercial relaunch, the FDA's 2023 for-cause inspection had uncovered: (i) unacceptably high concentrations of endotoxins (more than ***27 times*** higher than Integra's internal testing levels); (ii) issues with how Integra measured endotoxins in products; and (iii) over 80 customer complaints "in which patients reported high fevers, inflammation, revision surgical intervention, infection, and meningitis."

422. In addition, the 2023 Warning Letter revealed that the FDA had discovered repeat "deficienc[ies] from [the FDA's] 2019 Warning Letter to this facility," and further found that Integra still had not "identified all the necessary corrective actions to demonstrate that your quality system will ensure controls are in place to prevent the release of non-conforming products."

423. Krause, Myers, and multiple former employees confirmed that, rather than remediate long-standing deficiencies at the Boston Facility, Defendants "always went for the lowest budget option" to avoid disrupting manufacturing, and the Company's practice of

"squeezing" profits instead of remediating issues at the Boston Facility "was the biggest risk to public health."

424. Further, rather than being "on track" with remediation of the Boston Facility and taking "significant steps … towards the resumption of manufacturing by "the end of the fourth quarter 2023 and commercial distribution in mid- to late second quarter '24," Defendants had already decided to relocate manufacturing activities away from the Boston Facility to a new site in Braintree as early as 2021, which they later admitted would not be operational until the first half of 2026. Finally, as the Company would later admit, there remained "a series of operational and quality system gaps" at the Boston Facility, which would force the Company to implement a global compliance program "to bolster our manufacturing quality compliance processes across the organization."

425. On February 28, 2024, the Company issued a release reporting its Q4 2023 earnings results. In the release, the Company stated that, "***[r]elaunch remains on track for mid-to-late Q2 2024***." During the earnings call held that day, Defendant De Witte informed investors that the Boston Facility had undergone a "***successful dress rehearsal***" of the full external audit that the Company was required to pass prior to resuming commercial distribution. During the question and answer portion of the call, an analyst asked Defendants for "more color" on the results of the dress rehearsal and questioned "why that gives you confidence on the resumption of sales starting in the second quarter." In response, Defendant De Witte stated that the dress rehearsal gave the Company "confirmations" that it had performed the required remediation work, and yielded only "***limited observations on things that we could have improved***." He assured investors that the "***[s]uccessful audit will allow us to start building finished goods inventory to resume distribution mid- to late second quarter***."

426. The statements in ¶425 above were materially false and misleading and omitted material facts. It was misleading for Defendant De Witte to state that the Company had undergone a "successful dress rehearsal" and that the audit yielded only "limited observations on things that we could have improved" such that the Company would "start building finished goods inventory" when Integra's cGMP violations were far more widespread and serious than Defendants admitted, and Defendants were not taking sufficient or any steps to remediate the violations.

427. Indeed, only two days before Defendant De Witte made these statements, contamination from a variety of biologic and unknown sources was discovered within 97% of the freshly manufactured EMB sheets, or product batches, across all of Integra's EBM product lines, including SurgiMend, PriMatrix, TissueMend, and ReVize. Despite this concerning discovery, Integra leadership instructed its employees to bypass mandatory FDA remediation requirements and industry standards that mandated Integra to produce a nonconformance report regarding the issue and to take CAPAs, and instead simply "cut the contamination out of the product."

428. Defendant De Witte's statement that the Boston Facility had undergone a "***successful dress rehearsal***" was also misleading in light of his instruction to Krause, (approximately eight days earlier) to falsify a lower risk level for the Boston manufacturing facility in a slide for an upcoming Board presentation and obscure its true, high risk of receiving a non-compliant evaluation from the FDA.

429. Flouting remediation efforts was the norm; the 2021 Form 483 found systemic cGMP deficiencies in Integra's environmental controls, including violations from the 2018 inspection that Integra had explicitly assured the FDA it had implemented reforms to effectively remediate. Similarly, contrary to Integra's representations to the FDA, Integra did not remediate cGMP violations discovered in its bacterial endotoxin testing procedures during the 2018

inspection, including Integra's failure to test the "largest surface area as 'worst case' sampling for [its] bacterial endotoxin verification study."

430. Far from being able to resume manufacturing and a commercial relaunch, the FDA's 2023 for-cause inspection had uncovered: (i) unacceptably high concentrations of endotoxins (more than ***27 times*** higher than Integra's internal testing levels); (ii) issues with how Integra measured endotoxins in products; and (iii) over 80 customer complaints "in which patients reported high fevers, inflammation, revision surgical intervention, infection, and meningitis."

431. In addition, the 2023 Warning Letter revealed that the FDA had discovered repeat "deficienc[ies] from [the FDA's] 2019 Warning Letter to this facility," and further found that Integra still had not "identified all the necessary corrective actions to demonstrate that your quality system will ensure controls are in place to prevent the release of non-conforming products."

432. Multiple former employees, including Krause and Myers, confirmed that, rather than remediate long-standing deficiencies at the Boston Facility, Defendants engaged in a "concerted effort to downplay quality control issues, avoid FDA regulations, and risk patient safety in violation of multiple applicable laws and regulations"; always select "the lowest budget option" to avoid disrupting manufacturing at the Boston Facility, and that the Company's practice of "squeezing" profits instead of remediating issues at the Boston Facility "was the biggest risk to public health."

433. Further, rather than the "[r]elaunch remain[ing] on track for mid-to-late Q2 2024," Defendants had already decided to relocate manufacturing activities away from the Boston Facility to a new site in Braintree as early as 2021, which they later admitted would not be operational until the first half of 2026. As FE 17 confirmed, remediating the Boston Facility became a "non-issue" once the Company decided to relocate its operations to the Braintree facility. Finally, as the

Company would later admit, there remained "a series of operational and quality system gaps" at the Boston Facility, which would force the Company to implement a global compliance program "to bolster our manufacturing quality compliance processes across the organization."

434. On May 6, 2024, the Company issued a press release (filed on Form 8-K with the SEC), filed its Form 10-Q for Q2 2024, and held an accompanying earnings conference call with investors to announce the Company's financial results for the second quarter of 2024. During the question-and-answer portion of the earnings call, analysts questioned Defendant De Witte regarding the need to revisit long-range planning for the Boston Facility given the delayed restart of production. In response, De Witte misleadingly told investors that "[Integra has] made changes to the operations and quality leadership and structure to ensure the right focus and capabilities is [sic] applied to Boston," referring to Integra's recent terminations of its Chief Quality Officer (Krause) and Senior Director, Site Head of Quality Operations at the Boston Facility (Myers).

435. The statements in ¶434 above were materially false and misleading and omitted material facts. It was misleading for Defendant De Witte to state that the Company had to "make changes" to the "quality leadership" to fix the longstanding and pervasive cGMP violations at the Boston Facility, when, in reality, the "changes" were nothing more than unlawful retaliation and wrongful termination of Krause and Myers for reporting these issues to senior management and an external auditor, refusing De Witte's directives to lie to the FDA about remediation, quality, and manufacturing processes at the Boston Facility, and their extensive attempts to try to get Integra to meaningfully address the deficiencies.

### B. Defendants' Materially False And Misleading Statements Concerning Quality Assurance And Integra's Compliance With cGMP.

436. Defendants made false and misleading statements concerning the Company's quality assurance and purported cGMP compliance. Each of these statements was materially false

and misleading because, as discussed above, the Boston Facility was rife with serious, repeat cGMP violations, including widespread failures to adhere to mandatory product quality testing and standards. Therefore, as the FDA warned Integra by no later than 2019, Integra failed to adequately test for bacterial endotoxins in the EBM medical devices manufactured at the facility. Defendants' statements, along with a summary of the facts rendering them false and misleading, are set forth chronologically below.

437. On September 30, 2022, Integra issued its inaugural ESG Report for the year 2021, which remained on the Company's website throughout the remainder of the Class Period. In the 2021 ESG Report, the Company touted that it had "***numerous mechanisms and processes*** embedded within our business operations ***to protect and ensure product quality***, ***continuously improve the effectiveness of our quality management system, and ensure compliance with all regulatory requirements***." The ESG Report further stated, "To avoid defects and deliver the highest quality products, ***Integra adheres to Good Manufacturing Practices (GMPs), Quality System Regulations (QSRs), Good Laboratory Practices (GLPs), Good Tissue Practices (GTPs)*** and guidelines for conducting clinical studies."

438. The statements in ¶437 above were materially false and misleading and omitted material facts. It was misleading for Defendants to tout Integra's "numerous mechanisms and processes" to "protect and ensure product quality, continuously improve the effectiveness of our quality management system, and ensure compliance with all regulatory requirements" and that Integra "adhere[d]" to "good manufacturing practices" and other regulations when the Boston Facility was rife with serious cGMP violations, including widespread deficiencies "related to contamination controls, environmental controls, process validation, CAPA, and purchasing controls."

439. Further, far from "protect[ing] and ensur[ing] product quality," Integra failed to even establish procedures to "prevent contamination of equipment or product," including by failing to establish "adequate procedures to monitor or control product bioburden or bacterial endotoxins contamination"; testing medical devices for bacterial endotoxin before sterilization, rather than after; and failing to even test for fungal contamination in the Boston Facility's clean rooms. Moreover, instead of "improv[ing] the effectiveness of our quality management system," Integra's CAPA procedures specifically designed to correct and prevent cGMP violations and process validation controls were inadequate throughout the Class Period.

440. As multiple former employees confirmed, even after receiving warnings from the FDA concerning its CAPA procedures, Integra continued to fail to comply with important CAPAs that the Company assured the FDA it was implementing. Moreover, as the Company would later admit, even near the end of the Class Period, there remained "a series of operational and quality system gaps" at the Boston Facility, which would force the Company to implement a global compliance program "to bolster our manufacturing quality compliance processes across the organization."

441. On May 4, 2023, Integra held its Analyst/Investor Day. During the presentation, Defendant Leonard stated, "[l]ast year and this year, ***we made significant investments in quality across all of our manufacturing sites with a focus on accelerating our quality project in Boston*** involving testing, infrastructure, and physical layout changes," and that Integra was "***on a path to reach world-class quality assurance across all manufacturing sites***."

442. The statement in ¶441 above was materially false and misleading and omitted material facts. It was misleading for Defendant Leonard to state that Integra made "significant investments in quality" including "accelerating our quality project in Boston," and that Integra was

"on a path to reach world-class quality assurance across all manufacturing sites" when the Boston Facility was rife with serious cGMP violations, including widespread deficiencies "related to contamination controls, environmental controls, process validation, CAPA, and purchasing controls."

443. Further, just two days before Defendant Leonard made the above-referenced statements at Analyst/Investor Day, Krause was instructed by Defendant De Witte to import adulterated product from its European Distribution Center to Boston, re-label the product using unvalidated and undocumented printers outside of the verified medical device manufacturing process, and then illegally sell that adulterated product through interstate commerce. When Krause refused, De Witte responded that "no one would know." Defendant De Witte's instruction that Krause import and then personally transport, relabel, and distribute adulterated product across the country, is the antithesis of Leonard's assertion that Integra was "on a path to reach world-class quality assurance across all manufacturing sites."

444. Further, far from making "significant investments in quality," Integra failed to even establish procedures to "prevent contamination of equipment or product," including by failing to establish "adequate procedures to monitor or control product bioburden or bacterial endotoxins contamination"; testing medical devices for bacterial endotoxin before sterilization, rather than after; and failing to even test for fungal contamination in the Boston Facility's clean rooms.

445. Further, when Defendant Leonard made this statement, the FDA was conducting a for-cause inspection of the Boston Facility, which had been triggered by the October 2022 whistleblower complaint that had identified numerous adulterated lots. By this time, the FDA had uncovered: (i) unacceptably high concentrations of endotoxins (more than ***27 times*** higher than Integra's internal testing levels); (ii) issues with how Integra measured endotoxins in products; and

(iii) over 80 customer complaints "in which patients reported high fevers, inflammation, revision surgical intervention, infection, and meningitis."

446. Moreover, as the Company would later admit, even near the end of the Class Period, there remained "a series of operational and quality system gaps" at the Boston Facility, which would force the Company to implement a global compliance program "to bolster our manufacturing quality compliance processes across the organization."

447. On August 17, 2023, the Company issued its 2022 ESG Report. In the report, the Company stated that, "***To avoid defects and deliver the highest quality products, Integra adheres to good manufacturing practices (GMPs),*** quality system regulations (QSRs), good laboratory practices (GLPs), good tissue practices (GTPs) and guidelines for conducting clinical studies." The 2022 ESG Report further assured investors that "***product safety and quality are paramount,***" and stated that the Company "***continuously improves our Quality Management System (QMS) to meet the highest and most current quality standards***."

448. The statements in ¶447 above were materially false and misleading and omitted material facts. It was misleading for Defendants to state that Integra "adhere[d]" to "good manufacturing practices" and other regulations, that "product safety and quality are paramount" at Integra, and that Integra "continuously improves our Quality Management System (QMS) to meet the highest and most current quality standards" when the Boston Facility was rife with serious cGMP violations, including widespread deficiencies "related to contamination controls, environmental controls, process validation, CAPA, and purchasing controls."

449. Further, far from ensuring "product safety and quality [were] paramount," Integra failed to even establish procedures to "prevent contamination of equipment or product," including by failing to establish "adequate procedures to monitor or control product bioburden or bacterial

endotoxins contamination"; testing medical devices for bacterial endotoxin before sterilization, rather than after; and failing to even test for fungal contamination in the Boston Facility's clean rooms. Moreover, instead of "improv[ing] our Quality Management System," Integra's CAPA procedures specifically designed to correct and prevent cGMP violations and process validation controls were inadequate, such that even when a Company whistleblower lodged an internal complaint about these violations that was explicitly brought to the attention of Integra's executive management, Integra's CAPA control deficiencies prevented the Company from taking adequate, cGMP-compliant action.

450. As multiple former employees, including Krause and Myers, confirmed, even after receiving warnings from the FDA concerning its CAPA procedures, Integra continued to fail to comply with important CAPAs that the Company assured the FDA it was implementing. Integra's failures were evidenced in the FDA's 2023 for-cause inspection, which had uncovered: (i) unacceptably high concentrations of endotoxins (more than ***27 times*** higher than Integra's internal testing levels); (ii) issues with how Integra measured endotoxins in products; and (iii) over 80 customer complaints "in which patients reported high fevers, inflammation, revision surgical intervention, infection, and meningitis."

451. Further, less than five months before the 2022 ESG report was issued, Krause was instructed by Defendant De Witte to import adulterated product from its European Distribution Center to Boston, re-label the product using unvalidated and undocumented printers outside of the verified medical device manufacturing process, and then illegally sell that adulterated product through interstate commerce. When Krause refused, De Witte responded that "no one would know." Defendant De Witte's instruction that Krause import and then personally transport, relabel, and distribute adulterated product across the country, is the antithesis of the above-referenced

assertions in the 2022 ESG Report," including that "Integra adheres to good manufacturing practices (GMPs)" and "quality system regulations (QSRs)," and "continuously improves our Quality Management System (QMS) to meet the highest and most current quality standards."

452. Moreover, as the Company would later admit, even near the end of the Class Period, there remained "a series of operational and quality system gaps" at the Boston Facility, which would force the Company to implement a global compliance program "to bolster our manufacturing quality compliance processes across the organization."

### C. Defendants' Materially False And Misleading Statements Concerning The Company's Operating Capacity At The Boston Facility.

453. Throughout the Class Period, Defendants made materially false and misleading statements concerning the Boston Facility's production capacity for EBM products. Defendants repeatedly told investors that the FDA's observations and findings concerning Integra's deviations from cGMP at the Boston Facility would not impact the Company's capacity to manufacture EBM products, even after the production pause and subsequent recall at the Boston Facility. Each of these statements were materially misleading because Integra was only able to reach its manufacturing capacity at the Boston Facility—the sole plant dedicated to producing Integra's high-margin SurgiMend and PriMatrix devices—by skirting core cGMPs. In fact, as investors learned at the end of the Class Period, Defendants never intended to fully remediate the Boston Facility because they knew "the plant was never going to be big enough to 'deliver' SurgiMend's growth opportunities." Defendants' statements, along with a summary of the facts rendering them false and misleading, are set forth chronologically below.

454. On March 11, 2019, Integra filed a Current Report on Form 8-K, which stated that that the 2019 Warning Letter "***does not restrict the Company's ability to manufacture or ship products or require the recall of any products***."

455. The statement in ¶454 above was materially misleading and omitted material facts. It was materially misleading for Defendants to state that the 2019 Warning Letter did "not restrict the Company's ability to manufacture or ship products or require the recall of any products" when Integra's manufacturing capacity at Boston Facility was severely constrained by its persistent cGMP violations, and Defendants failed to take any action to remediate these cGMP violations.

456. For example, as set forth in the 2021 Form 483, the FDA found environmental control violations involving Integra's Clean Rooms that Integra had failed to remediate from the 2018 inspection. During the same inspection, the FDA also discovered that Integra lacked any "alert and action specifications for fungal organisms identified during routine clean room environmental monitoring," for which Integra had told the FDA it would implement a CAPA to address this violation.

457. It was also misleading for Defendants to state the warning letter did not "restrict" their "ability to manufacture or ship products" when Defendants were skirting cGMP regulations at the Boston Facility in order to meet customer demand. Integra "approved and released" a lot of finished EBM products for commercial distribution, even though "the bacterial endotoxin result … exceed[ed] their acceptance criteria."

458. As multiple former employees confirmed, Integra's top management chose not to take any steps to remediate the Boston Facility's cGMP violations if doing so would cost money or force the Boston Facility to pause manufacturing because SurgiMend was Integra's "golden child," and "front-runner" product. Further, Defendants never intended to remediate the Boston Facility because, as later admitted, Defendants "knew [the Boston Facility] was never going to be big enough to deliver to the growth opportunities, specifically with our breast strategy and SurgiMend."

459. On February 19, 2020, during the Company's Q4 2019 earnings call, Defendant Coleman stated that the Company had made "***changes… to the actual physical [Boston] facility***" after the Company "***went through an FDA audit***" specifically designed to "***get [the Company] 50% more capacity as [it] enter[s] 2020***."

460. The statements in ¶459 above were materially false and misleading and omitted material facts. It was misleading for Defendant Coleman to state that the Company had made "changes… to the actual physical [Boston] facility" after the Company "went through an FDA audit" specifically designed to "get [the Company] 50% more capacity as [it] enter[s] 2020" when Integra's manufacturing capacity at Boston Facility was severely constrained by its persistent cGMP violations, and Defendants failed to take any action to remediate these cGMP violations.

461. For example, as set forth in the 2021 Form 483, the FDA found environmental control violations involving Integra's Clean Rooms that Integra had failed to remediate from the 2018 inspection. During the same inspection, the FDA also discovered that Integra lacked any "alert and action specifications for fungal organisms identified during routine clean room environmental monitoring," for which Integra had told the FDA it would implement a CAPA to address this violation.

462. It was also misleading for Defendant Coleman to state that the Company had made "changes… to the actual physical [Boston] facility" after an FDA audit to "get [the Company] 50% more capacity as [it] enter[s] 2020" when Defendants were skirting cGMP regulations at the Boston Facility in order to meet customer demand. Integra "approved and released" a lot of finished EBM products for commercial distribution, even though "the bacterial endotoxin result … exceed[ed] their acceptance criteria."

463. In addition, Integra continued to fail to perform "quality control" and "bioburden [] testing" on lots of finished EBM products. As multiple former employees confirmed, Integra's top management chose not to take any steps to remediate the Boston Facility's cGMP violations if doing so would cost money or force the Boston Facility to pause manufacturing because SurgiMend was Integra's "golden child," and "front-runner" product. Further, Defendants never intended to remediate the Boston Facility because, as later admitted, Defendants "knew [the Boston Facility] was never going to be big enough to deliver to the growth opportunities, specifically with our breast strategy and SurgiMend."

464. On May 7, 2020, during the Company's Q1 2020 earnings call, in response to an analyst's question about the Company's "ability to ramp up and compete in the second half of the year and in 2021," Defendant Coleman stated that the Boston Facility was "***pretty much running normal capacity and during this period of lower demand, we're actually building safety stock.***" He added that the Company's regenerative tissue products like SurgiMend, "***should see very good growth*** when things come back to normal or we get back to the regular procedure," which would be "***double-digit growth***," and further assured investors that the Company would "***have plenty of safety stock to support that ramp when it comes back.***"

465. The statements in ¶464 above were materially false and misleading and omitted material facts. It was misleading for Defendant Coleman to state that Integra was "building safety stock" and that SurgiMend would see "double-digit growth" when Integra's manufacturing capacity at Boston Facility was severely constrained by its persistent cGMP violations, and Defendants failed to take any action to remediate these cGMP violations.

466. For example, as set forth in the 2021 Form 483, the FDA found environmental control violations involving Integra's Clean Rooms that Integra had failed to remediate from the

2018 inspection. During the same inspection, the FDA also discovered that Integra lacked any "alert and action specifications for fungal organisms identified during routine clean room environmental monitoring," for which Integra had told the FDA it would implement a CAPA to address this violation.

467. It was also misleading for Defendant Coleman to state that the Boston Facility was running at "normal capacity" when Defendants were skirting cGMP regulations at the Boston Facility in order to meet customer demand. Integra "approved and released" a lot of finished EBM products for commercial distribution, even though "the bacterial endotoxin result … exceed[ed] their acceptance criteria."

468. In addition, Integra continued to fail to perform "quality control" and "bioburden [] testing" on lots of finished EBM products. As multiple former employees confirmed, Integra's top management chose not to take any steps to remediate the Boston Facility's cGMP violations if doing so would cost money or force the Boston Facility to pause manufacturing because SurgiMend was Integra's "golden child," and "front-runner" product. Further, Defendants never intended to remediate the Boston Facility because, as later admitted, Defendants "knew [the Boston Facility] was never going to be big enough to deliver to the growth opportunities, specifically with our breast strategy and SurgiMend."

469. On May 20, 2020, Defendant Anderson attended the UBS Global Virtual Healthcare Conference on behalf of the Company. An analyst, noting that the Company's "wound care" product line was "an important franchise for the company," requested an update on "the factors driving the wound business" and "what's going on in the manufacturing side." In response, Defendant Anderson stated that "***in terms of the Boston facility, that's the one that really is untouched from an overall manufacturing plan perspective***. ***We're continuing to run that***

***factory as before in order for us to use this time to build up safety stock in SurgiMend and PriMatrix.***"

470. The statements in ¶469 above were materially false and misleading and omitted material facts. It was misleading for Defendant Anderson to state that the Boston Facility was "untouched from an overall manufacturing plan perspective" and that the Company was building up "safety stock in SurgiMend and PriMatrix" when Integra's manufacturing capacity at Boston Facility was severely constrained by its persistent cGMP violations, and Defendants failed to take any action to remediate these cGMP violations. For example, as set forth in the 2021 Form 483, the FDA found environmental control violations involving Integra's Clean Rooms that Integra had failed to remediate from the 2018 inspection. During the same inspection, the FDA also discovered that Integra lacked any "alert and action specifications for fungal organisms identified during routine clean room environmental monitoring," for which Integra had told the FDA it would implement a CAPA to address this violation. It was also misleading for Defendant Anderson to state that the Boston Facility was "untouched from an overall manufacturing plan perspective" when Defendants were skirting cGMP regulations at the Boston Facility in order to meet customer demand. Integra "approved and released" a lot of finished EBM products for commercial distribution, even though "the bacterial endotoxin result … exceed[ed] their acceptance criteria."

471. In addition, Integra continued to fail to perform "quality control" and "bioburden [] testing" on lots of finished EBM products. As multiple former employees confirmed, Integra's top management chose not to take any steps to remediate the Boston Facility's cGMP violations if doing so would cost money or force the Boston Facility to pause manufacturing because SurgiMend was Integra's "golden child," and "front-runner" product. Further, Defendants never intended to remediate the Boston Facility because, as later admitted, Defendants "knew [the

Boston Facility] was never going to be big enough to deliver to the growth opportunities, specifically with our breast strategy and SurgiMend."

472. On October 28, 2020, during the Company's Q3 2020 earnings call, Defendants Anderson and Coleman made false and misleading statements about the Company's production and supply of SurgiMend and other regenerative issue products at the Company's Boston Facility. In response to an analyst question about the growth of its Tissue Technologies' segment and the Company's "ability to meet demand," Defendant Anderson stated, "***high single, low double digit is what we're definitely positioned for within the TT [Tissue Technologies] portfolio***." Defendant Anderson then directed Defendant Coleman to "talk a little bit about supply." In response, Defendant Coleman stated, ***"we're in great shape when you look at our regenerative supply."*** He added, "I think about our Boston plant which makes SurgiMend and PriMatrix. And ***we've actually built more safety stock for those regenerative products. So we're in very good shape***."

473. The statements in ¶472 above were materially false and misleading and omitted material facts. It was misleading for Defendants to state that the Tissue Technologies portfolio was positioned for "high single, low double digit" growth and that the Company was "in great shape" in terms of supply and "safety stock" when Integra's manufacturing capacity at Boston Facility was severely constrained by its persistent cGMP violations, and Defendants failed to take any action to remediate these cGMP violations. For example, as set forth in the 2023 Form 483, the FDA found that Defendants had not remediated deficiencies previously identified in 2019 and 2021 in Integra's bacterial endotoxin testing procedures, despite Integra's repeated written assurances that they had done so, and also determined that Integra had again failed to establish proper CAPA procedures to comply with cGMP despite the FDA's repeated identification of

process validation control validations. It was also misleading for Defendants to state they were in "good shape" in terms of supply and "safety stock" when Defendants were skirting cGMP regulations at the Boston Facility in order to meet customer demand. As multiple former employees confirmed, Integra's top management chose not to take any steps to remediate the Boston Facility's cGMP violations if doing so would cost money or force the Boston Facility to pause manufacturing because SurgiMend was Integra's "golden child," and "front-runner" product. Further, Defendants never intended to remediate the Boston Facility because, as later admitted, Defendants "knew [the Boston Facility] was never going to be big enough to deliver to the growth opportunities, specifically with our breast strategy and SurgiMend."

474. On February 24, 2022, Integra filed its Form 10-K for FY 2021, which stated that the "***[2019] Warning Letter and the 2021 Form 483 do not restrict the Company's ability to manufacture or ship products or require the recall of any products***." The Form 10-K was signed by Defendants De Witte, and Anderson, and contained certifications by Defendants De Witte and Anderson that attested to the purported accuracy and completeness of the 10-K.

475. The statements in ¶474 above were materially false and misleading and omitted material facts. It was misleading for Defendants to state that the "[2019] Warning Letter and the 2021 Form 483 [did] not restrict the Company's ability to manufacture or ship products or require the recall of any products" when Integra's manufacturing capacity at Boston Facility was severely constrained by its persistent cGMP violations, and Defendants failed to take any action to remediate these cGMP violations.

476. For example, in late 2021, the FDA issued adverse findings and ordered a "regulatory meeting" with Integra "due to the seriousness of these repeat findings." The regulatory meeting was held on January 26, 2022. At the meeting, the FDA required Integra to "develop a

solid remediation plan or it would be issued further action in the form of a warning letter or consent decree."

477. In addition, as set forth in the 2023 Form 483, the FDA found that Defendants had not remediated deficiencies previously identified in 2019 and 2021 in Integra's bacterial endotoxin testing procedures, despite Integra's repeated written assurances that they had done so, and also determined that Integra had again failed to establish proper CAPA procedures to comply with cGMP despite the FDA's repeated identification of process validation control validations.

478. It was also misleading for Defendants to state that the "[2019] Warning Letter and the 2021 Form 483 [did] not restrict the Company's ability to manufacture or ship products or require the recall of any products" when Defendants were skirting cGMP regulations at the Boston Facility in order to meet customer demand. Integra "approved and released" a lot of finished EBM products for commercial distribution, even though "the bacterial endotoxin result … exceed[ed] their acceptance criteria."

479. In addition, Integra continued to fail to perform "quality control" and "bioburden [] testing" on lots of finished EBM products. As multiple former employees confirmed, Integra's top management chose not to take any steps to remediate the Boston Facility's cGMP violations if doing so would cost money or force the Boston Facility to pause manufacturing because SurgiMend was Integra's "golden child," and "front-runner" product. Further, Defendants never intended to remediate the Boston Facility because, as later admitted, Defendants "knew [the Boston Facility] was never going to be big enough to deliver to the growth opportunities, specifically with our breast strategy and SurgiMend."

480. On May 4, 2023, Integra held its Analyst/Investor Day. During the presentation, Defendant Leonard stated, "***the relocation of our Boston facility to a new PMA-ready site in nearby Braintree will more than double our capacity for SurgiMend and PriMatrix in 2025***."

481. The statement in ¶480 above was materially false and misleading and omitted material facts. It was misleading for Defendant Leonard to state that "the relocation of our Boston facility" to Braintree would "more than double" the Company's "capacity for SurgiMend and PriMatrix in 2025" when, in fact, it was not possible for the Braintree facility to be production-ready by 2025, Integra's manufacturing capacity at Boston Facility was severely constrained by its persistent cGMP violations, and Defendants failed to take any action to remediate these cGMP violations.

482. By this point, the FDA was in the midst of a 10-week inspection of the Boston Facility, which had begun in March 2023, and during which investigators discovered systemic, continuing cGMP violations at the Boston Facility. For example, as set forth in the 2023 Form 483, the FDA found that Defendants had not remediated deficiencies previously identified in 2019 and 2021 in Integra's bacterial endotoxin testing procedures, despite Integra's repeated written assurances that they had done so, and also determined that Integra had again failed to establish proper CAPA procedures to comply with cGMP despite the FDA's repeated identification of process validation control validations.

483. It was also misleading for Defendant Leonard to state that Braintree would "more than double" the Company's "capacity" for manufacturing its EBM products when Defendants were skirting cGMP regulations at the Boston Facility in order to meet customer demand. In fact, an internal employee had lodged a whistleblower complaint with the Company's hotline concerning multiple lots of adulterated product, which Integra's Legal department and executive

management handled. Despite this, Integra continued to approve products from the impacted lots for release, in violation of cGMP. In addition, Integra continued to fail to perform "quality control" and "bioburden [] testing" on lots of finished EBM products.

484. It was similarly misleading for Defendant Leonard to tout a "double" in "capacity for SurgiMend and PriMatrix in 2025" when the Company knew its ability to produce safe and marketable EBM product had been decimated by the systemic endotoxin contamination at the Boston facility, which was its one and only factory for the production of biologic mesh. Further illustrating the Boston Facility's capacity constraints, just two days before Defendant Leonard's statement, Krause had been instructed by Defendant De Witte to import adulterated product from its European Distribution Center to Boston, re-label the product using unvalidated and undocumented printers outside of the verified medical device manufacturing process, and then illegally sell that adulterated product through interstate commerce because Boston could not manufacture EBM product in conformance with cGMPs.

485. Defendant Leonard's statements were also false and misleading because, as Defendants knew, the "safety stock" was the product of a deeply flawed manufacturing process that did not comply with cGMPs and could not be legally or ethically sold. The Boston Facility's utter lack of *compliant* production capacity was illustrated by the Company's unlawful and unethical practice, throughout the entire Class Period, of employing dangerous "workarounds" for EBM sheets riddled with endotoxin contamination in which contaminated portions were cut out of whole sheets leaving the rest of the sheet to be sold to hospitals and implanted in patients. When the Company's external compliance auditor was informed of the "workaround," for biologic mesh, production at Boston was stopped indefinitely and the safety stock was required to be destroyed.

## VIII. LOSS CAUSATION

486. During the Class Period, as detailed in this Complaint, Defendants made materially false and misleading statements and omissions, and engaged in a scheme to deceive the market. Defendants' scheme artificially inflated the price of Integra stock and operated as a fraud and deceit on the Class. As a result of Defendants' materially false or misleading statements, omissions of material facts, and fraudulent course of conduct, Integra's common stock traded at artificially inflated prices during the Class Period. Relying on the integrity of the market price for Integra common stock and public information relating to Integra, Lead Plaintiffs and other Class members purchased or otherwise acquired Integra common stock at prices that incorporated and reflected Defendants' misrepresentations and omissions of material fact alleged herein.

487. Later, when the relevant truth regarding Defendants' prior misrepresentations and omissions of material fact were disclosed to the market on April 26, 2023, May 23, 2023, February 28, 2024, May 6, 2024, and July 29, 2024, the price of Integra's stock fell. As a result of their purchases of Integra securities during the Class Period, Lead Plaintiffs and other members of the Class suffered harm. Until the final disclosure on July 29, 2024, each of Integra's disclosures described below only partially revealed the relevant truth, and Defendants accompanied each disclosure with additional false and misleading information that maintained the artificial inflation of Integra's stock. As such, the full amount of inflation was not removed until after the final disclosure on the last day of the Class Period.

488. Specifically, Defendants' materially false and misleading statements misrepresented Integra's compliance with FDA regulations, including those governing cGMP, the remediation of the Boston Facility, and the Facility's capacity to continue manufacturing and producing the Company's EBM products. When the relevant truth regarding Defendants' prior misrepresentations and omissions of material fact were disclosed to investors, the price of Integra

securities fell significantly. As a result of these disclosures, the price of Integra common shares declined by nearly 55%, from a closing price of $55.14 on March 11, 2019 to a closing price of $25.42 per share on July 29, 2024.

489. The disclosures that partially corrected the market price of Integra's common stock and reduced the artificial inflation caused by Defendants' materially false and misleading statements and omissions are detailed below:

| **Date**[33] | **Disclosure Summary** | **Closing Stock Price** | **% Change** | **$ Change** |
|---|---|---|---|---|
| 4/26/2023 | Integra discloses its production pause at the Boston Facility and was belatedly taking steps to bring the Facility into compliance. | $54.20 | -8% | -$4.64 |
| 5/23/2023 | Integra announces a "voluntary global recall" of all product manufactured out of the Boston Facility for the past five years. | $40.48 | -22.5% | -$10.24 |
| 2/28/2024 (2/29/2024) | Integra announces the sudden "retirement" of its CEO and additional negative impacts from the recall. | $7.36 | -16% | -$7.15 |
| 5/6/2024 | Integra announces shutdown of the Boston Facility through at least the end of 2024 and refuses to provide any timeline for its reopening. | $23.14 | -22.5% | -$5.62 |
| 7/29/2024 | Integra discloses systemic compliance deficiencies and shipping holds across the Company. | $25.42 | -21% | -$6.14 |

490. It was entirely foreseeable to Defendants that their materially false and misleading statements and omissions regarding Integra's cGMP violations at the Boston Facility, the remediation of the Boston Facility, and the Facility's capacity to continue manufacturing and producing the Company's EBM products would artificially inflate the price of Integra's common stock. It was also foreseeable to Defendants that the revelation of the relevant truth about Integra's

[33] The date(s) in parentheses refer to additional date(s) of stock price decline caused by the corrective event.

cGMP violations at the Boston Facility, the remediation of the Boston Facility, and the Facility's capacity to continue manufacturing and producing the Company's EBM products would cause the price of the Company's securities to fall as the artificial inflation caused by Defendants' misstatements and omissions was removed. Thus, the economic losses (i.e., damages suffered by Lead Plaintiffs and other members of the Class) were a direct, proximate, and foreseeable result of Defendants' materially false and misleading statements and omissions of material fact, which artificially inflated the price of the Company's common stock, and the subsequent significant decline in the value of the Company's common stock when the relevant truth was revealed.

## IX. PRESUMPTION OF RELIANCE

491. At all relevant times, the market for the Company's common stock was an open, efficient and well-developed market for the following reasons, among others:

492. Integra's common stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

493. As a regulated issuer, Integra filed periodic reports with the SEC and the NASDAQ;

494. Integra regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services, and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

495. Integra was followed by several securities analysts employed by major brokerage firms who wrote reports which were distributed to those brokerage firms' sales force and certain customers. Each of these reports was publicly available and entered the public marketplace.

496. As a result of the foregoing, the market for Integra's common stock reasonably and promptly digested current information regarding the Company from all publicly available sources and reflected such information in the price of the Company's common stock. All investors who

purchased the Company's common stock during the Class Period suffered similar injury through their purchase of Integra's common stock at artificially inflated prices, and a presumption of reliance applies.

497. A Class-wide presumption of reliance is also appropriate in this action under the U.S. Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are grounded on Defendants' material omissions. Because this action involves Defendants' failure to disclose material adverse information regarding Integra's business and operations—information that Defendants were obligated to disclose— positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the material misstatements and omissions set forth above, that requirement is satisfied here.

## X. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR AND THE BESPEAKS CAUTION DOCTRINE

498. The statutory safe harbor or bespeaks caution doctrine applicable to forward-looking statements under certain circumstances does not apply to any of the false and misleading statements pleaded in this Complaint. The statements alleged to be false or misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false or misleading may be characterized as forward-looking, they were not adequately identified as forward-looking statements when made, and there were no meaningful cautionary statements identifying important facts that could cause actual results to differ materially from those in the purportedly forward-looking statements.

499. To the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements

because at the time each of those forward-looking statements was made, each of these Defendants had actual knowledge that the particular forward-looking statement was materially false or misleading. Defendants are liable for the statements pleaded because, at the time each of those statements was made, Defendants knew the statement was false, and the statement was authorized and/or approved by an executive officer and/or director of Integra who knew that such statement was false when made.

## XI. CLASS ACTION ALLEGATIONS

500. Lead Plaintiffs bring this action as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of all persons or entities that purchased or otherwise acquired shares of Integra common stock between March 11, 2019 and July 28, 2024 inclusive (the "Class"), and were damaged thereby. Excluded from the Class are Defendants, the officers and directors of Integra at all relevant times, members of their immediate families, and their legal representatives, heirs, agents, affiliates, successors or assigns, Defendants' liability insurance carriers, and any affiliates or subsidiaries thereof, and any entity in which Defendants or their immediate families have or had a controlling interest.

501. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Integra's shares were actively traded on the NASDAQ. As of July 26, 2024, the Company had more than 77 million shares outstanding. While the exact number of Class members is unknown to Lead Plaintiffs at this time, and can only be ascertained through appropriate discovery, Lead Plaintiffs believe that there are at least thousands of members of the proposed Class. Record owners and other members of the Class may be identified from records maintained by the Company, or its transfer agent(s), and may be notified of this class action using a form of notice similar to that customarily used in securities class actions.

502. Lead Plaintiffs' claims are typical of the claims of the other members of the Class as all members of the Class were similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

503. Lead Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Lead Plaintiffs have no interests that conflict with those of the Class.

504. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(i) whether Defendants violated the Exchange Act by the acts and omissions as alleged herein;

(ii) whether Defendants knew or recklessly disregarded that their statements and/or omissions were false and misleading;

(iii) whether documents, press releases, and other statements disseminated to the investing public and the Company's shareholders misrepresented material facts about the business, operations, and prospects of Integra;

(iv) whether statements made by Defendants to the investing public misrepresented and/or omitted to disclose material facts about the business, operations, and prospects of Integra;

(v) whether the market price of Integra shares during the Class Period was artificially inflated due to the material misrepresentations and failures to correct the material misrepresentations complained of herein; and

(vi) the extent to which the members of the Class have sustained damages and the proper measure of damages.

505. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden

of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this suit as a class action.

## XII. CLAIMS FOR RELIEF

### COUNT I

**For Violations of Section 10(b) of the Exchange Act and Rule 10b-5(b) Promulgated Thereunder (Against Defendants Integra, Anderson, Arduini, Coleman, De Witte, Leonard, and Knight)**

506. Lead Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

507. This Count is asserted on behalf of all members of the Class against Defendant Integra and the Individual Defendants for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5(b) promulgated thereunder, 17 C.F.R. § 240.10b-5.

508. During the Class Period, Defendant Integra and the Individual Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(b) in that they made untrue statements of material fact and/or disseminated and/or approved and/or omitted to state material facts necessary to make the false or misleading statements specified above not misleading. Defendants' actions did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; and (ii) cause Plaintiffs and other members of the Class to purchase Integra common stock at artificially inflated prices. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

509. Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or the mails, made various untrue and/or misleading statements of material facts and omitted to state material facts necessary in order to make the statements made about Integra and its business, operations, and future prospects in light

of the circumstances under which they were made, not misleading, as set forth more particularly herein.

510. Each of the Individual Defendants' primary liability and controlling person liability, arises from the following facts: (i) each of the Individual Defendants was a high-level executive and/or director at the Company and a member of the Company's management team or had control thereof; (ii) each of the Individual Defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development, and reporting of the Company's business, operations, and prospects; (iii) each of the Individual Defendants enjoyed significant personal contact and familiarity with the other Defendants and was advised of and had access to, other members of the Company's management team, internal reports, and other data and information about the Company's financial condition and performance at all relevant times; and (iv) each of the Individual Defendants was aware of the Company's dissemination of information to the investing public, which they knew and/or recklessly disregarded was materially false and misleading.

511. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Integra's operating condition, business practices, and prospects from the investing public and supporting the artificially inflated and/or maintained price of its common stock. As demonstrated by Defendants' overstatements and misstatements of the Company's business, operations, and prospects, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such

knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

512. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Integra shares was artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants or upon the integrity of the market in which the stock trades, and/or in the absence of material adverse information that was known or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants, Lead Plaintiffs and the other members of the Class purchased Integra shares during the Class Period at artificially inflated prices and were damaged thereby.

513. At the time of said misrepresentations and omissions, Lead Plaintiffs and other members of the Class were ignorant of their falsity and believed them to be true. Had Lead Plaintiffs and the other members of the Class and the marketplace known of the truth regarding the problems that Integra was experiencing, which were not disclosed by Defendants, Lead Plaintiffs and other members of the Class would not have purchased their Integra shares, or, if they had purchased such shares during the Class Period, they would not have done so at the artificially inflated prices that they paid.

514. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiffs and the other members of the Class suffered damages in connection with their purchases of the Company's common stock during the Class Period.

515. By virtue of the foregoing, Defendants each violated § 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

**COUNT II**

**For Violations of Section 10(b) of the Exchange Act and Rule 10b-5(a) and (c) Promulgated Thereunder (Against All Defendants)**

516. Lead Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

517. This Count is asserted on behalf of all members of the Class against Defendant Integra and the Individual Defendants for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5(a) and (c) promulgated thereunder, 17 C.F.R. § 240.10b-5.

518. Defendant Integra and the Individual Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(a) and (c) in that they: (1) employed devices, schemes, and artifices to defraud; and (2) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon Plaintiffs and others similarly situated in connection with their purchases of Integra common stock during the Class Period in an effort to maintain artificially high market prices for Integra common stock.

519. Defendant Integra and the Individual Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mails, employed devices, schemes, and artifices to defraud and engaged and participated in a continuous course of conduct that operated as a fraud and deceit upon Plaintiffs and the Class in connection with the purchase and sale of Integra common stock; which did: (i) deceive the investing public, including Plaintiffs and the Class, regarding, among other things, Integra's commitment and adherence to regulatory safety protocols in the production of infant formula, its compliance with cGMPs, and the unsanitary conditions at the Boston Facility; (ii) artificially inflate and maintain the market price of Integra common stock; and (iii) cause Plaintiffs and other members of the Class to purchase Integra common stock at artificially inflated prices and suffer losses when the true facts became known.

520. As part of their scheme to defraud investors in violation of Rule 10b-5(a) and (c), the Defendants engaged in the following course of business conduct, as described by, among things, the FDA's 2018, 2021, and 2023 Forms 483, the 2018 EIR, the 2019 and 2023 Warning Letters, the October 2022 Whistleblower Complaint, the Whistleblower Actions, and the accounts of former employees described above. For example, Defendants engaged in the following deceptive activities:

(i) Disregarding negative test results by giving passing grades to products that should not have passed, and re-testing non-passing products repeatedly until they eventually cleared screening tests in violation of cGMP;

(ii) Releasing finished EBM products that were adulterated to consumers on multiple occasions, including approving lots for release for an additional two months after an internal whistleblower complaint had already identified those adulterated lots and failing to conduct a health hazard assessment for six months after receiving the internal whistleblower complaint;

(iii) Failing to remediate repeated cGMP violations in environmental controls that Defendants told the FDA had been addressed;

(iv) Failing to adhere to internal policies and FDA rules that Integra timely inform its Chief Quality Officer of reports alleging quality-related issues, including issues with product quality, design, processes, and manufacturing;

(v) Failing to implement CAPAs to address cGMP violations discovered in endotoxin testing procedures and undetected bacterial and fungal growth that the FDA was told would be implemented and closed;

(vi) Failing to establish adequate procedures to monitor or control endotoxin contamination after telling the FDA that the Boston Facility's control procedures had been reformed;

(vii) Failing to comply with the Chief Quality Officer's orders to halt manufacturing at the Boston Facility after contamination was discovered;

(viii) Demanding that the Chief Quality Officer lower the risk assessment of products for multiple company sites, which were at high risk of receiving a warning letter from the FDA for non-compliance;

(ix) Refusing to install surveillance cameras in key manufacturing areas because Integra "did not want the FDA to find anything on these cameras";

(x) Failing to invest in and staff the newly created continuous improvement team at the Boston Facility;

(xi) Failing to address pervasive microbial contamination in the Boston Facility's water system, which posed known contamination risks;

(xii) Pursuing a Company-wide directive to prioritize profit and manufacturing output above product safety and quality;

(xiii) Explicitly instructing employees to violate FDA regulations, including by: knowingly importing adulterated product into the United States from Europe, relabeling it, and then selling the adulterated product through interstate commerce, demanding that employees provide false information to the FDA,

(xiv) instructing employees to bypass mandatory FDA remediation requirements that mandated Integra to produce reports regarding certain contamination issues;

(xv) Taking actions to retaliate against employees who spoke up concerning compliance issues; and

(xvi) Knowingly and intentionally choosing not to further investigate patient complaints about the Company's medical devices and instead attributing adverse events to patient comorbidities.

521. These deceptive acts were part of a course of conduct that operated as a fraud and deceit upon Plaintiffs and others similarly-situated in connection with their purchases of Integra common stock during the Class Period in an effort to maintain artificially high market prices for Integra common stock.

522. As described above, Defendant Integra and the Individual Defendants acted with scienter throughout the Class Period, in that they either had actual knowledge of the misrepresentations or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose the true facts, even though such facts were available to them. Defendant Integra and the Individual Defendants engaged in this misconduct to conceal Integra's true condition from the investing public and to support the artificially inflated prices of the Company's common stock.

523. Plaintiffs and the Class have suffered damages in that, in direct reliance on the integrity of the market, they paid artificially inflated prices for Integra common stock, which artificial inflation was removed from the stock when true facts became known. Plaintiffs and the Class would not have purchased Integra common stock at the prices they paid, or at all, had they been aware that the market prices for Integra common stock had been artificially inflated by Defendant Integra and the Individual Defendants' fraudulent course of conduct.

524. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages attributable to the fraud alleged herein in connection with their respective purchases of the Company's common stock, call options, or put options during the Class Period.

525. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(a) and (c), promulgated thereunder.

## COUNT III

### For Violations of Section 20(a) of the Exchange Act (Against the Individual Defendants)

526. Lead Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

527. The Individual Defendants acted as controlling persons of Integra within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions with the Company, participation in, and/or awareness of the Company's operations, and intimate knowledge of the false statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements that Lead Plaintiffs contend are false and

misleading. Each of the Individual Defendants was provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Lead Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

528. In particular, the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

529. As set forth above, Defendants each violated § 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, the Individual Defendants are liable pursuant to § 20(a) of the Exchange Act. As a direct and proximate result of these Defendants' wrongful conduct, Lead Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's shares during the Class Period.

## XIII. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiffs pray for relief and judgment as follows:

(i) Declaring this action to be a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of the Class defined herein;

(ii) Awarding all damages and other remedies available under the Securities Exchange Act in favor of Lead Plaintiffs and all other members of the Class against Defendants in an amount to be proven at trial, including interest thereon;

(iii) Awarding Lead Plaintiffs and the other members of the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and

(iv) Awarding such other and further relief as this Court deems appropriate.

## XIV. JURY DEMAND

530. Lead Plaintiffs demand a trial by jury.

Dated: August 14, 2025

Respectfully submitted,

By: */s/ James E. Cecchi*

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**CERTIFICATE OF SERVICE**

I hereby certify that on August 14, 2025, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send a Notice of Electronic Filing to all counsel of record.

I certify under penalty of perjury that the foregoing is true and correct.

Executed on August 14, 2025.

Respectfully submitted,

By: *<u>/s/ James E. Cecchi</u>*
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