

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

Case No.

CLASS ACTION

**COMPLAINT FOR VIOLATIONS OF
THE FEDERAL SECURITIES LAWS**

JURY TRIAL DEMANDED

Plaintiff,

v.

INTEGRA LIFESCIENCES HOLDINGS
CORPORATION, CARRIE ANDERSON,
PETER ARDUINI, GLENN COLEMAN,
JAN DE WITTE, ROBERT T. DAVIS, JR.,
STEVE LEONARD, and JEFFREY
MOSEBROOK,

Defendants.

Plaintiff

by and

through its counsel, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, *inter alia*, the investigation of its counsel, which included review and analysis of: (i) regulatory filings made by Integra LifeSciences Holdings Corporation ("Integra" or the "Company") with the United States Securities and Exchange Commission ("SEC"); (ii) press releases, presentations, and media reports issued by and disseminated by the Company; (iii) analyst and media reports concerning the Company; and (iv) other public information regarding the Company.

INTRODUCTION

1. This securities class action is brought on behalf of all persons or entities that purchased or otherwise acquired shares of Integra common stock between March 11, 2019 and

May 22, 2023, inclusive (the “Class Period”). The claims asserted herein are alleged against Integra and certain of the Company’s current and former senior executives (collectively, “Defendants”), and arise under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5, promulgated thereunder.

2. Integra develops regenerative tissue technologies and neurological solutions. The Company’s Tissue Technologies business—which generates approximately one-third of Integra’s total revenue—manufactures and sells collagen-based medical devices that are used for complex wound care, peripheral nerve repair, and reconstruction surgery. Several of those products are produced at the Company’s manufacturing plant located in Boston, Massachusetts (the “Boston Facility”), including SurgiMend, PriMatrix, Revize, and TissueMend. SurgiMend, one of Integra’s principal wound care products, is an implant approved by the U.S. Food and Drug Administration (“FDA”) for use as a reinforcement for soft tissue where weakness exists, including within plastic and reconstructive surgery.

3. On October 9, 2018, the FDA began an inspection in the Boston Facility during which it observed that Integra’s quality systems and manufacturing conditions were “not in conformity with the current good manufacturing practice requirements of the Quality System Regulation.” As a result, on November 2, 2018, the FDA issued a Notice of Inspectional Observations on Form 483 (the “2018 Form 483”) to put Integra on notice of those violations.

4. After receiving the 2018 Form 483, Integra issued a series of responses purporting to address the problems identified by the FDA. On March 6, 2019, after concluding that Integra’s responses were “not adequate to address the . . . violations,” the FDA issued a warning letter (the “2019 Warning Letter”) further documenting the quality control and manufacturing problems at the Boston Facility and noting that the “deficiencies observed during our inspection are significant

and demonstrate a systemic failure of your firm’s quality systems.” Most significantly, the FDA noted that Integra had failed to adequately test for bacterial endotoxins in its medical devices manufactured at the Boston Facility.

5. In the wake of the 2019 Warning Letter, and throughout the Class Period, Integra assured investors that it was making improvements to remediate the violations in the Boston Facility. For example, Integra repeatedly assured investors that it had “undertaken significant efforts” to address the concerns the FDA identified in the 2019 Warning Letter and, by early 2020, declared that there were “no patient safety issues” associated with the Boston Facility. The Company further assured investors that the “[2019 Warning Letter] does not restrict the Company’s ability to manufacture or ship products or require the recall of any products.”

6. In the third quarter of 2021, the Company submitted an application to the FDA for premarket approval (“PMA”) for SurgiMend to be used in implant-based breast reconstruction. This was the first PMA application for an implant-based breast reconstruction surgical matrix and represented a major opportunity for the Company to grow SurgiMend’s addressable market. As such, throughout the Class Period, analysts and investors were keenly focused on the approval process. As part of the approval process, Integra and the SurgiMend product would be required to undergo rigorous testing and review by the FDA to assess the product’s safety, efficacy, and quality. Throughout the Class Period, Integra repeatedly touted that it was on track to grow SurgiMend’s addressable market by obtaining FDA approval for use in post-mastectomy reconstruction. These misrepresentations caused the price of Integra common stock to trade at artificially inflated prices throughout the Class Period.

7. The truth began to emerge on April 26, 2023, when, before the market opened, the Company revealed that it had paused production at the Boston Facility. The Company also

disclosed declining operating margins for the quarter and flat revenue growth projections, which the Company attributed to the manufacturing stoppage. As a result of these disclosures, the price of Integra common stock declined by \$4.64 per share, or 8%. Later that day, after the market closed, Integra further revealed that, on March 1, 2023, the FDA had commenced another inspection at the Boston Facility and that the Company expected to receive another Form 483 as a result of that inspection.

8. However, the Company continued to reassure investors by downplaying the pause as an “acceleration of the Boston quality project” that would allow the Company “to maximize focus and efficiency in implementing these changes.” The Company also reiterated that it “remain[ed] confident in [its] efforts to obtain a breast reconstruction indication for SurgiMend[.]”

9. Then, on May 23, 2023, the Company announced a “recall” of all products manufactured at the Boston Facility between March 1, 2018 and May 22, 2023. Integra explained that it had determined that the Boston Facility deviated from good manufacturing practices in testing for bacterial endotoxin and allowed the release of products with unsafe levels of endotoxins. The Company also extended the pause on all production at the Boston Facility. As a result of the recall and manufacturing shutdown, the Company revised its guidance for the second quarter of 2023, lowering its revenue expectations by 6% and adjusted earnings per diluted share by 26%. The Company further disclosed that it expected to take a \$22 million impairment charge in the second quarter due to the inventory write-off. These disclosures caused the price of Integra stock to decline by an additional \$10.24 per share, or 20%.

10. As a result of Defendants’ wrongful acts and omissions, and the precipitous decline in the market value of the Company’s common stock, Plaintiff and other Class members have suffered significant losses and damages when the truth was revealed.

JURISDICTION AND VENUE

11. 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 (17 C.F.R. § 240.10b-5), promulgated thereunder. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

12. Venue is proper in this District under Section 27 of the Exchange Act (15 U.S.C. § 78aa), and 28 U.S.C. § 1391(b). Integra maintains its headquarters and conducts operations in this District. 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 mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

13. Plaintiff Pembroke Pines Firefighters & Police Officers Pension Fund is a public pension fund based in Pembroke Pines, Florida that provides firefighters, police and their families with income and benefits once the employees retire. As indicated in the certification submitted herewith, Plaintiff purchased shares of Integra common stock at artificially inflated prices during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

14. Defendant Integra develops regenerative tissue technologies and neurological solutions. Integra maintains its headquarters at 1100 Campus Road, Princeton, New Jersey. The Company's shares trade on NASDAQ under the ticker symbol "IART." As of April 25, 2023, Integra had over 81 million shares outstanding, owned by hundreds or thousands of investors.

15. Defendant Carrie Anderson ("Anderson") served as Integra's Chief Financial Officer from June 24, 2019 to February 2, 2023.

16. Defendant Peter Arduini (“Arduini”) served as Integra’s Chief Executive Officer from January 3, 2012 to December 1, 2021.

17. Defendant Glenn Coleman (“Coleman”) served as Integra’s Corporate Vice President and Chief Financial Officer from May 2, 2014 to June 24, 2019. Coleman, then served as the Company’s Chief Operating Officer from June 24, 2019 to September 23, 2022.

18. Defendant Jan De Witte (“De Witte”) has served as Integra’s Chief Executive Officer since December 2021.

19. Defendant Robert T. Davis, Jr. (“Davis”) is, and at all relevant times was, Integra’s Executive Vice President, President – Tissue Technologies.

20. Defendant Steve Leonard (“Leonard”) has served as Integra’s Vice President, Global Operations and Supply Chain since August 2020.

21. Defendant Jeffrey Mosebrook (“Mosebrook”) is, and at all relevant times was, Integra’s Principal Accounting Officer. Defendant Mosebrook also served as the Company’s principal financial officer from February 2, 2023 to June 28, 2023.

22. Defendants Anderson, Arduini, Coleman, De Witte, Davis, Leonard, and Mosebrook 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 to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors. 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.

BACKGROUND

23. Integra is a medical device company that manufactures, among other things, regenerative technology focused on the areas of complex wound surgery, surgical reconstruction, and peripheral nerve repair. Several of these products, which include SurgiMend, PriMatrix, Revize, and TissueMend, are principally manufactured at the Company's Boston Facility.

24. From October 9 through November 2, 2018, the FDA performed an inspection of the Boston Facility. During the inspection, the FDA identified serious violations of Current Good Manufacturing Practice regulations and issued the 2018 Form 483 documenting those violations. Then, on March 6, 2019, the FDA issued the 2019 Warning Letter after finding that Integra failed to remediate the serious violations it had found at the Boston Facility. Most significantly, Integra failed to adequately test for bacterial endotoxins in the devices manufactured in its Boston Facility, including SurgiMend. Bacterial endotoxins are toxic components present in the cell walls of certain bacteria, whose presence can lead to adverse reactions when introduced to the human body. The 2019 Warning Letter required that Integra "take prompt action to correct the violations addressed in this letter" and warned that "[f]ailure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice."

DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS CAUSE SUBSTANTIAL LOSSES TO INVESTORS

25. The Class Period begins on March 11, 2019, when Integra filed a Current Report with the SEC on Form 8-K disclosing that, on March 7, 2019, the Company received the FDA's 2019 Warning Letter, which was dated March 6, 2019, concerning quality systems issues that were

identified during the FDA's inspection of the Boston Facility between October 9 and November 2, 2018. Integra assured investors that "since the conclusion of the inspection, [it] has undertaken significant efforts to remediate the observations and continues to do so." Integra further assuaged investors' concerns by stating 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 that it does not "restrict [its] ability to seek FDA 510(k) clearance of products." Integra added that it "does not expect to incur material incremental expense for remediation activities."

26. On July 24, 2019, Integra announced its financial results for the second quarter of 2019. That same day, the Company held a conference call with analysts and investors to discuss its financial results. During that call, Defendant Arduini touted that "global sales of SurgiMend increased double-digit" and Integra "believe[s] there are significant global opportunities to expand this product line for plastic and reconstructive procedures and plan to make additional investments in the second half of 2019." Defendant Coleman elaborated that, as SurgiMend's principal manufacturing plant, the Company was "looking at ways to build out increased capacity and change some of the process steps" at the Boston Facility in order to "drive more products" and "drive more growth."

27. On February 19, 2020, Integra announced its financial results for the fourth quarter and full year ended December 31, 2019. That same day, the Company held a conference call with analysts and investors to discuss its financial results. During that call, Defendant Coleman, explained that Integra had gone through an "FDA audit" at its Boston Facility, which led to "supply constraint[s]." However, he assured investors that the Company had engaged in "quality remediation efforts throughout 2019," and that, as a result of those remediation efforts, "[t]here are no patient safety issues" in the Boston Facility. Defendant Coleman also stated that there were

“changes [the Company] had to make to the actual physical facility” in Boston, and that “[t]he good news is as we started off here in 2020, we now have more capacity, we’re on a better path forward in terms of supply out of Boston, and we expect to have the remediation efforts complete in the short term and then get the warning letter lifted in 2020.”

28. On May 7, 2020, Integra announced its financial results for the first quarter of 2020. That same day, the Company held a conference call with analysts and investors to discuss its financial results. During that call, Defendant Anderson touted that sales of “SurgiMend increased double digits in the quarter, driven by the increase in supply coming from the capital investments we initiated last year at our Boston [facility].” Defendant Coleman stated that the Boston Facility was “pretty much running at normal capacity” and was “building up safety stock” to meet future demand. He further touted the growth prospects of the Boston Facility’s SurgiMend and PriMatrix product, stating that “we should see very good growth. . . . So double-digit growth we were posting last year. We continue to expect that. . . . And we’re going to have plenty of safety stock to support that ramp[.]”

29. On May 20, 2020, Defendant Anderson represented Integra at the UBS Global Virtual Healthcare Conference. During the conference, Anderson stated that “if you recall, we had made key investments in capacity in our regenerative tissue supplies facilities in Boston” and “this was ramping up really nicely and we were seeing growth in the first two and half months of the quarter.”

30. On October 28, 2020, Integra announced its financial results for the third quarter of 2020. That same day, the Company held a conference call with analysts and investors to discuss its financial results. During that call, in response to an analyst’s question concerning the level of growth investors could expect from the Company’s Tissue Technologies business, Defendant

Arduini stated, “high single, low double digit is what we’re definitely positioned for.” Defendant Coleman further assured investors that the Company was in “great shape” with its Tissue Technology supply, stating “we actually were able to build supply even faster, build safety stock levels up despite the cost reductions that we went through. But the other nice thing is we’ve made some investments in these plants to build more capacity as we move forward. And I think about our Boston plant which makes SurgiMend and PriMatrix. . . . [W]e’ve actually built more safety stock for those regenerative products. . . . [T]hese are very high margin products for us, 80%-plus.”

31. On May 20, 2021, during Integra’s annual Investor Day conference, Defendant Coleman stated that “[w]e’ve made investments in our core plants, where we expect the greatest growth to come from over the next five years, including our regenerative plants in . . . Boston and that work is now complete.”

32. On November 2, 2021, Integra issued a press release announcing its financial results for the third quarter of 2021. In the press release, which was also filed with the SEC on Form 8-K, the Company announced that it had “submitted a PMA for SurgiMend® for a breast reconstruction indication that was the subject of an FDA Advisory Committee meeting on October 20, 2021.” Integra added that it “gained valuable insights to further inform [its] submission” and positively portrayed its communications with the FDA, stating, “we look forward to working with the FDA in the coming months as it completes its review of our PMA.”

33. On February 24, 2022, Integra filed with the SEC its 2021 annual report on Form 10-K for the year ended December 31, 2021. The Form 10-K was signed by Defendants De Witte, Anderson, and Mosebrook and contained certifications by Defendants De Witte and Anderson that attested to the purported accuracy and completeness of the 10-K. In the 10-K, the Company stated that “[o]n October 28, 2021 FDA initiated an inspection of the [Boston] facility and at the

conclusion of the inspection issued a Form 483 on November 12, 2021” (the “2021 Form 483”). Integra stated that “[t]he Company provided an initial response to the inspectional observations and will continue to provide responses to FDA.” While the Company’s Boston Facility was once again found to be in violation of good manufacturing practice requirements, Integra assured investors 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[.]”

34. Despite the ongoing quality control and manufacturing issues at the Company’s Boston Facility, Integra continued to assure investors that it was on track to obtain the PMA for SurgiMend to include an additional indication for breast reconstruction. On July 27, 2022, Integra announced its financial results for the second quarter of 2022. That same day, the Company held a conference call with analysts and investors to discuss its financial results. During that call, Defendant De Witte reported that Integra “continue[d] productive engagement with the FDA regarding [its] SurgiMend breast PMA[.]”

35. On September 7, 2022, Defendant De Witte represented Integra at the Wells Fargo Healthcare Conference. During that conference, Defendant De Witte assured analysts and investors that there was “good cooperation” with the FDA and as such the Company felt “comfortable” that it would “get the PMA” for SurgiMend by “early next year.”

36. On October 26, 2022, Integra announced its financial results for the third quarter of 2022. That same day, the Company held a conference call with analysts and investors to discuss its financial results. During that call, Defendant De Witte, with regard to the pending PMA for SurgiMend, stated that the Company “continue[s] to work interactively and collaboratively with the FDA[.]” De Witte added that the PMA approval “was planned for February 2023. However, last week, the FDA proposed an unsolicited COVID-19-related 180-day extension of the PMA

amendment timeline.” De Witte assuaged investor concerns by assuring that “[i]n any case, [Integra] continue[s] to feel optimistic [the Company] will receive FDA approval of a specific indication for use of SurgiMend in post-mastectomy reconstruction.”

37. On January 11, 2023, Defendants De Witte and Anderson participated in the J.P. Morgan Healthcare Conference. During that conference, Defendant De Witte updated analysts and investors that Integra was “going to continue to execute on the PMA” and expected FDA approval in 2024.

38. On February 22, 2023, Integra announced its financial results for the fourth quarter and full year ended December 31, 2022. That same day, the Company held a conference call with analysts and investors to discuss its financial results. During that call, Defendant De Witte reported the Company has “made substantial progress on [its] PMA for the use of SurgiMend in implant-based breast reconstruction” and “will remain on track with the approval timeline [it] discussed during the last earnings call and at the recent JPMorgan Healthcare Conference[.]” De Witte also stated that Integra “intend[s] to drive profitable growth in 2023,” that these “key growth accelerators” include “PMA resonance for SurgiMend,” and that it was therefore vital for the Company to ensure “delivery of the PMA submissions and preparation of [its] relevant manufacturing sites to produce PMA level of products,” which for the SurgiMend PMA was the Boston Facility.

39. On February 22, 2023, Integra filed with the SEC its 2022 annual report on Form 10-K for the year ended December 31, 2022. In the report, Integra repeated the language in paragraph 33 above. The Form 10-K was signed by Defendants De Witte and Mosebrook and contained certifications by Defendants De Witte and Mosebrook that attested to the purported accuracy and completeness of the 10-K.

40. The statements set forth above in paragraphs 25 to 39 were materially false and misleading and failed to disclose material facts necessary to make the statements made, in light of the circumstances in which they were made, not false and misleading. In truth, Integra had failed to take sufficient measures to remediate the violations identified by the FDA in the 2018 Form 483, 2019 Warning Letter, and the 2021 Form 483. As a result of those deficiencies, since March 2018, all products manufactured in the Boston Facility had the potential for higher-than-permitted levels of endotoxin and would need to be recalled. Moreover, the Company was not making progress towards obtaining its PMA indication for SurgiMend, in part, because the manufacturing site that would produce the PMA product, the Boston Facility, was in continued violation of the FDA standards that Integra failed to rectify years after the initial notice of the violations and as a result the facility had to be shutdown to correct those ongoing deficiencies.

THE TRUTH EMERGES

41. On April 26, 2023, before the market opened, Integra issued a press release announcing its financial results for the first quarter of 2023. In the press release, which was also filed with the SEC on Form 8-K, the Company disclosed that it had “[p]aused production at the Boston manufacturing site in March while pulling forward quality system upgrades project[.]” As a result of the shutdown, Integra announced lowered operating margins for the quarter and flat revenue growth projections. These disclosures caused the price of Integra common stock to decline by \$4.64 per share, or 8%, from a closing price of \$58.84 per share on April 25, 2023, to a closing price of \$54.20 per share on April 26, 2023.

42. That same morning, the Company held a conference call to discuss Integra’s financial results for the first quarter of 2023. During that call, Defendant De Witte assured investors that the Company had “been working the past couple of years to upgrade [its] Boston

facility based on FDA observations in 2018 and 2021” and told investors that the “FDA Inspection in March reinforced the urgency of these quality system upgrades.” De Witte further assured investors that the Company “remain[ed] confident in [its] efforts to obtain a breast reconstruction indication for SurgiMend” and was “on track to file [its] PMA update [in] August, as well as complet[e] related work at [its] Boston facility to upgrade [its] quality systems.” De Witte also downplayed the significance of the production pause, calling it an “acceleration” of the “Boston quality project” that would allow the Company “to maximize focus and efficiency in implementing these changes.” De Witte explained that SurgiMend was the main product being manufactured at the Company’s Boston Facility, which “requires a quality system that operates at a higher level.”

43. After the market closed on April 26, 2023, the Company filed with the SEC its quarterly report on Form 10-Q for the first quarter of 2023. The Company revealed 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.”

44. On May 4, 2023, during Integra’s annual Investor Day conference, Defendant Davis stated that the Company was “very confident” in its SurgiMend PMA and reported that the Company “will be submitting in full [its] submission” for the SurgiMend PMA later in the year and that the Company would be “on time to look at a 2024 indication [for breast reconstruction] for SurgiMend.” Davis further assured investors that the Company was “working weekly and frequently with the FDA” on the SurgiMend PMA. Defendant Leonard added 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 “[w]e are on a path to reach world-class quality assurance across all manufacturing sites by this summer.”

45. The statements set forth above in paragraphs 42 and 44 were materially false and misleading and failed to disclose material facts necessary to make the statements made, in light of the circumstances in which they were made, not false and misleading. In truth, the problems at the Boston Facility were pervasive and, as such, Integra was not on track to “reach world-class quality assurance” in all manufacturing sites by summer 2023. Moreover, the lingering violations at the Boston Facility were preventing Integra from obtaining a PMA for SurgiMend’s post-mastectomy breast reconstruction indication.

46. Then, on May 23, 2023, before the market opened, Integra filed a Current Report with the SEC on Form 8-K 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 stated 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.” The recall included Integra’s SurgiMend, PriMatrix, Revize, and TissueMend products, in which higher levels of endotoxins could have increased the risk of post-operative fever and other complications for the patients who received these medical implants.

47. Integra estimated that the recall and continued manufacturing stoppage would have the greatest impact on the Company’s Tissue Technologies segment and revised its guidance for the second quarter of 2023, lowering its expectations for revenue by 6% and adjusted earnings per diluted share by 26%. The Company also revealed that it expects to take a \$22 million impairment charge at the end of the second quarter of 2023 related to recalled inventory that would have to be

written off. The Company estimated that its full-year revenue and adjusted earnings per diluted share would be negatively affected by approximately \$60 million, or 5%, and \$0.35, or 10%, respectively.

48. A Bank of America analyst reported on May 23, 2023, that “[t]he PMA submission for SurgiMend’s breast indication is still on track for August and approval is expected in 2024, according to management.” The report additionally noted that “[d]espite’s management’s optimism, [Bank of America] think[s] the recall increases potential risk that the SurgiMend breast approval may be delayed.”

49. As a result of these disclosures, the price of Integra common stock declined by \$10.24 per share, or 20%, 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.

50. On July 27, 2023, after the end of the Class Period, 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 inspection of the Boston Facility in March 2023, the FDA not only issued a new Notice of Inspectional Observations on Form 483 but also issued another warning letter (the “2023 Warning Letter”). Integra admitted that the 2023 Warning Letter will prevent the Company from obtaining the SurgiMend PMA, 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.”

51. That same day, the Company held a conference call with analysts and investors to discuss its financial results. During that call, Defendant De Witte revealed that the commercial relaunch of the Boston Facility would not take place 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.”

LOSS CAUSATION

52. Defendants’ wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

53. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and omissions, and engaged in a scheme to deceive the market. This artificially inflated the price of Integra common stock and operated as a fraud or deceit on the Class (defined below). Later, when Defendants’ prior misrepresentations and fraudulent conduct were disclosed to the market, the price of Integra common stock fell precipitously as the prior artificial inflation came out of the price over time. As a result of their acquisition of Integra shares during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

CLASS ACTION ALLEGATIONS

54. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons or entities that purchased or otherwise acquired shares of Integra common stock during the Class Period (the “Class”). Excluded from the Class are Defendants and their families, directors, and officers of Integra and their families and affiliates.

55. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. As of April 25, 2023, Integra had over 81,904,442 million shares outstanding, owned by hundreds or thousands of investors.

56. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

- (a) Whether Defendants violated the Exchange Act;
- (b) Whether Defendants omitted and/or misrepresented material facts;
- (c) Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
- (d) Whether Defendants are personally liable for the alleged misrepresentations and omissions described herein;
- (e) Whether Defendants knew or recklessly disregarded that their statements and/or omissions were false and misleading;
- (f) Whether Defendants' conduct impacted the price of Integra common stock;
- (g) Whether Defendants' conduct caused the members of the Class to sustain damages; and
- (h) The extent of damage sustained by Class members and the appropriate measure of damages.

57. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct.

58. Plaintiff will fairly and adequately protect the interests of the Class and has retained counsel experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

59. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Joinder of all Class members is impracticable.

INAPPLICABILITY OF STATUTORY SAFE HARBOR

60. To the extent that any of the alleged false statements described in this Complaint were forward-looking, Integra's "Safe Harbor" warnings accompanying any purportedly forward-looking statements issued during the Class Period were ineffective to shield those statements from liability.

61. To the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false or misleading forward-looking statements because, at the time each such statement was made, the speaker knew the statement was false or misleading and the statement was authorized and/or approved by an executive officer of Integra who knew that the statement was false or misleading. None of the historic or present tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to, or stated to be dependent on, those historic or present tense statements when made.

PRESUMPTION OF RELIANCE

62. At all relevant times, the market for Integra common stock was an efficient market for the following reasons, among others:

(a) Integra common stock met the requirements for listing, and were listed and actively traded on NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Integra filed periodic public reports with the SEC and NASDAQ;

(c) Integra regularly and publicly communicated with 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

(d) Integra was followed by several securities analysts employed by major brokerage firm(s) who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firm(s). Each of these reports was publicly available and entered the public marketplace.

63. As a result of the foregoing, the market for Integra common stock promptly digested current information regarding Integra from all publicly available sources and reflected such information in the price of Integra common stock. Under these circumstances, all purchasers of Integra common stock during the Class Period suffered similar injury through their purchase of Integra common stock at artificially inflated prices and the presumption of reliance applies.

64. A Class-wide presumption of reliance is also appropriate in this action under the 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 material omissions. Because this action involves a failure to disclose material adverse information regarding Integra's business and operations—information that was required to be disclosed—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 significance of Integra's ability to provide high quality products and customer service that

adequately met the needs and expectations of its customer base in the digital printing market, that requirement is satisfied here.

CLAIMS FOR RELIEF

COUNT I

For Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

65. Plaintiff repeats, incorporates, and realleges each and every allegation contained above as if fully set forth herein.

66. During the Class Period, Defendants carried out a plan, scheme, and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Integra common stock at artificially inflated prices.

67. Defendants: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of Integra common stock in an effort to maintain artificially high market prices for Integra common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5, promulgated thereunder.

68. Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce, and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the Company's financial well-being, operations, and prospects.

69. During the Class Period, Defendants made the false statements specified above, which they knew or recklessly disregarded to be false and misleading in that they contained

misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

70. Defendants had actual knowledge of the misrepresentations and omissions of material fact set forth herein, or recklessly disregarded the true facts that were available to them. Defendants engaged in this misconduct to conceal Integra's true condition from the investing public and to support the artificially inflated prices of Integra common stock.

71. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Integra common stock. Plaintiff 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 Defendants' fraudulent course of conduct.

72. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases of Integra common stock during the Class Period.

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

COUNT II

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

74. Plaintiff repeats, incorporates, and realleges each and every allegation contained above as if fully set forth herein.

75. The Individual Defendants acted as controlling persons of Integra within the meaning of Section 20(a) of the Exchange Act. By virtue of their high-level positions, participation in and/or awareness of the Company's operations, direct involvement in the day-to-

day operations of the Company, and/or intimate knowledge of the Company's actual performance, and their power to control public statements about Integra, the Individual Defendants had the power and ability to control the actions of Integra and its employees. By reason of this conduct, the Individual Defendants are liable under Section 20(a) of the Exchange Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages in favor of Plaintiff and other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and

D. Awarding such equitable/injunctive or other further relief as the Court may deem just and proper.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff hereby demands a trial by jury in this action of all issues so triable.