EXHIBIT A

UNITED STATES DISTRICT COURTDISTRICT OF MASSACHUSETTS

SHELLIE BROEDER, AMY DELGADO, MARISA SAYERS, MICHELLE MARTINEZ, and ANITA MENDIOLA, **Plaintiffs,** **v.** **HOLOGIC, INC.,** **Defendant.**	**Case No. 1:23-cv-10823** **JURY TRIAL DEMANDED**

FIRST AMENDED COMPLAINT

Plaintiffs Shellie Broeder, Amy Delgado, Marisa Sayers, Michelle Martinez, and Anita Mendiola ("Plaintiffs") bring this action against Defendant Hologic, Inc. ("Defendant" or "Hologic"), a Massachusetts corporation.

JURISDICTION AND VENUE

Venue is proper in this Court pursuant to 28 U.S.C. §§ 101, 1391, and 1441(a). This Court has subject matter jurisdiction under 28 U.S.C. § 1332(a) because (1) there is complete diversity of citizenship between Plaintiffs and Defendant; and (2) the amountin controversy exceeds $75,000, exclusive of interests and costs.

INTRODUCTION

1. Plaintiffs, all breast cancer survivors and/or women at risk of breastcancer, were implanted with a medical device called BioZorb[1] ("BioZorb" or BioZorb Marker") manufactured by Hologic.

[1] The term "BioZorb" refers to all model numbers of BioZorb Marker and includes the BioZorb LP Marker.

2. BioZorb is a three-dimensional implantable radiographic marker used to mark soft tissue sites. Six titanium clips are distributed in a three-dimensional pattern into a bioabsorbable polylactic acid spacer in a circular, helical, or elliptical design.

3. This lawsuit is a personal injury action against Hologic, the company responsible for designing, researching, developing, testing, manufacturing, preparing, processing, inspecting, packaging, labeling, marketing, promoting, supplying, distributing, and/or selling of the BioZorb Marker.

PARTIES

Plaintiff Shellie Broeder

4. Plaintiff Shellie Broeder ("Ms. Broeder" or "Plaintiff Broeder") is and at all relevant times was a citizen of the state of Montana and the United States and over the age of eighteen (18) years.

5. Ms. Broeder was diagnosed with breast cancer in or around 2022. On or around October 3, 2022, she underwent a lumpectomy at Bozeman Deaconess Hospital, during which Dr. Shauna Werth Kronfuss ("Dr. Kronfuss") properly implanted a BioZorb.

6. Ms. Broeder suffered from a hard, painful lump. She had severe pain at and around the site of the BioZorb Marker, and the pain was worsened upon contact or movement. This pain resulted in the removal of the BioZorb.

7. Ms. Broeder had the BioZorb removed by Dr. Kronfuss at Bozeman Deaconess

Hospital on or around September 18, 2023. Upon removal of BioZorb, Ms. Broeder's pain improved.

8. As a result of the pain and complications of the BioZorb Marker, Plaintiff Broeder feared the possibility of another tumor every day until the surgical removal of BioZorb, causing significant emotional distress.

9. As a result of the BioZorb, Ms. Broeder has been caused to have additional procedures, significant pain, disfigurement, and worry, leaving her permanently and physically scarred. The complications, adverse local tissue reaction, disfigurement, non-absorption, palpable mass, and additional surgery are not warned of on the Instructions for Use but were risks Defendant knew or should have known and failed to disclose to patients, physicians, and hospitals.

Plaintiff Amy Delgado

10. Plaintiff Amy Delgado ("Ms. Delgado" or "Plaintiff Delgado") is and at all relevant times was a citizen of the State of Michigan and the United States and over the age of eighteen (18) years.

11. Ms. Delgado was diagnosed with breast cancer in or around 2020. She underwent a partial mastectomy on or around March 29, 2021, at Covenant Medical Center, during which Dr. Bayes properly implanted a BioZorb.

12. Ms. Delgado suffered severe pain and discomfort because of the BioZorb Marker.

13. The BioZorb failed to absorb as intended and migrated in Ms. Delgado's breast. Ms. Delgado was required to undergo additional surgery to remove the BioZorb Marker.

14. Ms. Delgado had the BioZorb removed by Dr. Bays at Mackinaw Surgery Center on or around December 6, 2023. Since the surgery, Ms. Delgado has suffered from infections, abscesses, and disfigurement.

15. As a result of the pain and complications of the BioZorb Marker, Plaintiff Delgado feared the possibility of another tumor every day until the surgical removal of BioZorb, causing

significant emotional distress.

16. As a result of the BioZorb, Ms. Delgado has been caused to have additional procedures, significant pain, disfigurement, worry, and infection, leaving her permanently and physically scarred. The complications, migration, adverse local tissue reaction, disfigurement, non-absorption, palpable mass, and additional surgery are not warned of on the Instructions for Use but were risks Defendant knew or should have known and failed to disclose to patients, physicians, and hospitals.

Plaintiff Marisa Sayers

17. Plaintiff Marisa Sayers ("Ms. Sayers" or "Plaintiff Sayers") is and at all relevant times was a citizen of the State of Michigan and the United States and is over the age of eighteen (18) years.

18. Ms. Sayers was diagnosed with breast cancer in or around 2018. She underwent a lumpectomy on or around May 8, 2018, at Corewell Health William Beaumont University Hospital, during which Dr. Dekhne properly implanted a BioZorb.

19. Ms. Sayers suffered from unrelenting and excruciating pain at and around the site of the BioZorb Marker. Plaintiff Sayers suffered from a stabbing sensation and severe discomfort that affected her daily life, making it difficult to lay down or perform daily activities. The BioZorb fractured into pieces and migrated in her breast, intensifying the pain she had to endure until the removal of the device.

20. Ms. Sayers had the BioZorb removed by Dr. Linsey Gold at Beaumont Hospital on or around November 1, 2019.

21. As a result of the pain and complications of the BioZorb Marker, Plaintiff Sayers feared the possibility of another tumor every day until the surgical removal of BioZorb, causing

significant emotional distress.

22. As a result of the BioZorb, Ms. Sayers has been caused to have additional procedures, significant pain, disfigurement, and worry, leaving her permanently and physically scarred. The complications, fracture, migration, adverse local tissue reaction, disfigurement, non-absorption, palpable mass, and additional surgery are not warned of on the Instructions for Use but were risks Defendant knew or should have known and failed to disclose to patients, physicians, and hospitals.

Plaintiff Michelle Martinez

23. Plaintiff Michelle Martinez ("Ms. Martinez" or "Plaintiff Martinez") is and at all relevant times was a citizen of the State of Michigan and the United States and over the age of eighteen (18) years.

24. Ms. Martinez was diagnosed with breast cancer in or around 2020. She underwent a mastectomy on or around October 15, 2020, at McLaren Medical Center – Bay Region, during which Dr. Tari S. Stull properly implanted a BioZorb.

25. Ms. Martinez suffered from a hard, painful lump at the site of the BioZorb Marker.

She suffered from discomfort, irritation, deformity of the breast, and constant pain. The device failed to absorb as intended.

26. Ms. Martinez had the BioZorb removed by Dr. Bays at Mackinaw Surgery Center on or around September 21, 2023.

27. As a result of the pain and complications of the BioZorb Marker, Plaintiff Martinez feared the possibility of another tumor every day until the surgical removal of BioZorb, causing significant emotional distress.

28. As a result of the BioZorb, Ms. Martinez has been caused to have additional

procedures, significant pain, disfigurement, and worry, leaving her permanently and physically scarred. The complications, adverse local tissue reaction, disfigurement, non-absorption, palpable mass, and additional surgery are not warned of on the Instructions for Use but were risks Defendant knew or should have known and failed to disclose to patients, physicians, and hospitals.

Plaintiff Anita Mendiola

29. Plaintiff Anita Mendiola ("Ms. Mendiola" or "Plaintiff Mendiola") is and at all relevant times was a citizen of the State of Texas and the United States and over the age of eighteen (18) years.

30. Ms. Mendiola was diagnosed with breast cancer in or around January 2020. She underwent a partial mastectomy on or around February 7, 2020, at Memorial Hermann, during which Dr. Glen Garner properly implanted a BioZorb.

31. Ms. Mendiola suffered from severe discomfort that caused difficulty while trying to sleep. The BioZorb failed to absorb and began protruding through the skin, causing severe pain and leading to additional procedures required to remove the device.

32. Ms. Mendiola had the BioZorb removed by Dr. Hoang Le at Memorial Hermann on or around June 10, 2022.

33. As a result of the pain and complications of the BioZorb Marker, Plaintiff Mendiola feared the possibility of another tumor every day until the surgical removal of BioZorb, causing significant emotional distress.

34. As a result of the BioZorb, Ms. Mendiola has been caused to have additional procedures, significant pain, disfigurement, and worry, leaving her permanently and physically scarred. The complications, migration, adverse local tissue reaction, disfigurement, non- absorption, palpable mass, and additional surgery are not warned of on the Instructions for Use but were risks Defendant knew or should have known and failed to disclose to patients, physicians, and hospitals.

Defendant Hologic

35. Defendant Hologic was and is engaged in the business of designing,manufacturing, developing, preparing, processing, inspecting, testing, packaging,promoting, marketing, distributing, labeling, supplying, and/or selling for profit, either directly or indirectly, through an agent, affiliate, predecessor, or subsidiary, the BioZorb Marker. Hologic is registered to do business in the Commonwealth of Massachusetts and has offices, does business through employees, contractors, and agents and enjoys the protection of the laws.

BACKGROUND AND FACTS

A. Background on BioZorb

36. The BioZorb Marker is a Class II medical device cleared by the United States Food and Drug Administration ("FDA") in February 2012 pursuant to Section 510(k) if the Food and Drug, and Cosmetic Act ("510(k)"). *See* Exhibit A (BioZorb® Marker, BioZorb® LP Marker Instructions for Use).

37. BioZorb is a three-dimensional implantable radiographic marker. It is comprised of a bioabsorbable spacer that holds six radiopaque titanium clips. The bioabsorbable spacer material (polylactic acid) is intended to be resorbed by the body through hydrolysis, leaving the radiopaque clips as permanent indicators of the soft tissue site. *Id*.

38. BioZorb is indicated for use in radiographic marking of sites in soft tissue and in situations where the soft tissue site needs to be marked for future medical procedures. It may be used with the following imaging modalities: X-ray (CT and mammography), MRI, and ultrasound. *Id*.

39. The contraindications and warnings in the BioZorb Instructions for Use ("IFU") state:

> The marker should not be placed in a tissue site with clinical evidence of infection. The marker should only be used by physicians trained in surgical techniques. The physician is responsible for its proper clinical use. The marker is shipped sterile; do **NOT** re-sterilize any portion of the marker. The Marker is for **SINGLE USE** only. Do **NOT** use if the package is open or damaged, or if the temperature indicator has a black

> center. Use the Marker prior to the expiry date shown on the product label.

Id.

40. The FDA rejected clearing BioZorb for the indication that it provides a reference from which treatment (e.g., radiotherapy) can be guided.

41. Defendant marketed BioZorb as a device that can fill space in breast tissue,[2] improve cosmetic outcomes after procedures,[3] and guide radiotherapy. [4] The FDA did not clear any of these indications for use.

B. The Problems with BioZorb and the Inadequacy of the Instructions for Use

42. The IFU for BioZorb contains no warnings or contraindications of any substance to effectively warn patients, physicians, or hospitals of the relevant risks associated with the use of the device.

43. The BioZorb IFU and Defendant's marketing of the BioZorb indicate the device is intended to completely resorb in up to one or more years. However, there is evidence that the device can take significantly longer than one year to absorb, or it may fail to absorb at all. These risks are not mentioned in BioZorb's IFU.

44. Hologic was aware of Medical Device Reports ("MDRs") that reported patient complications including but not limited to infection, fluid buildup, device migration, device erosion, pain, discomfort, rash, extended resorption time of the device, and additional surgeries. These risks are not mentioned in BioZorb's IFU.

---

[2] *See e.g.*, https://www.hologic.com/sites/default/files/bellingham-breast-center-poster_asbrs-2017.pdf

[3] *See e.g.*, https://hologicbreastsurgery.com/eur/portfolio/surgical-implant-targeted-therapy-biozorb/#

[4] *See e.g.*, https://www.hologic.com/sites/default/files/BioZorb-Marker-Case%20Study-Dr-Devisetty.pdf accessed August 6, 2024; inactive on August 19, 2024.

45. Hologic also knew or should have known of clinical evidence that BioZorb can cause a hard, palpable lump, causing patient pain and discomfort.[5] These risks are not mentioned in BioZorb's IFU.

46. Hologic also knew or should have known of clinical evidence that shows that BioZorb may increase a patient's radiation dose, contributing to further complications. As one breast surgeon noted, "[n]ormally, a lumpectomy cavity is treated for 5 fractions with low energy electrons such as 6 MeV or9MeV. Such energies give modest doses to the skin and leave no permanent scarring. As you increase in energy of electrons, it increases the skin dose, and you run the risk of seeing more early and late skin reactions. The most disfiguring side effect [of using BioZorb] is the appearance of telangiectasias, which look like red spider veins. No woman wants this on their legs and certainly not on their breasts!"[6] These risks are not mentioned in BioZorb's IFU.

47. Hologic also knew or should have known of clinical evidence that the device was causing infection, migration, necrosis, additional radiation, and additional surgery. These risks are not mentioned in BioZorb's IFU.

C. FDA Issues a Safety Communication Regarding Potential Risks of Using BioZorb Markers in Breast Tissue.

48. On February 27, 2024, the U.S. Food and Drug Administration issued a Safety Communication ("February 27 Notice") regarding BioZorb Markers.[7]

49. The February 27 Notice informed patients, healthcare providers, and hospitals about the potential risk of serious complications when using BioZorb Markers manufactured by Hologic.

---

[5] *See e.g.*, Puls, T.J., Fisher, C.S., Cox, A. et al. *Regenerative tissue filler for breast conserving surgery and other soft tissue restoration and reconstruction needs*. Sci Rep 11,2711 (2021). https://doi.org/10.1038/s41598-021-81771-x.

[6]https://web.archive.org/web/20231001130233/https://sugarlandradiationoncology.com/blog/entry/biozorb-device (originating website no longer available).

[7] BioZorb Markers and Potential Risks with Use in Breast Tissue: FDA Safety Communications, U.S. Food and Drug Administration (February 27, 2024), available at: https://wwww.fda.gov/medical-devices/safety-communications/biozorb-markers-and-potential-risks-use-breast-tissue-fda-safety-communication (last accessed March 6, 2024).

50. The FDA issued the February 27 Notice after receiving reports describing complications (adverse events) with the use of BioZorb Markers in breast tissue, including infection, fluid buildup (seroma), device moving out of position (migration), device breaking through the skin (erosion), pain, discomfort from feeling the device in the breast, rash, other complications "possibly associated with" extended resorption time (resorbable component of the device not resorbing in the patient's body for several years), and the need for additional medical treatment to remove the device.

51. The FDA noted in the February 27 Notice that it had cleared BioZorb Markers for radiographic marking of sites in soft tissue (including breast) or for marking the soft tissue site for future medical procedures.

52. In the February 27 Notice, the FDA stated that it had not cleared or approved the BioZorb Markers to fill space in the tissue or to improve cosmetic outcomes after procedures.

53. From its entry into the market, Defendant marketed and promoted the BioZorb Markers to hospitals and surgeons as a device that fills space in breast tissue and improves cosmetic outcomes following surgery.

54. Surgeons relied on the Defendant's representations and implanted BioZorb Markers in patients, including the Plaintiffs.

55. Hospitals relied on Defendant's representations and allowed use of BioZorb Markers in patients, including Plaintiffs.

56. The FDA noted that Defendant had not provided any data to support its claim that the device improved cosmetic outcomes.

D. FDA Class I Recall of BioZorb Marker.

57. On March 13, 2024, pursuant to FDA direction, Hologic sent an Important Medical Device Safety Notification ("Safety Notification") to affected customers.[8][9]

58. The Safety Notification was to request that patients contact their healthcare provider if they experience any adverse events following the placement of a BioZorb Marker; report any problems or complications experienced following the placement of the BioZorb Marker devices to Hologic and to the FDA's MedWatch Adverse Event Reporting program; and discuss the benefits and possible risks of implantable breast tissue markers for breast cancer procedures with their health care provider.

59. The Important Medical Device Safety Notification was also required to be sent to health care providers, and Hologic requested that the health care providers be aware of serious adverse events following possible risks of BioZorb Marker devices with each patient; inform all patients on which device will be used if a marking device will be used during breast conservation surgery; continue to monitor patients who have an implanted BioZorb Marker for signs of any adverse events; and report any problems or complications experienced by patients following placement of the BioZorb Marker devices to Hologic and the FDA's MedWatch Adverse Event Reporting program.

60. On May 22, 2024, the FDA classified Hologic's communications to its customers as a Class I recall.

61. Class I recalls are the most serious type of recall.

[8] Hologic, Inc. Recalls BioZorb Marker Due to Complications with Implanted Devices (May 22, 2024), available at https://www.fda.giv/medical-devices/medical-device-recalls/hologic-inc-recalls-biozorb-marker-due-complications-implanted-devices (last accessed June 3, 2024).

[9] The FDA says this Safety Notification was sent to "all affected customers," however, Plaintiffs are aware of affected patients and physicians who did not receive it.

62. The FDA further noted that the use of BioZorb Markers may cause serious injuries or death.

63. The FDA indicated that this recall was a correction, not a product removal.

64. Complaints that led to the recall included reports of pain, infection, rash, device migration, device erosion, seroma, discomfort, or other complications from feeling the device in the breast, and the need for additional medical treatment to remove the device.

CAUSES OF ACTION
COUNT I- NEGLIGENCE: FAILURE TO WARN

65. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein.

66. Under Massachusetts law, "[t]he manufacturer can be held liable even if the product does exactly what it is supposed to do, if it does not warn of the potential dangers inherent in a way a product is designed."[10]

67. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the BioZorb Marker.

68. Defendant knew and intended for the BioZorb Markers to be implanted into individuals for whom the device is indicated, including Plaintiffs.

69. Defendant had a duty to adequately warn and disclose the dangers and risks of the BioZorb Marker, which Defendant knew, or in the exercise of ordinary care should have known, at the time BioZorb Marker left its control.

70. Defendant knew, or in the exercise of ordinary care should have known that the BioZorb Marker could cause the injuries suffered by Plaintiffs. For example, Hologic was aware of post-marketing adverse event reports, otherwise known as Medical Device Reports ("MDRs"), that

[10] *Laaperi v. Sears, Roebuck Co., Inc*., 787 F.2d 726, 729 (1st Cir. 1986) (applying Massachusetts Law).

alleged the same injuries suffered by the Plaintiffs .

71. The BioZorb Markers were not accompanied by proper warnings and instructions to Plaintiffs, physicians, hospitals, or the public regarding potential adverse side effectsassociated with the device's implantation and the comparative severity andduration of such adverse side effects.

72. Specifically, the IFU failed to include warnings that the BioZorb Markers take far longer than one year to resorb and could require surgical removal. The warnings also failed to include information that a radiation oncologist might need to use a higher energy electron therapy, which can cause scarring and other complications in the breast.

73. The IFU also failed to warn that the device could cause pain, infection, rash, device migration, device erosion, seroma, discomfort, other complications from feeling the device in the breast, the need for additional medical treatment to remove the device, mass formation, infection, fluid buildup, scarring, fat necrosis, or adverse tissue reaction. The IFU did not warn that BioZorb could protrude from the breast and create a hole in the breast, expel from the breast, which could also lead to drainage and infection.

74. The IFU also failed to warn of the risks created due to BioZorb's negligent design including, but not limited to, the device breaking into shards, causing pain and inflammation, failing to absorb, and the device's long-term palpability.

75. The above warnings were known by the Defendant when Plaintiffs were implanted with BioZorb Markers.

76. As a direct and proximate result of Defendant's conduct, Plaintiffs have suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

77. Prudent patients in Plaintiffs' positions would have chosen not to be implanted with BioZorb if the IFU contained the above warnings.

78. Further Defendant marketed BioZorb to fill space in breast tissue, improve cosmetic outcomes after procedures, and provide radiotherapy guidance, all in direct contravention of the Indications for Use cleared by the FDA, of which Defendant knew or shoulder have known.

79. Example, Defendant published journal articles that promoted BioZorb for off-label uses, claimed no device-related complications, and did not disclose conflicts of interest.[11]

80. Defendant also published marketing materials, including brochures and educational materials, which failed to adequately warn physicians and patients about BioZorb's risks and/or stated the device had no impact on side effects.[12]

81. In addition, Defendant's sales representatives did not disclose to physicians the risks of BioZorb nor the rate of any risks.

82. WHEREFORE, the Plaintiffs demand judgment against Defendant and seek compensatory damages where applicable, together with costs and interest, and anyfurther relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT II
NEGLIGENCE: DESIGN DEFECT

83. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein.

84. At all relevant times, Defendant designed, researched, developed, inspected, tested, packaged, labeled, supplied, and/or sold BioZorb.

85. Plaintiffs were harmed because of the defective design of theBioZorb Marker.

---

[11] *See e.g.*, Cross MJ, Lebovic GS, Ross J, Jones S, Smith A, Harms S. *Impact of a Novel Bioabsorbable Implant on Radiation Treatment Planning for Breast Cancer*. World J Surg. 2017 Feb;41(2):464-471. doi: 10.1007/s00268-016-3711-y. PMID: 27709273. (scientific article written Gail Lebovic, the inventor of BioZorb and founder of Focal Therapeutics, and Michael Cross, a key opinion leader for Focal Therapeutics and Hologic, claiming the use of BioZorb resulted in a significant reduction in planned treatment volumes facilitating the use of hypo-fractioned radiation therapy with no device-related complications).

[12] *See e.g.*, https://www.hologic.com/sites/default/files/BioZorb-Marker-Case%20Study-Dr-Devisetty.pdf accessed August 6, 2024; inactive on August 19, 2024 ("BioZorb markers do not contribute to complications caused by treatment, including post-operation infection rates.")

86. The design of the BioZorb Marker is defective because of design aspects, including, but not limited to, its shape, surface, texture, material, and integration of parts.

87. BioZorb's shape, surface, texture, material, and integration of parts could all have been feasibly changed to make the device less harmful.

88. There are technologically feasible and practical alternative designs that would have reduced or prevented the Plaintiffs' harm.

89. In the oncological surgical market, alternative designs exist that are mechanically feasible, safer, and cost significantly less than BioZorb.

90. For example, titanium clipsthat have been on the market for years carry less clinical risk to the patient. [13] In fact, as one recent clinical study found: "the use of clips to mark thetumor bed is more cost-effective than the use of the BioZorb Marker which does not provide value given its relative high cost and lack of clinical advantage scientificallyshown over the use of surgical clips." [14]

91. BioZorb's design poses a high gravity of danger. For example, if the Marker does not fully absorb in the body, migrates, is expelled from the body, or causes an infection, a patient may be required to undergo an additional surgery to remove the device.

92. The design of the BioZorb Marker was a substantial factor in causing harm to the Plaintiffs.

93. WHEREFORE, Plaintiffs demand judgment against Defendant and seek compensatory damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

---

[13] *See* Sharon Smith, Clayton R. Taylor, Estella Kanevsky, Stephen P. Povoski & Jeffrey R. Hawley (2021) Long-term safety and efficacy of breast biopsy markers in clinical practice, Expert Review of Medical Devices, 18:1, 121-128, DOI: 10.1080/17434440.2020.1852928.

[14] Rashad, Ramy & Huber, Kathryn & Chatterjee, Abhishek. (2018). Cost-Effectiveness of the Biozorb Device for Radiation Planning in Oncoplastic Surgery. 7. 23. 10.5539/cco.v7n2p23.

COUNT III
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

94. Plaintiffs incorporate by reference all preceding paragraphs of thisComplaint as if fully set forth herein.

95. Every product or medical device sold in Massachusetts carries animplicit guarantee that it can safely serve the expected use for which it is sold.

96. Defendant impliedly warranted to prospective purchasers and users, including Plaintiffs, that the BioZorb Marker was safe, merchantable, and fit for the ordinary purposes for which it was to be used.

97. Plaintiffs reasonably relied upon the skill and judgment of Defendant as towhether the BioZorb Marker was of merchantable quality, safe, and fit for its intended use.

98. Upon information and belief, and contrary to such implied warranties, theBioZorb Marker was not of merchantable quality, safe, or fit for its intended use, because the product was, and is, unreasonably dangerous and unfit for the ordinary purposes for which it was used, as described above.

99. Restatement (Second) of Torts Section 402A, comment k, does notbar the plaintiff's breach of implied warranty claim based on the defendant's presumedposition that the medical device at issue was unavoidably unsafe.[15]

100. Defendant marketed BioZorb to fill space in breast tissue, to improve cosmetic outcomes after procedures, and to provide radiotherapy guidance, all in direct contravention of the Indications for Use cleared by the FDA.

101. Defendant marketed BioZorb to fill space in the breast tissue, improve cosmetic outcomes after procedures, or to provide radiotherapy guidance, all in contravention of the

[15] *See Taupier v. Davol, Inc.* 490 F. Supp. 3d 430 (D. Mass. 2020).

Indications for Use cleared by the FDA, of which the Defendant knew or should have known.

102. As a direct and proximate result of Defendant's conduct, Plaintiffs have suffered serious physical injury, harm, damages, and economic loss and will continue tosuffer such harm, damages, and economic loss in the future.

103. WHEREFORE, Plaintiffs demand judgment against Defendant and seek compensatory damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT IV
NEGLIGENCE

104. Plaintiffs incorporate by reference all preceding paragraphs of thisComplaint as if fully set forth herein.

105. At all times material hereto, Defendant, directly or indirectly, created, manufactured, assembled, designed, sterilized, tested, packaged, labeled, marketed, promoted, advertised, sold, and/or distributed into the stream of commerce the BioZorb Markers including the ones implanted in Plaintiffs.

106. Under federal and state law and regulation, Defendant was under a continuing duty to test and monitor the BioZorb Marker and its component parts, design, and manufacturing processes after FDA approval. These duties included establishing and validating its quality control systems and product suppliers, testing the device design, and investigating and reporting to the FDA any complaints about the device's performance and any malfunctions of which Defendant became aware and that are or may be attributable to the BioZorb Marker See 21 C.F.R. Part 803; 21 C.F.R. Part 814; 21 C.F.R. Part 820; 21 U.S.C. §§ 351(h), 360(i).

107. Defendant was negligent in designing, manufacturing, researching, developing, preparing, processing, packaging, promoting, marketing, labeling, supplying, inspecting, testing, distributing, and selling the BioZorb Marker by failing to use reasonable care in fulfilling its duty to

avoid foreseeable dangers.

108. Defendant was negligent in failing to comply with federal and state law and failing to use reasonable care in fulfilling its duty to inform users of dangerous risks, including risks posed by the device's negligent design. As a result of the foregoing conduct, Plaintiffs, physicians, and hospitals were sold defective medical devices without knowing the true risk-benefit ratio of the BioZorb Marker.

109. Defendant knew or should have known that the risk of the BioZorb Marker was different than what was in the IFU and communicated to patients, physicians, and hospitals.

110. Defendant knew or should have known that the BioZorb Marker's benefits differed from what was marketed, promoted, advertised, and communicated to patients, physicians, hospitals, and the general public.

111. Defendant knew or should have known that the FDA did not clear the BioZorb Marker to fill space in the breast tissue, improve cosmetic outcomes after procedures, or provide radiotherapy guidance.

112. Despite this knowledge, Defendant marketed the BioZorb Marker to fill space in breast tissue, to improve cosmetic outcomes after procedures, and to provide radiotherapy guidance, all in direct contravention of the Indications for Use cleared by the FDA.

113. It was readily foreseeable to Defendant that Plaintiffs and other consumers would be harmed as a result of Defendant's failure to exercise ordinary careand failure to report material information regarding the device's risks and claimed benefits. Defendant knew that Plaintiffs and their physicians and hospitals would use the medical device for their intended purpose, that their intended use would pose a substantial health risk to Plaintiffs, and that Plaintiffs, and the medical community would rely on Defendant's representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant the BioZorb Marker.

114. Under the same or similar circumstances, a reasonable manufacturer would have warned through an appropriate channel and medium of communication of the danger and reported the risks of the BioZorb Marker to patients, physicians, and hospitals.

115. Had Defendant adequately tested BioZorb, evidence regarding the device's risks, the rate of occurrence, and the extent of harm regarding each risk would have been found and could have been communicated to patients, physicians, and hospitals.

116. Had Defendant employed safety monitoring and pharmacovigilance measures for BioZorb, it could have mitigated or eliminated the risks posed by the BioZorb Marker.

117. Had Defendant timely reported the known risks associated with the BioZorb Marker to patients, physicians, and hospitals and allowed them to make informed decisions about using an alternative product that did not present the same risks, or foregoing the use of any marker, Plaintiffs would not have been implanted with BioZorb Markers.

118. Defendant knew that BioZorb's design was defective yet failed to take reasonable measures to mitigate or eliminate the risks posed by the defective design.

119. As a direct and proximate result of Defendant's actions and omissions,Plaintiffs suffered injuries, including but not limited to physical pain, infection, subsequent surgeries, and emotional injuries.

120. As a result of the above negligence, Plaintiffs suffered pain, medical expenses, emotional distress, and other economic and non-economic damages.

121. WHEREFORE, Plaintiffs demand judgment against Defendant and seek compensatory damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

PRAYER FOR RELIEF AS TO ALL COUNTS

WHEREFORE, Plaintiffs, prays for judgment against Defendant as follows:

a. judgment in favor of Plaintiffs and against Defendant, for damages insuch amounts as may be proven at trial;

b. compensation for both economic and non-economic losses, including butnot limited to medical expenses, loss of earnings, pain and suffering, mental anguish, and emotional distress, in such amounts as may be proven at trial;

c. punitive and/or exemplary damages in such amounts as may be provenat trial;

d. attorneys' fees, expenses, and costs of this action;

e. pre- and post-judgment interest as provided by law; and

f. any and all further relief, both legal and equitable, that the Court maydeem just and proper.

JURY DEMAND

Plaintiffs demand trial by jury as to all issues herein.

Dated: August 21, 2024.

Respectfully submitted,

/s/Christina D. Crow
Christina D. Crow (admitted *pro hac vice*)
C. Elizabeth Littell (admitted *pro hac vice*)
JINKS CROW, PC
P. O. Box 350
Union Springs, AL 36089
lisa.littell@jinkscrow.com
christy.crow@jinkscrow.com

John J. Roddy (BBO# 424240)
Elizabeth Ryan (BBO# 549632)
BAILEY & GLASSER LLP
176 Federal Street, 5th Floor.
Boston, MA 02110
jroddy@baileyglasser.com
eryan@baileyglasser.com
T: +1 617-439-6730
F: +1 617-951-3954

C. Moze Cowper (admitted *pro hac vice*)
COWPER LAW

12301 Wilshire Blvd., Ste. 303
Los Angeles, CA 90025
mcowper@cowperlaw.com
T: +1 877-529-3707
F: +1 877-284-0980

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non registered participants on August 21, 2024.

/s/Christina D. Crow
Christina D. Crow (admitted *pro hac vice*)