UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

NESSA WETTEMANN, NATRICIA HEAGY, STACEY BARTIS, PAMELA GARRETT, REBECCA MORROW, and LINDA BLAKE, **Plaintiffs,** **v.** **HOLOGIC, INC.,** **Defendant.**	**Case No. 1:25-cv-10242** **JURY TRIAL DEMANDED**

COMPLAINT

Nessa Wettemann, Natricia Heagy, Stacey Bartis, Pamela Garrett, Rebecca Morrow, and Linda Blake ("Plaintiffs") bring this action against Defendant Hologic, Inc. ("Defendant" or "Hologic"), a Massachusetts corporation.

JURISDICTION AND VENUE

1. 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 amount in controversy exceeds $75,000, exclusive of interests and costs. Venue is proper in this Court pursuant to 28 U.S.C. §§ 101, 1391, and 1441(a).

INTRODUCTION

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

[1] These terms refer to all model numbers of BioZorb Markers and include the BioZorb

3. 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.

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

PARTIES

Plaintiff Nessa Wettemann

5. Plaintiff Nessa Wettemann ("Ms. Wettemann" or "Plaintiff Wettemann") is, and at all relevant times was, a citizen of the State of California and the United States and over the age of eighteen (18) years.

6. Ms. Wettemann was diagnosed with left breast ductal carcinoma in situ in or around July 2022. She underwent a left breast lumpectomy on or around September 3, 2022 at Enloe Medical Center, during which Dr. Heidi Gorsuch-Rafferty ("Dr. Rafferty") properly implanted a BioZorb.

Low Profile ("LP") Marker.

7. Ms. Wettemann suffers from a hard, painful lump, swelling, and a sharp, stabbing pain at the site of the BioZorb Marker. Ms. Wettemann developed a seroma at the site of the BioZorb Marker in December of 2022 and again in March 2023, requiring multiple drain treatments of her breast. Ms. Wetteman has also attended physical therapy in an effort to alleviate her pain.

8. Ms. Wettemann discussed surgical removal of the BioZorb with her physicians, but her surgeon, Dr. Rafferty, has declined to explant the device.

9. As of March 27, 2024, the BioZorb was still present in Ms. Wetteman's left breast and visible on mammogram.

10. As a result of the pain and complications of the BioZorb Marker, Plaintiff Wettemann fears the possibility of another tumor every day, causing significant emotional distress.

11. As a result of the BioZorb, Ms. Wettemann has been caused to have additional procedures, significant pain, and worry, leaving her permanently and physically scarred. The complications, including, but not limited to, pain, non-absorption, palpable mass, and additional surgery, are not warned of on the BioZorb Instructions for Use ("IFU") but were risks Defendant knew or should have known yet failed to disclose to patients, physicians, and hospitals.

Plaintiff Natricia Heagy

12. Plaintiff Natricia Heagy ("Ms. Heagy" or "Plaintiff Heagy") is, and at all relevant times was, a citizen of the State of Idaho and the United States and over the age of eighteen (18) years.

13. Ms. Heagy was diagnosed with infiltrating ductal carcinoma in her right breast in or around June 2023. She underwent a right breast partial mastectomy on or around July 25, 2023 at Mountain View Hospital, during which Dr. David Chambler properly implanted a BioZorb.

14. Ms. Heagy suffered from pain, infection, seroma, and swelling at the site of the BioZorb Marker.

15. Due to the chronic infection at the site of the BioZorb, Ms. Heagy had the BioZorb removed by Dr. Mara Additon at Portneuf Medical Center on or around February 20, 2024.

16. Ms. Heagy suffered from complications following the removal of BioZorb and required multiple right breast drain treatments. The area of removal remains sore and causes Ms. Heagy physical and emotional stress.

17. As a result of the pain and complications of the BioZorb Marker, Plaintiff Heagy feared the possibility of another tumor every day, causing significant emotional distress.

18. As a result of the BioZorb, Ms. Heagy has been caused to have significant pain, disfigurement, worry, infection, and additional surgery, leaving her permanently and physically scarred. The complications, including, but not limited to, pain, infection, disfigurement, and additional surgery are not warned of in the IFU but were risks Defendant knew or should have known yet failed to disclose to patients, physicians, and hospitals.

Plaintiff Stacey Bartis

19. Plaintiff Stacey Bartis ("Ms.Bartis" or "Plaintiff Bartis") is, and at all relevant times was, a citizen of the State of Connecticut and the United States and over the age of eighteen (18) years.

20. Ms. Bartis was diagnosed with right breast invasive ductal carcinoma in or around February 2022. She underwent a right breast lumpectomy on or around March 2, 2022 at Hartford HealthCare Cancer Institute, during which Dr. Camelia Lawrence ("Dr. Lawrence") properly implanted a BioZorb.

21. Following implantation of the BioZorb, Ms. Bartis developed a seroma which required drainage and antibiotics. Ms. Bartis suffered from lymphedema at and around the site of the BioZorb. In addition, Ms. Bartis suffered from a hard lump, stabbing pain, discomfort, and swelling. Her pain was worsened upon contact at the site of the BioZorb, making it difficult to sleep.

22. Due to the injuries she suffered from the BioZorb Marker, Ms. Bartis had the BioZorb removed by Dr. Lawrence at Hartford HealthCare Cancer Institute on or around March 27, 2024.

23. As a result of the BioZorb, Ms. Bartis has been caused to have additional procedures, significant pain, disfigurement, worry, and infection, leaving her permanently and physically scarred. The complications, including, but not limited to, adverse local tissue reaction, disfigurement, and additional surgery, are not warned of in the IFU but were risks Defendant knew or should have known yet failed to disclose to patients, physicians, and hospitals.

Plaintiff Pamela Garrett

24. Plaintiff Pamela Garrett ("Ms. Garrett" or "Plaintiff Garrett") is, and at all relevant times was, a citizen of the State of Tennessee and the United States and over the age of eighteen (18) years.

25. Ms. Garrett was diagnosed with right breast Grade one mucinous carcinoma (colloid carcinoma) in or around October 2018. She underwent a partial mastectomy on or around November 8, 2018 at Comanche Memorial Hospital Breast Cancer Center, during which Dr. Elissa Hunter ("Dr. Hunter") properly implanted a BioZorb.

26. Ms. Garrett experienced deformity, scarring, infection, and protrusion at the BioZorb site. Ms. Garrett developed an infection and had to be put on IV antibiotics.

27. Due to the chronic infection at the site of the BioZorb, Ms. Garrett had the BioZorb removed by Dr. Hunter at Comanche Memorial Hospital Breast Cancer Center on or around June 17, 2019.

28. As a result of the pain and complications of the BioZorb Marker, Plaintiff Garrett feared the possibility of another tumor every day, causing significant emotional distress.

29. As a result of the BioZorb, Ms. Garrett has been caused to have significant worry, discomfort, pain, excessive scar tissue, adverse tissue reactions, disfigurement, additional radiation, and a hard lump, leaving her permanently and physically scarred. The complications, including, but not limited to, discomfort, pain, excessive scar tissue, adverse tissue reactions, disfigurement, and a hard lump, are not warned of in the IFU

but were risks Defendant knew or should have known yet failed to disclose to patients, physicians, and hospitals.

Plaintiff Rebecca Morrow

30. Plaintiff Rebecca Morrow ("Ms. Morrow" or "Plaintiff Morrow") is, and at all relevant times was, a citizen of the State of Maryland and the United States and over the age of eighteen (18) years.

31. Ms. Morrow was diagnosed with right breast ductal carcinoma in situ on or around November 27, 2017. She underwent a right breast partial mastectomy on or around January 10, 2018, at Anne Arundel Breast Center, during which Dr. Wen Liang properly implanted a BioZorb.

32. Ms. Morrow suffered from irritation, redness, pain, rash, swelling, infection, protrusion, and abscess at the site of the BioZorb.

33. In 2018, Ms. Morrow developed a seroma at the site of the BioZorb that required aspiration. In March of 2024, Ms. Morrow developed another cyst that required several aspirations, home wound vac treatments, and surgical removal.

34. Due to the chronic infection at the site of the BioZorb, Ms. Morrow had the BioZorb device removed by Dr. Steven Woodward at Anne Arundel Medical Center on or around April 15, 2024. Following removal of the BioZorb device, Ms. Morrow had to receive additional treatment to drain the abscess.

35. As a result of the pain and complications of the BioZorb Marker, Plaintiff Morrow feared the possibility of another tumor every day, causing significant emotional distress.

36. As a result of the BioZorb, Ms. Morrow has been caused to have significant worry, discomfort, pain, disfigurement, additional procedures, and a hard lump, leaving her permanently and physically scarred. The complications, including, but not limited to, discomfort, pain, disfigurement, a hard lump, additional procedures, and failure of the device to absorb, are not warned of in the IFU but were risks Defendant knew or should have known yet failed to disclose to patients, physicians, and hospitals.

Plaintiff Linda Blake

37. Plaintiff Linda Blake ("Ms. Blake" or "Plaintiff Blake") is, and at all relevant times was, a citizen of the State of Florida and the United States and over the age of eighteen (18) years.

38. Ms. Blake was diagnosed with invasive ductal carcinoma of the right breast in or around July 2018. She underwent a partial lumpectomy on or around July 13, 2018 at Baptist Health, during which Dr. Beth Ann Lesnikoski properly implanted a BioZorb.

39. Ms. Blake suffered from irritation, pain, hard lumps, and deformity at the site of the BioZorb. Ms. Blake also suffered from reoccurring infections at the site of the BioZorb between 2018 and 2023. In addition, the BioZorb failed to absorb.

40. As a result of the pain and complications of the BioZorb Marker, Plaintiff Blake feared the possibility of another tumor every day, causing significant emotional distress.

41. As a result of the BioZorb, Ms. Blake has been caused to have significant

worry, discomfort, pain, disfigurement, and infection, leaving her permanently and physically scarred. The complications, including, but not limited to, discomfort, pain, disfigurement, infection, and failure of the device to absorb, are not warned of in the IFU but were risks Defendant knew or should have known yet failed to disclose to patients, physicians, and hospitals.

Defendant Hologic

42. Defendant Hologic was and is engaged in the business of designing, manufacturing, researching, 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 its laws.

JURISDICTION AND VENUE

43. 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 amount in controversy exceeds $75,000, exclusive of interests and costs. Venue is proper in this Court pursuant to 28 U.S.C. §§ 101, 1391, and 1441(a).

BACKGROUND AND FACTS

A. Background on BioZorb

44. The BioZorb Marker is a Class II medical device first cleared by the United States Food and Drug Administration ("FDA") in February 2012 pursuant to Section

510(k) of the Food Drug, and Cosmetic Act ("510(k)"). *See* Exhibit A (BioZorb® Marker, BioZorb® LP Marker Instructions for Use).

45. 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*.

46. 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*.

47. 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.

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

49. Defendant marketed BioZorb as a device that can fill space in breast

tissue,[2] improve cosmetic outcomes after procedures,[3] and guide radiotherapy. [4] However, the FDA did not clear these indications for use.

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

50. 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.

51. 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.

52. 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.

53. Hologic also knew or should have known of clinical evidence that shows that BioZorb can cause a hard, palpable lump, causing patient pain and discomfort.[5]

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[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).

[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).

These risks are not mentioned in BioZorb's IFU.

54. 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 described, "[n]ormally, a lumpectomy cavity is treated for 5 fractions with low energy electrons such as 6 MeV or 9MeV. 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.

55. Hologic also knew or should have known of clinical evidence that BioZorb can cause 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.

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

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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:

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

58. 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.

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

60. 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 improve cosmetic outcomes after procedures.

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

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https://wwww.fda.gov/medical-devices/safety-communications/biozorb-markers-and-potential-risks-use-breast-tissue-fda-safety-communication (last accessed March 6, 2024).

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

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

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

D. February 2024 FDA Class I Recall of BioZorb Marker.

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

66. 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 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.

67. The Important Medical Device Safety Notification was also required to be sent to health care providers, and Hologic requested that they be aware of serious

[8] 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.

[9] 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).

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.

68. On May 22, 2024, the FDA classified Hologic's Safety Notification as a Class I recall, the most serious type of recall.

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

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

71. 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.

E. October 2024 FDA Class I Recall of BioZorb Marker.

72. On October 25, 2024, pursuant to FDA direction, Hologic announced a voluntary recall for removal of all lots of unused BioZorb Markers.

73. The FDA classified Hologic's October 2024 announcement as a Class I recall, the most serious type of recall.

74. The FDA also alerted health care providers and facilities, "Be aware the FDA has no cleared or approved the use of BioZorb markers to fill space in the tissue or

to improve cosmetic outcomes after procedures, or as a marker for radiation treatment."[10]

F. December 2024 FDA Warning Letter to Hologic.

75. The FDA inspected Hologic's Marlborough, Massachusetts facility on July 30, 2024 through September 24, 2024.

76. On December 18, 2024, the FDA sent a Warning Letter to Hologic, stating that the inspection revealed the BioZorb devices "are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), 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 found at Title 21, Code of Federal Regulations (CFR), Part 820."[11]

77. In the Warning Letter, the FDA noted violations, including, but not limited to, the following:

a. "[Hologic] failed to establish design inputs to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient, as required by 21 CFR 820.30(c);"

[10] Update: Do Not Use BioZorb Marker Implantable Radiographic Marker Devices: FDA Safety Communication (October 25, 2024), available at https://www.fda.gov/medical-devices/safety-communications/update-do-not-use-biozorb-marker-implantable-radiographic-marker-devices-fda-safety-communication

[11] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hologic-inc-698214-12182024

b. "[Hologic] failed to verify your device design to confirm that the design output meets the design input requirements, as required by 21CFR 820.30(f);"

c. "[Hologic] failed to validate your device design to ensure that devices conform to defined user/patient needs and intended uses, as required by 21 CFR 820.30(g);"

d. "[Hologic] failed to ensure that the device design is correctly translated into production specifications, as required by 21 CFR 820.30(h);"

e. "[Hologic's] review of quality data was not sufficient to detect recurring problems;"

f. "[Hologic] did not calculate the occurrence rate accurately when evaluating a spike of BioZorb medical device complaints and Medical Device Reports;"

g. "[Hologic's] BioZorb Marker is misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2);" and

h. The FDA found that their inspection "revealed that these devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), 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 found at Title 21, Code

of Federal Regulations (CFR), Part 820."[12]

78. The FDA also noted that the Warning Letter "is not intended to be an all-inclusive list of the violations at [Hologic's] facility."[13]

CAUSES OF ACTION

COUNT I:

STRICT LIABILITY – DESIGN DEFECT

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

80. At all relevant times, Defendant, directly or indirectly, developed, designed, researched, tested, inspected, manufactured, assembled, sterilized, packaged, marketed, labeled, distributed, supplied, and/or sold BioZorb Markers, including the ones implanted in Plaintiffs.

81. Defendant knew and intended for the BioZorb Markers to be implanted into individuals, including Plaintiffs.

82. The BioZorb Marker was expected to and did reach the Plaintiffs without substantial change in the condition in which it was sold.

83. The BioZorb Markers were in a defective condition and unreasonably dangerous to users, including Plaintiffs, when they left Defendant's control.

84. At the time the BioZorb Markers implanted in Plaintiffs left Defendant's control, the foreseeable risks associated with its design exceeded the benefits associated

[12] *Id.*

[13] *Id.*

with its design.

85. Defendant knew or should have known that BioZorb presented an unreasonable danger to patients implanted with the device when put to its intended and reasonably anticipated use.

86. The health risks associated with BioZorb Markers, as described herein, are of such a nature that ordinary consumers, including Plaintiffs and their physicians, would not have readily recognized the potential harm.

87. BioZorb is unsafe to an extent beyond that which would be contemplated by the ordinary consumer.

88. The risks of danger inherent in BioZorb's design outweigh the benefits of its design.

89. Defendant did not take reasonable precautions in an attempt to design a safe product and did not act as a reasonably prudent manufacturer would have under the circumstances.

90. Plaintiffs and Plaintiffs' physicians used the device in a normal, customary, intended, and foreseeable manner.

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

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

93. For example, the material of the BioZorb spacer makes the device defective because it is intended to absorb; however, it either does not absorb or, as it

does, the device fractures into pieces that can migrate throughout the breast and even protrude through a patient's skin. A different material with faster absorption and less crystallinity would help the device degrade in a melting fashion, instead of by fracturing, and would reduce the risks of palpability, pain, hard lumps, protrusion, and surgical removal of the device.

94. The material of the BioZorb spacer is also defective because it is a hard polymer that is placed in soft tissue, thus causing palpability, pain, hard lumps, and protrusion. A different material, or a chemical treatment of the material, could make the device flexible, thus resolving these risks.

95. In addition, the thickness of BioZorb's spacer could have been reduced to improve the device's degradation time, thus reducing the risks of palpability, pain, hard lumps, and surgical removal of the device.

96. The defects in the design of BioZorb resulted from Defendant's action and/or inaction.

97. For example, Defendant knew its design of BioZorb was defective and that it was feasible to design the device in a safer manner, yet failed to take any action to correct the design and/or to warn patients, physicians, and hospitals of the risks posed by the design.

98. There are technologically feasible and practical alternative designs available that would have reduced or prevented the Plaintiffs' harm without impairing the product's usefulness or desirability.

99. In the oncological surgical market, alternative designs exist that are

mechanically feasible, safer, and cost significantly less than BioZorb.

100. For example, titanium clips that have been on the market for years carry less clinical risk to the patient.[14] In fact, as one clinical study found: "The use of clips to mark the tumor 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 scientifically shown over the use of surgical clips."[15]

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

102. Defendant failed to establish design inputs for BioZorb to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient, as required by 21 CFR 820.30(c).[16]

103. Defendant failed to verify BioZorb's device design to confirm that the

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[14] *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.

[15] 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.

[16] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hologic-inc-698214-12182024

design output meets the design input requirements, as required by 21CFR 820.30(f).[17]

104. Defendant failed to validate BioZorb's device design to ensure that devices conform to defined user/patient needs and intended uses, as required by 21 CFR 820.30(g).[18]

105. Defendant failed to ensure that the BioZorb device design was correctly translated into production specifications, as required by 21 CFR 820.30(h).[19]

106. Defendant failed to identify the following for BioZorb Markers: the intended patient population, intended anatomy types, and surgical requirements, such as the appropriate placement and fixation of the device, and the appropriate depth of the implant into the soft tissue.[20]

107. Plaintiffs were harmed because of the defective design of the BioZorb Marker.

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

109. 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.

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[17] *Id*.

[18] *Id*.

[19] *Id*.

[20] *Id*.

COUNT II:
STRICT LIABILITY – FAILURE TO WARN

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

111. At all relevant times, Defendant, directly or indirectly, developed, designed, researched, tested, inspected, manufactured, assembled, sterilized, packaged, marketed, labeled, distributed, supplied, and/or sold BioZorb Markers, including the ones implanted in Plaintiffs.

112. 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 the BioZorb Markers left its control.

113. Defendant knew and intended for the BioZorb Markers to be implanted into individuals, including Plaintiffs.

114. The BioZorb Marker was expected to and did reach the Plaintiffs without substantial change in the condition in which it was sold.

115. The BioZorb Markers were in a defective condition and unreasonably dangerous to users, including Plaintiffs, when they left Defendant's control.

116. Defendant knew or should have known that BioZorb presented an unreasonable danger to patients implanted with the device when put to its intended and reasonably anticipated use.

117. 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 that alleged the same injuries the Plaintiffs in this lawsuit suffered.

118. The health risks associated with BioZorb Markers as described herein are of such a nature that ordinary consumers, including Plaintiffs and their physicians, would not have readily recognized the potential harm.

119. Plaintiff and Plaintiff's physicians used the device in a normal, customary, intended, and foreseeable manner.

120. Defendant failed to review quality data to detect recurring problems with the BioZorb Markers.[21]

121. Defendant did not calculate the occurrence rate accurately when evaluating a spike of BioZorb medical device complaints and Medical Device Reports.[22]

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

123. The IFU failed to include warnings that the BioZorb Markers take far longer than one year to resorb and could require surgical removal.

124. The IFU failed to warn that the device could cause severe injury to patients, including, but not limited to, pain, infection, rash, device migration, device

[21] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hologic-inc-698214-12182024

[22] *Id*.

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, and/or adverse tissue reaction. The IFU did not warn that BioZorb could be expelled from the breast, creating a hole, which could further lead to drainage and infection.

125. The IFU failed to warn of the risks created by 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.

126. The above complications and adverse effects were known by Defendant when Plaintiffs were implanted with BioZorb Markers.

127. 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.

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

129. Prudent physicians and hospitals would have chosen not to use BioZorb if the IFU contained the appropriate warnings.

130. 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 should have known.

131. For example, Defendant published journal articles that promoted BioZorb

for off-label uses, claimed no device-related complications, and did not disclose conflicts of interest.[23]

132. 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.[24]

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

134. WHEREFORE, the 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 III:

STRICT LIABILITY – MANUFACTURING DEFECT

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

136. At all relevant times, Defendant, directly or indirectly, developed,

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[23] *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 by 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).

[24] *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.")

designed, researched, tested, inspected, manufactured, assembled, sterilized, packaged, marketed, labeled, distributed, supplied, and/or sold BioZorb Markers, including the ones implanted in Plaintiffs.

137. Defendant knew and intended for the BioZorb Markers to be implanted into individuals, including Plaintiffs.

138. The BioZorb Markers were expected to and did reach the Plaintiffs without substantial change in the condition in which they were sold.

139. The BioZorb Markers were in a defective condition and unreasonably dangerous to users, including Plaintiffs, when they left Defendant's control.

140. Defendant knew or should have known that BioZorb presented an unreasonable danger to patients implanted with the device when put to its intended and reasonably anticipated use.

141. Plaintiff and Plaintiff's physicians used the device in a normal, customary, intended, and foreseeable manner.

142. The manufacturing defects resulted from Defendant's action and/or inaction.

143. Plaintiffs were harmed because of the manufacturing defects.

144. The FDA found that a fall 2024 inspection "revealed that [BioZorb Markers] are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), 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 found at

Title 21, Code of Federal Regulations (CFR), Part 820."[25]

145. 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

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

147. At all relevant times, Defendant, directly or indirectly, developed, designed, researched, tested, inspected, manufactured, assembled, sterilized, packaged, marketed, labeled, distributed, supplied, and/or sold BioZorb Markers, including the ones implanted in Plaintiffs.

148. Defendant owed Plaintiffs a duty to use reasonable care under the circumstances in developing, designing, researching, testing, inspecting, manufacturing, assembling, sterilizing, packaging, marketing, labeling, distributing, supplying, and selling BioZorb Markers.

149. Defendant knew and intended for the BioZorb Markers to be implanted into individuals, including Plaintiffs.

150. The BioZorb Markers were expected to and did reach the Plaintiffs without substantial change in the condition in which they were sold.

[25] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hologic-inc-698214-12182024

151. The BioZorb Markers were in a defective condition and unreasonably dangerous to users, including Plaintiffs, when they left Defendant's control.

152. Defendant knew or should have known that BioZorb presented an unreasonable danger to patients implanted with the device when put to its intended and reasonably anticipated use.

153. The health risks associated with BioZorb Markers as described herein are of such a nature that ordinary consumers, including Plaintiffs and their physicians, would not have readily recognized the potential harm.

154. Plaintiff and Plaintiff's physicians used the device in a normal, customary, intended, and foreseeable manner.

155. Defendant failed to use reasonable care under the circumstances in developing, designing, researching, testing, inspecting, manufacturing, assembling, packaging, marketing, labeling, distributing, and selling the BioZorb Markers.

156. 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; and 21 U.S.C. §§ 351(h), 360(i).

157. 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.

158. 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.

159. Defendant failed to evaluate or test how in-vivo radiation treatments can impact the performance of the device and the ability of the device to resorb into a patient's body.

160. Defendant failed to define the length of time for when the spacer material would be completely resorbed in a patient's body.

161. 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.

162. 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.

163. 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.

164. 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.

165. It was readily foreseeable to Defendant that Plaintiffs and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and 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.

166. 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.

167. 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.

168. Had Defendant employed safety monitoring and pharmacovigilance

measures for BioZorb, it could have mitigated or eliminated the risks posed by the BioZorb Marker.

169. 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.

170. 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.

171. 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.

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

173. 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 V:
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

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

175. At all relevant times, Defendant, directly or indirectly, developed,

designed, researched, tested, inspected, manufactured, assembled, sterilized, packaged, marketed, labeled, distributed, supplied, and/or sold BioZorb Markers, including the ones implanted in Plaintiffs.

176. Defendant knew and intended for the BioZorb Markers to be implanted into individuals, including Plaintiffs.

177. The BioZorb Marker was expected to and did reach the Plaintiffs without substantial change in the condition in which it was sold.

178. The BioZorb Markers were in a defective condition and unreasonably dangerous to users, including Plaintiffs, when they left Defendant's control.

179. Defendant knew or should have known that BioZorb presented an unreasonable danger to patients implanted with the device when put to its intended and reasonably anticipated use.

180. Plaintiff and Plaintiff's physicians used the device in a normal, customary, intended, and foreseeable manner.

181. 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.

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

183. Upon information and belief, and contrary to such implied warranties, the BioZorb 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.

184. Restatement (Second) of Torts Section 402A, comment k, does not bar the plaintiff's breach of implied warranty claim based on the defendant's presumed position that the medical device at issue was unavoidably unsafe.[26]

185. 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.

186. 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 pray for judgment against Defendant as follows:

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

b. compensation for both economic and non-economic losses, including, but not 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

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

proven at 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 may deem just and proper.

JURY DEMAND

Plaintiffs demand trial by jury as to all issues herein.

Dated: January 31, 2025

Respectfully Submitted,

/s/ John Roddy

John Roddy (BBO # 424240)
BAILEY & GLASSER LLP
176 Federal Street, 5th Floor
Boston, MA 02110
Tel.: 617.439.6730
Fax: 617.951.3954
jroddy@baileyglasser.com

Christina D. Crow (to be admitted *Pro Hac Vice*)
C. Elizabeth Littell (to be admitted *Pro Hac Vice*)
JINKS CROW PC
219 Prairie Street North, P.O. Box 350
Union Springs, AL 36089
Tel.: 334.738.4225
Fax: 334.738.4229
christy.crow@jinkslaw.com
lisa.littell@jinkslaw.com

C. Moze Cowper (to be admitted *Pro Hac Vice*)
COWPER LAW PC
12301 Wilshire Blvd., Ste. 303
Los Angeles, CA 90025
Tel.: 877.529.3707
Fax: 877.284.0980
mcowper@cowperlaw.com

Attorneys for Plaintiffs