UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

TAMMIE LOWRY, CATHERINE JAMES, SUSAN QUIDLEY, MELINDA BIANCONI, ANN BERRY, and TRISHA JOHNSON, **Plaintiffs,** **v.** **HOLOGIC, INC.,** **Defendant.**	**Case No. 1:25-cv-11353** **JURY TRIAL DEMANDED**

COMPLAINT

Tammie Lowry, Catherine James, Susan Quidley, Melinda Bianconi, Ann Berry, and Trisha Johnson ("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").

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

5. Plaintiff Tammie Lowry ("Ms. Lowry" or "Plaintiff Lowry") 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.

6. Plaintiff Catherine James ("Ms. James" or "Plaintiff James") is, and at all relevant times was, a citizen of the State of North Carolina and the United States and over the age of eighteen (18) years.

[1] These terms refer to all model numbers of BioZorb Markers and include the BioZorb Low Profile ("LP") Marker.

7. Plaintiff Susan Quidley ("Ms. Quidley" or "Plaintiff Quidley") 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.

8. Plaintiff Melinda Bianconi ("Ms. Bianconi" or "Plaintiff Bianconi") is, and at all relevant times was, a citizen of the State of Pennsylvania and the United States and over the age of eighteen (18) years.

9. Plaintiff Ann Berry ("Ms. Berry" or "Plaintiff Berry") is, and at all relevant times was, a citizen of the State of Oklahoma and the United States and over the age of eighteen (18) years.

10. Plaintiff Trisha Johnson ("Ms. Johnson" or "Plaintiff Johnson") 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.

11. 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.

BACKGROUND AND FACTS

A. Background on BioZorb

12. 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).

13. 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*.

14. 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*.

15. 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.

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

17. 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

18. 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.

19. 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.

20. 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.

21. 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). https://doi.org/10.1038/s41598-021-81771-x.

These risks are not mentioned in BioZorb's IFU.

22. 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.

23. 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

24. 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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[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-

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

26. 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.

27. 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.

28. 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.

29. 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.

30. Surgeons relied on the Defendant's representations and implanted

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and-potential-risks-use-breast-tissue-fda-safety-communication (last accessed March 6, 2024).

BioZorb Markers in patients, including the Plaintiffs.

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

32. 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

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

34. 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.

35. 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 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

[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).

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.

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

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

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

39. 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

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

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

42. 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

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

44. 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]

45. 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);"

b. "[Hologic] failed to verify your device design to confirm that the

[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

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]

46. 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]

G. FACTS APPLICABLE TO PLAINTIFFS

Plaintiff Tammie Lowry

47. Ms. Lowry was diagnosed with left breast ductal carcinoma in situ in or around March 2019. She underwent a left breast lumpectomy on or around April 01, 2019 at Baylor Scott & White Medical Center - Waxahachie, during which Dr. Valerie Gorman ("Dr. Gorman") properly implanted a BioZorb.

48. Following implantation of the BioZorb, Ms. Lowry suffered from a hard, painful lump, swelling, deformity, scarring, and sensitivity at the site of the BioZorb Marker. Her pain was worsened upon contact at the site of the BioZorb making it difficult to sleep.

49. As a result of the pain and complications caused by the BioZorb Marker, Plaintiff Lowry feared the possibility of another tumor every day, causing significant emotional distress.

50. As a result of the BioZorb's effect on her body, Ms. Lowry has suffered additional procedures, significant pain, inflammation, discomfort, disfigurement, worry, and a hard lump, leaving her permanently and physically scarred. These

[12] *Id.*
[13] *Id.*

complications — including, but not limited to discomfort, pain, disfigurement, inflammation, 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 Catherine James

51. Ms. James was diagnosed with invasive ductal cancer of her left breast in or around October 2016. She underwent a left breast partial mastectomy on or around April 04, 2017 at New Hanover Regional Medical Center, during which Dr. Gregory Bebb properly implanted a BioZorb.

52. Following implantation of the BioZorb, Ms. James suffered from pain, a hard lump, deformity, aches, inflammation, and extreme sensitivity at the site of the BioZorb Marker. Ms. James is unable to sleep because of the pain and discomfort caused by the BioZorb.

53. As a result of the pain and complications caused by the BioZorb Marker, Plaintiff James feared the possibility of another tumor every day, causing significant emotional distress.

54. As a result of the BioZorb's effect on her body, Ms. James has suffered significant pain, disfigurement, worry, and additional procedures, leaving her permanently and physically scarred. These complications — including, but not limited to, pain, disfigurement, large masses, and additional procedures — 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 Susan Quidley

55. Ms. Quidley was diagnosed with right infiltrating mammary carcinoma in or around September 2016. She underwent a right partial mastectomy on or around April 10, 2017 at Baptist Health System, during which Dr. Kathryn Wagner ("Dr. Wagner") properly implanted a BioZorb.

56. Following implantation of the BioZorb, Ms. Quidley suffered from suffered from a hard lump, severe pain, discomfort, deformity, irritation, infection, and swelling. Her pain was worsened upon contact at the site of the BioZorb, making it difficult to sleep.

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

58. As a result of the BioZorb, Ms. Quidley has suffered additional procedures, significant pain, disfigurement, worry, irritation, and infection, leaving her permanently and physically scarred. The complications, including, but not limited to, a hard lump, disfigurement, infection, and additional procedures, 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 Melinda Bianconi

59. Ms. Bianconi was diagnosed with right breast invasive ductal carcinoma in or around November 2021. She underwent a right breast lumpectomy on or around January 25, 2022 at Penn Highlands - DuBois, during which Dr. Kelley Smith ("Dr.

Smith") properly implanted a BioZorb.

60. Following implantation of the BioZorb, Ms. Bianconi suffered from deformity, vertigo, a hard painful lump, and irritation at the BioZorb site. Her pain was worsened upon contact at the site of the BioZorb, making it difficult to sleep.

61. As a result of the pain and complications caused by the BioZorb Marker, Plaintiff Bianconi feared the possibility of another tumor every day, causing significant emotional distress.

62. As a result of the BioZorb's effect on her body, Ms. Bianconi has suffered significant worry, discomfort, pain, irritation, deformity, disfigurement, additional radiation, and a hard lump, leaving her permanently and physically scarred. These complications, including — but not limited to, discomfort, pain, deformity, 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 Ann Berry

63. Ms. Berry was diagnosed with left breast invasive ductal carcinoma in situ on or around July 2021. She underwent a left breast lumpectoppmy on or around October 22, 2021, at OU Medical Center, during which Dr. William Dooley properly implanted a BioZorb.

64. Following implantation of the BioZorb, Ms. Berry suffered from a hard painful lump, hyperpigmentation, redness, sensitivity, spider veins, rash, failure to absorb, necrosis, and disfigurement at the site of the BioZorb.

65. Due to these injuries, Ms. Berry had the BioZorb device removed by Dr. Dooley at OU Medical Center on or around January 26, 2024.

66. As a result of the pain and complications caused by the BioZorb Marker, Plaintiff Berry feared the possibility of another tumor every day, causing significant emotional distress.

67. As a result of the BioZorb's effect on her body, Ms. Berry has suffered significant worry, discomfort, pain, disfigurement, additional surgery, necrosis, rashes, irritation, and a hard lump, leaving her permanently and physically scarred. The complications, including, but not limited to, discomfort, pain, disfigurement, a hard lump, necrosis, additional surgeries, 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 Trisha Johnson

68. Ms. Johnson was diagnosed with a left breast carcinoma in or around March 2024. She underwent a right breast localized lumpectomy on or about April 08, 2024, at Bozeman Health Deaconess Hospital, during which Dr. Robin Hape ("Dr. Hape") properly implanted a BioZorb.

69. Following implantation of the BioZorb, Ms. Johnson suffered from severe pain, hard painful lumps, sensitivity, protrusion, seroma, and deformity at the site of the BioZorb.

70. Due to these injuries, Ms. Johnson had the BioZorb device removed by Dr. Hape at Bozeman Health Deaconess Hospital on January 13, 2025.

71. As a result of the pain and complications caused by the BioZorb Marker, Plaintiff Johnson feared the possibility of another tumor every day, causing significant emotional distress.

72. As a result of the BioZorb's effect on her body, Ms. Johnson has suffered significant worry, discomfort, pain, disfigurement, seroma, and additional surgery, leaving her permanently and physically scarred. The complications, including, but not limited to, discomfort, pain, disfigurement, 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

73. 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.

CAUSES OF ACTION

COUNT I:

STRICT LIABILITY – DESIGN DEFECT

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

75. 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.

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

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

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

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

80. 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.

81. 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.

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

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

its design.

84. 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.

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

86. 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. 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.

89. 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.

90. 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.

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

92. 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.

93. 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.

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

95. 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]

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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.

96. BioZorb's design poses a significant risk 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.

97. 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]

98. Defendant failed to verify BioZorb's device design to confirm that the design output meets the design input requirements, as required by 21 CFR 820.30(f).[17]

99. 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]

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

101. 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

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

the implant into the soft tissue.[20]

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

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

104. 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 II:

STRICT LIABILITY – FAILURE TO WARN

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

106. 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.

107. 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.

108. Defendant knew and intended for the BioZorb Markers to be implanted

[20] *Id.*

into individuals, including Plaintiffs.

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

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

111. 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.

112. 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.

113. 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.

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

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

116. Defendant did not calculate the occurrence rate accurately when

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

evaluating a spike of BioZorb medical device complaints and Medical Device Reports.[22]

117. 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.

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

119. 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 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.

120. 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.

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

122. As a direct and proximate result of Defendant's conduct, Plaintiffs have

[22] *Id.*

suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

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

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

125. 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.

126. 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]

127. Defendant also published marketing materials, including brochures and educational materials, which failed to adequately warn physicians and patients about

[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).

BioZorb's risks and/or stated the device had no impact on side effects.[24]

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

129. 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

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

131. 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.

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

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

134. The BioZorb Markers were in a defective condition and unreasonably

[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.")

dangerous to users, including Plaintiffs, when they left Defendant's control.

135. 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.

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

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

138. Plaintiffs were harmed because of the manufacturing defects.

139. 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]

140. 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.

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

COUNT IV:

NEGLIGENCE

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

142. 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.

143. 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.

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

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

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

147. 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.

148. 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.

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

150. 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.

151. 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).

152. 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.

153. 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.

154. 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.

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

156. 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.

157. 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.

158. 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.

159. 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.

160. 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.

161. 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.

162. 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.

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

164. 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.

165. 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.

166. 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.

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

168. 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

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

170. 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.

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

172. The BioZorb Marker was expected to and did reach the Plaintiffs without

substantial change in the condition in which it was sold.

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

174. 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.

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

176. 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.

177. 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.

178. 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.

179. 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]

180. 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.

181. 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 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

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

may deem just and proper.

JURY DEMAND

Plaintiffs demand trial by jury as to all issues herein.

Dated: May 14, 2025

Respectfully submitted,

/s/ John Roddy
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