UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

LISA GALAINI, LAURA MAHONY, JACQUELINE DEMONTIGNY RAUH, LAUREN SIMS, GINGER ICONOS-WATKINS, JOAN HAYDEN, and JAIMA ALDRICH **Plaintiffs,** **v.** **HOLOGIC, INC.,** **Defendant.**	**Case No.**

COMPLAINT

Lisa Galaini, Laura Mahony, Jacqueline DeMontigny Rauh, Lauren Sims, Ginger Iconos-Watkins, Joan Hayden, and Jaima Aldrich ("Plaintiffs") bring this action against Defendant Hologic, Inc. ("Defendant" or "Hologic"), a Massachusetts corporation.

JURISDICTION AND VENUE

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

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

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

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

PARTIES

Plaintiff Lisa Galaini

4. Plaintiff Lisa Galaini ("Ms. Galaini" or "Plaintiff Galaini") is and at all relevant times was a citizen of the State of Kentucky and the United States and over the age of eighteen (18) years.

5. Ms. Galaini was diagnosed with cancer in her left breast in or around 2023. She underwent a left breast lumpectomy on or around February 14, 2023 at Mercy Health – Lourdes

[1] The term "BioZorb" refers to all model numbers of BioZorb Markers and includes the BioZorb Low Profile ("LP") Marker.

Hospital ("Mercy Health"), during which Dr. Daniel A. Howard ("Dr. Howard") properly implanted a BioZorb.

6. Ms. Galaini suffered from a hard lump, infection, adverse tissue reactions, and intense, excruciating, and unrelenting pain, itching, and tenderness at the site of the BioZorb Marker. Her pain worsened upon contact or movement, inhibiting her daily life. The BioZorb was visible through Ms. Galaini's skin.

7. Due to the complications caused by BioZorb, Ms. Galaini underwent additional surgery to have the BioZorb removed. Dr. Howard explanted the BioZorb, which had broken into shards, from Ms. Galaini's left breast at Mercy Health on or around April 16, 2024.

8. Following the explant, Ms. Galaini developed a painful bump on her breast at the site of the BioZorb removal. On or around July 23, 2024, Dr. Howard extracted trapped fluid from Ms. Galaini's breast.

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

10. As a result of the BioZorb, Ms. Galaini has been caused to have significant worry, discomfort, pain, infection, excessive scar tissue, adverse tissue reactions, disfigurement, a hard lump, and additional procedures, leaving her permanently and physically scarred. The complications, including, but not limited to, discomfort, pain, infection, excessive scar tissue, adverse tissue reactions, disfigurement, a hard lump, and additional surgery, are not warned of in 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 Laura Mahony

11. Plaintiff Laura Mahony ("Ms. Mahony" or "Plaintiff Mahony") 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.

12. Ms. Mahony was diagnosed with cancer in her left breast in or around January 2020. She underwent a left breast lumpectomy on or around March 9, 2020 at Morton Plant Hospital, during which Dr. Peter Blumencranz properly implanted a BioZorb.

13. Ms. Mahony suffered from a hard lump at and around the site of the BioZorb that caused constant pain and discomfort. Ms. Mahony suffered from tenderness, shooting pains, inflammation, fat necrosis, excessive scar tissue, and adverse tissue reactions at and around the site of the BioZorb. Ms. Mahony's pain affected her daily life and made it difficult to sleep.

14. Due to the complications caused by BioZorb, Ms. Mahony underwent additional surgery to have the BioZorb removed. Dr. Evgenios Evgeniou explanted the BioZorb and fat necrosis and scar tissue surrounding it from Ms. Mahony's left breast at Moffitt Cancer Center on or around March 19, 2024.

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

16. As a result of the BioZorb, Ms. Mahony has been caused to have significant worry, discomfort, pain, inflammation, fat necrosis, excessive scar tissue, adverse tissue reactions, disfigurement, a hard lump, and additional procedures, leaving her permanently and physically scarred. The complications, including, but not limited to, discomfort, pain, inflammation, fat necrosis, excessive scar tissue, adverse tissue reactions, disfigurement, hard lump, and additional

surgery, are not warned of in the BioZorb IFU but were risks Defendant knew or should have known yet failed to disclose to patients, physicians, and hospitals.

Plaintiff Jacqueline DeMontigny-Rauh

17. Plaintiff Jacqueline DeMontigny-Rauh ("Ms. Rauh" or "Plaintiff Rauh") is and at all relevant times was a citizen of the State of South Carolina and the United States and over the age of eighteen (18) years.

18. Ms. Rauh was diagnosed with invasive ductal carcinoma in her left breast in or around November 2016. She underwent a left breast lumpectomy on or around December 16, 2016 at Tidelands Health Breast Center, during which Dr. Angela Mislowsky properly implanted a BioZorb.

19. Ms. Rauh suffered from intense and unrelenting pain, tenderness, and pressure at the site of the BioZorb Marker. Ms. Rauh's pain worsened upon contact or movement, disrupting her daily life, making it difficult to sleep, and causing excruciating pain during mammograms. Ms. Rauh also suffers from breast deformity.

20. Due to the complications caused by BioZorb, Ms. Rauh underwent additional surgery to have the BioZorb removed. Dr. Scott Berry explanted the BioZorb from Ms. Rauh's left breast at McLeod Seacoast Hospital on or around May 20, 2024.

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

22. As a result of the BioZorb, Ms. Rauh has been caused to have significant worry, discomfort, pain, excessive scar tissue, adverse tissue reactions, disfigurement, a hard lump, and additional procedures, leaving her permanently and physically scarred. The complications,

including, but not limited to, discomfort, pain, excessive scar tissue, adverse tissue reactions, disfigurement, hard lump, and additional surgery, are not warned of in the BioZorb IFU but were risks Defendant knew or should have known yet failed to disclose to patients, physicians, and hospitals.

Plaintiff Lauren Sims

23. Plaintiff Lauren Sims ("Ms. Sims" or "Plaintiff Sims") is and at all relevant times was a citizen of the State of Florida or the State of Colorado and the United States and over the age of eighteen (18) years.

24. Ms. Sims was diagnosed with breast cancer in or around 2019. She underwent a lumpectomy in or around June 2019 at Physicians Regional Medical Center, during which Dr. Troy Shell-Masouras properly implanted a BioZorb.

25. Ms. Sims suffered from intense and unrelenting pain, itching, and tenderness at the site of the BioZorb Marker. She also suffered from necrosis, excessive scar tissue, tissue damage, inflammation, infections, disfigurement, and a hard lump at and around the site of the BioZorb.

26. Ms. Sims had the BioZorb removed by Dr. Jodi Widner at UCHealth Highlands Ranch Hospital.

27. Due to the complications caused by BioZorb, Ms. Sims underwent additional surgery to have the BioZorb removed. Dr. Jodi Widner explanted the BioZorb from Ms. Rauh's breast at UCHealth Highlands Ranch Hospital.

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

29. As a result of the BioZorb, Ms. Sims has been caused to have significant worry, discomfort, pain, inflammation, infection, necrosis, excessive scar tissue, adverse tissue reactions, disfigurement, a hard lump, and additional procedures, leaving her permanently and physically scarred. The complications, including, but not limited to, discomfort, pain, inflammation, infection, necrosis, excessive scar tissue, adverse tissue reactions, disfigurement, a hard lump, and additional surgery, are not warned of in the BioZorb IFU but were risks Defendant knew or should have known yet failed to disclose to patients, physicians, and hospitals.

Plaintiff Ginger Iconos-Watkins

30. Plaintiff Ginger Iconos-Watkins ("Ms. Watkins" or "Plaintiff Watkins") 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.

31. Ms. Watkins was diagnosed with cancer in her left breast in or around October 2021. She underwent a left breast lumpectomy on or around December 8, 2021 at Austin Cancer Center, during which Dr. Sangeetha Kolluri properly implanted a BioZorb.

32. Ms. Watkins suffered from sensitivity, discomfort, and a hard, painful, and palpable lump at the site of the BioZorb Marker. Her discomfort and pain worsened upon contact or movement. In addition, the BioZorb migrated to a different area in Ms. Watkins's breast, causing the BioZorb to become visible through her skin.

33. Due to the complications caused by BioZorb, Ms. Watkins underwent additional surgery to have the BioZorb removed. Dr. Aimee Mackey explanted the BioZorb from Ms. Watkins's left breast at St. David's South Austin Medical Center in or around October 2023.

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

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

Plaintiff Joan Hayden

36. Plaintiff Joan Hayden ("Ms. Hayden" or "Plaintiff Hayden") is and at all relevant times was a citizen of the State of Indiana and the United States and over the age of eighteen (18) years.

37. Ms. Hayden was diagnosed with right breast invasive ductal carcinoma in or around October 2019. She underwent a partial mastectomy on or around November 4, 2019 at Parkview Regional Medical Center, during which Dr. Linda Han properly implanted a BioZorb.

38. Ms. Hayden suffers from a hard, painful lump at and around the site of the BioZorb Marker. The area around the BioZorb is tender and uncomfortable and the BioZorb failed to properly absorb.

39. As a result of the pain and complications of the BioZorb device, Plaintiff Hayden fears the possibility of another tumor every day, causing significant emotional distress.

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

Plaintiff Jaima Aldrich

41. Plaintiff Jaima Aldrich ("Ms. Aldrich" or "Plaintiff Aldrich") is and at all relevant times was a citizen of the State of Indiana and the United States and over the age of eighteen (18) years.

42. Ms. Aldrich was diagnosed with right breast invasive ductal carcinoma in or around September 2019. She underwent a right breast partial mastectomy on or around February 28, 2020 at Parkview Regional Medical Center, during which Dr. Lindsay Hardley properly implanted a BioZorb.

43. Ms. Aldrich suffers from a hard, painful lump at and around the site of the BioZorb Marker. The area around the BioZorb is tender, uncomfortable, and itchy. The BioZorb has failed to properly absorb and is still palpable in her breast.

44. As a result of the pain and complications of the BioZorb device, Plaintiff Aldrich fears the possibility of another tumor every day, causing significant emotional distress.

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

Defendant Hologic

46. 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 the laws.

BACKGROUND AND FACTS

A. Background on BioZorb

47. 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).

48. 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*.

49. 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*.

50. 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.

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

52. 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

53. 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.

54. 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.

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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

55. 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.

56. 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] These risks are not mentioned in BioZorb's IFU.

57. 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.

58. 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.

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

[6] https://sugarlandradiationoncology.com/blog/entry/biozorb-device.

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

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

61. 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.

62. 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.

63. 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.

64. 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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[7] BioZorb Markers and Potential Risks with Use in Breast Tissue: FDA Safety Communications, U.S. Food and Drug Administration (February 27, 2024), available at: https://wwww.fda.gov/medical-devices/safety-communications/biozorb-markers-and-potential-risks-use-breast-tissue-fda-safety-communication (last accessed March 6, 2024).

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

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

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

D. FDA Class I Recall of BioZorb Marker.

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

69. 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.

70. 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 breast conservation surgery; continue to monitor patients who have an implanted BioZorb Marker for signs of any adverse events; and

[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).

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.

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

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

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

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

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

CAUSES OF ACTION
COUNT I- NEGLIGENCE: FAILURE TO WARN

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

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

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

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

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

80. 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 Marker left its control.

81. 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.

82. 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.

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

84. The IFU also 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, 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.

85. The IFU also 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.

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

87. 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.

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

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

90. 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.

91. 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 II
NEGLIGENCE: DESIGN DEFECT

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

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

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

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

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

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

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

99. For example, titanium clips that have been on the market for years carry less clinical risk to the patient.[11] 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."[12]

100. 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.

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

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[11] 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.

[12] 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.

102. 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 III
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

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

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

105. 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.

106. 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.

107. 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.

108. Further, 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.[13]

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

109. Moreover, 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.

110. 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.

111. 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.

112. 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

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

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

115. 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).

116. Defendant was negligent in designing, assembling, 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.

117. 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.

118. 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.

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

120. 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.

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

122. Despite this knowledge, Defendant marketed the BioZorb Marker 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.

123. 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.

124. Defendant knew that Plaintiffs and their physicians and hospitals would use BioZorb 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.

125. 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.

126. 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.

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

128. 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.

129. 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.

130. 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.

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

132. 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 may deem just and proper.

JURY DEMAND

Plaintiffs demand trial by jury as to all issues herein.

Dated: July 25, 2024 Respectfully Submitted,

/s/ John Roddy

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