UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SHELLIE BROEDER, AMY DELGADO, MARISA SAYERS, MICHELLE MARTINEZ, and ANITA MENDIOLA, **Plaintiffs,** **v.** **HOLOGIC, INC.,** **Defendant.**	**Case No. 1:24-cv-10823** **JURY TRIAL DEMANDED**

COMPLAINT

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

VENUE AND JURISDICTION

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

INTRODUCTION

1. Plaintiffs, all breast cancer survivors, were implanted with a device Hologic manufactured called BioZorb ("BioZorb" or "BioZorb Marker").

2. BioZorb is a radiographic bioabsorbable device used to mark soft tissue. It is comprised of a bioabsorbable spacer that holds six (6) titanium radiopaque marker clips. The bioabsorbable spacer material (polylactic acid) is supposed to be resorbed by the body, leaving the

radiopaque clips as a permanent indicator of the soft tissue site.

3. The BioZorb Marker may be used with the following imaging modalities: X-ray (CT, mammography), MRI, and ultrasound. The bioabsorbable spacer is supposed to be resorbed by a process of hydrolysis whereby the degradation products of the spacer material are designed and intended to be metabolized by the body. The spacer material is intended to retain its functional integrity for approximately two (2) months, while complete resorption may require up to one or more years.[1]

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 Shellie Broeder

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

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

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

[1] See Exhibit A- BioZorb® Marker, BioZorb® LP Marker Instructions for Use.

8. Ms. Broeder had the BioZorb removed by Dr. Kronfuss at Bozeman Deaconess Hospital on or around September 18, 2023. Upon removal of BioZorb, Ms. Broeder's pain improved.

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

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

Plaintiff Amy Delgado

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

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

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

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

abscesses, and disfigurement.

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

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

Plaintiff Marisa Sayers

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

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

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

20. Ms. Sayers had the BioZorb removed by Dr. Linsey Gold at Beaumont Hospital on

or around November 1, 2019.

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

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

Plaintiff Michelle Martinez

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

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

25. Ms. Martinez suffered from a hard, painful lump at the site of the BioZorb Marker. She suffered from discomfort, irritation, deformity of the breast, and constant pain. The device failed to absorb as intended.

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

27. As a result of the pain and complications of the BioZorb Marker, Plaintiff Martinez

feared the possibility of another tumor every day until the surgical removal of BioZorb, causing significant emotional distress.

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

Plaintiff Anita Mendiola

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

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

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

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

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

34. As a result of the BioZorb, Ms. Mendiola has been caused to have additional

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

Defendant

35. 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 has offices, does business through employees, contractors, and agents, and enjoys the protection of the laws in the Commonwealth of Massachusetts.

BACKGROUND AND FACTS

A. Background on BioZorb

36. BioZorb is a Class II medical device first cleared by the FDA in 2012. It is an implantable tissue marker developed to mark the surgical site of tissue removal in three dimensions. Six titanium marker clips are distributed in a three-dimensional (3D) pattern inside a bioabsorbable polylactic acid (PLA) coil in either a helical or low profile (LP) flat, oval option.

37. The Indication for Use states: "[t]he BioZorb LP Marker is indicated for radiographic marking of sites in soft tissue. In addition, the Marker is indicated in situations where the soft tissue site needs to be marked for future medical procedures." See 510(k) numbers: K143484, K152070, and K192371.

B. The Problems with BioZorb and the Inadequacy of the Device Label

38. The Instructions for Use ("IFU") and marketing indicate the BioZorb Marker is to

be absorbed within one or more years. Yet some studies have found it takes over two years to dissolve.[2] The current BioZorb marketing material and website indicate it should absorb within "several years," but "several years" is not listed in the IFU. Moreover, the label fails to warn that the device may not dissolve at all.

39. The contraindications and warnings in the BioZorb 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."

40. The IFU for BioZorb contains no significant warnings or contraindications of any substance to effectively warn patients, physicians, or hospitals of the relevant risks associated with the use of the product, which include its failure to dissolve (properly or at all) and the fact that the device can migrate in the breast and cause significant pain when it does. The IFU also fails to warn that the device can protrude out of the breast and create a hole in the breast. As a result of these device failures and others, patients often require additional surgery. None of this is mentioned in the product label.

41. As a result of post-approval studies, Hologic has received strong clinical evidence that some patients have also developed a palpable mass reminiscent of a tumor, which causes

[2] 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
Kaufman CS, et al. *Long Term Value of 3 D Bioabsorbable Tissue Marker on Radiation Planning & Targeting, Cosmesis and Followup Imaging*. Poster presented at the American Society of Breast Surgeons 17th Annual Meeting, April 27 30, 2017.

severe pain and discomfort. Hologic was also aware of strong clinical evidence that the device was causing infection, migration, necrosis, additional radiation, and additional surgery. None of these complications are warned of in the IFU.

42. As a result of Medical Device Reports ("MDRs"), Hologic has received strong clinical evidence that some patients have suffered from infection, fluid buildup, device migration, device erosion, pain, discomfort, rash, extended resorption time of the device, and additional surgeries. None of these complications are warned of in the IFU.

43. Finally, and in the words of one breast surgeon, "[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 the 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!"[3] The current IFU says nothing about an increased use of radiation because of the implantation of BioZorb.

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

44. On February 27, 2024, the U.S. Food and Drug Administration issued a Safety Communication ("February 27 Notice") about BioZorb Markers and the potential risks with use in breast tissue.[4]

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

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

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

46. 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.

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

48. 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.

49. From its entry into the market, Defendant marketed the BioZorb Markers to hospitals and surgeons as improving cosmetic outcomes after procedures and filling in space in breast tissues.

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

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

52. Later, Defendant attempted to obtain FDA approval of the BioZorb Marker and

BioZorb LP Marker as "designed to improve cosmetic outcomes for patients using it."[5]

53. The FDA noted that Defendant had not provided any data to support its claim that the device improved cosmetic outcomes and provided Defendant an opportunity to remove the "designed to improve cosmetic outcomes" language in the future. Id.

CAUSES OF ACTION

COUNT I- NEGLIGENCE: FAILURE TO WARN

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

55. 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."[6]

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

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

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

59. 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, the Defendant was

[5] Response to Submission K232851, U.S. Food and Drug Administration (Jan. 19, 2024), HOLOGIC_BZ_00037025-32.
[6] *Laaperi v. Sears, Roebuck Co., Inc.*, 787 F.2d 726, 729 (1st Cir. 1986) (applying Massachusetts law)

aware of post-marketing adverse event reports, otherwise known as Medical Device Reports ("MDRs"), that alleged the same injuries the Plaintiffs in this lawsuit suffered.

60. 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 implantation of the device and the comparative severity and duration of such adverse side effects.

61. Specifically, the IFU failed to include warnings that the BioZorb may not dissolve in one year, ever dissolve in the breast, and need to be surgically removed. 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. The IFU also failed to warn that the device could cause pain, discomfort, mass formation, infection, fluid buildup, scarring, fat necrosis, and adverse tissue reaction. The IFU did not warn that BioZorb could migrate in the breast, including protruding from the breast, creating a hole in the breast, and expelling from the breast, which could also lead to drainage and infection.

62. The IFU also failed to warn of the risks created due to BioZorb's negligent design.

63. The above warnings were known or knowable by Defendant when Plaintiffs were implanted with the BioZorb Marker.

64. As a direct and proximate result of the 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 because prudent patients in Plaintiffs' position would have chosen not to be implanted with BioZorb if the warnings included in the relevant IFU contained the above warnings, which are stronger and more clinically accurate.

65. Further, Defendant marketed BioZorb to fill in space in breast tissue and to improve

cosmetic outcomes after procedures.

66. WHEREFORE, the Plaintiffs demand judgment against the 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

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

68. Hologic manufactured and distributed BioZorb.

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

70. The Plaintiffs were harmed because of the defective design of the BioZorb Marker.

71. The design of the BioZorb Marker is defective because of its shape, surface, texture, and material.

72. The shape, surface, texture, and material of BioZorb could all have been feasibly changed to make the device less harmful.

73. Also, a technologically feasible and practical alternative design exists that would have reduced or prevented the Plaintiffs' harm because there are titanium clips that have been on the market for years that carry less clinical risk to the patient.[7]

74. As one recent clinical study found: "[T]he 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

[7] 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

relative high cost and lack of clinical advantage scientifically shown over the use of surgical clips."[8]

75. The gravity of the danger posed by the current design of BioZorb is high because if the BioZorb Marker does not fully absorb in the body, if it migrates or is expelled from the body, or causes an infection, a patient is required to undergo an additional surgery to remove the device.

76. In the oncological surgical market, a different and simpler design already exists that is mechanically feasible, safer, and costs significantly less than BioZorb.

77. Further, Defendant marketed BioZorb to fill in space in breast tissue and to improve cosmetic outcomes after procedures.

78. 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

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

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

81. 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 said product was to be used.

[8] 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.

82. 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.

83. Upon information and belief, and contrary to such implied warranties, the BioZorb Marker was not of merchantable quality or safe and 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.

84. Further, the Defendant marketed BioZorb to fill in space in breast tissue and to improve cosmetic outcomes after procedures.

85. Defendant knew or should have known that the BioZorb Marker was not cleared or approved to fill space in breast tissue or to improve cosmetic outcomes after procedures.

86. 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.[9]

87. As a direct and proximate result of the Defendant's conduct, the 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. 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

89. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if

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

fully set forth herein and further allege as follows:

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

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

92. Defendant was negligent in designing, manufacturing, researching, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labeling, supplying, and/or selling the BioZorb Marker by failing to use reasonable care in fulfilling their duty to avoid foreseeable dangers by complying with federal and state law, including but not limited to, failing to use reasonable care in fulfilling their duty to inform users of dangerous risks, including risks posed by the dangerous design of the device.

93. Such safety monitoring and pharmacovigilance measures, if implemented, would have mitigated or eliminated the risk posed by the BioZorb Marker and would have enabled patients, including Plaintiffs, to avoid the risks of pain, discomfort, fat necrosis, migration, failure to absorb, expulsion, infection, scarring, or subsequent surgery because a prudent patient in a similar situation would have chosen an alternative radiographic marker.

94. As a result of the foregoing conduct, the Plaintiffs were sold a defective medical device without knowing the true risk/benefit of the BioZorb Marker.

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

96. Defendant knew or should have known that the BioZorb Marker was not cleared or approved to fill space in breast tissue or to improve cosmetic outcomes after procedures.

97. Despite this knowledge, Defendant marketed the BioZorb Marker to fill in space in breast tissue and to improve cosmetic outcomes after procedures.

98. It was readily foreseeable to the Defendant that Plaintiffs and other consumers would be harmed as a result of the Defendant's failure to exercise ordinary care and to report material information regarding the device's risks, including migration, failure to absorb, expulsion, infection, scarring, or subsequent surgery.

99. Defendant knew that Plaintiffs and their physicians would use BioZorb for its intended purpose and hospitals would approve the use of BioZorb for its intended purpose. Defendant knew BioZorb's 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 their products in deciding whether to purchase the BioZorb Marker.

100. 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.

101. Had Defendant timely reported the known risks associated with the BioZorb

Marker to patients, physicians, and hospitals and allowed them to make an informed decision about using an alternative product that did not present the same risks, Plaintiffs would not have used the BioZorb Marker if they had known of the true safety risks.

102. 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 because prudent patients in similar situations would not have agreed to implantation of the BioZorb Marker if the label would have included additional warnings.

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

104. WHEREFORE, the Plaintiffs demand judgment against the 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, the Plaintiffs pray for judgment against the 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: March 29, 2024

Respectfully submitted,

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