UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MARGARET CIERS, JULIE BAUER, SELENA FISHER, KAREN SELLARDS, and SARAH FARLEY, **Plaintiffs,** **v.** **HOLOGIC, INC.,** **Defendant.**	**Case No. 1:23-cv-13215** **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiffs Margaret Ciers, Julie Bauer, Selena Fisher, Karen Sellards, and Sarah Farley, bring this action against Defendant Hologic, Inc., a Massachusetts corporation, ("Defendant" or "Hologic").

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 called BioZorb that was manufactured by Hologic.

2. BioZorb is a radiographic bioabsorbable marker 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 retains its functional integrity for approximately two (2) months, while complete resorption may require up to one (1) or more years.[1]

4. This lawsuit is a personal injury action against Defendant Hologic who is responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing and/or selling of the BioZorb medical device.

PARTIES

Plaintiff Margaret Ciers

5. Plaintiff Margaret Ciers ("Ms. Ciers" or "Plaintiff Ciers") 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.

6. Ms. Ciers was diagnosed with breast cancer in or around 2017. She underwent a lumpectomy on or around November 1, 2017, at Gulf Coast Regional Medical Center, during which a BioZorb was properly implanted by Dr. George Erwin

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

Reiss.

7. Ms. Ciers suffered from excruciating pain at and around the site of the BioZorb device. The pain was worsened upon contact, which made it difficult for Ms. Ciers to lay on her right side and caused problems with her sleep. Plaintiff Ciers suffers from deformity and had to have additional surgery to remove the device.

8. Ms. Ciers had the BioZorb removed by Dr. Allison Moody at Ascension Sacred Heart on or around August 23, 2023.

9. As a result of the pain and complications of the BioZorb device, Plaintiff Ciers 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. Ciers 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 physicians and patients.

Plaintiff Julie Bauer

11. Plaintiff Julie Bauer ("Ms. Bauer" or "Plaintiff Bauer") 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.

12. Ms. Bauer was diagnosed with breast cancer in or around July 2020. She underwent a lumpectomy on or around January 4, 2021 at UPMC Bayview Breast Care,

during which a BioZorb was properly implanted by Dr. Carol A. Hager.

13. Ms. Bauer suffers from a hard, painful lump at and around the site of the BioZorb device. The pain in the area is worsened by touch, making it difficult for Ms. Bauer to lay on her left side and affecting her sleep. Ms. Bauer believes that the BioZorb device has not yet properly absorbed.

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

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

Plaintiff Selena Fisher

16. Plaintiff Selena Fisher ("Ms. Fisher" or "Plaintiff Fisher") is and at all relevant times was a citizen of the State of Georgia and the United States and over the age of eighteen (18) years.

17. Ms. Fisher was diagnosed with breast cancer in or around December 2020. She underwent a partial mastectomy on or around December 23, 2020, at Southern Regional Medical Center, during which a BioZorb was properly implanted by Dr. Janine Pettiford.

18. Ms. Fisher suffers from a hard, painful lump and reddening of the skin near

the area where the BioZorb device was implanted. Ms. Fisher suffers from itchiness, discomfort, and pain that is worsened by touch. The pain caused by BioZorb affects Ms. Fisher's daily life by making it painful to sleep and shower. Ms. Fisher believes that the device has migrated in her breast and that it has not been properly absorbed.

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

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

Plaintiff Karen Sellards

21. Plaintiff Karen Sellards ("Ms. Sellards" or "Plaintiff Sellards") is and at all relevant times was a citizen of the State of West Virginia and the United States and over the age of eighteen (18) years.

22. Ms. Sellards was diagnosed with breast cancer in or around October 2020. She underwent a partial mastectomy on or around October 27, 2020, at Cabell Huntington Hospital, during which a BioZorb was properly implanted by Dr. Mary Legenza.

23. Ms. Sellards suffers from pain, itching, tenderness, and a burning sensation at and around the site of the BioZorb device. Ms. Sellards also suffers from adverse skin reactions and has suffered from infection.

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

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

Plaintiff Sarah Farley

26. Plaintiff Sarah Farley ("Ms. Farley" or "Plaintiff Farley") 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.

27. Ms. Farley was diagnosed with breast cancer on January 10, 2019. She underwent a bilateral lumpectomies in or around May 2019 at Baylor Scoot & White, during which multiple BioZorb devices were properly implanted in both breasts by Dr. Valerie Jean Gorman.

28. Ms. Farley suffers from hard, painful lumps at the sites of the BioZorb devices. Plaintiff Farley suffers from tenderness, discomfort, and pain that is worsened by touch. The pain caused by BioZorb affects Ms. Farley's daily life by making it difficult for her to sleep and difficult to move her arm as it causes a tugging sensation. Additionally, Plaintiff Farley suffers from deformity at the site of the BioZorb devices. Plaintiff Farley also suffered from infection in her right breast and had to have additional

surgery to remove the device.

29. Ms. Farley had one of the BioZorb devices removed at Baylor Scott & White in or around October 2019.

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

31. As a result of the BioZorb, Ms. Farley has been caused to have additional procedures, significant pain, disfigurement, worry and infection, 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 physicians and patients.

Defendant

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

33. The BioZorb device is a Class II medical device first cleared by the FDA in 2012. BioZorb is a tissue marker and is an implantable device developed to mark the surgical site of tissue removal in three dimensions. It has six (6) titanium marker clips

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, that is intended to facilitate the identification and delivery of more focused radiation therapy.

BACKGROUND AND FACTS

A. Background on BioZorb

34. The BioZorb is intended to target titanium marker clips to delineate the tumor bed for radiation therapy planning. The structure is claimed to promote or allow tissue around the resected area to grow and surround the implant during the healing process, and the body is supposed to slowly resorb the polylactic acid aspect of the implant over time, leaving the titanium markers in place[2].

35. The Indication for Use ("IFU") 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.

36. The 510(k) number K171467 has the following indication: "[t]he Marker is intended to be implanted into the body to accurately visualize and constitute the reference frame for stereotactic radiosurgery and radiotherapy target localization." and is Class II IYE.

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

37. The Information For Use ("IFU") and early marketing indicate the BioZorb

[2] 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. Feb 2017;41(2):464-471. https://doi.org/10.1007/s00268-016-3711-y

device is to be absorbed within one or more years. Yet some studies have found it to take more than two years to dissolve[3] and the current BioZorb marketing material and website indicates it should absorb within "several years," but "several years" is not listed in the IFU. Moreover, the label fails to adequately warn that the device may not dissolve at all.

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

39. Further, and as a result of both post-approval studies and post-marketing Medical Device Reports ("MDRs"), Hologic has received strong clinical evidence that there are patients that have also developed a palpable mass, reminiscent of a tumor, which causes 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 for mastectomy. None of these complications are warned of in the current IFU.

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[3] 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.

40. 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 device] is the appearance of telangiectasias, which look like red spider veins. No woman wants this on their legs and certainly not on their breasts!"[4] The current IFU says nothing about an increase use of radiation because of the implantation of the device.

CAUSES OF ACTION

COUNT I- NEGLIGENCE: FAILURE TO WARN

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

42. 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."[5]

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

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

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

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

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

46. Defendant knew, or in the exercise of ordinary care should have known that the BioZorb device could cause the injuries suffered by Plaintiffs because they were aware of post-marketing adverse event reports, otherwise known as Medical Device Reports ("MDRs") that alleged the same injuries that were suffered by the Plaintiffs in this lawsuit.

47. The BioZorb devices were not accompanied by proper warnings and instructions to physicians and 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.

48. Specifically, the IFU failed to include warnings that the BioZorb device may not ever dissolve in the breast and need to be surgically removed. The warnings also failed to include information that a radiologist might need to use a higher energy electron therapy which can cause scarring on the breast. The IFU also failed to adequately warn that the device could migrate in the breast and cause a painful lump and scarring. The IFU also failed to adequately warn that the device could protrude from the breast creating a hole in the breast, could be expelled from the breast which can lead to drainage and infection.

49. The above warnings were known or knowable by the Defendant at the time these devices were implanted with the BioZorb device.

50. 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 because a prudent person in the patient's position would have chosen not to be implanted with BioZorb if the warnings included in the relevant IFU contained the above warnings that are stronger more clinically accurate.

51. 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

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

53. Hologic manufactured and distributed BioZorb.

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

55. The Plaintiffs were harmed because of the current defective design of the BioZorb device.

56. 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.[6]

57. In fact, as one recent clinical study found: "the use of clips to mark the tumor bed is more cost-effective than the use of the BioZorb device which does not provide value given its relative high cost and lack of clinical advantage scientifically shown over the use of surgical clips."[7]

58. The gravity of the danger posed by the current design of BioZorb is high because if the BioZorb device 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.

59. In the oncological surgical market, there already exists a different and more simple design that is mechanically feasible, safer, and costs significantly less than BioZorb.

60. 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

61. Plaintiffs incorporate by reference all preceding paragraphs of this

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[6] 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

[7] 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.

Complaint as if fully set forth herein.

62. 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.

63. Defendant impliedly warranted to prospective purchasers and users, including Plaintiffs, that the BioZorb device was safe, merchantable, and fit for the ordinary purposes for which said product was to be used.

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

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

66. Further, Restatement (Second) of Torts Section 402A, comment k, does not bar the Plaintiffs' breach of implied warranty claim based on the defendant's presumed position that the medical device at issue was unavoidably unsafe.[8]

67. 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.

68. WHEREFORE, Plaintiffs demand judgment against Defendant and seek

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

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

69. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein and further allege as follows:

70. 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 device including the one implanted in Plaintiffs.

71. Under federal and state law and regulation, Defendant was under a continuing duty to test and monitor the BioZorb device as well as their 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 device 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.

72. Defendant was negligent in designing, manufacturing, supplying, inspecting, testing, distributing, and selling the BioZorb device by failing to use reasonable care in fulfilling their duty to avoid foreseeable dangers by complying with federal and state law, and failing to use reasonable care in fulfilling their duty to inform

users of these dangerous risks.

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

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

75. Defendant knew or should have known that the risk/benefit of the BioZorb device was different than what was in the label and what was communicated to patients and physicians.

76. 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 to report material information regarding the true risks of the device including migration, failure to absorb, expulsion, infection, scarring, or a subsequent surgery to remove the device.

77. Defendant knew that Plaintiffs and their physicians 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 their products in deciding whether to purchase the BioZorb device.

78. 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 true risk of the BioZorb device to patients and physicians.

79. Had Defendant timely reported the known risks associated with the BioZorb device with patients and physicians, 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 device if they had known of the true safety risks.

80. 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 a prudent patient in a similar situation would not have agreed to be implanted with the BioZorb device if the label would have included additional warnings.

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

82. 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: December 28, 2023

Respectfully submitted,

/s/ Elizabeth Ryan
Elizabeth Ryan, BBO # 549632
BAILEY & GLASSER LLP
176 Federal Street, 5th Floor
Boston, MA 02110
Telephone: 617.439.6730
Fax: 617.951.3954
eryan@baileyglasser.com

Christina D. Crow (to be admitted *pro hac vice*)
Lisa Littell (to be admitted *pro hac vice*)
JINKS CROW & DICKSON, PC
219 Prairie Street North | P.O. Box 350
Union Springs, AL 36089
Telephone: 334.738.4225
Fax: 334.738.4229
christy.crow@jinkslaw.com
lisa.littell@jinkslaw.com

C. Moze Cowper (to be admitted *pro hac vice*)
COWPER LAW P.C.
12301 Wilshire Blvd. Ste. 303
Los Angeles, CA 90025
Telephone: 877.529.3707
Fax: 877.284.0980
mcowper@cowperlaw.com