UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

REBECCA SHIRKEY, ANN THALMAN, PAMELA MAZZANTI, BETH DEUEL, DIANE ANDERSON, **Plaintiffs,** **v.** **HOLOGIC, INC.,** **Defendant.**	**Case No. 1:23-cv-10579** **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiffs Rebecca Shirkey, Ann Thalman, Pamela Mazzanti, Beth Deuel, and Diane Anderson 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 and/or women at risk of breast cancer, 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 2 months, while complete resorption may require up to one 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 Rebecca Shirkey

5. Plaintiff Rebecca Shirkey ("Ms. Shirkey" or "Plaintiff Shirkey") is and at all relevant times was a citizen of the State of Ohio and the United States and over the age of eighteen (18) years.

6. Ms. Shirkey was diagnosed with left breast invasive ductal carcinoma. She underwent a lumpectomy on or around March 14, 2017 at James Cancer Hospital and

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

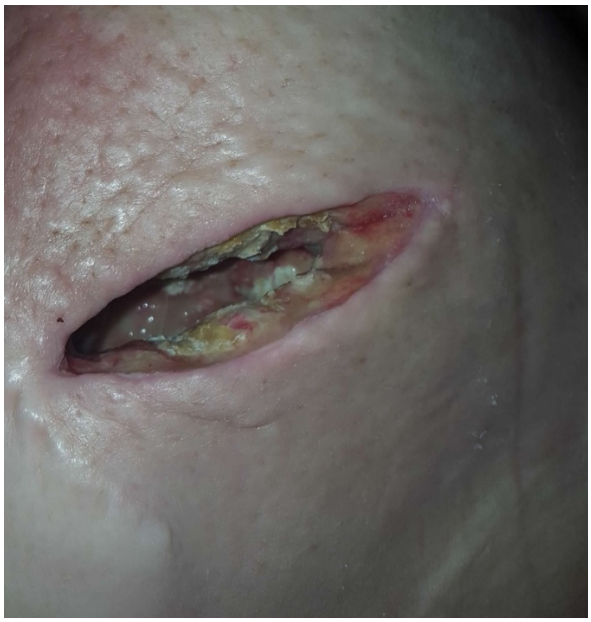
Solove Research Institute at Ohio State University, during which a BioZorb was properly implanted by Dr. Doreen Agnese ("Dr. Agnese").

7. Ms. Shirkey suffered from a hard, painful lump where BioZorb was implanted. Instead of absorbing, the device grew. Ms. Shirkey could not sleep and had to have a special pillow made to help her sleep.

8. In or around February 2018, Plaintiff Shirkey developed cellulitis in her breast. Not long after, the breast turned septic. Her breast was swollen, purple and red, and in constant pain.

9. In or around March 2018, Ms. Shirkey had the BioZorb removed by Dr. Agnese at James Cancer Hospital and Solove Research Institute at Ohio State University.

10. Ms. Shirkey's wound from the explant surgery did not heal. Plaintiff Shirkey was in and out of the hospital for three (3) months following the surgery. She suffered from seroma, necrosis, infection, and pain.



11. In or around June 2018, Plaintiff Shirkey had additional surgery to debride the infected area of her breast. Muscle was taken from her back and put into her breast to aid in healing. Following the surgery, home health visited Ms. Shirkey for three months to change and redress her wound.

12. As a result of the pain and complications of the BioZorb device, Plaintiff Shirkey feared the possibility of another tumor every day until the surgical removal of BioZorb. Moreover, Ms. Shirkey feared death, both before and after BioZorb was removed, because of the infections brought about by the device, causing significant emotional distress.

13. As a result of the BioZorb, Ms. Shirkey 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.

Plaintiff Ann Thalman

14. Plaintiff Ann Thalman ("Ms. Thalman" or "Plaintiff Thalman") is and at all relevant times was a citizen of the State of California and the United States and over the age of eighteen (18) years.

15. Ms. Thalman was diagnosed with left breast invasive ductal carcinoma in April of 2016. She underwent a lumpectomy on or around September 15, 2016 at California Pacific Medical Center, during which a BioZorb was properly implanted by

Dr. Anne Grayson Peled ("Dr. Peled").

16. Ms. Thalman developed a significant amount of scarring along her chest wall where the BioZorb became embedded. She suffered from deformity, scarring, and hard, painful lumps in her breast that limited her mobility.

17. Ms. Thalman had the BioZorb separated from her chest wall in a second surgery by Dr. Peled at California Pacific Medical Center on or around September 15, 2017.

18. Ms. Thalman went to physical therapy and certified trainers for years trying to address the pain, mobility, and muscle loss caused by BioZorb. Plaintiff Thalman has not been able to go back to work and incurred financial loss in doing everything she could to get well. She continues to do physical therapy exercises daily in an attempt to control the persistent pain.

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

20. As a result of the BioZorb, Ms. Thalman has been caused to have additional procedures, significant pain, disfigurement, and worry, leaving her permanently and physically scarred. The complications, 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 Pamela Mazzanti

21. Plaintiff Pamela Mazzanti ("Ms. Mazzanti" or "Plaintiff Mazzanti") is and at all relevant times was a citizen of the State of Wisconsin and the United States and over the age of eighteen (18) years.

22. Ms. Mazzanti was diagnosed with ductal carcinoma in situ in her left breast. She underwent a lumpectomy on or around March 31, 2017 at Advocate Condell Medical Center, during which a BioZorb was properly implanted by Dr. Anna Katz.

23. Ms. Mazzanti suffers pain and discomfort, sleep problems, diveting and deformity of her breast, and loss of intimacy with her husband.

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

25. As a result of the BioZorb, Ms. Mazzanti has been caused to have significant pain, disfigurement, and worry, leaving her permanently and physically scarred. The complications, 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 Beth Deuel

26. Plaintiff Beth Deuel ("Ms. Deuel" or "Plaintiff Deuel") 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.

27. Ms. Deuel was diagnosed with right breast invasive lobular carcinoma in May 2018. She underwent a lumpectomy on or around May 22, 2018 at McLaren Macomb Hospital, during which a BioZorb was properly implanted by Dr. Steven Cahill ("Dr. Cahill").

28. The BioZorb device stuck out of Ms. Deuel's chest and caused constant pain and discomfort. She had difficulty sleeping because of searing pain through her chest anytime she rolled onto the BioZorb. Hugs were also especially painful for Ms. Deuel.

29. Plaintiff Deuel contacted Hologic in 2019 because what she was experiencing was not in the brochure information she received before her lumpectomy. A doctor from Hologic told her that there was no issue and that new studies suggested that the BioZorb usually dissolves within two years. Ms. Deuel relied on this information, suffering through three (3) more years of pain while waiting for the BioZorb to absorb.

30. Ms. Deuel had the BioZorb removed by Dr. Cahill at McLaren Macomb Hospital in May of 2022. When she woke up from surgery, Ms. Deuel felt relief immediately.

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

32. As a result of the BioZorb, Ms. Deuel 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 Diane Anderson

33. Plaintiff Diane Anderson ("Ms. Anderson" or "Plaintiff Anderson") is and at all relevant times was a citizen of the State of Washington and the United States and over the age of eighteen (18) years.

34. Ms. Anderson was diagnosed with invasive lobular right breast carcinoma in July 2022. She underwent a lumpectomy on or around July 15, 2022 at EvergreenHealth Medical Center Kirkland, during which a BioZorb was properly implanted by Dr. Marion Johnson ("Dr. Johnson").

35. Ms. Anderson suffered constant pain and discomfort. She had recurrent infections in her breast and a seroma was found in February 2023.

36. Ms. Anderson had the BioZorb removed by Dr. Johnson on March 10, 2023 at EvergreenHealth Medical Center Kirkland. Ms. Anderson felt immediate relief from the pain caused by BioZorb upon waking from her explant surgery.

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

38. As a result of the BioZorb, Ms. Anderson 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

39. 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 and does business through employees, contractors and agents and enjoys protection of the laws of the Commonwealth of Massachusetts.

40. The BioZorb Device is a Class II medical device 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 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

41. 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].

42. 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.

43. 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

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

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[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

[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.

device may not dissolve at all.

45. 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.

46. 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.

47. 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

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

49. 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]

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

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

52. 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.

53. 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

[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)

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.

54. 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.

55. 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.

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

57. 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.

58. 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

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

60. Hologic manufactured and distributed BioZorb.

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

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

63. 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]

64. 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

[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

shown over the use of surgical clips."[7]

65. 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.

66. 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.

67. 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

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

69. 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.

70. Defendant impliedly warranted to prospective purchasers and users, including Plaintiffs, that the BioZorb Device was safe, merchantable, and fit for the

[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.

ordinary purposes for which said product was to be used.

71. 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.

72. 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.

73. 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.[8]

74. 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.

75. 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

76. Plaintiffs incorporate by reference all preceding paragraphs of this

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

Complaint as if fully set forth herein and further allege as follows:

77. 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.

78. 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.

79. 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.

80. 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.

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

82. 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.

83. 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.

84. 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.

85. 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.

86. 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.

87. 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.

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

89. 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, prays 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: March 15, 2023

Respectfully submitted,

/s/ John Roddy
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EXHIBIT A

BioZorb® Marker, BioZorb® LP Marker

Instructions for Use

DESCRIPTION

The Marker is a radiographic implantable marker used to mark soft tissue.
It is comprised of a bioabsorbable spacer that holds Titanium radiopaque marker clips. The bioabsorbable spacer material (poly lactic acid) is resorbed by the body leaving the radiopaque clips as a permanent indicator of the soft tissue site.
The Marker may be used with the following imaging modalities: X-Ray (CT, mammography), MR and ultrasound.
The bioabsorbable spacer is resorbed by a process of hydrolysis whereby the degradation products of the spacer material are metabolized by the body. The spacer material retains its functional integrity for approximately 2 months, while complete resorption may require up to one or more years.

INDICATIONS

The 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.

CONTRAINDICATIONS

The Marker should not be placed in a tissue site with clinical evidence of infection.

WARNINGS

- 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.

PLACEMENT OF MARKER

PREPARATION

1) Remove the Marker from the sterile packaging.
2) Visually inspect the product for any damage.

INSERTION

1) Using sterile technique, place the Marker in the desired tissue site.
2) Suture the marker to adjacent tissue at multiple locations as desired for secure positioning.
3) Where required, close the surgical cavity using standard surgical technique.

DISPOSAL PROCEDURES

When necessary, dispose of any product in accordance with local regulations.

STORAGE

Store at room temperature. Avoid storing the Marker at conditions of excessive heat or humidity. If the temperature indicator has a black center, do not use product. Handle with care. Packages should be stored in a manner that protects the integrity of the package and the sterile barrier.

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated the BioZorb® Marker / BioZorb® LP Marker is MR Conditional. A patient with this device can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5 T; Maximum spatial field gradient of 1,900 gauss/cm (19 T/m); Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode); 15 minutes of continuous scanning

Under the scan conditions defined above in non-clinical testing, the Marker was shown to produce a maximum temperature rise of less than 1.6°C. In addition, the image artifact caused by the marker clip of the device extended an average of 3.8mm from the Marker when imaged with a gradient echo and spin echo pulse sequence and a 1.5T MRI system. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the implant. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

HOLOGIC®

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MAN-07631 Rev. 001

JS 44 (Rev. 04/21)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

REBECCA SHIRKEY, ANN THALMAN, PAMELA MAZZANTI, BETH DEUEL, and DIANE ANDERSON,

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

John Roddy, Bailey & Glasser LLP, 176 Federal Street, 5th Floor, Boston, MA 02110 (617) 439-6730

DEFENDANTS

HOLOGIC, INC.

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☒ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

INTELLECTUAL PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. Section 1332(a)

Brief description of cause:
Product liability

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE Allison D. Burroughs DOCKET NUMBER 22-11895, 22-12194, 23-10260

DATE
Mar 15, 2023

SIGNATURE OF ATTORNEY OF RECORD
/s/ John Roddy

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

1. **Title of case (name of first party on each side only)** Rebecca Shirkey v. Hologic, Inc.

2. **Category in which the case belongs based upon the numbered nature of suit code listed on the civil cover sheet. (See local rule 40.1(a)(1)).**

☐ **I.** **160, 400, 410, 441, 535, 830*, 835*, 850, 880, 891, 893, R.23, REGARDLESS OF NATURE OF SUIT.**

☐ **II.** **110, 130, 190, 196, 370, 375, 376, 440, 442, 443, 445, 446, 448, 470, 751, 820*, 840*, 895, 896, 899.**

☑ **III.** **120, 140, 150, 151, 152, 153, 195, 210, 220, 230, 240, 245, 290, 310, 315, 320, 330, 340, 345, 350, 355, 360, 362, 365, 367, 368, 371, 380, 385, 422, 423, 430, 450, 460, 462, 463, 465, 480, 485, 490, 510, 530, 540, 550, 555, 560, 625, 690, 710, 720, 740, 790, 791, 861-865, 870, 871, 890, 950.**
***Also complete AO 120 or AO 121. for patent, trademark or copyright cases.**

3. **Title and number, if any, of related cases. (See local rule 40.1(g)). If more than one prior related case has been filed in this district please indicate the title and number of the first filed case in this court.**
Evers, et al. v. Hologic, Inc., 22-11895; Block, et al. v. Hologic, Inc., 22-12194; Chambers, et al. v. Hologic, Inc., 23-10260

4. **Has a prior action between the same parties and based on the same claim ever been filed in this court?**
YES ☐ **NO** ☑

5. **Does the complaint in this case question the constitutionality of an act of congress affecting the public interest? (See 28 USC §2403)**
YES ☐ **NO** ☑
If so, is the U.S.A. or an officer, agent or employee of the U.S. a party?
YES ☐ **NO** ☑

6. **Is this case required to be heard and determined by a district court of three judges pursuant to title 28 USC §2284?**
YES ☐ **NO** ☑

7. **Do all of the parties in this action, excluding governmental agencies of the United States and the Commonwealth of Massachusetts ("governmental agencies"), residing in Massachusetts reside in the same division? - (See Local Rule 40.1(d)).**
YES ☑ **NO** ☐

A. **If yes, in which division do all of the non-governmental parties reside?**
Eastern Division ☑ **Central Division** ☐ **Western Division** ☐

B. **If no, in which division do the majority of the plaintiffs or the only parties, excluding governmental agencies, residing in Massachusetts reside?**
Eastern Division ☐ **Central Division** ☐ **Western Division** ☐

8. **If filing a Notice of Removal - are there any motions pending in the state court requiring the attention of this Court? (If yes, submit a separate sheet identifying the motions)**
YES ☐ **NO** ☐

(PLEASE TYPE OR PRINT)

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TELEPHONE NO. 617.439.6730