

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

DENICE CHAMBERS, CYNTHIA  
KRESCH, JOYE RISHELL, KIMBERLY  
TAYLOR, KATY WHARTON,

Plaintiffs,

v.

HOLOGIC, INC.,

Defendant.

Case No. 1:23-cv-10260

JURY TRIAL DEMANDED

COMPLAINT

Plaintiffs Denice Chambers, Cynthia Kresch, Joye Rishell, Kimberly Taylor, and Katy Wharton 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.<sup>1</sup>

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 Denice Chambers**

5. Plaintiff Denice Chambers (“Ms. Chambers” or “Plaintiff Chambers”) 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.

6. Ms. Chambers was diagnosed with a phyllodes tumor in her right breast. She underwent a lumpectomy on or around May 31, 2018 at the St. Agnes Medical

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<sup>1</sup> See Exhibit A- BioZorb® Marker, BioZorb® LP Marker Instructions for Use.

Center, during which a BioZorb was properly implanted by Dr. Carol Machado.

7. Ms. Chambers suffered pain and discomfort for over four years because of the BioZorb. Her skin was red and bruised throughout that time and she occasionally suffered infection at the site.

8. In the Fall of 2022, Ms. Chambers noticed the BioZorb had migrated to a new area of her breast, just above her incision and right under the skin.

9. Ms. Chambers had the BioZorb removed by Dr. Casandra Anderson at cCARE Cancer Center on November 1, 2022.

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

11. As a result of the BioZorb, Ms. Chambers 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 Defendants knew or should have known and failed to disclose to physicians and patients.

**Plaintiff Cynthia Kresch**

12. Plaintiff Cynthia Kresch (“Ms. Kresch” or “Plaintiff Kresch”) is and at all relevant times was a citizen of the State of South Carolina and the United States and is over the age of eighteen (18) years.

13. Ms. Kresch was diagnosed with ductal carcinoma in situ of the right

breast in September 2020. She underwent a lumpectomy on or around October 30, 2020 at Prisma Health Greenville Memorial Hospital, during which a BioZorb was properly implanted by Dr. John Rinkliff.

14. After Plaintiff Kresch's surgery, she suffered lymphedema, a large abscess, and had an open wound for over a year with recurrent staph infections. She went to a wound doctor from July 2021 to June 2022 because the wound was not healing. Ms. Kresch had to pack the wound daily and had the abscess drained in September 2021.

15. In June 2022, a broken piece of the BioZorb device poked through Ms. Kresch's skin and protruded through her breast. Ms. Kresch's doctor cut the piece that was sticking out of Ms. Kresch and sent her back to the surgeon to remove the rest of the device. Plaintiff Kresch underwent surgery on or around June 27, 2022 to remove the remaining pieces of the device from her breast.

16. As a result of the BioZorb, Ms. Kresch has been caused to have additional procedures, significant pain, disfigurement, worry and is permanently scarred. The complications, pain, disfigurement, non-absorption, lymphedema, abscess, recurrent staph infections, palpable mass, and protrusion of the device from the breast, which required 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 Joye Rishell**

17. Plaintiff Joye Rishell ("Ms. Rishell" or "Plaintiff Rishell") is and at all relevant times was a citizen of the State of Pennsylvania and the United States and is

over the age of eighteen (18) years.

18. In 2022, Plaintiff Rishell was diagnosed with breast cancer. She underwent a lumpectomy on or around April 11, 2022 at Evangelical Community Hospital, during which a BioZorb was properly implanted by Dr. John Turner.

19. Plaintiff Rishell suffered pain at the site of the BioZorb, felt the device pressing on her skin and noticed a wound forming.

20. Around August 2022, Ms. Rishell's doctor noticed the BioZorb breaking through her skin. On Ms. Rishell's way home from the appointment, she received a call from her doctor telling her to immediately go back to the hospital for emergency surgery. Ms. Rishell went back to the hospital and her breast surgeon removed the BioZorb that was coming out of her breast. Her radiation was pushed back until she had time to recover from the emergency surgery.

21. As a result of the BioZorb, Ms. Rishell has been caused to have additional procedures, significant pain, disfigurement, non-absorption, adverse tissue reaction, worry, is permanently and physically scarred, and had to had to wait to receive vital radiation therapy. The complications, pain, disfigurement, non-absorption, and palpable, protruding mass, which required 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 Kimberly Taylor**

22. Plaintiff Kimberly Taylor ("Ms. Taylor" or "Plaintiff Taylor") is and at all relevant times was a citizen of the State of New York and the United States and is over

the age of eighteen (18) years.

23. In 2021, Plaintiff Taylor was diagnosed with breast cancer. She underwent a lumpectomy on or around June 8, 2021 at Weill Cornell Medical Center, during which a BioZorb was properly implanted by Dr. Rachel Simmons.

24. Ms. Taylor suffered pain, a hard lump, and inflammation at the site of the BioZorb. She had to massage it every day to help keep the inflammation down. Eventually, Ms. Taylor's doctor decided the device needed to be removed.

25. Ms. Taylor's doctor initially implanted BioZorb to prevent dimpling and concavity. In July 2022, Ms. Taylor had to have a mastectomy to remove the BioZorb device that was not resorbing.

26. As a result of the pain and complications of the BioZorb device, Plaintiff Taylor was forced to relive her breast cancer diagnosis and fear it had returned, causing significant emotional distress.

27. As a result of the BioZorb, Ms. Taylor had to have additional procedures, significant pain, disfigurement, non-absorption, adverse tissue reaction, and is permanently scarred. The complications, pain, disfigurement, non-absorption, and additional procedures 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 Katy Wharton**

28. Plaintiff Katy Wharton ("Ms. Wharton" or "Plaintiff Wharton") is and at all relevant times was a citizen of the State of Texas and the United States and is over

the age of eighteen (18) years.

29. Plaintiff Wharton was diagnosed with ductal carcinoma in situ in July 2020. She underwent a segmentectomy on or around September 21, 2020 at Hill Country memorial hospital, during which a BioZorb was properly implanted by Dr. Lance Love.

30. Ms. Wharton immediately developed a hard, swollen lump at the site of BioZorb and suffered extreme pain for two years. She had difficulty sleeping and doing daily activities because of the pain BioZorb caused her.

31. Ms. Wharton developed cancer in the same location as the BioZorb and underwent a double mastectomy on November 4, 2022.

32. As a result of the pain and complications of the BioZorb device, Plaintiff Wharton was forced to relive her breast cancer diagnosis and feared it had returned, causing significant emotional distress.

33. As a result of the BioZorb, Ms. Wharton had to have additional procedures, significant pain, disfigurement, non-absorption, and adverse tissue reaction. The complications, pain, disfigurement, non-absorption, palpable mass, and additional surgery are not warned of in the Instructions for Use but were risks Defendant knew or should have known and failed to disclose to physicians and patients.

**Defendant Hologic**

34. 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.

35. 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**

36. 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<sup>2</sup>.

37. 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

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<sup>2</sup> 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>



procedures.” See 510(k) numbers: K143484, K152070, and K192371.

38. 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**

39. 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<sup>3</sup> 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.

40. 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 must have an additional

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<sup>3</sup> 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 Follow up Imaging*. Poster presented at the American Society of Breast Surgeons 17th Annual Meeting, April 27 30, 2017.

surgery to remove the device. None of this is mentioned in the product label.

41. 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.

42. 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!”<sup>4</sup> The current IFU says nothing about an increased use of radiation because of the implantation of the device.

### **CAUSES OF ACTION**

#### **COUNT I- NEGLIGENCE: FAILURE TO WARN**

43. Plaintiffs incorporate by reference all preceding paragraphs of this

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<sup>4</sup> <https://sugarlandradiationoncology.com/blog/entry/biozorb-device>

Complaint as if fully set forth herein.

44. 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.”<sup>5</sup>

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

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

47. 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.

48. 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.

49. 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.

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

50. 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.

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

52. 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.

53. 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**

54. Plaintiffs incorporate by reference all preceding paragraphs of this

Complaint as if fully set forth herein.

55. Hologic manufactured and distributed BioZorb.

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

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

58. 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.<sup>6</sup>

59. 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."<sup>7</sup>

60. 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.

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<sup>6</sup> 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

<sup>7</sup> Rashad, Ramy & Huber, Kathryn & Chatterjee, Abhishek. (2018). Cost-Effectiveness of the BioZorb Device for Radiation Planning in Oncoplastic Surgery. 7. 23. 10.5539/ccov7n2p23.

61. 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.

62. 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

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

64. 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.

65. 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.

66. 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.

67. 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.

68. 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.<sup>8</sup>

69. 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.

70. 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

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

72. 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.

73. 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

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<sup>8</sup> See *Taupier v. Davol, Inc.* 490 F. Supp. 3d 430 (D. Mass. 2020).

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.

74. 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.

75. 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.

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

77. 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.

78. 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.

79. 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.

80. 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.

81. 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.

82. 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.

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

84. 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: January 31, 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

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
DENICE CHAMBERS, CYNTHIA KRESCH, JOYE RISHELL, KIMBERLY TAYLOR, KATY WHARTON
(b) County of Residence of First Listed Plaintiff
(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
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
2 U.S. Government Defendant
3 Federal Question (U.S. Government Not a Party)
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)
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.

Table with columns: CONTRACT, REAL PROPERTY, CIVIL RIGHTS, TORTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes categories like Personal Injury, Labor, Intellectual Property Rights, etc.

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: [X] Yes [ ] No

VIII. RELATED CASE(S) IF ANY (See instructions):
JUDGE Allison D. Burroughs DOCKET NUMBER 1:22-cv-11895, 1:22-cv-12194

DATE Jan 31, 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) Denice Chambers 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., 1:22-cv-11895-ADB; Block, et al. v. Hologic, Inc., 1:22-cv-12194-ADB

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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