**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

| | |
|---|---|
| **DEBRA SIGMUND, MEGAN CLAPPER, JOANNE DOWNING-MALIK, CINDY CORDER, AND LILIA RATHBURN**<br><br>**Plaintiffs,**<br>**v.**<br><br>**HOLOGIC, INC.,**<br><br>**Defendant.** | **Case No. 1:25-cv-10567** |

## COMPLAINT

Debra Sigmund, Megan Clapper, Joanne Downing-Malik, Cindy Corder, and Lilia Rathburn ("Plaintiffs") bring this action against Defendant Hologic, Inc. ("Defendant" or "Hologic"), a Massachusetts corporation.

## JURISDICTION AND VENUE

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

## INTRODUCTION

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

[1] These terms refer to all model numbers of BioZorb Markers and include the BioZorb Low Profile ("LP") Marker.

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

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

## PARTIES

### Plaintiff Debra Sigmund

5. Plaintiff Debra Sigmund ("Ms. Sigmund" or "Plaintiff Sigmund") is, and at all relevant times was, a citizen of the State of New Jersey and the United States and over the age of eighteen (18) years.

6. Ms. Sigmund was diagnosed with right breast invasive ductal carcinoma in or around October 2020. She underwent a right breast lumpectomy on or around October 26, 2020 at Inspira Medical Center Vineland, during which Dr. Nandini Kulkarni ("Dr. Kulkarni") properly implanted a BioZorb.

7. Ms. Sigmund suffers from pain and discomfort at the site of the BioZorb Marker. In addition, the BioZorb marker failed to absorb.

8. As a result of the pain and complications of the BioZorb Marker, Plaintiff Sigmund fears the possibility of another tumor every day, causing significant emotional distress.

9. As a result of the BioZorb, Ms. Sigmund has been caused to have significant pain, and worry, leaving her permanently and physically scarred. The complications, including, but not limited to, pain, and non-absorption are not warned of on the BioZorb Instructions for Use ("IFU") but were risks Defendant knew or should have known yet failed to disclose to patients, physicians, and hospitals.

**Plaintiff Megan Clapper**

10. Plaintiff Megan Clapper ("Ms. Clapper" or "Plaintiff Clapper") is, and at all relevant times was, a citizen of the State of Alaska and the United States and over the age of eighteen (18) years.

11. Ms. Clapper was diagnosed with left breast ductal carcinoma in or around December 2016. She underwent a left breast partial mastectomy on or around December 15, 2016 at Alaska Regional Hospital, during which Dr. Karen Barbosa ("Dr. Barbosa") properly implanted a BioZorb.

12. Ms. Clapper suffered from a hard painfull lump, deformity, scarring, sensitivity, itching, swelling and redness at the site of the BioZorb Marker. In addition, the BioZorb marker failed to absorb.

13. As a result of the pain and complications of the BioZorb Marker, Plaintiff Clapper feared the possibility of another tumor every day, causing significant emotional distress.

14. As a result of the BioZorb, Ms. Clapper has been caused to have significant pain, disfigurement, and worry leaving her permanently and physically scarred. The complications, including, but not limited to, pain, disfigurement, and non-absorption are not warned of in the IFU but were risks Defendant knew or should have known yet failed to disclose to patients, physicians, and hospitals.

**Plaintiff Joanne Downing-Mallik**

15. Plaintiff Joanne Downing-Malik ("Ms. Downing-Malik" or "Plaintiff Downing-Malik") 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.

16. Ms. Downing-Malik was diagnosed with right breast invasive ductal carcinoma in or around May 2018. She underwent a right breast lumpectomy on or around November 02, 2018 at Baptist Health Northeast, during which Dr. Beth Lesnikoski ("Dr. Lesnikoski") properly implanted a BioZorb.

17. Following implantation of the BioZorb, Ms. Downing-Malik experienced pain and discomfort at and around the site of the BioZorb. In addition, in 2022, the BioZorb device migrated under her armpit making it difficutl to move and sleep.

18. As a result of the BioZorb, Ms. Downing-Malik has been caused to have significant pain, disfigurement, and worry leaving her permanently and physically scarred. The complications, including, but not limited to pain, disfigurement, and

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

**Plaintiff Cindy Corder**

19. Plaintiff Cindy Corder ("Ms. Corder" or "Plaintiff Corder") is, and at all relevant times was, a citizen of the State of Kentucky and the United States and over the age of eighteen (18) years.

20. Ms. Corder was diagnosed with right breast carcinoma in or around March 2023. She underwent a lumpectomy on or around May 11, 2023 at Mercy Health Lourdes Hospital, during which Dr. Daniel Howard ("Dr. Howard") properly implanted a BioZorb.

21. Ms. Corder experienced a hard painful lump, pain, redness, and fluid build up at the site of the BioZorb. Shortly after Ms. Corder was implanted with the BioZorb, on or around May 25, 2023, her right breast began to retain fluid at the site of the BioZorb. Due to the fluid at the site of the BioZorb, Ms. Corder had to have the area aspirated eight times throughout the year.

22. Due to the ongoing fluid retention and the February FDA warning notice, Ms. Corder underwent an additional surgery to have BioZorb removed. On or around August 27, 2024, at Mercy Health Lourdes Hopital, Dr. Howard sucessfuly removed a fragmanented BioZorb.

23. As a result of the pain and complications of the BioZorb Marker, Plaintiff Corder feared the possibility of another tumor every day, causing significant emotional distress.

24. As a result of the BioZorb, Ms. Corder has been caused to have significant worry, discomfort, pain, fluid build up, and redness, leaving her permanently and physically scarred. The complications, including, but not limited to, discomfort, pain, additional surgery, and disfigurement, are not warned of in the IFU but were risks Defendant knew or should have known yet failed to disclose to patients, physicians, and hospitals.

**Plaintiff Lilia Rathburn**

25. Plaintiff Lilia Rathburn ("Ms. Rathburn" or "Plaintiff Rathburn") 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.

26. Ms. Rathburn was diagnosed with left breast ductal carcinoma in situ on or around August 2022. She underwent a left breast lumpectomy on or around May 11, 2023, at Sutter Medical Plaza Jackson, during which Dr. Isabella Flores-Merritt ("Dr. Flores-Meritt") properly implanted a BioZorb.

27. Ms. Rathburn suffered from a hard lump, shooting pain, swelling, discoloration, and edema at the site of the BioZorb.

28. Due to the pain at the site of the BioZorb, Ms. Rathburn had the BioZorb device removed by Dr. Kimberlee Reed, at Adventist Health Hospital on or around August 26, 2024. Following removal of the BioZorb device, Ms. Rathburn had to receive phycial therapy for lymphedema. The Swelling and discoloration remains; however, Ms. Rathburn's pain has decreased significantly since the removal of the BioZorb.

29. As a result of the pain and complications of the BioZorb Marker, Plaintiff Rathburn feared the possibility of another tumor every day, causing significant emotional distress.

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

**Defendant Hologic**

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

## BACKGROUND AND FACTS

### A. Background on BioZorb

32. The BioZorb Marker is a Class II medical device first cleared by the United States Food and Drug Administration ("FDA") in February 2012 pursuant to Section

510(k) of the Food Drug, and Cosmetic Act ("510(k)"). *See* Exhibit A (BioZorb® Marker, BioZorb® LP Marker Instructions for Use).

33. BioZorb is a three-dimensional implantable radiographic marker. It is comprised of a bioabsorbable spacer that holds six radiopaque titanium clips. The bioabsorbable spacer material (polylactic acid) is intended to be resorbed by the body through hydrolysis, leaving the radiopaque clips as permanent indicators of the soft tissue site. *Id*.

34. BioZorb is indicated for use in radiographic marking of sites in soft tissue and in situations where the soft tissue site needs to be marked for future medical procedures. It may be used with the following imaging modalities: X-ray (CT and mammography), MRI, and ultrasound. *Id*.

35. The contraindications and warnings in the BioZorb Instructions for Use ("IFU") state:

> The marker should not be placed in a tissue site with clinical evidence of infection. The marker should only be used by physicians trained in surgical techniques. The physician is responsible for its proper clinical use. The marker is shipped sterile; do **NOT** re-sterilize any portion of the marker. The Marker is for **SINGLE USE** only. Do **NOT** use if the package is open or damaged, or if the temperature indicator has a black center. Use the Marker prior to the expiry date shown on the product label.

*Id*.

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

37. Defendant marketed BioZorb as a device that can fill space in breast tissue,[2] improve cosmetic outcomes after procedures,[3] and guide radiotherapy.[4] However, the FDA did not clear these indications for use.

**B. The Problems with BioZorb and the Inadequacy of the Instructions for Use**

38. The IFU for BioZorb contains no warnings or contraindications of any substance to effectively warn patients, physicians, or hospitals of the relevant risks associated with the use of the device.

39. The BioZorb IFU and Defendant's marketing of the BioZorb indicate the device is intended to completely resorb in up to one or more years. However, there is evidence that the device can take significantly longer than one year to absorb, or it may fail to absorb at all. These risks are not mentioned in BioZorb's IFU.

40. Hologic was aware of Medical Device Reports ("MDRs") that reported patient complications including, but not limited to, infection, fluid buildup, device migration, device erosion, pain, discomfort, rash, extended resorption time of the device, and additional surgeries. These risks are not mentioned in BioZorb's IFU.

41. Hologic also knew or should have known of clinical evidence that shows that BioZorb can cause a hard, palpable lump, causing patient pain and discomfort.[5] These risks are not mentioned in BioZorb's IFU.

---

[2] *See e.g.*, https://www.hologic.com/sites/default/files/bellingham-breast-center-poster_asbrs-2017.pdf

[3] *See e.g.*, https://hologicbreastsurgery.com/eur/portfolio/surgical-implant-targeted-therapy-biozorb/#

[4] *See e.g.*, https://www.hologic.com/sites/default/files/BioZorb-Marker-Case%20Study-Dr-Devisetty.pdf (accessed August 6, 2024; inactive on August 19, 2024).

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

42. Hologic also knew or should have known of clinical evidence that shows that BioZorb may increase a patient's radiation dose, contributing to further complications. As one breast surgeon described, "[n]ormally, a lumpectomy cavity is treated for 5 fractions with low energy electrons such as 6 MeV or 9MeV. Such energies give modest doses to the skin and leave no permanent scarring. As you increase in energy of electrons, it increases the skin dose and you run the risk of seeing more early and late skin reactions. The most disfiguring side effect [of using BioZorb] is the appearance of telangiectasias, which look like red spider veins. No woman wants this on their legs and certainly not on their breasts!"[6] These risks are not mentioned in BioZorb's IFU.

43. Hologic also knew or should have known of clinical evidence that BioZorb can cause infection, migration, necrosis, additional radiation, and additional surgery. These risks are not mentioned in BioZorb's IFU.

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

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

---

81771-x.

[6] https://web.archive.org/web/20231001130233/https://sugarlandradiationoncology.com/blog/entry/biozorb-device (originating website no longer available).

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

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

46. The FDA issued the February 27 Notice after receiving reports describing complications (adverse events) with the use of BioZorb Markers in breast tissue, including infection, fluid buildup (seroma), device moving out of position (migration), device breaking through the skin (erosion), pain, discomfort from feeling the device in the breast, rash, other complications "possibly associated with" extended resorption time (resorbable component of the device not resorbing in the patient's body for several years), and the need for additional medical treatment to remove the device.

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

48. In the February 27 Notice, the FDA stated that it had not cleared or approved the BioZorb Markers to fill space in the tissue or improve cosmetic outcomes after procedures.

49. From its entry into the market, Defendant marketed and promoted BioZorb to hospitals and surgeons as a device that fills space in breast tissue and improves cosmetic outcomes following surgery.

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

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

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

**D. February 2024 FDA Class I Recall of BioZorb Marker.**

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

54. The Safety Notification was to request that patients contact their healthcare provider if they experience any adverse events following the placement of a BioZorb Marker; report any problems or complications experienced following the placement of the BioZorb Marker to Hologic and to the FDA's MedWatch Adverse Event Reporting program; and discuss the benefits and possible risks of implantable breast tissue markers for breast cancer procedures with their health care provider.

55. The Important Medical Device Safety Notification was also required to be sent to health care providers, and Hologic requested that they be aware of serious adverse events following possible risks of BioZorb Marker devices with each patient; inform all patients on which device will be used if a marking device will be used during breast conservation surgery; continue to monitor patients who have an implanted

[8] The FDA says this Safety Notification was sent to "all affected customers," however, Plaintiffs are aware of affected patients and physicians who did not receive it.

[9] Hologic, Inc. Recalls BioZorb Marker Due to Complications with Implanted Devices (May 22, 2024), available at https://www.fda.giv/medical-devices/medical-device-recalls/hologic-inc-recalls-biozorb-marker-due-complications-implanted-devices (last accessed June 3, 2024).

BioZorb Marker for signs of any adverse events; and report any problems or complications experienced by patients following placement of the BioZorb Marker devices to Hologic and the FDA's MedWatch Adverse Event Reporting program.

56. On May 22, 2024, the FDA classified Hologic's Safety Notification as a Class I recall, the most serious type of recall.

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

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

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

**E. October 2024 FDA Class I Recall of BioZorb Marker.**

60. On October 25, 2024, pursuant to FDA direction, Hologic announced a voluntary recall for removal of all lots of unused BioZorb Markers.

61. The FDA classified Hologic's October 2024 announcement as a Class I recall, the most serious type of recall.

62. The FDA also alerted health care providers and facilities, "Be aware the FDA has no cleared or approved the use of BioZorb markers to fill space in the tissue or

to improve cosmetic outcomes after procedures, or as a marker for radiation treatment."[10]

**F. December 2024 FDA Warning Letter to Hologic.**

63. The FDA inspected Hologic's Marlborough, Massachusetts facility on July 30, 2024 through September 24, 2024.

64. On December 18, 2024, the FDA sent a Warning Letter to Hologic, stating that the inspection revealed the BioZorb devices "are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820."[11]

65. In the Warning Letter, the FDA noted violations, including, but not limited to, the following:

a. "[Hologic] failed to establish design inputs to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient, as required by 21 CFR 820.30(c);"

[10] Update: Do Not Use BioZorb Marker Implantable Radiographic Marker Devices: FDA Safety Communication (October 25, 2024), available at https://www.fda.gov/medical-devices/safety-communications/update-do-not-use-biozorb-marker-implantable-radiographic-marker-devices-fda-safety-communication

[11] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hologic-inc-698214-12182024

b. "[Hologic] failed to verify your device design to confirm that the design output meets the design input requirements, as required by 21CFR 820.30(f);"

c. "[Hologic] failed to validate your device design to ensure that devices conform to defined user/patient needs and intended uses, as required by 21 CFR 820.30(g);"

d. "[Hologic] failed to ensure that the device design is correctly translated into production specifications, as required by 21 CFR 820.30(h);"

e. "[Hologic's] review of quality data was not sufficient to detect recurring problems;"

f. "[Hologic] did not calculate the occurrence rate accurately when evaluating a spike of BioZorb medical device complaints and Medical Device Reports;"

g. "[Hologic's] BioZorb Marker is misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2);" and

h. The FDA found that their inspection "revealed that these devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice

requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820."[12]

66. The FDA also noted that the Warning Letter "is not intended to be an all-inclusive list of the violations at [Hologic's] facility."[13]

## CAUSES OF ACTION

### COUNT I:
### STRICT LIABILITY – DESIGN DEFECT

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

68. At all relevant times, Defendant, directly or indirectly, developed, designed, researched, tested, inspected, manufactured, assembled, sterilized, packaged, marketed, labeled, distributed, supplied, and/or sold BioZorb Markers, including the ones implanted in Plaintiffs.

69. Defendant knew and intended for the BioZorb Markers to be implanted into individuals, including Plaintiffs.

70. The BioZorb Marker was expected to and did reach the Plaintiffs without substantial change in the condition in which it was sold.

71. The BioZorb Markers were in a defective condition and unreasonably dangerous to users, including Plaintiffs, when they left Defendant's control.

[12] *Id.*

[13] *Id.*

72. At the time the BioZorb Markers implanted in Plaintiffs left Defendant's control, the foreseeable risks associated with its design exceeded the benefits associated with its design.

73. Defendant knew or should have known that BioZorb presented an unreasonable danger to patients implanted with the device when put to its intended and reasonably anticipated use.

74. The health risks associated with BioZorb Markers, as described herein, are of such a nature that ordinary consumers, including Plaintiffs and their physicians, would not have readily recognized the potential harm.

75. BioZorb is unsafe to an extent beyond that which would be contemplated by the ordinary consumer.

76. The risks of danger inherent in BioZorb's design outweigh the benefits of its design.

77. Defendant did not take reasonable precautions in an attempt to design a safe product and did not act as a reasonably prudent manufacturer would have under the circumstances.

78. Plaintiffs and Plaintiffs' physicians used the device in a normal, customary, intended, and foreseeable manner.

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

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

81. For example, the material of the BioZorb spacer makes the device defective because it is intended to absorb; however, it either does not absorb or, as it does, the device fractures into pieces that can migrate throughout the breast and even protrude through a patient's skin. A different material with faster absorption and less crystallinity would help the device degrade in a melting fashion, instead of by fracturing, and would reduce the risks of palpability, pain, hard lumps, protrusion, and surgical removal of the device.

82. The material of the BioZorb spacer is also defective because it is a hard polymer that is placed in soft tissue, thus causing palpability, pain, hard lumps, and protrusion. A different material, or a chemical treatment of the material, could make the device flexible, thus resolving these risks.

83. In addition, the thickness of BioZorb's spacer could have been reduced to improve the device's degradation time, thus reducing the risks of palpability, pain, hard lumps, and surgical removal of the device.

84. The defects in the design of BioZorb resulted from Defendant's action and/or inaction.

85. For example, Defendant knew its design of BioZorb was defective and that it was feasible to design the device in a safer manner, yet failed to take any action to correct the design and/or to warn patients, physicians, and hospitals of the risks posed by the design.

86. There are technologically feasible and practical alternative designs available that would have reduced or prevented the Plaintiffs' harm without impairing the product's usefulness or desirability.

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

88. For example, titanium clips that have been on the market for years carry less clinical risk to the patient.[14] In fact, as one clinical study found: "The use of clips to mark the tumor bed is more cost-effective than the use of the BioZorb Marker which does not provide value given its relative high cost and lack of clinical advantage scientifically shown over the use of surgical clips."[15]

89. BioZorb's design poses a high gravity of danger. For example, if the BioZorb Marker does not fully absorb in the body, migrates or is expelled from the body, or causes an infection, a patient may be required to undergo additional surgery to remove the device.

90. Defendant failed to establish design inputs for BioZorb to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient, as required by 21 CFR 820.30(c).[16]

---

[14] *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.

[15] 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.

[16] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hologic-

91. Defendant failed to verify BioZorb's device design to confirm that the design output meets the design input requirements, as required by 21CFR 820.30(f).[17]

92. Defendant failed to validate BioZorb's device design to ensure that devices conform to defined user/patient needs and intended uses, as required by 21 CFR 820.30(g).[18]

93. Defendant failed to ensure that the BioZorb device design was correctly translated into production specifications, as required by 21 CFR 820.30(h).[19]

94. Defendant failed to identify the following for BioZorb Markers: the intended patient population, intended anatomy types, and surgical requirements, such as the appropriate placement and fixation of the device, and the appropriate depth of the implant into the soft tissue.[20]

95. Hologic violated the following state laws by manufacturing, marketing, selling, and distributing its defectively designed BioZorb Marker:

| **Jurisdiction** | **Authority** |
|---|---|
| Alaska | *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1199-1200 (Alaska 1992); *Caterpillar Tractor Co. v. Beck*, 593 P.2d 871, 884-884 (Alaska 1979); *General Motors Corp. v. Farnsworth*, 965 P.2d 1209, 1220-21 (Alaska 1998); |
| California | *Barker v. Lull,* supra at 413; *Lewis v. American Hoist & Derrick Co.*, 20 Cal.App.3d 570; *Campbell v. GMC,* 32 Cal.3d 112 (1982); |
| Florida | *Force v. Ford Motor Co.*, 879 So. 2d 103 (Fla. Dist. Ct. App. 2004); |

inc-698214-12182024

[17] *Id.*

[18] *Id.*

[19] *Id.*

[20] *Id.*

| | |
|---|---|
| | *McConnell v. Union Carbide Corp.*, 937 So. 2d 148, 151 n.4 (Fla. 4th DCA 2006); *Aubin v. Union Carbide Corp*., 177 So.3d 489, 511–12 (Fla. 2015); |
| Kentucky | *Toyota Motor Corp. v. Gregory*, 136 S.W.3d 35 (Ky. 2004); |
| New Jersey | N.J. Stat. Ann. § 2A:58C-2("New Jersey Products Liability Act"), *et seq*. |

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

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

98. 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 II:**
**STRICT LIABILITY – FAILURE TO WARN**

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

100. At all relevant times, Defendant, directly or indirectly, developed, designed, researched, tested, inspected, manufactured, assembled, sterilized, packaged, marketed, labeled, distributed, supplied, and/or sold BioZorb Markers, including the ones implanted in Plaintiffs.

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

102. Defendant knew and intended for the BioZorb Markers to be implanted into individuals, including Plaintiffs.

103. The BioZorb Marker was expected to and did reach the Plaintiffs without substantial change in the condition in which it was sold.

104. The BioZorb Markers were in a defective condition and unreasonably dangerous to users, including Plaintiffs, when they left Defendant's control.

105. Defendant knew or should have known that BioZorb presented an unreasonable danger to patients implanted with the device when put to its intended and reasonably anticipated use.

106. Defendant knew, or in the exercise of ordinary care should have known, that the BioZorb Marker could cause the injuries suffered by Plaintiffs. For example, Hologic was aware of post-marketing adverse event reports that alleged the same injuries the Plaintiffs in this lawsuit suffered.

107. The health risks associated with BioZorb Markers as described herein are of such a nature that ordinary consumers, including Plaintiffs and their physicians, would not have readily recognized the potential harm.

108. Plaintiff and Plaintiff's physicians used the device in a normal, customary, intended, and foreseeable manner.

109. Defendant failed to review quality data to detect recurring problems with the BioZorb Markers.[21]

[21] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hologic-inc-698214-12182024

110. Defendant did not calculate the occurrence rate accurately when evaluating a spike of BioZorb medical device complaints and Medical Device Reports.[22]

111. The BioZorb Markers were not accompanied by proper warnings and instructions to Plaintiffs, physicians, hospitals, or the public regarding potential adverse side effects associated with the device's implantation and the comparative severity and duration of such adverse side effects.

112. The IFU failed to include warnings that the BioZorb Markers take far longer than one year to resorb and could require surgical removal.

113. The IFU failed to warn that the device could cause severe injury to patients, including, but not limited to, pain, infection, rash, device migration, device erosion, seroma, discomfort, other complications from feeling the device in the breast, the need for additional medical treatment to remove the device, mass formation, infection, fluid buildup, scarring, fat necrosis, and/or adverse tissue reaction. The IFU did not warn that BioZorb could be expelled from the breast, creating a hole, which could further lead to drainage and infection.

114. The IFU failed to warn of the risks created by BioZorb's negligent design, including, but not limited to, the device breaking into shards, causing pain and inflammation, failing to absorb, and the device's long-term palpability.

115. The above complications and adverse effects were known by Defendant when Plaintiffs were implanted with BioZorb Markers.

[22] *Id*.

116. 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.

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

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

119. Further, Defendant marketed BioZorb to fill space in breast tissue, improve cosmetic outcomes after procedures, and provide radiotherapy guidance, all in direct contravention of the Indications for Use cleared by the FDA, of which Defendant knew or should have known.

120. For example, Defendant published journal articles that promoted BioZorb for off-label uses, claimed no device-related complications, and did not disclose conflicts of interest.[23]

121. Defendant also published marketing materials, including brochures and educational materials, which failed to adequately warn physicians and patients about BioZorb's risks and/or stated the device had no impact on side effects.[24]

---

[23] *See e.g.*, 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. 2017 Feb;41(2):464-471. doi: 10.1007/s00268-016-3711-y. PMID: 27709273. (scientific article written by Gail Lebovic, the inventor of BioZorb and founder of Focal Therapeutics, and Michael Cross, a key opinion leader for Focal Therapeutics and Hologic, claiming the use of BioZorb resulted in a significant reduction in planned treatment volumes facilitating the use of hypo-fractioned radiation therapy with no device-related complications).

[24] *See e.g.*, https://www.hologic.com/sites/default/files/BioZorb-Marker-Case%20Study-Dr-Devisetty.pdf accessed August 6, 2024; inactive on August 19, 2024 ("BioZorb markers do not contribute to complications caused by treatment, including post-operation infection rates.")

122. In addition, Defendant's sales representatives did not disclose to physicians the risks of BioZorb, nor the rate of any risks.

123. Hologic is strictly liable for failing to adequately warn of the risks and risk profile of the BioZorb Marker pursuant to the laws of all states recognizing this cause of action, including:

| **Jurisdiction** | **Authority** |
|---|---|
| Alaska | *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1199-1200 (Alaska 1992); |
| California | *Carlin v. Superior Court,* 920 P.2d 1347 (CA 1996); CA Jury Instruction: 1205 Strict Liability—Failure to Warn; *Anderson v. Owens-Corning Fiberglas Corp.,* 53 Cal.3d 987, 1002 [281 Cal.Rptr. 528, 810 P.2d 549] (1991); *Saller v. Crown Cork & Seal Company,*187 Cal.App.4th 1220, 1239 [115 Cal.Rptr.3d 151] (2010); *Rosa v. City of Seaside*, 675 F.Supp.2d 1006, 1012 (N.D. Cal. 2009); |
| Florida | *Brewer v. Stop Stick, Ltd.*, No. 2:04-CV-613FTM33DNF, 2005 WL 2614537 (M.D. Fla. Oct. 14, 2005); *Union Carbide Corp. v. Aubin,* 97 So.3d 886, 898 (Fla. 3d DCA 2012); *McConnell v. Union Carbide Corp.*, 937 So.2d 148, 151–52 (Fla. 4th DCA 2006); *Union Carbide Corp. v. Kavanaugh,* 879 So.2d 42, 45 (Fla. 4th DCA 2004); *Scheman–Gonzalez v. Saber Manufacturing Co.,* 816 So.2d 1133 (Fla. 4th DCA 2002); *Ferayorni v. Hyundai Motor Co.*, 711 So.2d 1167 (Fla. 4th DCA 1998); |
| Kentucky | K.R.S. § 411.130, *et seq.*; *Post v. American Cleaning Equip. Corp.*, 437 S.W.2d 516 (Ky. 1968); |
| New Jersey | N.J. Stat. Ann. § 2A:58C-2, *et seq.* |

124. 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 III:**
**STRICT LIABILITY – MANUFACTURING DEFECT**

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

126. At all relevant times, Defendant, directly or indirectly, developed, designed, researched, tested, inspected, manufactured, assembled, sterilized, packaged, marketed, labeled, distributed, supplied, and/or sold BioZorb Markers, including the ones implanted in Plaintiffs.

127. Defendant knew and intended for the BioZorb Markers to be implanted into individuals, including Plaintiffs.

128. The BioZorb Markers were expected to and did reach the Plaintiffs without substantial change in the condition in which they were sold.

129. The BioZorb Markers were in a defective condition and unreasonably dangerous to users, including Plaintiffs, when they left Defendant's control.

130. Defendant knew or should have known that BioZorb presented an unreasonable danger to patients implanted with the device when put to its intended and reasonably anticipated use.

131. Plaintiff and Plaintiff's physicians used the device in a normal, customary, intended, and foreseeable manner.

132. The manufacturing defects resulted from Defendant's action and/or inaction.

133. Plaintiffs were harmed because of the manufacturing defects.

134. The FDA found that a fall 2024 inspection "revealed that [BioZorb Markers] are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current

good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820."[25]

135. Hologic is strictly liable for the defective manufacture of its BioZorb Marker pursuant to the laws of all states recognizing this cause of action:

| **Jurisdiction** | **Authority** |
|---|---|
| Alaska | *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1199-1200 (Alaska 1992); *Caterpillar Tractor Co. v. Beck* 593 P.2d 871, 884-884 (Alaska 1979); *General Motors Corp. v. Farnsworth*, 965 P.2d 1209, 1220-21 (Alaska 1998); |
| California | *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 771 (Ct. App. 1996); *Barker v. Lull, supra* at 413; *Lewis v. American Hoist & Derrick Co.*, 20 Cal.App.3d 570; *Campbell v. GMC*, 32 Cal.3d 112 (1982); |
| Florida | *Force v. Ford Motor Co.*, 879 So. 2d 103 (Fla. Dist. Ct. App. 2004); *McConnell v. Union Carbide Corp.*, 937 So. 2d 148, 151 n.4 (Fla. 4th DCA 2006); *Aubin v. Union Carbide Corp.*, 177 So.3d 489, 511–12 (Fla. 2015); |
| Kentucky | *Edwards v. Hop Sin, Inc.*, 140 S.W.3d 13, 15 (Ky. Ct. App. 2003); |
| New Jersey | N.J. Stat. Ann. § 2A:58C-2a, *et seq.* |

136. 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**

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

138. At all relevant times, Defendant, directly or indirectly, developed, designed, researched, tested, inspected, manufactured, assembled, sterilized, packaged,

[25] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hologic-inc-698214-12182024

marketed, labeled, distributed, supplied, and/or sold BioZorb Markers, including the ones implanted in Plaintiffs.

139. Defendant owed Plaintiffs a duty to use reasonable care under the circumstances in developing, designing, researching, testing, inspecting, manufacturing, assembling, sterilizing, packaging, marketing, labeling, distributing, supplying, and selling BioZorb Markers.

140. Defendant knew and intended for the BioZorb Markers to be implanted into individuals, including Plaintiffs.

141. The BioZorb Markers were expected to and did reach the Plaintiffs without substantial change in the condition in which they were sold.

142. The BioZorb Markers were in a defective condition and unreasonably dangerous to users, including Plaintiffs, when they left Defendant's control.

143. Defendant knew or should have known that BioZorb presented an unreasonable danger to patients implanted with the device when put to its intended and reasonably anticipated use.

144. The health risks associated with BioZorb Markers as described herein are of such a nature that ordinary consumers, including Plaintiffs and their physicians, would not have readily recognized the potential harm.

145. Plaintiff and Plaintiff's physicians used the device in a normal, customary, intended, and foreseeable manner.

146. Defendant failed to use reasonable care under the circumstances in developing, designing, researching, testing, inspecting, manufacturing, assembling, packaging, marketing, labeling, distributing, and selling the BioZorb Markers.

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

148. Defendant was negligent in designing, manufacturing, researching, developing, preparing, processing, packaging, promoting, marketing, labeling, supplying, inspecting, testing, distributing, and selling the BioZorb Marker by failing to use reasonable care in fulfilling its duty to avoid foreseeable dangers.

149. Defendant was negligent in failing to comply with federal and state law and failing to use reasonable care in fulfilling its duty to inform users of dangerous risks, including risks posed by the device's negligent design. As a result of the foregoing conduct, Plaintiffs, physicians, and hospitals were sold defective medical devices without knowing the true risk-benefit ratio of the BioZorb Marker.

150. Defendant failed to evaluate or test how in-vivo radiation treatments can impact the performance of the device and the ability of the device to resorb into a patient's body.

151. Defendant failed to define the length of time for when the spacer material would be completely resorbed in a patient's body.

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

153. Defendant knew or should have known that the BioZorb Marker's benefits differed from what was marketed, promoted, advertised, and communicated to patients, physicians, hospitals, and the general public.

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

155. Despite this knowledge, Defendant marketed the BioZorb Marker to fill space in breast tissue, to improve cosmetic outcomes after procedures, and to provide radiotherapy guidance, all in direct contravention of the Indications for Use cleared by the FDA.

156. It was readily foreseeable to Defendant that Plaintiffs and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and failure to report material information regarding the device's risks and claimed benefits. Defendant knew that Plaintiffs and their physicians and hospitals 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 its products in deciding whether to purchase and/or implant the BioZorb Marker.

157. Under the same or similar circumstances, a reasonable manufacturer would have warned through an appropriate channel and medium of communication of the danger and reported the risks of the BioZorb Marker to patients, physicians, and hospitals.

158. Had Defendant adequately tested BioZorb, evidence regarding the device's risks, the rate of occurrence, and the extent of harm regarding each risk would have been found and could have been communicated to patients, physicians, and hospitals.

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

160. Had Defendant timely reported the known risks associated with the BioZorb Marker to patients, physicians, and hospitals and allowed them to make informed decisions about using an alternative product that did not present the same risks, or foregoing the use of any marker, Plaintiffs would not have been implanted with BioZorb Markers.

161. Defendant knew that BioZorb's design was defective yet failed to take reasonable measures to mitigate or eliminate the risks posed by the defective design.

162. 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.

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

164. The state law duties and requirements are paralelled to, and not different from or in addition to, the federal requirements with regard to the negligence of Defendant. Hologic is liable for its negligence related to its BioZorb Marker which caused Plaitiffs' injuries pursuant to the laws of all states recognizing this cause of action, including:

| **Jurisdiction** | **Authority** |
|---|---|
| Alaska | *Swenson Trucking & Excavating, Inc. v. Truckweld Equipment Co.*, 604 P.2d 1113, 1117 (Alaska 1980); |
| California | *Howard v. Omni Hotels Management Corp*., 203 Cal.App.4th 403, 428 (2012); Judicial Council Of California Civil Jury Instruction 1221; |
| Florida | *Cintron v. Osmose Wood Preserving, Inc*., 681 So.2d 859, 861 (Fla. Dist. Ct. App. 1996); |
| Kentucky | *Clark v. Hauck Mfg. Co.*, 910 S.W.2d 247, 251 (Ky. 1995), overruled on other grounds by *Martin v. Ohio Cty. Hosp. Corp.*, 295 S.W.3d 104 (Ky. 2009); *Estate of Jones v. Process Machinery, Inc*., No. 2013-CA-000383-MR, 2015 WL 7573942, at *4 (Ky. Ct. App. Nov. 25, 2015). |

165. 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 V:**
**BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

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

167. At all relevant times, Defendant, directly or indirectly, developed, designed, researched, tested, inspected, manufactured, assembled, sterilized, packaged, marketed, labeled, distributed, supplied, and/or sold BioZorb Markers, including the ones implanted in Plaintiffs.

168. Defendant knew and intended for the BioZorb Markers to be implanted into individuals, including Plaintiffs.

169. The BioZorb Marker was expected to and did reach the Plaintiffs without substantial change in the condition in which it was sold.

170. The BioZorb Markers were in a defective condition and unreasonably dangerous to users, including Plaintiffs, when they left Defendant's control.

171. Defendant knew or should have known that BioZorb presented an unreasonable danger to patients implanted with the device when put to its intended and reasonably anticipated use.

172. Plaintiff and Plaintiff's physicians used the device in a normal, customary, intended, and foreseeable manner.

173. Defendant impliedly warranted to prospective purchasers and users, including Plaintiffs, that the BioZorb Marker was safe, merchantable, and fit for the ordinary purposes for which it was to be used.

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

175. Upon information and belief, and contrary to such implied warranties, the BioZorb Marker was not of merchantable quality, safe, or fit for its intended use, because the product was, and is, unreasonably dangerous and unfit for the ordinary purposes for which it was used, as described above.

176. Hologic breached the implied warranty of merchantability in connection with the sale and distribution of recalled BioZorb Markers. They were not in the conditions as represented or manufactured in accordance with specifications, in violation of state law and parallel federal law, for example 21 C.F.R. § 820.1(a), 21 C.F.R. § 820.5, 21 C.F.R. § 820.3(y), 21 C.F.R.§ 820.70(a), (c), (e); 21 U.S.C. § 351. At the point of sale, the implants were not of merchantable quality, safe and fit for their intended use, in violation of the following statutes:

| **Jurisdiction** | **Authority** |
|---|---|
| Alaska | Alaska. Stat. §§ 45.02.314, *et seq.;* |
| California | Cal. Comm. Code §§ 2314, *et seq.;* |
| Florida | Fla. Stat. Ann. §§ 672.314, *et seq.;* |
| Kentucky | Ky. Rev. Stat. Ann. §§ 355.2-314, *et seq.;* |
| New Jersey | N.J. Stat. Ann. §§ 12A:2-314, *et seq.* |

177. 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.[26]

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

178. 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.

179. 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: March 7, 2025

Respectfully Submitted,

*/s/ John Roddy*

John Roddy (BBO # 424240)
**BAILEY & GLASSER LLP**
101 Arch Street, 8th Floor
Boston, MA 02110
Tel.: 617.439.6730
Fax: 617.951.3954
jroddy@baileyglasser.com

Christina D. Crow (to be admitted *Pro Hac Vice*)
Lisa Littell (to be admitted *Pro Hac Vice*)
**JINKS CROW PC**
219 Prairie Street North, P.O. Box 350
Union Springs, AL 36089
Tel.: 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 PC**
12301 Wilshire Blvd., Ste. 303
Los Angeles, CA 90025
Tel.: 877.529.3707
Fax: 877.284.0980
mcowper@cowperlaw.com

*Attorneys for Plaintiffs*

**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®

**Hologic, Inc.**
**250 Campus Drive.**
**Marlborough, MA 01752 USA.**
**Phone: 877-371-4372**
**BreastHealth.Support@hologic.com**

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

Debra Sigmund, Megan Clapper, Joanne Downing-Malik, Cindy Corder, and Lilia Rathburn,

**(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, 101 Arch Street, 8th 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

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

**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

**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

**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

## 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 see attached

DATE
Mar 7, 2025

SIGNATURE OF ATTORNEY OF RECORD
/s/ John Roddy

**FOR OFFICE USE ONLY**

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

***Sigmund v. Hologic, Inc.***

**Attachment to Civil Cover Sheet**

VIII. Related case(s) if any

- Evers v. Hologic, Inc., 22-11895, Judge Allison D. Burroughs;
- Block v. Hologic, Inc., 22-12194, Judge Allison D. Burroughs;
- Chambers v. Hologic, Inc., 23-10260, Judge Allison D. Burroughs;
- Shirkey v. Hologic, 23-10579, Judge Allison D. Burroughs;
- Stine v. Hologic, Inc., 23-10599, Judge Allison D. Burroughs;
- Baker v. Hologic, Inc., 23-10717, Judge Allison D. Burroughs;
- Slater v. Hologic, Inc., 23-10888, Judge Allison D. Burroughs;
- Rivera v. Hologic, Inc., 23-11012, Judge Allison D. Burroughs;
- English v. Hologic, Inc., 23-11512, Judge Allison D. Burroughs;
- Webb v. Hologic, Inc., 23-11823, Judge Allison D. Burroughs;
- Price v. Hologic, Inc., 23-12011, Judge Allison D. Burroughs;
- Heffner v. Hologic, Inc., 23-12278, Judge Allison D. Burroughs
- Blanchenay v. Hologic, Inc., 23-12458, Judge Allison D. Burroughs;
- Austin v. Hologic, Inc., 23-12651, Judge Allison D. Burroughs;
- Swafford v. Hologic, Inc., 23-12687, Judge Allison D. Burroughs;
- Bonvillain v. Hologic, Inc., 23-12833, Judge Allison D. Burroughs;
- Ciers v. Hologic, Inc., 23-13215, Judge Allison D. Burroughs;
- Broeder v. Hologic, Inc., 24-10823, Judge Allison D. Burroughs;
- Galaini v. Hologic, Inc., 24-11939, Judge Allison D. Burroughs;
- Bates v. Hologic, Inc., 24-12472, Judge Allison D. Burroughs;
- Wetteman v. Hologic, Inc., 25-10242, Judge Allison D. Burroughs.

**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

1. **Title of case (name of first party on each side only)** Debra Sigmund 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 v. Hologic, Inc., 22-11895

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)**

**ATTORNEY'S NAME** John Roddy, Bailey & Glasser LLP
**ADDRESS** 101 Arch Street, 8th Floor, Boston, MA 02110
**TELEPHONE NO.** 617.439.6730