UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

JOANNE BATES, PATRICIA MARKWAY, SHAWN ALLEN, DENISE BIBRO, and SHERYL PORETZ, **Plaintiffs,** **v.** **HOLOGIC, INC.,** **Defendant.**	**Case No. 1:24-cv-12472**

COMPLAINT

Joanne Bates, Patricia Markway, Shawn Allen, Denise Bibro, and Sheryl Poretz ("Plaintiffs") bring this action against Defendant Hologic, Inc. ("Defendant" or "Hologic"), a Massachusetts corporation.

JURISDICTION AND VENUE

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

1. 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.

2. 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.

3. 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 Joanne Bates

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

5. Ms. Bates was diagnosed with right breast ductal carcinoma in situ in or around October 2020. She underwent a right breast lumpectomy on or around November 9, 2020 at Kadlec Regional Medical Center, during which Dr. John Droesch ("Dr. Droesch") properly implanted a BioZorb.

6. Ms. Bates suffered from a hard, painful lump at the site of the BioZorb Marker. Ms. Bates' pain was constant, and the severity of her pain worsened upon contact, making it difficult to wear a bra. Ms. Bates suffered from a burning sensation and itchiness in the area that extended

from the site of the BioZorb to her back and right armpit.

7. Ms. Bates had the BioZorb removed by Dr. Droesch at Kadlec Regional Medical Center on or around May 20, 2021.

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

9. As a result of the BioZorb, Ms. Bates has been caused to have additional procedures, significant pain, disfigurement, and worry, leaving her permanently and physically scarred. The complications, including, but not limited to, disfigurement, pain, non-absorption, palpable mass, and additional surgery, 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 Patricia Markway

10. Plaintiff Patricia Markway ("Ms. Markway" or "Plaintiff Markway") is and at all relevant times was a citizen of the State of Illinois and the United States and over the age of eighteen (18) years.

11. Ms. Markway was diagnosed with right breast invasive ductal carcinoma in or around July 2022. She underwent a right breast lumpectomy on or around August 29, 2022 at Advocate Good Shepherd Hospital, during which Dr. Anna Katz ("Dr. Katz) properly implanted a BioZorb.

12. Ms. Markway suffered from pain, redness, and swelling, along with burning and stabbing sensations at the site of the BioZorb Marker. The BioZorb migrated, and Ms. Markway developed an infection at the site of the device.

13. Ms. Markway had the BioZorb removed by Dr. Katz at Advocate Lutheran General Hospital on or around October 27, 2022.

14. Following removal, Ms. Markway suffered from a chronic wound for several months and permanent disfigurement. Ms. Markway underwent an additional surgery in or around March 2023 to address complications caused by the removal of the BioZorb.

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

16. As a result of the BioZorb, Ms. Markway has been caused to have significant pain, disfigurement, worry, infection, and additional surgery, leaving her permanently and physically scarred. The complications, including, but not limited to, pain, migration, infection, disfigurement, and additional surgery 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 Shawn Allen

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

18. Ms. Allen was diagnosed with right breast invasive ductal carcinoma in or around September 2020. She underwent a partial mastectomy on or around March 31, 2021 at Anne Arundel Medical Center, during which Dr. Wen Liang properly implanted a BioZorb.

19. Ms. Allen suffered from infection and an abscess formed around the BioZorb. Ms. Allen had to undergo fluid aspirations on or around October 31, 2022, February 23, 2023, May 26, 2023, October 27, 2023, and February 22, 2024.

20. Due to the infection caused by BioZorb, Ms. Allen had the BioZorb removed by Dr. Rubie Sue Jackson at Anne Arundel Medical Center on or around February 27, 2024. Ms. Allen has been suffering from deformity and an open wound since having the BioZorb removed.

21. As a result of the BioZorb, Ms. Allen has been caused to have additional procedures, significant pain, disfigurement, worry and infection, leaving her permanently and physically scarred. The complications, including, but not limited to, adverse local tissue reaction, disfigurement, and additional surgery 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 Denise Bibro

22. Plaintiff Denise Bibro ("Ms. Bibro" or "Plaintiff Bibro") is and at all relevant times was a citizen of the State of New York and the United States and over the age of eighteen (18) years.

23. Ms. Bibro was diagnosed with left breast adenoid cystic carcinoma in or around March 2019. She underwent a lumpectomy on or around May 14, 2019 at Weill Cornell Medical Center, during which Dr. Rache Simmons properly implanted a BioZorb.

24. Ms. Bibro experiences soreness, sharp pain, and burning sensations at the BioZorb site. Her pain is worsened upon contact, making it difficult for Ms. Bibro to lie on her left side. Ms. Bibro has developed rashes and reddening of the skin at and around the BioZorb. The BioZorb has failed to properly absorb.

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

26. As a result of the BioZorb, Ms. Bibro has been caused to have significant worry, discomfort, pain, excessive scar tissue, adverse tissue reactions, disfigurement, additional

radiation, and a hard lump, leaving her permanently and physically scarred. The complications, including, but not limited to, discomfort, pain, excessive scar tissue, adverse tissue reactions, disfigurement, and a hard lump, 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 Sheryl Poretz

27. Plaintiff Sheryl Poretz ("Ms. Poretz" or "Plaintiff Poretz") is and at all relevant times was a citizen of the State of Maryland and the United States and over the age of eighteen (18) years.

28. Ms. Poretz was diagnosed with left breast cancer in or around March of 2019. She underwent a left breast partial mastectomy on or around April 12, 2019, at Anne Arundel Medical Center, during which a BioZorb was properly implanted by Dr. Rubie Sue Jackson.

29. Ms. Poretz suffers from pain at the site of the BioZorb Marker that has worsened over time. Ms. Poretz's breast is disfigured, and there is scarring and dimpling around the BioZorb. The BioZorb has failed to properly absorb.

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

31. As a result of the BioZorb, Ms. Poretz has been caused to have significant worry, discomfort, pain, disfigurement, and a hard lump, leaving her permanently and physically scarred. The complications, including, but not limited to, discomfort, pain, disfigurement, a hard lump, 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

32. 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

33. 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).

34. 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*.

35. 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*.

36. 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.

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

38. 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

39. 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.

40. 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.

41. 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.

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[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)

These risks are not mentioned in BioZorb's IFU.

42. 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.

43. 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.

44. 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.

45. On February 27, 2024, the U.S. Food and Drug Administration issued a Safety

[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/s41598-021-81771-x.

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

Communication ("February 27 Notice") regarding BioZorb Markers.[7]

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

47. 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.

48. 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.

49. 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.

50. 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.

51. Surgeons relied on the Defendant's representations and implanted BioZorb Markers

[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).

in patients, including the Plaintiffs.

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

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

D. FDA Class I Recall of BioZorb Marker.

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

55. 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.

56. 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 BioZorb Marker for signs of any adverse events; and report any problems or complications experienced by patients following placement of the BioZorb

[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).

Marker devices to Hologic and the FDA's MedWatch Adverse Event Reporting program.

57. On May 22, 2024, the FDA classified Hologic's Safety Notification as a Class I recall.

58. Class I recalls are the most serious type of recall.

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

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

61. 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.

CAUSES OF ACTION
COUNT I- NEGLIGENCE: FAILURE TO WARN

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

63. 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 the way a product is designed."[10]

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

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

66. Defendant had a duty to adequately warn and disclose the dangers and risks of the

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

BioZorb Marker, which Defendant knew, or in the exercise of ordinary care should have known, at the time the BioZorb Markers left its control.

67. 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.

68. 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.

69. Specifically, the IFU failed to include warnings that the BioZorb Markers take far longer than one year to resorb and could require surgical removal. The warnings also failed to include information that a radiation oncologist might need to use a higher energy electron therapy, which can cause scarring and other complications in the breast.

70. The IFU also 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, 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.

71. The IFU also 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.

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

73. 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.

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

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

76. 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.

77. 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.[11]

78. 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.[12]

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[11] *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).

[12] *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.")

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

80. 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

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

82. At all relevant times, Defendant designed, researched, developed, inspected, tested, packaged, labeled, supplied, and/or sold BioZorb.

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

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

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

86. There are technologically feasible and practical alternative designs that would have reduced or prevented the Plaintiffs' harm.

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.[13] In fact, as one clinical study found: "The use of clips to mark the tumor bed

[13] *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

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."[14]

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

91. 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

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

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

94. 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.

95. Plaintiffs reasonably relied upon the skill and judgment of Defendant as to whether

Review of Medical Devices, 18:1, 121-128, DOI: 10.1080/17434440.2020.1852928.

[14] 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.

the BioZorb Marker was of merchantable quality, safe, and fit for its intended use.

96. 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.

97. 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.[15]

98. 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.

99. 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

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

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

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

102. 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).

103. 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.

104. 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.

105. 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.

106. 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.

107. 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.

108. 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.

109. It was readily foreseeable to Defendant that Plaintiffs and other consumers would be harmed as a result of Defendant's failure to exercise ordinary careand 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.

110. 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.

111. 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.

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

113. 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.

114. 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.

115. 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.

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

117. 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: September 26, 2024

Respectfully Submitted,

/s/ John Roddy

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Attorneys for Plaintiffs

JS 44 (Rev. 10/20)

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

Joanne Bates (Please, see Addendum A)

(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 (Please, see Addendum A)

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)*

Andrew Hannemann, Arnold & Porter Kaye Scholer LLP (Please, see Addendum A)

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

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

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

(For Diversity Cases Only)

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

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

Click here for: Nature of Suit Code Descriptions.

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

TORTS

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

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

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

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

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

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

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

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

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

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

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

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

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

PRISONER PETITIONS

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

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

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

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

VI. CAUSE OF ACTION

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

Brief description of cause:
Plaintiffs allege personal injury against Hologic, Inc for the designing, manufacturing, marketing, and sale of the BioZorb Marker.

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 1:22-cv-11895

DATE 9/26/2024

SIGNATURE OF ATTORNEY OF RECORD /s/ John Roddy

FOR OFFICE USE ONLY

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

ADDENDUM A

I. (a) **PLAINTIFFS:**

Patricia Markway, Shawn Allen, Denise Bibro, and Sheryl Poretz

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

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

1. **Title of case (name of first party on each side only)** Joanne Bates 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.**

Lyons et al v. Hologic, Inc. et al, 1:22-cv-11895-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)

ATTORNEY'S NAME John Roddy

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