UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MARIA RIVERA, MARY MUNNEY GRIFFITHS, MARTHA GOTTSCHALK, SHARON HICKS, and DELORES GOODSON, **Plaintiffs,** **v.** **HOLOGIC, INC.,** **Defendant.**	**Case No. 1:23-cv-11012** **JURY TRIAL DEMANDED** **MOTION FOR LEAVE TO AMEND GRANTED SEPTEMBER 6, 2024**

SECOND AMENDED COMPLAINT

Plaintiffs Maria Rivera, Mary Munney Griffiths, Martha Gottschalk, Sharon Hicks, and Delores Goodson bring this action against Defendant Hologic, Inc., ("Defendant" or "Hologic"), a Massachusetts corporation.

VENUE AND JURISDICTION

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 amountin 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 breastcancer, were implanted with a medical device called BioZorb("BioZorb" or "BioZorb Marker")[1]

[1] These terms refer to all model numbers of the BioZorb Marker and include the BioZorb LP Marker.

manufactured by Hologic.

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, researching, developing, testing, manufacturing, preparing, processing, inspecting, packaging, labeling, marketing, promoting, supplying, distributing and/or selling the BioZorb Marker.

PARTIES

Plaintiff Maria Rivera

4. Plaintiff Maria Rivera ("Ms. Rivera" or "Plaintiff Rivera") 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.

5. Ms. Rivera was diagnosed with right breast cancer. She underwent a right partial mastectomy on or around April 23, 2021 at Garnet Health Medical Center, during which Dr. Howard Karpoff properly implanted a BioZorb.

6. Ms. Rivera suffers a hard, painful, and large lump, deformity and scarring of her skin, sensitivity, itching, swelling and reddening of her skin, and the BioZorb marker has failed to dissolve. She has trouble sleeping and has suffered intimacy problems because of the device.

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

8. As a result of the BioZorb, Ms. Rivera has been caused to have 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 non- absorption are not warned of in the Instructions for Use but were risks Defendant knew or should have known yet failed to disclose to physicians and patients.

Plaintiff Mary Munney Griffiths

9. Plaintiff Mary Munney Griffiths ("Ms. Munney Griffiths" or "Plaintiff Munney Griffiths") 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.

10. Ms. Munney Griffiths was diagnosed with left breast cancer. She underwent a lumpectomy on or around July 21, 2020 at St. Joseph's Hospital, during which Dr. Kara C. Kort properly implanted a BioZorb.

11. Ms. Munney Griffiths was told the BioZorb Marker would dissolve within twelve (12) months. When the device had not dissolved by month twelve (12), she was then told to wait for it to dissolve within eighteen (18) months. It remained fully palpable.

12. After two (2) years of daily pain from the BioZorb Marker, Ms. Munney Griffiths had the BioZorb properly removed by Dr. Kara C. Kort at St. Joseph's Hospital on or around August 23, 2022. The device was shattered and approximately twenty-four (24) pieces of sharp, plastic-like fragments from the device were removed from Ms. Munney Griffith's breast during the surgery.

13. There is now a larger lump at Ms. Munney Griffith's lumpectomy site that is still extremely painful. She has experienced swelling and sensitivity, now has lymphedema, and has difficulty wearing bras and difficulty sleeping because of the pain.

14. Ms. Munney Griffiths believes there are still shards of BioZorb in her breast. She is considering a mastectomy, hoping that it would finally relieve her pain.

15. As a result of the pain and complications of the BioZorb Marker, Plaintiff Munney Griffiths has experienced significant emotional distress.

16. As a result of the BioZorb, Ms. Munney Griffiths 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, migration, adverse local tissue reaction, disfigurement, non-absorption, palpable mass, and additional surgery are not warned of in the Instructions for Use but were risks Defendant knew or should have known yet failed to disclose to physicians and patients.

Plaintiff Martha Gottschalk

17. Plaintiff Martha Gottschalk ("Ms. Gottschalk" or "Plaintiff Gottschalk" is, and at all relevant times was, a citizen of the State of Michigan and the United States and

over the age of eighteen (18) years.

18. Ms. Gottschalk was diagnosed with ductal carcinoma in situ in her right breast on or around May 23, 2019. She underwent a right partial mastectomy with needle localization and placement of BioZorb on or around June 19, 2019 at Hills and Dales General Hospital, during which Dr. Sussan M. Bays, MD properly implanted a BioZorb.

19. Ms. Gottschalk suffered from a palpable mass, sensitivity, itching, swelling, redness of the skin, and pain at the site of the BioZorb.

20. Ms. Gottschalk had the BioZorb properly removed by Sussan M. Bays, MD at Hills and Dales General Hospital on or around September 8, 2021.

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

22. As a result of the BioZorb, Ms. Gottschalk 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, adverse local tissue reaction, disfigurement, non-absorption, palpable mass, and additional surgery are not warned of in the Instructions for Use but were risks Defendant knew or should have known yet failed to disclose to physicians and patients.

Plaintiff Sharon Hicks

23. Plaintiff Sharon Hicks ("Ms. Hicks" or "Plaintiff Hicks") is, and at all relevant times was, a citizen of the State of Virginia and the United States and over the age of eighteen

(18) years.

24. Ms. Hicks was diagnosed with ductal carcinoma in situ in her left breast around October 2017. She underwent a partial mastectomy on or around December 13, 2017 at Sentara CarePlex Hospital, during which Dr. Richard A. Hoefer properly implanted a BioZorb.

25. Ms. Hicks suffered a hard, painful lump and irritation at the site of the BioZorb device. The device failed to dissolve for almost five (5) years.

26. Ms. Hicks had the BioZorb properly removed by Dr. Mark J. Kanter at Sentara CarePlex Hospital on or around October 7, 2022.

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

28. Ms. Hicks has continued to suffer since her explant surgery. Her left breast is still hard, painful, and sensitive, and it has been riddled with infections and open wounds.

29. As a result of the BioZorb, Ms. Hicks 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, non-absorption, palpable mass, and additional surgery are not warned of in the Instructions for Use but were risks Defendant knew or should have known yet failed to disclose to physicians and patients.

Plaintiff Delores Goodson

30. Plaintiff Delores Goodson ("Ms. Goodson" or "Plaintiff Goodson") is, and at

all relevant times was, a citizen of the State of Michigan and the United States and over the age of eighteen (18) years.

31. Ms. Goodson was diagnosed with left breast invasive ductal carcinoma in May 2019. She underwent a lumpectomy on or around July 30, 2019 at Ascension St. John Hospital in Detroit, Michigan, during which Dr. Jeffrey Lane Williams properly implanted a BioZorb.

32. Ms. Goodson suffered a hard, painful lump, significant pain, fat necrosis, deformity and scarring of the skin, sensitivity, itching, swelling and reddening of the skin, spider veins on her breast, and the marker failed to dissolve.

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

34. As a result of the BioZorb, Ms. Goodson has been caused to have 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 palpable mass are not warned of on the Instructions for Use but were risks Defendant knew or should have known and failed to disclose to physicians and patients.

Defendant

35. Defendant Hologic was and is engaged in the business of designing, manufacturing, 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 thereof.

BACKGROUND AND FACTS

A. Background on BioZorb

36. The BioZorb Marker is a Class II medical device cleared by the United States Food and Drug Administration ("FDA") in February 2012 pursuant to Section 510(k) if the Food and Drug, and Cosmetic Act ("510(k)"). *See* Exhibit A (BioZorb® Marker, BioZorb® LP Marker Instructions for Use).

37. 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*.

38. 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*.

39. 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.

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

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

41. The BioZorb IFU and Defendant's marketing of the BioZorb indicate that 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.

42. Hologic also knew or should have known of clinical evidence that BioZorb can cause a hard, palpable lump, causing patient pain and discomfort.[2] 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, "[n]ormally, a lumpectomy cavity is treated for 5 fractions with low

[2] *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.

energy electrons such as 6 MeV or9MeV. 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!"[3] These risks are not mentioned in BioZorb's IFU.

44. Hologic also knew or should have known of clinical evidence that the device was causing infection, migration, necrosis, additional radiation, and additional surgery. These risks are not mentioned in BioZorb's IFU.

CAUSES OF ACTION
COUNT I
NEGLIGENCE: FAILURE TO WARN

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

46. Under Massachusetts law, "[t]he manufacturer can be held liable even ifthe product does exactly what it is supposed to do, if it does not warn of the potentialdangers inherent in a way a product is designed."[4]

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

48. Defendant knew and intended for the BioZorb Markers to be implanted

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

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

into individuals for whom the device is indicated, including Plaintiffs.

49. 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 BioZorb Marker left its control.

50. 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, otherwise known as Medical Device Reports ("MDRs"), that alleged the same injuries that were suffered by the Plaintiffs in this lawsuit.

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

52. 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 radiologist might need to use a higher energy electron therapy, which can cause scarring on the breast. The IFU also failed to adequately warn that the device could protrude from the breast creating a hole in the breast, could be expelled from the breast which can lead to drainage and infection.

53. The above warnings were known by the Defendant when Plaintiffs were implanted with BioZorb Markers.

54. As a direct and proximate result of Defendant's conduct, Plaintiffs have

suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages and economic loss in the future because a prudent person in the patient's position would have chosen not to be implanted with BioZorb if the warnings included in the relevant IFU contained the above warnings that are stronger and more clinically accurate.

55. 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

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

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

58. Plaintiffs were harmed because of the defective design of theBioZorb Marker.

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

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

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

62. In the oncological surgical market, alternative designs exist that are mechanically feasible, safer, and cost significantly less than BioZorb. For example, titanium clips that have been on the market for years carry less clinical risk to the patient. 5In fact, as one recent clinical study found: "the use of clips to mark the tumor bed is more cost-effective than the use of the BioZorb Marker which does not provide value given its relative high cost and lack of clinical advantage scientifically shown over the use of surgical clips." [6]

63. BioZorb's design poses a high gravity of danger. For example, if the 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.

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

65. 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

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

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[5] 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.

[6] 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.

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

68. 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.

69. 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.

70. 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.

71. Restatement (Second) of Torts Section 402A, comment k, does not bar the plaintiff's breach of implied warranty claim based on the defendant's presumedposition that the medical device at issue was unavoidably unsafe.[7]

72. 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.

73. 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.

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

COUNT IV
NEGLIGENCE

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

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

76. 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; 21 U.S.C. §§ 351(h), 360(i).

77. 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.

78. 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 and physicians were sold defective medical devices without knowing the true risk-benefit ratio of the BioZorb Marker.

79. 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 and physicians.

80. 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 would use the BioZorb for its intended purpose, that its 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.

81. 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 and physicians.

82. 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 and physicians.

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

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

85. Had Defendant timely reported the known risks associated with the BioZorb Marker to patients and physicians 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.

86. 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.

87. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs suffered injuries, including but not limited to physical pain, infection, subsequent surgeries, and emotional injuries.

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

89. WHEREFORE, Plaintiffs demand judgment against Defendant and seek compensatory damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

PRAYER FOR RELIEF AS TO ALL COUNTS

WHEREFORE, Plaintiffs 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: October 18, 2024.

Respectfully submitted,

/s/Christina D. Crow

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CERTIFICATE OF SERVICE

I hereby certify that on this the 18th day of October 2024, I have served a copy of the foregoing upon the following parties via electronic mail as follows:

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BioZorb® Marker, BioZorb® LP Marker

Instructions for Use

DESCRIPTION

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

INDICATIONS

The Marker is indicated for radiographic marking of sites in soft tissue. In addition, the Marker is indicated in situations where the soft tissue site needs to be marked for future medical procedures.

CONTRAINDICATIONS

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

WARNINGS

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

PLACEMENT OF MARKER

PREPARATION

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

INSERTION

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

DISPOSAL PROCEDURES

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

STORAGE

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

MRI SAFETY INFORMATION

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

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

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

HOLOGIC®

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