IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF KENTUCKY
AT PADUCAH

PATRICIA SHEMWELL, and husband, JOHN SHEMWELL,	)	
Plaintiffs,	)	No.: 5:25CV-71-BJB
vs.	)	JUDGE Benjamin Beaton
HOLOGIC, INC.,	)	MAGISTRATE_____
Defendant.	)	JURY DEMANDED

COMPLAINT

Comes now the plaintiffs, PATRICIA SHEMWELL, and husband, JOHN SHEMWELL, for complaint against the defendant complain as follows:

NATURE OF ACTION

1. Plaintiffs PATRICIA SHEMWELL, and husband JOHN SHEMWELL, bring this cause of action pursuant to 28 U.S.C. § 1332 (a) based on diversity of citizenship between the plaintiffs and the defendant, and the amount in controversy exceeds $75,000.00, exclusive of interests and costs.

PARTIES

2. The plaintiff, PATRICIA SHEMWELL, was at all times relevant a citizen and resident of Trenton, Todd County, Kentucky.

3. The plaintiff, JOHN SHEMWELL, is the husband of Plaintiff PATRICIA SHEMWELL, and was, likewise, at all times relevant a citizen

and resident of Trenton, Todd County, Kentucky.

4. The defendant, HOLOGIC, INC, was at all times relevant a foreign corporation incorporated under the laws of the State of Delaware with its principle office at: 250 Campus Drive, Marlborough, MA, 01752. Defendant HOLOGIC, INC., may be served through its registered agent: CT Corporation System, 306 W. Main Street, Suite 512, Frankfort, KY, 40601.

JURISDICTION

5. Jurisdiction of this Honorable Court is invoked pursuant to 28 U.S.C. § 1332. Venue is proper within this district pursuant to 28 U.S.C. Sections 1391(b)(e) and 1402(b) as the unlawful actions and injuries occurred in the Western District of Kentucky.

FACTUAL ALLEGATIONS

6. Defendant HOLOGIC, INC. (Hereinafter HOLOGIC) was at all times relevant a medical technology company primarily focused on women's health; it sells medical devices for diagnostics, surgery, and medical imaging. Defendant HOLOGIC designed, researched, created, developed, tested, manufactured, promoted, distributed, and sold a medical device known as a BioZorb Marker. BioZorb Markers are implantable devices, (Class II medical devices), used in soft tissue sites, including breast tissue. A BioZorb Marker is a spiral plastic device designed to be implanted into the soft tissue of the body. Six (6) titanium clips are placed along the spiral and are meant to stay in permanently. The plastic

spiral is meant to absorb into the body over the course of a year while the titanium clips are meant to stay in permanently continuing to mark a tumor excision site even after tissue has grown into the space where the spiral once was.

7. Plaintiff Patricia Shemwell, was diagnosed with breast cancer in or about 2022. Plaintiff underwent a left partial mastectomy, lumpectomy, and removal of four (4) lymph nodes at Jennie Stuart Medical Center in Hopkinsville, Christian County, Kentucky, on or about May 19, 2022. At the time of this surgery, a BioZorb LP Marker bearing lot number 21E19RJ, manufactured by Defendant Hologic, was implanted in Plaintiff.

8. In October of 2022, Plaintiff Patricia Shemwell began to have problems in her left breast including but not limited to, a hard painful knot, infection, fluid build-up, and much pain. Plaintiff sought emergency medical treatment and was diagnosed with a massive infection at the site of her prior surgery. While receiving treatment the BioZorb Marker pentrated through Plaintiff's skin.

9. On February 27, 2024, the U.S. Food and Drug Administration issued a Safety Communication (February 27 Notice) regarding BioZorb Markers.

10. The February 27 Notice advised of potential risk of serious complications when using BioZorb Markers manufactured by Defendant. This Notice was issued after receiving reports describing complications (adverse

events) with the use of the BioZorb Markers in breast tissue including, infection, fluid buildup (seroma), pain, device moving out of position (migration), device breaking through the skin (erosion), discomfort from feeling the device, rash, and other complications "possibly associated with" extended resorption time, and the need for additional medical treatment to remove the device.

11. On March 13, 2024, pursuant to FDA direction, Defendant sent out an Important Medical Device Safety Notification (Safety Notification). The Safety Notification asked health care providers to be aware of serious adverse events and risks with Defendant's BioZorb Markers.

12. On May 22, 2024, the FDA classified Defendant's communication as a Class I recall. A class I recall is a situation where there is a reasonable chance that a product will cause serious health problems or death.

13. On May 29, 2024, Plaintiff Patricita Shemwell met with her surgeon, Dr. Matthew Robinson, and discovered that she had received Defendant's BioZorb Marker and that the serious problems she suffered in October of 2022 and continuing thereafter, were in effect adverse consequences of Defendant's BioZOrb Marker.

COUNT 1

STRICT LIABILITY AND/OR FAILURE TO WARN

14. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully setforth herein.

15. At all relevant times, Defendant designed, tested, manufactured, labeled, distributed, and sold the BioZorb Marker device.

16. The BioZorb Marker was sold and implanted in Plaintiff without a substantial change in condition.

17. Defendant sold the BioZorb Marker in a defective condition in that it contained inadequate warnings regarding the unreasonably dangerous condition of the BioZorb Marker.

18. Defendant had a duty to produce a product that contained adequate warnings and had a duty to disclose the dangers and risks of the device, which Defendant knew or should have known, at the time the device, the BioZorb Marker, left Defendant's control.

19. Defendant knew, or in the exercise of ordinary care, should have known that the BioZorb device could cause the injuries suffered by Plaintiff because Defendant was aware of post marketing adverse event reports, otherwise known as Medical Device Reports (MDRs), that alleged the same or substantially similar injuries that were suffered by Plaintiff Patricia Shemwell.

20. Defendant was aware that BioZorb was designed in such a way that, following implant, it would perform in the recipient's body in a way that was not consistent with what Defendant stated in the product's instructions for use, and in a way that posed an unreasonably dangerous risk for patients.

21. The BioZorb device was not accompanied by proper

warnings and instructions to physicians and the public regarding potential adverse side effects associated with the implantation of the device and the comparative severity and duration of such adverse side effects. The BioZorb's Instructions for Use (IFU) failed to include warnings that the BioZorb device may take several years to (and in some cases, may never) dissolve in the breast and need to be surgically removed. The warnings also failed to include information that a radiologist might need to use a higher energy electron therapy which could cause scarring on the breast.

The IFUs also failed to warn that the adverse side effects pose a significant risk of subsequent surgical treatment to remove the device and/or otherwise pose a risk of clinically significant sequelae including mass formation, infectious buildup, scarring, fat necrosis, adverse tissue reaction, failure to absorb, migration of the device, and extrusion of the device from breast skin and tissue.

22. The above clinically significant issues and their association with the BioZorb device were known or knowable by the defendant at the time the device was implanted into Plaintiff, which necessitated warnings, but Defendant failed to place such warnings in the IFU.

23. Had Plaintiff been warned of the serious adverse effects of this device, she would not have consented to this implant.

24. Defendant's sales representatives failed to disclose to physicians the risks of BioZorb, which caused physicians to recommend to patients the BioZorb device without fully knowing the risk and dangers of this device.

25. As a direct and proximate result of Defendant's conduct, Plaintiff has suffered serious physical injury, including disfigurement, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

COUNT II

STRICT LIABILITY AND/OR NEGLIGENT DESIGN DEFECT

26. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully setforth herein.

27. At all relevant times, Defendant designed, researched, developed, inspected, tested, manufactured, labeled, packaged, distributed, supplied, and sold the BioZorb Marker device.

28. The design of the BioZorb Marker was defective and unreasonably dangerous because of its design aspects, including, but not limited to, its shape, surface, texture, material, and integration of parts. The design aspects of the BioZorb Marker could have been feasibly changed to make the device less harmful and not unreasonably dangerous.

29. There are technologically feasible and practical alternative designs that would have reduced or prevented Plaintiff's harm.

30. In the oncological surgical market, alternative designs exist that are mechanically feasible, safer, and cost significantly less that BioZorb. (Titanium clips carry less clinical risk to the patient.)

31. The BioZorb's design poses a danger beyond that of the

reasonable consumer's knowledge. The risks of the design of the BioZorb device outweigh the benefits of its design aspects.

32. The design of the BioZorb device was a substantial factor in causing harm to Plaintiff.

33. As a direct and proximate result of Defendant's conduct, Plaintiff has suffered serious physical injury, including disfigurement, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

COUNT III

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

34. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully setforth herein.

35. At all relevant times, Defendant designed, tested, manufactured, labeled, distributed, and sold the BioZorb Marker device.

36. Defendant impliedly warranted that the BioZorb Marker was safe, merchantable, and fit for the ordinary purposes for which said product was to be used.

37. The BioZorb device was not of merchantable quality or safe and fit for its intended use, because the product was and is unreasonably dangerous and unfit for the ordinary purposes for which it was used.

38. Further, Defendant marketed BioZorb tp fill in space in

breast tissue, to improve cosmetic outcomes after procedures, and to prove radiotherapy guidance, all in direct contravention of the IFU cleared by the FDA, of which Defendant knew or should have known.

39. As a direct and proximate result of Defendant's conduct, Plaintiff has suffered serious physical injury, including disfigurement, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

COUNT IV

NEGLIGENCE

40. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully setforth herein.

41. At all relevant times, Defendant designed, tested, manufactured, labeled, distributed, and sold the BioZorb Marker device.

42. Under federal and state law and regulations, Defendant was under a continuing duty to test and monitor the BioZorb device as well as their component parts, design, and manufacturing processes after premarket approval. The duties included establishing and validating its quality control systems and product suppliers, testing the device design, and investigating and reporting to the FDA any complaints about the device's performance and any malfunctions of which Defendant became aware and that are or may be attributable to the BioZorb device. See 21 C.F.R. Part 803; 21 C.F.R. Part 814; 21 C.F.R. Part

820; 21 U.S.C. §§351 (h), 360i.

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

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

45. Defendant knew or should have known that the risk of the BioZorb device was different than what was in the IFU and communicated such information to patients, physicians, hospitals and the general public.

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

47. It was readily foreseeable to Defendant that Plaintiff 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 Plaintiff and her physician and hospitals would use the medical device for its intended purpose, that their intended

use would pose a substantial health risk to Plaintiff, and that Plaintiff, and the medical community would rely of Defendant's representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant the device.

48. Under the same or similar circumstances, a reasonable manufacturer would have warned through an appropriate channel of the danger and reported risks of BioZorb to patients, physicians, hospitals, and the public. With adequate testing of the BioZorb device, evidence of the device's risks, rate of occurrence, and extent of harm regarding each risk would have been discovered and could have been communicated to patients, physicians, and hospitals.

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

50. 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 this product or an alternative product, Plaintiff would not have been implanted with this product.

51. 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.

52. Defendant owes a duty of care to Plaintiff which it

breached causing damages to Plaintiff.

53. As a direct and proximate result of Defendant's conduct, Plaintiff has suffered serious physical injury, including disfigurement, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

54. Plaintiff Patricia Shemwell seeks damages from Defendant to include but, not limited to, compensatory damages, punitive, lost income, attorney fees and costs.

55. Plaintiff John Shemwell seeks damages for loss of consortium.

WHEREFORE, PLAINTIFFS pray for the following relief:

A. That service of process issue as to the defendant as set forth in Rule 4 of the Federal Rules of Civil Procedure;

B. That Plaintiff Patricia Shemwell recover compensatory damages greater than $75,000.00, 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 amounts to be proven at trial;

C. That Plaintiff John Shemwell recover loss of consortium for his wife's injuries and disabilities;

D. That Plaintiff Patricia Shemwell punitive damages from this Defendant;

E. That Plaintiffs recover prejudgment and post judgment

interest and costs of this action;

F. That the court award Plaintiff Patricia Shemwell such other, further, general and different relief to which she may show herself entitled.

G. That a jury be empaneled to try this cause.

Respectfully submitted,

/s/ Stephanie Ritchie-Mize
STEPHANIE RITCHIE-MIZE
Attorney for Plaintiff
133 Franklin Street
Clarksville, TN 37040
telephone: (931) 648-9400
facsimile: (931) 648-8616
e-mail:stephanie@rmblawofficecom