March, 2026

Introduction:
This handout is intended for clinicians caring for patients that have had BioZorb® or BioZorb® LP breast markers implanted including F0202 (15420045513983), F0203 (15420045513990), F0303 (15420045514003), F0304 (15420045514010), F0404 (15420045514058), F0405 (15420045514065), F0221 (15420045514027), F0231 (15420045514034), F0331 (15420045514041). This document provides a brief background on the breast markers and focuses on the evaluation and management of symptoms and adverse events.

This is not a newly initiated recall, but an updated resource for clinicians who have previously used Biozorb® breast markers or are currently caring for patients implanted with BioZorb markers. Hologic recalled and removed from market BioZorb and BioZorb LP on October 24, 2024; therefore, all patients with these implants have had them in place for at least one year. The original notification that was distributed as a part of the previous recall can be found as an appendix to this resource.

Clinicians should use this document in conjunction with their own clinical judgment and institutional protocols when assessing patient complaints, determining appropriate workup, monitoring, and considering treatment options. For details regarding the original notification and recall, refer to the section at the end of this handout titled “Please take the Following Steps”.

1. What is the purpose of this resource?

This document is intended to support clinicians in the management and understanding of adverse events in patients who have an implanted BioZorb or BioZorb LP marker. It is also to educate providers who may be less familiar with BioZorb. This document will be posted on Hologic’s website, sent to all BioZorb customer sites, and will be available to representatives.

2. What is BioZorb?

The BioZorb Marker made by Hologic (previously Focal Therapeutics), is an implantable radiographic marker used to mark soft tissues (such as breast tissue) for future medical procedures. The device has two components: a permanent component which is made of titanium metal clips and a resorbable spacer component which is made of a biocompatible polylactic acid (PLA) material that is intended to be resorbed in the body during a period of up to 1 year or longer. It is meant for one-time use.

3. Is BioZorb commercially available?

No, Hologic recalled and removed BioZorb Marker and BioZorb LP Marker from the market on October 24, 2024. No new BioZorb Markers have been distributed since this time. As a result, Hologic believes that all patients implanted with a BioZorb marker will have had their marker implanted prior to this date, and all devices have been in place for one year or more.

4. What does BioZorb look like?

There are two designs, a spiral framework designed to fit larger surgical cavities, and low-profile framework designed for smaller surgical cavities. All designs consist of six titanium marker clips with a bioabsorbable PLA spacer framework. Profiles and sizes per marketed SKU are shown in the table below.

BioZorb Profile	SKU	Length (cm)	Width (cm)
BioZorb Marker (Standard Spiral)	F0202	2.0	2.0
	F0203	3.0	2.0
	F0303	3.0	3.0
	F0304	4.0	3.0
	F0404	4.0	4.0
	F0405	5.0	4.0

BioZorb Profile	SKU	Length (cm)	Width (cm)	Height (cm)
BioZorb LP (Low Profile)	F0221	2.0	2.0	1.0
	F0231	3.0	2.0	1.0
	F0331	3.0	3.0	1.0

5. Is BioZorb marker palpable after implantation?
Yes, in some instances the BioZorb marker can be palpable externally after implantation.

Patients may be unaware of the marker or report feeling a hard lump. Clinically, it may be challenging to distinguish the marker from scar tissue. In any patient with a history of breast conserving surgery or lumpectomy presenting with a palpable lump, consider the presence of a BioZorb marker as part of your differential diagnosis.

6. How long does it take for the BioZorb spacer component to be absorbed?
The BioZorb implant is designed for the spacer component to gradually resorb over time, while the titanium clips permanently remain inert in the body.

The device's Instructions for Use state that complete resorption of the spacer material may take up to one or more years.

Post-market clinical experience has shown that the spacer component may persist and has been observed in some patients for 5 or more years after implantation.

The rate of resorption is variable and may be influenced by factors such as individual patient biology, local tissue environment, prior radiation therapy, and the size or type of implant used.

7. What patient complaints have been reported with BioZorb?
Patients have reported complaints associated with the BioZorb implant, such as pain, infection, device palpability, swelling, redness or erythema, failure to reabsorb, seroma, device erosion, breast deformity, sleep dysfunction, delayed wound healing, scar tissue/fibrosis, itching, migration, limited mobility, hematoma, fat necrosis, lymphedema, adverse reactions to device material, and calcification.

Hologic received a total of 532 complaint reports for the device through October 30, 2025. These reports were filed by patients or clinicians and represent individual complaint events. They do not necessarily represent unique patients because a single patient may report more than one symptom or adverse event.

Across all reports, the number of individual symptoms or adverse events ranged from approximately 6 (for Calcifications) to 349 (for Pain) out of 91,531 devices that were distributed. We do not have verified data on the number of devices implanted.

8. Are all reported complaints definitely related to BioZorb?
Published literature indicates that BioZorb implantation and standard lumpectomy procedures share common postoperative complications, such as infection, seroma, and pain [1-7]. Some adverse events observed in BioZorb patients may result from the lumpectomy itself, post-lumpectomy radiation, the device, or a combination of these factors. However, adverse events such as migration and erosion have been reported to be

device-specific and can occur independently of the surgical procedure or radiation therapy.

Differentiating device-related from procedure-related complaints requires a thorough clinical assessment, taking into account timing of symptom onset, imaging findings, clinical findings, and overall clinical presentation.

9. What is the expected timing of symptoms onset relative to BioZorb implantation?
The timing of symptom onset is variable and not well defined in available data. Clinicians have reported symptoms developing up to a year or more after implantation.

10. Are there concerning symptoms or findings providers should be aware of?
While many of these symptoms are part of the typical healing and recovery process after breast surgery or radiation and could persist for long periods of time, certain findings may warrant further clinical investigation or intervention beyond conservative management. They include:

- Device migration with erosion
- Device extrusion
- Infection with or without abscess around implant site
- Adverse reactions to device materials
- Non-healing wound
- Pain for chronic periods
- Symptoms significantly affecting quality of life or causing patient distress
- Symptoms unresponsive to conservative management
- Device interferes with imaging quality or evaluation

Clinicians are encouraged to investigate all complaints regardless of temporal connection to implantation, especially those that are chronic, severe, of unexpected late onset, or impact the patient's quality of life. Ongoing monitoring for any change in symptoms is important in all patients, and timely evaluation and management should be considered when appropriate.

Report suspected device complaints and/or adverse events to Hologic and the FDA (contact details below).

11. Are there unique management protocols for patients with BioZorb implants?
No. There are no unique management protocols required specifically for BioZorb implants beyond the standard of care. Feedback from breast surgical oncologists and radiologists indicates that standard clinical and foreign body management protocols should be followed for all patients presenting with complaints, regardless of the presence of a BioZorb implant.

12. How should patients with comorbidities be managed?
No BioZorb-specific modifications are necessary. Patients with comorbidities should be managed according to standard care protocols.

13. Is device explantation an option for patients experiencing severe or concerning symptoms?
Yes, device explantation is an option for patients experiencing severe or concerning symptoms listed above. Device explantation should be considered following an informed discussion with the patient about the risks and benefits of device removal versus leaving the device in place. The decision should also be guided by standard of care foreign body management protocols in place at your institution.

Clinicians should be aware that device removal may become more technically challenging over time as the spacer material absorbs, this potential challenge should be included in risk-benefit discussions with patients.

14. Does device migration require explantation or any other treatment?
No, device migration alone is not an indication for explantation since the risks associated with removal often outweigh the benefits in patients without complications. Most patients with migration can be managed conservatively with observation and reassurance. Surgical intervention for device migration should be considered for patients with complications such as device erosion through the skin, towards the chest wall, or cases where migration leads to safety concerns or interferes with follow-up imaging quality.

15. How should clinicians address patient concerns about prolonged device palpability?
Post-market reports show that prolonged device palpability may cause patient anxiety and even prompt requests for device removal. In these cases, clinicians should consider patient counseling and education as the first line of care. Ultimately, the decision to proceed with explantation should be made collaboratively with the patient following a discussion on the potential risks and benefits associated with device removal surgery versus leaving the device in place.

16. What are the risks associated with device explantation?
Clinical feedback from experienced breast surgeons suggests that while explantation is possible, it carries risks such as anesthetic complications, irreversible cosmetic changes, and delayed healing particularly when the affected breast tissue has been irradiated.

Clinicians should be aware and communicate to their patients that device removal may not resolve symptoms, especially those that may be related to prior surgery or radiation rather than the device itself.

17. Where can providers get help or report new complaints?
Patients who have a problem with their device should report it through FDA's MedWatch Voluntary Reporting Form. Healthcare professionals employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities. Patients and healthcare professionals can email any questions to FDA's Division of Industry and Consumer Education at DICE@fda.hhs.gov or call 800-638-2041 or 301-796-7100.

Additionally, if you experience any suspected device complaints and/or adverse events please contact BreastHealth.Support@hologic.com, call 1-877-371-4372, or visit https://www.hologic.com/product-feedback.

18. How can I communicate with the device manufacturer?
Please email BreastHealth.Support@Hologic.com with questions or concerns.

Please take the Following Steps:
1. Refer to the Customer Response Form Instructions provided alongside this handout to confirm receipt of this communication. Hologic has partnered with IQVIA for distribution and acknowledgement of this notice.
2. Confirming receipt of this communication may be completed using the online Customer Response Portal. The original recall notification letter can also be found on the portal for reference.
3. If no response is received to this letter, IQVIA will conduct follow-up communications to confirm receipt.
4. Forward this notice to anyone in your facility that needs to be informed.
5. If you have any Biozorb product still in your possession, please submit the details through the acknowledgement portal and Hologic will facilitate return of these devices.
6. Post a copy of this notice in a visible area for awareness and keep a copy for your records.

Thank you for your attention and cooperation.
Sincerely,

Tim Crowley
Director, Post Market Quality Engineering

Reference List

1. Kwee, E., et al., *Neuropathic Pain Following Breast-conserving Surgery: A Systematic Review and Meta-Analysis*. JPRAS Open, 2024. **42**: p. 48-57.
2. Admoun, C. and H. Mayrovitz, *Choosing Mastectomy vs. Lumpectomy-With-Radiation: Experiences of Breast Cancer Survivors*. Cureus, 2021. **13**(10): p. e18433.
3. Brewer, V.H., et al., *Risk factor analysis for breast cellulitis complicating breast conservation therapy*. Clin Infect Dis, 2000. **31**(3): p. 654-9.
4. Chen, V.E., et al., *Post-mastectomy and post-breast conservation surgery pain syndrome: a review of etiologies, risk prediction, and trends in management*. Transl Cancer Res, 2020. **9**(Suppl 1): p. S77-S85.
5. Knowles, S., et al., *An alternative to standard lumpectomy: a 5-year case series review of oncoplastic breast surgery outcomes in a Canadian setting*. Can J Surg, 2020. **63**(1): p. E46-E51.
6. Adesunkanmi, A.O., et al., *Oncoplastic Breast-Conserving Surgery in African Women: A Systematic Review*. JCO Glob Oncol, 2024. **10**: p. e2300460.
7. Sfarad, H.K. and T.M. Allweis, Postoperative Complications Following Lumpectomy With Intraoperative X-Ray Radiation Therapy: A Retrospective Comparative Study. Clin Breast Cancer, 2024. 24(3): p. 237-242.
8. Smilowitz, N.R. and J.S. Berger, *Perioperative Cardiovascular Risk Assessment and Management for Noncardiac Surgery: A Review*. JAMA, 2020. **324**(3): p. 279-290.
9. Li, G., et al., *Epidemiology of anesthesia-related mortality in the United States, 1999-2005*. Anesthesiology, 2009. **110**(4): p. 759-65.
10. Neal, C.H., et al., *Imaging of breast cancer-related changes after surgical therapy*. AJR Am J Roentgenol, 2014. **202**(2): p. 262-72.
11. Clough, K.B., et al., *Improving breast cancer surgery: a classification and quadrant per quadrant atlas for oncoplastic surgery*. Ann Surg Oncol, 2010. **17**(5): p. 1375-91.
12. Wei, J., L. Meng, X. Hou, C. Qu, B. Wang, Y. Xin, and X. Jiang. 2019. 'Radiation-induced skin reactions: mechanism and treatment', *Cancer Manag Res*, 11: 167-77.
13. Karami, R.A., O.A. Ghanem, and A.E. Ibrahim, *Radiotherapy and breast reconstruction: a narrative review*. Annals of Breast Surgery, 2020. **4**.