OBJECTIVE
To provide radiologists with greater familiarity with BioZorb’s presentation on mammography.

BACKGROUND
As mammography allows for earlier detection of breast cancer, more women are opting for partial mastectomy or lumpectomy with adjuvant radiation therapy. Breast conserving therapy (BCT) is becoming the standard treatment for women with early stage breast cancer. The goal of BCT is full resection of the tumor while protecting healthy tissue and reducing patient morbidity. BCT is aided by oncoplastic surgical techniques, the combination of tumor removal and immediate reconstruction of the ipsilateral breast. This trend is expected to continue.

To preserve the breast’s original shape and contour, oncoplastic techniques include tissue mobilization, additional dissecting planes, and tunneling; however, maintaining volume can be challenging. Such large-scale tissue rearrangement also presents challenges for post-surgery radiation planning and long-term follow-up. Even without these new techniques, identifying the tumor site with traditional methods, (eg, seroma cavity, incision, surgical clips) was not always reliable and could be confounding long term. Inexact identification of the tumor bed can lead to overly large boost volumes, increasing toxicity for healthy tissue and negatively affecting cosmesis—with up to 30% of patients reporting suboptimal outcomes. It can also limit the opportunities for new options in radiation therapy, such as intensity-modulated radiation therapy (IMRT).

To help address these issues, oncoplastic breast cancer surgeons at our center have begun placing a novel 3D bioabsorbable implant (BioZorb, Focal Therapeutics, Inc.)

METHODS
Retrospective review of follow-up mammograms in 28 consecutive lumpectomy cases utilizing BioZorb from two oncoplastic surgeons at the Lynn Women’s Health & Wellness Institute, in Boca Raton, Florida. Surgeries were conducted between 2015 and 2017.

In total, 28 cases were reviewed for this report. Months from surgery ranged from 4 to 18, average 10 months. Data presented here reflects an additional case review since abstract submission.

RESULTS
The implant was rated as visible on mammography in all cases and there was no interference in interpretation in the 28 cases reviewed.

• No artifacts were found.
• Calcifications were seen at the surgical site in only one patient.
• Two seromas were visible.
• There was no evidence of complications, device migration, or extrusion.

INTRODUCING BIOZORB®
BioZorb is an FDA-cleared bioabsorbable surgical implant with 6 titanium clips suspended in a fixed spiral framework made of polylactic acid, which is sutured directly in the excised tumor bed (Fig. 1).

• BioZorb framework typically absorbs over 12–18 months, leaving six titanium clips to identify location of the tumor bed in three dimensions for long-term follow-up.
• Studies show it is easily identifiable on subsequent imaging years after surgery. In partial breast reconstruction, the 3D marker provides constructive support which aids in:
  • Immediate volume replacement
  • Long-term tissue in-growth
  • Maintains breast contour
  • Improves cosmetic outcome
• For post-surgical treatment planning, radiation oncologists report more consistent and easier identification of the surgical margins regardless of surgical technique.
• Use of BioZorb leads to a reduction in radiation treatment volume for boost and accelerated partial breast irradiation.
• One study reported planned treatment volumes were reduced by 55%, with a 47% reduction in brachytherapy catheters.
• For long-term imaging, breast imagers report improved visualization of the excision site which allows for attention to the area at greatest recurrence risk.
• Subsequent mammograms show minimal fibrosis and scarring.

• In a study from New Zealand, 3-year mammograms showed no artifact and minimal fibrosis with normal regrowth of tissue.

BioZorb is available in multiple sizes.
Use In Lumpectomy
With/Without BioZorb
Figure 3. A 75-year-old woman was found to have bilateral breast cancer.
The right breast had a 1.4 cm invasive lobular carcinoma at 12 o’clock, 9 cm from the nipple, and a 1 cm invasive ductal carcinoma was found in the left breast. BioZorb was placed in the lumpectomy site on the right as it was deeply positioned. Standard surgical hemoclips were placed on the left as the lesion was more superficially located and a BioZorb may have been palpable if utilized.

12 Months After Surgery
Figure 4. An 83-year-old woman was found to have a 5 mm invasive ductal carcinoma 1 o’clock in the right breast. A 2x3 cm BioZorb was placed at the time of lumpectomy. Minimal distortion is seen at mammography performed 12 months after surgery.

COMMENTS & CONCLUSIONS
In this review of 28 breast cancer lumpectomy cases
- Mammographic imaging of patients implanted with the 3D bioabsorbable marker was not adversely affected
- Implant assisted with identification of the surgical site without introducing any artifact or diagnostic interference
- Scarring at the surgical site was minimal or mild in nearly 75% of cases
- Contour of the breast had no or minimal deformity in ~86% of cases

This 3D bioabsorbable implant permanently delineates surgical site location for more effective radiologic long-term follow-up of breast cancer patients. While the identified cases may be unique, they represent typical findings that breast imagers can expect to see as more patients ask for oncoplastic surgery and more breast surgeons make use of this implant.

REFERENCES

EDITORIAL ASSISTANCE
Editorial assistance was provided by Janice T. Radak of Dowling & Dennis.