Surgical Marker Provides New Tool for Breast Cancer Patients

Focal Therapeutics

Unique Three-Dimensional Device Is Praised by Surgeons and Radiation Oncologists for Clinical Utility and Ease of Use

Focal Therapeutics announced that its BioZorb three-dimensional tissue marker has now been successfully used in over 100 patients - marking a significant milestone for the company and the field of post-surgical radiation treatment for breast cancer.

BioZorb is an innovative three-dimensional device that is designed to clearly and accurately identify the surgical site of tumor removal. The device, which is placed by surgeons, enables clinicians to easily target the surgical site for radiation treatment and follow up. This approach, which is applicable to various kinds of radiation treatment, assists with radiation treatment planning, patient positioning during treatment, and long-term follow-up.

"This device represents a significant advancement towards the precise delivery of radiation treatment," said Robert R. Kuske, Jr., M.D., an internationally known radiation oncologist who is using BioZorb in his medical practice at Arizona Breast Cancer Specialists. "It gives us a reliable, visible marker of exactly where the tumor started in three dimensions to target with radiotherapy, which has never been available before. With the BioZorb, we know exactly where to aim the dose, so we can irradiate a smaller amount of tissue. That gives us the ability to get better results with less risk to healthy tissues nearby."

BioZorb's unique open-spiral design incorporates six permanent titanium clips in a three-dimensional, fixed arrangement, which provides specific "landmarks" of the surgical site for treatment planning, delivery, and follow-up. The device, which has been used successfully in both the U.S. and New Zealand, is made of a bioabsorbable material. That feature allows it to be absorbed by the patient's body over time rather than requiring a surgeon to remove it at a later date.

"The learning curve for placing this device is straightforward, and it fit smoothly into my routine from day one. I've been using it in most of my patients," said Michael J. Cross, M.D., F.A.C.S., a surgical oncologist who was the first U.S. surgeon to place the BioZorb tissue marker. "The best thing about using it is the confidence we have that our patient's tumor site will be well-defined for the radiation oncologist. Instead of having surgical clips that can migrate to a different area, the BioZorb is sutured directly to the tissues surrounding the cavity where the tumor was removed. That way, the marker stays in the right spot and enables more precise targeting of the radiation after surgery."

The BioZorb tissue marker was developed by Focal Therapeutics, whose

management team and investors include three medical pioneers: George D. Hermann, the CEO; Gail S. Lebovic, M.A., M.D., F.A.C.S., the Chief Medical Officer; and investor Thomas J. Fogarty, M.D. They have played instrumental roles in the development of numerous commercially successful medical devices in women's healthcare, including the Mammotome® breast biopsy technology (Devicor Medical Products, Inc.); the MammoPad® Breast Cushion (Hologic); and the SAVI® Applicator for radiation therapy (Cianna Medical). A breast surgeon, Dr. Lebovic is also a leading innovator in oncoplastic breast surgical techniques.

BioZorb has received 510(k) clearance from the U.S. Food and Drug Administration. The device is available in a range of sizes to accommodate a variety of clinical situations.

Source URL (retrieved on *12/26/2014 - 12:35pm*):
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