

# CLINICAL UPDATE



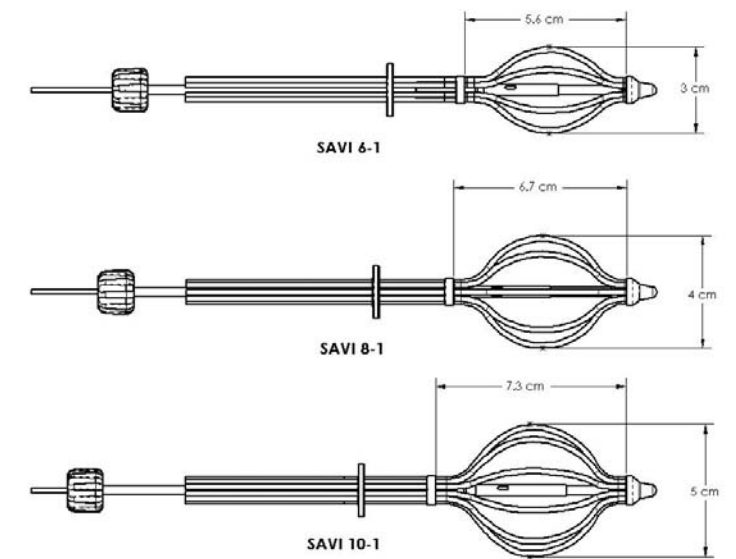
## Surgical Considerations for the Strut-Adjusted Volume Implant (SAVI™) Breast Brachytherapy Device

Victor J. Zannis, MD, FACS

Irradiation after breast conservation therapy for breast cancer is now a routine practice to minimize local recurrence. The need for traditional whole-breast radiation over a 6 to 7 week period has been challenged by the evolution of accelerated courses of therapy that, at least initially, are allowing shorter (5 day) periods of applications, lesser toxicities, and equivalent local recurrence rates. Accelerated partial breast irradiation (APBI) techniques include brachytherapy, where a radioactive source is placed inside or next to the area to be treated, or external beam radiotherapy, where radiation is applied externally.

Breast brachytherapy began with the use of multiple catheters being inserted into the breast lumpectomy walls, creating multiple localized accessible conduits for a high dose <sup>192</sup>Ir radiation pellet sitting at the leading edge of an applicator cable. Because of the complexity of this multi-catheter technique, a balloon brachytherapy catheter device (MammoSite®) (Hologic, Inc., Bedford, MA) was invented to allow a simpler alternative for the application of the high dose radiation. In spite of its simplicity in placement and radiation delivery, the MammoSite has limitations, including the risk of toxic skin dosages if the skin-to-balloon distance is less than 5 to 7 mm secondary to the lumpectomy cavity being superficial in the breast.

In light of this history, the SAVI breast brachytherapy device was created to maintain a simple design and placement procedure, to have fewer anatomic constraints, and to allow greater flexibility in



**Figure 2** Three sizes of the SAVI applicator

treatment planning. (Figure 1) As a single-entry expandable bundle of catheters, this device blends the adjustable dosimetry of multi-catheter therapy with the simple lumpectomy cavity indwelling design of a balloon catheter. Additionally, the SAVI is made in three different sizes to accommodate a broad range of cavity volumes. (Figure 2)

### Patient Selection:

The use of breast brachytherapy devices is presently indicated for patients with invasive or in-situ neoplasms that are  $\leq 3$  cm in diameter.<sup>1-3</sup> Patients in whom larger tumor resections are performed, especially when using oncoplastic techniques that transfer tissue within the breast, are typically not candidates. These patients usually have tissue cavities that are non-conforming to the indwelling device and, additionally, the accuracy of tissue targeting is compromised.

Patients with breast prostheses may be treated with SAVI brachytherapy if the lumpectomy cavity can



**Figure 1** SAVI Applicator



Cianna Medical, Inc., 6 Journey, Suite 125, Aliso Viejo, California 92656  
866.920.9444 • 949.360.0059 • Fax 949.297.4527  
www.ciannamedical.com

Customer Care: info@ciannamedical.com

©2008 Cianna Medical, Inc. All rights reserved. Patents Pending.  
Cianna Medical and SAVI are trademarks of Cianna Medical, Inc.

accommodate the device. The presence of a prosthesis adjacent to a brachytherapy catheter is of no significance when delivering radiation.

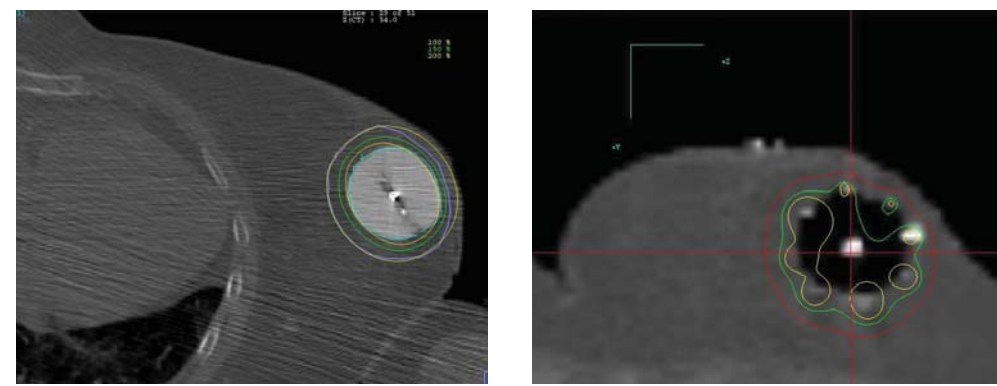
### Breast Lumpectomy Cavity Requirements:

Because the SAVI applicator is designed to sit within a cavity, the surgeon optimizes the success of brachytherapy by leaving an appropriate lumpectomy cavity at the time of surgery. Though routinely approximated in prior years, the walls of the lumpectomy cavity should not be approximated to close dead space.

While creating lumpectomy cavities with eccentric shapes can be problematic for spherical balloon devices, the SAVI can conform to elliptically-shaped and asymmetrical cavities. (Figure 3) Additionally, superficial breast tumors

close to the skin may disqualify the patient or require excision of a thinned skin layer with elliptical incisions placed directly over the tumor area. In contrast, the SAVI allows superficial cavities to be treated, so even tunneling dissections from more cosmetic incisions may be performed and are many times preferred. (Figure 4)

Planning a cosmetic skin incision and parenchymal dissection is facilitated by mapping the location of the tumor prior to surgery. Mapping is performed with image-guidance, either mammographically or with ultrasound (intraoperative ultrasound is now a common procedure in many surgical centers). Cosmetic incisions, such as circumferentially-shaped incisions placed close



**Figure 4** Left: Balloon with inadequate cavity to skin separation. Right: SAVI 8-1 in same cavity limits skin dose to <100%.

to or at the areolar edge, may then be used. These peri-areolar incision sites also fall within skin-sparing mastectomy incisions if a follow-up mastectomy is later found to be necessary.

### SAVI Device Insertion Technique:

The optimal time to place a SAVI device is postoperatively, when the final pathology results are known and the patient is confirmed as a brachytherapy candidate. If performed postoperatively, the procedure requires image-guidance for device insertion, specifically using ultrasound. If the physician is not experienced with ultrasound-guided percutaneous methods, an alternative is to insert and leave a temporary balloon catheter indwelling at the time of lumpectomy surgery, which is then exchanged for a SAVI device; this is typically done without ultrasound-guidance in the postoperative period after the pathology results are finalized. Both the intraoperative temporary balloon catheter placement and the postoperative SAVI device insertion procedures are described below.

#### Open Cavity Temporary Balloon Catheter Placement

**Technique:** This method places a temporary balloon catheter at the time of lumpectomy, with a Cavity Evaluation Device (CED) (Hologic, Inc., Bedford, MA). The catheter is placed within the lumpectomy cavity after all tissue specimens have been removed from the breast. (Metal clipping of the lumpectomy wall for future radiographic site identification may cause potential clip damage to the catheter balloon; therefore, if clipping is desired, embedding the clip in the wall of the cavity is an option and has worked well in the author's experience.) Hemostasis is then secured and the cavity is assessed for size and symmetry. (If the cavity is longer in one direction, the balloon catheter will be inserted into the cavity through the wall of the longest axis, which allows the walls of the asymmetric cavity to later conform better to the elliptical configuration of the SAVI device.)

A 1 cm incision is then made, preferably laterally or inferiorly away from the original incision, and a trocar (supplied in the provided catheter insertion kit) is used to create a tract into the lumpectomy cavity. After the trocar is removed, the deflated catheter is inserted through the tract and inflated with saline to an appropriate volume, confirming an adequate fit of the balloon within the cavity. The balloon is deflated one last time to allow efficient and safe subcutaneous tissue closure



**Figure 5** Top: 8mm trocar is placed through 1cm incision creating a tract to lumpectomy cavity; Center: SAVI inserted following the tract created by the trocar; Bottom: Clockwise rotation of the expansion tool expands the peripheral catheters, conforming to the cavity.

with interrupted sutures, avoiding injury to the balloon catheter. Because of its inherent stiffness, monofilament suture material is not utilized during subcutaneous tissue closure to avoid potential injury to the inflated balloon. Skin closure is accomplished in the surgeon's usual manner and the balloon is re-inflated with saline. The catheter entrance site is not sutured (to allow further seroma drainage) and is dressed with sterile gauze. Postoperatively, when appropriate, the temporary balloon catheter may be exchanged for a SAVI device.

#### Postoperative Ultrasound-guided Technique:

The postoperative ultrasound-guided implantation technique is performed in the surgeon's office or outpatient center after the final pathology report confirms the candidacy of the patient for brachytherapy. This method involves sonographic visualization of the breast to size the lumpectomy cavity and, if the cavity is asymmetrical, to determine the long axis. (Because of the SAVI device's elliptical form, asymmetrical cavities will conform to the SAVI better if the device is inserted down the long axis.)

After cavity size assessment, one of the three SAVI size choices (6-1, 8-1, or 10-1) is selected with the aid of the SAVI Size Reference Chart provided by the manufacturer. After skin and subcutaneous tissue infiltration with lidocaine solution, a sharp metal trocar provided by the manufacturer is inserted with ultrasound guidance into the lumpectomy cavity through a 1 cm skin incision made in the lateral or inferior breast, away from the original incision, and in line with the long axis of the cavity. The cavity seroma decompresses when the trocar is removed, and the non-expanded SAVI device is inserted into the cavity through the trocar tract. The tip of the SAVI device is pushed through the cavity to abut the opposite wall, and then expanded with clockwise turning

of the expansion tool that is provided by the manufacturer. (Figure 5) An audible click is noted when the device reaches its maximum expansion. The catheter entrance site is not sutured (to allow further seroma drainage) and is dressed with sterile gauze.

An optional procedural step in the above protocol is to insert a SAVI Preparation Device (SPD) (Cianna Medical Inc., Aliso Viejo, CA) balloon catheter immediately prior to the SAVI device insertion. The SPD is inserted into the cavity through the trocar tract and inflated with 20 to 60 cc of saline to expand the lumpectomy cavity, thereby breaking up any fibrinous adhesions and thus allowing the struts of the SAVI device to more easily expand and conform to the cavity walls.

The SAVI device is removed at the completion of radiation by collapsing the device with the same expansion tool, turning now in a counter-clockwise direction while periodically rotating the entire device. The collapsed device is then retracted gently out of the breast and discarded. Topical anesthetic is optional but not required as there is minimal discomfort with device removal. The skin catheter site is not sutured closed thus allowing seroma drainage during healing.

### Clinical Experience:

Initial clinical experience has shown that the SAVI device is easy to place and remove, and that treatment was unaffected by seroma.<sup>4</sup> Studies have also found that the multiple struts of SAVI allow for dose-contouring, thereby reducing toxicity secondary to irradiation of normal tissues, including skin and chest wall.<sup>4-6</sup>

### Summary:

The SAVI device's single-entry simplicity and its ability to apply asymmetric radiation dosing to minimize skin and chest wall toxicity and treat elongated as well as spherical lumpectomy cavities makes SAVI a valuable addition to the tools conventionally used for breast brachytherapy. These product qualities allow more women with breast cancer to have the option of accelerated partial breast irradiation.

### References:

1. Arthur D, Vicini F, Kuske R, et al. Accelerated partial breast irradiation: An updated report from the American Brachytherapy Society. *Brachytherapy* 1(4):184-190, 2002.
2. The American Society of Breast Surgeons consensus statement for accelerated partial breast irradiation (revised Dec. 8, 2005). [www.breastsurgeons.org/apbi](http://www.breastsurgeons.org/apbi).
3. NSABP Clinical Trials Overview, Protocol B-39/RTOG. [www.nsabp.pitt.edu/B-39](http://www.nsabp.pitt.edu/B-39)
4. Gurdalli S, Kuske R, Quiet C. New Single-Entry, Multi-Catheter Breast Brachytherapy Device: Initial Clinical Experience and Dosimetric Performance. Poster session presented at the American Society for Therapeutic Radiology and Oncology Annual Meeting, Oct 28-Nov 1, 2007
5. Mantz C, Brown A, et al. Favorable Acute Toxicity Utilizing SAVI Breast Brachytherapy Device: Initial Results of a Phase II Trial. Poster session presented at the annual Miami Breast Cancer Conference, Feb 20-23, 2008.
6. Gurdalli S, Kuske R, Quiet C. Dosimetric Characteristics of SAVI™, a New Single-Entry, Multi-Catheter Breast Brachytherapy Device. Poster session presented at the American Brachytherapy Society Annual Meeting, Apr 29-May 1, 2007.