Clinical Orientation for the SAVI® Applicator
The SAVI® Applicator

Greater flexibility

*Treats the widest array of cavity & breast sizes*

Enhanced performance

*Eliminates skin spacing restrictions*

Better outcomes

*Lowers toxicity & risk of persistent seroma*

Exceptional precision

*Sculpt dose with selective radiation*

Added convenience

*Simple, secure placement and removal*
SAVI Product Line

• SAVI Applicator
  • 6-1Mini
  • 6-1
  • 8-1
  • 10-1
• SAVI Prep Catheter
1. **Size the Cavity** - Measure the long axis and diameter of cavity under US

2. **Apply the SAVI Prep Catheter (SPC)** - Fill SPC with saline based upon probable SAVI size until resistance is achieved.

3. **Verify Conformance** - Using ultrasound confirm conformance of SPC to cavity. If necessary increase fill volume until conformance is achieved.

4. **Insert SAVI** - compare measurement and select proper size.

**Diameter Table**

<table>
<thead>
<tr>
<th>Long Axis</th>
<th>2-3 cm</th>
<th>3-4 cm</th>
<th>4-5 cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-3 cm</td>
<td>SAVI Prep (20cc) 6-1Mini</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>3-4 cm</td>
<td>SAVI Prep (20cc) 6-1Mini</td>
<td>SAVI Prep (20cc) 8-1Mini</td>
<td>-</td>
</tr>
<tr>
<td>4-5 cm</td>
<td>SAVI Prep (20cc) 6-1Mini</td>
<td>SAVI Prep (20cc) 8-1Mini</td>
<td>SAVI Prep (30cc) 6-1</td>
</tr>
<tr>
<td>5-6 cm</td>
<td>SAVI Prep (20cc) 6-1</td>
<td>SAVI Prep (30cc) 6-1</td>
<td>SAVI Prep (40cc) 8-1</td>
</tr>
<tr>
<td>6-7 cm</td>
<td>SAVI Prep (30cc) 6-1</td>
<td>SAVI Prep (40cc) 8-1</td>
<td>SAVI Prep (40cc) 8-1</td>
</tr>
<tr>
<td>7-8 cm</td>
<td>SAVI Prep (40cc) 6-1</td>
<td>SAVI Prep (60cc) 10-1</td>
<td>SAVI Prep (60cc) 10-1</td>
</tr>
</tbody>
</table>

*This chart is for reference only. Not intended to replace clinical discretion.*
Patient Selection

• Any patient that is an APBI candidate
  – ABS guidelines
  – ASBS guidelines
  – ASTRO Consensus Statement

• If inserted post-op
  – less than 6 weeks from lumpectomy
Who is Not Now a Balloon SAVI Candidate?

- Breast size too small
  - A-cup & B-cup
- Lumpectomy site inappropriate
  - Axillary tail
  - Medial, parasternal
  - Inframammary fold
  - Retroareolar
  - Peripheral breast
- Augmented breasts
In Your Expert Hands,
SAVI Delivers

• Lower Toxicity Profile
• Better Outcomes
• More Women
Lower Overall Toxicity Profile

• Skin and rib dose less than 100% regardless of spacing

• Lower persistent seroma rate
  – Peripheral multi-catheter design results in non-contiguous V200
  – No tissue compression
    • Open architecture design allows cavity to conform to applicator
      – tissue does not stretch around a sphere

• Lower infection rate
Balloon Skin Toxicity

• Recent data suggests strong correlation between max skin dose >120% and negative cosmetic outcomes
  – M. Wallace, et. al., William Beaumont Hospital Royal Oak, MI; Poster session ASTRO 2008

• 9.7% of ASBS MammoSite Registry patients developed telangiectasia correlated to
  – 6, 7, and 8mm skin distance
  – Balloon fill volume ≤ 50cc
  – A/B bra cup size
Balloon Chest Wall Toxicity

• Recent data suggests higher incidence of late chest wall toxicity with max rib dose > 125%
  – L. Cuttino, et al., Department of Radiation Oncology, Virginia Commonwealth University, Richmond, VA; Brachytherapy 2009

• 5 rib fractures in 105 patients treated with max dose of 35.8Gy
  – Brashears, et al., Medical University of South Carolina; Brachytherapy 2009
What Happens After a Balloon?

Fig. 5. Mammogram, mediolateral oblique view, at 26 months after treatment with MammoSite in same patient pictured in Fig. 6. Seroma cavity has begun to mimic balloon shape.

Fig. 1. Sonogram of persistent seroma with irregular contour (arrow), prompting biopsy.

Fig. 3. Gross pathologic specimen of excised persistent seroma cavity, exhibiting glistening fibrous capsule with thick, 2-mm fibrous rind (arrow).

Evans, et. al., Tufts-New England Medical Center, Tufts University School of Medicine, Boston, MA; IROBP 2005
### SAVI Delivers Better Patient Outcomes

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong># of Patients</strong></td>
<td>102</td>
<td>30</td>
<td>63</td>
<td>12</td>
<td>18</td>
</tr>
<tr>
<td><strong>Median F/U</strong></td>
<td>22 months</td>
<td>12 months</td>
<td>18 months</td>
<td>6 months</td>
<td>6 months</td>
</tr>
<tr>
<td><strong>Infection Rate</strong></td>
<td>2.7%</td>
<td>5%</td>
<td>3%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Persistent Seroma</strong></td>
<td>8%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Fat Necrosis</strong></td>
<td>2%</td>
<td>1%</td>
<td>Not Reported</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>% of Patients &lt; 7mm to skin</strong></td>
<td>55%</td>
<td>33%</td>
<td>39%</td>
<td>100%</td>
<td>55%</td>
</tr>
</tbody>
</table>
Clinical Case Review

<table>
<thead>
<tr>
<th>PTV</th>
<th>D90</th>
<th>V200</th>
<th>$D_{max}$ Skin</th>
<th>$D_{max}$ Rib</th>
<th>$D_{max}$ Lung</th>
</tr>
</thead>
<tbody>
<tr>
<td>54cc</td>
<td>96.7%</td>
<td>11.5cc</td>
<td>100%</td>
<td>110%</td>
<td>75%</td>
</tr>
</tbody>
</table>
SAVI – Excellent Cosmetic Results
SAVI Procedures

1. Pre-implant CT Evaluation
   a. No more than 72 hours prior to implant
2. Surgeon implants SAVI
3. CT of SAVI Implant
   a. 24-48 hours post-implant
4. SAVI Length Measurement
5. Treatment Planning
6. Pre-fraction QA
7. HDR Fraction Delivery BID for 5 days, 6 hours apart
8. SAVI Removal

Commonly Used Supplies for the SAVI Applicator
Pre-Implant CT Evaluation

1. Obtain CT scan of breast to be treated
   - ≤ 3 mm slices
     - no gaps between slices
   - Patient arms up or down
   - Scan with breath hold if possible
   - Scan over the entire cavity ± 2 cm superiorly and inferiorly

2. Send CT data set to planning software

3. Have MD evaluate cavity and record data
   - Outline cavity margins on axial images
   - Determine volume (cc) of cavity
   - Measure the long axis (cm) and short axis (cm)
   - Assess the best insertion site and entry angle
Pre-Implant CT Evaluation

4. Using data, determine the most appropriate SAVI applicator size using the SAVI Size Reference Chart

5. Communicate SAVI size and cavity/insertion parameters to SAVI Representative and the Physician who will implant SAVI
CT Simulation of SAVI Implant

1. Retrieve “Expansion Tool” from patient
2. Remove all dressings
3. Use breast board or Vac-Lock to assist in positioning
4. Place CT laser alignment marks on patient
5. Acquire AP and Lateral scouts for daily QA
6. Note position of markers on the 2, 4, and 6 catheters
7. Acquire planning CT data set
   - For 8-1 and 10-1 applicators
     a. Use $\leq 3$ mm slices with no gaps between slices
   - For 6-1Mini and 6-1
     a. Use $<3$ mm slices with no gaps
   - Use same patient positioning for treatment
   - Scan cavity $\pm 2$ cm superiority and inferiorly (or whole breast per your SOP)
   - True axial if feasible
   - Scan with breath hold if possible
CT Simulation of SAVI Implant

8. Evaluate placement and expansion on CT
   - Physician may adjust device if necessary using the Expansion Tool

9. Measure and record* distance from skin surface to catheter handle (axial assessment)

10. Mark white ring and skin in continuous line (rotational assessment)
10. Measure & record catheter/transfer guide tube lengths
11. Export CT to Treatment Planning Software
1. Remove all dressings
2. Measure distance from skin to central channel handle
   a. Compare to reference value taken at planning CT
3. Position patient on CT table to match original positioning
4. Align marks on patient with CT simulator lasers
5. Acquire AP and Lateral scouts and axial images
6. Evaluate scouts for movement or rotation of SAVI using disk markings and scouts.
7. If changes are noted notify Physician to re-plan/reposition device if needed.
8. Compare position of catheters against recorded data on SAVI Prescription and Treatment Summary Template obtained at the planning CT session.

6-1 and 6-1Mini  8-1  10-1
Pre-Fraction QA

Rotation assessment using scouts
HDR Fraction Delivery

1. In HDR suite, duplicate patient position from planning CT
2. Remove purple catheter protectors, place in basin
3. Insert Expansion Tool over central catheter and engage
4. Confirm all connections between SAVI catheters, transfer guide tubes and afterloader
5. Secondary check of all connections for correct numbering
6. Keep transfer guide tubes as straight as possible
7. Follow SOPs for fraction delivery
8. Disconnect Transfer Guide tubes from SAVI
Emergency Removal of Device

• In the event the source does not retract and device must be removed emergently:
  a. Ensure Expansion Tool is engaged
  b. Turn Expansion Tool counter clock-wise until click is heard or felt
  c. Rotate SAVI in either direction releasing it from tissue
  d. Remove device and insert in bail out pig

• See “Emergency Removal Procedure for the SAVI Applicator” located in Medical Physics Implementation binder
Site Dressing for SAVI

1. Replace Catheter Protectors
2. Slide white disc away from skin
3. Cleanse entry site with antiseptic
4. Allow antiseptic to air dry
5. Apply antibiotic ointment to insertion site
Site Dressing for SAVI

6. Place drain sponges around base of SAVI at incision site

7. Wrap exposed portion of SAVI in ABD pad
Site Dressing for SAVI

• Care must be taken **not** to bend the central shaft or any of the treatment catheters beyond 90 degrees.

• Bending beyond 90 degrees can result in damage to the central shaft.
Site Dressing for SAVI

8. Cushion as necessary for comfort, put bra on and close to hold dressing in place

9. Send patient home with Dressing Change Instructions
Patient Instructions

• While under treatment, pt should notify Physician if
  a. Fever over 100.5 degrees
  b. Painful, red, or swollen along area of implant
  c. Excess bright red drainage at site
• Mild analgesic such as ibuprophen, if needed
• Keep bra on at all times
• Do NOT shower with applicator in place
• Dressing change instructions over weekend, if desired
• Do not torque device disturbing it’s position
Removal of SAVI

- **DO** assure that expansion tool is seated before attempting to collapse

- **DO NOT** attempt to collapse applicator with expansion tool un-seated
Removal of SAVI

1. Apply anesthetic cream/gel to insertion site prior to last fraction

2. Partially collapse SAVI by turning expansion tool counterclockwise

3. Hold SAVI close to insertion site, turning it left and right until it turns freely
4. Fully collapse SAVI by turning expansion tool counterclockwise until “click” is heard or felt

5. Turn the entire device again, checking that it moves freely then slide it out of the breast

6. Apply pressure to breast to express any seroma in the cavity and dress the insertion site
Infection Management

• Prophylactic Antibiotics used at Physician discretion
• Antibiotics at earliest sign of potential infection
  a. More than expected erythema, swelling, pain, purulent drainage, fever
• If infection develops
  a. Treat with antibiotics
  b. Continue brachytherapy
• Antibiotics
  a. Keflex (if allergic, use Clindamycin)
  b. Ciprofloxacin if infection gram negative

Pallet, et. al., Arizona Oncology Services and Foundation for Cancer Research and Education, Phoenix, AZ; Seminars in Breast Disease 2007
The SAVI Advantage

Sophisticated APBI technology

– Treat the widest array of breast and cavity sizes
– Offer to more women
– Lower toxicity profile
– Manage fewer infections, persistent seromas and skin changes caused by higher doses of radiation

Education and training

– #1 goal is for the entire team to become expert
Cianna Medical®️, Inc.

Experience the Difference