GammaMed\textit{plus}™ High Dose Rate Afterloader Procedures

For Performing Breast Brachytherapy with
the SAVI™ Applicator
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SAVI™ – GammaMedplus™ Procedure

I. CT Evaluation (~1 week prior to insertion)

Patients being considered for APBI using the SAVI applicator should undergo an evaluation CT within 1 week of the planned implant. The CT scan is to be used to evaluate the suitability of the patient’s excision cavity for accommodating the SAVI applicator. Key aspects of the cavity to review include; cavity size (linear dimensions of the cavity’s major axes), approximate volume (cubic centimeters), and the best orientation and approach angle for insertion of the SAVI applicator.

Procedure:
1. Obtain CT scan of breast to be treated;
   a. Use ≤ 3 mm slices, with no gaps between slices
   b. Patient should have arms up (over head)
   c. Scan with breath hold if possible
   d. Scan over the entire cavity plus and minus 2 cm superiorly and inferiorly.
2. Send CT data set to planning software (BrachyVision™).
3. Have the physician evaluate the cavity for treatment parameters by performing the following tasks:
   a. Outline cavity margins on axial images.
   b. Determine volume (cc) of cavity.
   c. Measure the long axis (cm).
   d. Measure the short axis (cm).
   e. Rotate the images until the long axis is best seen in two orthogonal views. Use these views to assess the best insertion angle and point of entry on the skin.
4. Determine the most appropriate SAVI applicator size (6-strut, 8-strut, or 10-strut) from the treatment parameters obtained in step 3.
5. Communicate the choice of SAVI model and the cavity/insertion parameters to the physician who will perform the implant.

II. SAVI Applicator Implantation

Refer to the SAVI Applicator Instructions for Use (CR-1017) for specific instructions on how to use the device.
III. SAVI Length Confirmation

The GammaMed plus HDR units are designed to treat at a fixed length treatment distance. The combined length of the source guide tube and SAVI applicator lumen *should always be 1300 mm*. Therefore prior to obtaining the planning CT it is critical to confirm each treatment lumens length (source guide tube length + SAVI applicator lumen length). Should any of the treatment lengths fall outside the 1300 mm specification the physician has the following options available:

- **Case 1: SAVI Length measurement > 1300mm**
  - The SAVI lumen may be shortened using the proper tools.

- **Case 2: SAVI Length measurement < 1300**
  - The failing SAVI lumen should not be used during treatment.
    - or
  - The entire SAVI applicator may be replaced.

**Equipment and Supplies Needed**

- Two packets (6 per packet) of GammaMed plus source guide tubes with locking mechanism, 200 mm interstitial, for peripheral lumens (GM11000370)
- One GammaMed plus source guide tube with locking mechanism, 250 mm interstitial, for central lumen (GM11010020)
- Length gauge for GammaMed plus (GM11000330).

**Figure 1. GammaMedplus Length gauge and source guide tubes.**
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SAVI Length Confirmation (continued)

1. Obtain a copy of the Connection Procedure for the SAVI™ Applicator and the GammaMedplus HDR Unit.
2. Confirm source lumen length of source channel #1:
   a. Connect the appropriate source guide tube to the central lumen of the SAVI applicator
   b. Without using excessive force, insert the length gauge (GM1100330) to the proximal end of the source guide tube until it reaches the distal position of the SAVI applicator. Observe that the length gauge does not encounter obstructions during insertion.
   c. Check that the entrance of the device connector falls within the **thin dark region** located on the proximal end of the length gauge while holding onto the device connector.
   d. Remove the length gauge.
   e. Record the results as shown below (see example below).
   f. Failure of this test may require a replacement of the SAVI applicator if the applicator's central lumen is to be used (It may be possible to trim the lumen if the length is >1300mm).

   **NOTE: If you have any questions regarding lumen measurement vs. treatment length, please contact the VBT helpdesk.**

3. Repeat step 2a-e for all source guide tubes and peripheral catheters of the SAVI applicator using the length gauge GM1100330.
4. Failure of this test in any of the peripherals may require the replacement of the SAVI applicator (It may be possible to trim the lumen if the length is >1300mm).

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<tr>
<th>Source Channel #</th>
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SAVI™ – GammaMedplus™ Procedure

IV. CT Simulation of SAVI Implant
In the simulation phase of the SAVI treatment, the first task is to assess the implant for the desired expansion using CT. The SAVI’s size can be adjusted if desired and the patient re-scanned.

1. If using a marker wire, follow steps 1a-1c. If omitting the marker wire, go to step 2.
   a. Carefully retract the Catheter Protectors from central catheter (#1) of the SAVI applicator.
   b. Place Catheter Protector in safe location to avoid damage and loss.
   c. Insert a marker wire into channel #1 until the marker wire reaches the distal end. Tape the wires in place on the catheters to prevent their dislocation during the CT scanning.

2. Perform CT scan to evaluate placement and expansion.

3. Based on the physician’s review of the implant images, adjust and expand/contract as necessary.

4. Place alignment marks on patient as close to SAVI as possible and align with CT lasers (see figure).

5. Acquire AP and lateral scouts.

6. Acquire planning CT data set;
   a. Use ≤ 3 mm slices, with no gaps between slices
   b. Patient should be in the same position as she will be for the HDR fractions (e.g., supine, ipsilateral arm positioning).
   c. Scan over the entire cavity plus and minus 2 cm superiorly and inferiorly.
   d. Scan with breath hold if possible

7. Remove marker wire and tape (if used).

8. Replace the Catheter Protector in SAVI catheter #1.

9. Measure the distance from the skin surface to a fixed point on the central catheter. Record this measurement for daily pretreatment evaluation (see figure).

10. Export CT data set to BrachyVision for planning.

11. Retain the AP & lateral scouts in a convenient location as reference images for pre-fraction evaluation.
V. Treatment Planning With BrachyVision

Refer to the BrachyVision instructions for use for tasks that are software-specific. The following procedure provides guidance on treatment planning activities specific to SAVI, as performed using BrachyVision.

1. Open BrachyVision.
2. Create a new patient and import CT data set.
3. Create new body structures. Consider a structure template for efficiency.
   a. Cavity – this will be the margin of the cavity in all slices
   b. PTV – this will be a 1.0 cm positive expansion of the “Cavity”
   c. Body – this is the surface of the skin
   d. Skin – this is a negative 5 mm margin from the “Body”
   e. Chest – this surface is defined as the chest wall or pectoralis, upon physician selection
   f. PTV-Eval – perform Boolean subtraction of Cavity from PTV. Subtract additional structures (e.g., Skin and Chest) as needed
   g. Other structures as needed (e.g., “Air” outside struts of SAVI device)
4. Contour anatomy
   a. Contour around struts of the device
   b. Contour any air outside device
   c. Contour invaginated tissue
   d. Make 1.0 cm margin on Cavity and call it the PTV.
   e. Make PTV_Eval by subtracting the Cavity from PTV. Obtain volume of PTV_Eval.
   f. Determine if Air volume exceeds 10% of PTV_Eval volume. If <10%, use existing PTV_Eval contours. If >10%, seek MD input on modifying contours or desirability of waiting 1-2 days and obtaining new CT.
5. Move to the Planning workspace to define the plan, applicator channels and dwell positions. Call this an intracavitary implant and prescribe 3.4 Gy per fraction for a single fraction.
6. Use the Multi-Planar Reformatting functionality to rotate the orthogonal views until the axis of the applicator is seen clearly in 2 orthogonal views. The third view should be a “head-on” view of the applicator (e.g., an axial orientation through the struts and central lumen).
7. Move through the stack of images in the “head-on” view from the applicator’s most distal tip to the proximal end where the struts rejoin the central lumen.
   a. Look for the integrated markers on source channels
      i. The marker on channel #2 is the most distal marker,
      ii. The marker on channel #4 is the marker nearest the center,
      iii. The marker on channel #6 is the most proximal marker,
8. Move to one of the views showing the full length of the applicator. Using the ruler-tool, measure ~12.6 m beyond the bright metal band (distal tip of SAVI). This is the end of source channel #1. One can use the distal end of the marker wire if one was used.

9. Create “Applicator1” and define the tip at this position. The applicator length is 1300 mm.

10. Continue defining “Applicator1” along the central channel until you reach the point where the proximal ends of the struts rejoin the central channel.

11. Go to the “head-on” view window and determine which strut is channel #2 (find the strut with the distal marker). Rotate the images in this window until channel #2 is visualized fully in one of the orthogonal view windows.
   a. If the strut is straight the entire strut will be visible in a single view of the orthogonal window. You may need to perform rotations in the third window to bring the strut into better view.
   b. If the strut has some curvature out of plane, you may need to perform several small rotations to fully identify the strut from proximal to distal connections.

12. Insert “Applicator2” obtaining the applicator length from the applicator length table, and define the distal tip at the point of the most distal marker on its marker wire (~0.5 cm from the distal end of the bright band).

13. Continue to define “Applicator 2” in the orthogonal view that best shows the source channel. Rotate images as needed to continue following the channel until it rejoins the central channel.

14. Find channel 3 by determining where strut 4 is by looking for strut #4’s marker. Channel 3 will be between the applicator just defined and strut #4.

15. Repeat steps 11-13 for all remaining struts, thus defining all applicators.

16. Review the image of all source applicators.
   a. Source channels appear in top right window (may need to magnify and rotate to optimize viewing).
   b. Turn off all structures (e.g., Cavity, PTV-EVAL, etc.) except source channels.
   c. Verify that Applicator1 is the straight, central channel (click on Applicator1, it turns red).
   d. Click on each successive source channel and verify that each one sequentially appears in the upper right window (see figure below)
17. Populate the desired source positions from distal ends to proximal location where struts rejoin central channel of applicator. It may be appropriate to establish the source locations using a contour.

18. Compute 3-D doses by volume optimization, or other means according to the physician’s directives.

19. Dose optimization goals can be input as follows:
   a. PTV-Eval; 95% of volume receives ≥ 95% of prescribed dose
   b. PTV-Eval receiving ≥ 200% of dose must be < 20 cc
   c. PTV-Eval receiving ≥ 150% of dose must be < 50 cc

20. Evaluate DVH of the optimized plan
   a. Review 3-D dose distribution for clinical adequacy with physician.
   b. With physician input, manually adjust dose to relevant tissues and anatomy using local Graphical Optimization.

21. After approval by physician, follow standard operating and QA procedures for recording, documenting and exporting plan to HDR afterloader.

22. Export plan to treatment console.
VI. **Connection Procedure for the SAVI™ Applicator and the GammaMedplus™ HDR Unit**

1. Carefully retract the Catheter Protectors from each catheter of the SAVI applicator.
2. Place Catheter Protectors in safe location to avoid damage and loss.
3. Carefully insert the Expansion Tool over the center catheter until properly engaged into the fitting of the SAVI™ applicator (only needed for fraction delivery).
4. Obtain requisite number of source guide tubes
   a. SAVI 6-1 applicator requires seven source guide tubes (#1-7).
   b. SAVI 8-1l applicator requires nine source guide tubes (#1-9).
   c. SAVI 10-1 applicator requires eleven source guide tubes (#1-11).
5. Insert proximal end of SAVI catheter #1 into the catheter connector on the distal end of source guide tube #1 (source guide tube numbers are on both the distal and proximal ends of the tubes).
   a. While applying pressure downward on the source guide connector fully insert the applicator catheter into the connector. Continue insertion until fully seated.
   b. Release the source guide connector to secure the catheter to the source guide tube.
   c. Insert the proximal end of source guide tube #1 into the HDR unit turret’s #1 opening.
   d. Double-check that the correctly numbered source guide tube is connected to the corresponding catheter channel and turret slot.
6. Repeat step 5 until all source guide tubes connect the SAVI catheters to the HDR unit.
7. Reposition HDR unit to maintain straightness of source guide tubes (as much as possible).
8. Following the repositioning of the HDR unit and prior to leaving the treatment room confirm that each source guide tube is securely connected to the HDR unit.
VII. QA and HDR Fraction Delivery

Refer to the Connection Procedure for the SAVI™ Applicator and the GammaMedplus™ HDR Unit to make the connections between the SAVI source lumens and the source guide tubes as well as the connections of the source guide tubes to the turret of the GammaMedplus afterloader. As needed, refer to the GammaMedplus Instructions For Use to complete patient setup, fraction delivery and emergency procedures.

1. Obtain QA images (scouts and CT scan)
   a. Measure the distance from the skin surface to the fixed point on the central catheter. Record this measurement in the patient chart and compare to reference value taken at planning CT.
   b. Reposition patient on CT couch in the same position as the planning CT was obtained.
   c. Align marks on patient with CT simulator lasers.
   d. Acquire AP and Lateral scouts images and axial images.
   e. Evaluate scouts and images for movement or rotation of SAVI relative to patient anatomy.
   f. If changes are noted in position, location or degree of expansion, notify physician and re-plan patient if needed (per physician).

2. In the HDR suite, position the patient in the same position as the planning CT was obtained.

3. Make all connections between the SAVI source lumens, the source guide tubes and afterloader using the Connection Procedure for the SAVI™ Applicator and the GammaMedplus™ HDR Unit. Be certain the Expansion Tool is in place on the center lumen.

4. Second check all connections for correct numbering (per previous procedure).

5. Verify the applicator length of each channel.

6. Reposition HDR unit to maintain straightness of source guide tubes (as much as possible).

7. If necessary import a new treatment plan from BrachyVision using standard techniques.

8. Follow institutional procedures for fraction delivery

9. Upon completion of fraction, follow facility procedures for entering HDR suite and radiation surveys as applicable.

10. Disconnect patient from HDR afterloader and disconnect source guide tubes from SAVI source lumens.

11. Insert purple Catheter Protectors.

12. Re-bandage or dress the SAVI-skin entrance site using standard techniques.