The SAVI® Applicator Instructions for Use

DESCRIPTION
The SAVI Applicator is an expandable cylindrical device with radially positioned catheters, which is inserted into the desired region to be treated (e.g., breast, rectum and vagina). The SAVI Applicator is provided sterile and is a single use device.

INDICATIONS
The SAVI Applicator is intended for use with commercially available remote afterloading equipment used during brachytherapy procedures. The multiple lumens of the SAVI Applicator are intended to provide pathways from which a prescribed radiation dose is delivered to the treatment area.

CONTRAINDICATIONS
As with other brachytherapy devices, treatment of tumors in generally poor condition (e.g., ulcerated) is not recommended with the SAVI Applicator.

WARNINGS
The SAVI Applicator should only be used by physicians trained in brachytherapy techniques. The physician is responsible for its proper clinical use and prescribed radiation dose. Prescribing and administering an unsuitable radiation dose may lead to clinical complications.

Prior to placement, use imaging modalities to confirm proper SAVI Applicator size. Improper sizing may result in inverted or splayed catheters.

When dressing patients between fractions, care must be taken to not bend the central catheter beyond 90 degrees. Bending beyond 90 degrees can result in damage to the central catheter.

After completion of treatment plan, verify no Applicator parts remain in the patient.

The SAVI Applicator is shipped sterile and MUST NOT BE RESTERILIZED.

The SAVI Applicator is for SINGLE USE only.

Do not use if the package is open or damaged.

The safety and effectiveness of the SAVI Applicator Kit for breast brachytherapy as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.

The SAVI Applicator is compatible with the afterloader equipment listed in the table below:

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Afterloader</th>
<th>Transfer Tube</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nucletron</td>
<td>microSelectron Digital microSelectron v2</td>
<td>Transfer Tubes 111.031 (Channels 1-9) 111.032 (Channel 10) 111.043 (Channel 11)</td>
</tr>
<tr>
<td></td>
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<tr>
<td>Nucletron</td>
<td>microSelectron v1 (aka “Classic”) with Alpha-Omega Services source wire P/N CSN0016-192</td>
<td>Transfer Tubes 096.073 (Channels 1-9) 096.230 (Channel 10) 096.231 (Channel 11)</td>
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<tr>
<td>Varian Medical Systems</td>
<td>Varisource™ ID Varisource™ 200</td>
<td>Catheter Transfer Guide Tubes AL13301000 (Channels 1-10) AL13301001 (Channels 11-20)</td>
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<td></td>
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</tr>
<tr>
<td>Varian Medical Systems</td>
<td>GammaMedplus</td>
<td>Source Guide Tube GM10100020 (Catheter 1) GM10000370 (Catheters 2-11)</td>
</tr>
</tbody>
</table>

Confirm the Applicator compatibility with the afterloader (e.g. source configuration, transfer tube fittings, etc…) prior to the placement of the Applicator.

1. Select the appropriate size Applicator for treatment.
2. Attach the Expansion Tool into the fitting at the proximal end of the Applicator. No slippage in either the clockwise or counter clockwise confirms that the Expansion Tool is properly engaged.
3. Rotate the Expansion Tool in a clockwise direction until the Applicator expands to the maximum diameter. An audible click should be noted upon maximum expansion.
4. Rotate the Expansion Tool in a counter clockwise direction until the Applicator is in a collapsed configuration.
5. Using the scalpel provided in the SAVI™ Applicator Kit, create a skin nick at the desired point of entry.
6. Through the skin nick and using ultrasound guidance, advance the obturator and sheath provided in the SAVI Applicator Kit into the cavity. Always align the long axis of the obturator to the long axis of the cavity.
7. Retract the obturator, leaving the sheath in place.
8. Insert the Applicator through the sheath until the distal tip of the device contacts the far wall of the cavity.
9. Rotate the Expansion Tool in a clockwise direction until the Applicator expands to the desired diameter.
10. Once the placement of the Applicator is confirmed via image guidance, carefully retract the Catheter Protector from the center catheter.
11. Remove the Expansion Tool and carefully reinsert the catheter protector.

Optional: The SAVI Prep™ catheter may be inserted into the desired region to be treated at the time of lumpectomy or just prior to placement of the SAVI applicator. This balloon-type catheter acts as a volume indicator for the anatomical site and subsequent cavity evaluation prior to placement of the SAVI applicator.

1. Under ultrasound guidance advance the SAVI Prep catheter through the sheath until the distal tip of the device contacts the far wall of the cavity.
2. Inflate the SAVI Prep catheter with sterile solution to the desired fill volume. Refer to the SAVI Size Reference Chart for fluid fill volumes and the corresponding SAVI applicator model*: 3-4cm

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

*This chart is for reference only. It is not intended to replace clinician discretion.

3. Prior to placement of the SAVI applicator, attach syringe to the luer fitting at the distal end of the SAVI Prep catheter and withdrawn all the fluid from the balloon.
4. Gently remove the SAVI Prep catheter and discard.

RADIATION THERAPY DELIVERY
Timing of radiation treatment planning is at the discretion of the physician; however, it is recommended that treatment planning be initiated at least 24 hours after applicator placement. Prior to delivering brachytherapy fractions, verify the SAVI Applicator position. Follow internal QA procedures to assure appropriateness of the treatment plan.

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During periods when the SAVI Applicator is not being used for brachytherapy treatment, carefully insert the appropriate size Catheter Protector into each of the applicator catheters.

   a. The short protectors, with a working length of 7.75", are used in the outer catheters of the applicator
   b. The longer protector, with a working length of 10", is used in the central catheter of the applicator

1. Prior to administering a brachytherapy treatment fraction, carefully retract the Catheter Protector from each of the catheters.

2. With the central catheter straightened, re-insert the Expansion Tool into the fitting at the proximal end of the Applicator. No slippage in either the clockwise or counter clockwise confirms that the Expansion Tool is properly engaged.

3. Attach the Applicator catheters to the afterloader transfer tubes using the desired numerical sequence.

4. Confirm that the afterloader transfer tubes have a straight pathway between the afterloader and the Applicator. If necessary, support proximal end of the SAVI Applicator to maintain proper positioning.

5. After completion of the brachytherapy treatment fraction, disconnect the transfer tubes and carefully reinsert the Catheter Protectors into each of the catheters.

REMOVAL OF APPLICATOR

After the prescribed radiation treatment plan has been completed:

1. Disconnect the transfer tubes from the Applicator.

2. Attach the Expansion Tool into the fitting at the proximal end of the Applicator.

3. Rotate the Expansion Tool in a counter clockwise direction until the Applicator is in a collapsed configuration.

4. Gently remove the Applicator and discard.

DISPOSAL PROCEDURES

It is the user’s responsibility to dispose of all parts according to local regulations. Upon disposal of the product or related parts, it is suggested to:

   • Check the part for radioactive contamination
   • Disinfect the parts prior to disposal
   • Dispose of sharp objects in a safe manner

STORAGE

Store at room temperature. Avoid storing the SAVI Applicator at conditions of excessive heat or humidity.

COMPONENTS

<table>
<thead>
<tr>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicator</td>
<td>1</td>
</tr>
<tr>
<td>Expansion Tool</td>
<td>1</td>
</tr>
<tr>
<td>Scalpel, #11</td>
<td>1</td>
</tr>
<tr>
<td>Obturator w/ Sheath</td>
<td>1</td>
</tr>
</tbody>
</table>