

INSTRUCTIONS FOR USE

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) for up to fourteen days. 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. The SAVI Applicator is not MRI compatible.

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, is for SINGLE USE only, and MUST NOT BE RESTERILIZED OR REUSED. The safety and effectiveness of reuse has not been evaluated.

The safety and effectiveness of the SAVI Applicator has not been evaluated in patients who are pregnant or lactating.

Do not use if the package is open or damaged.

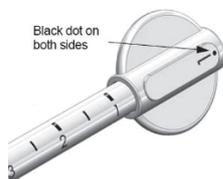
The safety and effectiveness of the SAVI Applicator Kit for breast brachytherapy as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.

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

Savi	Manufacturer	Afterloader	Transfer Tube
6-1Mini 6-1 8-1 10-1	Nucletron	microSelectron® Digital microSelectron® v2	Transfer Tubes 111.031 (Channels 1-9) 111.042 (Channels 10) 111.043 (Channels 11)
6-1Mini Gamma 6-1 Gamma 8-1Gamma 10-1Gamma	Nucletron	microSelectron® v1 (aka "Classic") with Alpha-Omega Services source wire P/N CSN0010-192	Transfer Tubes 096.073 (Channels 1-9) 096.230 (Channels 10) 096.231 (Channels 11)
6-1Mini 6-1 8-1 10-1	Varian Medical Systems	VariSource™ iX VariSource™ 200	Catheter Transfer Guide Tubes AL13301000 (Channels 1-9) AL13301001 (Channels 11-20) GM19003000 (Channels 1-10) GM19003001 (Channels 1-10)
6-1Mini Gamma 6-1 Gamma 8-1Gamma 10-1Gamma	Varian Medical Systems	GammaMedplus™	Source Guide Tube GM11010020 (Channels 1) GM11000370 (Channels 2-11)
6-1Mini Gamma 6-1 Gamma 8-1Gamma	Varian Medical Systems	BRAVOS™	Source Guide Tube GM11011870 (Channels 1) GM11011870 (Channels 2-11)

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

- GammaMedplus compatible SAVI Applicator can be distinguished by a black dot on the proximal handle as depicted in the image below.



1. Select the appropriate size Applicator for treatment.

2. Insert the Expansion Tool into the fitting at the proximal end of the Applicator until the black line on the shaft of the Expansion Tool for the respective model is no longer visible. These markings serve as confirmation that the expansion tool is fully engaged. (Figure 1)

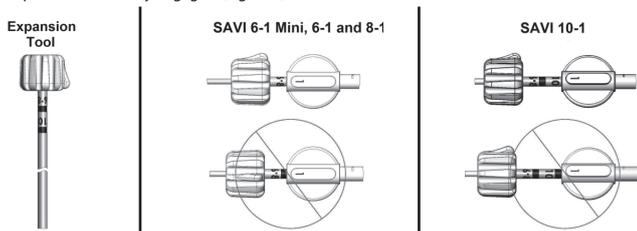


Figure 1 Expansion Tool Markings

3. No slippage in either the clockwise or counter clockwise direction provides additional confirmation that the Expansion Tool is properly engaged.

4. 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.

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

6. Using the scalpel provided in the SAVI Applicator Kit, create a skin nick at the desired point of entry.

7. 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.

8. Retract the obturator, leaving the sheath in place.

9. Insert the Applicator through the sheath until the distal tip of the device contacts the far wall of the cavity.

10. Rotate the Expansion Tool in a clockwise direction until the Applicator expands to the desired diameter.

11. If radiation treatment is to be performed with the Varian BRAVOS Afterloader, follow the device expansion steps below.

- Fully expand the selected Savi Applicator size, then rotate the expansion tool counterclockwise one full 360 degree rotation to collapse the device to the corresponding compatible diameters on Bravos sizing chart.

12. It is important that the afterloader guides tubes have a straight pathway from the Savi Applicator to the Afterloader. Provide additional support for afterloader guide tubes if necessary.

*Reference the Varian BRAVOS sizing chart below to ensure sizing and cavity conformance are confirmed.

13. Once the placement of the Applicator is confirmed via image guidance, carefully retract the Catheter Protector from the center catheter.

14. 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 and Afterloader model*:

Diameter

	2-3cm	3-4cm	4-5cm
2-3cm	SAVI Prep (20cc) 6-1Mini	-	-
3-4cm	SAVI Prep (20cc) 6-1Mini	SAVI Prep (20cc) 6-1Mini	-
4-5cm	SAVI Prep (20cc) 6-1Mini	SAVI Prep (20cc) 6-1Mini	SAVI Prep (30cc) 6-1
5-6cm	SAVI Prep (30cc) 6-1	SAVI Prep (30cc) 6-1	SAVI Prep (40cc) 8-1
6-7cm	SAVI Prep (30cc) 6-1	SAVI Prep (40cc) 6-1	SAVI Prep (40cc) 8-1
7-8cm	SAVI Prep (40cc) 8-1	SAVI Prep (60cc) 6-1	SAVI Prep (60cc) 8-1

Long Axis

Varian BRAVOS Afterloader Sizing Chart

Diameter

	2-3cm	3-4cm	4-5cm
2-3cm	SAVI Prep (20cc) 6-1Mini	-	-
3-4cm	SAVI Prep (20cc) 6-1Mini	SAVI Prep (20cc) 6-1Mini	-
4-5cm	SAVI Prep (20cc) 6-1Mini	SAVI Prep (20cc) 6-1Mini	SAVI Prep (30cc) 6-1
5-6cm	SAVI Prep (30cc) 6-1	SAVI Prep (30cc) 6-1	SAVI Prep (40cc) 8-1
6-7cm	SAVI Prep (30cc) 6-1	SAVI Prep (40cc) 8-1	SAVI Prep (40cc) 8-1
7-8cm	SAVI Prep (40cc) 8-1		

Long Axis

*The size charts are 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 withdraw 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.

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.

- The short protectors, with a working length of 7.75", are used in the outer catheters of the applicator
- 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 using the same technique as described earlier.

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 using the same technique as described earlier.
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

Description	Quantity
Applicator	1
Expansion Tool	1
Scalpel, #11	1
Obturator w/ Sheath	1

SYMBOL	DESIGNATION
	Instructions for Use Included
	Instructions for Use Prior to Use
	Part Number
	Lot Number
	USE BY (M/YYYY)
	Sterilized by Gamma Radiation
	DO NOT USE IF PACKAGE IS DAMAGED
	DO NOT REUSE
	Manufacturer

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