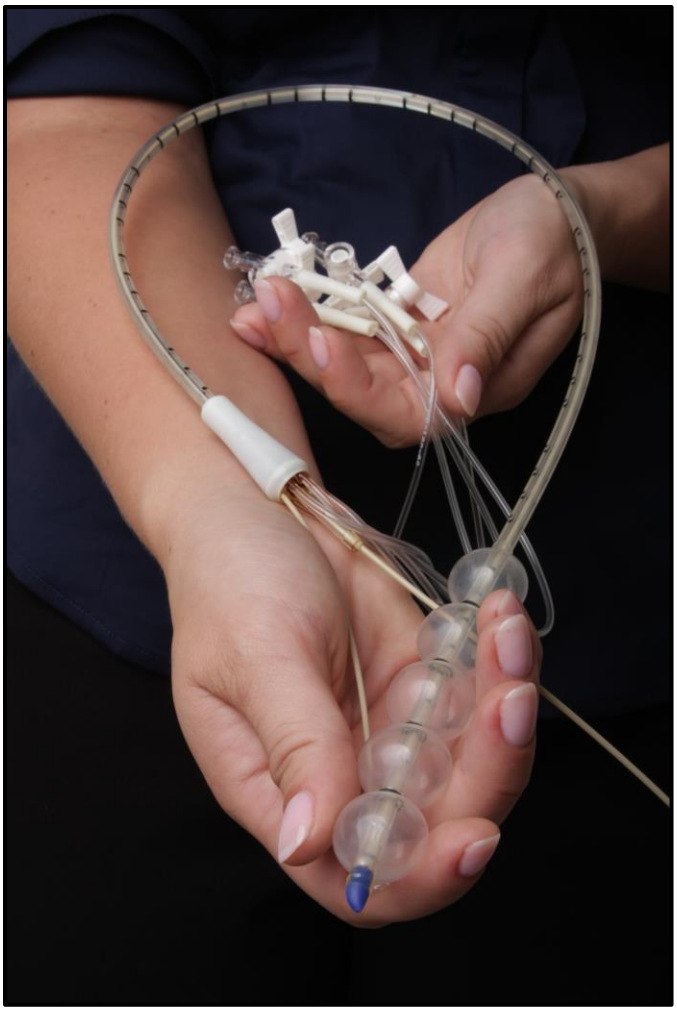
Esophageal Applicator (E Applicator)

Instructions for Use



Contents

Instructions for Use

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

DESCRIPTION

The Esophageal Applicator is a specialized applicator, which is temporarily inserted into the esophagus to facilitate the placement of an HDR brachytherapy remote afterloading source within the target area. The E Applicator is provided sterile for single use and is disposable.

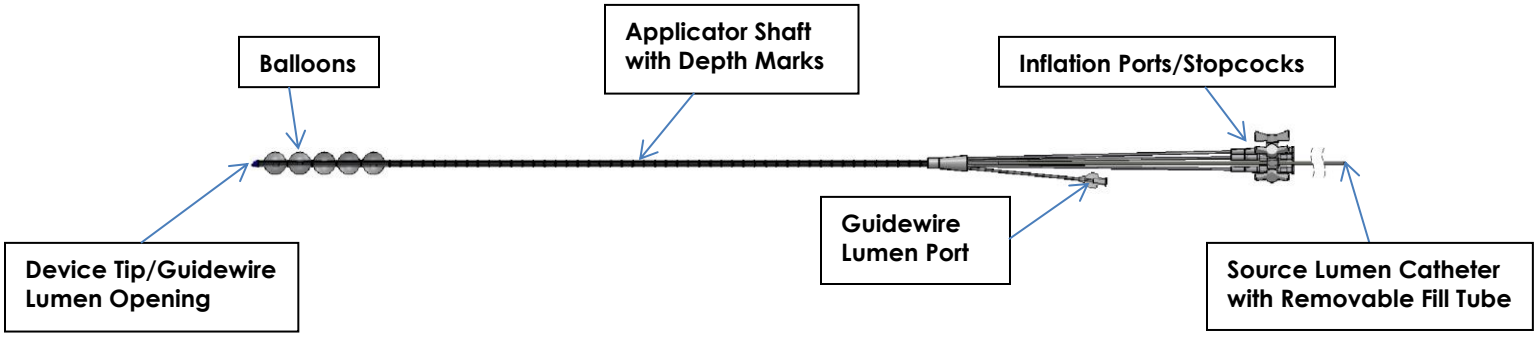


Figure 1. Esophageal Applicator Components

Indications for Use

The E Applicator is an applicator used to facilitate delivery of a prescription of radiation to the esophagus when used in conjunction with a high dose rate afterloader.

Contraindications

- All situations in which remote afterloading brachytherapy treatment is not recommended.
- Treatment of tumors in generally poor condition (e.g. ulcerated) is not recommended with the E Applicator.

Storage

- Store in a cool dry place.
- Handle with care. Packages should be stored in a manner that protects the integrity of the package and the sterile barrier.

Warnings

- Only physicians trained in brachytherapy techniques should use the E Applicator. The physician is responsible for its proper clinical use and prescribed radiation dose.
- After completion of the brachytherapy treatment, verify the applicator is intact.
- The E Applicator is shipped sterile; the method of sterilization for the E Applicator is Ethylene Oxide Sterilization. Do NOT re-sterilize any portion of the E Applicator. Attempts to re-sterilize may damage the device and result in infection and / or patient injury.
- The E Applicator is for SINGLE USE only; do NOT reuse. Attempts to reuse may damage the device and result in infection and / or patient injury.
- Do NOT use if the package is open or damaged.

- The E Applicator must be used by the expiry date shown on the product label.
- Inspect applicator for damage prior to use. Do NOT place in patient if damage is present in any component of the applicator.
- Do NOT place in patient if a sharp foreign object within the esophagus may cause rupture of the E applicator.

Technical Information

Prior to use of the E Applicator, confirm compatibility with your facility's high dose rate remote afterloader prior to placement of the E Applicator.

The E Applicator is available in the following catalog codes.

REF	Description
E-APP-1	Esophageal Applicator compatible with 6F connectors / adaptors
E-APP-1-GM	Esophageal Applicator compatible with 5.5F connectors / adaptors
E-APP-1-VS	Esophageal Applicator compatible with 4.7F connectors / adaptors

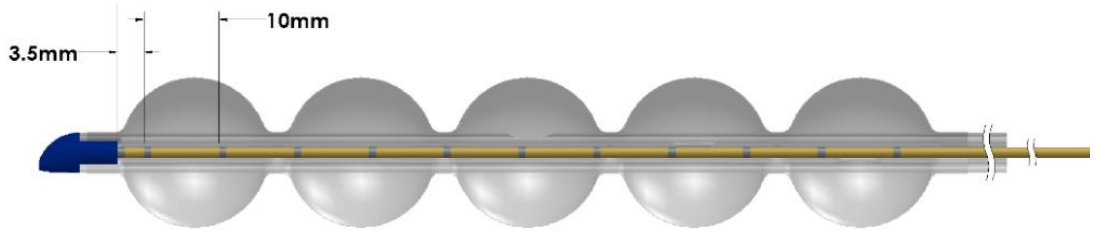


Figure 2. Source Lumen Catheter Radiopaque Marker Band Positions

Note: Colors of different parts depicted in the figure above are for clarity purposes. They do not necessarily depict the colors of the actual device parts.

The E Applicator is compatible with high dose rate remote afterloaders and connectors / adaptors from the following manufacturers: Varian Medical Systems and Elekta/Nucletron.

Manufacturer	Afterloader	HDR Afterloader Adaptor Part Number	Compatible E Applicator
Varian Medical Systems	VariSource™	AL12500000	E-APP-1-VS (4.7F)
Varian Medical Systems	GammaMed*plus*™	GM11000550	E-APP-1-GM (5.5F)
Elekta / Nucletron	microSelectron™	080.026	E-APP-1 (6F)
Elekta / Nucletron	Flexitron™	137.064	E Applicator not currently compatible with 5F

CAUTION: Confirm compatibility with your facility's afterloader prior to using the E Applicator.

The E Applicator contains 12 radiopaque marker bands located on the Source Lumen Catheter to aid in visualization of the Source Lumen Cather. The 1st marker band is flush with the distal end of

the Source Lumen Catheter. The distance between the 1st distal most marker band and the second marker band is 3.5mm. The distance between all other marker bands is 10mm (Figure 2).

Indexer Length Table		
Manufacturer	**Afterloader**	**Indexer Length**
Varian Medical Systems	VariSource™	1276 – 1281 mm
Varian Medical Systems	GammaMed*plus*™	1276 – 1281 mm
Elekta / Nucletron	MicroSelectron™	1275.5 – 1280.5 mm
This table is for reference only.		

⚠ **CAUTION: Determination of the indexer length must be established clinically (e.g. source position simulator) prior to EVERY use of the applicator. The 2nd marker band should not be used to identify the indexer length.**

The E Applicator may be inserted into the esophagus either orally or nasally. It is suggested to manually fixate the device once inserted into the esophagus. The applicator may be fixated with the use of a Bite Block (provided) when inserted orally or with sterile medical tape when inserted nasally.

The E Applicator has 5 independently operable balloons. Each balloon corresponds to a specified inflation port / stopcock (as indicated in Device Preparation). The #1 inflation port is connected to the most distal balloon (Figure 3). The #2 inflation port is connected to the next most distal balloon, etc. The #5 inflation port is connected to the proximal balloon. The balloons may be inflated in any physician designated sequence. For example, Balloon #3, Balloon #1, Balloon #5, Balloon #2, then Balloon #4.

Figure 3. Balloon Numbering Sequence

The balloons may be inflated with either air or liquid based on physician / physicist preference. The use of 5% contrast media with liquid can assist in visualization of the balloons during imaging and is detailed later in this document.

Verification of the placement of the applicator can be improved through the use of either external skin markers placed on the patient's chest or internal fiducial markers.

Accessories

* Accessories provided with E Applicator

- Sterile 10 ml Syringe (qty. 5) *
- 0.035" Diameter x 180 cm Long Guidewire
- Aqueous-based lubricant (e.g. K-Y® jelly) *
- Bite Block *

- Sterile Medical Tape
- Contrast Media

Device Removal from Packaging

1) Remove the E Applicator from the sterile pouch. Remove the paperboard tray and the syringe box cover from the device. Inspect the device for any damage.

   Note: Do not remove the Fill Tube from the Source Lumen Catheter at this point. The Fill Tube should only be removed immediately prior to connecting the applicator with the afterloader.

Inflation of E Applicator with Air

1) Prepare the E Applicator for purging.
   a) Prior to connecting to the E Applicator, depress the plunger on the syringe.
   b) Connect the syringe to a stopcock on the E Applicator.
   c) Withdraw the syringe plunger to evacuate the balloon.
   d) Close the stopcock and remove the syringe.
   e) Repeat steps “1a” through “1d” for each balloon.
2) Open each stopcock briefly to allow air to backfill the balloons. Close each stopcock.
3) Fill each syringe to the desired volume of air as determined by the physician and attach the syringes to the stopcocks (Refer to Reference Air Inflation Volume Table below). Open each stopcock and fill the balloons in a physician selected sequence, then close the stopcocks.

Reference Air Fill Volume	Balloon Diameter	**Caution: The balloons are not recommended for volumes greater than 7.2ml of air. Desired balloon inflation volume will be determined by physician preference.**
4.0 mL	20 mm	
7.2 mL	23 mm	
This table is for reference only.		

Inflation of E Applicator with Liquid

1) Prepare the E Applicator for purging.
   a) Prior to connecting to the E Applicator, fill a syringe with approximately 4 mL of the desired fill liquid first.
   b) Connect the syringe to a stopcock on the E Applicator.
   c) In an elevated position with respect to the balloon (Figure 4), withdraw the syringe plunger to evacuate the balloon. It may be necessary to cycle the syringe multiple times by pulling the syringe plunger and allowing the liquid to backfill until few or no air bubbles can be observed in the syringe when drawing vacuum.

      Note: Allow vacuum to draw fluid into the device. Do not actively depress the syringe plunger to inject fluid into the balloon(s).

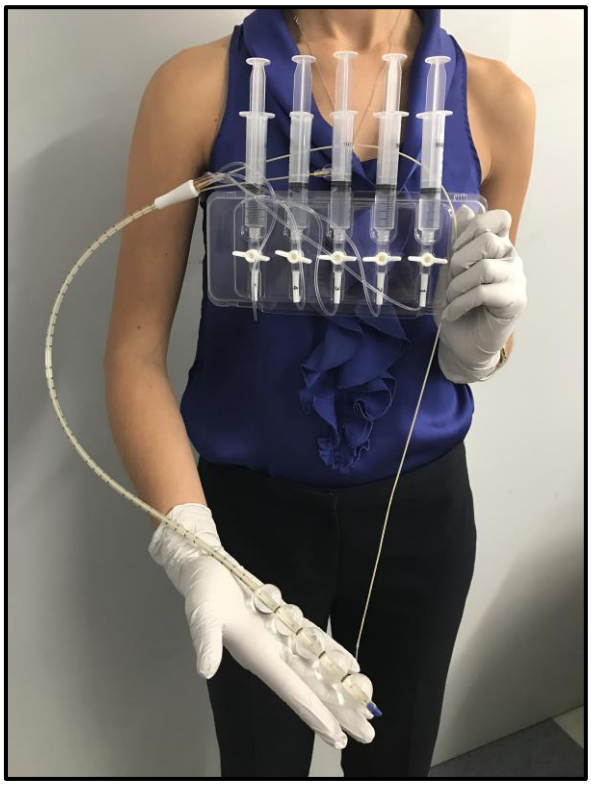


Figure 4. Proper Positioning for Device Preparation with Liquid

d) Close the stopcock and remove the syringe.

e) Repeat steps “1a” through “1d” for each balloon.

2) Fill each syringe to the desired volume of liquid as determined by the physician and attach the syringes to the stopcocks (Refer to Reference Liquid Inflation Volume Table below). Open each stopcock. Gently depress the syringe plungers in a physician selected sequence to fill each balloon.

3) Close each stopcock.

Reference Liquid Fill Volume	Balloon Diameter	**Caution: The balloons are not recommended for volumes greater than 5.9ml of liquid. Desired balloon inflation volume will be determined by physician preference.**
4.2 mL	20 mm	
5.9 mL	23 mm	
This table is for reference only.		

Applicator Insertion

1) Although optional, the application of an aqueous-based lubricant (e.g. K-Y® jelly) to the device is highly recommended to facilitate insertion of the device.

2) With balloons prepped and evacuated, insert the Applicator into the esophagus using a physician preferred insertion technique.

   Note: A 0.035" Diameter x 180 cm Guidewire may be used to facilitate insertion of the device by placing the guidewire in the esophagus and backloading the E Applicator onto the guidewire through the hole in the E Applicator tip.

3) Use fluoroscopy or other visualization method to position the device in the desired treatment site.

4) Inflate the balloons as described in the sections above.

5) After the applicator is in position, perform imaging for treatment planning purposes.

Reverification of E Applicator and Connection to Remote Afterloader

1) Re-verify positioning of device. Once in position, secure the device to the patient using either sterile medical tape or a bite block.

2) If desired, attach the clear plastic syringe/stopcock tray to a stand.

3) Remove the fill tube from the Source Lumen Catheter.

4) Connect the Source Lumen Catheter to the afterloader and administer the radiation treatment plan as prescribed by the physician.

Removal of Applicator

After the prescribed radiation treatment plan has been completed:

1) Disconnect the afterloader from the Source Lumen Catheter.
2) Deflate each balloon by drawing a vacuum and close the stopcock.
3) Gently remove the E Applicator from the patient and discard.

Disposal Procedures

The applicator and components that require disposal should be considered a biohazard and disposed of in accordance with local regulations and hospital guidelines.

Imaging Methods

The E-Applicator has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the E-Applicator in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

The E-Applicator is safe for use with CT and X-ray imaging.

Label Symbol Glossary

(Note: not all symbols may be applicable to this product)

Symbol	Title of Symbol	Description of Symbol	Symbol Designation Number	Title of Symbol Standard Development Org. Standard
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1	ISO 15223-2012
EC REP	Authorized representative in the European Community	Indicates the authorized representative in the European Community.	5.1.2	ISO 15223-2012
	Date of manufacture	Indicates the date when the medical device was manufactured.	5.1.3	ISO 15223-2012
	Use-By Date	Indicates the date after which the medical device is not to be used.	5.1.4	ISO 15223-2012
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5	ISO 15223-2012
REF	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.	5.1.6	ISO 15223-2012
SN	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	5.1.7	ISO 15223-2012
STERILE EO	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	5.2.3	ISO 15223-2012
STERILE R	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	5.2.4	ISO 15223-2012
	Do Not Resterilize	Indicates a medical device that is not to be resterilized.	5.2.6	ISO 15223-2012
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	5.2.7	ISO 15223-2012
	Do Not Use if Package is Damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	5.2.8	ISO 15223-2012
	Biological Risks	Indicates that there are potential biological risks associated with the medical device.	5.4.1	ISO 15223-2012
	Do Not Reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2	ISO 15223-2012
	Consult Instructions For Use	Indicates the need for the user to consult the instructions for use.	5.4.3	ISO 15223-2012
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	5.4.4	ISO 15223-2012
CE 0459	European Conformity	EC Declaration of Conformity by Notified Body	Annex XII	MDD 93/42/EEC:2007
Only	By Prescription Only	Federal (USA) law restricts this device to sale, distribution, and use by or on the order of a physician.	N/A	FDA 81 Federal Register pg. 38911-38931

Table of Figures

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