Contura®
Multi-Lumen Balloon • MLB

Multi-Lumen Balloon Applicator For Brachytherapy

REF B01245, B01256, B11245, B11256, B02245, B02256, B03245, B03256

INSTRUCTIONS FOR USE

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

DESCRIPTION

The Contura® MLB Applicator consists of a multi-lumen catheter attached to an inflatable spherical balloon (Figure 1). Lumens are provided for attachment to commercially available HDR (High Dose Rate) remote afterloader equipment for passage of the radiation treatment delivery wire. Five treatment lumens are provided; one central lumen located along the long axis of the Applicator and four curved lumens symmetrically offset from the central lumen. A removable stiffening stylet is positioned in the central treatment lumen, and treatment lumens #1-4 have lumen caps. Two proximal ports are also provided with Luer-type connectors for balloon inflation/deflation and for application of intracavitary vacuum.

The Contura® MLB accessories provided for introduction and deployment include: trocar with split sheath, drainage catheter, three, 30 ml and one, 10 ml inflation syringes, #11 scalpel, contrast media tray, radiation lumen caps and labels (Figure 2).

Afterloader compatibility:

Varian	Nucletron
• VariSource ID™ • VariSource™ 200 Series • GammaMedplus™ Series • VariSource™ iX Series	• microSelectron™ V2 • microSelectron™ Digital • Flexitron™

Warning: The safety and effectiveness of the Contura® Applicator as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.

INDICATIONS FOR USE

The Contura® MLB Applicator is intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.

CONTRAINDICATIONS

- The Applicator is not intended for use in cavities that are too small, too large and/or of shapes unable to conform to the inflated balloon.
- The Applicator is not intended for use in patients with unusual anatomy including a highly curved rib structure and/or unequal amounts of tissue surrounding the cavity that may cause the Contura® balloon to be asymmetrical.

WARNINGS

- **Use caution when positioning the trocar tip near the chest wall or skin margin to avoid unintended tissue damage.**
- **Do not fill the Applicator with more than 58 ml (B01245, B11245, B02245, B03245) or 108 ml (B01256, B11256, B02256, B03256) of fluid as overfilling may result in balloon rupture and/or device failure.**
- **The Applicator must be pre-tested before implantation. Do not use the balloon if it is not approximately symmetrical and/or any leakage is detected.**
- **The breast cavity must be imaged before implantation to insure the Applicator will fit appropriately. Do not use if the cavity is too small. Do not use if the balloon surface to skin surface distance is less than 5 mm unless the maximum skin dose is ≤ 145% of the prescription dose. Use of the appropriate off-set lumen(s) should be used to minimize the exposure to the skin.**
- **To insure appropriate treatment dose distribution, the Applicator must be imaged prior to delivering each fraction of radiation to confirm correct position, balloon volume, skin spacing and conformance.**
- **If excessive resistance is encountered when attempting to remove the Applicator from the patient, surgical removal is recommended.**
- **Contrast media concentrations of less than 10% are recommended to prevent dose attenuation.**
- **Non-ionic contrast media is recommended for patients who are allergic to iodine-based agents.**
- **This device has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints, and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications.**
- **Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/or resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.**

PRECAUTIONS

- The Applicator must be used only by physicians trained in catheter implantation, radiation treatment planning and delivery.
- Metal vascular and marking clips should not be used during the lumpectomy procedure to prevent potential abrasion or puncture of the Contura® balloon. Care should also be taken to direct suture knots and tails away from the cavity and whenever possible position tissue between the potential balloon surface and the tails.
- Store the Contura® Applicator at room temperature (25ºC maximum).
- Care must be taken when handling and manipulating the Contura® balloon to prevent damage and foreign material contamination of the balloon surface.
- A scalpel should be used to incise the skin prior to inserting the trocar tip.
- Do not inject fluids into the Vacuum Port.
- Replace Luer caps and radiation lumen caps after use.
- Only clinical personnel trained in the operation of HDR afterloaders should deliver radiation using the Applicator.
- Verify that the appropriate afterloader connectors are available and function with the Applicator prior to treatment.
- Important: the Applicator must remain as straight as possible and free of sharp bends and kinks when connected to the HDR afterloader. Treatment length measurements should be obtained prior to each treatment fraction with the device in the same orientation as treatment. Orientation should remain consistent for each treatment fraction.
- Inspect package before use. Discard if seal is compromised or packaging is damaged.

COMPLICATIONS

Complications that may be associated with the use of the Contura® MLB Applicator are the same as those associated with the use of similar devices. These may include: erythema, catheter site drainage, breast pain, ecchymosis, breast fibrosis, telangiectasia, breast induration, breast seroma, breast edema, dry desquamation, dry skin, skin discoloration, parasthesia, axilllary pain, fatigue, pruritis, breast retraction, nausea, skin irritation, moist desquamation, hematoma, rash, asymptomatic fat necrosis, breast infection, breast blister and lymphedema.

HOW SUPPLIED

The Contura® MLB Applicator and accessories are provided sterile and are intended for single patient use only.

DIRECTIONS FOR USE

PLACEMENT - Refer to Figures 1 & 2

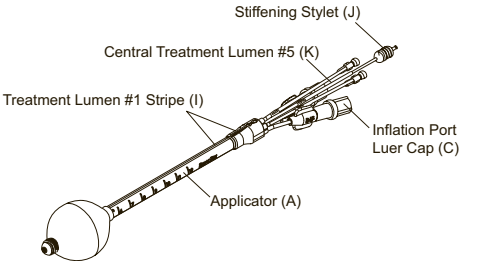

Figure 1: Contura®APPLICATOR

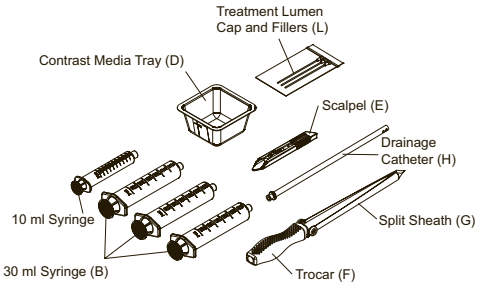

Figure 2: ACCESSORIES

1. Use ultrasound to identify the lumpectomy cavity.
2. Open the CONTURA® MLB Applicator sterile package and remove the Applicator (A) and one 30 ml Syringe (B). Remove the Inflation Port Luer Cap (C) and inject 58 ml (B01245, B11245, B02245, B03245) or 108 ml (B01256, B11256, B02256, B03256) of sterile saline into the Applicator and inspect for leaks and symmetry. Discard Applicator if defective. Holding the Applicator by the connectors, with the balloon hanging vertically, completely withdraw the saline from balloon.
3. Prepare a maximum 3% contrast media/sterile saline solution in the Tray (D) provided.

   Note: Higher concentrations of contrast media may inhibit lumen marker visualization.
4. Determine the desired point on the breast surface for the insertion of the Applicator. Inject appropriate anesthetic to the skin and pathway to the lumpectomy cavity. Make a skin incision with the scalpel at the insertion point of sufficient length to fully insert the Trocar (F) tip. Dilate the skin incision, if desired. Advance the Trocar with Split Sheath (G) into the cavity. Remove the Trocar.
5. Attach a 30 ml syringe to the Drainage Catheter (H) and drain any fluids within the cavity by inserting the Drainage Catheter through the Split Sheath and suctioning. Remove the Drainage Catheter.
6. Insert the Applicator through the Split Sheath into the cavity. Remove the Sheath.
7. Align the Treatment Lumen #1 Stripe (I) on the catheter shaft with the skin incision.
8. Remove the stiffening Stylet (J) from the Central Treatment Lumen (K). Attach a red Treatment Lumen Cap (L).
9. Using the syringes provided, purge any air from the applicator and inflate the Applicator balloon with the contrast media solution to the desired fill volume. Purge any air from the fill syringes before attaching them to the Applicator.

Model	Desired balloon diameter	Approximate balloon fill volume
B01245 B11245 B02245 B03245	4 cm Dia. x 4.4 cm length	33 ml
	5 cm Dia. x 4.4 cm length	58 ml
B01256 B11256 B02256 B03256	4.5 cm Dia. x 5.4 cm length	51 ml
	6 cm Dia. x 5.4 cm length	108 ml

10. Replace the Luer Cap on to the Inflation Port (M).
11. Use ultrasound to confirm appropriate placement, volume and cavity conformance. Fluid and air surrounding the Applicator balloon may be aspirated with a 30 ml Syringe attached to the white Vacuum Port (N). The volume of the balloon may be adjusted through the blue Inflation Port (M). Replace Luer Caps when finished.
12. Confirm that the Treatment Lumen #1 Stripe is aligned with the skin incision.
13. Position catheter to minimize bending and to align marker with skin incision.
14. Apply a surgical dressing to the exit site with the catheter positioned to minimize bending.
15. Record the final balloon fill volume on the labels provided and attach to the patient's chart.

RADIATION DELIVERY - Refer to Figures 1 & 3

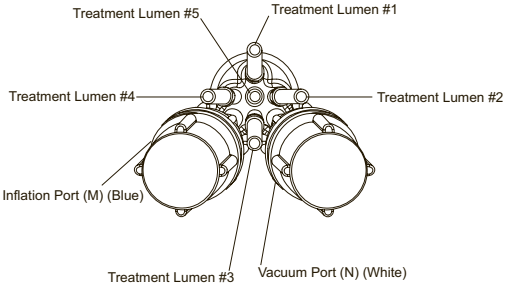

Figure 3: TREATMENT LUMEN ORIENTATION

1. Important: the Applicator must remain as straight as possible and free of sharp bends and kinks when connected to the HDR afterloader. Treatment length measurements should be obtained prior to each treatment fraction with the device in the same orientation as treatment. Orientation should remain consistent for each treatment fraction.
2. CT imaging should be used in conjunction with commercially available treatment planning software to determine the appropriate treatment lumens, treatment dwell positions and dwell times for optimized radiation delivery of a prescribed dose to the targeted treatment volume.
3. Using Treatment Lumen #1 Stripe as a reference, note the orientation of the CONTURA® Applicator. Verify correct Applicator orientation, balloon position, balloon volume, skin spacing and conformance using imaging prior to delivery of each fraction of radiation. Adjust if necessary.
4. The Treatment Lumens are numbered '1', '2', '3', '4' and '5' and positioned as shown in Figure 3. Lumen number '1' corresponds to the offset lumen closest and parallel to the Treatment Lumen #1 Stripe (I) along the catheter shaft. Treatment Lumen number '5' corresponds to the central lumen. Remove the red caps and use commercially available connectors to attach the treatment lumens to the afterloader.

   Note: When using the GammaMedplus™ afterloader, the treatment lumens of the applicator must first be trimmed to length using the appropriate GammaMedplus™ length cutting gauge.
5. After each treatment replace the red caps and secure catheter shaft.

REMOVAL

1. Remove the CONTURA® MLB Applicator by first attaching a syringe to the blue Inflation Port and deflating the balloon.

   Note: If difficulty is encountered deflating balloon with syringe:

   1) Re-attach syringe and securely rotate clockwise to completely activate the valve. If the balloon, still does not deflate, then
   2) Cut the blue Inflation Port tubing. The saline/contrast contents of the balloon will now drain from the end of the cut tubing
   3) If the balloon still cannot be deflated, insert a syringe with needle directly into the balloon. Deflate the balloon by withdrawing contents using the syringe.
2. Rotate and withdraw (unscrew) the Applicator from the cavity.

℞ Only

Attention, See Instructions For Use

Single Use

Contents

Keep Dry

Lot Number

Keep Away from Sunlight

Use By

Sterilized Using Irradiation

Manufactured For:

Do Not Use if the Product Sterilization Barrier or its Packaging is Compromised

Do Not Resterilize

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Catalogue Number

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