The Contura® Cavity Maintenance Catheter is temporarily implanted at the time of lumpectomy within the cavity as a placeholder until it is exchanged for the Contura® MLB Brachytherapy Catheter.

CONTRAINICATIONS

The Contura® Cavity Maintenance Catheter is not intended for use in patients who are known not to meet the selection criteria for brachytherapy treatment using the Contura® MLB Brachytherapy Catheter at the time of lumpectomy.

WARNINGS

- Use caution when positioning a sharp tip near the chest wall or skin margin to avoid unintended tissue damage.
- 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 lumens, 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 pyrogenical 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.
- Never fill the system with more fluid than the maximum specified fill volume of 58 ml. Overfilling of the balloon could result in rupture of the balloon and/or failure of the device.
- The Contura® Cavity Maintenance Catheter must be pre-tested before implantation. Do not use the balloon if any leakage is detected.
- Do not use excessive force to implant or remove the Contura® Cavity Maintenance Catheter. If the catheter becomes bound to the breast tissue, through tissue adhesion, the physician should consider surgical removal.
- For patients who have or may have an allergic reaction to iodinated materials, consider using a non-ionic contrast agent.

PRECAUTIONS

- This device is not designed nor can be used to deliver any form of radiation.
- Do not use if the product sterilization barrier or its packaging is compromised.
- For optimal balloon imaging, less than 5% contrast is recommended.
- Keep catheter away from foreign materials at all times. Exercise caution when handling the Contura® Cavity Maintenance Catheter prior to and during implantation. Balloon materials are susceptible to damage by sharp object/instruments and excessive pulling or pushing.
- In case of balloon rupture, carefully inspect the device upon removal to ensure no fragments remain within the lumpectomy cavity.
- Remove the Contura® Cavity Maintenance Catheter within 10 days of implant. The safety of implantation of the Contura® Cavity Maintenance Catheter beyond 10 days has not been established.

COMPLICATIONS

Complications that may be associated with the use of the Contura® Cavity Maintenance Catheter are the same as those associated with the use of similar devices. These may include: erythema, catheter site drainage, breast pain, ecchymosis, breast seroma, breast edema, paraesthesia, pruritis, breast retraction, nausea, skin irritation, hematoma, rash, and breast infection.

HANDLING AND STORAGE

- Store in a cool dry place. Rotate inventory so that the catheters are used prior to the “Use By” date.

HOW SUPPLIED

- The Contura® Cavity Maintenance Catheter is supplied sterile unless the package has been opened or damaged. For single use only. Do not reuse. Do not resterilize.

ACCESSORIES SUPPLIED

The following accessories are supplied to place the Contura® Cavity Maintenance Catheter:
- 30ml syringes
- Media tray
- Contura® Introducer with split sheath

DIRECTIONS FOR USE

Note: Contura® Cavity Maintenance Catheter should be placed at the time of lumpectomy.

Refer to Figures 1 and 2

PRE-TEST

1. Open the Contura® Cavity Maintenance Catheter sterile package and remove the Catheter (A) and one syringe (E). Remove the Inflation Port Luer Cap (B). Attach a syringe to the Inflation Port (C) and inject up to, but not to exceed 58 ml of sterile saline into the Contura® Cavity Maintenance Catheter. Inspect for leaks. Discard catheter if defective. Completely withdraw the saline from balloon.
PLACEMENT

1. Prepare a sterile saline solution or, if desired, a less than 5% contrast solution in the Media Tray (F) provided.

2. Placement of the Contura® Cavity Maintenance Catheter may be accomplished through a variety of techniques. Placement of this device is at the discretion of the physician.

3. Choose an entry point that provides an optimum pathway for the Contura® Cavity Maintenance Catheter and later, the Contura® Multi-Lumen Balloon applicator.

4. If the Contura® Cavity Maintenance Catheter is being placed through an entry point other than the original lumpectomy surgical incision, create a path by making a small incision (approximately 1.3cm in length) in the skin with a scalpel and advancing the provided Contura® Introducer (G) or other tissue dissection device through the incision and into the surgical cavity. Once the cavity is penetrated withdraw the trocar from the Contura® Introducer sheath or remove the tissue dissection device.

5. Insert the Contura® Cavity Maintenance Catheter through the entry point, Contura® Introducer sheath or tract, into the lumpectomy cavity until the tip contacts the distal end of the cavity. Remove the Introducer sheath, if used, and withdraw the stiffening stylet (D) from the Cavity Maintenance Catheter.

6. Attach a syringe to the Inflation Port and inflate the Contura® Cavity Maintenance Catheter balloon with sterile saline or contrast solution to the desired size within the cavity (refer to chart).

<table>
<thead>
<tr>
<th>Desired Balloon Diameter</th>
<th>Approximate Fill Volume*</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.5 cm</td>
<td>25 ml</td>
</tr>
<tr>
<td>4.0 cm</td>
<td>34 ml</td>
</tr>
<tr>
<td>4.5 cm</td>
<td>44 ml</td>
</tr>
<tr>
<td>5.0 cm</td>
<td>58 ml*</td>
</tr>
</tbody>
</table>

*Fill Volume must not exceed 58 ml

7. Verify placement and balloon volume using direct visualization. The volume of the balloon may be adjusted through the Inflation Port.

8. Prior to closing the lumpectomy cavity, deflate the Contura® Cavity Maintenance Catheter balloon and retract the Contura® Cavity Maintenance Catheter from the cavity to prevent balloon perforation. After closure, advance the Contura® Cavity Maintenance Catheter back into the cavity, and refill the balloon to the same volume.

9. Replace the Luer cap on the Inflation Port.

10. Dress the catheter exit site and secure the portion of the catheter remaining outside of the breast to the torso using additional dressing.

11. Record the final balloon fill volume on the labels provided (H). Attach one to the dressing and one to the patient’s chart.

REMOVAL

1. Remove the Contura® Cavity Maintenance Catheter by attaching a syringe to the Inflation Port and aspirating the entire fluid volume, thereby deflating the balloon.

   Note: If difficulty is encountered deflating the balloon with syringe:
   1) Re-attach syringe and securely rotate clockwise to ensure valve activation. If the balloon still does not deflate, then,
   2) Cut the Inflation Port tubing. The saline or contrast solution contents of the balloon will not drain from the end of the cut tubing. Manually compress the balloon to facilitate drainage.
   3) After use, the Contura® Cavity Maintenance Catheter and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

2. Rotate and withdraw (unscrew) the Contura® Cavity Maintenance Catheter from the cavity.

3. Dispose of the Contura® Cavity Maintenance Catheter as medical waste.

If any device malfunction is suspected, please call: Bard Peripheral Vascular, Inc., 1-800-321-4254.

WARRANTY

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular’s sole discretion or refunding your net paid price. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.
CONTURA® Cavity Maintenance Catheter

Rx Only

Attention, See Instructions for Use

Contents

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

Lot Number

Manufacturer

Do Not Resterilize

Catalogue Number

Single Use

STERILE R

Sterilized Using Irradiation

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Use By

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