**WARNINGS**

The Symetrex® Long Term Hemodialysis Catheter is a trach. 15, 5, French, dual-lumen, radicus catheter made of polyethylene. It has a polymer retention cuff and tunnel adapter that promotes tissue ingrowth to anchor the catheter in the subcutaneous tunnel. The luer adapters are identical in color to indicate the reversed flow. This catheter features symmetrical side channels with a distal tip configuration designed to separate the intake from the output flow.

**CONTRAINDICATIONS**

Do not use this catheter if package, catheter or components show any signs of damage (crimped, crushed, cut, opened, etc.).

Do not use device if labeling has been removed or defaced or has been damaged or made partially illegible.

Do not use sharp instruments near the extension tubing or catheter body. Catheter failure may result from contact with sharp objects. Do not use aerosols to remove the dressing as this could possibly cut or damage the device.

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Flow Rate vs. Pressure Profile

The Flow Rate vs. Pressure profile of the Symetrex® Long Term Hemodialysis Catheter is presented below:

<table>
<thead>
<tr>
<th>Flow Rate (ml/min)</th>
<th>Pressure (mm Hg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>50</td>
<td>60</td>
</tr>
<tr>
<td>60</td>
<td>70</td>
</tr>
<tr>
<td>80</td>
<td>90</td>
</tr>
<tr>
<td>100</td>
<td>110</td>
</tr>
</tbody>
</table>

Flow rate vs. Pressure Data was obtained in vitro using a Luer Lock (threaded) connector failure. Use only Luer Lock (threaded) connectors.

WARNING:

To prevent severe damage to catheter tip, do not attempt to remove tunneled tubing tool from distal tip of catheter.

**CHEMICAL EXPOSURE WARNINGS**

Do not use acetone on any part of the catheter or components. This catheter is intended for arterial use.

The valved pull-apart sheath/introducer is not aseptically processed. The valve will substantially reduce air intake. The valve will allow free flow through the designated lumen. Do not use catheter if package has been damaged or has been opened.

Do not use catheter if package, catheter or components show any signs of damage (crimped, crushed, cut, opened, etc.).

Do not use device if labeling has been removed or defaced or has been damaged or made partially illegible.

**NOTICE**

To reduce the number of connection attempts and mechanical complications, CDC Guidelines recommend the use of Ultrasound Guidance. If available, Ultrasound Guidance should always be used. Regimen changes may lead to development of adverse events. Do not use Acephalic Lock solution.

To prevent severe damage to catheter tip, do not attempt to remove tunneled tubing tool from distal tip of catheter.

**NOTICE**

Do not clamp the distal portion of the catheter. Use only a few centimeters at a time

**CAUTION:**

To prevent cuffed diverticulum formation, the anticoagulant solution should be removed from each lumens prior to treatment. This catheter is normal saline solution prior to catheter insertion.

Do not use excessive force to flush obstructed catheter.

**CONTRAINDICATIONS**

Do not use this catheter in thrombosed vessels or for subcutaneous puncture when ventilator is in use.

**WARNING**

This device is for single patient and patient use only. DO NOT REUSE, REPROCESS OR RESTERILIZE.

Reuse of a single-use device carries with it the potential risk for transmission of the disease of the patient/user infection or cross infection including but not limited to the transmission of infectious disease(s) from one patient to another. Contamination, cross-contamination and/or cross-infection may lead to injury, illness, or death of the patient. Re-stereilization or Reprocessing of the device is ineffective and may compromise the structural integrity of the device and/or lead to device failure, which in turn may lead to patient injury, illness, or death.

**WARNINGS & GENERAL PRECAUTIONS**

Health care professionals should always use universal blood and body fluid precautions in the care of all patients. Be informed of all disease transmission routes to HEP (Human Immunodeficiency Virus) or other body borne pathogens. Site technique must be performed with the utmost cleanliness to prevent introduction of bacteria into the device.

The risk of infection is increased with hemoral vein insertion.

To minimize the risk of air embolism or extravasation, keep the catheter clamped closed at all times when not in use or when attached to a syringe. IV tubing should be flushed regularly.

**Possible complications**

• Arterial Emboli
• Allograft Loss
• Breast Prothesis Irritation
• Cardiac Arrhythmia
• Cardiac Tamponade
• Deep Vein Thrombosis of the Lower Extremity
• Diaphragmatic herniation
• Distal Site Necessity
• Femoral Artery Dissection
• Femoral Nerve Damage
• Femoral Vein Damage
• Herniation
• Hematemesis
• Hemorrhage
• Infusion, Necrosis, or Scarring of Skin over implant area
• Lower Extremity Ischemia
• Mediastinitis
• Mediastinal Widening
• Necrotizing Fasciitis
• Pulmonary Embolism
• Renal Artery Stenosis
• Renal Failure
• Retropitoneal Bleed
• Subclavian/Subclavian Thrombosis
• Subclavian/Subclavian Vein Thrombosis
• Trauma to Right Atrium
• Veno-venous Thrombosis

**INSERTION SITES**

The ideal site for inserting the Symetrex® Long Term Hemodialysis Catheter is in the right internal jugular vein. Although this catheter may be placed in the subclavian vein, for the patient with Medicare as required.

Do not administer local anesthesia to the insertion area and tunnel site before attempting insertion. Ensure that the luers are closed between uses. Do not clamp the distal portion of the catheter.

Failure to verify catheter placement with fluoroscopy may result in serious trauma or fatal complications.

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Lumen Volume

2.6cc
3.2cc
2.3cc

Povidone-iodine ointment to catheter exit sites during exposure, this agent is known to degrade polyurethane. The causes may include inadequate catheter tip position, catheter kink and clot. One of the following may resolve the obstruction:

- Verify the clamps are in open position when attempting to aspirate.
- Reposition patient. Have patient cough.
- Provided there is no resistance, attempt to open or move the tip by vigorously flushing the catheter with sterile normal saline.
- If thrombus develops in either lumen, first attempt to aspirate the clot with a syringe. If it fails, the physician may consider using a thrombolytic solution (i.e. tPA) to dissolve the clot. Excessive force should not be used to flush an obstructed lumen.

**INFECTION**

Catheter-related infection is a serious concern of indwelling catheters. Sterile technique should always be strictly adhered to. Clinically recognized infection at a catheter exit site should be treated promptly with the appropriate antibiotic therapy.

Per CDC Guidelines for the Prevention of Intravascular Catheter-Related Infections:

- Use maximal sterile barrier precautions, including the use of a cap, mask, sterile gown, sterile gloves, and a sterile full-body shape, for the insertion of central venous catheters.
- Before central venous catheter insertion, prepare clean skin with a >0.5% chlorhexidine preparation with alcohol. If there is a contraindication to chlorhexidine, tincture of iodine, an isopropyl, or 70% alcohol can be used as alternatives.
- Antibiotics should be allowed to dry according to the manufacturer’s recommendation prior to placing the catheter.
- After central venous catheter insertion, see SITE CARE for compatible antiseptics.

**DIRECTIONS FOR CATHETER EXCHANGE**

Only a qualified, licensed physician or other qualified health care professional under the direction of a physician should insert, manipulate, and remove the catheter. The medical procedures, techniques, and methods outlined in these Instructions are used as a guide, and do not represent the only medically acceptable protocols available. KDOQI Guidelines recommend the use of fluorescent visualization for placement.

**CAUTION:** Hospital or unit protocol, potential complications, and their treatment, warnings and precautions must be reviewed prior to catheter removal.

**CAUTION:** Insert, maintain and remove catheter under strict aseptic conditions and technique.

1. If necessary, cut sutures from suture wings following hospital protocol for skin sutures.
2. Use blunt or sharp dissection to free cuff from the skin at the exit site.
3. Advise BCI forward with gentle forward motion through the venous lumen into the designated position, unless contraindicated.

**NOTE:** Guidewires must be the proper length so the guidewire will extend distal to the tip of the catheter for the duration of the placement procedure.

4. Hold the guidewire in place while gently pulling out the catheter over the wire.

**CAUTION:** Remove catheter with care. Sharp, jerking movements and undue force may tear the catheter.

5. Immediately apply manual pressure to the puncture site after removal to control bleeding.
6. Flush each lumen of the replacement catheter with flushing solution.
7. Insert a stylet into each lumen of catheter and secure to catheter using luer lock connector.
8. Using standard technique, place stylets and catheter over guidewire.
9. Once the guidewire exits through the lumen connector, hold the guidewire securely and advance the catheter over the wire, through the existing tunnel until proper catheter tip positioning is confirmed with fluorescent visualization, per KDOQI guidelines.

**CAUTION:** The guidewire should be held securely during this procedure. For jugular insertion, allowing the guideewire to pass into the right atrium may result in cardiac arrhythmias. Patient should be placed on a cardiac monitor and monitored for arrhythmias throughout the jugular insertion procedure. Do not advance the catheter and stillner past the tip of the guidewire as this could cause vessel perforation and/or bleeding.

10. Once position is confirmed, slowly remove guideewire.
11. Leaving the catheter in place, gently remove stylet and immediately clamp extension lines.
12. Attach needleless injection site luer cap.
13. Align syringes to both extensions and open clamps. Aspirate blood from both lumens. Blood should be aspirated slowly. Once proper blood aspiration has been established, ensure both lumens are unclamped and flush both lumens with flushing solution.

**CAUTION:** Take the following steps to avoid or minimize:

- Ensure the internal valve of the needleless injection site cap are in their closest position without use. Aspiration then impairs the catheter with saline prior to each use. Purge air from the catheter and lumen as tubing whenever tubing connections are changed.
- Clamp only the extension tubes with the in-line clamps provided with the Symetrex® Long Term Hemodialysis Catheter. Do not use formainds and do not clamp the distal portion of the catheter. Do not clamp over stylets.

**REFERENCES**


**ALWAYS ENSURE BOTH INJECTION CAPS ARE ATTACHED TO CATHETER LUERS POST EXCHANGE**

**FAILURE:** Failure to verify catheter placement with fluoroscopy may result in serious trauma or fatal complications.

- Suture site as needed and apply an adhesive wound dressing.
- Suture wounds to patient's skin.

**FEMORAL VEIN PLACEMENT PROCEDURE**

For femoral placement, position the patient supine, and insert the tip of the lumen into the iliac vein and inferior vena cava.

**WARNING:** The risk of infection is increased with femoral vein insertion.

**NOTE:** Catheters greater than 17Gm are intended for femoral vein insertion.

**NOTE:** To reduce the number of cannulation attempts and mechanical complications, CDC Guidelines recommend the use of Ultrasound Guidance. Ultrasound guidance should only be used by those fully trained in its technique.

1. Assess the right and left femoral areas for suitability for catheter placement. Ultrasound may be helpful.
2. On the same side as the insertion site, have the patient flex the knee with the thigh abducted and the foot placed across the opposite leg.
3. Locate the femoral vein, posterior medial to the femoral artery.
4. Go to Part C Percutaneous Access (Common Steps)
5. Go to Part B Tunnel Catheter (Common Steps)
6. Go to Part C Catheter Insertion Technique (Common Steps)
7. Go to Part D Catheter Aspiration (Common Steps)

**CATHETER REMOVAL**

Free cuff from surrounding tissue prior to removal. Withhold the catheter through the exit site. Do not apply pressure to proximal tunnel for approximately 10-15 minutes until bleeding stops. Suture incision and apply dressing in a manner to promote optimal healing.

**CAUTION:** Remove catheter with care. Sharp, jerking motions and undue force may tear catheter.

**STORAGE**

Store at room controlled temperature. Do not expose to extremes, freezing or radiation or ultraviolet light. Rotate inventory so that catheters are used before the expiration date on the package label.

**WARRANTY**

Medtronic® WARRANTS THAT THIS PRODUCT WILL BE FIT FOR ITS PURPOSE TO THE EXTENT STATED IN THIS INSTRUCTION AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN. Because of continuing product improvement, price, specifications, and local availability may be subject to change without notice. Medtronic reserves the right to modify its products or contents in accordance with all relevant regulatory requirements.

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