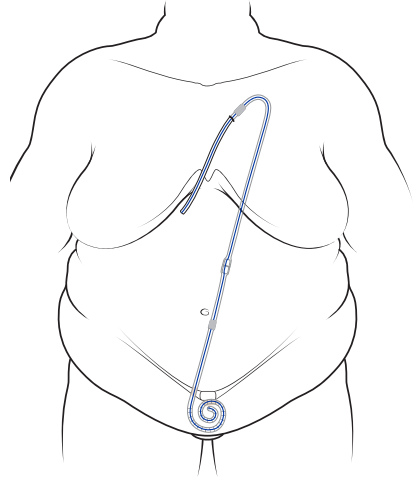
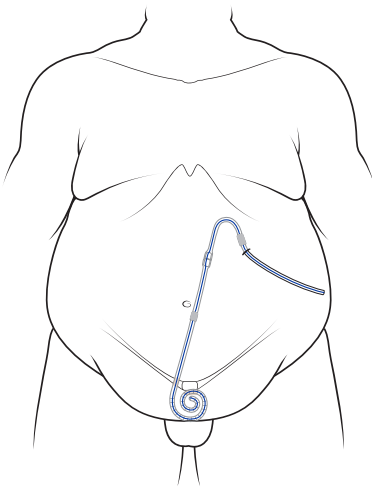


# FLEX-NECK® EXXTENDED™ CATHETER IMPLANTATION PROCEDURE KIT

Upper Abdomen Catheter Placement  
Upper Chest Catheter Placement

## INSTRUCTIONS FOR USE



# FLEX-NECK EXXTENDED CATHETER KIT

## INSTRUCTIONS FOR USE

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### Product Description

Each Flex-Neck ExxTended Catheter Kit contains a sealed tray and a separate sealed pouch.

### Tray Contents:

- Lower Catheter
- Upper Catheter
- Titanium tube-to-tube connector, double barbed (internal use)
- Tape measure
- Flex-Neck® ExxTended™ Catheter Implantation Stencil Set
- Surgical marking pen
- Plastic catheter connector (external use)
- Plastic catheter connector cap (external use)

### Pouch Contents:

- Tunneling Tool, curved
- Measuring Rod

### Indications for Use

If a patient is a suitable adult candidate for peritoneal dialysis (PD) therapy, the Flex-Neck ExxTended peritoneal dialysis catheter can be implanted either surgically, laparoscopically, or peritoneoscopically for acute or chronic peritoneal dialysis. Stencils sold with the device, and marketed separately, will be used to assist the physician to locate the optimum primary implantation site and the optimum catheter exit site for the Flex-Neck ExxTended Catheter.

### Contraindications for Use

Do not use the ExxTended Catheter if the patient is not a suitable candidate for peritoneal dialysis therapy.

### WARNING:

The Upper Chest exit-site location of the ExxTended Catheter should not be used if the patient has had breast implantation or breast reconstruction, or has a tracheostomy. However, this group of patients may be suitable candidates for the Upper Abdomen exit-site location of the ExxTended Catheter.



### MRI Safety Information: MR Conditional

This product has been evaluated to determine MRI compatibility and have been found to be compatible.

Non-clinical testing has demonstrated that the Peritoneal Dialysis Catheter is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static Magnetic Field of 1.5T and 3.0T only
- Maximum spatial gradient magnetic field of 3,000 Gauss/cm (30T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

### MRI-Related Heating

Under the scan conditions defined above, the Peritoneal Dialysis Catheter is expected to produce a maximum temperature rise of 1.5°C after 15 minutes of continuous scanning.

### Artifact Information

In a non-clinical testing, the image artifact caused by the device extends approximately 10mm from the Peritoneal Dialysis Catheter when imaged with a gradient echo pulse sequence and a 3Tesla MRI system. The artifact does not obscure the device lumen.

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

### PRECAUTIONS:

- Read manufacturer's instructions prior to use.
- Contents are sterile (via ethylene oxide). Do not use if packaging is opened, damaged or broken.
- For single patient use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure, which in turn may result in patient injury, illness, or death. Reuse, reprocessing or resterilization may also create

a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

- Do not use after expiration date.
- The medical techniques, procedures, and potential complications stated herein do NOT give full and/or complete coverage or descriptions. They are not a substitute for adequate training and sound medical judgment by a physician.
- Use an aseptic procedure to open the package and to remove the contents.

### Potential Complications

Peritoneal dialysis potentially has a number of complications that may occur, which generally are not caused by the implantation, but may affect the quality of therapy. These complications may include, but are not limited to, the following:

- Infections (exit-site or tunnel)
- Peritonitis
- Sepsis
- Bowel Perforation
- Leakage (initial or latent)
- Fluid flow obstruction (inflow or outflow)
- Bleeding (subcutaneous or peritoneal)
- Ileus
- Proximal exit cuff erosion
- Distal (rectus/deep) cuff erosion
- Risks normally associated with surgical procedures.

### Cautions:

- Do not twist or rotate catheter during the implantation procedure.
- ExxTended Stencils cannot be used with other brands of PD catheters.
- Enclosed Stencils are designed for Flex-Neck, ExxTended, Coiled Adult Peritoneal Dialysis Catheters ONLY.
- Do NOT use ExxTended stencils with Flex-Neck Adolescent, Pediatric, or Infant Catheters.
- Do NOT sterilize or reuse Stencils.
- Catheter tubing can tear when subjected to repeated clamping, serrated-jaw forceps, excessive force, or rough tools.
- Do NOT use forceps with a serrated jaw.
- Do NOT use excessive force to lock the forceps closed.
- Use ONLY smooth-jawed forceps or equivalent.
- Do NOT clamp the catheter, or repair tubing repeatedly in

- the same area.
- Do NOT clamp near the connector.

Use only catheter connectors and repairs kits which are specifically labeled and approved for use with Flex-Neck Peritoneal Dialysis Catheters. Approved catheter connectors and repair kits can be ordered directly from Merit Medical Systems, Inc.

For best results, use the Stencils included with each catheter kit. If not using the included Stencils, follow generally accepted standard hospital protocols to make arcuate-shaped tunnels.

**Cautions:** Use the radiopaque stripe as a guide to keep the catheter straight. The catheter must not be twisted or rotated during the implantation procedure. Any twist or rotation in the catheter can lead to kinks, migration, and/or occlusion.

**Assumptions to Successful ExxTended™ Catheter Implantation**

As with any medical/surgical procedure, there are a number of assumptions and prerequisites made for the successful implantation of the ExxTended catheter.

- The implanting physician has had a reasonable number of successful peritoneal dialysis catheter implantations, preferably via laparoscopic or peritoneoscopic implantation. The ExxTended catheter can also be implanted via a cut-down method or guide-wire technique.
- Preferably, the patient's lower abdomen and exit-site area either Upper Chest or Upper Abdomen have been previously marked by the Flex-Neck ExxTended Catheter Implantation Stencils, in the clinic or during pre-op evaluation. At a minimum, the patient should be evaluated preoperatively to determine a proper, accessible location for the catheter exit site. These marking should be noted for reference during implantation.
- The implanting physician should use the Flex-Neck ExxTended Catheter Stencils (included with each catheter pack) to verify the primary implantation site, the Upper Catheter tunnel track, and the exit-site, as previously chosen and marked in the clinic or pre-op evaluation.
- For Upper Chest Catheter exit-site procedures, the implanting physician will keep the subcutaneous part of the catheter and the catheter exit-site off the sternum. Doing so will protect the integrity of the catheter in the event of future cardiovascular surgery that may require a midline sternotomy.

Outer Diameter	Inner Diameter	Overall length, Straightened, Untrimmed	Fill Volume
5.1 mm	3.5 mm	62.0 cm (Lower Cath) 62.0 cm (Upper Cath)	Maximum: 12.0 mL
		<i>Must be trimmed to fit patient physique and exit-site location.</i>	<i>To find fill volume of trimmed, joined catheter, multiply total length of joined catheter (in cm) by 0.096 to get fill volume in cc.</i>

**Section A**  
**INSTRUCTIONS FOR FLEX-NECK EXXTENDED CATHETER IMPLANTATION STENCIL SET**

The Implantation Stencils for Flex-Neck ExxTended Peritoneal Dialysis (PD) Catheters help choose the best implantation and exit- sites for each patient. Note that these Implantation Stencils cannot be used with other brands of PD catheters, or with other sizes or styles of Flex-Neck PD Catheters.

For best results, the Implantation Stencils can also be used during operative preparations, to mark, coordinate, verify and/or

adopt the markings made during the preoperative examination as needed after laparoscopic visualization of the peritoneal space. Please refer to the complete "Implantation Stencils for Flex-Neck ExxTended Catheter Instructions for Use" distributed by Merit Medical Systems, for more information.

The Stencil pattern contains essential catheter design information including the distance between the deep cuff and the coil-tip, the shapes of preformed tubing bends, and the distance between the superficial cuff and the exit-site. Additional features of the Stencil permit its precise orientation on the torso, according to stable anatomical landmarks: the pubic symphysis, representing the anterior cranial border of the deep pelvis, and the anatomical midline of the torso. The Stencils permit accurate and reproducible association of the catheter design elements to these vital anatomical landmarks to help determine the best catheter insertion site and deep cuff placement that will produce the optimal pelvic position of the catheter coil and the ideal exit-site location, either in the upper abdomen below the costal margin, or in the upper chest off the sternum.

**NOTE:**  
Each ExxTended Catheter Kit includes three Stencils. Each Stencil has a reverse side for Right (R) and Left (L) catheter placements. L-1, L-2 and R-1, R-2 are used for Upper Abdomen Catheter placement. L-1, L-3 and R-1, R-3 are used for Upper Chest Catheter placements.

**CAUTION**  
These ExxTended Implantation Stencils are specific for ONLY Flex-Neck ExxTended Adult Peritoneal Dialysis Catheters.

- Do NOT use these Stencils for other catheter brands.
- Do NOT use these Stencils for Flex-Neck Classic or ARC™ Catheters, in Adult, Adolescent, Pediatric, or Infant sizes.
- Do NOT sterilize these Stencils
- Stencils are available through Merit Medical Systems., Inc.

**Patient Marking in the Surgical Suite – Upper Abdomen and Upper Chest**

**NOTE:**  
These instructions are for marking the ExxTended Catheter Upper Chest and Upper Abdomen configurations.

The following instructions are specific for implanting the ExxTended Catheter on the patient's left side. If the ExxTended Catheter is to be implanted on the patient's right side, substitute the R-Series Stencils.

**Upper Abdomen Stencil Instructions**  
Align the midline edge of the L-1 Stencil on the patient's abdominal midline. Adjust the Stencil caudally or cranially to position the notched cutout on the upper border of the pubic symphysis. This will be the location of the upper extent of the catheter coil as it lies in the pelvis. See Figure 1.

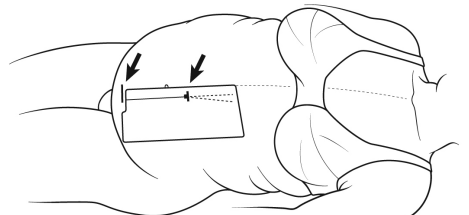




Figure 1

With the Stencil aligned on the patient's midline, and the notched cutout positioned as above, mark the T-bar cutout which indicates the location of the primary incision site through which the lower catheter will be inserted during the implantation procedure and specifies the final resting position of the rectus cuff.

- Align the midline edge of the L-2 Stencil with the midline

of the patient's abdomen. Adjust the Stencil up or down until exit-site Circle  cutout is in desired position according to pre-procedural patient markings. Confirm that the upper edge of the catheter tunnel track, or arcuate bend, is below the costal margin. If the subcutaneous path indicated by the Stencil overlaps the costal margin, then shift the Stencil caudally until the rib margin is cleared. The midline edge of the Stencil should remain parallel to the patient's midline but may not exactly coincide with midline due to lateral shift from weight of skin. Mark the exit-site Circle  with the Stencil in this position. See Figure 2.

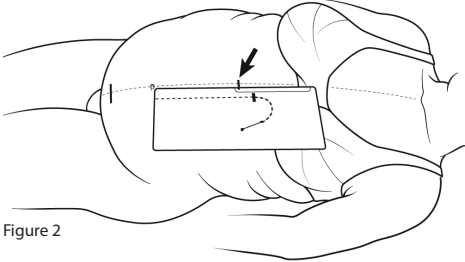







Figure 2

Confirm that selected exit-site does not conflict with belt line, skin creases or folds. Exit site should be easily visible to the patient as indicated by pre-procedural consultation and markings.

When satisfactory locations for the Exit-Site, Circle  and the arcuate bend are achieved, mark the secondary incision site, Rectangle . This is where the Tunneling Tool with the attached ExxTended Catheter will temporarily emerge. With proper implantation of the Upper Catheter segment, the black marker ring will rest at the level of the secondary incision.

Mark the exit cuff location, Diamond . Trace the shape of the arcuate tunnel path on the skin, using the Stencil cutouts as a guide. The guidelines on Stencils L-1 and L-2 indicate the planned pathway to connect the primary incision site, T-bar  and secondary incision, Rectangle . See Figure 3.

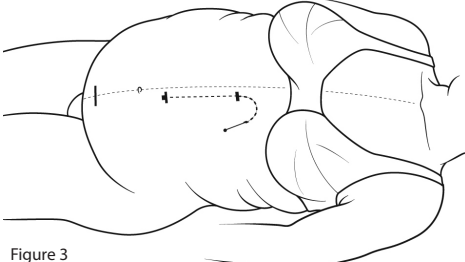


Figure 3

### Upper Chest Stencil Instructions

**NOTE:** The following Instructions are specific for implanting the ExxTended Catheter on the patient's left side. If the ExxTended Catheter is to be implanted on the patient's right side, substitute the R-Series stencils.

Align the midline edge of the L-1 Stencil on the patient's abdominal midline. Adjust the Stencil caudally or cranially to position the notched cutout on the upper border of the pubic symphysis. This will be the location of the upper extent of the catheter coil as it lies in the pelvis. See Figure 4.

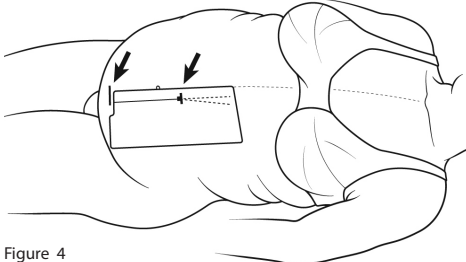





Figure 4

With the Stencil aligned on the patient's midline, and the notched cutout positioned as above, mark the T-bar cutout  which indicates the location of the primary incision site through which the lower catheter will be inserted during the implantation procedure and specifies the final resting position of the rectus cuff.

Align the midline edge of the L-3 Stencil with midline of chest. Adjust the Stencil up or down until the Exit-Site, Circle , is in desired position. Mark the exit-site, Circle . See Figure 5.

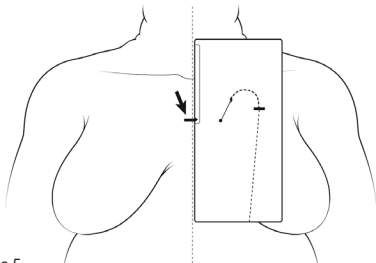


Figure 5

Confirm that selected exit-site is free from open collar area, infraclavicular region, median sternotomy zone, and fleshy part of breast. See Figure 6 for overlay of regions.

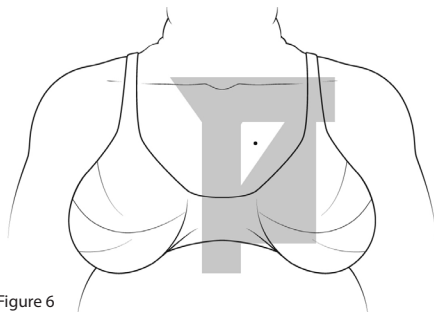







Figure 6

The midline edge of the Stencil should remain parallel to the patient's midline but may not exactly coincide with midline due to lateral shift from weight of skin. Confirm that the subcutaneous path indicated by the Stencil for the arcuate bend does not conflict with the clavicle. If the subcutaneous path indicated by the Stencil overlaps the clavicle, then shift the Stencil caudally until the clavicle is cleared.

When satisfactory locations for the exit-site, Circle  and the arcuate bend are achieved, mark the secondary incision site, Rectangle . This is where the Tunneling Tool with the attached ExxTended Catheter will temporarily emerge. With proper implantation of the Upper Catheter segment, the marker ring will rest at the level of the secondary incision. Mark the Exit Cuff location, Diamond . Trace the shape of the arcuate tunnel path on the skin, using the Stencil cutouts as a guide. The

guidelines on Stencils L-1 and L-3 indicate the planned pathway to connect the primary incision site, T-bar , and secondary incision, Rectangle . See Figure 7.

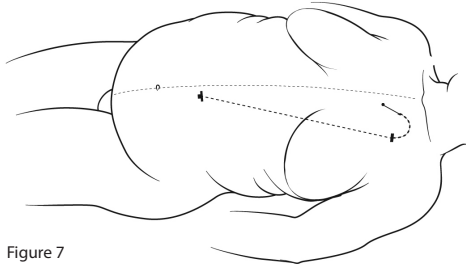


Figure 7

## Section B

### EXTENDED™ LOWER CATHETER IMPLANTATION FOR UPPER ABDOMEN AND UPPER CHEST EXIT-SITE

#### Implanting the Lower Catheter

There are 3 options for implanting the Lower Catheter:

1. Laparoscopic approach, with or without Y-TEC® catheter implantation system. This approach is recommended. Y-TEC peritoneal dialysis catheter implantation systems including Instructions for Use are available through Merit Medical Systems, Inc.


**NOTE:** If laparoscopy is used to implant the Lower Catheter, deflate the abdomen before testing catheter patency to avoid false fluid outflow rates.

2. Open surgical dissection (cut-down technique).
3. Percutaneous or Modified Seldinger technique, with or without fluoroscopic guidance.

Regardless of which implantation technique is used, ALWAYS make sure to:

- Place the deep cuff within the rectus muscle.
- Angle the catheter inferiorly as it passes through the rectus muscle to direct it into the pelvis.
- Do not twist or rotate the catheter; verify that the radiopaque stripe is straight throughout the procedure.
- Test Lower Catheter patency by infusing a minimum of 60 cc of sterile saline and observing the outflow rate before proceeding with the implantation procedure.

The following is a general implantation procedure for the ExxTended Catheter's Lower Catheter. Adapt as appropriate to the technique used.

- Administer patient anesthesia as appropriate for the technique used.
- Abdominal preparation: Surgical skin preparation is performed according to hospital protocol. Drape patient and abdomen in standard manner. Consider the use of plastic adhesive skin barriers with or without iodine impregnation when large skin surface areas will be exposed.  
Optional: Place patient in typical Trendelenburg position.
- Prepare the catheter by soaking it in sterile saline. Squeeze the air out of the cuffs by rolling the submerged cuffs between fingers. Flush the lumen of the catheter with sterile saline.
- At the designated primary incision site, T-bar , make a horizontal skin incision appropriate in length according to the catheter implantation technique being used. The primary incision is the Lower Catheter insertion site and the rectus muscle cuff location.
- Dissection is performed down to and exposing the anterior

rectus muscle sheath. Perform dissection on the surface of the fascia in a cranial direction along the anticipated path of the catheter to the planned upper abdominal secondary incision. This subcutaneous path will create a starting point for insertion of the Tunneling Tool tip at a later step.

6. Catheter insertion should be performed through the body of the rectus muscle appropriate to the technique being employed, and may include puncture or muscle-splitting incision.

7. With the Lower Catheter straightened over a stylette (sold separately), keeping the radiopaque stripe straight, the catheter tip should be directed toward a deep pelvic location between the parietal and visceral peritoneum.

**NOTE:** The Lower Catheter must be used only with the coordinating Flex-Neck Adult Catheter Implantation Stylette that is specifically sized to match the overall length and inner diameter of the Lower Catheter.

8. If the catheter is implanted in the patient's left side, the Lower Catheter radiopaque stripe will face up (anteriorly). If the catheter is implanted in the patient's right side, the Lower Catheter radiopaque stripe will face down (posteriorly).

9. The catheter cuff should be positioned in the rectus muscle to provide for good tissue ingrowth and firm fixation of the catheter to prevent pericatheter leaks and hernias.

10. Appropriate to the technique being used to insert the catheter, careful placement of purse-string sutures may be performed to reduce the risk of pericatheter leaks.

**NOTE:** Use care in placing sutures to assure catheter is not damaged and flow is not impeded.



11. Test catheter patency via infusion of a minimum of 60 ml sterile saline, and observe the outflow rate.

**NOTE:** If the abdomen was insufflated during laparoscopic insertion, deflate the abdomen to avoid false fluid outflow rates.

## Section C

### INSTRUCTIONS FOR IMPLANTING UPPER ABDOMINAL CATHETER: SIZING, CONNECTING AND PLACEMENT

#### Measurement Locations for Sizing the Upper Abdominal Catheter

Measurements are based on three locations: 1) the Primary Incision Site, T-bar , where the rectus cuff is located and the Lower Catheter is temporarily exiting the abdomen; 2) the Secondary Incision Site, as indicated by the Rectangle ; and

3) the location where the two catheters will be joined together. These instructions presume that the primary and secondary incision sites were marked during patient preparation prior to surgery. See Figure 8.

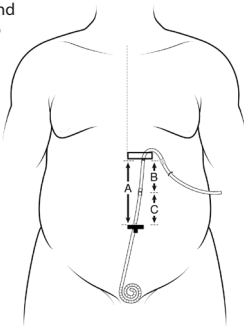



Figure 8

**Preparation for Sizing the Upper Abdominal Catheter**

1. Catheters should NOT be trimmed until after the Lower (abdominal) Catheter has been implanted and the rectus cuff is securely in place in the muscle, and after the secondary incision has been made at the marked Rectangle . This will prevent catheter waste in case some aspect of the surgical procedure should change, thus modifying the measurements.

2. The patient should be supine in order to properly measure the distance between the primary and secondary incision marks. The flat position will assure that the patient will be provided the maximum required catheter length, and prevents the catheter from being trimmed too short. If the patient was placed in the Trendelenburg position during implantation of the Lower Catheter, return the patient to a supine position for this portion of the procedure.

Although the patient may normally have a slumping posture in the upright position, if the catheter is properly positioned on the fascial surface between the primary and secondary incisions, kinking will not occur.



Ensure that: a) no padding was placed behind the shoulders by the anesthesia personnel; b) that there are no bends (flexion or hyperextension) in the table; and c) that there is no abdominal distension from laparoscopically-induced pneumoperitoneum.

**3. NOTE:**

- a) All measurements described herein are in centimeters.
- b) The distance on the Upper Catheter from the marker ring to tip is 30 cm.
- c) The distance on the Lower Catheter from the rectus cuff to distal tip is 31 cm.


**Measuring and Cutting the Upper Abdominal Catheter**

**NOTE:** Alternative measuring instructions follow this section.

1. Using the provided sterile tape measure, measure the distance between the primary incision site, T-bar  (where the Lower Catheter is temporarily exiting the patient), and the secondary incision site, Rectangle . Keep the tape taut, without stretching, over the torso between the primary and secondary incision sites, keeping the tape above the abdomen contour. Do not allow the tape to follow the body contour, and do not compensate for the amount of or depth of body fat. If the tape is allowed to follow the body contour or if the measurements are adjusted for body fat depth, the result will be an excessive length of tubing between the primary and secondary incisions, possibly leading to kinking of the catheter.
2. Record that distance, "A", in centimeters, between the primary and secondary incision sites. This distance, A, represents the total length needed when combining Upper and Lower Catheters. See Figure 8.

3. Select and note a potential location where the Upper and Lower Catheters will be connected together by the internal double-barbed Titanium Connector. The Titanium Connector should rest on the flat surface of the abdominal wall fascia, avoiding locations subject to pressure discomfort from the belt line and/or angulation produced by flexing of the torso at skin creases.

**NOTE:** When selecting the location to cut and join the catheters, ensure that the connector will be positioned over the abdominal wall, and not over the costal margin or chest.

4. Using the provided tape measure, measure the distance between the secondary incision site, Rectangle , and the chosen union site. See Figure 9. Record that distance in centimeters, as "B". This will be the length needed of the Upper Catheter tubing from the marker ring to the catheter union site.

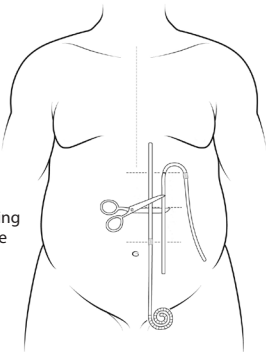


Figure 9

5. Subtract B from A to get the length of Lower Catheter tubing needed to reach from the location of the deep cuff under the fascia to the location of the catheter union. Record that distance in centimeters, as "C". See Figure 9.

**A - B = C**, C is the total length needed for the Lower Catheter.

**NOTE:** In order to be able to work with the Lower Catheter, avoid using a length of C less than 5 cm.

6. Insert the Measuring Rod (located in the separate sterile pouch along with the Tunneling Tool) beginning with the tip marking 1 cm, into the primary incision next to the Lower Catheter, perpendicular to the fascia and parallel to the catheter. Advance the Measuring Rod until the tip meets the rectus fascia. See Figure 10.

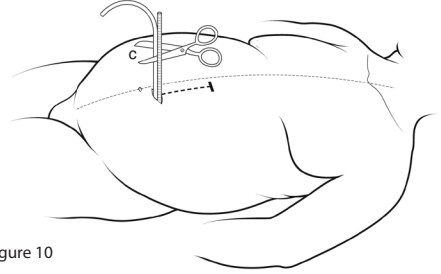


Figure 10

7. Hold the external limb of the Lower Catheter next to, and parallel to, the Measuring Rod. Using the centimeter markings on the Measuring Rod, cut the Lower Catheter at the C length above the level of the fascia (Figure 10). Make a single, straight, perpendicular cut of the tubing with suture scissors.

8. Place the Measuring Rod alongside the Upper Catheter with the B recorded length on the Measuring Rod at the level of the Catheter marker ring.

Cut the Upper Catheter at the level of the tip of the Measuring Rod Figure 11. Make a single, straight, perpendicular cut of the tubing with suture scissors.

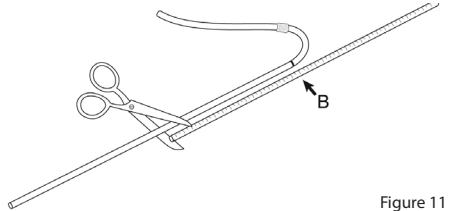



Figure 11

**Alternative Measuring and Cutting Instructions for the Upper Abdominal Catheter**

1. Position the Upper Catheter on the abdominal wall with the black marker ring on the secondary incision, Rectangle .
  2. Overlap the Upper and Lower Catheters and choose an appropriate location to cut and join the two. See figure 12.
- NOTE:** Keep in mind that one of the catheters will need to be further shortened as described in step 5 below.
3. Cut the two catheters at the location selected in step 2.
  4. Using the Measuring Rod, measure the distance from the fascia to the skin at the primary incision site, at the skin surface level.

5. Cut either the Upper OR the Lower catheter (not both) to further shorten it by the distance measured in step 4.

**NOTE:** In order to be able to work with the Lower Catheter, avoid using a length of less than 5 cm.

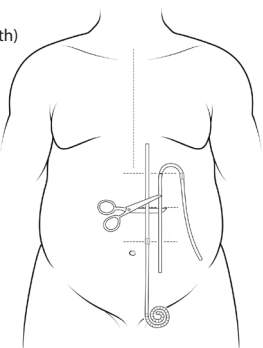


Figure 12

### Connecting the Lower and Upper Catheters

1. Wet the tapered tips of the double-barbed Titanium Connector in sterile saline or sterile water. Do not use any other lubricant.

1. Insert one end of the double-barbed Titanium Connector into the proximal end of the Lower Catheter. Push the catheter tip all the way to the connector's center ring barrier. Do not use a twisting motion to force the catheter onto the Connector. Push the Connector into the catheter with a single forward motion. Do not dislodge the deep (rectus) cuff.

2. Insert the opposite end of the double-barbed Titanium Connector onto the ascending limb of the Upper Catheter, that is, the limb with the marker ring, NOT the limb with the cuff. Push the catheter tip all the way to the connector's center ring barrier. Do not use a twisting motion to force the catheter onto the Connector. Push the Connector into the catheter with a single forward motion.

**NOTE:** When inserting the Titanium Connector into the Upper Catheter, rotate the Upper Catheter as necessary.

3. Check that radiopaque stripes are 180° opposite. If the catheter is implanted in the patient's left side, the Lower Catheter stripe will face up, while the Upper Catheter stripe will face down. If the catheter is implanted in the patient's right side, the radiopaque stripes will be inverted: the Lower Catheter stripe will face down, and the Upper Catheter stripe will face up. When connecting the Upper Catheter, ensure that the catheter is oriented so that the cuff and exit site face laterally.

4. Tie a non-absorbable suture, such as 2-0 or 0-polypropylene, around each catheter, behind the barb on the Titanium Connector. The two sutures may then be tied to each other to further prevent tubing separation.

5. Test the integrity of the junctions by pulling firmly on each catheter in turn while holding the connector. Do not dislodge the deep (rectus) cuff during this pull test.

### Implanting the Upper Catheter with an Upper Abdomen Exit-Site

1. Make a 2.0 - 3.0 cm horizontal incision at the marked secondary incision site, Rectangle  .

2. At the secondary incision site, Rectangle  , perform dissection in the subcutaneous tissue to the anterior rectus fascia. On the surface of the fascia, create a subcutaneous pocket to contain the preformed arcuate bend of the Upper Catheter. In addition, perform dissection caudally on the surface of the fascia to facilitate passage of the ExxTended Catheter Tunneling Tool tip from the primary (lower) incision to the secondary (upper) incision.

3. Insert the blunt, bullet-shaped end of the Tunneling Tool into the primary incision site.

4. Guide the Tunneling Tool along the surface of the fascia to the secondary incision site.

### NOTE:

- Make sure that the Tunneling Tool stays in the relatively loose avascular areolar tissue plane between the muscle fascia and subcutaneous tissue. Do not insert the tool and catheter into the subcutaneous fat. Doing so may cause the catheter to kink during certain patient activities.
- Do not cross the patient's midline of the abdomen or chest.
- Follow the marked Tunnel Track, as indicated by the Stencil, when feasible.
- If a laparoscopic catheter implantation approach is being used, the presence of a pneumoperitoneum provides a firm fascial surface that facilitates passage of the Tunneling Tool.

5. Advance the Tunneling Tool far enough through the secondary incision site so that it can be grasped with the other hand.

6. Attach the proximal end of the Upper Catheter to the barbed tip of the ExxTended™ Catheter Tunneling Tool.

7. Secure the catheter end onto the tip with a suture.

8. Carefully pull the Tunneling Tool out through the secondary incision site far enough so that the Tool can be laid down.

**NOTE:** Do not twist the catheter. Observe the radiopaque stripe to ensure that the catheter remains straight.

9. Continue to pull the catheter gently until the marker ring is visible at the secondary incision site.

### NOTE:

- When the marker ring is visualized on the surface of the fascia at the secondary incision site, the length of the catheter between the marker ring and the deep (rectus) cuff should be relatively straight.
- Do not dislodge the deep (rectus) cuff.
- Do not twist or rotate the catheter. Observe the radiopaque stripe to ensure that the catheter remains straight. Excess, non-straightened tubing may cause future kinking and flow failures under some conditions.

10. Cut the catheter free of the Tunneling Tool.

### NOTE:

- Do not attempt to use the end of the catheter that was inserted over the barbed tip of the Tunneling Tool. It is stretched too much to be able to hold the connector securely.
- When cutting the catheter free of the Tunneling Tool, make a straight, perpendicular cut of the tubing with suture scissors. Always verify that the cuts are perpendicular to the catheter tubing so that the connector fits well in the catheter.

11. Infuse a minimum of 60 mL of sterile saline to verify patency, and that there are no twists or kinks in the catheter.

**NOTE:** If the abdomen was insufflated during laparoscopic insertion, deflate the abdomen to avoid false fluid outflow rates.

### Finalizing Catheter Placement

Merit Medical Systems, Inc. provides three options for tunneling the catheter through the skin exit-site location. The technique for creating the exit-site will vary according to the particular tool selected to perform this function. A plastic retrograde Tunnelor® Tool, plastic antegrade Faller Trocar, and stainless steel antegrade Faller Trocar are sold separately.

1. The exit site location should be lateral to the primary site. The exit-site should be approximately 3-4 cm distal to the exit site cuff if possible.

**NOTE:** For reduced infection and optimal placement, the catheter should have a gentle, curved downward-facing exit-site.

**WARNING:** Check catheter at primary site and exit-site to ensure the catheter is not twisted or kinked.

2. After the catheter has been tunneled to the exit-site, verify catheter patency by infusing and draining a minimum of 1.0 L of sterile saline.



3. Attach the catheter connector and cap, or alternatively, a connector and transfer set. See below, "Catheter Connector Instructions", for details.

4. Close the primary and secondary incision sites, appropriate to the implantation technique used.

#### NOTE:


- Do not suture the exit-site.
- Do not use anchoring stitches to secure the catheter to the skin. Instead, use sterile adhesive strips to immobilize the catheter on the skin adjacent to the exit-site.
- Apply appropriate dressings to all incision sites and to the catheter itself.

#### Supplemental Information


- The external catheter limb can be embedded at this point, if desired. An Embedding™ Tool is available from Merit Medical.
- Urgent or supportive dialysis can begin immediately with reduced volumes (1 liter maximum) and the patient in a supine position. If possible, the abdomen should be continuously dry (nocturnally) for 8-12 hours within each 24 hour period after catheter placement for the first full week of dialysis. If the patient assumes an upright position, there should be no fluid in the abdomen for the first 7 days or until the catheter sites are healed.
- Catheter immobilization is important to allow for proper tissue in-growth.
- The catheter should be flushed with heparinized saline within 24 to 72 hours and a minimum of every 7 days thereafter.

## Section D

### INSTRUCTIONS FOR IMPLANTING UPPER CHEST CATHETER: SIZING, CONNECTING AND PLACEMENT

Measurement Locations for Sizing the Upper Chest Catheter Measurements are based on three locations: 1) The Primary Incision Site, T-bar, where the rectus cuff is located and the Lower Catheter is temporarily exiting the abdomen; 2) The Secondary Incision Site, as indicated by the Rectangle  and 3) the location where the two catheters will be joined together. These instructions presume that the primary and secondary incision sites were marked during patient preparation prior to surgery.

#### Preparation for Sizing the Upper Chest Catheter

1. Catheters should NOT be trimmed until after the Lower (abdominal) Catheter has been implanted and the rectus cuff is securely in place in the muscle, and after the secondary incision has been made at the marked Rectangle . This will prevent catheter waste in case some aspect of the surgical procedure should change, thus modifying the measurements.

2. The patient should be supine in order to properly measure the distance between the primary and secondary incision marks. The flat position will assure that the patient will be provided the maximum required catheter length, and prevents the catheter from being trimmed too short. If the patient was placed in the Trendelenburg position during implantation of the Lower Catheter, return the patient to a supine position for this portion of the procedure.

Although the patient may normally have a slumping posture in the upright position, if the catheter is properly positioned on the fascial surface between the primary and secondary incisions, kinking will not occur.

Ensure that: a) no padding was placed behind the shoulders by the anesthesia personnel; b) that there are no bends (flexion or hyperextension) in the table; and c) that there is no abdominal distension from laparoscopically-induced pneumoperitoneum.



#### NOTE:

- All measurements described herein are in centimeters.
- The distance on the Upper Catheter from the marker ring to tip is 30 cm.

c) The distance on the Lower Catheter from the rectus cuff to distal tip is 31 cm.

#### Measuring and Cutting the Upper Chest Catheter

**NOTE:** Alternative measuring instructions follow this section.

1. Using the provided sterile tape measure, measure the distance between the primary incision site, T-bar  (where the Lower Catheter is temporarily exiting the patient), and the secondary incision site, Rectangle . Keep the tape taut, without stretching, over the torso between the primary and secondary incision sites, keeping the tape above the chest and abdomen contours. Do not allow the tape to follow the body, breast, and abdomen contours, and do not compensate for the amount of or depth of body fat. If the tape is allowed to follow the body and/or breast contours, or if the measurements are adjusted for body fat depth, the result will be an excessive length of tubing between the primary and secondary incisions, possibly leading to kinking of the catheter.

2. Record that distance, "A", in centimeters, between the primary and secondary incision sites. This distance, A, represents the total length needed when combining Upper and Lower Catheters. See Figure 13.

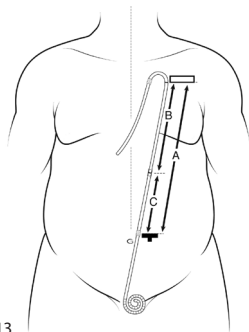



Figure 13

3. Select and note a potential location where the Upper and Lower Catheters will be connected together by the internal double-barbed Titanium Connector. The Titanium Connector should rest on the flat surface of the abdominal wall fascia, avoiding locations subject to pressure discomfort from the bra or belt line and/or angulation produced by flexing of the torso at skin creases.

**NOTE:** When selecting the location to cut and join the catheters, ensure that the connector will be positioned over the abdominal wall, and not over the costal margin or chest.

4. Using the provided tape measure, measure the distance between the secondary incision site, Rectangle , and the chosen union site. Record that distance, in centimeters, as "B". This will be the length needed of the Upper Catheter tubing from the marker ring to the Titanium Connector. See Figure 13.

5. Subtract B from A to get the length of Lower Catheter tubing needed to reach from the location of the deep cuff under the fascia to the location of the deep cuff under the fascia to the location of the catheter union. Record that distance in centimeters as "C".

$A - B = C$ , C is the total length needed for the Lower Catheter.

**NOTE:** In order to be able to work with the Lower Catheter, avoid using a length of C less than 5 cm.

6. Insert the Measuring Rod (located in the separate sterile pouch along with the Tunneling Tool) beginning with the tip marking 1 cm, into the primary incision next to the Lower Catheter, perpendicular to the fascia and parallel to the catheter. Advance the Measuring Rod until the tip meets the rectus fascia. See Figure 14.



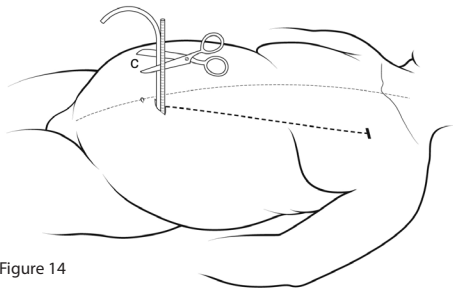


Figure 14

7. Hold the external limb of the Lower Catheter next to, and parallel to, the Measuring Rod. Using the centimeter markings on the Measuring Rod, cut the Lower Catheter at the C length above the level of the fascia (Figure 14). Make a single, straight, perpendicular cut of the tubing with suture scissors.

8. Place the Measuring Rod alongside the Upper Catheter with the B recorded length on the Measuring Rod at the level of the Catheter marker ring. Cut the Upper Catheter at the level of the tip of the Measuring Rod (Figure 15). Make a single, straight, perpendicular cut of the tubing with suture scissors.

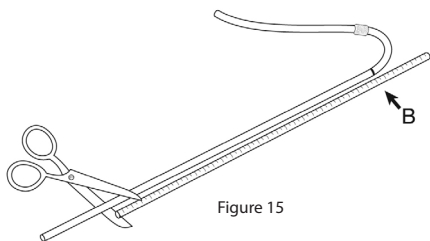


Figure 15

#### Alternative Measuring and Cutting Instructions for the Upper Chest Catheter

1. Position the Upper Catheter on the abdominal wall with the black marker ring on the secondary incision, Rectangle   .
2. Overlap the Upper and Lower catheters and choose an appropriate location to cut and join the two. See figure 16  
**NOTE:** Keep in mind that one of the catheters will need to be further shortened as described in step 5 below.
3. Cut the two catheters at the location selected in step 2.
4. Using the Measuring Rod, measure the distance from the fascia to the skin at the primary incision site, at the skin surface level.

5. Cut either the Upper OR the Lower Catheter (not both) to further shorten it by the distance measured in step 4.  
**NOTE:** In order to be able to work with the Lower Catheter, avoid using a length of less than 5 cm.

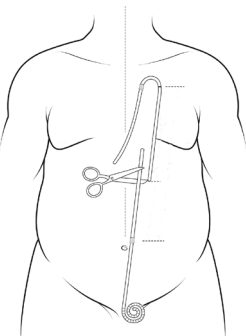


Figure 16

#### Connecting the Lower and Upper Catheters

1. Wet the tapered tips of the double-barbed Titanium Connector in sterile saline or sterile water. Do not use any other lubricant.

2. Insert one end of the double-barbed Titanium Connector into the proximal end of the Lower Catheter. Push the catheter tip all the way to the connector's center ring barrier. Do not use a twisting motion to force the catheter onto the Connector. Push the Connector into the catheter with a single forward motion. Do not dislodge the deep (rectus) cuff.

3. Insert the opposite end of the double-barbed Titanium Connector onto the ascending limb of the Upper Catheter, that is, the limb with the marker ring, NOT the limb with the cuff. Push the catheter tip all the way to the connector's center ring barrier. Do not use a twisting motion to force the catheter onto the Connector. Push the Connector into the catheter with a single forward motion.

Note that for the Upper Chest exit-site, the Lower and Upper Catheters will be implanted with the same "side" up relative to the positions of the radiopaque stripes. When inserting the Titanium Connector into the Upper Catheter, rotate the Upper Catheter as necessary to ensure that the radiopaque stripes are aligned.

4. Check that radiopaque stripes are aligned. If the catheter is implanted in the patient's left side, both radiopaque stripes will be face up (anteriorly). If the catheter is implanted in the patient's right side, both radiopaque stripes will be face down (posteriorly).

5. Tie a non-absorbable suture, such as 2-0 or 0-polypropylene, around each catheter, behind the barb on the Titanium Connector. The two sutures may then be tied to each other to further prevent tubing separation.

6. Test the integrity of the junctions by pulling firmly on each catheter in turn while holding the connector. Do not dislodge the deep (rectus) cuff during this pull test.

#### Implanting the Upper Catheter with an Upper Chest Exit-Site

1. Make a 2.0 - 3.0 cm horizontal incision at the marked secondary incision site, Rectangle   .

2. At the secondary incision site, Rectangle   , perform dissection with a combination of hemostat clamps and ribbon retractors to the pectoralis fascia. On the surface of the fascia, create a subcutaneous pocket to contain the preformed arcuate bend of the Upper Catheter. In addition, perform dissection caudally in the retromammary space to facilitate passage of the ExTended Catheter Tunneling Tool tip from the primary (lower) incision to the secondary (upper) incision.

3. Insert the blunt, bullet-shaped end of the Tunneling Tool into the primary incision site.

4. Guide the Tunneling Tool along the surface of the fascia to the secondary incision site.

#### NOTE:

- a. Make sure that the Tunneling Tool stays in the relatively loose avascular areolar tissue plane between the muscle fascia and subcutaneous tissue. Do not insert the tool and catheter into the subcutaneous fat. Doing so may cause the catheter to kink during certain patient activities.
- b. Do not cross the patient's midline of the abdomen or chest. Do not cross the sternum.
- c. Follow the marked Tunnel Track, as indicated by the Stencil, when feasible.
- d. If a laparoscopic catheter implantation approach is being used, the presence of a pneumoperitoneum provides a firm fascial surface that facilitates passage of the Tunneling Tool.

5. Advance the Tunneling Tool far enough through the secondary incision site so that it can be grasped with the other hand.

6. Attach the proximal end of the Upper Catheter (the end of the catheter closest to the cuff) to the barbed tip of the

7. Secure the catheter end onto the tip with a suture.

8. Carefully pull the Tunneling Tool out through the secondary incision site far enough so that the Tunneling Tool can be laid down.

**NOTE:** Do not twist the catheter. Observe the radiopaque stripe to ensure that the catheter remains straight.

9. Continue to pull the catheter gently until the marker ring is visible at the secondary incision site.

**NOTE:**

- When the marker ring is visualized on the surface of the fascia at the secondary incision site, the length of the catheter between the marker ring and the deep (rectus) cuff should be relatively straight.
- Do not dislodge the deep (rectus) cuff.
- Do not twist or rotate the catheter. Observe the radiopaque stripe to ensure that the catheter remains straight. Excess, non-straightened tubing may cause future kinking and flow failures under some conditions.

10. Cut the catheter free of the Tunneling Tool.

**NOTE:**

- Do not attempt to use the end of the catheter that was inserted over the barbed tip of the Tunneling Tool. It is stretched too much to be able to hold the Connector securely.
- When cutting the catheter free of the Tunneling Tool, make a straight, perpendicular cut of the tubing with suture scissors. Always verify that the cuts are perpendicular to the catheter tubing so that the connector fits well in the catheter.

11. Infuse a minimum of 60 mL of sterile saline to verify patency, and that there are no twists or kinks in the catheter.

## Finalizing Catheter Placement

Merit Medical Systems, Inc. provides three options for tunneling the catheter through the skin exit-site location. The technique for creating the exit-site will vary according to the particular tool selected to perform this function. A plastic retrograde Tunnelor® Tool, plastic antegrade Faller Trocar, and stainless steel antegrade Faller Trocar are sold separately.

1. The exit-site should be approximately 3-4 cm distal to the exit site cuff if possible.

**NOTE:** For reduced infection and optimal placement, the catheter should have a gentle, curved downward-facing exit-site  
**WARNING:** Check catheter at primary site and exit-site to ensure the catheter is not twisted or kinked.

2. After the catheter has been tunneled to the exit-site, verify catheter patency by infusing and draining a minimum of 1.0 L of sterile saline.

3. Attach the Catheter Connector and Cap, or alternatively, a connector and transfer set. See below, "Catheter Connector Instruction" for details.

4. Close the primary and secondary incision sites, appropriate to the implantation technique used.

**NOTE:**

- Do not suture the exit-site.
- Do not use anchoring stitches to secure the catheter to the skin. Instead, use sterile adhesive strips to immobilize the catheter on the skin adjacent to the exit-site.
- Apply appropriate dressings to all incision sites and to the catheter itself.

## Supplemental Information

- Urgent or supportive dialysis can begin immediately with reduced volumes (1 liter maximum) and the patient in a supine position. If possible, the abdomen should be continuously dry (nocturnally) for 8-12 hours within each 24 hour period

after catheter placement for the first full week of dialysis. If the patient assumes an upright position, there should be no fluid in the abdomen for the first 7 days or until the catheter sites are healed.

- Catheter immobilization is important to allow for proper tissue in-growth.
- The catheter should be flushed with heparinized saline within 24 to 72 hours and a minimum of every 7 days thereafter.

## SECTION E

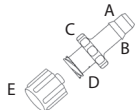
### CATHETER CONNECTOR INSTRUCTION

A Plastic Connector is included with each Flex-Neck Peritoneal Dialysis Catheter. A two-piece Titanium Connector for Flex-Neck Adult, Adolescent, and Pediatric Peritoneal Dialysis Catheters is available separately from Merit Medical.

After successful implantation of the Flex-Neck Peritoneal Dialysis Catheter, attach a Merit Peritoneal Dialysis (PD) Catheter Connector to the catheter.

Each catheter kit contains one Connector and one Cap.

- Tapered Tip (A)
- Raised Shoulder Ridge (B)
- Finger Grip (C)
- Threaded Luer (D)
- Cap (E)



- Wet the Tapered Tip (A) of the Connector with sterile saline or sterile water, and insert it into the catheter.
  - Do not use any other lubricant.
  - Do not use a twisting motion to force the catheter onto the Connector.
  - Push the Connector into the catheter with a single forward motion.

2. Advance the catheter completely to the Raised Shoulder Ridge of the Connector. The catheter tubing must completely pass over the Tapered Tip and to the Raised Shoulder Ridge, but not beyond that onto the Finger Grip. See diagram.



3. Pull carefully on the Connector and catheter to test the strength of the connection.

4. Attach either the Cap (E), or a dialysis transfer set, to the threaded Luer (D).

## Catheter Cleaning and Care

All Flex-Neck Peritoneal Dialysis Catheters are made of silicone. Exit-site cleaning agents that are compatible with silicone catheters therefore may be acceptable for use on Flex-Neck Peritoneal Dialysis Catheters. Such cleaning agents include:

- Electrolytically-produced sodium hypochlorite solutions (i.e., ExSept Plus®)
- Normal (sterile) saline

Cleaning agents that are non-irritating, non-toxic, anti-bacterial, and in liquid form are generally recommended.

The following cleaning agents are not compatible with silicone catheters, and are not recommended for use with Flex-Neck Peritoneal Dialysis catheters:

- Acetone or acetone-based products
- Povidone-iodine or iodine-based products

Merit Medical Systems, does not provide specific recommendations or protocols for exit-site care and cleaning, whether by the healthcare professional or by the patient. Appropriate exit-site and catheter care treatment protocols should be individualized for each patient, and established by the patient's physician(s), nurse(s), dialysis center(s), and/or other relevant dialysis healthcare professionals.

ExSept Plus is a registered trademark of Alcavis HDC, LLC or one of its affiliates.

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CE<sub>2797</sub>



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