



## PERITONEAL DIALYSIS CATHETERS

### INSTRUCTIONS FOR USE

#### INDICATIONS FOR USE:

- The Peritoneal Catheter is indicated for chronic peritoneal dialysis.
- The extended length of the “X” Series Catheter makes it especially applicable for peritoneal dialysis patients when it is necessary to locate the skin exit site remote from the usual lower abdominal region. The catheter may be particularly indicated in patients with obesity, floppy abdominal skin folds, urinary or fecal incontinence, chronic yeast intertrigo, intestinal stomas, or in patients who desire to take deep tub baths.

#### CONTRAINDICATIONS:

- This catheter is contraindicated in patients who are not suitable candidates for peritoneal dialysis therapy.
- An upper chest (presteral) exit-site location of the X-Series Catheter may be contraindicated in patients who have had breast augmentation or breast reconstruction, or have a tracheostomy. However, this group of patients may be suitable candidates for an upper abdominal exit-site location of the X-Series Catheter.

#### DESCRIPTION:

- Medcomp’s peritoneal catheters are made of translucent silicone rubber tubing containing a radiopaque stripe.
- A variety of lengths and cuff configurations are available in straight or curled catheters styles.
- The “X” Series Catheter is comprised of a silicone rubber, coiled tip, single Dacron cuff abdominal catheter segment that is joined with a titanium double barbed connector to a silicone rubber, double Dacron cuff subcutaneous extension catheter possessing a preformed tubing arc bend between the two cuffs. The abdominal catheter segment is implanted into the peritoneal cavity. The attached subcutaneous extension piece allows remote location of the catheter skin exit site away from the lower abdominal region.

#### WARNINGS:

- Tray contents are sterilized by ethylene oxide (EO) STERILE | EO
- Use aseptic procedures to open the tray to remove contents.
- Tray contents are designed for one-time (single) use only. Do not re-clean and resterilize any components. 2  
STERILE
- Do not use components if tray packaging has been previously opened or damaged. X
- Federal law (USA) restricts the device to sale by or on the order of a physician.
- This device is for single use only. **DO NOT RE-USE.** Re-use could lead to infection or illness/injury. X

#### CATHETER PRECAUTIONS:

- Exercise caution when using sharp instruments near the catheters.
- Catheter tubing can tear when subjected to excessive force or rough edges.
- Use only smooth-jawed forceps for clamping when not using the subclavian clip.
- Clamping the catheter repeatedly in the same spot could weaken the tubing. Change the position of the clamp regularly to prolong life of the tubing. Avoid clamping near the female luer.
- Overtightening the catheter connection can crack the female luer.
- Do not use acetone or acetone-based products on any part of the catheter.
- Skin exit site cleaning agents that are acceptable for long-term contact with the silicone rubber include:
  - Antibacterial soap with triclosan
  - Hydrogen peroxide
  - Chlorhexidine
  - Sodium hypochlorite

#### POTENTIAL COMPLICATIONS:

- Peritoneal dialysis may include a number of potential complications that are not directly related to the catheter but can influence the quality and duration of

time on therapy.

These complications may include:

- Peritonitis
- Exit site and/or tunnel infection
- Fluid flow obstruction
- Fluid flow pain
- Pericatheter leak
- Pericatheter hernia
- Catheter tubing erosion through skin
- Polyester cuff erosion through skin
- Dacron cuff erosion through skin
- Bowel or bladder perforation
- Bleeding in abdominal wall or peritoneal cavity

#### GENERAL PRINCIPLES OF “X” SERIES CATHETER IMPLANTATION:

- Read instructions carefully before using this device. The catheter should be implanted, manipulated, and removed by a qualified, licensed physician or other qualified health care professional under the direction of a physician. The medical techniques and procedures described in these instructions for use do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician’s experience and judgment in treating any specific patient. Use standard hospital protocols when applicable.
- Strict aseptic technique must be used during catheter implantation, maintenance, and catheter removal procedures. Provide a sterile operative field. The Operating Room is the preferred location for catheter placement. Use sterile drapes, instruments, and accessories. Removal of body hair at the operative sites should be performed in the preoperative holding area, preferably with electric clippers. Empty the bladder before surgery; otherwise, an indwelling urinary catheter is inserted. A single preoperative dose of prophylactic antibiotic is administered to provide antistaphylococcal coverage. Perform surgical scrub, Wear gown, cap, gloves, and mask.
- Selection of catheter insertion and exit sites and determination of tubing lengths of the abdominal and extension catheter segments is at the sole discretion of the physician. Achieving proper catheter placement and proper length of catheter components is important. A Peritoneal Dialysis Catheter Marking Stencil to assist in determining the most optimal catheter insertion site and skin exit site location through a process of “Stencil-Based Preoperative Mapping” is available from Medcomp®. Guidelines for measuring and trimming the abdominal and extension catheters to appropriate length are described in these instructions for use.
- Performing measurements to determine the combined length of the abdominal and extension catheters is generally conducted in the operating room at the time of the implantation procedure. Primary incision site for insertion of the lower abdominal catheter and secondary incision site for placement of the upper abdominal extension catheter are marked on the skin depending on preoperative evaluation of the patient. The use of the Peritoneal Dialysis Catheter Marking Stencil available from Medcomp® facilitates this process.
  - The patient should be flat supine for measuring the distance between the primary and secondary incision marks.
  - Using the provided measuring tape, measure the distance between the primary and the secondary incision sites. Keep the tape above the contour of the torso between the primary and secondary incision sites. Do not allow the tape to follow the body contour. If the tape is allowed to follow the body contour, the result will be an excessive length of tubing between the primary and secondary incisions, possibly leading to kinking of the catheter.
  - Record the distance, “**A**”, in centimeters, between the primary and secondary incision sites. As will be described in the following sections, this measurement is important for correct trimming of the abdominal and extension catheter segments.
  - Catheters should not be trimmed until the abdominal catheter segment has been implanted and the secondary incision has been created. This will prevent catheter wastage in the event that some aspect of the surgical procedure should change, leading to modification of the measurements.

#### “X” SERIES CATHETER IMPLANTATION - ABDOMINAL CATHETER SEGMENT:

Implanting the abdominal catheter segment is generally performed by one of the following techniques:

- Laparoscopy
- Open surgical dissection (mini-laparotomy)
- Percutaneous needle-guidewire with or without

fluoroscopic guidance

See appropriate medical texts and references for procedural details. The following is a general description of the procedure for implanting the abdominal catheter segment. Adapt as appropriate to the technique used.

- Appropriate anesthetic technique and monitoring is employed to assure the most optimal comfort and safety for the patient.
- Surgical skin preparation is performed with chlorhexidine gluconate scrub or povidone-iodine (scrub or gel). 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.
- Prepare the catheter by soaking it in sterile saline and squeeze the air out of the cuffs by rolling the submerged cuffs between fingers.
- Make a transverse skin incision with scalpel at the catheter insertion site appropriate in length according to the catheter implantation technique being used. The incision at the abdominal catheter insertion site is designated as the primary incision.
- Dissection is performed down to and exposing the anterior rectus muscle sheath. Perform blunt finger dissection on the surface of the fascia in a cephalad 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 rod tip at a later step.
- 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.
- With the catheter straightened over a stylet, the catheter tip should be directed toward a deep pelvic location between the parietal peritoneum and the underlying viscera.
- 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.
- Appropriate to the technique being used to implant the catheter, placement of purse-string sutures may be performed to reduce the risk of pericatheter leaks.
- Test catheter placement and flow function with infusion and drainage of 500 - 1,000 ml of sterile normal saline. Observe for unimpeded inflow and outflow. If needed, revise the catheter position until acceptable flow function is achieved.

Proceed to the section describing implantation of the extension catheter segment according to the planned exit site location to the upper abdomen or upper chest (presteral).

#### “X” SERIES CATHETER IMPLANTATION - EXTENSION CATHETER FOR UPPER ABDOMINAL EXIT SITE :

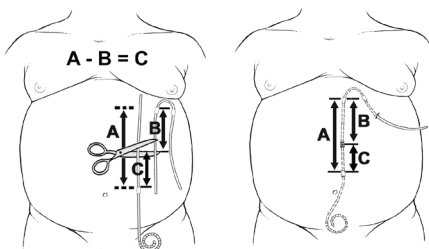
As a rule, the subcutaneous ascending limb of the extension catheter is directed cephalad toward the secondary incision in the same paramedian plane as the primary incision. The arcuate bend and external limb of the extension segment is oriented laterally to descend to the skin exit site. This configuration allows the highest possible placement of the upper abdominal exit site which being fixed by the catheter’s arcuate design will necessarily lie below the level of the secondary incision. In this arrangement, the external catheter limb can be placed in a more cephalad position without conflict with the costal arch. Lateral orientation of the external limb will parallel the angle of the costal arch in its descent to the exit site. The extension catheter should not cross the midline in the event that the patient subsequently requires a midline surgical incision. A laterally placed exit site prevents trauma to the exit site in patients with occupational activities that places pressure over the anterior abdominal wall.

- Make a 2.0 - 3.0 cm horizontal incision at the marked secondary incision site with scalpel and perform blunt dissection with a combination of hemostat clamps and ribbon retractors to the anterior rectus fascia. On the surface of the fascia cephalad of the incision, bluntly create a subcutaneous pocket to contain the preformed arcuate bend of the extension catheter. In addition, perform blunt dissection caudally on the surface of the fascia to facilitate tunneling from the primary incision to the secondary incision.
- The recorded distance, “**A**”, in centimeters, between the primary and secondary incision sites represents the total length needed when combining the abdominal and extension catheters (Figure 1). A defined length will need to be trimmed from both catheter components.
- Select and note a location where the abdominal and extension catheters will be joined together with the 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.
- Using the provided measuring tape, measure and record the distance, **B**, between the secondary

incision and the chosen titanium connector junction site.

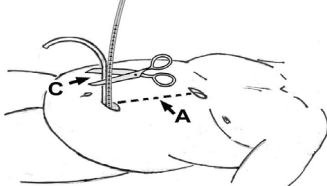
- Subtract **B** from **A** to get the length, **C**, of abdominal catheter tubing needed to reach from the location of the deep cuff under the fascia to the location of the catheter union. Therefore, **A – B = C** defines the length of needed abdominal catheter component (Figure 1). In order to be able to work with the abdominal catheter end, avoid using a length of **C** less than 5 cm.

**FIGURE 1**



- Insert the ruled end of the tunneling rod into the primary incision next to the abdominal catheter, perpendicular to the fascia and parallel to the catheter. Advance the tunneling rod until the tip meets the rectus fascia (Figure 2).
- Hold up the external limb of the abdominal catheter next to and parallel to the tunneling rod. Using the centimeter markings on the tunneling rod, cut the abdominal catheter at the **C** length above the level of the fascia (Figure 2). Make a single, straight, perpendicular cut of the tubing with suture scissors.

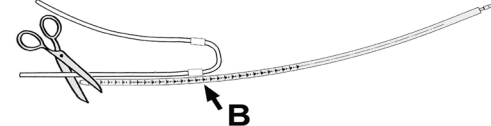
**FIGURE 2**



**FIGURE 3**

- Place the ruled edge of the tunneling rod alongside one limb of the extension catheter with the **B** recorded length at the level of the upper border of the Dacron cuff. Cut the extension catheter at the level of the end of the tunneling rod (Figure 3). Make a single, straight, perpendicular cut of the tubing with suture scissors.

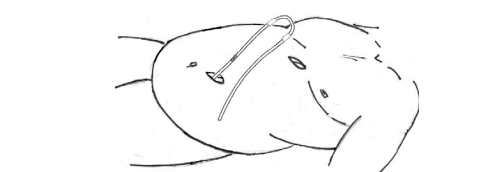
**FIGURE 4**



**FIGURE 5**

- Join the trimmed ends of the abdominal and extension catheters with the titanium connector (Figure 4). Tie permanent sutures, such as 2-0 or 0-polypropylene, around each catheter over the grooves of the connector. The two sutures may then be tied to each other to further prevent tubing separation.

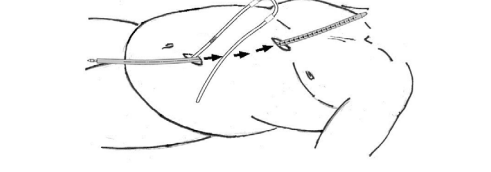
**FIGURE 6**



**FIGURE 7**

- Insert the blunt, bullet-shaped end of the tunneling rod into the primary incision site. Guide the tunneling rod along the surface of the fascia to the secondary incision site (Figure 5). Advance the tunneling rod far enough through the secondary incision site so that it can be grasped with the other hand.

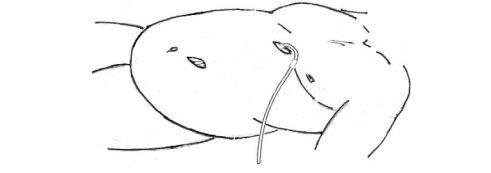
**FIGURE 8**



- Attach the end of the extension catheter to the barbed tip of the tunneling rod. Secure the catheter end onto the tip of the rod with a suture.

- Pull the tunneling rod and the catheter through the subcutaneous track until the upper border of the internal Dacron cuff of the extension catheter rests at the level of the secondary incision (Figure 6). Observe that the radiopaque guidestripe of the catheter remains straight during the passage to avoid kinking of the catheter. Detach the tunneling rod.

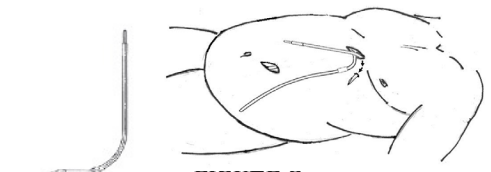
**FIGURE 9**



- Advance a Faller tunneling stylet (available from Medcomp®) from the subcutaneous pocket of the secondary incision to the designated exit site (Figure 7). The Faller stylet can be advanced through the skin without making a prior skin incision. Attach the end of the extension catheter to the ribbed end of the Faller stylet. Secure the catheter onto the end of the stylet with a suture tie. Pull the stylet and catheter through the exit site. Detach the stylet and insert the female luer (Figure 8). Attach the end cap or, alternatively, a peritoneal dialysis catheter transfer/extension set. Position carefully the arcuate portion of the catheter in the subcutaneous pocket. The external Dacron cuff should come to rest 3 cm from the exit wound.

**FIGURE 10**

#### Faller Stylet



**FIGURE 11**



- Close the primary and secondary incision sites appropriate to the implantation technique used. Sterile adhesive strips may be used to immobilize the catheter at the exit site. Do not use anchoring stitches to secure the catheter to the skin. Appropriate dressings are applied to protect the exit site and further immobilize the catheter.

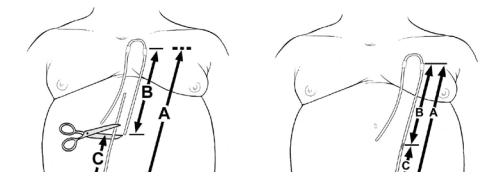
#### X-SERIES CATHETER IMPLANTATION - EXTENSION CATHETER FOR UPPER CHEST (PRESTERAL) EXIT SITE:

Ordinarily, the arcuate bend and external limb of the extension catheter is oriented medially to produce a presteral exit site location. Compared to a laterally oriented catheter exit site, the presteral location is subject to less catheter motion as a consequence of upper extremity movements. The exit site should be free of the open collar area, median sternotomy zone, and the fleshy part of the breast. The subcutaneous path of the tubing should not cross the midline or conflict with the clavicle.

- Make a 2.0 - 3.0 cm transverse incision at the marked secondary incision site with scalpel in the upper chest and perform blunt dissection with a combination of hemostat clamps and ribbon retractors to the pectoralis fascia. On the surface of the fascia cephalad to the incision, bluntly create a subcutaneous pocket to contain the preformed arcuate bend of the extension catheter. In addition, perform blunt dissection caudally to develop a track on the surface of the fascia deep to the breast tissue in the retromammary space to facilitate passage of a vascular tunneler, such as a Scanlan tunneler (8 mm vascular tunneler, sheath, and tip; Scanlan International, St. Paul, MN, USA) from the primary incision to the secondary incision.
- The recorded distance, “**A**”, in centimeters, between the primary and secondary incision sites represents the total length needed when combining the abdominal and extension catheters (Figure 9).
- Select and note a location where the abdominal and extension catheters will be joined together with the titanium connector. The titanium connector should rest on the flat surface of the abdominal wall fascia, avoiding locations subject to pressure discomfort from the costal margin, bra line and/or angulation produced by flexing of the torso.

- Using the provided measuring tape, measure and record the distance, **B**, between the secondary incision and the chosen titanium connector junction site. Generally, to assure that the titanium connector rests on the flat abdominal fascia, the entire usable length of the limb of the extension catheter below the level of the upper border of the Dacron cuff (29 cm) will be required for upper chest exit sites.

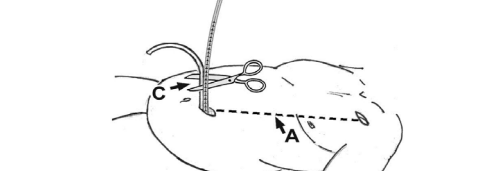
**FIGURE 12**



- Subtract **B** from **A** to get the length, **C**, of abdominal catheter tubing needed to reach from the location of the deep cuff under the fascia to the location of the catheter union. Therefore, **A – B = C** defines the length of needed abdominal catheter (Figure 9). In order to be able to work with the abdominal catheter end, avoid using a length of **C** less than 5 cm.

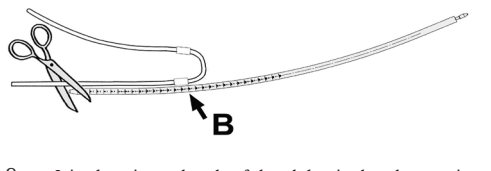
- Insert the ruled end of the tunneling rod into the primary incision next to the abdominal catheter, perpendicular to the fascia and parallel to the catheter. Advance the tunneling rod until the tip meets the rectus fascia (Figure 10).
- Hold up the external limb of the abdominal catheter next to and parallel to the tunneling rod. Using the centimeter markings on the tunneling rod, cut the abdominal 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.

**FIGURE 13**



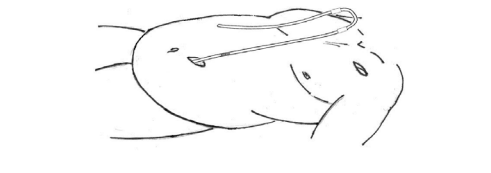
- If a length less than 29 cm was determined for **B**, place the ruled edge of the tunneling rod alongside one limb of the extension catheter with the **B** recorded length at the level of the upper border of the Dacron cuff. Cut the extension catheter at the level of the end of the tunneling rod (Figure 11). Make a single, straight, perpendicular cut of the tubing with suture scissors.

**FIGURE 14**

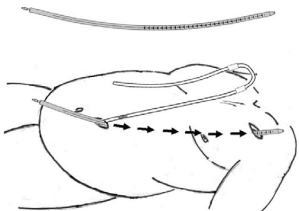


- Join the trimmed ends of the abdominal and extension catheters with the titanium connector (Figure 12). Tie permanent sutures, such as 2-0 or 0-polypropylene, around each catheter over the grooves of the connector. The two sutures may then be tied to each other to further prevent tubing separation.

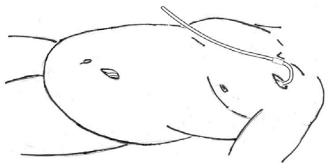
**FIGURE 15**



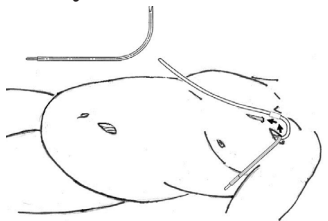
- Insert the blunt, bullet-shaped end of the tunneling rod into the primary incision site. Guide the tunneling rod along the surface of the fascia to the secondary incision site (Figure 13). The rod should pass on the surface of the pectoralis fascia in the retromammary space in its path to the secondary incision. Advance the tunneling rod far enough through the secondary incision site so that it can be grasped with the other hand.

**FIGURE 13**

- Attach the end of the extension catheter to the barbed tip of the tunneling rod. Secure the catheter end onto the tip of the rod with a suture.
- Pull the tunneling rod and the catheter through the subcutaneous track until the upper border of the internal Dacron cuff of the extension catheter rests at the level of the secondary incision (Figure 14). Observe that the radiopaque guidestripe of the catheter remains straight during the passage to avoid kinking of the catheter. Detach the tunneling rod.

**FIGURE 14**

- Advance a Faller tunneling stylet (available from Medcomp<sup>®</sup>) from the subcutaneous pocket of the secondary incision to the designated exit site (Figure 15). The Faller stylet can be advanced through the skin without making a prior skin incision. Attached the end of the extension catheter to the ribbed end of the Faller stylet. Secure the catheter onto the end of the stylet with a suture tie. Pull the stylet and catheter through the exit site. Detach the stylet and insert the female luer (Figure 16). Attach the end cap or, alternatively, a peritoneal dialysis catheter transfer/extension set. Position carefully the arcuate portion of the catheter in the subcutaneous pocket. The external Dacron cuff should come to rest 3 cm from the exit wound.

**FIGURE 15****Faller Stylet****FIGURE 16**

- Close the primary and secondary incision sites appropriate to the implantation technique used. Sterile adhesive strips may be used to immobilize the catheter at the exit site. Do not use anchoring stitches to secure the catheter to the skin. Appropriate dressings are applied to protect the exit site and further immobilize the catheter.

**REMOVAL OF X-SERIES CATHETER:**

- Appropriate anesthetic technique and monitoring is employed to assure the most optimal comfort and safety for the patient.
- Surgical skin preparation is performed with chlorhexidine gluconate scrub or povidone-iodine in standard manner. Infected exit sites can be prepped but excluded with draping from the primary surgical field until the last step in catheter removal.
- Identify and enter the primary incision scar and dissect down to the fascia. The catheter is identified as it penetrates the fascia. In most instances, the deep Dacron cuff of the catheter will be located just under the anterior rectus sheath. Traction on the catheter and dissecting along the path of the catheter will lead to the cuff.
- Mobilize the deep cuff from the tissues by sharp or cautery dissection. Once the cuff is dissected free, the catheter is withdrawn from the peritoneal cavity. For convenience, the catheter is transected external of the

- Identify the secondary incision scar (either in the upper abdomen or upper chest). Enter the secondary incision scar and dissect down to the fascia. Usually both cuffs can be mobilized from the subcutaneous tissues through the secondary incision by extending the incision slightly. The tubing is cut with a scissors external of the superficial cuff. Pull the catheter segment from the tunnel between the primary and secondary incisions. This segment will contain the titanium connector. The remainder of the catheter tubing is pulled from the exit site and discarded.
- Closure of skin and subcutaneous tissues will depend upon the presence of pus. Usually, wounds can be closed if the catheter was removed electively or for peritonitis. Wounds are left open for tunnel track abscesses.

"X" Series Catheter Size	Priming Volume (cc)
	<b>Average</b>
15F	7.42

**DETERMINING CATHETER AND SUBSECTION LENGTH:**

The catheter may need to be customized before being used in a small or unusually obese patient. As a rule, the required intra-abdominal catheter length for adults corresponds closely to the distance between the upper rim of the symphysis pubis and the umbilicus when the patient is lying supine (except in obese patients with a grossly protuberant or pendulous lower abdomen.) The depth of the abdominal subcutaneous adipose tissue after implantation at the usual site (about 3 cm below the umbilicus) gives the catheter sufficient length to reach deep into the pelvic gutter. If the straight catheter is too long for small adults, up to 5 cm can be pared off the distal intra-abdominal segment. In unusually tall subjects, the implantation site can be moved downwards by a few centimeters. For obese patients, a longer intra-abdominal segment may be required.

**IMPLANTING THE "V" OR "I" SERIES CATHETER:**

Beginning with the description in 1968 by Tenckhoff and Schechter<sup>11</sup> of the peritoneal access catheter, several effective methods for insertion of this device have come into use. Many physicians prefer to use an open method<sup>12</sup> of implantation, performing all steps under direct vision and securely closing each layer of the abdominal wall to prevent a dialysate leak. The open technique permits omentectomy, which has been recommended for pediatric patients.<sup>13</sup> Other authors have described a closed method using a guidewire and Peel-Cath.<sup>14</sup>

Patients who have had previous surgery, in whom it may be difficult to position correctly a peritoneal catheter, may be candidates for peritoneoscopic placement.<sup>15,16</sup>

Instructions for implanting a peritoneal catheter by both the open and closed (percutaneous) methods are presented below. It is suggested that physicians with limited previous experience first consult the published literature and enlist the assistance of an experienced colleague.

**Choosing the Exit Site****Straight Catheters:**

The catheter may be implanted at the medial border of the rectus muscle between the umbilicus and symphysis pubis, through the rectus muscle just below belt line, or at the lateral border of the rectus muscle, in a line between the umbilicus and anterior iliac crest. Do not implant at the belt line, beneath a scar or fat fold, in areas of known or suspected intra-abdominal adhesions, or in areas of abdominal or skin infection. Determine fat folds while the patient is sitting. It also is useful to consider the patient's preferences and whether he or she is right- or left-handed.

**Preparing the Patient**

Ask the patient to empty both bladder and bowel. An enema may be given if requested by the physician. Explain the procedure to the patient. This will enable the patient to cooperate during insertion. Bedside insertion, in selected patients, is acceptable provided strict aseptic technique is observed.

- Shave the insertion area as requested. Some physicians prefer the use of an electric razor to maintain skin integrity. Scrub the area with bactericidal agent selected. A single preoperative dose of prophylactic intravenous antibiotics may be administered to provide antistaphylococcal coverage.
- Prepare a sterile field. Those persons handling the components should perform a surgical scrub and then don appropriate surgical attire. The patient should also wear a mask.
- Place sterile drapes and anesthetize the skin and surrounding tissues of the tunnel with local anesthesia.

NOTE: The catheter can be inserted either surgically or percutaneously through a Peel-Cath introducer. Procedures for both methods follow.

**A. Open Surgical Insertion Procedure**

- To reduce leakage and hernia risk, we recommend insertion through the rectus sheath and muscle. Make a 3-4 cm transverse incision through the skin and subcutaneous tissue. Ensure hemostasis, preferably with cauterization. The anterior rectus sheath is exposed and may be infiltrated with more local anesthetic. Make a transverse incision in the anterior rectus sheath.
- Separate the rectus muscle down to the posterior rectus sheath. Place a purse string suture through the posterior rectus sheath, transversalis fascia, and peritoneum. Make a small incision, approximately 5-6 mm, in the peritoneum to accommodate the catheter.
- Immediately prior to insertion, soak the catheter in sterile saline. Gently squeeze the cuffs to expel air.
- Thread the catheter onto a long, blunt stiffening stylet. To protect the bowels, a tiny portion of the catheter overlaps the tip of the stylet. Insert the catheter caudally into the deep pelvis if there is no resistance. Correct positioning can be confirmed in the awake patient by a sensation of "rectal pressure." When the catheter is ½ to ¾ inserted, remove the stylet and push the catheter the rest of the way into the pelvis.
- Tie the purse string suture securely. Position the cuff longitudinally on the posterior rectus sheath. Make a small stab wound in the anterior rectus sheath above the transverse incision and pull the catheter through this incision. Use another purse string suture here to make the area watertight.
- Close the anterior rectus sheath with a nonabsorbable suture in an uninterrupted fashion. This will help to avoid leakage.
- Create a subcutaneous tunnel (see one of the methods in "Creating a Subcutaneous Tunnel" following).

**After creating the subcutaneous tunnel:**

- Attach the female luer and subclavian clip. Ensure there are no kinks or twists in the catheter.
- Attach a transfer set and assess catheter function. Check the wound for leaks and hemostasis.
- At least 200 ml of solution should drain within one minute. If good flow is obtained, close the subcutaneous tissue and the entry site with absorbable suture. Do not suture the exit site. Complete incision closure with Steri-strips.
- To prevent accidents, assure the security of all caps and line connections prior to and between treatments. Place several layers of gauze dressings over the area and secure. The dressing should remain in place for one week unless there is bleeding or excessive drainage at the site.

Postpone dialysis for 1 to 3 days if possible (2 weeks is optimal) to allow proper healing. If dialysis is done sooner, the patient should be in a supine position with reduced volume exchanges of 500 ml. For patients who will continue on intermittent dialysis, increase the initial volume gradually, providing it is tolerated well.

**CREATING A SUBCUTANEOUS TUNNEL:****With a Peritoneal Tunneling Stylet:**

- If necessary, anesthetize the skin exit site approximately 6 cm to one side of the entry site. Make a 5 mm incision.
- For a curved tunnel, place the tunneling stylet between the two incision sites and bend the stylet to match the desired shape of the tunnel (be sure the cap is on the plastic end of the stylet before creating the curve).
- Wet the subcutaneous cuff thoroughly with saline.
- Attach the catheter to the tunneling stylet by pushing the catheter over the plastic end of the stylet until it meets the hub. Slide the cap over the connection. Remove the subclavian clip.
- Insert the tip of the tunneling stylet into the primary incision. Thread the stylet through the tissue, creating a curved subcutaneous tunnel to the exit site. The catheter should exit at a downward angle to the skin.

NOTE: Some physicians may prefer to make a straight tunnel. For efficient dialysis, slant a straight tunnel slightly upwards to lessen the risk of catheter migration.

- Spread the tunnel entrance with a hemostat to guide the cuff into the tunnel.
- Pull the tunneling stylet through the exit site, positioning the catheter as desired in the tunnel.
- Position the cuff 2-3 cms from the exit site, deep subcutaneously, to avoid cuff infection or extrusion. Clamp the catheter.
- Detach the tunneling stylet carefully and discard.

**B. Percutaneous Insertion Procedure (Modified Seldinger Technique Using Vascu-Sheath Introducer) Procedure**

- Make a 1.5 to 2.0 cm incision with scalpel at the selected abdominal entry site.
- Use blunt dissection to form a pocket for the preperitoneal cuff (if applicable).
- Attach the introducer needle to a 10 cc syringe filled with heparinized saline. Insert the needle through the incision into the peritoneal cavity and carefully inject the saline. Aspiration of peritoneal fluid indicates the needle tip is in the peritoneal cavity.
- Immediately remove the syringe and insert the flexible end of the guidewire through the introducer needle, directing it caudally and posteriorly. Advance the wire approximately one-fourth its length (approximately 18 cm).
- Withdraw the introducer needle, leaving the guidewire in the peritoneum.
- Check that the dilator is locked within the introducer sheath to prevent separation of the two components during insertion.
- Thread the Peel-Cath introducer over the end of the guidewire. **Caution: To avoid damaging the tissue and the sheath tip, do not let the sheath advance over the dilator. The two must be grasped as one unit.**

Advance the introducer into the peritoneum, gently rocking it back and forth to assist passage through the tissue. **Do not force the introducer into the peritoneum. Do not insert it further than necessary for the patient's size and access site. Ensure that the guidewire does not move further into the peritoneum.**

- Hold the sheath in place and gently remove the dilator and guidewire.
- Use a straightening stylet to insert the coiled catheter. Lubricate the catheter with sterile normal saline and insert the stylet into the catheter.

NOTE: If not using a catheter straightening stylet, lubricate the catheter with sterile, water-soluble lubricant.

Roll the cuffs between thumb and index finger to expel air. Position the stylet approximately 4 mm above the tip of the catheter. Clamp a hemostat on the stylet (**do not clamp the catheter**) to prevent it from advancing further towards the tip. **Caution: Do not insert the stylet beyond the tip of the catheter. This can cause injury during insertion.**

- Insert the catheter with catheter stylet into the sheath, directing it towards the desired position.
- Remove the catheter straightening stylet. Confirm drainage by infusing and draining dialysate.

NOTE: Confirming drainage immediately after insertion does not guarantee permanent function. There is a five percent incidence of drainage problems caused by catheter migration occurring within a week after placement.<sup>17</sup>

- Grasp the tabs of the sheath and, while holding the catheter in place, pull the tabs outward simultaneously to peel the sheath from the catheter.

- Create a subcutaneous tunnel (see one of the methods in the preceding section "Creating a Subcutaneous Tunnel").

**After creating the subcutaneous tunnel:**

- Attach the female luer and subclavian clip. Ensure there are no kinks or twists in the catheter. Attach a transfer set and assess catheter function.
- If there is no leakage of solution, and good outflow is obtained, close the subcutaneous tissue and the entry site with absorbable suture in a subcuticular fashion. Do not suture the exit site. Complete incision closure with Steri-strips.
- To prevent accidents, assure the security of all caps and line connections prior to and between treatments. Place several layers of gauze dressings over the area and secure. The dressing should remain in place for one week unless there is bleeding or excessive drainage at the site.

NOTE: Confirm proper catheter placement with fluoroscopy before use.

Postpone dialysis for 1-3 days if possible (2 weeks is optimal) to allow proper healing. If dialysis is done sooner, the patient should be in a supine position with reduced volume exchanges of 500 ml. For patients who will continue on intermittent dialysis, increase the initial volume gradually, providing it is tolerated well.

**CATHETER REMOVAL:**

Elective removal of the uninfected catheter is an outpatient procedure. Double cuff catheters may require two incisions, one over each cuff, though many physicians prefer simply to reopen the original incision to avoid creating another scar.

Perform surgical scrub with particular emphasis on the umbilicus and create a sterile field. Administer anesthesia to the area of the deep cuff. If the cuff cannot be palpated, one can put traction on the catheter and dissect along its path.

Sharp dissection of the cuff is usually necessary because of connective tissue ingrowth.

Note: Discard biohazard according to facility protocol.

**Deep or Preperitoneal Cuff**

Identify the deep cuff and the distal sinus tract leading from the cuff to the peritoneal cavity. Incise the distal sinus tract, taking care not to transect the catheter.

Close the distal sinus tract with a purse string suture or mattress stitch. After hemostasis is secure, close the wound in layers.

**Subcutaneous Cuff**

If it is necessary to make a second incision to release the subcutaneous cuff, infiltrate the skin and area surrounding the subcutaneous cuff with local anesthesia. Make an incision either by extending the exit site or directly over the cuff. Dissect the skin cuff free. Pull out the catheter and close the incision.

**Site Opening Care**

In most cases, the "old" exit site sinus tract is excised and the small wound left open for drainage.

**WHEN INFECTION IS PRESENT:****Exit Site Infection:**

If the exit site is infected, fill the abdomen with 500 cc dialysate containing an appropriate antibiotic before removing the catheter. After removal, approximate the wound edges loosely and allow the site to drain.

**Tunnel Infection – No Peritonitis:**

If the tunnel is infected, but there is no peritonitis, fill the abdomen with 500 cc dialysate containing an appropriate antibiotic before catheter removal. Systemic therapy may also be indicated. During removal, avoid the area of the deep cuff and subcutaneous sinus tract.

Close the peritoneum, mobilize the deep cuff and subcutaneous sinus tract and sew a Penrose drain to the catheter. Remove the subcutaneous cuff and excess catheter. After the catheter is freed, pull the catheter and drain through the remnant of the sinus tract, leaving the drain protruding from both incisions. Irrigate both wounds with antibiotic and partially close them. Over the next few days, pull the drain gradually out the exit site as the tissue inflammation subsides.

**Tunnel Infection – Peritonitis:**

Peritonitis related to a peritoneal dialysis catheter can be a serious problem. Therefore, it should be treated aggressively. In some cases, the catheter should be removed immediately and the patient treated with intravenous antibiotics. Other patients respond to intraperitoneal antibiotics and the catheter need not be removed. Treatment should be individualized and is at the physician's direction.

NOTE: An option is to allow the incisions to heal by secondary intention.

**MRI Safety Information**

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

- Static magnetic field of 1.5T and 3.0T.
- Maximum spatial gradient field of 19T/m (1900 G/cm).
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2.0W/kg (normal operating mode).

Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of less than or equal to 2.7 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends up to 6.1cm when imaged with a gradient echo pulse sequence in a 3.0T MR system.

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**ADDITIONAL READING MATERIAL:**

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














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