



Peritoneal Catheters and Kits For Acute and Chronic Peritoneal Dialysis

INSTRUCTIONS FOR USE

Sterilized with ethylene oxide. Sterile and non-pyrogenic in unopened and undamaged package.

STERILE EO

READ ALL INSTRUCTIONS, WARNINGS, AND CAUTIONS CAREFULLY PRIOR TO USE.

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.

INDICATIONS

The peritoneal catheter is indicated for acute and chronic peritoneal dialysis.

CONTRAINDICATIONS

Infected anterior abdominal wall.

Patients with extensive intra-abdominal adhesions.

Conditions resulting in diaphragmatic tears or abdominal-chest communication.

Unresolved peritonitis.

Severe respiratory insufficiency: distending the abdomen with large amounts of dialysate may further compromise pulmonary function.

The catheter is not intended for the Tenckhoff trocar method of insertion, nor is it meant to be used for any purpose other than indicated.

Recent intestinal surgery.

POTENTIAL EARLY COMPLICATIONS

- Bleeding
- Dialysate leak
- Obstruction (one- or two-way)
- Ileus
- Viscus perforation
- Abdominal pain
- Subcutaneous hematoma

POTENTIAL LATE COMPLICATIONS

- Exit site infection
- Tunnel infection
- External-cuff extrusion
- Obstruction by omentum
- Dialysate leak
- Peritonitis
- Sepsis
- Infusion pressure or pain
- Organ erosion
- Genital edema
- Allergic reaction

WARNINGS AND PRECAUTIONS

- The medical techniques and procedures described in these instructions 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.

- The catheter should be inserted and removed only by a qualified, licensed physician or other health care practitioner authorized by and under the direction of such physician.
- Observe sterile technique at all times when handling catheter or insertion components.
- Caution is necessary to avoid injuring the abdominal viscera, particularly when using the sharp introducer needle. Do not use excessive force when inserting the catheter and other components of the Kit. Carefully confirm correct tip placement before beginning the subcutaneous tunnel.
- Use the guidewire straightener to insert the "J" end of the guidewire into the introducer needle.

Do not insert or withdraw the guidewire forcibly from any component; the wire could break or unravel.

- Overtightening catheter connections can crack some adapters.
- Clamping the catheter repeatedly in the same spot could weaken the tubing: change the position of the clamp regularly to prolong the life of the tubing. Avoid clamping near the adapter.
- Use only smooth-jawed forceps for clamping when not using the clamp supplied with the catheter.
- Exercise caution when using sharp instruments near the catheter.
- Catheter tubing can tear when subjected to excessive force or rough edges
- Inspect the catheter frequently for nicks, scrapes, cuts, etc., which could impair its performance.
- Catheter and kit components are for single patient use; discard; do not resterilize after use.
- Do not use components if package has been previously opened or damaged.
- Do not use the catheter or components if they appear damaged or defective.
- To avoid exposure to blood-borne pathogens, observe universal precautions during use.
- Remove the catheter as soon as it is no longer necessary. Discard after use: the catheter is for one time insertion only. Re-Use may lead to infection or illness/injury.
- Do not use iodine-based disinfectants for exit site care. The recommended disinfectant solution is chlorhexidine gluconate (i.e. Chloraprep).

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 CATHETER

Beginning with the description in 1968 by Tenckhoff and Schechter¹ of the peritoneal access catheter, several effective methods for insertion of this device have come into use. Many physicians prefer to use an open method² 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.³ Other authors have described a closed method using a guidewire and Peel-Cath.⁴

Patients who have had previous surgery, in whom it may be difficult to position correctly a peritoneal catheter, may be candidates for peritoneoscopic placement.^{5, 6}

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 adapter and clamp provided. 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 catheter clamp.
- 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 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.
- Caution: Do not advance the needle further; it could injure the viscera.**
- 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 the 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.⁷

- 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 adapter and clamp provided and 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.

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.

WARRANTY

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ADDITIONAL READING MATERIAL

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