

# PERCUTANEOUS PD CATHETER IMPLANTATION SYSTEM

## INSTRUCTIONS FOR USE

### VP – 511 and VP-511M

Implantation System for Peritoneal Dialysis Catheters

#### Product Description:

Implantation System Components:

- 0.038" Guide Wire
- 12 French Dilator
- 14 French Dilator
- 18 Gauge Introducer Needle
- 18 French Peelable Introducer Sheath
- Cuff Implantor™
- Faller Trocar
- Scalpel
- 10 mL Syringe
- 4x4 Gauze
- Clip

#### Indications for Use:

The Percutaneous Implantation Kit can be used to implant a peritoneal dialysis catheter in patients who are suitable candidates for peritoneal dialysis therapy.

#### Contraindications:

- Do NOT use if the patient is not a suitable candidate for peritoneal dialysis therapy.

**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 catheter implantation procedures have inherent risks associated with their use. All such risks apply to the use of the Percutaneous Implantation System. 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 peritoneoscopic and laparoscopic procedures
- Allergic reaction
- Abdominal pain
- Infusion pressure/pain
- Organ erosion
- Genital edema

#### Catheter Implantation Site Options

An Implantation Stencil may help to achieve consistent effective catheter placement and assure proper coil location. Implantation Stencils (Figure 1) are sold separately with the Flex-Neck® Catheter kits.

#### PD Catheter Implantation Site Options

Locate preferred implantation, tunnel, and exit sites as indicated by an appropriate Implantation Stencil (Figure 2). Please see anatomical landmarks as indicated in Figure 3.

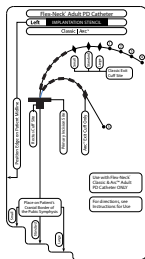


Figure 1  
Implantation Stencil

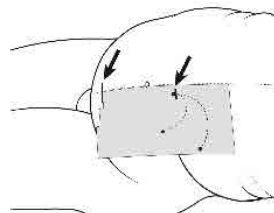


Figure 2-Stencil on body

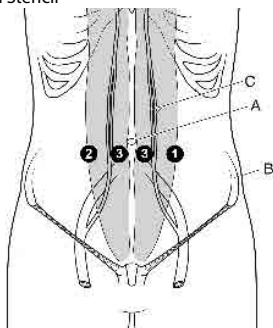


Figure 3 – Potential lower catheter implantation sites

- A. Umbilicus
- B. Iliac crest
- C. Inferior and superior epigastric arteries

1. Left, lateral border of rectus sheath, 2-3 cm below umbilicus
2. Right, lateral border of rectus sheath, 2-3 cm below umbilicus
3. Medial border of rectus sheath, 2-3 cm below umbilicus

**NOTE:** Implantation sites should be above superior iliac crest.

**WARNING:** Do NOT implant the catheter or place the exit-site in the patient's skin folds or beltline.

#### Patient Preparation:

1. Operating personnel should perform a surgical scrub, and use sterile hat, mask, gown and gloves according to hospital protocol.
2. The patient should also wear a mask.
3. Attach appropriate patient monitors and sedate patient.
4. Prepare abdomen and drape patient in standard sterile manner.
5. Use ultrasound at the intended entrance site to identify any exclusionary pathology. Duplex ultrasound may also be useful to identify proper catheter placement site and avoid injury to the inferior epigastric vessels prior to needle placement.
6. Anesthetize the proposed tissue tract and primary catheter insertion site with proper local anesthetic.

#### Percutaneous Insertion of Introducer Sheath:

7. Make a 2-3cm long horizontal skin incision at selected catheter implantation site.
8. Use a blunt dissection and cautery device as necessary to maintain hemostasis. See figure 4.

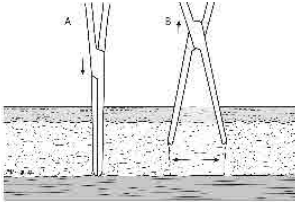


Figure 4

9. If appropriate, the implantation of the deep cuff into the rectus abdominus muscle can be aided by creating a small puncture or fasciotomy into the superficial rectus fascia with a hemostat or scalpel prior to needle placement.
10. At a 30-45 degree angle from horizontal, using ultrasound guidance, advance the introducer needle through the anterior rectus sheath, rectus muscle and through the posterior rectus sheath.

**Note:** A non-vascular micropuncture set (sold separately and available from Merit Medical) may be used to access the peritoneum. If using a non-vascular micropuncture set, assure the length is adequate for peritoneal access and follow manufacturer's instructions for use.

11. Once access to the peritoneal space is obtained, attach a 10 mL syringe containing appropriate iodinated contrast material to the needle using flexible clear tubing (sold separately).
12. Under fluoroscopy, verify needle placement into the peritoneal space by identifying the free flow of contrast outlining regional bowel loops. An amorphous, irregular or striated appearance of injected contrast may indicate that the needle tip is inappropriately located in the bowel mesentery, greater omentum, preperitoneal space or rectus abdominus muscle.

**Warning:** Do not use barium-based contrast.

**Note:** Contrast media should outline bowel loops. Contrast identified within a bowel loop may indicate bowel perforation.

**Warning:** If a bowel perforation is identified, the procedure should be abandoned and the patient should be treated with antibiotics for an appropriate duration before attempting a repeat catheter placement.

13. Once proper access to the peritoneal space is achieved and confirmed via contrast, remove syringe from introducer needle and insert the flexible end of the guide wire through the introducer needle. Direct the wire into the caudal and posterior position. Advance the wire as appropriate under fluoroscopy into the peritoneum. The guide wire should advance easily into the peritoneal space.

**Note:** Optional: A hydrophilic, Amplatz or super-stiff guide wire (sold separately) can also be used. Normal saline may also be infused, when necessary, in order to increase the space between the abdominal wall and the bowel loops.<sup>1</sup>

**Warning:** Saline infusion is not recommended in the presence of ascites.<sup>1</sup>

**Warning:** Forcible advancement of the guide wire against resistance can result in internal organ injury and should be avoided.

14. Withdraw the introducer needle, leaving the guide wire positioned in the peritoneum.
15. Further advance the guide wire to the optimal position in the pelvic gutter.
16. To accommodate catheter passage into the peritoneal cavity, dilate the rectus muscle with the 12 French and 14 French dilators respectively, under fluoroscopic guidance.
17. Verify that the dilator and introducer sheath are locked together to prevent separation during insertion.

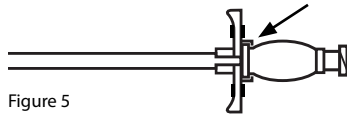


Figure 5

18. Under fluoroscopy, advance the 18 French peelable introducer sheath over the guide wire, gently twisting it back and forth to assist with passage through the tissue.

**Warning:** In order to avoid internal injury, care should be taken to avoid advancing the introducer or dilators beyond the tip of the guide wire.

**Warning:** Care should be taken to avoid creating a kink into the guide wire with the introducer.

19. Once the sheath is in place, gently remove the dilator from the peelable introducer sheath. If using the "Implantation Stylette Technique" as noted below, the peelable sheath and wire can be removed simultaneously.

**Caution:** Do not force the introducer into the peritoneum. Take care not to insert further than necessary for the patient's size and access site.

#### Preparing the catheter

20. Prepare the catheter by soaking it in sterile saline, and squeeze the air out of the cuffs by rotating the submerged cuffs between fingers. See Figure 6.

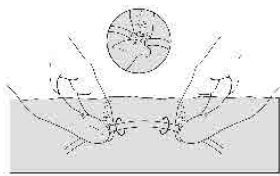


Figure 6

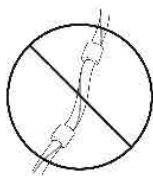


Figure 7

**Note:** Use the radiopaque stripe as a guide to avoid twisting the catheter. (Figure 7) For optimal catheter placement, radiopaque stripe should be oriented directly anterior or directly posterior in the patient.

## Implanting the Catheter

### Technique #1 – Over-the-Wire using a Peelable Introducer Sheath

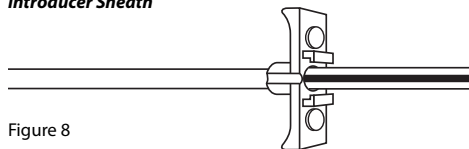


Figure 8

21.

- A. Maintaining the position of the distal end of the guide wire, if placing a coiled catheter, straighten catheter coil in order to load the catheter over the proximal end of the wire.
- B. Continue to advance the catheter over the guide wire and through the peelable sheath introducer (Figure 8). Under fluoroscopic guidance, manipulate the guide wire and catheter in tandem until the distal end of the wire is in appropriate position.
- C. Once optimal catheter positioning is achieved, continue to "Implanting the Rectus Cuff."

### Technique #2 – Implantation Stylette Technique

**Note:** A Merit catheter straightening stylette (sold separately non-sterile) can be used in place of the guide wire included in the kit.

**Caution:** Extreme care should be taken when using the stylette with or without fluoroscopy.

**Warning:** Organ perforation may occur if fluoroscopic guidance is not utilized.

22.

- A. Remove the guide wire and internal sheath dilator simultaneously, once optimal peritoneal placement is achieved.
- B. Lubricate the facility-sterilized catheter stylette with sterile gel or saline.
- C. Insert the stylette into the catheter.
- D. Lubricate the distal part of the catheter with sterile gel or saline.
- E. Insert catheter, with stylette, carefully into the peelable sheath.
- F. Under fluoroscopic guidance, advance the catheter through the sheath, periodically retracting the stylette.

**Note:** Keep the tip of the stylette within the abdomen to help the catheter move through the rectus muscle.

**Caution:** Make sure the catheter is not doubled on itself, kinked, or twisted (Figure 7).

## Implanting the Rectus Cuff

23. Grasp the tabs of the peelable sheath and crack and peel the sheath to the level of the anterior rectus sheath, approximately 5 cm.
24. Place the Cuff Implantor between the two cuffs of the catheter and advance to the distal (deep) cuff.
25. While bracing the cuff with the Cuff Implantor, advance the distal cuff with the Cuff Implantor and peeled part the sheath into the rectus fascia.
26. Holding the distal cuff with the Cuff Implantor in the rectus muscle, peel the remaining sheath with assistance from the procedural assistant.
27. Once the peelable sheath is completely removed, continue to advance the Cuff Implantor until the distal cuff is passed through the opening of the anterior rectus sheath. The bracket on the Cuff implantor will keep the Cuff Implantor from passing through the anterior rectus sheath.
28. Retract the Cuff Implantor tool parallel with the catheter, without dislocating or moving the distal cuff.

## Removing Tools and Tunneling the Catheter

29. Digitally and visually verify that the distal cuff is just below anterior rectus sheath.

**Note:** To improve visualization of the cuff, it is helpful to retract incision site tissue.

30. Remove the guide wire or stylette.
31. Slide the proximal end of the catheter over the barbed end of the Faller Trocar, onto the indented section of the Trocar past the barb.
32. Secure the catheter with a suture by tying the suture around the catheter to ensure holding strength during the tunneling process.
33. Insert the sharp end of the Faller Trocar into the initial implantation site, as indicated by the Implantation Stencil markings, aiming the sharp tip toward the planned exit-site as indicated by the Implantation Stencil markings.
34. Advance the sharp tip of the trocar along the planned track.

**Cautions:** The Faller Trocar is very sharp and can create severe hematomas or lacerations in the patient or injure the user if not used correctly by qualified medical personnel.

**Warning:** Do not twist the catheter.

35. When the trocar tip is close to the exit-site, make a stab incision not to exceed 5.0 mm with a #11 blade at the exit-site.
36. Advance the Faller Trocar through the exit-site incision.

**Note:** Do not twist or kink the catheter.

37. Pull the catheter through the tunnel, and out through the exit-site and assure the subcutaneous cuff is optimally located.
38. Cut the catheter off of the Faller Trocar at the end of the barbed tip of the trocar.

**Cautions:**

- Verify that the catheter is not twisted or kinked.
  - Do not use excessive force as the catheter is pulled. Excessive force can permanently damage the integrity of the catheter walls or dislocate the distal part of the catheter.
  - If resistance is noted, carefully use a hemostat inserted into the primary implantation site to open the tunnel track for the exit cuff.
  - Never use a hemostat at the exit-site.
  - DO NOT pull the catheter off the tunneler.
  - DO NOT cut the suture off. Attempting to cut the suture off creates a very high risk of damaging the catheter.
39. Inject a small amount of non-ionic contrast to check that the catheter placement and assure it is not twisted or kinked.
  40. Close the primary incision with sutures.
  41. DO NOT suture the exit-site.
  42. Confirm placement by infusing 100 to 1000 mL of warmed sterile saline.
  43. If necessary, use clip included in kit to clamp the catheter to control the flow of saline.
  44. Lock the catheter with 10 mL heparin before applying connector and cap or transfer set (sold separately, not available from Merit).
  45. According to standard hospital protocol, close the initial catheter insertion site, attach the appropriate connector, and wound dressing.

**References:**

1. Abdel-Aal AK, Fluoroscopic and Sonographic Guidance to Place Peritoneal Catheters: How We Do It, AJR: 2009; 192:1085-1089



Manufacturer:

Merit Medical Systems, Inc.

1600 West Merit Parkway, South Jordan, Utah 84095 U.S.A.

1-801-253-1600 U.S.A. Customer Service 1-800-356-3748



Authorized Representative:

Merit Medical Ireland Ltd,

Parkmore Business Park West, Galway, Ireland

[www.merit.com](http://www.merit.com)

