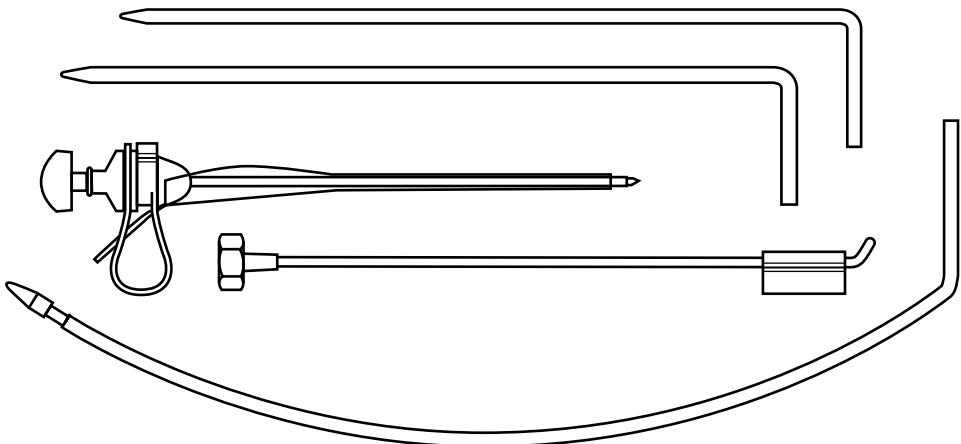


# **INSTRUCTIONS FOR USE**

**Y-TEC® VP-210 and VP-211  
Implantation System for  
Peritoneal Dialysis Catheters**



**MERIT MEDICAL™**

# Y-TEC® VP-210 and VP-211

Implantation System for Peritoneal Dialysis Catheter

English

## PRODUCT DESCRIPTION

Y-TEC® VP-210 and VP-211

IMPLANTATION SYSTEM CONTAINS:

- Small Dilator
- Large Dilator
- Luke® Guide Assembly:  
    (Trocars, Cannula and Clip, Luke Guide)
- Cuff Implantor™ Tool
- Tunnelor® Tool

## INDICATIONS FOR USE

The Y-TEC Implantation System 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

Peritoneoscopic and Laparoscopic procedures and general anesthesia all have inherent risks associated with their use. All such risks apply to the use of the Y-TEC 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.

## INSTRUCTIONS FOR USE

Catheter Implantation Site Options

Locate preferred implantation and exit sites as indicated by an appropriate Implantation Stencil (Figure 1 and Figure 2) and the anatomical landmarks as indicated in Figure 3. If using an Implantation Stencil (sold separately), consult Instructions for Use.

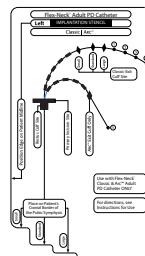


Figure 1  
Implantation Stencil

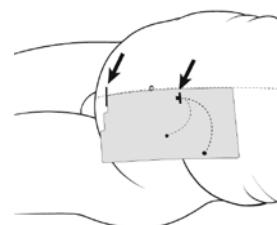
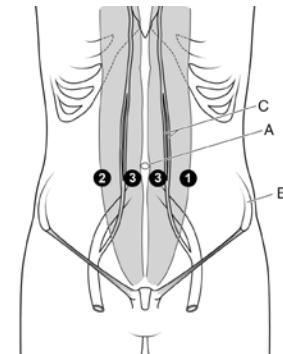


Figure 2-Stencil on body



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

Figure 3-Anatomical landmarks

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 at the patient's beltline, or skin folds.

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

## PATIENT PREPARATION

1. Sedate patient.
2. Attach appropriate patient monitors.
3. Prepare abdomen and drape patient in standard sterile manner.
4. Anesthetize primary catheter insertion site.

## INSERTING LUKE GUIDE ASSEMBLY

1. Make 3-5 cm long horizontal skin incision.
2. Perform blunt dissection with hemostats to the anterior surface of the rectus sheath (Figure 4 A & B), use cauterization device as necessary to control bleeding.

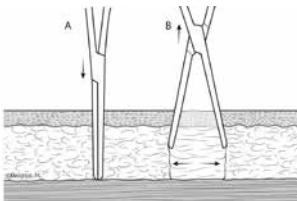


Figure 4

3. Ask patient to tighten abdominal muscles prior to inserting the Luke Guide Assembly.
  4. Insert Luke Guide Assembly at a 45° angle from horizontal, pointing towards the coccyx (Figure 5).
- CAUTION:** It is important to maintain a 45° angle to assure proper anchoring in the rectus muscle and final catheter placement.

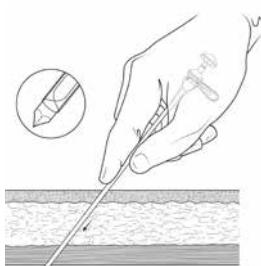


Figure 5

#### CHECKING THE POSITION

1. Remove trocar from assembly (Figure 6).

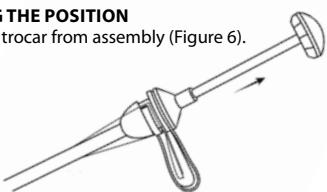


Figure 6

2. Insert Y-TEC Peritoneoscope (scope) into cannula and lock together (Figure 7).

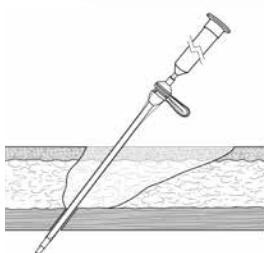


Figure 7

3. Confirm location of distal end of cannula and scope within the peritoneum (Figure 8).

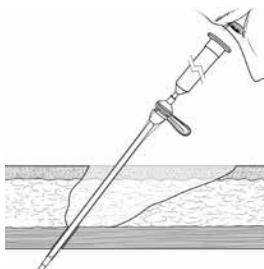


Figure 8

4. Remove scope (Figure 9).

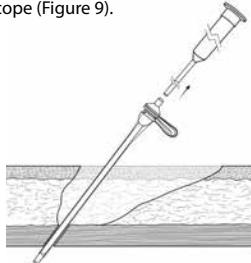


Figure 9

5. (Optional) Attach Air Insufflation Set, (sold separately, not available in all areas) as needed to cannula (Figure 10).

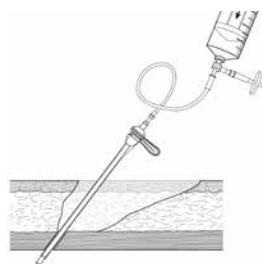


Figure 10

6. Place patient in typical Trendelenburg position.
7. Insufflate filtered room air (approximately 700-1200 cc, depending on patient size).
8. Detach Air Insufflation Set. Place thumb or finger on cannula to retain air.

#### POSITIONING THE CATHETER

1. Re-insert peritoneoscope (Figure 11).

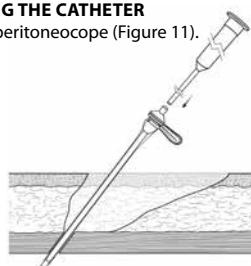


Figure 11

2. Aim distal tip of scope into the air pocket by making the scope more parallel with the abdomen (Figure 12).

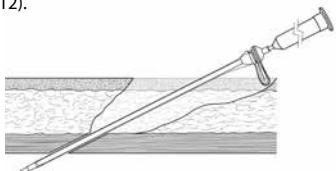


Figure 12

3. Examine peritoneum to find optimal location for catheter. Note any adhesions or abdominal characteristics that may impede proper catheter placement. (Figure 13).

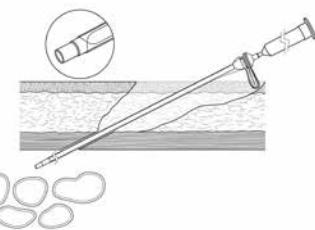


Figure 13

4. Advance the scope and Luke Guide Assembly fully into the peritoneum so that the distal end is pointed to the desired location.

### REMOVING THE CANNULA

1. Remove the scope from the cannula (Figure 14).
- CAUTION:** Do not change position of the cannula or the Luke Guide Assembly.

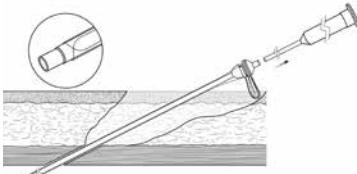


Figure 14

2. Return patient to normal supine position.
3. Remove clip from Luke Guide Assembly and cannula (Figure 15).



Figure 15

4. Remove cannula out of the Luke Guide by pulling it straight out (Figure 16).

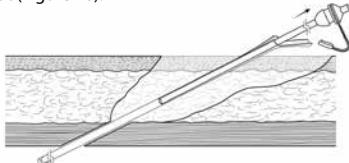


Figure 16

5. Leave Luke Guide in position and clamp. (Figure 17).

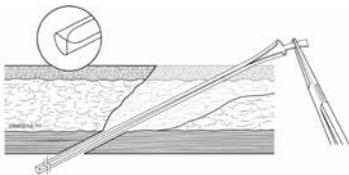
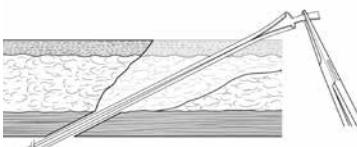


Figure 17

6. Clamp hemostat to tab of the Luke Guide perpendicular to the Guide (Figure 18).

**WARNING:** Luke Guide must be secured to prevent inadvertent advancement into the abdominal cavity.



7. Optional: Lubricate the Small Dilator and Large Dilator with sterile gel or saline.
8. Insert the Small Dilator into the Luke Guide to dilate the Guide and the rectus muscle while holding the Luke Guide stationary with the hemostat (Figure 19).

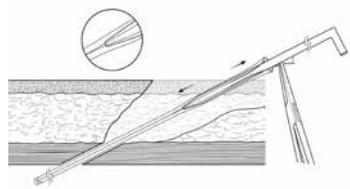


Figure 19

9. Repeat with the Large Dilator.

### INSERTING THE CATHETER

CONSULT FLEX-NECK CATHETER IFU

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

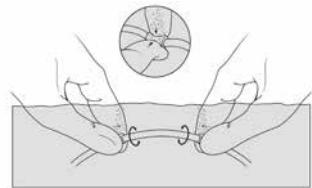


Figure 20

2. Lubricate the catheter stylette (sold separately) with sterile gel or saline.
3. Insert the stylette into the catheter per the stylette Instructions for Use (Figure 21).



Figure 21

4. Lubricate the distal part of the catheter with sterile gel or saline.
5. Insert catheter (with stylette) carefully into the Luke Guide. Be sure to follow the angle of the Luke Guide through the rectus muscle (Figure 22).

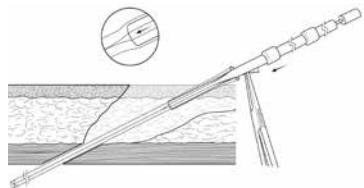


Figure 22

6. Advance catheter through the Luke Guide, periodically retracting the stylette.

**NOTE:** Keep the tip of the stylette within the abdomen to help the catheter move through the rectus muscle (Figure 23).

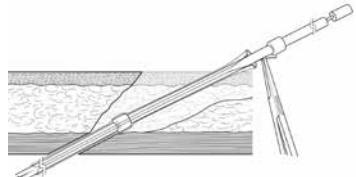


Figure 23

7. Use the radiopaque stripe as a guide to avoid twisting the catheter. (Figure 24). For optimal catheter placement, radiopaque stripe should be oriented directly anterior or directly posterior in the patient.

**CAUTION:** Make sure the catheter is not doubled on itself, kinked, or twisted.

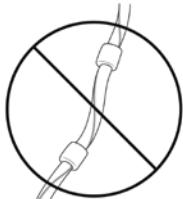


Figure 24

8. Advance catheter until distal cuff reaches rectus sheath. (There will be an increase in resistance to movement of the catheter) (Figure 25).

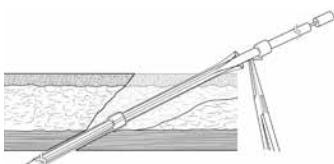


Figure 25

9. Position the Cuff Implantor Tool parallel with and over the catheter, between the two cuffs (Figure 26).

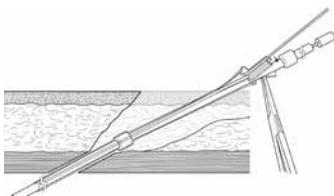


Figure 26

10. Advance Cuff Implantor Tool to edge of distal cuff (Figure 27).

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

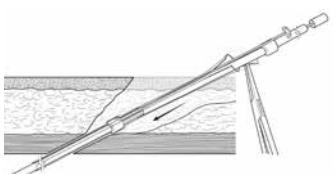


Figure 27

11. Advance catheter and Cuff Implantor Tool simultaneously 1.0 cm to both dilate the rectus muscle and advance the cuff into the rectus muscle while holding the Luke Guide stationary with the hemostat (Figure 28).

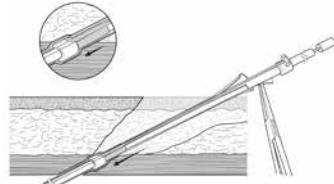


Figure 28

## REMOVING TOOLS

1. Verify cuff position visually or digitally.

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

2. Retract the Luke Guide parallel with the catheter (Figure 29).

**NOTE:** Maintain pressure on cuff with the Cuff Implantor Tool to hold it in position.

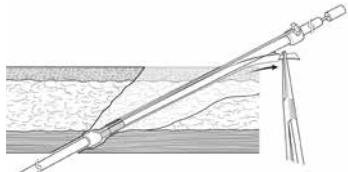


Figure 29

3. Retract Cuff Implantor Tool, parallel with the catheter, without dislocating or moving the distal cuff (Figure 30).

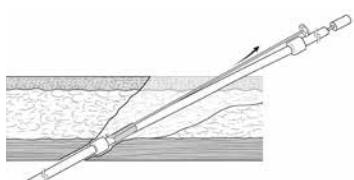


Figure 30

4. Retract the catheter stylette.

5. Allow any remaining air to exit.

## CHECKING CATHETER PATENCY

1. Test catheter patency via infusion of 100-500 cc sterile saline (Figure 31).

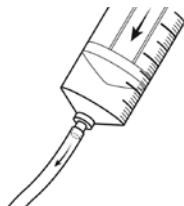


Figure 31

2. If catheter is functioning well, fluid will flow out in a steady drip or flow when proximal end of the catheter is lowered below the primary site when the syringe has been removed.

3. The proximal end of the catheter can also be raised approximately 12-15 cm above the patient's abdomen. Fluid will rise and fall within the catheter tube in conjunction with respiration.

## TUNNELING THE CATHETER

1. Locate the previously marked exit-site as determined by the Implantation Stencil (Figure 32).

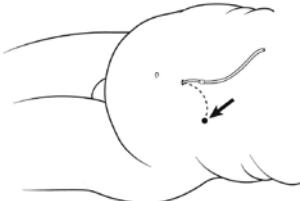


Figure 32

2. Alternatively, if the Implantation Stencil was not previously used to mark the exit-site:

Lay the catheter on the patient's abdomen to determine the best exit-site location. That location should be lateral to the primary site. Then, mark a spot so that the exit-site is about 3-4 cm distal to the exit site cuff (Figure 33).

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

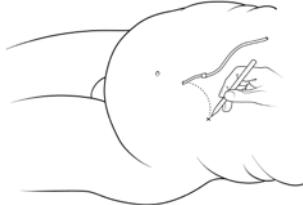


Figure 33

3. Anesthetize exit-site location and the tunnel path.  
4. Make a stab incision with #11 scalpel blade to full width of blade at the exit site. (Figure 34).

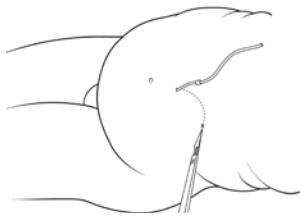


Figure 34

5. Insert Tunnelor Tool at the exit-site (Figure 35).

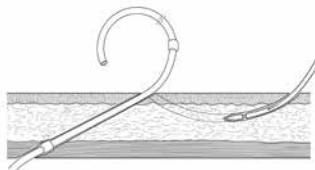


Figure 35

6. Advance Tunnelor Tool to primary insertion site.  
7. Slide end of catheter over tip of Tunnelor Tool approximately 3-4 cm. (Figure 36).  
8. Secure catheter to Tunnelor Tool using sutures if desired.

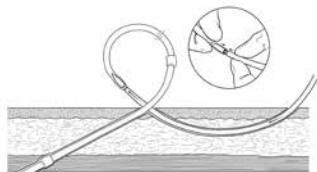


Figure 36

9. Retract Tunnelor Tool and catheter into tunnel and out of exit-site (Figure 37). **WARNING:** Do not dislodge the distal cuff.

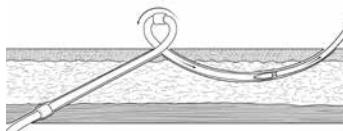


Figure 37

10. (Optional) Create a space within the tunnel for the distal cuff.

**CAUTION:** Check catheter at primary site and exit-site to ensure the catheter is not twisted or kinked (Figure 38).

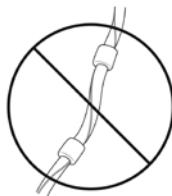


Figure 38

11. Push catheter off the Tunnelor Tool (Figure 39). Alternatively, cut the catheter off the Tunnelor Tool if sutures were used.

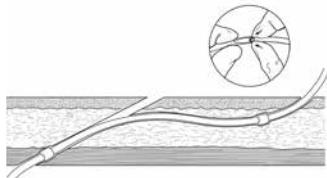


Figure 39

12. Attach catheter connector to catheter assuring catheter is completely advanced to connector hub. (Figure 40).

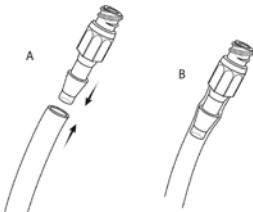


Figure 40

#### CHECKING CATHETER PATENCY

1. Deflate the abdomen if not already deflated from steps above.  
2. Test catheter patency by infusing 1 liter sterile saline (Figure 41) after attaching appropriate transfer set to the connector.

**NOTE:** It is helpful to place the patient in reverse Trendelenburg position. A steady outflow of fluid from the bag or consistent drip confirms a well-functioning catheter.

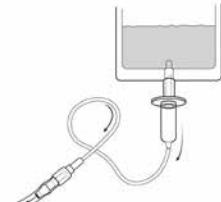


Figure 41

3. Attach cap to the connector or transfer set.

## CLOSING THE INCISION

1. Close primary incision site with sutures.

**CAUTION:** Do not suture the exit-site (Figure 42).

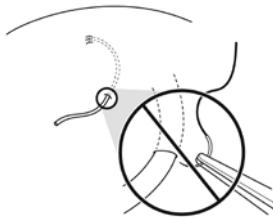


Figure 42

2. Apply appropriate dressings to the primary site, catheter exit-site, and catheter itself.

3. Secure the catheter in standard manner.

**CAUTION:** Do not suture around the catheter to secure the catheter as sutures could damage the catheter.

## SUPPLEMENTAL NOTES

- 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, at a minimum, every 7 days thereafter.

Patents U.S. 6,589,212B1. Canadian 2,390,543.

Additional foreign patents pending.

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