VP-411
Laparoscopic Implantation of Peritoneal Dialysis Catheters

INSTRUCTIONS FOR USE

VP-411 English
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PRODUCT CONTENTS
Luke™ Guide Assembly (trocar, Luke Guide, and clip)
- Large Dilator
- Cuff Implantor™ Tool
- Faller Trocar, plastic

INDICATIONS FOR USE
The Y-TEC™ system can be used to implant a peritoneal dialysis catheter in patients who are suitable candidates for peritoneal dialysis therapy.

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

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

Contents and packaging are latex free. Sterilized by ethylene oxide.

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
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 or the catheter, but which may affect the quality of the therapy. These complications include:
- Allergic reaction
- Abdominal pain
- Infusion pressure/pain
- Organ erosion
- Genital edema
- 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 that are included in each Flex-Neck® catheter kit.

FIG. 1

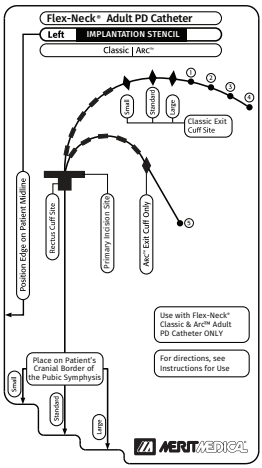
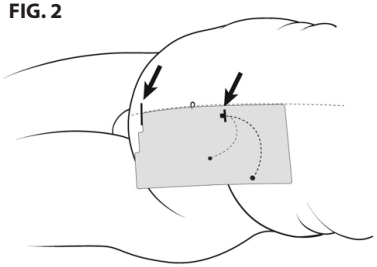


FIG. 2

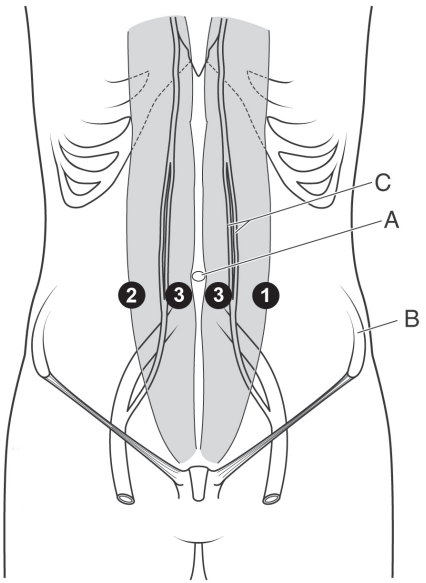


1.Left, lateral border of rectus sheath, 2-3 cm below umbilicus.

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

3. Medial border of rectus sheath, 2-3 cm below umbilicus.

FIG. 3



Anatomical landmarks

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

NOTE: Implantaton 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.

Laparoscopic Abdominal Examination

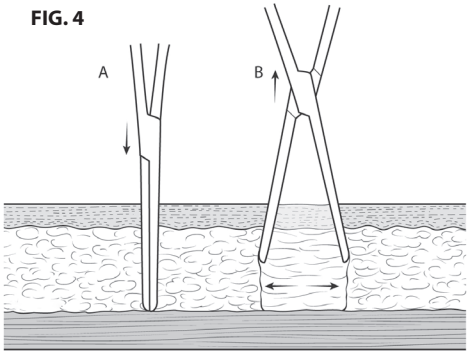
1. Examine peritoneal cavity to identify and note condition and location of adhesions and/or omentum.
2. Perform adhesiolysis if necessary
3. Perform omentopexy If necessary

The following is a general implantation procedure for the Laparoscopic implantation. Please follow hospital and/or physician protocol.

Inserting Luke Guide Assembly

1. Make 3-5 cm long horizontal skin incision.
2. Perform blunt dissection with hemostats to the anterior sheath of the rectus muscle (Fig 4).

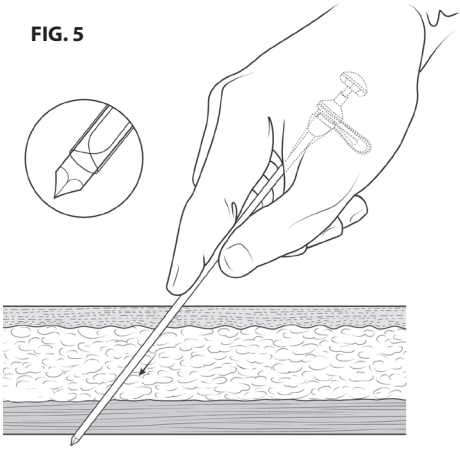
FIG. 4



3. Insert Luke Guide Assembly at 45° angle from horizontal toward coccyx into the peritoneum (Fig 5).

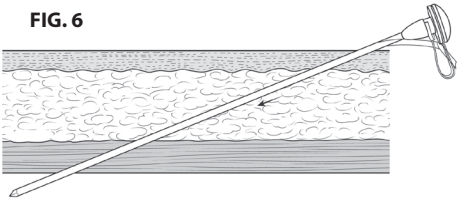
CAUTION: Maintaining a 45 degree angle to assure proper anchoring in the rectus muscle and final catheter placement.

FIG. 5



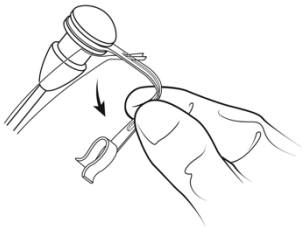
4. Advance the Luke Guide Assembly into optimum location, as noted via laparoscopic visualization.

FIG. 6



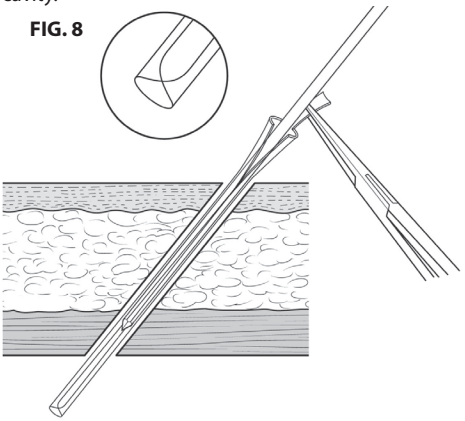
5. Leaving Luke Guide in position, remove Clip from the Luke Guide Assembly and Guide (Fig 7). Clamp Luke Guide.

FIG. 7



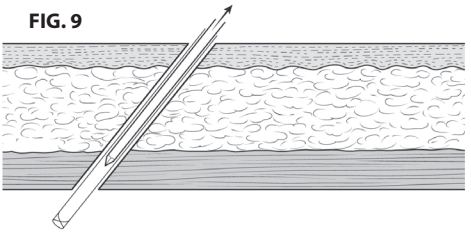
6.Clamp hemostat to tab of Luke Guide perpendicular to the Guide (Fig 8).
WARNING: Luke Guide must be secured to prevent inadvertent advancement into the abdominal cavity.

FIG. 8



7. Remove Trocar from Luke Guide (Fig 9) assuring the angle of initial insertion is maintained.

FIG. 9

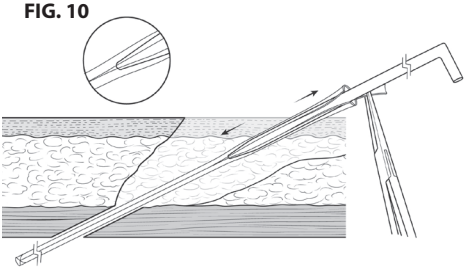


8. Return patient to normal supine position, if the patient is in Trendelenburg position previously.

Dilating the Luke Guide

1. Lubricate the dilator with sterile gel or saline.
2. Insert the dilator into the Luke Guide to dilate the rectus muscle, again assuring initial insertion angle is maintained. (Fig 10).

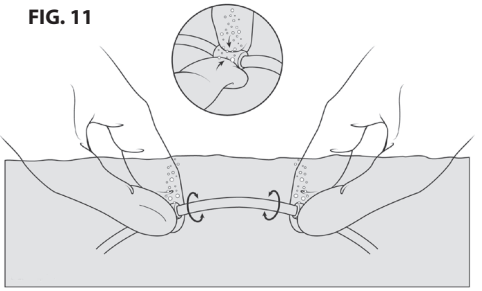
FIG. 10



Inserting the Catheter

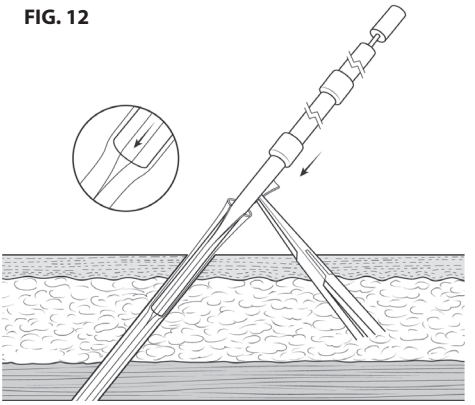
1. Prepare the catheter by soaking in sterile saline, and squeeze the air out of the cuffs by rotating the submerged cuffs between fingers (Fig 11).

FIG. 11



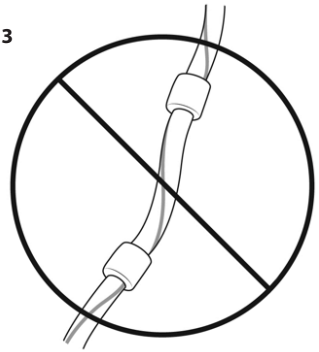
2. Lubricate the catheter stylette with sterile gel or saline.
3. Insert the stylette into the catheter (Fig 12).
4. Lubricate the distal part of the catheter with sterile gel or saline.
Remove dilator.
5. Insert catheter (with stylette) carefully into the Luke Guide. Be sure to follow the existing angle of the Luke Guide through the rectus muscle (Fig 13).

FIG. 12



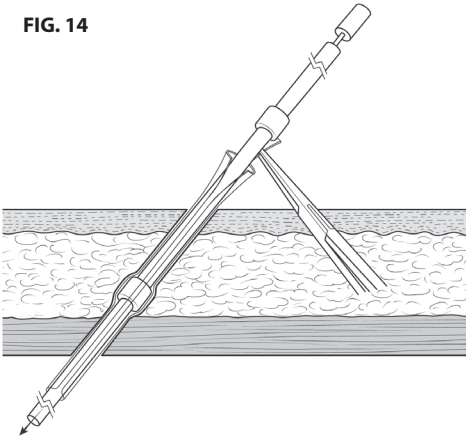
6 .Advance catheter through the Luke Guide, periodically retracting the stylette.
NOTE: Keep the tip of the stylette within the abdomen to help the catheter through the rectus.
7. Use the radiopaque stripe as a guide to avoid twisting the catheter. For optimal catheter placement, radiopaque stripe should be oriented directly anterior or directly posterior to the patient.
Caution: Make sure the catheter is not doubled on itself, kinked, or twisted. Use the radiopaque stripe as a guide to avoid twisting the catheter (Fig 13).
8. Confirm the proper placement of the catheter visually via the scope.

FIG. 13



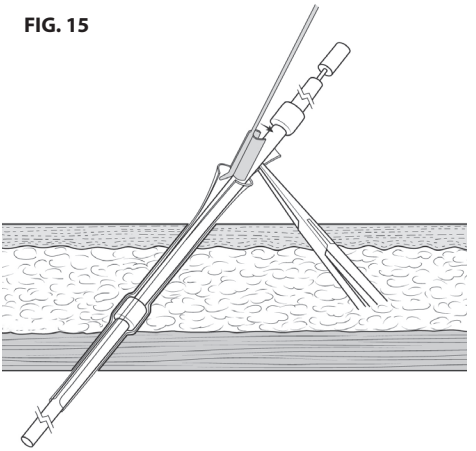
9. Advance catheter until distal cuff reaches rectus sheath. (Fig 14).

FIG. 14



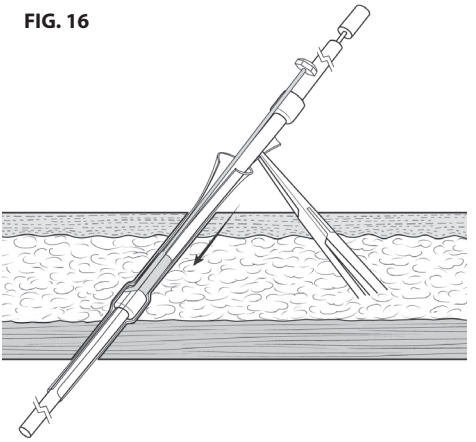
10. Position Cuff Implantor™ Tool parallel with and over the catheter, between the two cuffs (Fig 15).

FIG. 15



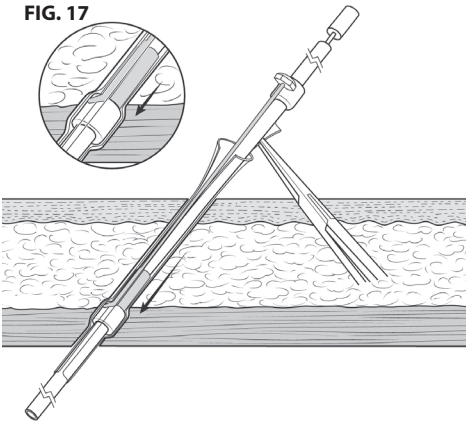
11. Advance Cuff Implantor Tool to edge of distal cuff (Fig 16). **NOTE:** To improve visualization of the cuff, it is helpful to retract incision site tissue.

FIG. 16



12. Advance catheter and Cuff Implantor Tool simultaneously approximately 1.0 cm to both dilate the rectus and advance the cuff into the rectus muscle while holding the Cuff Implantor stationary with the hemostat. (Fig 17).

FIG. 17



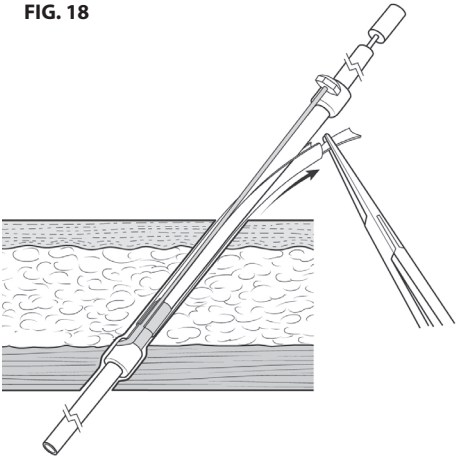
Removing Tools

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 (Fig 18).

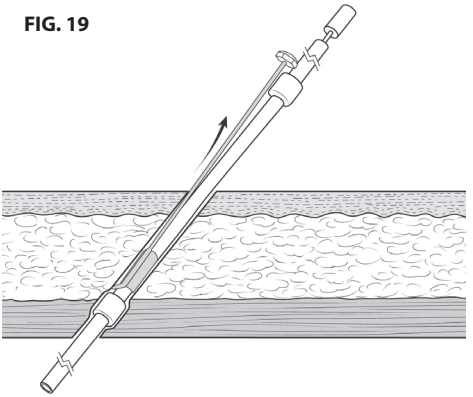
FIG. 18



NOTE: Maintain pressure on cuff with cuff implantor to hold it in position.

3. Retract Cuff Implantor Tool, parallel with the catheter, without dislocating or moving the distal cuff (Fig 19).

FIG. 19

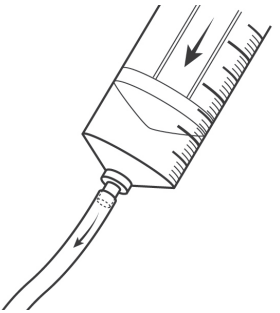


4. Retract the catheter stylette. Verify cuff position visually and digitally.

CHECKING CATHETER PATENCY

1. Test catheter patency via infusion of 100-500 cc sterile saline .

FIG. 20

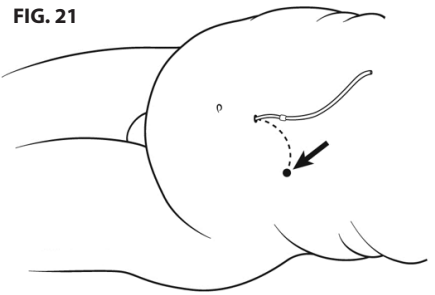


2. If catheter is functioning well, fluid will flow out in a steady drip or flow when proximal end of the catheter is lowered below the primary site when the syringe has been removed.

Tunneling the Catheter

1. Locate previously marked exit-site as determined by the Implantation Stencil (Fig 21).

FIG. 21



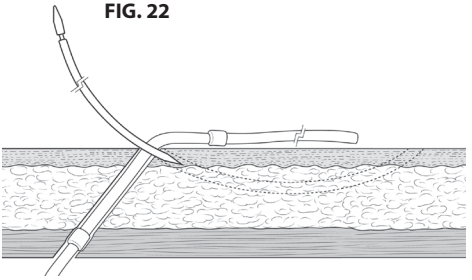
2. Alternatively, if the implantation Stencil was not used to mark the exit-site location: Lay the catheter on the patient's abdomen to determine the best

exit-site location. That location should be distal, lateral, and below the primary site. The goal is to have a gentle, curved downward-facing exit-site. Then, mark a spot so that the exit-site is about 3-4 cm distal to the distal cuff (Fig 21).

3. Insert the sharp end of the Fallar Trocar into the primary insertion site and advance the trocar through the subcutaneous tissue (Fig 22).

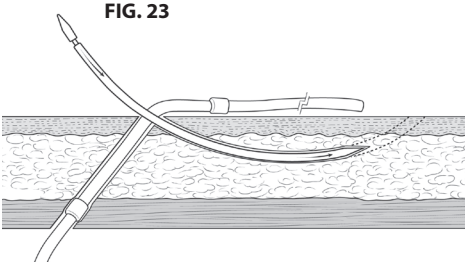
CAUTION: The proximal end of the trocar is very sharp.

FIG. 22



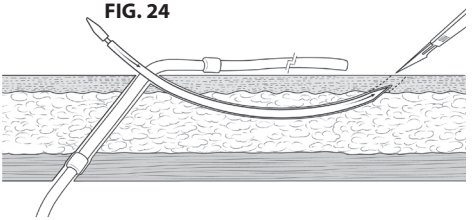
4. Follow the appropriate tunnel track toward the planned exit-site (Fig 23).

FIG. 23



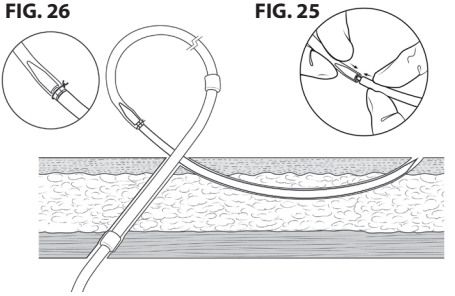
5. Make a stab incision with #11 scalpel blade to full width of blade (Fig 24).

FIG. 24



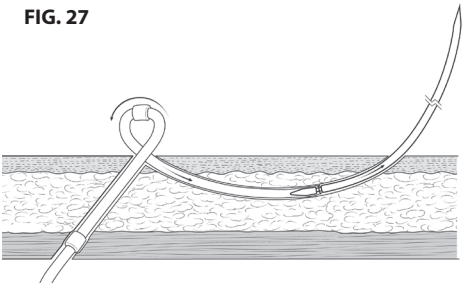
6. Attach the proximal end of the catheter over the distal (barbed) end of the Faller Trocar, onto the indented section of the trocar past the barb (Fig 25). Secure the catheter with a suture by tying the suture around the catheter to ensure holding strength during the tunneling process (Fig 26).

FIG. 26 **FIG. 25**



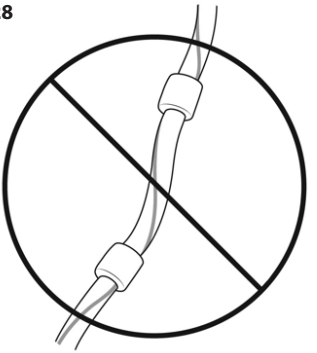
7. Pull the catheter through the tunnel track (Fig 27). **Optional:** Create a space within the tunnel for the distal cuff.

FIG. 27



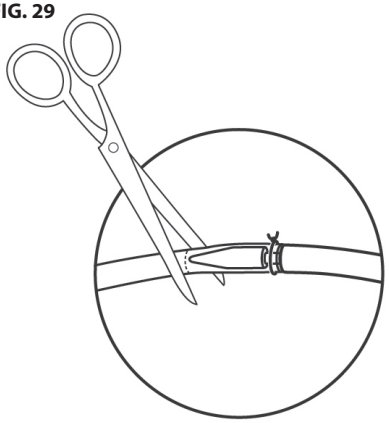
CAUTION: Check catheter at primary site and exit-site to ensure it is not twisted or kinked (Fig 28). Do not dislodge the distal cuff from the rectus muscle.

FIG. 28



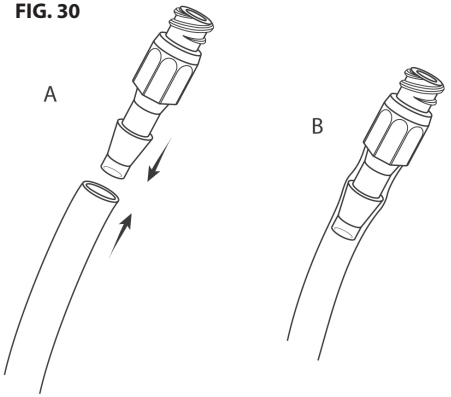
8. Cut the catheter off the trocar (Fig 29).

FIG. 29



9. Attach catheter connector, included in catheter kit, or two-part titanium connector (sold separately). (Fig 30 A & B)

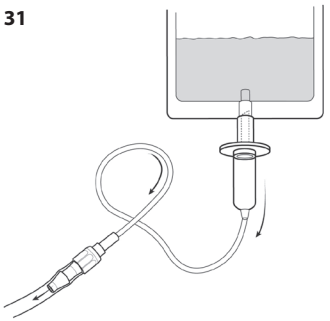
FIG. 30



Checking Catheter Patency

1. Test catheter patency by infusing and draining a minimum of 1 liter sterile saline. (Fig 31).

FIG. 31

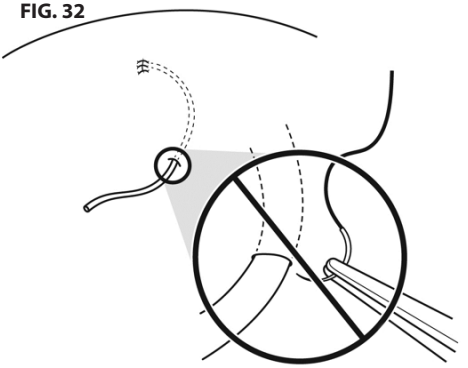


2. Attach cap or transfer set to connector.

Closing

1. Close primary incision site.
2. Do not suture the exit-site. (Fig 32).

FIG. 32



3. Apply appropriate dressings to the primary site, catheter exit-site, laparoscope site, and the catheter itself.
4. Secure the catheter in standard manner.

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

www.merit.com

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401401002_001 ID 2022-12-22