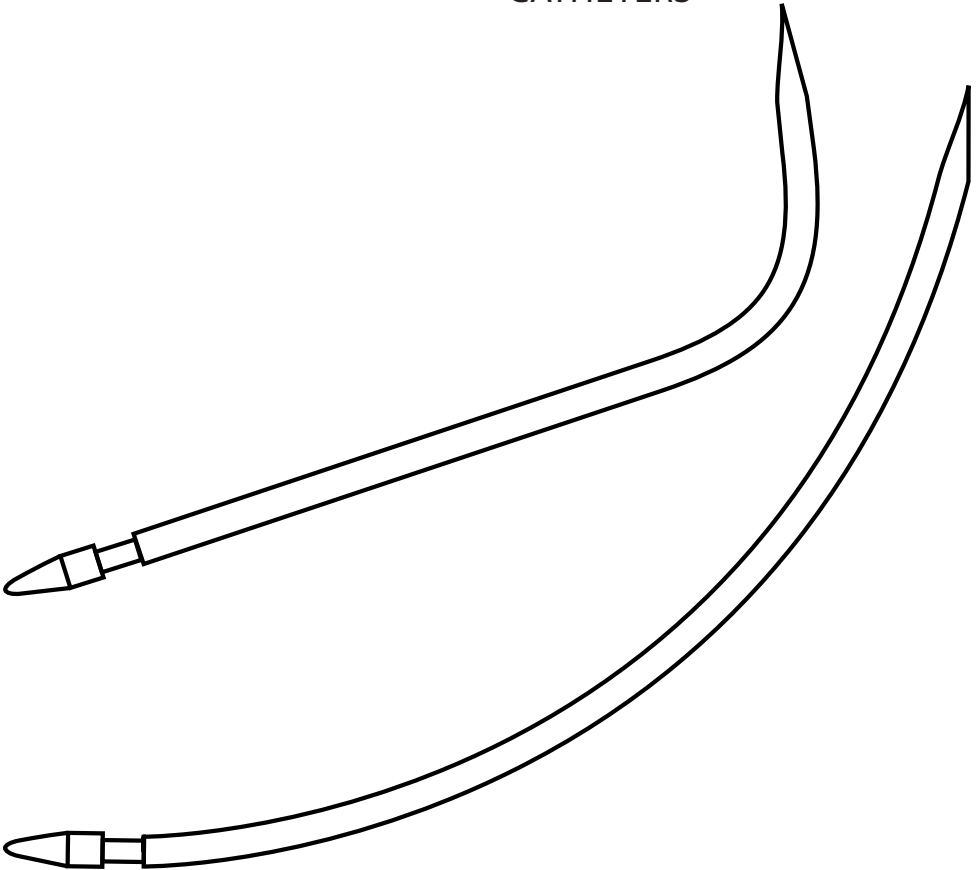


INSTRUCTIONS FOR USE

FALLER TROCAR

FOR IMPLANTATION OF
PERITONEAL DIALYSIS
CATHETERS



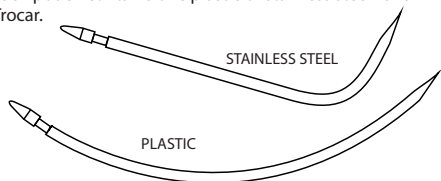
FALLER TROCAR

For Implantation of Peritoneal Dialysis Catheters

English

PRODUCT DESCRIPTION

Each pouch contains one plastic or stainless steel Faller Trocar.



INDICATIONS FOR USE

The Faller Trocar is used to create an antegrade subcutaneous tunnel for a peritoneal dialysis catheter from the initial implantation site to the preferred exit-site. It separates the tissue as it leads the catheter through to the skin exit-site.

CONTRAINDICATIONS FOR USE

The Faller Trocar is contraindicated for use if the distal part of the catheter is not implanted properly.

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 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.

- Subcutaneous hematoma
- Dislocation of the previously implanted proximal part of the catheter

CAUTIONS

- The Faller Trocar is very sharp and can create severe hematomas on the patient or injure the user if not used correctly by qualified medical personnel.
- Do not use the Faller Trocar if the sharp tip is damaged in any way or has a burr at the sharp tip.
- This Instruction for Use does not address the implantation of the catheter. Each style of catheter or implantation kit used will have its own set of implantation instructions, which should be followed.
- This Instruction for Use is only for the Faller Trocar, which is used after the intraperitoneal part of the catheter has been implanted.
- The desired tunnel track and exit-site should be marked in advance to serve as a guide for the trocar and catheter.
- Do not twist or kink the catheter.

INSTRUCTIONS FOR USE

1. Select and mark an appropriate exit-site on the skin. Refer to the implantation kit or catheter's specific implantation instructions for details.
2. If conscious sedation was used to implant the catheter, anesthetize the planned exit-site. Optional: Anesthetize the planned tunnel track.
3. 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.
4. Secure the catheter with a suture by tying the suture around the catheter, holding strength during the tunneling process.
5. Insert the sharp end of the Faller Trocar into the initial implantation site, aiming the sharp tip toward the planned exit-site.
6. Advance the sharp tip of the Faller Trocar along the planned track. Do not twist the catheter.
7. When the Faller 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.
8. Advance the Faller Trocar through the exit-site incision. Do not twist or kink the catheter.
9. Pull the catheter through the tunnel, and out through the exit-site.

CAUTIONS:

- Verify that the catheter is not twisted or kinked.
- Do not change the shape of the tunneled catheter track from the track made by the Faller Trocar.
- 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.

10. Cut the catheter off of the Faller Trocar at the end of the barbed tip of the trocar.

CAUTIONS:

- DO NOT pull the catheter off.
- DO NOT cut the suture off.
- Attempting to cut the suture off creates a very high risk of damaging the catheter.

11. Check that the catheter is not twisted or kinked.

12. DO NOT suture the exit-site.

13. Attach the appropriate connector to the catheter as recommended by the catheter manufacturer. Attach a cap or transfer set to the connector.

14. Complete the balance of the catheter implantation procedure as per established protocol or catheter instructions for use.

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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

EC REP

Authorized Representative:

Merit Medical Ireland Ltd,

Parkmore Business Park West, Galway, Ireland

www.merit.com