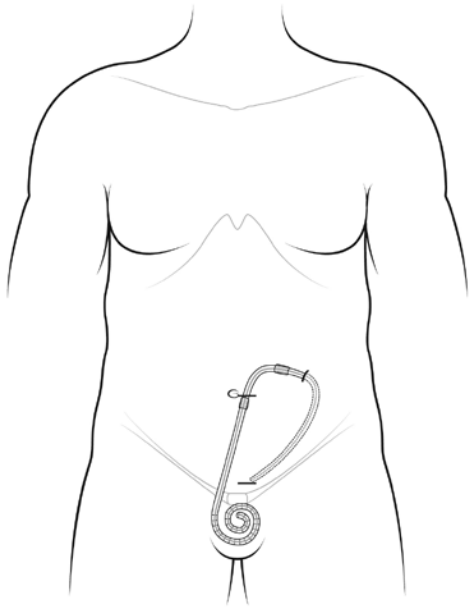
INSTRUCTIONS FOR USE

EMBEDDING® TOOL

EMBEDDING THE EXTERNAL PORTION OF A PERITONEAL DIALYSIS CATHETER



MERIT MEDICAL™

EMBEDDING THE EXTERNAL PORTION OF A PERITONEAL DIALYSIS CATHETER

English

INTRODUCTION

Merit Medical Systems, Inc.'s Embedding® Tool, TE-1000, is used to temporarily embed (bury) the external portion of a peritoneal dialysis (PD) catheter in the patient's subcutaneous tissue at the time of implantation. The PD catheter is implanted and embedded in advance of the need for peritoneal dialysis. When dialysis treatment is needed, the catheter is retrieved (exteriorized) in a simple procedure, done with no additional special tools.

PREFACE

These Instructions make several assumptions that are critical to know and understand prior to successful use of the Embedding Tool.

1. *The distal catheter coil has been optimally placed in the peritoneal cavity for good hydraulic function, to avoid entrapment by omentum, and to minimize catheter migration.*
2. *The PD catheter has two polyester felt cuffs.*
3. *The distal (deep) cuff is correctly positioned within the rectus muscle.*
4. *Catheter patency has been clearly established prior to the embedding procedure.*
5. *The catheter has been tunneled through an exit-site.*
6. *The embedding procedure is done during the same operative procedure as the initial implantation of the PD catheter itself. There is no adequate way to sterilize the external limb of a previously implanted catheter, and then embed it, without significant risk of infectious complications.*
7. *The retrieval procedure is assumed to be done later as a separate procedure. The retrieval timing is determined by the patient's need to start dialysis and by catheter cuff ingrowth, allowing adequate time for tissue ingrowth into the cuffs (3 – 5 weeks).*
8. *The embedding and retrieval procedures are designed to be performed by a qualified physician.*

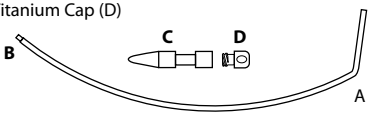
INSTRUCTIONS FOR USE

Embedding Tool

PRODUCT DESCRIPTION

Each box contains one pouch with the following components;

- Curved plastic handle, (A) with threaded tip (B)
- Titanium Plug (C)
- Titanium Cap (D)



INDICATIONS FOR USE

This device can be used to embed most known brands and styles of peritoneal dialysis (PD) catheters when the nephrologist determines this action is in the best interest of the patient, however, only immediately after successful catheter implantation. The Embedding Tool is indicated for embedding the external portion of most PD catheters subcutaneously in anticipation of future retrieval of that part of the catheter, provided that:

- The embedding procedure is done immediately following PD catheter implantation.
- Catheter patency has been completely established.
- The normally external part of the PD catheter can be embedded.
- The patient is a candidate for delayed onset of PD treatment.
- The patient is a candidate for PD.

CONTRAINDICATIONS FOR USE

The use of this device and technique is contraindicated if one or more of the following conditions exist:

- The PD catheter was implanted at a different time or setting.
- PD catheter patency was not clearly demonstrated prior to embedding.
- The patient has or will receive a Flex-Neck® Infant Catheter.
- The patient is not a candidate for delayed onset of PD treatment.

℞ 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.
- This package contains small parts, assure all parts are placed on sterile area, prior to performing procedure.

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.

CAUTIONS

- Catheter tubing can tear when subjected to repeated clamping, serrated-jaw forceps, excessive force, or rough tools.
- Do NOT use forceps with a serrated jaw.
- Do NOT use excessive force to lock the forceps closed.
- Use ONLY smooth-jawed forceps or equivalent.
- Do NOT clamp the catheter repeatedly in the same area.

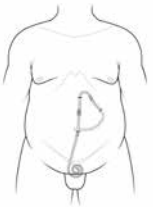
EMBEDDING INSTRUCTIONS

STEP 1: PREPARATION

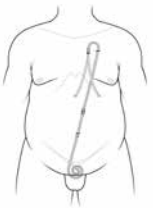
1. During the PD catheter implantation procedure, implant and tunnel the catheter according to hospital protocol or product Instructions for Use, with the superficial cuff 3.0 cm from the future exit-site (primary exit-site). The exit-site incision should be about 1.5 cm long (equal to three catheter widths).
2. Mark the desired track of the portion of the catheter to be embedded. The embedding track can be made wherever there is suitable space. The path of the subcutaneous embedding track should be straight or curvilinear in order to facilitate subsequent catheter retrieval.

NOTE:

A. If using a Flex-Neck Classic or ARC™ catheter, or an ExxTended catheter with an upper abdomen exit-site, the shape of the embedding track should form a gentle curvilinear turn back toward the midline.



B. If using a Flex-Neck ExxTended Catheter with an upper chest exit-site, a straight subcutaneous embedding track down the torso may be used.



3. Determine that the external length of the catheter to be embedded fits the patient's anatomy. Trim the external catheter length, if necessary.

NOTE: If the external part of the catheter is trimmed, make sure that the cut is perpendicular to the catheter tube, and that the face of the cut is smooth.

5. Disassemble the titanium Plug from the Cap. Do NOT discard the Cap.
6. Thread the Plug onto the plastic Handle. Be careful not to cross-thread the Plug and Handle threads.

STEP 2: EMBEDDING

1. Lay the external (subcutaneous) part of the catheter to be embedded on the patient's abdomen to assure proper placement.
2. Mark a location on the patient's abdomen to indicate the end of the embedding track which also will become the temporary secondary exit-site.

NOTE: Allow for the extra length of the Plug and Cap. This is typically 1.0 – 2.0 cm.

3. Make an incision, approximately 0.5 – 0.7 cm, with a #11 blade at the secondary exit-site.
4. Insert the tip of the Handle, with the Plug attached, through the secondary exit-site and through the middle of the subcutaneous tissue toward the primary exit-site.
5. Advance the Handle until the entire titanium Plug is visible.
6. Dry the Plug thoroughly.
7. Infuse heparin or equivalent into the catheter, as per standard protocol.
8. Insert the Plug into the catheter so that the end of the catheter is next to (touching) the shoulder of the Plug.

NOTE:

- Do NOT detach or separate the Plug from the Handle.
- A correctly positioned catheter and Plug should form a relatively smooth and continuous surface from catheter to Plug.

9. Secure the catheter to the Plug with a permanent, non-absorbable suture.
10. Retract the Handle and catheter through the subcutaneous tissue until the Plug is visible at (external to) the secondary exit-site.

CAUTION: Do NOT twist or kink the catheter.

11. Hold the catheter and Plug stationary.
12. Separate the Handle and the Plug by rotating the Handle counter-clockwise.

CAUTION: Do NOT twist the catheter or the Plug.

13. Verify that the catheter is not twisted by making sure that the radiopaque stripe is consistently positioned from the subcutaneous cuff to the end where the plug is inserted.
14. Thread the titanium Cap onto the Plug and tighten firmly. There should be no gaps between the Cap and Plug when completely fastened.
15. Insert the Plug, with the Cap attached, and catheter into the subcutaneous tissue.

NOTE:

- If necessary, use forceps to push the Plug into the subcutaneous tissue.
- If necessary, use a second set of forceps at the primary exit-site to retract the catheter into the subcutaneous tissue.
- If the catheter (with Plug attached) seems to be too close to the secondary exit-site, enlarge the secondary exit-site incision and position the Plug deeper into the subcutaneous tissue, or trim off additional length of the catheter and reinsert the Plug.

CAUTION:

- Do NOT retract the catheter more than 2.0 cm back through the primary exit-site.
- Do NOT dislodge or reposition the superficial subcutaneous cuff.

16. Carefully verify that:
- The catheter is not kinked or twisted.
- The subcutaneous cuff is in the proper location relative to the future primary exit-site.
- The embedding track forms a straight or curvilinear path that will facilitate pulling the catheter from the subcutaneous path during the retrieval procedure.

17. Close the original catheter insertion incision, as well as the primary and secondary exit-site incisions, as per normal hospital protocol.

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EC REP

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