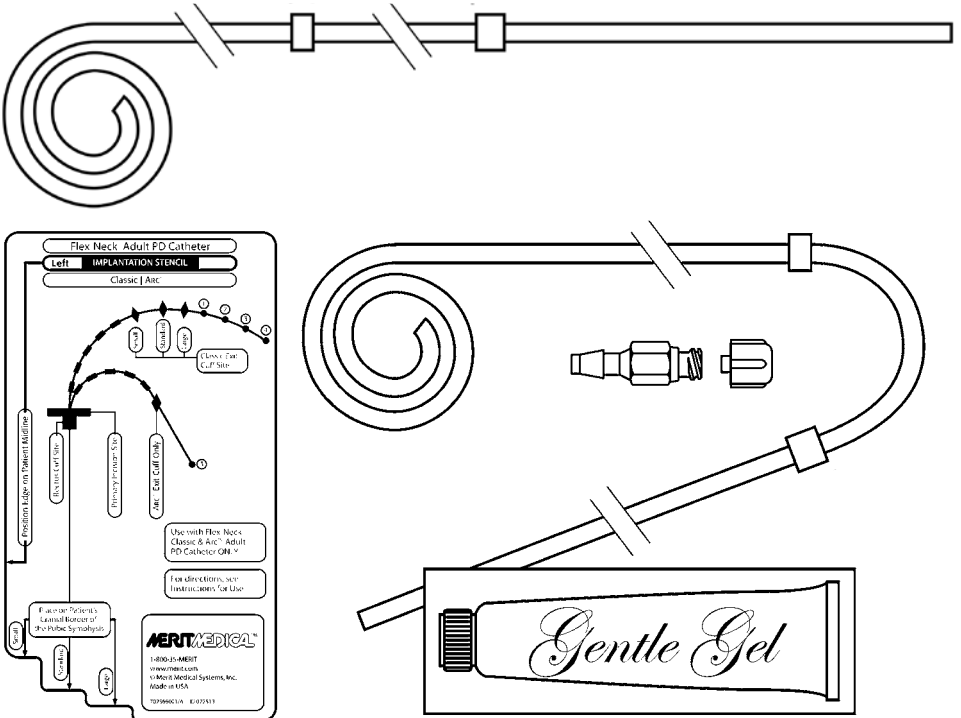


INSTRUCTIONS FOR USE

Flex-Neck® Classic and ARC™ Peritoneal Dialysis Catheters



Flex-Neck® Classic and ARC™ Peritoneal Dialysis Catheters

English

PRODUCT DESCRIPTION

Each Flex-Neck Catheter package contains:

- Flex-Neck Peritoneal Dialysis Catheter
- Implantation Stencil (for left and right sided placement)
- Plastic Connector and Cap
- Lubricating Gel

INDICATIONS FOR USE

CLASSIC

If the patient is a suitable candidate for Peritoneal Dialysis (PD) therapy, the Flex-Neck PD Catheter can be implanted either surgically or peritoneoscopically. The only contraindication to implantation of the Flex-Neck PD Catheter is if the patient is not a candidate for peritoneal dialysis. Numerous prior surgeries or suspected or documented intraperitoneal adhesions may be relative contraindications to PD. However, since the Y-TEC® System of peritoneoscopic implantation enables inspection of the peritoneum to confirm the presence of adhesions and to avoid them, all patients who are suitable for PD can receive this catheter.

ARC

A patient is a suitable candidate for PD therapy, the Flex-Neck ARC peritoneal dialysis catheter can be implanted either surgically, laparoscopically, or peritoneoscopically for acute or chronic peritoneal dialysis.

INFANT

If the patient is a suitable candidate for PD therapy and is too small for the current Flex-Neck catheters, the Flex-Neck Catheter, Infant, can be implanted either surgically, peritoneoscopically or percutaneous. The only contraindication to implantation of the Flex-Neck PD Catheter, Infant is if the patient is not a candidate for peritoneal dialysis.

CONTRAINDICATIONS

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

Rx Only: CAUTION: Federal law (USA) 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

- 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

- Do not twist or rotate catheter during the implantation procedure.
- This Stencil cannot be used with other brands of PD catheters, or with other sizes or styles of Flex-Neck PD Catheters.
- This Stencil is designed for, and to be used with, Flex-Neck Classic and ARC Coiled Adult Peritoneal Dialysis Catheters ONLY.
- Do NOT use the Classic and ARC stencil with Flex-Neck Adolescent, Pediatric, Infant, or ExxTended™ Catheters.
- Do NOT use this Stencil with other catheter brands.
- Do NOT sterilize this Stencil.
- 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, or repair tubing repeatedly in the same area.
- Do NOT clamp near the connector.

Use only catheter connectors and repairs kits which are specifically labeled and approved for use with Flex-Neck Peritoneal Dialysis Catheters. Approved catheter connectors and repair kits can be ordered directly from Merit Medical Systems, Inc.

For best results, use the Stencils included with each catheter kit. If not using the included Stencils, follow generally accepted standard hospital protocols to make arcuate-shaped tunnels.

For Implantation Stencils

Implantation Stencils for Classic and ARC and Adult Coiled Peritoneal Dialysis Catheters can be used to indicate the optimum implantation site, exit-site, catheter size, and catheter style for each patient. The stencil will help choose the best primary incision site, coil location, rectus cuff location, tunnel track, and exit-site location in advance of the implantation procedure.

For Tunneling Stencils

Tunneling stencils are included with Flex-Neck Adult Straight, Adolescent, Pediatric and Infant Catheters. Tunneling stencils will help choose the best tunnel track for the catheter.

General Instructions for Classic and ARC Implantation Stencils

Implantation stencils utilize fixed anatomical landmarks, such as the pubic symphysis and the midline, to guide accurate and reproducible skin marking, in the clinic or pre-op evaluation suite. Please consult Stencil Instructions for Use (distributed by Merit Medical) for patient marking in the PD outpatient clinical setting.

NOTE: The Classic and ARC Stencil cannot be used with other brands of PD catheters, or with other sizes or styles of Flex-Neck PD Catheters.

Flex-Neck Classic and ARC Coiled Adult Catheters are each available in three sizes – Small, Standard, and Large. The notched cutouts (Small, Standard, and Large) apply to both Classic and ARC catheter styles. The exit-site options for the various sizes of catheters are denoted by circles 1-5.

ALWAYS verify that all location choices and markings are not at belt lines, skin fold apexes, or blind sides of skin folds, and that the patient is able to see and reach the proposed exit-site.

The Flex-Neck ExxTended Catheter is highly recommended for patients who are not candidates for the Classic or ARC catheter, according to the stencil exit-site markings. Please consult Exxtended Catheter Instructions for Use for additional information.

For all Classic Catheters, do not make the arcuate bend too acute. If the bend is too acute, the catheter may migrate; the exit cuff may erode; and/or a kink may occur occluding the catheter. For all ARC Catheters, do not attempt to change the preformed arcuate bend; doing so will greatly increase the risk of catheter migration.

INSTRUCTIONS FOR STENCIL USE

Pre-Procedure Stencil Marking

The Stencils can be used in the clinic prior to the scheduled implantation or on the day of the implantation procedure in the surgical suite as part of the preoperative preparations. Proper Stencil use is done in 2 to 3 stages, first with the patient supine, and then with the patient sitting and/or standing.






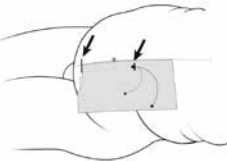
1. Determine from OR staff which Flex-Neck Catheter size and style will be implanted in the patient.
2. Based on the chosen size and style, with the patient supine, align the Stencil on the patient's midline, with the appropriate notched cut-out  placed on the upper border of the pubic symphysis. See figure A.
3. With the Stencil located properly based on the chosen catheter, mark the T-bar cutout , which is the location of the primary incision site and the rectus cuff. Mark the Rectangles cutout  which indicate the tunnel track.
4. Choose the most appropriate exit-cuff location, as indicated by the Diamond cutout , and exit-site location, as indicated by the Circle cutout , as appropriate both to patient physique and chosen catheter size and style.
5. Verify the markings with the patient supine, sitting, and standing. This ensures that the markings, and the catheter placement locations that they indicate, will be ideally located and readily visible and accessible to the patient.

figure A








Stencil Marking in the Surgical Suite

Sterile Stencils are included in each Flex-Neck catheter kit.




If no patient marking was done in advance in the clinic, the Stencil can be used during the procedure, particularly after laparoscopic or peritoneoscopic visualization of the peritoneum to:

- Coordinate and verify the location choices and markings.
- Adapt or adjust those markings, if necessary.




1. Determine from OR staff which Flex-Neck Catheter size and style will be implanted in the patient.
2. Based on the chosen size and style, with the patient supine, align the Stencil on the patient's midline, with the appropriate notched cut-out  placed on the upper border of the pubic symphysis.
3. With the Stencil located properly based on the chosen catheter, mark the T-bar cutout , which is the location of the primary incision site and the rectus cuff. Mark the Rectangles cutout  which indicate the tunnel track.
4. Choose the most appropriate exit-cuff location, as indicated by the Diamond cutout , and exit-site location, as indicated by the Circle cutout , as appropriate both to patient physique and chosen catheter size and style.

Flex-Neck Catheter Options: Style, Size and Location

ARC Catheter Options: Size and Location

ARC Catheter Size	Coil Location	Exit-Site Location	Exit-Cuff Location
			
Adult Small	Small	5	ARC
Adult Standard	Standard	5	ARC
Adult Large	Large	5	ARC

Classic Catheter Options: Size and Location

Classic Catheter Size	Coil Location	Exit-Site Location	Exit-Cuff Location
			
Adult Small	Small	1 or 2	Small
Adult Standard	Standard	2 or 3	Standard
Adult Large	Large	3 or 4	Large

INSTRUCTIONS FOR USE CATHETER IMPLANTATION

Flex-Neck Peritoneal Dialysis Catheters can be implanted via a number of implantation methods according to standard hospital protocols, including:

- Peritoneoscopy
- Laparoscopy
- Surgery (Open; Blind; Cut-down)
- Percutaneous (with or without fluoroscopy; with or without guide wire)

For specific instructions, please consult Instructions for Use, included with all Merit peritoneal dialysis catheter Implantation System Kits (sold separately).

CAUTIONS: Use the radiopaque stripe as a guide to keep the Flex-Neck catheter straight. The catheter must not be twisted or rotated during the implantation procedure. Any twist or rotation in the catheter can lead to kinks, migration, and/or occlusion.

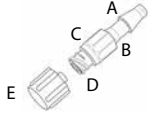
CATHETER CONNECTOR INSTRUCTION

A plastic connector is included with each Flex-Neck Peritoneal Dialysis Catheter. A two-piece titanium connector for Flex-Neck Adult, Adolescent, and Pediatric Peritoneal Dialysis Catheters is available separately from Merit Medical.

After successful implantation of the Flex-Neck Peritoneal Dialysis Catheter, attach a Merit Peritoneal Dialysis (PD) catheter connector to the catheter.

Each catheter kit contains one Connector and one Cap.

- Tapered Tip (A)
- Raised Shoulder Ridge (B)
- Finger Grip (C)
- Threaded Luer (D)
- Cap (E)



1. Wet the Tapered Tip (A) of the Connector with sterile saline or sterile water, and insert it into the catheter.
 - Do not use any other lubricant.
 - Do not use a twisting motion to force the catheter onto the Connector.
 - Push the Connector into the catheter with a single forward motion.
2. Advance the catheter completely to the Raised Shoulder Ridge of the Connector. The catheter tubing must completely pass over the Tapered Tip and to the Raised Shoulder Ridge, but not beyond that onto the Finger Grip. See diagram.



3. Pull carefully on the Connector and catheter to test the strength of the connection.
4. Attach either the Cap (E), or a dialysis transfer set, to the threaded Luer (D).

Catheter Cleaning and Care

All Flex-Neck Peritoneal Dialysis Catheters are made of silicone. Exit-site cleaning agents that are compatible with silicone catheters therefore may be acceptable for use on Flex-Neck Peritoneal Dialysis Catheters. Such cleaning agents include:

- Electrolytically-produced sodium hypochlorite solutions (i.e., ExSept Plus®)
- Normal (sterile) saline

Cleaning agents that are non-irritating, non-toxic, anti-bacterial, and in liquid form are generally recommended.

The following cleaning agents are not compatible with silicone catheters, and are not recommended for use with Flex-Neck Peritoneal Dialysis catheters:

- Acetone or acetone-based products
- Povidone-iodine or iodine-based products

Merit Medical Systems, does not provide specific recommendations or protocols for exit-site care and cleaning, whether by the healthcare professional or by the patient. Appropriate exit-site and catheter care treatment protocols should be individualized for each patient, and established by the patient's physician(s), nurse(s), dialysis center(s), and/or other relevant dialysis healthcare professionals.

ExSept Plus is a registered trademark of Alcavis HDC, LLC or one of its affiliates.

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