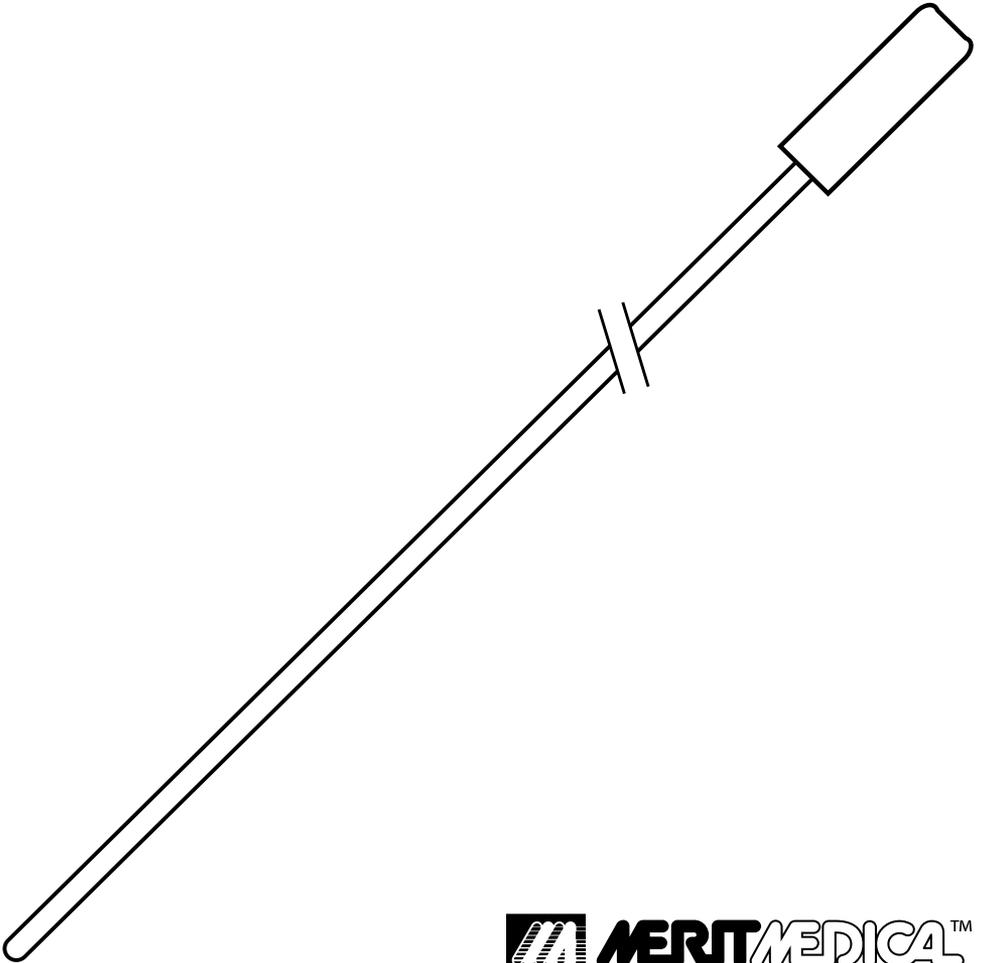


INSTRUCTIONS FOR USE

PERITONEAL DIALYSIS
CATHETER IMPLANTATION
STYLETTE



PERITONEAL DIALYSIS CATHETER IMPLANTATION STYLETTE

English

PRODUCT DESCRIPTION

The Merit Peritoneal Dialysis (PD) Catheter Implantation Stylettes, CS-242, CS-352, CS-362 are intended to be used with Flex-Neck® Peritoneal Dialysis Catheters. Please refer to appropriate instructions for use for complete implantations instructions. Complete instructions are included in the Merit VP-211 and VP-411 Y-TEC Implantation System Kits (Sold Separately).

INDICATIONS FOR USE

The PD Catheter Implantation Stylette is intended to be used with the Flex-Neck Peritoneal Dialysis Catheters to stiffen the catheter during catheter insertion.

Rx Only; CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

PRECAUTIONS

- Read manufacturer's instructions prior to use.
- 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.

CAUTION

Limits on reprocessing: Repeated processing has minimal effect on the PD Catheter Implantation Stylette as it is a stainless steel instrument. End of life is normally determined by wear and damage due to use.

INSTRUCTIONS FOR USE

PD Catheter Implantation Stylette Sterilization

PD Catheter Implantation Stylettes are reusable devices that are intended to be sterilized by the user prior to use.

1. Point of use: Remove excess soil with disposable cloth/paper wipe.
2. Containment and transportation: No particular requirements. It is recommended that instruments are reprocessed as soon as is reasonably practical following use.
3. Preparation for cleaning: No particular requirements.
4. Cleaning:
 - Use Enzol® (or comparable hospital-approved medical device cleaning detergent) prepared according to manufacturer's recommendations (1 oz/gal) using cool tap water.
 - Fully immerse the PD Catheter Implantation Stylette in the detergent and allowed to soak for a minimum of 10 minutes.
 - Brush the PD Catheter Implantation Stylette using a soft bristled brush.
 - After brushing, rinse the PD Catheter Implantation Stylette under clean running cool tap water until all evidence of detergent is gone.
 - Rinse the PD Catheter Implantation Stylette under running reverse osmosis/de-ionized (RO/DI) water until all remaining visible detergent is removed.
 - Dry with a soft, clean, lint-free cloth.

5. Inspection: Visually inspect the PD Catheter Implantation Stylette with an unaided eye for signs of visible soil or debris. Also, visually inspect for damage and wear. PD Catheter Implantation Stylette must have a smooth surface and remain straight and undamaged.

6. Drying: Ensure PD Catheter Implantation Stylette is completely dry before proceeding with sterilization instructions below.

7. Packaging: Place each individual Merit PD Catheter Implantation Stylette in a single-use self-sealing autoclavable pouch. Ensure that the pouch is large enough to contain the PD Catheter Implantation Stylette without stressing the seals.

8. Sterilization: Process packaged device in a steam pre-vacuum autoclave unit using a 5 minute cycle at 132° C (270°F) with a minimum dry time of 30 minutes or per hospital protocol.

9. Storage: No particular requirements.

NOTE: When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

NOTE: The instructions provided above have been validated by the medical device manufacturer as being CAPABLE of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing as actually performed, using equipment, materials, and personnel in the processing facility, achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

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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



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