

PERITONEAL CATHETER STRAIGHTENING STYLET INSTRUCTIONS FOR USE

Sterilized with ethylene oxide. Sterile and non-pyrogenic in unopened and undamaged package.

STERILE EO



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

READ ALL INSTRUCTIONS, WARNINGS, AND CAUTIONS CAREFULLY PRIOR TO USE.

DESCRIPTION:

The straightening stylets for peritoneal catheters are made of stainless steel.

INDICATIONS:

The straightening stylet is used to keep a peritoneal catheter straight and maneuverable during insertion into the peritoneum.




CONTRAINDICATIONS:

Use only with catheter provided by Medcomp®.

POTENTIAL COMPLICATIONS:

- Abdominal Viscera Injury
- Bladder Perforation
- Bowel Perforation
- Inadvertent Preperitoneal Placement
- Peritoneal Bleed
- Peritonitis
- Sepsis

WARNINGS AND PRECAUTIONS:

- The stylet should be inserted only by a qualified, licensed physician or other health care practitioner authorized by and under the direction of such physician.
- The medical techniques and procedures described in these instructions do not represent ALL medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient.
- Do not use the stylet if it is bent, broken, or appears otherwise defective.
- Observe sterile technique at all times when inserting the stylet.
- To prevent damaging the catheter, do not insert or withdraw the stylet forcibly.
- Use only smooth-jawed forceps for clamping.
- This device is for single use only. 
- Do not resterilize by any method. 
- Re-use may lead to infection or illness/injury.
- Do not use if package is damaged. 
- Note: Discard biohazard according to facility protocol.
- Caution when using this device. Be aware of sharps.

USING THE STYLET:

IMPORTANT: These instructions pertain only to using the straightening stylet once the catheter insertion procedure is underway. They do not provide details for complete peritoneal catheter insertion. Please read the instructions for use that come with the peritoneal catheter before performing catheter insertion.

1. After lubricating the catheter as instructed in the catheter instructions, insert the straightening stylet into the catheter. Position it approximately 4 mm above the tip of the catheter. Clamp a hemostat on the stylet (**do not clamp the catheter**) to prevent it from advancing further towards the tip. **Caution: Do not insert the stylet beyond the tip of the catheter. This can cause injury during insertion.**
2. Insert the catheter with stylet into the peritoneal cavity. **Caution: Do not damage the viscera.**

3. When the catheter is positioned, gently remove the stylet.
4. Continue the procedure following the instructions provided with the peritoneal catheter.

Medcomp® does not recommend a particular technique for the use of this device. The physician should evaluate the appropriateness of the device according to individual patient conditions and his or her medical training and experience.













WARRANTY

Medcomp® WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATMENT, AND PRODUCT MAINTENANCE MAY AFFECT THE PERFORMANCE OF THIS PRODUCT. USE OF THIS PRODUCT SHOULD BE IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN.

Because of continuing product improvement, prices, specifications, and model availability are subject to change without notice. Medcomp® reserves the right to modify its products or contents without notice.

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SYMBOL TABLE

5.1.1		Manufacturer *
5.3.4		Keep Dry *
5.6.3		Non-pyrogenic *
5.3.2		Keep Away from Sunlight *
5.2.3		Sterilized Using Ethylene Oxide *
5.2.8		Do Not Use if Package is Damaged *
5.1.4		Use-by Date *
5.2.6		Do Not Resterilize *
5.1.5		Batch/Lot Number *
5.1.6		Catalogue Number *
5.4.4		Caution, consult Accompanying Documents *
5.4.2		Do Not Re-use *
Rx Only		Prescription Use Only ***

***This symbol is in accordance with ISO 15223-1.**

***** FDA guidance Use of Symbols in Labeling.**



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