

PERITONEAL TUNNELING 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:

Medcomp®'s peritoneal tunneling stylet is a stainless steel rod with a radial tip, a plastic hub, and a movable cone-shaped cap.

INDICATIONS:

The tunneling stylet is used to create a subcutaneous tunnel for the cuffed portion of a catheter. Functioning as a dilator, the tunneling stylet separates the tissue while simultaneously pulling the attached catheter through the tunnel.




CONTRAINDICATIONS:

Use only as indicated.

POTENTIAL COMPLICATIONS:

- Subcutaneous Hematoma
- Tunnel or Exit Infection
- Peritonitis

WARNINGS AND PRECAUTIONS:

- 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.
- The stylet should be used only by a qualified, licensed physician or other health care practitioner authorized by and under the direction of such physician.
- To avoid exposure to blood-borne pathogens, observe universal precautions during use.
- Observe sterile technique when handling the tunneling stylet.
- Single use only. Do not re-use. Re-use may lead to infection or illness/injury. 
- Do not resterilize by any method. 
- Do not use if package is damaged. 
- Do not use the stylet if it appears damaged in any way.
- Caution when using this device. Be aware of sharps.

HOW TO USE THE PERITONEAL TUNNELING STYLET:

NOTE: This procedure covers use of the tunneling stylet only. For complete catheter insertion procedure, refer to instructions supplied with the catheter.

The tunneling stylet is used after the catheter has been inserted into the peritoneum. At this point, the catheter should be free of air and clamped securely, approximately 7.5 centimeters from the external end.

1. Anesthetize the exit site approximately 6 cm to one side of the entry site. Make a 5 mm incision.
2. For curved tunnels: place the tunneling stylet between the two incision sites and bend the stylet to match the desired shape of the tunnel (be sure the cap is on the radial end of the stylet before creating the curve).
3. Attach the catheter to the tunneling stylet. To do so, push the catheter over the radial end of the stylet until it meets the hub. Slide the cap over the connection. Remove the catheter clamp.
4. Insert the tip of the tunneling stylet into the primary incision. Thread the stylet through the tissue, creating a curved subcutaneous tunnel to the exit site.

NOTE: Some physicians may prefer to make a straight tunnel. For efficient dialysis, slant a straight tunnel slightly upwards to lessen the risk of catheter migration.

5. Wet the subcutaneous cuff thoroughly with saline.

6. Pull the tunneling stylet through the exit site, positioning the catheter as desired in the tunnel.
7. Place the cuff immediately (1/2 cm to 1 cm) beneath the skin exit in the subcutaneous fat tissue. Clamp the catheter.
8. Detach the tunneling stylet carefully and discard.
9. Attach the adapter and cap the catheter.
10. Do not suture the exit site. Use subcuticular sutures with delayed absorption to close the entry site.

Note: Discard biohazard according to facility protocol.

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 EFFECT 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 *
5.1.2		Authorized Representative in the European Community
		Prescription Use Only ***

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

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

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