

TUNNELER INSTRUCTIONS FOR USE

INDICATION FOR USE:

- Use tunneler to dissect tissue to create the subcutaneous tunnel opening.





DEVICE DESCRIPTION:

- Plastic or stainless-steel instrument in a variety of lengths, diameters and tip configurations. See product label for tunneler specifications.

POTENTIAL COMPLICATIONS:

- Bleeding
- Device dislodgement
- Hematoma
- Infection
- Trauma to tissue

WARNINGS:

- Federal Law (USA) restricts the device to sale by or on the order of a physician.
- This device is for Single Use Only. 
- Do not resterilize the needle by any method. 
- Re-Use may lead to infection or illness/injury.
- The manufacturer shall not be liable for any damages caused by re-use or resterilization of the device.
- Contents sterile and non-pyrogenic in unopened, undamaged package.
- STERILIZED BY ETHYLENE OXIDE 
- Do not use if package is opened or damaged.
- Do not use if any sign of product damage is visible. 
- Caution when using this device. Be aware of sharps.

INSTRUCTIONS FOR USE:

- Administer sufficient local anesthetic to completely anesthetize the insertion and exit site.
- Attach distal end of catheter ID fully over the barbed end of tunneler.
- If tunneler includes a sleeve, slide tunneling sleeve over the catheter making certain that the sleeve covers the arterial holes of the catheter.
- Make a small incision at the exit site. Make the incision at the exit site wide enough to accommodate the cuff.
- Make a second incision at the insertion site.
- Insert the tunneler into the exit site and create a short subcutaneous tunnel using blunt or sharp dissection. The tunnel should be made with care to prevent damage to surrounding vessels.
- Lead catheter into the tunnel. Do not pull or tug the catheter tubing. If resistance is encountered, further dissection may facilitate insertion.
- Remove the catheter from the tunneler with a slight twisting motion, or cut (depending on catheter tip configuration) to avoid damage to the catheter tip.
- Discard biohazard according to facility protocol.

Note: A tunnel with a wide gentle arc lessens the risk of kinking. The tunnel should be short enough to keep the hub of the catheter from entering the exit site.

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.













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EC REP

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5.1.1 	Manufacturer *	5.6.3 	Non-pyrogenic *
5.1.4 	Use-by Date *	5.3.2 	Keep Away from Sunlight *
5.4.2 	Do Not Re-use *	5.2.6 	Do Not Resterilize *
5.3.4 	Keep Dry *	Rx Only	Prescription Use Only ***
5.1.5 	Batch/Lot Number *	5.1.6 	Catalogue Number *
5.2.8 	Do Not Use if Package is Damaged *		
5.1.2 	Authorized Representative in the European Community *		
5.2.3 	Sterilized Using Ethylene Oxide *		

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

*** FDA guidance Use of Symbols in Labeling.

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