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Tunneling Needle

(en) Instructions for Use














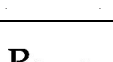
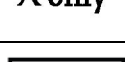
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Explanation of the symbols on label and packaging

	Do not re-use
	Do not use if package is damaged and consult instructions for use
	Use-by date
	Consult instructions for use or consult electronic instructions for use
	Keep away from sunlight
	Keep dry
	Non-pyrogenic
	Batch Code
	Do not Resterilize
	Catalogue number
	Manufacturer
	Sterilized using ethylene oxide
	Single sterile barrier system with protective packaging inside
	Requires prescription in the United States
	Unique device identifier

(en) Instructions for Use

Tunneling Needle

Product Description

Stainless-steel instrument in a variety of lengths, diameters, and tip configurations. See product label for tunneling needle specifications.

Indications for Use

To create a subcutaneous tunnel between percutaneous entry and exit incisions for the subcutaneous placement of a device such as a catheter. It is also used to lead or pull the device through subcutaneous tissue.

Contraindications

This device is contraindicated whenever:

- Previous surgical interventions in the area of the puncture site
- Active inflammation in the area of the puncture site
- The patient is known or is suspected to be allergic to materials contained in the device.
- There has been past irradiation of prospective insertion site.
- There are local tissue factors/skin conditions that may prevent proper device use.
- Tunnelling through deep tissues (i.e. muscles, fascia)
- Patient anatomy/condition that may prevent proper device use (i.e. lack of subcutaneous tissue to form tunnel track)
- Catheter not suitable for tunneling.

Undesirable Side-Effects

Ensure that you are familiar with possible undesirable side-effects and their emergency treatment should any of them occur.

Potential undesirable side-effects include:

- Trauma to tissue/organs
- Infection
- Bleeding
- Hematoma
- Intolerance Reaction to Device
- Device dislodgement
- Risks Normally Associated with Local Anesthesia

General Information and Warnings

The product described in this Instructions for Use may be used only by clinicians who are familiar with the techniques and clinical practices. The Instructions for Use and the information on the packaging should be read carefully before each use.

- Failure to follow instructions could lead to trauma to tissue/organs, infection, bleeding, hematoma, intolerance reaction to device dislodgement, patient discomfort, and delay of procedure.
- 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 re-sterilization 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:** Federal (USA) law restricts this device to sale by or on the order of a physician.

Device Information

The Tunneling Needle can be used with catheter accessories via luer connector meeting ISO requirements.

Tunneling Needle Configurations

- 5F x 220 mm Tunneling Needle
- 7F x 200 mm Tunneling Needle
- 9F x 220 mm Tunneling Needle

Directions for Use

The clinician should evaluate the appropriateness of the device, including compatibility with the catheter, according to individual patient conditions and previous medical training and experience.

- Administer sufficient local anesthetic to completely anesthetize the intended tunnel track, as well as the insertion and exit site.
- Attach end of catheter fully over the barbed end of tunneling needle per specific catheter manufacturer instructions. **Caution:** Do not bend tunneling needle.
- Make a small incision at the exit site. If the catheter has a cuff, make the incision at the exit site wide enough to accommodate the cuff.
- Make a second small incision at the insertion site.
- Insert the tunnelling needle into the desired site and create a short subcutaneous tunnel. The tunnel should be made with care to prevent damage to surrounding tissue and organs. **Note:** Tunneling needle should only be used for subcutaneous tunneling.
- Lead catheter into the tunnel. Do not pull or tug the catheter tubing. If resistance is encountered, further dissection may facilitate insertion. **Caution:** Do not force tunneling needle against resistance. Forcing may result in tissue/organ damage.
- Remove the catheter from the tunneling needle. Follow specific catheter manufacturer's instructions for removal from the tunnelling needle.

Disposal After Use

- After use, medical products and accessories pose a potential biological hazard. For this reason, the products and their accessories should be handled and disposed of in accordance with recognized medical procedure, and in compliance with applicable institutional policy and local, state, and federal laws and regulations.

Notice

Report any serious incident that has occurred in relation to the device to PFM Medical, Inc.

Warranty

PFM Medical, Inc. 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.