

PROMETRA®

TUNNELER

For use with Intrathecal Catheter



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

Contents

The following components are sterile and non-pyrogenic:

1 – Intrathecal Catheter Tunneler, 45.7 cm (18 in.) Long

Description

The Tunneler is a malleable stainless steel tunneler with a pointed tip to penetrate subcutaneous tissue and a threaded end for attachment to the Intrathecal Catheter, supplied separately.

For Indications, Contraindications, Warnings, Precautions and potential adverse events related to the Programmable Pump, refer to the appropriate Prometra Programmable Pump Physician's Manual.

Indications

The Tunneler is indicated for subcutaneous positioning of the Intrathecal Catheter.

Contraindications

The Tunneler is contraindicated when the presence of infection is known or suspected.

Warnings

- The device is supplied sterile and is non-pyrogenic. The package should be examined carefully prior to opening. Do not use the contents if there is any evidence of damage to the package or package seal that could compromise sterility. Do not resterilize contents of any damaged or opened packages.
- Use sterile technique.
- After use, this product is a potential biohazard. Handle and dispose of in accordance with accepted hospital practice and all applicable laws and regulations.

Precautions

- Carefully read and follow all instructions prior to use. Follow all instructions.
- This device should only be used by qualified medical personnel specifically trained in its use.
- Please consult the Instructions for Use provided with the Intrathecal Catheter and appropriate Prometra Programmable Pump for a complete description of catheter and pump placement.

Potential Adverse Events

- Hematoma formation
- Perforation or laceration of vessels or viscus
- Puncture of skin, thoracic wall or abdominal wall

Equipment

- Tunneler
- Programmable Pump, supplied separately
- Intrathecal Catheter Kit, supplied separately

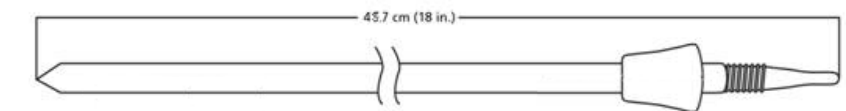
Instructions

1. Push the intrathecal catheter onto the threaded tip of the tunneler until it stops, then turn catheter clockwise until it is fully threaded onto the threaded tunneler tip.



2. Insert the pointed tunneler tip at the paravertebral incision site and advance the pointed tunneler tip to the pump pocket site. If necessary, use a second tunneling procedure with a temporary exit in the plane of the midaxillary line.

Warning: Do not puncture the skin, thoracic or abdominal wall with the tip of the tunneler.



Tunneler

3. Please refer to the Instructions for Use provided with the Intrathecal Catheter and appropriate Prometra Programmable Pump for further instructions.

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US and Foreign patents issued and pending. Please consult www.flowonix.com for the most up-to-date information.

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