

PROMETRA[®]

CATHETER ACCESS KIT (REF 11824)

For use with Prometra[®] Programmable Infusion Systems



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

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Contents

The following components are sterile and non-pyrogenic:

- 2 - Adhesive Bandages, Round
- 1 - CSR Wrap
- 1 - Fenestrated Drape
- 1 - Extension Tubing, 20 cm (8 in.), with Clamp
- 1 - Filter, 0.22 micron
- 4 - Gauze Pads, 10 cm x 10 cm (4 in. x 4 in.)
- 1 - Needle, Catheter Access, 0.9 mm (20G) x 45 mm (1.75 in.)
- 1 - Syringe, 10 mL, Luer Lock
- 1 - Catheter Access Template

Description

The Catheter Access Port (CAP) Kit contains a catheter access needle and accessories to access the catheter access port of the Programmable Pump.

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 CAP Kit is indicated for use in patients receiving a Prometra Programmable Infusion System. It is intended for use in accessing the Intrathecal Catheter and the catheter access port of the Programmable Pump.

Contraindications

This Catheter Access Kit is contraindicated when the presence of infection is known or suspected.

Warnings

- Prior to infusion of approved drug into the pump system, medical personnel should be familiar with and observe all warnings, cautions, contraindications, and instructions as specified by the manufacturer of the infusate.
- The Catheter Access Kit is supplied sterile and nonpyrogenic. 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.
- 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.
- Pain on injection that was not noted during previous injections may be an early sign of infection.
- Use of this device should only be conducted by qualified medical personnel specifically trained in its use. Use of this device by non-qualified or untrained personnel could lead to serious consequences involving under- or over-medication. In the event of over-medication, refer to the approved drug labeling for appropriate treatment.
- Use only the included 20G catheter access needle to access the catheter access port.

Potential Adverse Events

The use of implanted pumps provides an important means of treating patients. However, the potential exists for serious complications. Please refer to the appropriate Prometra Programmable Pump Instructions for Use for a complete list.

Equipment

- Catheter Access Kit

The following items may be needed and are not provided:

- Sterile preservative-free 0.9% saline
- Infusate

Instructions

Aspirating the Intrathecal Catheter

Drug solution remaining in the Intrathecal Catheter, Catheter Access chamber and Pump T-Stem can be removed via aspiration. Also, catheter patency can be checked by aspirating and looking for cerebrospinal fluid in the aspirate.

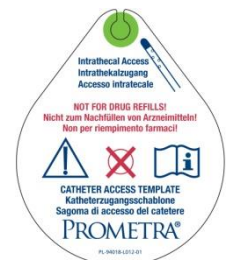
To aspirate the Catheter:

1. **USE STERILE TECHNIQUE.** Always inspect and aseptically prepare the site according to standard practice.
2. Locate the catheter access port with palpation and by placing the Catheter Access Template over the pump and aligning the edges of the template with the edges of the pump. Use a sterile pen to mark the site for needle entry. Set template aside.

Warning: Always use the Prometra Catheter Access Template to ensure proper access to the catheter access port. Using the incorrect template may result in drug overdose or infusate delivery into the pump pocket. If you are unsure of the proper access, use image guidance to verify proper needle placement.

3. Fill a 10mL or larger syringe with 10 mL of sterile preservative-free 0.9% saline.

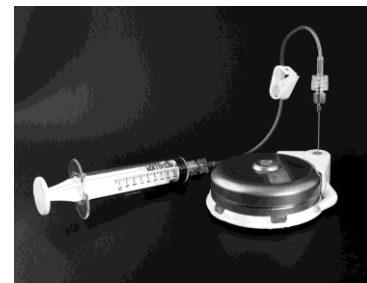
Warning: Always use a syringe that is 10 mL or larger. Small syringes can generate very high pressures that may damage the intrathecal catheter or catheter connections.



Catheter Access Template

- Attach the syringe to the extension tubing. Attach the needle to the extension tubing to create the catheter access aspiration setup (right). Prime setup with saline to remove air.
- Insert the needle through the center of the catheter access port, perpendicular to the skin and the pump. Advance the needle until the needle tip resides completely inside the catheter access chamber.

Caution: Do not force the needle. Excessive force on the needle may damage the needle tip. Do not rock the needle sideways as this may damage the septum or cause infusate to leak into the pump pocket.



Catheter Access Aspiration Setup

- Refer to the patient's chart or implant card for implanted catheter volume. Then, add 0.259 mL to the implanted catheter volume (mL) to account for the fluid in the Catheter Access Chamber plus the Pump T-Stem. This gives you the total volume of aspirate.

Alternately, refer to the Calculations Guide.

Aspirate Volume = Implanted Catheter Volume (mL) + 0.259 mL

- Open the extension tubing clamp and aspirate the total calculated volume to ensure removal of drug from the intrathecal catheter and the catheter access chamber.
- Close the clamp, remove the syringe, and discard the syringe with aspirate.

Warning: After aspiration, the drug metering mechanism contains approximately 0.137 mL of drug at the concentration previously in the reservoir. This volume of drug will be administered to the patient at the drug flow rate programmed into the pump. Refer to the Calculations Guide for more information.

Performing Manual Bolus Injection or Flushing of Catheter

Drug solution remaining in the Intrathecal Catheter, Catheter Access chamber and T-Stem can be bolused or flushed.

To perform a manual bolus injection, or catheter flushing:

- USE STERILE TECHNIQUE.** Always inspect and aseptically prepare the site according to standard practice.
- Fill a syringe with the desired infusate or contrast solution approved for intrathecal use.

Warning: Always use a syringe that is 10mL or larger. Small syringes can generate very high pressures that may damage the intrathecal catheter or catheter connections.

- Attach the 0.22 micron filter to the refill syringe containing the prescribed infusate. Prime the filter with infusate to remove air.
- Attach the filter-syringe assembly to the extension tubing. Attach extension tubing to the needle to create the bolus setup. Verify that there is no air in the system.
- Locate the catheter access port with palpation and by placing the Catheter Access Template over the pump and aligning the edges of the template with the edges of the pump. Use a sterile pen to mark the site for needle entry. Set template aside.

Warning: Always use the Prometra Catheter Access Template to ensure proper access to the catheter access septum. Using the incorrect template may result in



Catheter Access Template

drug overdose or infusate delivery into the pump pocket. If you are unsure of the proper access, use image guidance to verify proper needle placement.

6. Insert the needle through the center of the catheter access septum, perpendicular to the skin and the pump. Advance the needle until the needle tip resides completely inside the catheter access chamber.

Caution: Do not force the needle. Excessive force on the needle may damage the needle tip. Do not rock the needle sideways as this may damage the septum or cause infusate to leak into the pump pocket.

7. Unclamp the extension tubing. Keep downward pressure on the needle and begin slowly infusing the solution into the catheter access chamber at a rate not to exceed 1 mL per 6 seconds.

Warning: If this procedure is performed without prior aspiration, the patient will receive a bolus of medication. The physician needs to assess the risk associated with the administration of the bolus of medication. Refer to the Calculations Guide for more information.

Catheter Access Bolus Setup

8. When the procedure is completed, clamp the extension tubing, remove and discard the syringe. Attach the syringe with the saline solution and inject 3 mL of saline into the catheter access chamber.
9. If you desire to re-prime the intrathecal catheter, attach syringe with desired infusate to the tubing. Unclamp the tubing and inject the desired amount of infusate to prime the catheter.
10. Remove and discard the tubing, syringe and needle.

Calculations

Please refer to the appropriate supplementary **Calculations Guide**.

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

Manufactured by:

Flowonix Medical, Inc.

500 International Drive, Suite 200

Mount Olive, NJ 07828 USA

T 973.426.9229

F 973.426.0035

www.flowonix.com



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