PROMETRA®

INTRATHECAL CATHETER (REF 91823)

For use with Prometra® Programmable Infusion Systems

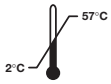
FLOWONIX

Explanation of Symbols

Refer to the package and product labeling to see which symbols apply to this product.

	Catalog number
	Serial number
	Batch code
	Use by date
	Date of manufacture
	Sterilized using ethylene oxide
	Sterilized using steam or dry heat
	Do not re-use
	Caution, consult accompanying documents
	Do not use if package is damaged
	Authorized Representative in the European Community
	Fragile, handle with care

Explanation of Symbols

	Temperature limitations
	Keep away from sunlight
	MR Conditional
Nonpyrogenic	Non-pyrogenic
Latex-Free	No patient or fluid contact with latex components
PVC-Free	No patient or fluid contact with polyvinyl chloride components
DEHP-Free	No patient or fluid contact with di(2-ethylhexyl)phthalate components
Rx Only	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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Introduction

The Flowonix Programmable Pump is designed to provide controlled delivery of drugs to the intrathecal space via the separately supplied Intrathecal Catheter.

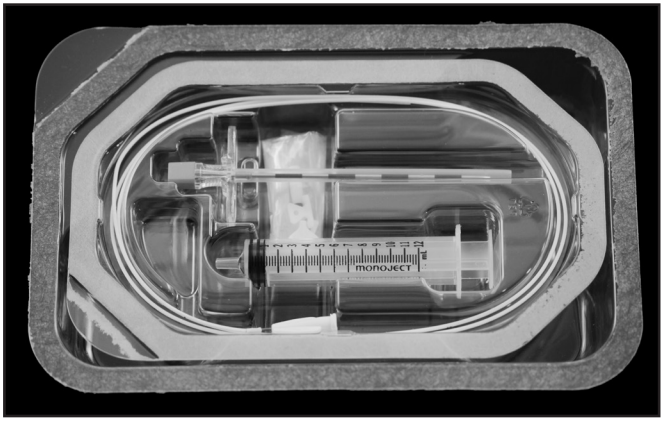
Contents

1 - Catheter, Radiopaque, 1.3 mm OD (4F) x 110 cm x 0.6 mm ID
1 - Catheter Lock
1 - Hub, Flushing, 0.6 mm (23G) x 13 mm (0.5 in.)
1 - Needle, Tuohy, 1.8 mm (15G) x 89 mm (3.5 in.)
1 - Stylet, Hydrophilic, Flush-Through, 0.43 mm (0.017 in.) x 109 cm
1 - Syringe, 12 mL, Luer Slip
2 - Wings, Suture, 90°, Angled with:
    2 – Anchors, Angled
1 Wing, Suture, Slit with:
    1 – Anchor, Straight
1 – Sheet of Catheter Stickers
1 – Device Tracking Form
4 – Temporary Patient ID Cards
2 – Calculations Guide

Description

Catheter Description

The Intrathecal Catheter is a single-piece, radiopaque, silicone catheter with pre-inserted hydrophilic stiffening stylet that is used to assist in placing the catheter. The catheter has a tungsten-filled tip to enhance radiopacity and side-holes at the tip for dispersion of the infusate into the intrathecal space. The catheter also features depth markings indicated in centimeters starting 5 cm from the distal end of the catheter, extending to a distance 30 cm from its distal end. The intrathecal catheter is provided with accessories to assist in its placement and securement at implant and a radiopaque catheter lock to secure the catheter onto the stem of the Programmable Pump. The intrathecal catheter and package contents are sterilized using ethylene oxide.



Indications

The Intrathecal Catheter is indicated for use in patients receiving a Flowonix Programmable Pump. The Intrathecal Catheter is intended to be attached to the Programmable Pump to provide access to the intrathecal space.

The Prometra Programmable Infusion System is indicated for use in the treatment of chronic intractable pain and the management of severe spasticity. In the treatment of chronic intractable pain, it is intended for chronic, intrathecal infusion of preservative-free morphine sulfate solution. For the management of severe spasticity, it is indicated for chronic intrathecal infusion of baclofen injection sterile solution. Sterile preservative-free 0.9% saline solution may be used when therapy is interrupted to maintain catheter patency. When required, infusion of radiopaque contrast media labeled for intrathecal use may be used.

The labeling for the drug will govern the indications, contraindications, dose rates and warnings related to the use of the drug.

Contraindications

Implantation of this device is contraindicated when:

- The presence of infection is known or suspected.
- The patient's body size or anatomy is insufficient to accommodate the size of the implanted pump or catheter.
- The pump cannot be implanted 2.5 cm (1 in.) or less from the surface of the skin. Deeper implants could interfere with septum access or telemetry.
- The patient is known or is suspected to be allergic to materials contained in the catheter: silicone rubber, acetal resin, or tungsten.
- The patient is known or is suspected to be allergic to materials contained in the pump: silicone rubber, polyphenylsulfone, buna-n rubber, MP35N metal (multiphase quaternary nimonic alloy primarily composed of chromium, cobalt, molybdenum and nickel), titanium, polyvinylidene fluoride, stainless steel, epoxy resin, acetal resin or tungsten.
- The patient has exhibited a prior intolerance to implanted devices.
- The patient has a spinal column anatomy that would obstruct cerebrospinal fluid flow or that would prevent intraspinal drug administration.
- The patient has emotional, psychiatric or substance abuse problems that are deemed to prohibit intrathecal drug administration.
- The patient is under 18 years old. Safety and effectiveness for use in pediatric patients under 18 years old has not been investigated or established
- The patient will require magnetic therapies.
- The patient will require hyperbaric treatments.
- The patient has an occupation where he/she would be exposed to high current industrial equipment, powerful magnets or transmitting towers, such as, electricians, electrical engineers or MRI technicians.

Refer to the appropriate Programmable Pump IFU for MRI conditions for safe scanning or contact Flowonix Medical for assistance.

Contraindications relating to preservative-free morphine sulfate or baclofen sterile injection must be observed and followed per the approved drug labeling.

Warnings

General

- Prior to infusion of any substance into the catheter, medical personnel should be familiar with and observe all warnings, cautions, contraindications, and instructions as specified by the manufacturer of the infused substance.
- Only use this device with drugs listed under "Indications." Use of non-indicated drugs, such as drug cocktails, pharmacy-compounded drugs, or morphine with preservatives with this product may cause pump failure.
- Always select and program drug dosages consistent with the drug labeling to prevent improper drug administration.
- In the event of over-medication, refer to the approved drug labeling for appropriate treatment.
- Clinicians implanting, programming, accessing, or maintaining implanted programmable pumps must comply with the instructions for use. Technical errors may result in a return of underlying symptoms, drug withdrawal symptoms, or clinically significant or fatal overdose.
- The effects of implanting this device in patients with medical devices, other than neurostimulators, are unknown.
- Pain on injection that was not noted during previous injections may be an early sign of infection.
- The Intrathecal Catheter and Prometra Programmable Pump components are supplied sterile and non-pyrogenic. The packages 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 device is a biohazard. Handle and dispose of in accordance with accepted hospital practice and all applicable laws and regulations.
- Do not incinerate or cremate the pump.
- Do not expose the pump to temperatures above 57˚C (122˚F) or below 2˚C (41˚F)

Device Compatibility

- **Alcohol.** Do not use alcohol on any part of the pump or catheter system. Alcohol is neurotoxic.
- **Contrast media.** Do not inject contrast media into the refill reservoir since this may damage the pump or impair pump function.

Refer to the appropriate Programmable Pump IFU for MRI conditions for safe scanning or contact Flowonix Medical for assistance.

Precautions

General

- Carefully read all instructions prior to use. Follow all instructions.
- Certain equipment may cause electrical noise, which may interfere with programming. If suspected, move the patient from the suspected source of interference to facilitate the programming procedure.
- Do not use accessories that are not referenced in these instructions for use. Only use devices and accessories that are referenced for use with the Prometra® Programmable Pump in these instructions.

Implant

- Implantation of this device and subsequent use, reprogramming, and refill should only be conducted by qualified medical personnel specifically trained for surgical implantation, use, and maintenance of the device. 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.
- The pump and catheter system should be implanted carefully to avoid any sharp or acute angles, which could compromise the patency of the catheter lumen.
- Over-pressurization can damage the catheter. Small syringes can generate very high pressures and may damage the catheter or catheter connection. Do not use a syringe smaller than 10 mL when accessing the catheter access chamber.
- If therapy is discontinued for an extended period, the pump should be emptied of the drug and filled with a preservative-free sterile saline solution to maintain catheter patency.

Adverse Events

The use of implanted pumps provides an important means of treating patients with intractable pain or severe spasticity. However, the potential exists for serious complications including the following:

- Bleeding
- Body rejection phenomena
- Catheter breakage
- Catheter disconnection
- Catheter fibrosis
- Catheter migration
- Catheter occlusion or kinking
- Catheter or pump erosion through the skin
- Cerebrospinal fluid (CSF) leak leading to spinal headache, CSF subcutaneous collection, or rare Central Nervous System (CNS) pressure-related problems
- Cessation of therapy due to pump battery depletion or pump failure
- Epidural abscess
- Fever
- Granulomas
- Implant site cellulitis
- Inability to program the device due to Prometra® Pump Programmer failure or loss of telemetry
- Infection of intrathecal space, including meningitis, pocket, or subcutaneous catheter tract
- Inflammation, necrosis, or scarring of skin over implant area
- Malpositioning of catheter
- Neurological impairment, including paralysis.
- Pain on injection
- Pocket seroma, hematoma, or infection

Adverse Events

- Programming or refill errors resulting in under-dosing or over-dosing
- Pump flipped over
- Risks normally associated with use of the prescribed medication for delivery, local and general anesthesia, surgery, and post-operative recovery
- Spinal cord or nerve injury
- Spinal cord pressure leading to paralysis
- Subcutaneous catheter tract infection.

In rare instances, the development of an inflammatory mass at the tip of the implanted catheter may occur, which can result in serious neurological impairment. Patients should be monitored carefully at each visit for any new neurological signs or symptoms, including:

- progressive change in the character, quality, or intensity of pain or spasticity
- an increase in the level and degree of pain or spasticity despite dose escalation
- sensory changes (i.e., numbness, tingling, burning)
- hyperesthesia and/or hyperalgesa

Presentations that require immediate diagnosis include:

- bowel and/or bladder dysfunction
- myelopathy
- conus syndrome
- gait disturbances or difficulty ambulating
- paraparesis or paralysis

If the presence of an inflammatory mass is suspected, recommended evaluation should include a review of the patient history and neurological evaluation, radiological diagnostic procedures (such as an MRI with contrast) and appropriate clinical consultation.

Refer to the appropriate Programmable Pump IFU for MRI conditions for safe scanning or contact Flowonix Medical for assistance.

Possible Risks Associated with baclofen Intrathecal Infusion

Prevention of abrupt discontinuation of intrathecal baclofen requires careful attention to programming and monitoring of the infusion. Early symptoms of under dosing include: return to baseline spasticity, pruritis, hypotension and paresthesias.

Abrupt withdrawal of baclofen may be life-threatening. Symptoms include: high fever, altered mental status, exaggerated rebound spasticity and muscle rigidity. Withdrawal left untreated may result in: rhabdomyolysis, multiple organ failure and death.

Overdosing signs and symptoms include: drowsiness, lightheadedness, dizziness, somnolence, respiratory depression, seizures, rostral progression of hypotonia, loss of consciousness progressing to coma.

Equipment

- Prometra Programmable Pump
- Intrathecal Catheter
- Tunneler
- Prometra Pump Programmer (Not Sterile)

The following items may be needed and are not provided:

- Sterile Programmer Sleeve
- Sterile preservative-free 0.9% saline
- Drug solution (infusate) for refill, not to exceed 20 mL

Implantation Instructions

The implanting physician is responsible for choosing the surgical procedure, techniques, and the intended therapy for the patient. These instructions are provided as a guide.

Implantation of the Programmable Pump

1. Implant the Pump as per the appropriate Programmable Pump IFU.

Implantation of the Intrathecal Catheter

1. **USE STERILE TECHNIQUE.** Always inspect and aseptically prepare the site according to standard practice.
2. Position the patient and mark the pump implant location and catheter entry location for tunneling.
3. Access the intrathecal space according to standard practice using the 15G Tuohy needle. Proper entry into the intrathecal space is confirmed by observation of clear cerebrospinal fluid (CSF) forming at the hub of the Tuohy needle.

   Caution: Only use smooth-edged atraumatic instruments to handle the catheter to avoid mechanical damage. Do not use the catheter if there is any evidence of mechanical damage or leakage.

4. Flush catheter with saline through flush-through hub of stylet. This activates the hydrophilic stylet coating to increase lubricity.

   Warning: Do not flush stylet with IPA or drugs. Flushing with solutions other than saline may result in difficulty withdrawing the stylet.

5. Immediately withdraw the needle stylet from the Tuohy needle.

   Caution: Always flush saline through the catheter hub immediately prior to withdrawing the stylet to facilitate stylet withdrawal.

   Warning: Do not allow unnecessary CSF backflow during the implant procedure. Replace the needle stylet if catheter insertion is delayed.

6. Insert the intrathecal catheter with the preloaded stylet in place through the needle and into the desired location within the intrathecal space. Confirm proper placement radiographically.
7. **Warning: Always carefully advance the catheter with stylet to avoid perforation of the spinal cord.**
8. **Warning: Always position catheter with at least 3 vertebral spaces in the intrathecal space. Failure to advance the catheter sufficiently may result in subcutaneous migration of the catheter or retrograde flow of infusate.**
9. Carefully withdraw the Tuohy needle while maintaining catheter position. Disconnect the stylet from the catheter. Firmly hold the catheter near the insertion site and slowly remove the stylet with constant tension.
10. **Warning: Do not withdraw the catheter back through the Tuohy needle. Doing so may damage the catheter or result in part of the catheter being dislodged in the intrathecal space. If necessary, withdraw the needle and catheter from the tissue as a unit before attempting to reposition the catheter.**
11. If flushing the catheter is necessary after the stylet has been removed, use the flushing hub included in the Catheter Kit. Do not reinsert stylet.

Implantation Instructions

Implantation of the Intrathecal Catheter

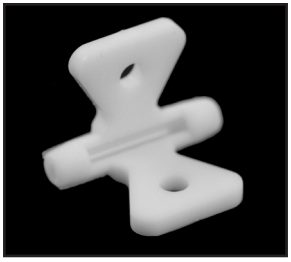
12. Select the angled or the slit suture wings from the tray and position over the catheter.

    Caution: Always position the suture wings over the catheter carefully to avoid mechanical damage to the suture wings or the catheter.

13. Secure the catheter in place.

    Caution: Always make sure the catheter is straight as it comes out of the spinal entry location to avoid catheter kinking.

    13.1. For angled suture wings, fold the wings together with the slit on the inside and suture the wings to the spinous ligaments.



    13.2. **Warning: Always fold the angled suture wings together, with the slit on the inside, to assure proper tension on the catheter and minimize catheter migration.**

    13.3. For the slit suture wing, keep the suture wing in a flat position while suturing to the spinous ligaments. Place sutures around the tubular ends of the suture wing, making sure the sutures do not directly contact the catheter.

    13.4. **Warning: Always ensure the flat suture wings remain in a flat position when being sutured to minimize catheter migration.**

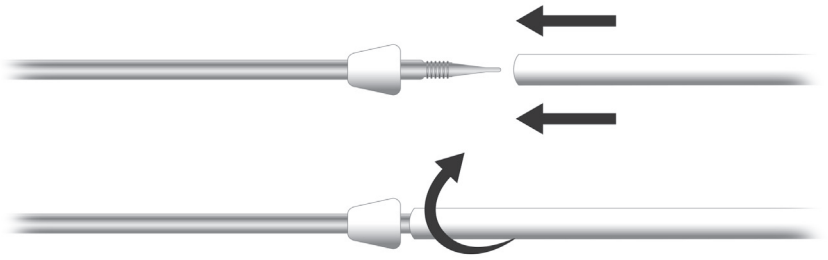
    Warning: Always place sutures around tubular ends of the flat suture wings to minimize catheter migration.

    Caution: Do not let sutures come in direct contact with the catheter. Sutures in direct contact with the catheter may result in catheter occlusion or damage.

Implantation Instructions

Implantation of the Intrathecal Catheter

14. Create a subcutaneous tunnel using the Tunneler.
    14.1. Push the catheter onto the tunneler until it stops, then turn catheter clockwise until it is fully threaded onto the tunneler.



    14.2. Insert the tunneler at the paravertebral incision site and advance the 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.

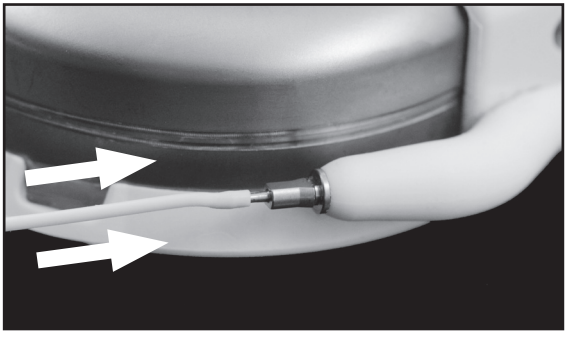
    Warning: Do not puncture the skin or thoracic wall with the tip of the tunneler.

    14.3. Trim the catheter to length at a 90˚ angle allowing sufficient slack for body movement, pump connection, and an additional 2-3 cm in case a pump reconnection is required. Always trim at least 5 cm from the proximal end of the catheter. Assure that the cut is straight and no catheter fragments are produced. Save the trimmed portion of the catheter – the measurement of this piece will be used to calculate the catheter implant volume.

    Caution: Always trim excess catheter length. Failure to trim excess length may result in catheter occlusion or kinking.

    Warning: Always save trimmed portion of catheter to measure length and calculate implanted catheter volume. This calculation is required to prevent under- or over-medication.

15. Slide catheter lock on to catheter with larger end towards the pump. Align pump stem with catheter lumen. Advance catheter over barb on pump stem to midway point.

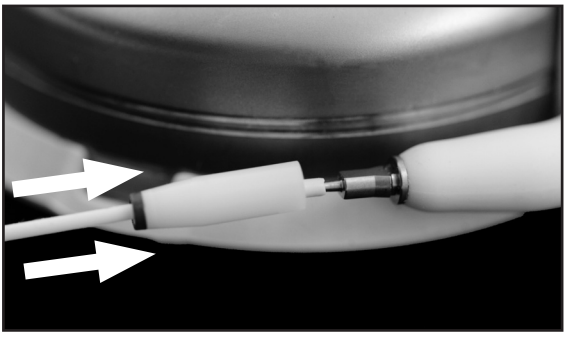


Implantation Instructions

Implantation of the Intrathecal Catheter

15.1. **Warning: Prior to advancing the catheter lock, ensure that the catheter is properly positioned on the pump stem. The catheter must be straight with no sign of kinking prior to advancing the catheter lock. A slight pull on the catheter is sufficient to straighten it. Advancing the catheter lock over a kinked catheter may damage the catheter.**

16. Advance the catheter lock until it clicks into place, ensuring that the radiopaque band is distal to the pump.



17. Once the catheter and lock are connected, if disconnection and reconnection are required, trim 2-3 cm of the catheter end to ensure a secure connection.

    Caution: Always cut the catheter as close to the pump stem as possible to avoid excessive stretching. Excessive stretching may damage the catheter.

18. Place the pump in the subcutaneous pocket away from the incision line about 2.5 cm (1 in.) beneath the skin surface. The pump should be positioned so that the Catheter Access septum is medial. This allows the catheter a direct line to the spine and keeps this area away from the ribs.
19. Secure to the underlying fascia using one non-absorbable, monofilament suture per pump suture hole. This will reduce the risk of pump migration and the possibility of the pump rotating or flipping over.
20. Verify that the catheter is not kinked or constrained by the pump sutures.
21. After suturing the pump in the pocket, flush the wound with an appropriate antibiotic solution.
22. Close the incision site so that the pump does not lie beneath the incision.
23. Flush the paravertebral site with an appropriate antibiotic solution.
24. Close the entry site making sure the catheter remains straight.

Implantation Instructions

Implantation of the Intrathecal Catheter

25. Measure and record in the patient's records the length of intrathecal catheter that was trimmed off. This measurement is required to determine the volume of the implanted catheter.
26. Calculate and record the implanted catheter length and volume:

    Implanted Catheter Length (cm) = 110 cm – Trimmed Catheter Length (cm)
    Implanted Catheter Volume (mL) = Implanted Catheter Length (cm) x 0.0026 mL/cm

    Warning: Always measure and record the length of the trimmed portion of the catheter, and calculate and record the implanted catheter length and volume. These calculations are required to prevent under- or over-medication.

Patient Implant Card and Registration

Included with each Prometra Programmable Pump and Catheter Kit package is a Patient Implant Tracking/Registration Form. This pre-addressed form should be completed and returned to Flowonix Medical, Inc. Flowonix Medical will use this information to create a record of the implant in their database. A copy should also be placed in the patient's implant records.

The appropriate patient guide and two patient implant cards are also provided for the patient. The patient implant card contains information pertinent to the implanted Intrathecal Catheter and Programmable Pump. The implant card should be carried by the patient at all times. A second card is provided for placement in their glovebox, to be given to a caregiver, or other easily accessible location.

Catheter Explantation

The Intrathecal Catheter should only be explanted in accordance with the hospital procedures. Explanted product is to be treated as a biohazard.

Calculations

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

IMPLANTABLES WARRANTY

An issued or revision date for these instructions is included for the user's information. In the event two years have elapsed between this date and product use, the user should contact Flowonix Medical, Inc. to see if additional product information is available.

Flowonix Medical, Inc. ("Flowonix") warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase, and liability under this limited product warranty will be limited to repairing or replacing the defective product, at Flowonix's sole discretion, or refunding the net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

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

Rx Only

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