PROMETRA®

INTRATHECAL CATHETER (REF 11823)

For use with Prometra® Programmable Infusion Systems

MR Conditional

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

Table of Contents

Refer to the Prometra and Prometra II Programmable Pump MRI Scan Instructions Guide (PL-21604) for important MRI procedures, warnings and related information.

Refer to the indications, drug stability, and emergency procedures manual (PL-39701) for indications and related information.

Introduction

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

Note: The use of the terms “medication” and “drug” throughout this document refer to the use of Infumorph or baclofen injection (intrathecal).

Contents

The following components are sterile and non-pyrogenic:

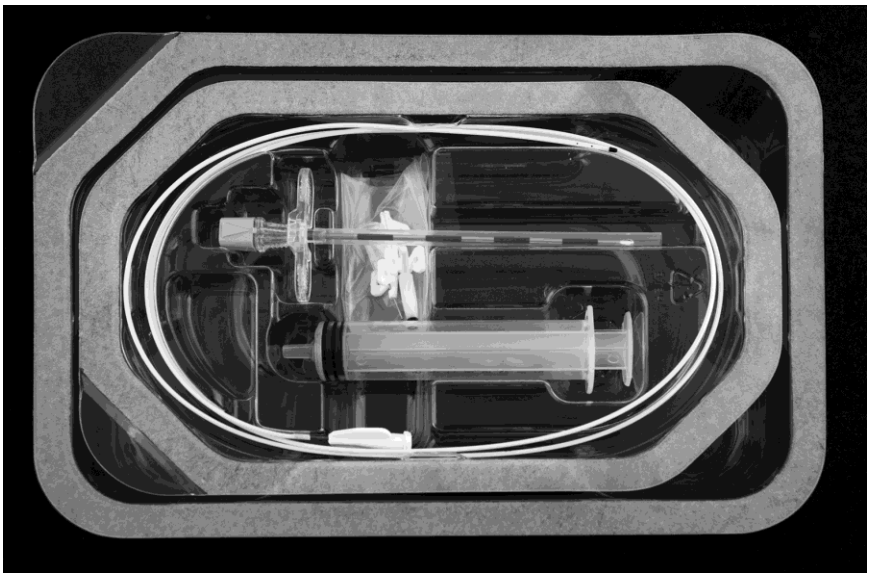
1 - Catheter, Radiopaque, 1.3 mm OD (4F) x 110 cm x 0.6 mm ID
1 - Catheter Lock
1 - Hub, Flushing, 0.6 mm (23G) x 13 mm (0.5 in.)
1 - Needle, Tuohy, 1.8 mm (15G) x 89 mm (3.5 in.)
1 - Stylet, Hydrophilic, Flush-Through, 0.43 mm (0.017 in.) x 109 cm
1 - Syringe, 12 mL, Luer Slip
2 - Wings, Suture, 90°,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

Non-sterile components:

1 – Patient and Physician Information Packet:
  1 – Instructions for Use
  2 – Calculations Guides
  4 – Temporary Patient Implant Cards
  1 – Sheet of Device ID Stickers
  1 – Patient Device Tracking Form
  1 – Warranty Card

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 fixation at implant and a radiopaque catheter lock to connect the catheter to the Programmable Pump.



The Patient Information packet contains a total of four patient implant cards. The appropriate two implant cards are to be completed and given to the patient along with the appropriate patient guide. Additionally, a federally-mandated patient device tracking form is included.

Indications

The Prometra® Programmable Infusion Pump System is indicated for intrathecal infusion of drug therapy, including: Infumorph ® (preservative free morphine sulfate sterile solution), preservative-free sterile 0.9% saline solution (Sodium Chloride Injection, USP), and baclofen (baclofen injection, intrathecal, 500-2000 mcg/mL). The pump is indicated for use in adult populations of 22 years and older.

The approved drug labeling governs the indications, contraindications, warnings and precautions related to the use of the drug.

Drug Information

Refer to the drug labeling for a complete list of indications, contraindications, warnings, precautions, dosage administration information and screening procedures

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 elastomers, barium sulfate, tungsten, polyacetal resin, ink, stainless steel, hydroglide hydro gel coating, or plastic needle hubs (polypropylene and acrylic based).
- The patient is known or is suspected to be allergic to materials contained in the pump: titanium, silicone elastomers, polyphenylsulfone, silicone adhesive, polyvinylidene fluoride, MP35N metal (nickel-cobalt-chromium-molybdenum alloy), or stainless steel (AL29-4, 316L).
- 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.
- Contraindications relating to Infumorph or baclofen injection (intrathecal) must be observed and followed per the approved drug labeling.

Warnings

General

WARNING: USE OF UNAPPROVED DRUGS (e.g., DRUG COCKTAILS, PHARMACY-COMPOUNDED DRUGS, MORPHINE WITH PRESERVATIVES, ETC.) WITH THE PUMP COULD RESULT IN PUMP FAILURE AND/OR SERIOUS ADVERSE EVENTS SUCH AS SEVERE UNDERDOSE, OVERDOSE OR DEATH.

WARNING: FAILURE TO EMPTY THE PUMP PRIOR TO EXPOSURE TO MRI ENVIRONMENT COULD RESULT IN DRUG OVERDOSE THAT COULD LEAD TO SERIOUS PATIENT INJURY OR DEATH. THE PUMP MAY NEED TO HAVE AS MUCH AS 20ML OR 40ML OF DRUG REMOVED DEPENDING ON THE PUMP TYPE AND MODEL NUMBER.

- 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 drug manufacturer.
- Patients should not undergo hyperbaric therapy since exposure could result in drug underdose.
- Physicians must be familiar with the drug stability information in the product insert and must understand the dose relationship to drug concentration and pump flow rate before prescribing pump infusion.
- Always select and program dosages consistent with the drug labeling to prevent improper drug administration.
- Inform patients of the signs and symptoms of drug under- or overdose, appropriate drug warnings and precautions regarding drug interactions, potential side effects, and signs and symptoms that require medical attention.
- If suspected that all or part of the drug was injected into the pocket during the refill procedure, monitor the patient closely for signs and symptoms of overdose.
- 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 Intrathecal Catheter and 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 (134.6˚F) or below 2˚C (35.6˚F).
- 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.

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. Examples of equipment that may cause interference include cathode ray tube (CRT) monitors and large electric motors.
- Do not use accessories that are not referenced in these instructions for use. Only use devices and accessories that are referenced for use with Prometra® Programmable Infusion Systems in these instructions.
- Safety and effectiveness for use in pediatric patients under 22 years old has not been investigated or established.
- The effects of implanting this device in patients with other implanted medical devices, other than neurostimulators, are unknown.
- Pain on injection that was not noted during previous injections may be an early sign of infection.

Implant

- Implantation of this device and subsequent use 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-dosage, refer to the approved drug labeling for appropriate treatment. The catheter system should be implanted carefully to avoid any sharp or acute angles, which could compromise the patency of the catheter lumen.
- Monitor patients after pump and/or catheter implant or replacement for signs of underdose/overdose.
- 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 0.9% sterile saline solution and programmed to a low infusion rate to maintain catheter patency.

Device Compatibility

- **Alcohol.** Do not use alcohol on any part of the pump or catheter system. Alcohol is neurotoxic.
- **External devices.** Do not connect any external devices or pumps to the Prometra Pump. Pressures generated by an external pump could damage the implanted pump/catheter system and result in serious patient injury or death.

Potential Adverse Events

The potential exists for serious complications including the following:

Possible Risks Associated with Programmable Implantable Pump:

- Adverse reaction to pump materials
- Battery depletion
- Bleeding
- Body rejection phenomena
- Defective pump (e.g. propellant chamber leakage, pump rupture)
- Inability to locate septum
- Inability to program pump due to programmer failure or loss of telemetry
- Inflammation, necrosis, or scarring of skin over implant area
- Potential withdrawal and decreased efficacy due to end of device service life
- Programming errors, resulting in over or under dosing
- Pump flipping or twisting
- Pump implanted too deep, resulting in difficulty accessing or inability to access port
- Pump migration
- Pump pocket pain/soreness
- Pump pocket seroma/hematoma, with or without infection
- Pump rotation
- Pump site skin erosion
- Pump stoppage
- Refill errors, including injection into pump pocket, injection into wrong port, incorrect volume, incorrect concentration, difficulty accessing pump port
- Septum dislodgement
- Septum leakage
- Slow, erratic or fast flow
- Software error

Possible Risks Associated with Intrathecal Catheter:

- Catheter disconnection
- Catheter kinking
- Catheter fracture
- Catheter migration (unrelated to surgical complication)
- Cerebrospinal fluid (CSF) leak
- Disconnection
- Erosion
- Fibrosis
- Infection in intrathecal space, including meningitis
- Inflammatory mass formation (e.g., granuloma)
- Malpositioning
- Nerve damage
- Pain on injection

- Poor radiopacity
- Post dural puncture headache
- Reaction to catheter materials
- Reversible or irreversible partial or complete occlusions
- Spinal cord pressure leading to paralysis
- Spinal cord trauma, perforation, laceration
- Subcutaneous catheter tract infection
- Subcutaneous tunnel infection
- Tears/breaks

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
- an increase in the level and degree of pain despite dose escalation
- sensory changes (i.e., numbness, tingling, burning)
- hyperesthesia and/or hyperalgesia

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 a CT scan with contrast) and appropriate clinical consultation.

Inflammatory mass has been associated with a wide range of doses and concentrations of opioids. No dose or concentration of Infumorph can be considered completely free of risk from inflammatory mass. The risk of inflammatory mass occurrence appears to be cumulative over time and increases with higher concentrations and doses of opioids.

Possible Risks Associated with Infumorph injection (intrathecal):

Contraindications:

- Significant respiratory depression
- Acute or severe bronchial asthma in an unmonitored setting in absence of resuscitative equipment
- Concurrent use of monoamine oxidase inhibitors (MAOIs) or use of MAOIs within the last 14 days
- Known or suspected gastrointestinal obstruction, including paralytic ileus
- Hypersensitivity or intolerance to morphine

- Contraindications to the use of neuraxial analgesia include: the presence of infection at the injection microinfusion site, concomitant anticoagulant therapy, uncontrolled bleeding diathesis and the presence of any other concomitant therapy or medical condition which would render epidural or intrathecal administration of medication especially hazardous.

Select Warnings and Precautions:

- Morphine sulfate may be habit forming. Overdoses may cause respiratory depression, coma, and death.
- Chronic Neuraxial opioid analgesia is appropriate only when less invasive means of controlling pain have failed and should only be undertaken by those who are experienced in applying this treatment in a setting where its complications can be adequately managed.
- Because of the risk of severe adverse effects, patients must be observed in a fully equipped and staffed environment for at least 24 hours after the initial (single) test dose and, as appropriate, for the first several days after catheter implantation.
- The facility must be equipped to resuscitate patients with severe opiate overdosage, and the personnel must be familiar with the use and limitations of specific narcotic antagonists (naloxone, naltrexone) in such cases.
- Reservoir filling must be performed by fully trained and qualified personnel following directions provided in the Pump Instructions for Use.
- Extreme care must be taken to ensure that the needle is properly in the filling port of the device before attempting to refill the reservoir. Injection of the solution into the tissue around the device or attempting to inject the refill dose into the catheter access port may result in a large, clinically significant, overdosage to the patient.
- A period of observation appropriate to the clinical situation should follow each refill or manipulation of the drug reservoir. Before discharge, the patient and attendant(s) should receive proper home care instructions for the device.
- Risk of Inflammatory Masses: Monitor patients receiving continuous infusion of INFUMORPH via indwelling intrathecal catheter for new signs or symptoms of neurologic impairment.
- Risk of Tolerance and Myoclonic Activity: Monitor patients for unusual acceleration of neuraxial morphine, which may cause myoclonic-like spasm of lower extremities. Detoxification may be required.
- Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients: Monitor closely, particularly during initiation and titration.
- Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid.
- Severe Hypotension: Monitor during dosage initiation and titration. Avoid use of INFUMORPH in patients with circulatory shock.
- Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness: Monitor for sedation and respiratory depression. Avoid use of INFUMORPH in patients with impaired consciousness or coma.

For more information, refer to the prescribing information of the drug.

Possible Risks Associated with baclofen injection (intrathecal):

Contraindications

- Hypersensitivity to baclofen injection (intrathecal)
- Baclofen injection (intrathecal) is not recommended for intravenous, intramuscular, subcutaneous or epidural administration.

Select Warnings and Precautions

- There are no adequate and well controlled studies in pregnant women.
- Nursing mothers should exercise caution, as oral baclofen injection has been shown to pass milk at therapeutic doses.
- Patients suffering from impaired renal function, autonomic dysreflexia, psychotic disorders, schizophrenia, or confusional states should be carefully evaluated.
- It is mandatory that all patients, caregivers, and treating physicians receive adequate information regarding the risks of baclofen injection (intrathecal). Instruction should be given on signs and symptoms of underdose and overdose, procedures to be followed in the event of an underdose or overdose, and proper home care of the pump and insertion site.
- Due to the possibility of life-threatening CNS depression, cardiovascular collapse, and/or respiratory failure, physicians must be adequately trained and educated in chronic intrathecal infusion therapy.
- Patients should be infection-free prior to both a screening trial and a pump implantation. The presence of infection may interfere with an assessment of the patient's response to bolus baclofen injection (intrathecal), increase the risk of surgical complications and complicate dosing.
- Following pump implantation, and for each adjustment of the dosing rate of the pump and/or concentration of baclofen injection (intrathecal), the patient should be monitored closely.

Prevention of abrupt discontinuation of baclofen injection (intrathecal) 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 injection (intrathecal) 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. Should overdose appear likely, the patient should be taken immediately to a hospital for assessment and emptying of pump reservoir.

Baclofen injection (intrathecal) should ordinarily be reduced slowly if the drug is discontinued for any non-emergent reason.

For more information, refer to the prescribing information of the drug.

Equipment

- Programmable Pump
- Intrathecal Catheter
- Tunneler

The following items may be needed and are not provided:

- Sterile preservative-free 0.9% saline
- Drug solution (infusate) for refill, not to exceed 20 mL for pumps with 20 mL reservoir capacities and not to exceed 40 mL for pumps with 40 mL reservoir capacities

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

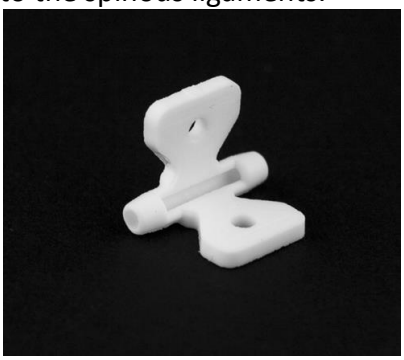
1. **Implant the Pump as per the appropriate Programmable Pump IFU.**

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 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 sterile preservative-free 0.9% 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 sterile preservative-free 0.9% saline may result in difficulty withdrawing the stylet.
5. Immediately withdraw the needle stylet from the Tuohy needle.
   Caution: Always flush sterile preservative-free 0.9% 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.
   Warning: Always carefully advance the catheter with stylet to avoid perforation of the spinal cord.

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.

7. 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.
   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.
8. 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.
9. 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.
10. 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.
11. For angled suture wings, fold the wings together with the slit on the inside and suture the wings to the spinous ligaments.



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.

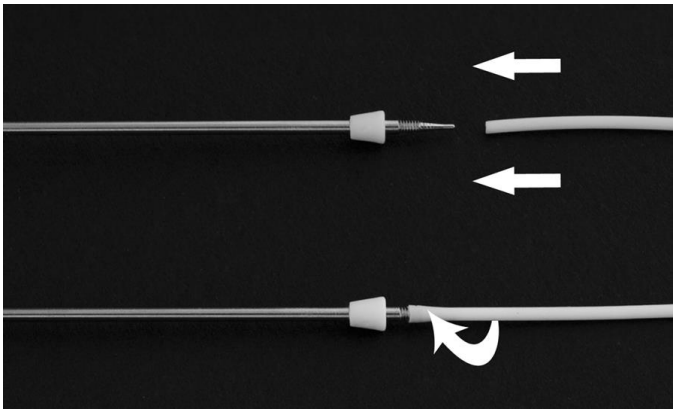
12. For the slit suture wing, keep the suture wing in a flat position while suturing to the spinous ligaments. Place sutures around the tubular ends of the suture wing, making sure the sutures do not directly contact the catheter.

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.

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

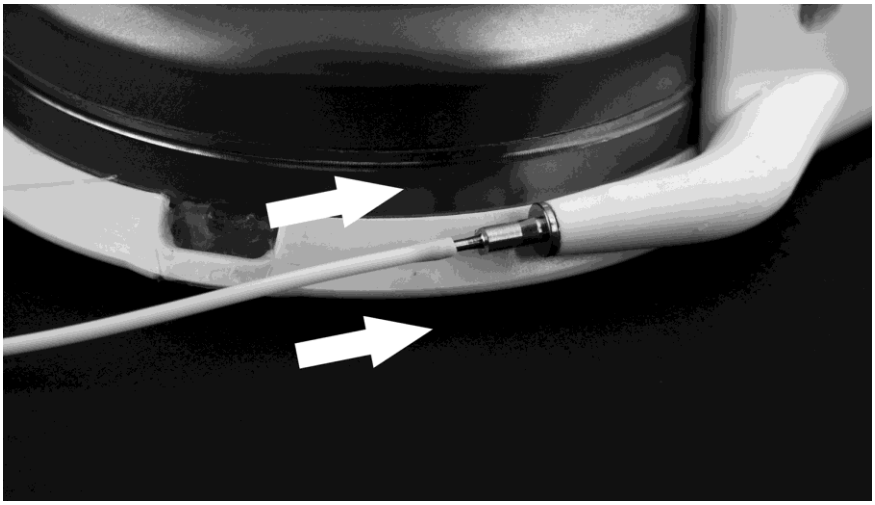


15. Insert the tunneler at the paravertebral incision site and advance the tunneler tip to the pump pocket site. If necessary, use a second tunneling procedure with a temporary exit in the plane of the midaxillary line.

    Warning: Do not puncture the skin or thoracic wall with the tip of the tunneler.
16. 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.

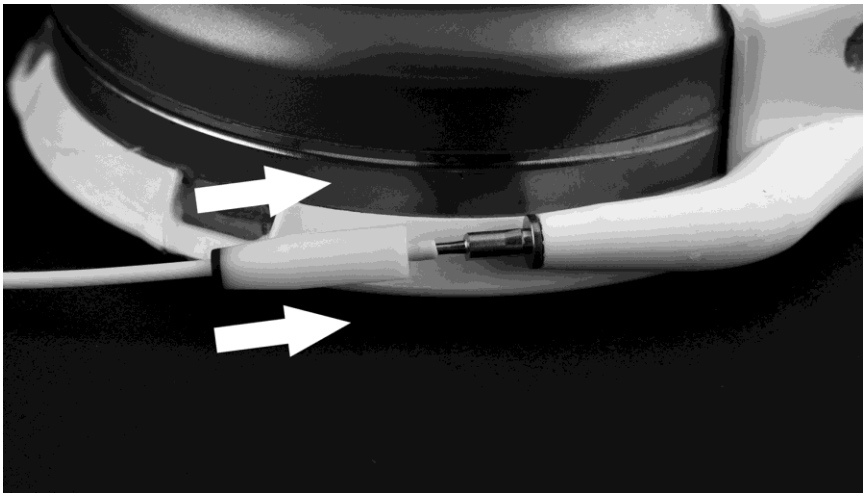
    Caution: Always trim excess catheter length. Failure to trim excess length may result in catheter occlusion or kinking.

    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.
17. 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.



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.

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



19. 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.
20. Verify that the catheter is not kinked or constrained by the pump sutures.
21. 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.

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 Programmable Pump package is a Patient Implant Tracking/Registration Form. This pre-addressed form should be completed and returned to Flowonix Medical. 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 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 and Pump Explantation

The Intrathecal Catheter and Programmable Pump should only be explanted in accordance with the hospital procedures. Explanted product is to be treated as a biohazard.
Warning: Prior to cremation, the pump should always be explanted. The pump will explode at high temperatures.

Calculations

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

Issue Date: June 2019

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.

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