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.
Introduction

The Flowonix Programmable Pump is designed to provide controlled delivery of Infumorph® 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.

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
   12 – Calculations Guide
   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

Prometra Programmable Infusion Systems are indicated for intrathecal infusion of Infumorph® (preservative-free morphine sulfate sterile solution) or preservative-free sterile 0.9% saline solution (Sodium Chloride Injection, USP).

Drug Information

Refer to the Infumorph 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 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 INCLUDING 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.

- Prior to infusion of Infumorph into the catheter, 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.
- Always select and program dosages consistent with the Infumorph® labeling to prevent improper drug administration.
- In the event of over-medication, refer to the approved Infumorph labeling for appropriate treatment.
- Clinicians implantaing, 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.
Magnetic Resonance Imaging (MRI)

Prometra® and Prometra® II Programmable Pumps Magnetic Resonance Imaging (MRI) Instruction Guide

GENERAL

MR Conditional

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.

Warning: Patients should not be exposed to MRI environments until the surgical site following pump implantation is fully healed.

Warning: EMPTY ALL DRUG SOLUTION FROM BOTH PROMETRA AND PROMETRA II PUMPS PRIOR TO ENTERING THE MRI ENVIRONMENT. If a patient with a Prometra II Pump requires an emergent MRI, please see page 12 of these instructions for more details on the potential risks involved.

Strong magnetic fields, such as those created in MRI scanners, may cause the Inlet and Outlet Valves to open, resulting in the immediate discharge of the contents of the Drug Reservoir and Catheter into the patient. This could result in drug overdose that could lead to serious patient injury or death.

Prior to initiating the MRI procedure, the physician must determine if the patient can safely be deprived of medication for the length of the MRI procedure. If medication is needed, then alternate means of drug delivery (such as I.V. administration) should be employed for the duration of the MRI procedure.

Prior to scheduling an MRI scan and upon its completion, pump status should be confirmed by inquiring the pump to verify pump operation and settings.

Note: Pre-MRI, Post-MRI, and Medical Emergency Use instructions are provided in this document.

SCANNING PARAMETERS

The Prometra® and Prometra® II Programmable Pumps can be safely exposed to an MRI system when ALL of the following conditions are met:

1. The MRI device has a static magnetic field of 1.5 Tesla.
2. The MRI device has a maximum spatial gradient field of 2,000 Gauss/cm (20 T/m) at 1.5 Tesla.

Warning: Exceeding the 2,000 Gauss/cm (20T/m) at 1.5T limit could result in excessive force or torque which could lead to patient injury.
3. A maximum whole body average specific absorption rate (SAR) of 2 W/kg for 20 minutes of safe scanning in the Normal Operating Mode.

4. All Pre-MRI Instructions must be completed.

**NOTE:** The MRI conditions for safe scanning detailed in this document only pertain to the Prometra Pumps implanted in the abdomen. Testing has not been conducted in other implantation locations or in the presence of other implanted active or passive medical devices. Other implanted devices (such as pacemakers, abandoned leads, knee implants, etc.) could have conflicting MR conditions which could lead to patient injury or device malfunction.

**Tissue Heating Adjacent to Implant during MR Scans**

In non-clinical testing, the Prometra® Pump produced a maximum temperature rise of 1.5°C during 20 minutes of continuous MR scanning in the Normal Operation Mode at a maximum whole-body averaged specific absorption rate (SAR) of 2 W/kg using a transmit body coil, therefore the Prometra II will experience a similar maximum temperature rise under the same MR scanning conditions.

The local temperature increase produced by the pump is considered to be below level of concern. In the unlikely event that the patient experiences uncomfortable warmth near the pump, the MRI scan should be stopped and the scan parameters adjusted to reduce SAR to comfortable levels.

**Warning: Static Magnetic Field**

In a 1.5 Tesla MR environment, the pump has a significant magnetically induced deflection force and very strong torque. The static and gradient magnetic fields produced by an MRI scanner could potentially interact with the pump and cause vibration. However, when pumps are implanted with proper techniques, the patient may safely be scanned under the conditions listed above. Not following the specific conditions may result in serious patient injury. The patient may experience a tugging and/or vibration sensation at the implant site when placed within the magnetic field. An elastic garment or wrap will help restrict movement and reduce these sensations while the patient is in the magnetic field.

**Image Artifacts**

The programmable pump contains ferromagnetic components that will cause image distortion and localized voids in regions of the image around the pump. MR image quality will be compromised if the area of interest is near the pump.

Worst case artifacts measured from the edge of the device in non-clinical tests using a spin echo sequence were found to extend more than 11 cm from the pump. Image artifacts were reduced up to 36% when sequences were optimized for imaging (e.g. shorter echo time, decreased water fat shift, etc.). Images of the head and lower extremities away from the location of the Prometra Pump should be largely unaffected. The nonclinical testing was performed using the ASTM F2119 GRE and SE sequences in a 1.5T Philips Medical Systems Intera (software release 12.6.4.3, 2010-12-02) MR system with a body coil in transmit and receive mode.

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1There are no changes between the Prometra® pump and Prometra® II pump that would significantly affect the ASTM MRI testing and MRI Scanning Parameters.
SPECIFIC PRE-MRI INSTRUCTIONS

**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.

Prometra® (REF 11827) and Prometra® II (REF 13827) Programmable Pumps

**Protocol for Prometra® (REF 11827) and Prometra® II (REF 13827) Programmable Pumps**

**Pre-MRI Procedure**

**Warning:** EMPTY ALL DRUG SOLUTION FROM BOTH PROMETRA AND PROMETRA II PUMPS PRIOR TO ENTERING THE MRI ENVIRONMENT. If a patient with a Prometra II Pump requires an emergent MRI, please see page 12 of these instructions for more details on the potential risks involved.

Strong magnetic fields, such as those created in MRI scanners, may cause the Inlet and Outlet valves to open, resulting in the immediate discharge of the contents of the Drug Reservoir and Catheter into the patient. This could result in drug overdose that could lead to serious patient injury or death.

The physician must determine if the patient can safely be deprived of medication during the MRI procedure. If medication is needed then alternative means of drug delivery (such as I.V. administration or analgesic patch) should be employed.

**IF AN MRI PROCEDURE IS NECESSARY, THE PUMP MUST BE EMPTIED** of drug solution, not refilled and the PUMP PROGRAMMED TO 0.0 MG/DAY DRUG FLOW RATE prior to entering the environment of the MRI.

**PERFORM THE FOLLOWING STEPS PRIOR TO ENTERING THE MRI ENVIRONMENT.**

1. **Pump Inquiry**
   
   Inquire the pump with the programmer to verify pump model, the pump is operational and without errors. Print inquiry page.

**WARNING:** IF PUMP STATUS CANNOT BE PROPERLY CONFIRMED, DO NOT PROCEED SINCE THE PUMP MAY NOT BE OPERATING PROPERLY, PLEASE CONTACT FLOWONIX TECHNICAL SOLUTIONS FOR ASSISTANCE AT: 855-356-9665.
2. **Pump Programming**
   Set the flow mode to a constant flow rate of 0.0 mg/day. Re-inquire the pump and print inquiry page to confirm a constant flow rate of 0.0 mg/day.

3. **Empty Drug Reservoir**
   Follow the procedures for emptying the Drug Reservoir in the Refill Kit Instructions for Use.
SPECIFIC POST-MRI INSTRUCTIONS

Protocol for Prometra® (REF 11827) and Prometra® II (REF 13827) Programmable Pumps

Post-MRI Procedure

1. **Confirm Pump Operational Status** –
   a. Inquire the pump with the programmer to verify pump operation and settings.
   b. Confirm that settings are unchanged from the Pre-MRI settings, e.g., flow rate must be 0.0 mg/day.
   c. If the programmer displays any pump errors, proceed to Step 2 “Clear Pump Errors”.
   d. If no pump errors are displayed, proceed to Step 3 “Inlet and Outlet Valve Closure Confirmation”.

2. **Clear Pump Errors**
   a. If pump errors are displayed from the Inquiry performed in Step 1, perform an Emergency Pump Stop using the programmer, and contact Flowonix Technical Solutions for assistance 855-356-9665.
   b. If pump errors are cleared, proceed to Step 3.

3. **Confirm Inlet / Outlet Valve Closure**
   a. Attempt to aspirate the Drug Reservoir through the Refill Port. To aspirate, attach the 22G non-coring needle (available in Refill Kit) to a sterile syringe.
   b. Advance needle through center Refill Port Septum until needle tip resides completely inside the Drug Reservoir.
   c. Pull a vacuum with the syringe for approximately 10 to 30 seconds to confirm Inlet / Outlet Valve closure.

**Warning:** If any significant volume (>1ml) is retrieved, it may be indicative that the pump Inlet / Outlet Valves are open, providing direct access to the catheter/cerebral spinal fluid; if so, DO NOT proceed with the refill since the pump may not be operating properly. The pump may need to be explanted and replaced. For questions, Contact Flowonix Technical Solutions for assistance at: 855-356-9665.

4. **Refill The Drug Reservoir**
   a. Proceed to refill the Drug Reservoir in accordance with the refill procedure defined in the Refill Kit Instructions for Use.
   b. Confirm the correct prescription is programmed, or program a new prescription.

**Warning:** A period of observation should follow the Refill Procedure to closely monitor patients for clinical symptoms of underdose or overdose based upon Infumorph’s prescribing information.

**WARNING:** IF PUMP STATUS CANNOT BE PROPERLY CONFIRMED, DO NOT PROCEED SINCE THE PUMP MAY NOT BE OPERATING PROPERLY, PLEASE CONTACT FLOWONIX TECHNICAL SOLUTIONS FOR ASSISTANCE AT: 855-356-9665.
IN THE EVENT OF A MEDICAL EMERGENCY REQUIRING AN MRI SCAN:

Prometra® Programmable Pump (REF 11827)

Medication MUST be removed from the Prometra® Pump REF 11827. Do not expose patient to MRI magnetic fields with drug in the Prometra Drug Reservoir, even in the event of a medical emergency. Follow instructions above (Pre-MRI) for removing drug from the Prometra Pump.

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.

Prometra® II Programmable Pump (REF 13827)

In the event of a medical emergency requiring a STAT MRI, the treating physician must be aware of the following as inputs to decision making regarding proceeding with an Emergency MRI for the Prometra II Pump (REF 13827):

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.

WARNING: In the event an MRI scan was performed on a patient with a Prometra® II Pump where the drug was NOT removed due to a medical emergency situation, the Prometra® II Pump contains a Flow Activated Valve (FAV) intended to reduce, but not eliminate, the risk of drug overdose. A physician must evaluate the patient immediately for signs and symptoms of drug overdose and develop a plan for immediate monitoring in a medically supervised and adequately equipped environment. Resuscitative equipment should be available, as should medications to manage drug overdose.

FLOWONIX STRONGLY RECOMMENDS THAT ALL DRUG BE REMOVED FROM THE PROMETRA® II DRUG RESERVOIR PRIOR TO ANY MRI SCAN.

The Prometra® II Pump includes a Flow Activated Valve (FAV) intended to reduce, but not eliminate, the risk of drug over-infusion during an MRI procedure.

If the Drug Reservoir volume is ≤1mL or expected to be ≤1mL at the time of the Emergency MRI scan, do not proceed with an Emergency MRI scan without first emptying the drug from the Reservoir.
≤1mL of drug in the Reservoir, the drug must be removed prior to the Emergency MRI procedure. When the Reservoir volume is at < 1 mL, the FAV may not close. Thus, the drug within the Reservoir may be bolused to the patient. This could result in drug overdose that could lead to serious patient injury or death. To determine the volume of drug in the Reservoir, inquire the pump with a Prometra® Programmer. The Reservoir volume is shown on the inquiry screens. If a Programmer is not available, then all drug must be removed from the Drug Reservoir prior to the Emergency MRI scan.

The Flow Activated Valve (FAV) of the Prometra® II Pump is intended to shut off drug flow when exposed to strong magnetic fields. When this occurs a small amount of drug, ≤10 μL, will be delivered to the patient. The physician must determine if the patient can safely receive this 10 μL bolus dose during the Emergency MRI procedure¹. If not, then all drug must be completely emptied from the Drug Reservoir prior to the Emergency MRI procedure.

NOTE: For a pump containing Infumorph® at a concentration of 25 mg/mL, a bolus dose of < 0.25 mg would be delivered to the patient during an Emergency MRI procedure if the drug was not removed from the Drug Reservoir prior to the MRI.

Following an MRI, the FAV will be closed, and will prevent further drug delivery to occur until the pump is manually reset after the completion of the MRI procedure. The physician must determine if the patient can safely be deprived of medication until the FAV is reset after the MRI procedure. If medication is needed, then alternate means of drug delivery (such as I.V. administration or analgesic patch) should be employed keeping in mind that the patient will be receiving up to a 10 μL bolus of drug during the Emergency MRI if drug was not removed from the Reservoir prior to the MRI procedure.

In the event that an Emergency MRI scan was performed on a patient with a Prometra® II pump in which the drug was NOT removed due to a medical emergency situation, the Prometra II FAV must be reset by performing a reset procedure.

¹Per Deer et al., Polyanalgesic Consensus Conference 2012: Recommendation for the Management of Pain by Intrathecal (Intraspinal) Drug Delivery: Report of an Interdisciplinary Expert Panel, bolus doses of 5%-20% of the daily dose are typical, but cautions that doses are additive to baseline infusion and cumulative side effects could occur.
Emergency Procedure PRE-MRI Steps for Prometra II Pump

1. Pump Inquiry
   a. Inquire the pump with the programmer to verify pump model, the pump is operational and without errors.
   b. Verify that more than 1mL of drug is present in the Drug Reservoir.
   c. Print inquiry page.


2. Pump Programming
   a. Set the flow mode to a constant flow rate of 0.0 mg/day.
   b. Re-inquire the pump and print inquiry page to confirm a constant flow rate of 0.0 mg/day.

Emergency Procedure POST-MRI Steps for Prometra II Pump

1. Confirm Pump Operational Status –
   a. Inquire the pump with the programmer to verify pump operation and settings.
   b. Confirm that settings are unchanged from the Pre-MRI settings, e.g., flow rate must be 0.0 mg/day.
   c. If the programmer displays any pump errors, proceed to Step 2 “Clear Pump Errors”.
   d. If no pump errors are displayed, proceed to Step 3 “FAV Reset Procedure”.


2. Clear Pump Errors
   a. If pump errors are displayed from the Inquiry performed in Step 1, perform an Emergency Pump Stop using the programmer, and contact Flowonix Technical Solutions for assistance 855-356-9665.
   b. If pump errors are cleared, proceed to Step 3.

3. FAV Reset Procedure
   a. Remove drug from Drug Reservoir by aspirating through the Refill Port.
   b. To aspirate, attach the 22G non-coring needle to a syringe barrel (available in Refill Kit).
   c. Advance needle through the center Refill Port Septum until needle tip resides completely inside the Drug Reservoir.
d. Empty the Drug Reservoir until there is no more fluid returning to the syringe barrel. (Refer to Refill Kit Instructions for Use for further details on emptying the pump).

e. After ensuring the Drug Reservoir is fully empty, program a Demand Bolus to deliver (0.03 mL x concentration) over 2 minutes (this will not dispense drug since the Drug Reservoir is empty).

f. Wait for the 2-minute Demand Bolus to complete before proceeding.

4. **Confirm Inlet / Outlet Valve Closure**
   
a. Attempt to aspirate the Drug Reservoir through the Refill Port. To aspirate, attach a sterile syringe to the 22G non-coring needle used in Step 3c above.

b. Pull a vacuum with the syringe for approximately 10 to 30 seconds to confirm Inlet / Outlet Valve closure.

   **Warning:** If any significant volume (>1ml) is retrieved, it may be indicative that the pump Inlet / Outlet Valves are open, providing direct access to the catheter/cerebral spinal fluid; If so, DO NOT proceed with the refill since the pump may not be operating properly. The pump may need to be explanted and replaced.

   For questions, Contact Flowonix Technical Solutions for assistance at: 855-356-9665.

5. **Refill The Drug Reservoir**
   
a. Proceed to refill the Drug Reservoir in accordance with the refill procedure defined in the Refill Kit Instructions for Use.

b. Confirm the correct prescription is programmed, or program a new prescription.

   **Warning:** A period of observation should follow the Refill Procedure to closely monitor patients for clinical symptoms of underdose or overdose based upon Infumorph’s prescribing information.
Pump Model Determination

To identify the pump model prior to an Emergency MRI scan use the following methods:

- **Inquiry by programmer:** Identifies model either as Prometra® or Prometra® II on the Programmer’s Inquiry Screen. Contact Flowonix Technical Solutions at 855-356-9665 if you require access to a Flowonix Programmer.

- **Patient ID Card:** Identifies the pump model either as Prometra® II (Model # 13827) or Prometra® (Model # 11827) as noted in the examples on the following page.
  
  ![Note: Patients with Prometra® and Prometra® II Pumps also have Medical Alert bracelets that indicate that the pump must be emptied prior to an MRI.](image)

- **Contact patient’s pump management physician:** The patient’s medical records indicate the pump model and serial number implanted. Flowonix provides medical chart labels to facilitate patient record documentation.

- **Pump serial number:** There is a distinct difference in the serial numbers for the Prometra® Pump versus the Prometra® II Pump. The Prometra® II pump’s serial number ends with an X, while the Prometra® Pump’s serial number ends with a number.

- **Contact Flowonix Technical Solutions at 855-356-9665:** Pump information may be determined from our patient registration system. This number is staffed 24 hours a day.

- **Perform an X-ray of the pump:** The Prometra® II pump can be differentiated from the Prometra® Pump via X-rays as shown on the following page. The image of the Prometra® II Pump shows the addition of the flow-activated valve (FAV) within the Catheter Access Port.
INTRATHECAL CATHETER
FOR USE WITH PROMETRA® PROGRAMMABLE INFUSION SYSTEMS
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-dosage of Infumorph. In the event of over-dosage, refer to the approved Infumorph 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.
- 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 Infumorph 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 use of implanted pumps provides an important means of intrathecally delivering Infumorph. However, the potential exists for serious complications including the following:

Possible Risks Associated with Programmable Implantable Pump:

INTRATHecal CATHeter
FOR USE WITH PROMETRA® PROGRAMMABLE INFUSION SYSTEMS
• 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
• 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 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 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.

**Equipment**

• Programmable Pump
• Intrathecal Catheter
• Tunneler

The following items may be needed and are not provided:
• Sterile preservative-free 0.9% saline
• Infumorph 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 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.

![Image of angled suture wings]

*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.

![Image of slit suture wing]

*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:

   Implant Catheter Length (cm) = 110 cm – Trimmed Catheter Length (cm)
   Implant Catheter Volume (mL) = Implant 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.*
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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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