PROMETRA®

CATHETER REVISION KIT (REF 11830)

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 Catheter Revision Kit is designed to facilitate replacement of a section of an intrathecal catheter. The kit contains the following items:

The following components are sterile and non-pyrogenic:
1 - Catheter Segment, Radiopaque, 1.3mm OD (4F) x 30cm x 0.6mm ID
1 - Catheter Lock
1 - Catheter Connector
1 - Connector Sleeve
1 - Suture Wing, Angled 90°
1 - Suture Wing, Straight

Non-sterile components:
1 - Instructions for Use
1 - Sheet of Device ID Stickers
1 - Measurement Tape (30 cm)
1 - Patient Device Tracking Form
4 - Temporary Patient Implant Cards

Description

The Catheter Revision Kit is used when a revision to the catheter used with the Prometra Programmable Infusion System is required. A replacement Catheter Lock is provided to allow attachment of the new Catheter Segment to the pump. A Catheter Connector (and sleeve) are provided to allow this segment to be attached to the existing catheter. Replacement suture wings are provided to allow the catheter and replacement segment to be secured as required.

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 the Programmable Pump 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.
- Monitor patients after pump and/or catheter implant or replacement for signs of underdose/overdose.
- 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.

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 <u>immediate</u> 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.

Other provided equipment that may be required for catheter revision related procedures:

- Catheter Revision Kit
- Intrathecal Catheter Kit
- Prometra CAP Kit
- Prometra Refill Kit
- Tunneler
- Prometra Programmer (not sterile)

The following items may be needed and are not provided:

- Refill syringe, 20 mL (if pump reservoir capacity is 40 mL, 2 syringes are required)
- 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
- 2 ea. 10 mL syringe filled with 5 mL PFSS.
- Sterile preservative-free 0.9% saline
- Sterile pen

Implantation Instructions

Note: **"Segment"** will be used to denote the Catheter Segment being added to the existing Catheter. **"Catheter"** will be used to denote the existing implanted catheter.

Preparation

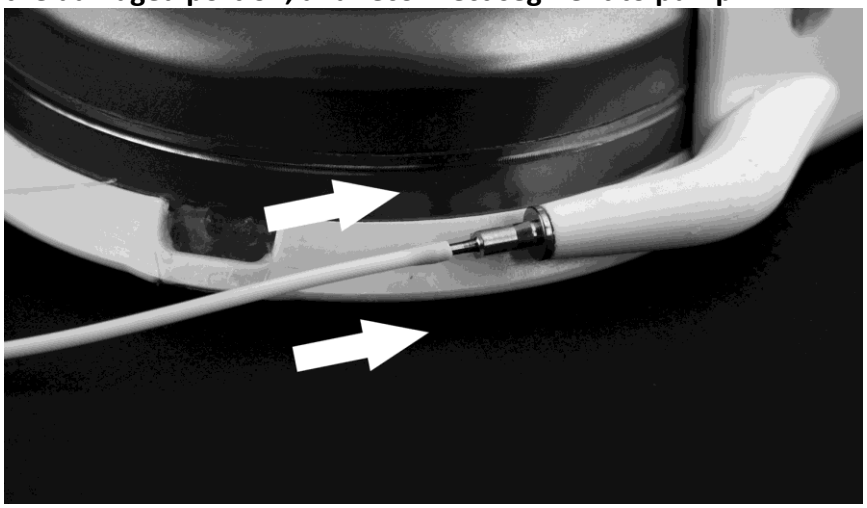
- Use the Programmer to discontinue the flow of medicine through pump.
- Aspirate the catheter through the Catheter Access Port (CAP).

For Pump Removal Procedure:

1. Use Sterile Technique. Always inspect and aseptically prepare the site according to standard practice. Access affected section of catheter/pump per appropriate hospital procedures.
2. Cut the catheter 3-6" (7-15cm) distal to the pump connection.
   Note: Remove any damaged sections of catheter prior to connecting to new Segment. If more than approximately 30cm are removed from the catheter, then additional Catheter Revision Kits will be required.
3. Remove the pump and disconnect the catheter from the pump. Measure and record the discarded catheter length. Retain for patient records.
4. Prepare replacement pump as per the appropriate Programmable Pump IFU.

Connect Segment to Pump

5. Slide catheter lock onto segment with larger end towards the proximal end of the segment. Align pump stem with segment lumen. Advance segment over barb on pump stem to midway point.
   Warning: Prior to advancing the catheter lock, ensure that the segment is properly positioned on the pump stem. The segment must be straight with no sign of kinking prior to advancing the catheter lock. A slight pull on the segment is sufficient to straighten it. Advancing the catheter lock over a kinked catheter may damage the catheter. Should the segment become damaged, cut the damaged portion, and reconnect segment to pump.



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

Note: Once the segment and lock are connected, if disconnection and reconnection are required, retract catheter lock off pump-catheter connection and disconnect catheter from pump stem; prior to reconnection, trim 2-3 cm off the catheter end to ensure a secure connection.

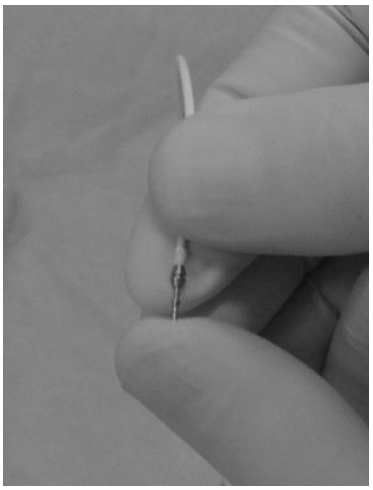
- Verify that the segment is not kinked.

Trim Segment

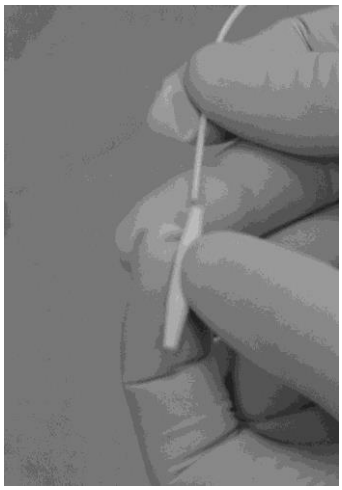
7. Trim the new segment to length at a 90˚ angle allowing sufficient slack for body movement, pump connection, and an additional 2-3 cm in case a pump reconnection is required. Always trim at least 5 cm from the proximal end of the segment. Ensure that the cut is straight and no catheter fragments are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

Connect Segment to Catheter

8. Insert the catheter connector into the segment. Push the segment to the stop on the connector.

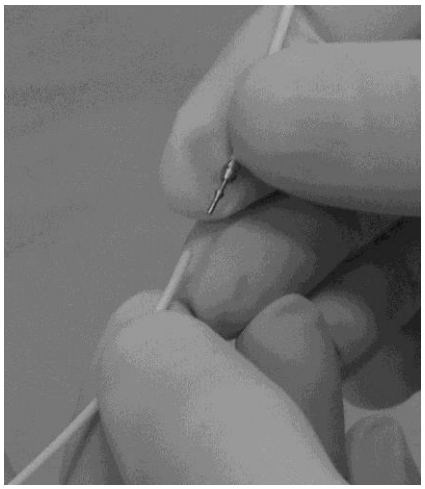


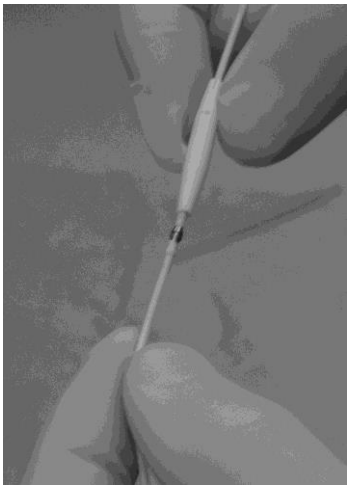
9. Slide the connector sleeve over the proximal implanted catheter tip. The sleeve is designed with a slit so it will open as it moves over the center portion of the barb.



10. Insert the other end of the catheter connector into the proximal end of the implanted catheter. Push the catheter to the stop on the barb.

11. Slide the connector sleeve over the catheter connector. Slide the sleeve until it stops and locks into place. When properly positioned, the sleeve should have minimal axial movement.





12. If intrathecal segment of catheter has been replaced, the angled 90^{o} suture wings can be utilized for anchoring catheter to the spinous ligaments.
    Caution: Always make sure the catheter is straight as it comes out of the spinal entry location to avoid catheter kinking.

Preparing the Pump

Using the Prometra programmer, perform a Demand Bolus to prime the catheter with infusate to the tip and prepare it for therapeutic delivery.

Post-Implant Record-Keeping

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.

Calculate and record the implanted catheter length and volume:

Implanted Catheter Length (cm) = Previous Implanted Catheter Length (reference patient records) – Removed Catheter Length (cm) + New Catheter Segment Length (cm)

Implanted Catheter Volume (mL) = (Previous catheter volume - Removed catheter volume) + segment catheter volume (Length (cm) x 0.0026 mL/cm)

Warning: Always measure and record on the Catheter Revision Patient Tracking Form:

- **Model, length and volume of existing catheter**
- **length and volume of the trimmed portion of the removed catheter**
- **length and volume of the new catheter segment**
- **Calculate and record the new total implanted catheter length and volume.**

These calculations are required to prevent under- or over-medication.

Patient Implant Card and Registration

Included with each **Prometra** Catheter Revision Kit 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.

Two temporary patient implant cards are provided for the patient. The patient implant card contains information pertinent to the implanted Intrathecal Catheter (length and volume) and Programmable Pump. The implant card should be carried by the patient at all times. A second card is provided for placement in their glove box, 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.

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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