Prometra® Programmable Pump System Brief

Summary

Indications, Safety and Warnings

Product Instructions for Use and the Infumorph® drug labeling must be reviewed prior to use for detailed disclosure.

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

Indications

The Prometra Programmable Infusion System is 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 PROMETRA 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 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 Prometra Programmable Pump components are supplied sterile and non-pyrogenic. The packages should be examined carefully prior to opening. Do not use the contents if there is any evidence of damage to the package or package seal that could compromise sterility. Do not resterilize contents of any damaged or opened packages.
• After use, this device is a biohazard. Handle and dispose of in accordance with accepted hospital practice and all applicable laws and regulations.
• Do not incinerate or cremate the pump.
• Do not expose the pump to temperatures above 57°C (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)**

⚠️ **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.**

**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. Strong magnetic fields, such as those created in Magnetic Resonance Imaging (MRI) devices, may cause the valves of the pump to open, resulting in the immediate discharge of the contents of the drug reservoir and catheter into the patient.

Prior to initiating the MRI procedure, the physician should determine if the patient could safely be deprived of pain medication for the length of the procedure. If pain 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.

Non-clinical testing has demonstrated the Prometra Programmable Pump is MR Conditional. It can be scanned safely under the following conditions:

- The pump’s reservoir is completely emptied by following the procedures for emptying the reservoir in the Refill Kit Instructions for Use.
- The pump is programmed to 0.0 mg/day flow prior to MRI exposure and throughout the scanning sequence.
- A static magnetic field of 1.5 Tesla
- A maximum spatial gradient field of 410 Gauss/cm
- A maximum whole body averaged specific absorption rate (SAR) of 2W/kg for 20 minutes of scanning in the Normal Operating Mode.
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.

Static Magnetic Field
In a 1.5 T MR environment, the pump has a significant magnetically induced deflection force and very strong torque; 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 slight tugging sensation at the implant site when placed within the magnetic field. An elastic garment or wrap will help restrict movement and reduce the sensation the patient may experience while 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 by up 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.

Post MRI Procedures
1. Confirmation of Pump Operational Status
   a) Pump Inquiry
      Upon the completion of an MRI procedure, inquire the pump with the programmer to verify pump operation and settings. Confirm that settings are unchanged from the Pre-MRI settings, e.g., flow rate must be 0.0 mg/day.

      Warning: If pump status cannot be properly confirmed, DO NOT proceed since the pump is not operating properly and should be explanted and replaced.

   b) Pump Aspiration
      • Once the pump status and flow rate is confirmed to be 0.0 mg/day via inquiry, attempt to aspirate the pump reservoir through the refill port.
      • To aspirate, attach the 22G non-coring needle (available in Refill Kit) to a sterile syringe.
• Advance needle through center refill septum until needle tip resides completely inside the drug refill reservoir.
• Pull a vacuum with the syringe for approximately 10 to 30 seconds.

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

2. Refill Procedure
After confirming that the pump is operating properly, proceed to refill the pump in accordance with the refill procedures defined in the Refill Kit Instructions for Use.

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.

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 Prometra® 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.

Implant
• Implantation of this device and subsequent use, reprogramming, and refill should only be conducted by qualified medical personnel specifically trained for surgical implantation, use, and maintenance of the device. Use of this device by non-qualified or untrained personnel could lead to serious consequences involving under- or over-dosage of Infumorph. In the event of over-dosage, refer to the approved Infumorph labeling for appropriate treatment.
• The pump and catheter system should be implanted carefully to avoid any sharp or acute angles, which could compromise the patency of the catheter lumen.
- Over-pressurization can damage the catheter. Small syringes can generate very high pressures and may damage the catheter or catheter connection. Do not use a syringe smaller than 10 mL when accessing the catheter access chamber.

- If therapy is discontinued for an extended period, the pump should be emptied of 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
- **Pump accessories.** Only use the Prometra Programmable Pump with the accessories listed in these instructions for use. Use of alternate accessories may result in damage to Prometra components, less than adequate therapy, or increased risks to the patient.
- **Pump.** Only use with Prometra Programmer.
- **Alcohol.** Do not use alcohol on any part of the pump or catheter system. Alcohol is neurotoxic.
- **Contrast media.** Do not inject contrast media into the refill reservoir since this may damage the pump or impair pump function.
- **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.
- **Therapeutic ultrasonics or lithotripsy.** Use of therapeutic ultrasonic devices, such as electrohydraulic lithotriptors, has not been tested on the Prometra pump. If lithotripsy must be used, do not focus the beam in proximity of the pump.
- **Medical devices.** The Prometra Pump Programmer may affect other medical devices. Use or interference with medical devices, other than neurostimulators, has not been established.
- **Applied electric currents.** Interaction of the Prometra Pump with electric currents applied to the body such as cardioversion or defibrillation has not been established. Care must be exercised if the patient receives these treatments. Where practical, the pump should be turned off before application of electric currents to the patient’s body. Confirmation that the pump programming has not changed must be carried out as soon as possible after the procedure.
- **Radiation.** Do not use radiation therapy in the area of the pump. The effects of ionizing radiation on the Prometra Pump have not been established, and these therapies may have effects on pump operation that are not immediately apparent.

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:
- 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 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.

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