PROMETRA® II PROGRAMMABLE PUMP (REF 93827)
For use with Intrathecal Catheter

MR Conditional
## Explanation of Symbols

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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF</td>
<td>Catalog number</td>
</tr>
<tr>
<td>SN</td>
<td>Serial number</td>
</tr>
<tr>
<td>LOT</td>
<td>Batch code</td>
</tr>
<tr>
<td></td>
<td>Use by date</td>
</tr>
<tr>
<td></td>
<td>Date of manufacture</td>
</tr>
<tr>
<td>STERILE EO</td>
<td>Sterilized using ethylene oxide</td>
</tr>
<tr>
<td>STERILE</td>
<td>Sterilized using steam or dry heat</td>
</tr>
<tr>
<td></td>
<td>Do not re-use</td>
</tr>
<tr>
<td></td>
<td>Caution, consult accompanying documents</td>
</tr>
<tr>
<td></td>
<td>Do not use if package is damaged</td>
</tr>
<tr>
<td></td>
<td>Fragile, handle with care</td>
</tr>
<tr>
<td></td>
<td>Temperature limitations</td>
</tr>
<tr>
<td></td>
<td>Keep away from sunlight</td>
</tr>
</tbody>
</table>
### Explanation of Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>MR</td>
<td>MR Conditional</td>
</tr>
<tr>
<td>EC REP</td>
<td>Authorized Representative in the European Community</td>
</tr>
<tr>
<td>!</td>
<td>Warning</td>
</tr>
<tr>
<td>i</td>
<td>Information</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nonpyrogenic</strong></td>
<td>Non-pyrogenic</td>
</tr>
<tr>
<td><strong>Latex-Free</strong></td>
<td>No patient or fluid contact with latex components</td>
</tr>
<tr>
<td><strong>PVC-Free</strong></td>
<td>No patient or fluid contact with polyvinyl chloride components</td>
</tr>
<tr>
<td><strong>DEHP-Free</strong></td>
<td>No patient or fluid contact with di(2-ethylhexyl)phthalate components</td>
</tr>
</tbody>
</table>
Table of Contents

1. Introduction.................................................................................................................................................. 1
2. Contents ......................................................................................................................................................... 1
3. Description ..................................................................................................................................................... 1
4. Indications ...................................................................................................................................................... 4
5. Contraindications ......................................................................................................................................... 4
6. Warnings ....................................................................................................................................................... 5
   6.1 General...................................................................................................................................................... 5
   6.2 Magnetic Resonance Imaging (MRI) Conditions For Safe Scanning ....................................................... 5
      6.2.1 Pump Model Determination........................................................................................................... 6
      6.2.2 Pre-MRI Instructions – Non-Emergency Situation ...................................................................... 7
      6.2.3 Pre-MRI Instructions – Emergency Situation ............................................................................ 7
      6.2.4 MRI Scanning Parameters – Emergent and Non-Emergent Situations ...................................... 8
      6.2.5 Tissue Heating, Magnetic Field and Image Artifacts ................................................................... 9
      6.2.6 Post-MRI Procedures ................................................................................................................... 9
7. Precautions .................................................................................................................................................... 10
   7.1 General.................................................................................................................................................... 10
   7.2 Implantation .......................................................................................................................................... 11
   7.3 Device Compatibility .......................................................................................................................... 11
8. Potential Adverse Events .......................................................................................................................... 12
   8.1 Possible Risks Associated with Programmable Implantable Pumps .................................................... 12
   8.2 Possible Risks Associated with Intrathecal Catheter: ......................................................................... 12
   8.3 Possible Risks Associated with baclofen Intrathecal Infusion ............................................................. 13
9. Equipment .................................................................................................................................................... 14
10. Pump Operation......................................................................................................................................... 14
    10.1 Programmable Features.................................................................................................................... 14
    10.2 Programming Medication Regimens ............................................................................................... 14
        10.2.1 Constant Flow .......................................................................................................................... 15
        10.2.2 Multiple Rates ......................................................................................................................... 15
        10.2.3 Periodic Flow .......................................................................................................................... 15
        10.2.4 Demand Bolus ....................................................................................................................... 16
    10.3 Pre-Programmed Pump Settings ....................................................................................................... 16
    10.4 Pump Alarms ...................................................................................................................................... 17
        10.4.1 Low Reservoir Alarm ............................................................................................................. 17
        10.4.2 Critical Error Alarm .............................................................................................................. 17
11. Implantation Instructions ........................................................................................................................... 18
    11.1 Pre-Implant Pump Preparation .......................................................................................................... 18
        11.1.1 Pump Priming Preparation .................................................................................................... 18
        11.1.2 Pump Priming .......................................................................................................................... 20
    11.2 Implantation of the Intrathecal Catheter ............................................................................................. 21
    11.3 Implantation of the Prometra II Programmable Pump ....................................................................... 21
    11.4 Patient Implant Card and Registration ............................................................................................. 23
12. Pump Explantation ..................................................................................................................................... 23
13. Calculations .................................................................................................................................................. 23
14. Patient-Related Variables and Flow Rate Accuracy ................................................................................ 24
    14.1 Geographical Elevation ..................................................................................................................... 24
    14.2 Temperature Variation ....................................................................................................................... 24
    14.3 Flow Rate Accuracy .......................................................................................................................... 25
    14.4 Device Longevity .............................................................................................................................. 25
15. Implantables Warranty .............................................................................................................................. 26
1. Introduction

The Prometra II Programmable Pump is designed to provide controlled delivery of drugs to the intrathecal space via the separately supplied Intrathecal Catheter. The Prometra II Pump incorporates a patented flow activated safety valve (FAV™) that will shut off drug flow to the patient in the event that a high flow rate is encountered. The Prometra Clinician Programmer is a separately supplied handheld, menu-driven device that enables remote programming of the Prometra II Pump.

2. Contents

The following contents are sterile and non-pyrogenic:
1 – Prometra II Programmable Pump
1 – Needle, Non-Coring, 0.7 mm (22G) x 38 mm (1.5 in.)
1 – Needle, Catheter Access, 0.9 mm (20G) x 45 mm (1.75 in.)

Non-sterile components:
1 – Patient and Physician Information Packet:
   1 – Prometra Programmable Pump Instructions for Use
   1 – Supplementary Calculations Guide
   1 – Patient Guide
1 – Patient Implant Cards
1 – Patient Device Tracking Form
1 – Sheet of Device ID Stickers

3. Description

The Prometra II Pump is a battery-powered, teardrop-shaped pump with a rigid titanium housing and a triple redundancy flow controller system. To help increase safety, the Prometra II Pump incorporates a safety valve (flow-activated valve or FAV) that will shut off drug flow to the patient in the event a high flow rate occurs, such as during an MRI.

The triple redundancy flow control system is designed to provide a precise and accurate flow rate. The flow rate accuracy is independent of normal operating environmental conditions such as altitude, temperature and reservoir volume.
3. Description

Once implanted, the device can be identified by using the programmer to inquire the system. If a programmer is not available, the shape of the pump, tear drop access port and raised refill port provide features distinct to the Prometra II pump for easy identification. The programmable pump and package contents are sterilized using steam.

Specifications of the Prometra II Programmable Pump are:

<table>
<thead>
<tr>
<th>Device Longevity</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pump</td>
<td>10 years at 0.25 mL/day</td>
</tr>
<tr>
<td>Septum (Refill and CAP)</td>
<td>1000 punctures maximum</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>External Properties</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Material</td>
<td>Titanium Polyphenylsulfone access ports</td>
</tr>
<tr>
<td>Thickness (nominal)</td>
<td>20 mm</td>
</tr>
<tr>
<td>Diameter (excluding CAP)</td>
<td>69 mm</td>
</tr>
<tr>
<td>Average Volume Displacement</td>
<td>100 mL</td>
</tr>
<tr>
<td>Weight, unfilled</td>
<td>150 g</td>
</tr>
<tr>
<td>Pump to Catheter Connection Strength</td>
<td>1.1 lbs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Reservoir</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Material</td>
<td>Titanium</td>
</tr>
<tr>
<td>Usable Capacity</td>
<td>20 mL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Precision Dosing System</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Accumulator stroke volume</td>
<td>2 µL</td>
</tr>
<tr>
<td>Material</td>
<td>Titanium</td>
</tr>
<tr>
<td></td>
<td>MP35N alloy</td>
</tr>
<tr>
<td></td>
<td>Stainless steel</td>
</tr>
<tr>
<td></td>
<td>Silicone rubber</td>
</tr>
</tbody>
</table>
3. Description

<table>
<thead>
<tr>
<th>Refill Septum</th>
<th>Catheter Access Septum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Septum material</td>
<td>Septum material</td>
</tr>
<tr>
<td>Silicone rubber</td>
<td>Silicone rubber</td>
</tr>
<tr>
<td>Access needle</td>
<td>Access needle</td>
</tr>
<tr>
<td>Huber point, 22G non-coring needle</td>
<td>Lancet point with side hole, 20G</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bacterial filter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material</td>
</tr>
<tr>
<td>Polyvinylidene fluoride</td>
</tr>
<tr>
<td>Pore size</td>
</tr>
<tr>
<td>0.22 micron</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Flow Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range</td>
</tr>
<tr>
<td>0-28.8 mL/day</td>
</tr>
<tr>
<td>Accuracy</td>
</tr>
<tr>
<td>95.9-97.7% (90% confidence limit)</td>
</tr>
<tr>
<td>Refill Interval</td>
</tr>
<tr>
<td>Not more than 90 days</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Flow Activated Valve (FAV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material</td>
</tr>
<tr>
<td>Same as Precision Dosing System</td>
</tr>
<tr>
<td>Maximum volume dispersed when closed</td>
</tr>
<tr>
<td>10 µL</td>
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The Prometra II Pump is supplied with a Catheter Access needle and a non-coring Refill needle for priming the pump at implantation. The Patient and Physician Information Packet contains a Patient Guide and two Patient Implant Cards to be completed and given to the patient. Additionally, a Patient Device Tracking Form is included and needs to be completed and returned to Flowonix.
4. Indications

The Prometra II Programmable Pump System is indicated for use in the treatment of chronic intractable pain and the management of severe spasticity. In the treatment of chronic intractable pain, it is intended for chronic, intrathecal infusion of preservative-free morphine sulfate solution. For the management of severe spasticity, it is indicated for chronic intrathecal infusion of baclofen injection sterile solution. Sterile preservative-free 0.9% saline solution may be used when therapy is interrupted to maintain catheter patency. Clinical safety and efficacy has been established in adult populations.

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

5. 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.
- The patient will require magnetic therapies.
- The patient will require hyperbaric treatments.
- The patient has an occupation where he/she would be exposed to high current industrial equipment, powerful magnets or transmitting towers, such as, electricians, electrical engineers or MRI technicians.

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

6.1 General

**WARNING: USE OF UNAPPROVED DRUGS (e.g., DRUG COCKTAILS, PHARMACY-COMPUNDED DRUGS, MORPHINE WITH PRESERVATIVES, ETC.) WITH THE PROMETRA II PUMP COULD RESULT IN PUMP FAILURE AND/OR SERIOUS ADVERSE EVENTS INCLUDING DEATH.**

- Prior to infusion of any substance into the catheter, medical personnel should be familiar with and observe all warnings, cautions, contraindications, and instructions as specified by the manufacturer of the infused substance.
- Patients should not undergo hyperbaric therapy since exposure could result in drug underdose.
- Always select and program drug dosages consistent with the drug labeling to prevent improper drug administration.
- In the event of over-medication, refer to the approved drug labeling for appropriate treatment.
- Clinicians implanting, programming, accessing, or maintaining implanted programmable pumps must comply with the instructions for use. Technical errors may result in a return of underlying symptoms, drug withdrawal symptoms, or clinically significant or fatal overdose.
- The Intrathecal Catheter and Prometra II 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).
- For MRI procedures, always follow the specific instructions detailed below in section titled, “Magnetic Resonance Imaging (MRI) Conditions for Safe Scanning”.
- If the Low Reservoir Alarm is **NOT** turned “On”, then the patient will not be warned when the drug amount reaches below a certain volume in the pump reservoir. The Low Reservoir Alarm is turned “Off” by default. To turn it “On”, see the Low Reservoir Alarm section.

6.2 Magnetic Resonance Imaging (MRI) Conditions For Safe Scanning

**MR Conditional**

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

**Warning:** Prior to performing an MRI on a patient with a Flowonix pump implanted, the exact pump model must be identified, since the pre-MRI and post MRI procedures differ significantly for each pump model.

**Warning:** If the pump model **CANNOT** be determined **OR** it is identified as a Prometra Pump, then the **PUMP MUST BE EMPTIED** of drug solution prior to entering the MRI environment. Strong magnetic fields, such as those created in MRI scanners, may cause the Prometra Pump 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 Prometra II Pump includes a Flow Activated Valve (FAV) designed to prevent a free-flow event in the presence of strong magnetic fields. However, prior to elective MRI procedures, it is required to empty the drug from the pump’s reservoir to prevent any possibility of an overdose to the patient.
6. Warnings

6.2 Magnetic Resonance Imaging (MRI) Conditions For Safe Scanning

6.2.1 Pump Model Determination

The pump model can be identified by one of the following methods:

- **Inquiry by programmer** - Identifies model either as Prometra II or Prometra on the Programmer’s Inquiry Screen.
- **Patient ID Card** - Identifies the pump model either as Prometra II (Model # 93827) or Prometra (Model # 91827) as noted in the examples below:

**Prometra II Pump Patient ID Card**

**Prometra Pump Patient ID Card**

- **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 Medical: Customer Care at +1 844-229-6729**: Pump information may be determined from our patient registration system. This number is staffed 24 hours a day.
6. **Warnings**

6.2 Magnetic Resonance Imaging (MRI) Conditions For Safe Scanning

6.2.1 Pump Model Determination

- **Perform an X-ray of the pump:** The Prometra II pump can be differentiated from the Prometra Pump via X-rays as shown in the images below. The image of the Prometra II Pump shows the addition of the flow-activated valve (FAV) within the Catheter Access Port.

![Prometra Pump X-ray](image1)

![Prometra II Pump X-ray](image2)

*Model is identified as a Prometra or cannot be identified*

If the model is identified as a Prometra or cannot be identified, do not proceed with the MRI procedure. The pump reservoir must be emptied prior to MR exposure. Please contact Customer Care with any questions: +1 844-229-6729.

6.2.2 Pre-MRI Instructions – Non-Emergency Situation

- The pump reservoir must be completely emptied of drug by following the procedures for emptying the Drug Reservoir that can be found in the Refill Kit Instructions for Use.
- Prior to initiating the MRI procedure, the physician should determine if the patient could 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.

6.2.3 Pre-MRI Instructions – Emergency Situation

If the model is positively identified as a Prometra II, and there is no time to remove the drug from the pump, proceed with the following Pre-MRI instructions:

*Warning:* Do not proceed with an MRI scan if the reservoir volume is ≤1mL or expected to be ≤1mL at the time of the MRI scan. If there is ≤1mL of drug in the reservoir, it should be removed prior to the procedure. When the reservoir volume is at < 1 mL, the Flow Activated Safety Valve (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 amount of drug in the pump, inquire with a Prometra Programmer. The reservoir volume is shown on the inquiry screens. If a Programmer is not available, then the drug should be removed from the pump.
6. **Warnings**

6.2 Magnetic Resonance Imaging (MRI) Conditions For Safe Scanning

6.2.3 Pre-MRI Instructions – Emergency Situation

- If > 1mL of drug is present in the reservoir, the FAV will shut during the MRI and the following applies:
  - During an MRI, the FAV of the Prometra II Pump will shut off drug flow. When this occurs a small amount, ≤10 µL, is delivered. The physician should determine if the patient can safely receive this bolus dose during the MRI procedure.\(^1\)\(^2\) If not, then the drug should be completely emptied from the pump’s drug reservoir prior to the MRI procedure.

**NOTE:**

1. For a pump containing morphine at a concentration of 25 mg/mL, a bolus dose of < 0.25 mg would be delivered to the patient during the MRI procedure.
2. For a pump containing baclofen at a concentration of 2 mg/mL, a bolus dose of < 20 µg would be delivered to the patient during the MRI procedure.

- Additionally, the FAV safety valve will prevent further drug delivery to occur until the pump is manually reset after the completion of the MRI procedure. The physician should determine if the patient can safely be deprived of medication until the pump 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 MRI.

6.2.4 MRI Scanning Parameters – Emergent and Non-Emergent Situations

The Prometra II Programmable Pump 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 410 Gauss/cm

**Warning:** Exceeding the 410 Gauss/cm 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 scanning in the Normal Operating Mode.

**NOTE:** The MRI conditions for safe scanning detailed in this document only pertain to the Prometra II Pump 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.

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\(^1\) Per 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.

\(^2\) Lioresal (Baclofen Injection) Instructions for Use. Medtronic, Inc., Minneapolis, MN. Gablofen (Baclofen Injection) Instruction for Use. Mallinckrodt Pharmaceuticals, Inc., Hazelwood, MO.
6. **Warnings**

6.2 Magnetic Resonance Imaging (MRI) Conditions For Safe Scanning

6.2.5 Tissue Heating, Magnetic Field and Image Artifacts

**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.

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.

**Static Magnetic Field**
In a 1.5 T 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 large 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 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 II 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.

6.2.6 Post-MRI Procedures

1. **Confirmation of Pump Operational Status**
   Inquire the pump with the programmer to verify pump operation and settings. If the programmer displays any pump errors, proceed to Step 2 “Clear Pump Errors”. If no pump errors are displayed, proceed to Step 3 “Pump Reset”.

   **Warning:** If pump status cannot be properly confirmed, DO NOT proceed since the pump may not be operating properly, please contact Flowonix Customer Care for assistance at: +1 844-229-6729.

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3 There are no changes between the Prometra pump and Prometra II pump that would significantly affect the ASTM MRI testing and MRI Scanning Parameters.
6. **Warnings**

6.2 Magnetic Resonance Imaging (MRI) Conditions For Safe Scanning

6.2.6 Post-MRI Procedures

2. Clear Pump Errors
   a. Inquire the pump with the programmer to determine if any errors have been generated during the MRI procedure.
   b. If pump errors are displayed, perform an emergency stop using the programmer.
   c. Program a Demand Bolus of 0mg for 1 minute
   d. Allow 1 minute to elapse to allow all errors to clear.
   e. Inquire the pump with the programmer to confirm errors are cleared, if errors persist please contact Flowonix Customer Care for assistance: +1 844-229-6729.

3. Pump Reset (Performed if drug remained in reservoir during MRI procedure. If drug was removed during MRI procedure, skip this step and proceed to Step 4, Refill Procedure)
   a. Aspirate the pump reservoir 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 center refill septum until needle tip resides completely inside the drug refill reservoir.
   d. Empty the pump 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. Once the pump is fully empty, program a demand bolus to deliver (0.03mL * concentration) over 2 minutes (this will not displace drug since the reservoir is empty)
   f. Wait for the 2 minute Demand Bolus to complete before proceeding to refill.

4. Refill Procedure
   a. Proceed to refill the pump 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 the drug’s prescribing information.

7. Precautions

7.1 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 II Programmable Pump in these instructions.
- The effects of implanting this device in patients with medical devices, other than neurostimulators, are unknown.
- Pain on injection that was not noted during previous injections may be an early sign of infection.
7. Precautions

7.2 Implantation

- Implantation of this device and subsequent use, reprogramming, and refill should only be conducted by qualified medical personnel specifically trained for surgical implantation, use, and maintenance of the device. Use of this device by non-qualified or untrained personnel could lead to serious consequences involving under- or over-medication. In the event of over-medication, refer to the approved drug labeling for appropriate treatment.
- The pump and catheter system should be implanted carefully to avoid any sharp or acute angles, which could compromise the patency of the catheter lumen.
- Over-pressurization can damage the catheter. Small syringes can generate very high pressures and may damage the catheter or catheter connection. Do not use a syringe smaller than 10 mL when accessing the catheter access chamber.
- If therapy is discontinued for an extended period, the pump should be emptied of the drug and filled with a preservative-free 0.9% sterile saline solution and programmed to a low infusion rate to maintain catheter patency.

7.3 Device Compatibility

- **Pump accessories.** Only use the Prometra II Programmable Pump with the accessories listed in these instructions for use. Use of alternate accessories may result in damage to Prometra II 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 II 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 II 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 II Pump with electric currents applied to the body such as cardioversion, defibrillation, or RF surgical tools 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 II Pump have not been established, and these therapies may have effects on pump operation that are not immediately apparent.
- **Magnetic fields.** Magnetic fields of 50 gauss or less will generally not affect the pump (e.g. Common therapeutic magnets or theft/security screening devices found in airports, libraries, and some department stores).
8. Potential Adverse Events

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

8.1 Possible Risks Associated with Programmable Implantable Pumps

- 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
- Overdose as a result of bolus delivered during MRI procedure (see MR conditions for safe scanning)
- Programming errors, resulting in over or under dosing
- Pain on injection
- 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

8.2 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
8. Potential Adverse Events

8.2 Possible Risks Associated with Intrathecal Catheter

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

8.3 Possible Risks Associated with baclofen Intrathecal Infusion

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

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

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

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

The following items may be needed and are not provided:
- Sterile Programmer Sleeve
- Sterile preservative-free 0.9% saline
- Drug solution (infusate) for refill, not to exceed 20 mL

10. Pump Operation

10.1 Programmable Features

The Prometra Pump Programmer uses telemetry to exchange information with the pump. This information includes the following:
- Date and Time
- Current Prescription
- Patient Identification
- Drug Name and Concentration
- Flow Mode, Drug Dose and Delivery Rate
- Pump Model and Serial Number
- Low Reservoir Setting and Alarm
- Low Battery Alarm
- Next Refill Date

The Prometra Programmer allows clinicians convenient, non-invasive access for interrogating and programming the implanted Prometra II Pump. Refer to the Prometra Programmer Instructions for Use for further information regarding pump programming.

10.2 Programming Medication Regimens

The Prometra II Programmable Pump can be programmed to deliver a precise flow of medication at a constant or variable rate, or it can be set to periodically deliver a drug dosage at distinct intervals of time (i.e. Periodic Flow Mode). There is also an option to interrupt the pump’s current medication regimen and deliver an immediate infusion of medication (Demand Bolus). Refer to the Prometra Programmer Instructions for Use for further information regarding pump programming.

⚠️ Warning: Implantation of the Prometra II Programmable Pump System 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. Prescription of pump infusion regimens may only be conducted by physicians with a full understanding of the relationships between concentration, dose, and infusion rate. Use of this device by non-qualified or untrained personnel could lead to serious consequences involving under or over-medication. In the event of over-medication, refer to the approved drug labeling for appropriate treatment.
10. Pump Operation

10.2 Programming Medication Regimens

The following illustrations describe the four basic medication regimens:

10.2.1 Constant Flow

The Constant Flow regimen delivers a specific daily dose, e.g. mg/24 hr, of drug at a constant flow rate dependent on the drug concentration.

```
Flow Rate
```

```
Time
```

Constant Flow Regimen

10.2.2 Multiple Rates

The Multiple Rates regimen delivers medication using one to four user-programmed rates that repeat daily. For each prescribed rate, the specific medication dose and time period is programmed.

```
Dose
```

```
Time (24 Hour)
```

Multiple Rates Regimen

10.2.3 Periodic Flow

The Periodic Flow regimen delivers medication in a sequence of periodic infusions. The medication dose, the time over which the dose is delivered, and the interval at which the dose is repeated are programmed.

```
Flow Rate
```

```
Time
```

Periodic Flow Regimen
10. Pump Operation

10.2 Programming Medication Regimens

10.2.4 Demand Bolus

The Demand Bolus regimen temporarily replaces the current dose regimen to deliver an immediate, one-time infusion of medication. The medication dose and the time over which the dosage is delivered are programmed. Once the Demand Bolus is complete, the pump resumes its previously programmed regimen.

![Demand Bolus Regimen Diagram]

10.3 Pre-Programmed Pump Settings

When the Prometra Programmer inquires the Prometra II Pump for the first time, the pump status screens display the pre-programmed pump settings. The clinician can change these presets using the programmer.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
<th>Data Preset</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>Name or code</td>
<td>No</td>
</tr>
<tr>
<td>Pump Model</td>
<td>Model of Pump</td>
<td>Yes, Prometra</td>
</tr>
<tr>
<td>Pump SN</td>
<td>Serial Number of Pump (e.g., 36DA4A77)</td>
<td>Yes, pump specific</td>
</tr>
<tr>
<td>Pump Ver.</td>
<td>Current control software version (e.g. 1.02)</td>
<td>Yes, pump specific</td>
</tr>
<tr>
<td>Drug</td>
<td>Drug contained in pump</td>
<td>No, specified by user</td>
</tr>
<tr>
<td>Conc</td>
<td>Concentration of drug in pump</td>
<td>Yes, preset to 1.000 mg/mL</td>
</tr>
<tr>
<td>Accum</td>
<td>Accumulator Volume Constant (e.g. 2.010 µL)</td>
<td>Yes, pump specific</td>
</tr>
<tr>
<td>Reservoir Volume</td>
<td>Current estimated volume contained in reservoir</td>
<td>Yes, 00.0 mL</td>
</tr>
<tr>
<td>Low Res. Alarm</td>
<td>Alarm to indicate reservoir volume is low</td>
<td>Yes, to OFF</td>
</tr>
<tr>
<td>Low Res. Volume</td>
<td>Setting to actuate Low Reservoir Alarm</td>
<td>Yes, 2.0 mL</td>
</tr>
<tr>
<td>Battery</td>
<td>Pump battery charge status</td>
<td>No, reports condition, e.g. OK or Low</td>
</tr>
<tr>
<td>Flow Mode</td>
<td>Constant Flow, Multiple Rates, Periodic Flow or Demand Bolus</td>
<td>Yes, to Constant Flow</td>
</tr>
<tr>
<td>Next Refill</td>
<td>Date: month/day/year (mo/da/yr) Calculated by programmer, appears after refill is programmed</td>
<td>No</td>
</tr>
<tr>
<td>Daily Dose</td>
<td>Programmed daily dose (e.g. 2.005 mg)</td>
<td>Yes, to 0.000 mg</td>
</tr>
</tbody>
</table>
10. Pump Operation

10.4 Pump Alarms

The Prometra II Pump has two audible alarms that alert patients and clinicians to low reservoir volume and critical errors that cause the drug delivery to stop. All alarms use the same tone but can be distinguished from each other by the number of “beeps” in a group and the length of each beep.

10.4.1 Low Reservoir Alarm

The Low Reservoir Alarm warns patients when the medication in the pump reservoir gets below a certain volume. The pump signals a low volume condition by sounding two short (1/4 second) beeps every 30 minutes. The alarm continues to sound until turned off by telemetry using the Prometra Pump Programmer or until a new volume of drug is programmed into the pump.

The Low Reservoir Alarm must be turned “On” and the threshold volume programmed using the Prometra Pump Programmer. When pumps are shipped from the factory, the Low Reservoir Alarm is set to “Off”. For information on setting the low reservoir volume and enabling the alarm, refer to the Prometra Programmer Instructions for Use.

10.4.2 Critical Error Alarm

The Critical Error Alarm alerts patients and clinicians that the pump has stopped delivering medication. The pump signals an error condition by sounding three long (1/2 second) beeps every 30 minutes. This alarm occurs for any detected condition that results in the pump not delivering medication, including a low pump battery.

If due to a low battery, the alarm will continue to sound until the pump is explanted or until the battery power is depleted to a point that the pump can no longer communicate with the programmer. As the battery is further depleted, the alarm signal may convert to a continuous tone. If due to another error condition, the alarm continues to sound until a drug delivery schedule is programmed using the Prometra Pump Programmer.

Each time the pump is inquired, the Prometra Pump Programmer reads and displays the condition(s) causing the alarm to sound. The Prometra Pump Programmer clears the error and attempts to restart the pump. If the error condition remains, the pump will restart the error alarm.

11. 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.

11.1 Pre-Implant Pump Preparation

Warning: Examine all packages carefully. If any package has been damaged or opened prior to use, do not use package contents. If the pump has been dropped onto a hard surface or shows signs of damage, do not implant. Do not resterilize any pump system components.

Warning: Make sure the Programmer is sealed in a Sterile Sleeve before approaching the sterile field.
11. Implantation Instructions

11.1 Pre-Implant Pump Preparation

1. Open the outer pump box and verify that the pump serial number on the pump matches that on the Patient Implant Card.
2. Place one of the pump labels on the patient implant card.
3. While the pump is still in the packaging and facing upward, turn the Programmer on, press inquire and place the Programmer over the pump.
4. From the Main Menu select Setup, Pump Setup, and then Patient Name.
5. Enter the patient's name using the select and navigation keys.
6. Transfer patient's name by placing the programmer over the pump.
7. Under Pump Setup, select low reservoir alarm and program the low reservoir alarm to the “ON” position at a level of 2.0 mL.
8. Verify that the daily dose limit is NOT enabled.
9. Program by placing the Programmer over the pump while still in the inner box.
10. From the main menu select refill.
11. Enter the appropriate information (drug, concentration, refill volume) into each field and then program the pump.
12. Again, from the main menu select constant flow and continue to program in the physician's prescribed daily dose.
13. Remove the pump from the package and pass the pump, catheter, and tunneler to the scrub nurse in sterile fashion.

11.1.1 Pump Priming Preparation

1. Attach a sterile syringe filled with 5 mL of sterile preservative-free 0.9% saline solution to the 22G non-coring needle provided in the Prometra II Pump tray.
2. Advance needle through center refill septum until needle tip resides completely inside the drug refill reservoir.

Caution: Do not force the needle. Excessive force on the needle may damage the needle tip. Do not rock the needle sideways as this could damage the septum or cause drug to leak from the reservoir.
11. Implantation Instructions

11.1 Pre-Implant Pump Preparation

11.1.1 Pump Priming Preparation

3. Inject the 5 mL of sterile preservative-free 0.9% saline solution into the drug reservoir.
4. Allow the saline solution to return from the pump reservoir into the empty syringe barrel (ensure that all air is removed, if a plunger is present it may prevent all air from being expelled).
5. **Note:** Return volume may be more or less than the infused volume. If air is noted, repeat the priming procedure with another 5 mL of the sterile saline solution.
6. Remove the syringe from the needle.
7. **Note:** Since some sterile saline will remain in the pump reservoir, the final concentration of drug varies based on the fill method. See the below table for the expected reduction in concentration.

<table>
<thead>
<tr>
<th>Expected concentration of drug in pump reservoir based on fill method</th>
<th>Filling without rinsing</th>
<th>Rinsing with 20 mL of drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>86%</td>
<td>97%</td>
<td></td>
</tr>
</tbody>
</table>

8. If rinsing the pump before filling, rinse and discard the returned volume based on the fill method shown above.
9. Verify that the volume of infusate in the syringe does not exceed 20 mL, the maximum volume of the pump reservoir. Attach the syringe filled with the infusate to the 22G non-coring needle provided with the pump.
10. **Caution:** When first filled, the Prometra II Pump has a small amount (2-3mL) of sterile water in the pump. As a result, there is an approximate 13% reduction in concentration of morphine sulfate or baclofen as a result of dilution in the initial filling of the 20mL drug reservoir.
11. Prior to using the syringe to fill the Prometra II Pump reservoir, ensure that air is purged from the syringe and needle using customary medical procedure.
12. Inject the infusate into the pump reservoir. Remove the needle and syringe assembly from the refill septum.
13. Remove and discard the knotted silicone rubber tubing from the pump stem.
14. Attach a syringe filled with 5 mL of sterile preservative free 0.9% saline to the 20G Catheter Access Port needle. Advance needle through the Catheter Access septum until needle tip resides completely inside the Catheter Access chamber.
11. Implantation Instructions

11.1 Pre-Implant Pump Preparation

11.1.2 Pump Priming

**Standard Priming Technique**

1. Flush 3mL of the 5ml slowly through the Catheter Access septum to remove air from the fluid pathway.
   - Remove the needle and syringe assembly from the Catheter Access chamber and discard.
2. Obtain a 1 L bag of heated (35-40°C) sterile saline.
3. Program 0.3 mg over a 16 minute demand bolus and immediately submerge the pump in the heated sterile saline bath.
4. After 11 minutes have elapsed, remove the pump from the saline and place on the sterile table.
5. Observe the pump for the remaining 5 minutes, fluid should be expelling from the pump stem every 8 seconds (could be observed as rhythmic spurting or growing fluid bead).

**Warning:** Please note that the bolus must be completed or if not completed, canceled prior to attaching pump to catheter to avoid medication advancement into the catheter. Do not cancel prior to 11 minutes to ensure fluid pathway is fully primed.

6. If fluid is not observed after following these steps, perform the “Alternate Priming Technique”
7. If fluid is not observed after performing the “Alternate Priming Technique” call Flowonix Customer Care at +1 844-229-6729. for further instructions.

**Alternate Priming Technique**

1. If not already performed, flush 3mL of the 5ml slowly through the Catheter Access septum to remove air from the fluid pathway. Remove the needle and syringe assembly from the Catheter Access chamber and discard.
2. Open a Prometra Refill kit, and using sterile scissors (or sterile blade) cut off one end of the extension set then remove and discard the clip.
3. Attach the cut end of the modified extension set tubing to the pump stem.
4. Retrieve 1 L pre-warmed sterile saline from the incubator.
5. Program a 0.3 mg over 16 minute demand bolus and immediately submerge the pump and modified extension set tubing in the heated sterile saline bath.
6. Confirm that fluid in the extension set tubing is advancing approximately 2-5mm every 8 seconds with the actuation of the valves. Ensure that the fluid movement is pulsatile and not due to thermal expansion.
7. If fluid is not observed after performing the “Alternate Priming Technique” call Customer Care at +1 844-229-6729 for further instructions.

**Warning:** Please note that the bolus must be completed or if not completed, canceled prior to attaching pump to catheter to avoid medication advancement into the catheter. Do not cancel prior to 11 minutes to ensure fluid pathway is fully primed.
11. Implantation Instructions

11.2 Implantation of the Intrathecal Catheter
1. Implant the Intrathecal Catheter as per the Prometra Intrathecal Catheter IFU.

11.3 Implantation of the Prometra II Programmable Pump
1. **USE STERILE TECHNIQUE.** Always inspect and aseptically prepare the site according to standard practice.
2. Form a subcutaneous pocket using standard technique ensuring snug fit for the pump. Do a trial placement to verify that the pocket is large enough to accommodate the pump and that the pump does not lie beneath the incision.

⚠️ **Warning:** Implant the pump 2.5 cm (1 in.) or less under the skin. Deeper implants could interfere with septum access or programming.

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

5. 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.

6. 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.
11. Implantation Instructions

11.3 Implantation of the Prometra II Programmable Pump

7. 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.

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

9. 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.

10. Place the pump in the subcutaneous pocket away from the incision line about 2.5 cm (1 in.) beneath the skin surface. The pump should be positioned so that the Catheter Access septum is medial. This allows the catheter a direct line to the spine and keeps this area away from the ribs.
11. Implantation Instructions

11.3 Implantation of the Prometra II Programmable Pump

11. Secure to the underlying fascia using one non-absorbable, monofilament suture per pump suture hole. This will reduce the risk of pump migration and the possibility of the pump rotating or flipping over.
12. Verify that the catheter is not kinked or constrained by the pump sutures.
13. After suturing the pump in the pocket, flush the wound with an appropriate antibiotic solution.
14. Close the incision site so that the pump does not lie beneath the incision.
15. Flush the paravertebral site with an appropriate antibiotic solution.
16. Close the entry site making sure the catheter remains straight.
17. 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.
18. Calculate and record the implanted catheter length and volume:

\[
\text{Implanted Catheter Length (cm)} = 110 \text{ cm} - \text{Trimmed Catheter Length (cm)}
\]
\[
\text{Implanted Catheter Volume (mL)} = \text{Implanted Catheter Length (cm)} \times 0.0026 \text{ mL/cm}
\]

**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.

11.4 Patient Implant Card and Registration

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

A patient guide and two patient implant cards are also provided for the patient. The patient implant card contains information pertinent to the implanted Intrathecal Catheter and Prometra II 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.

12. Pump Explantation

The Intrathecal Catheter and Prometra II 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.

13. Calculations

Please refer to the Prometra II Supplementary Calculations Guide.
14. Patient-Related Variables and Flow Rate Accuracy

The Prometra II Pump was designed such that changes in pressure or temperature in normal operating environments do not affect the pump’s operation.

14.1 Geographical Elevation

Activities that involve temperature or elevation changes such as skiing, flying, hot-tubbing, or saunas will not affect the operation of the pump.

Activities that involve an increase in environmental pressure of approximately 1 atmosphere or greater, such as scuba diving or hyperbaric therapy may cause the pump to temporarily stop delivering drug. When normal atmospheric pressure is returned, the pump will resume its programmed delivery rate.

14.2 Temperature Variation

Activities that involve temperature or elevation changes such as skiing, flying, hot-tubbing, or saunas will not affect the operation of the pump. Temperature related therapies such as deep heat therapy, e.g. diathermy, will not affect the operation of the pump.
14. Patient-Related Variables and Flow Rate Accuracy

14.3 Flow Rate Accuracy

Although it is strongly recommended to program the low reservoir volume alarm to 2 mL, it is important to know that reservoir volume down to 1 mL will not affect the operation of the pump. This margin of safety was designed to offer your patients an additional measure of comfort and safety.

Pump flow rate accuracy was evaluated at multiple infusion rates (≈0.05mL/day – 28.8mL/day), at 37°C body temperature, utilizing both constant flow and variable flow regimes.

14.4 Device Longevity

The useful life of the Prometra II Programmable Pump is dependent on the drug delivery rate. The Prometra II pump utilizes an accumulator and dual-gated valve system to regulate the flow rate in order to conserve energy required for pump operation. The life of the pump is a minimum of 10 years at a drug delivery rate of 0.25mL/day.
15. IMPLANTABLES WARRANTY

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

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

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