PROMETRA®

REFILL KIT (REF 11825)

For use with Prometra® Programmable Infusion Systems

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

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Contents

The following components are sterile and non-pyrogenic:

2 - Adhesive Bandages, Round
1 - Calibrated Syringe Barrel, 12 mL
1 - Syringe Cap
1 - Stopcock
1 - CSR Wrap
1 - Extension Tubing, 20 cm (8 in.), with Clamp
1 - Fenestrated Drape
1 - Filter, 0.22 micron
4 - Gauze Pads, 10 cm x 10 cm, (4 in. x 4 in.)
2 - Non-Coring Needles, 0.7 mm (22G) x 38 mm (1.5 in.)
1 - Refill Template

Description

The Refill Kit contains two (2) non-coring needles, a bacterial filter and other accessories for Drug Refill/Reservoir Access to the Programmable Pump.

For Indications, Contraindications, Warnings, Precautions and potential adverse events related to the Programmable Pump, refer to the appropriate Prometra Programmable Pump Physician's Manual.

Indications

The Refill Kit is indicated for use in patients with a Prometra Programmable Infusion System. It is intended for use in refilling the Drug Reservoir of the Pump.

Contraindications

The Refill Kit is contraindicated when the presence of infection is known or suspected.

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. 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 Infumorph® into the pump, medical personnel should be familiar with and observe all warnings, cautions, contraindications, and instructions as specified by the manufacturer of the infusate.
- The Refill Kit is supplied sterile and non-pyrogenic. The package 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 product is a potential biohazard. Handle and dispose of in accordance with accepted hospital practice and all applicable laws and regulations.

Magnetic Resonance Imaging (MRI) Safety Information

Prometra® 20 mL (REF 11827), Prometra® II 20 mL (REF 13827) and Prometra® II 40 mL (REF 16827) Programmable Pumps Magnetic Resonance Imaging (MRI) Instruction Guide

GENERAL

MR Conditional

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

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

Warning: EMPTY ALL DRUG SOLUTION FROM ALL PROMETRA 20 ML (REF 11827), PROMETRA II 20 ML (REF 13827) AND PROMETRA II 40 ML (REF 16827) PUMPS PRIOR TO ENTERING THE MRI ENVIRONMENT. If a patient with a Prometra II 20 mL (REF 13827) or Prometra II 40 mL (REF 16827) Pump requires an emergent MRI, please see page 11 of these instructions for more details on the potential risks involved.

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

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

WARNING: IF SUSPENDING INTRATHECAL DRUG THERAPY, ALTERNATIVE DRUG THERAPY ADMINISTRATION ROUTES (E.G., ORAL OR INTRAVENOUS) MAY BE NECESSARY. AN ALTERNATIVE ORAL OR PARENTERAL DOSE "EQUIVALENT" TO THE INTRATHECAL DOSE MAY RESULT IN SIDE EFFECTS THAT WARRANT TEMPORARY MONITORING IN AN EMERGENCY DEPARTMENT OR INPATIENT FACILITY.

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

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

SCANNING PARAMETERS

Non-clinical testing has demonstrated that the Prometra 20 mL (REF 11827), Prometra II 20 mL (REF 13827), and Prometra II 40 mL (REF 16827) Programmable Pumps are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

1. Static magnetic field of 1.5 T
2. Maximum spatial field gradient of 1,900 gauss/cm (19 T/m)

Warning: Exceeding the 1,900 gauss/cm (19T/m) at 1.5T limit could result in excessive force or torque which could lead to patient injury.

3. Maximum MR System reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) using body coil transmission.
4. Scan duration should be limited to 10 minutes per pulse sequence
5. All Pre-MRI Instructions must be completed.

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

Tissue Heating Adjacent to Implant during MR Scans

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

Warning: Static Magnetic Field

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

Image Artifacts

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

In non-clinical testing, the image artifact caused by Flowonix Medical's Prometra II 20 mL (REF 13827) and Prometra II 40 mL (REF 16827) Pumps extends approximately 18.5 cm from the device when imaged with a spin-echo or gradient-echo pulse sequence in a 1.5 T MRI system. Image artifacts may be reduced when sequences are 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.

SPECIFIC PRE-MRI INSTRUCTIONS

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

Prometra® 20 mL (REF 11827), Prometra® II 20 mL (REF 13827), and Prometra® II 40 mL (REF 16827) Programmable Pumps

Protocol for Prometra® 20 mL (REF 11827), Prometra® II 20 mL (REF 13827), Prometra® II 40 mL (REF 16827)Programmable Pumps

Pre-MRI Procedure

Warning: EMPTY ALL DRUG SOLUTION FROM ALL PROMETRA 20 ML (REF 11827), PROMETRA II 20 ML (REF 13827), AND PROMETRA II 40 ML (REF 16827) PUMPS PRIOR TO ENTERING THE MRI ENVIRONMENT. If a patient with a Prometra II 20 mL (REF 13827) or Prometra II 40 mL (REF 16827) Pump requires an emergent MRI, please see page 11 of these instructions for more details on the potential risks involved.

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

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

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

PERFORM THE FOLLOWING STEPS PRIOR TO ENTERING THE MRI ENVIRONMENT.

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

NOTE: If the Clinician Programmer repeatedly displays the message “Pump Communication Failed. Please try again”, the Programmer software version may not be compatible with the pump model. In the event that a Programmer is confirmed to not be compatible with the pump model,

Flowonix Technical Solutions will provide instructions to empty the drug reservoir prior to an MRI without performing additional pump programming. Prior to emptying the drug reservoir, the physician must determine if the patient can safely be deprived of medication until the post-MRI procedure can be completed with a Programmer that is compatible with the pump model. An alternate means of drug delivery (such as IV administration or oral drug therapy) should be employed, if medically necessary, while the pump is not delivering drug therapy. Please contact Flowonix Technical Solutions for assistance at: 855-356-9665.

WARNING: IF PUMP STATUS CANNOT BE PROPERLY CONFIRMED, DO NOT PROCEED SINCE THE PUMP MAY NOT BE OPERATING PROPERLY OR THE PROGRAMMER SOFTWARE MAY NOT BE COMPATIBLE WITH THE PUMP. PLEASE CONTACT FLOWONIX TECHNICAL SOLUTIONS FOR ASSISTANCE AT: 855-356-9665.

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

3. **Empty Drug Reservoir**
   Follow the procedures for emptying the Drug Reservoir in the Refill Kit Instructions for Use. Be sure to recall the maximum volume of the pump, which may be either 20mL or 40mL, depending on the pump type and model.

SPECIFIC POST-MRI INSTRUCTIONS

Protocol for Prometra® 20mL (REF 11827), Prometra® II 20 mL (REF 13827), and Prometra® II 40 mL (REF 16827) Programmable Pumps

Post-MRI Procedure

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

WARNING: IF PUMP STATUS CANNOT BE PROPERLY CONFIRMED, DO NOT PROCEED SINCE THE PUMP MAY NOT BE OPERATING PROPERLY OR THE PROGRAMMER SOFTWARE MAY NOT BE COMPATIBLE WITH THE PUMP. PLEASE CONTACT FLOWONIX TECHNICAL SOLUTIONS FOR ASSISTANCE AT: 855-356-9665.

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

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

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

4. **Refill The Drug Reservoir**
   a. Proceed to refill the Drug Reservoir in accordance with the refill procedure defined in the Refill Kit Instructions for Use. Be sure to recall the maximum volume of the pump, which may be either 20mL or 40mL, depending on the pump type and model.
   b. Confirm the correct prescription is programmed, or program a new prescription.

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

IN THE EVENT OF A MEDICAL EMERGENCY REQUIRING AN MRI SCAN:

Prometra® 20 mL Programmable Pump (REF 11827)

Medication **MUST** be removed from the Prometra® 20 mL Pump (REF 11827). Do not expose patient to MRI magnetic fields with drug in the Prometra Drug Reservoir, even in the event of a medical emergency. Follow instructions above (Pre-MRI) for removing drug from the Prometra Pump.

WARNING: FAILURE TO EMPTY THE PUMP PRIOR TO EXPOSURE TO MRI ENVIRONMENT COULD RESULT IN DRUG OVERDOSE THAT COULD LEAD TO SERIOUS PATIENT INJURY OR DEATH.

Prometra® II 20mL (REF 13827) and Prometra® II 40 mL (REF 16827) Programmable Pumps

In the event of a medical emergency requiring a STAT MRI, the treating physician must be aware of the following as inputs to decision making regarding proceeding with an Emergency MRI for the Prometra II 20mL Pump (REF 13827) and the Prometra II 40mL Pump (REF 16827):

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.

WARNING: In the event an MRI scan was performed on a patient with a **Prometra® II 20 mL (REF 13827) or Prometra® II 40 mL (REF 16827) Pump** where the drug was NOT removed due to a medical emergency situation, the **Prometra® II 20 mL (REF 13827) and Prometra® II 40 mL (REF 16827) Pumps** contain a Flow Activated Valve (FAV) intended to reduce, but not eliminate, the risk of drug overdose. A physician must evaluate the patient immediately for signs and symptoms of drug overdose and develop a plan for immediate monitoring in a medically supervised and adequately equipped environment. Resuscitative equipment should be available, as should medications to manage drug overdose.

FLOWONIX STRONGLY RECOMMENDS THAT ALL DRUG BE REMOVED FROM THE PROMETRA® II 20 ML (REF 13827) AND PROMETRA® II 40 ML (REF 16827) DRUG RESERVOIRS PRIOR TO ANY MRI SCAN.

The Prometra® II 20 mL (REF 13827) and Prometra® II 40 mL (REF 16827) Pumps include a Flow Activated Valve (FAV) intended to reduce, but not eliminate, the risk of drug over-infusion during an MRI procedure.

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

The Flow Activated Valve (FAV) of the Prometra® II 20 mL (REF 13827) and Prometra® II 40 mL (REF 16827) Pumps is intended to shut off drug flow when exposed to strong magnetic fields. When this occurs a small amount of drug, ≤10 µL, will be delivered to the patient. **The physician must determine if the patient can safely receive this 10 µL bolus dose during the Emergency MRI procedure[1].** If not, then all drug must be completely emptied from the Drug Reservoir prior to the Emergency MRI procedure.

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

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

In the event that an Emergency MRI scan was performed on a patient with a Prometra® II 20 mL (REF 13827) or Prometra® II 40 mL (REF 16827) pump in which the drug was NOT removed due to a medical emergency situation, the FAV must be reset by performing a reset procedure.

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

Emergency Procedure PRE-MRI Steps for Prometra® II 20 mL (REF 13827) and Prometra® II 40 mL (REF 16827) Pumps

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

NOTE: If the Clinician Programmer repeatedly displays the message "Pump Communication Failed. Please try again", the Programmer software version may not be compatible with the pump model. In the event that a Programmer is confirmed to not be compatible with the pump model, Flowonix Technical Solutions will provide instructions to empty the drug reservoir prior to an MRI without performing additional pump programming. Prior to emptying the drug reservoir, the physician must determine if the patient can safely be deprived of medication until the post-MRI procedure can be completed with a Programmer that is compatible with the pump model. An alternate means of drug delivery (such as IV administration or oral drug therapy) should be employed, if medically necessary, while the pump is not delivering drug therapy. Please contact Flowonix Technical Solutions for assistance at: 855-356-9665.

WARNING: IF PUMP STATUS CANNOT BE PROPERLY CONFIRMED, DO NOT PROCEED SINCE THE PUMP MAY NOT BE OPERATING PROPERLY OR THE PROGRAMMER SOFTWARE MAY NOT BE COMPATIBLE WITH THE PUMP. PLEASE CONTACT FLOWONIX TECHNICAL SOLUTIONS FOR ASSISTANCE AT: 855-356-9665.

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

Emergency Procedure POST-MRI Steps for Prometra® II 20 mL (REF 13827) and Prometra® II 40 mL (REF 16827) Pumps

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

WARNING: IF PUMP STATUS CANNOT BE PROPERLY CONFIRMED, DO NOT PROCEED SINCE THE PUMP MAY NOT BE OPERATING PROPERLY OR THE PROGRAMMER SOFTWARE MAY NOT BE COMPATIBLE WITH THE PUMP. PLEASE CONTACT FLOWONIX TECHNICAL SOLUTIONS FOR ASSISTANCE AT: 855-356-9665.

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

3. **FAV Reset Procedure**
   a. Remove drug from Drug Reservoir by aspirating through the Refill Port.
   b. To aspirate, attach the 22G non-coring needle to a syringe barrel (available in Refill Kit).
   c. Advance needle through the center Refill Port Septum until needle tip resides completely inside the Drug Reservoir.
   d. Empty the Drug Reservoir until there is no more fluid returning to the syringe barrel. Be sure to recall the maximum volume of the pump which may be either 20mL or 40mL, depending on the pump type and model. (Refer to Refill Kit Instructions for Use for further details on emptying the pump).
   e. After ensuring the Drug Reservoir is fully empty, program a Demand Bolus to deliver (0.03 mL x concentration) over 2 minutes (this will not dispense drug since the Drug Reservoir is empty).
   f. Wait for the 2-minute Demand Bolus to complete before proceeding.

4. **Confirm Inlet / Outlet Valve Closure**
   a. Attempt to aspirate the Drug Reservoir through the Refill Port. To aspirate, attach a sterile syringe to the 22G non-coring needle used in Step 3c above.
   b. Pull a vacuum with the syringe for approximately 10 to 30 seconds to confirm Inlet / Outlet Valve closure.

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

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

5. **Refill The Drug Reservoir**
   a. Proceed to refill the Drug Reservoir in accordance with the refill procedure defined in the Refill Kit Instructions for Use. Be sure to recall the maximum volume of the pump which may be either 20mL or 40mL, depending on the pump type and model.

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

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

Pump Model and Volume Determination

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

- **Inquiry by programmer:** See tables below for information on pump compatibility and pump model information displayed on the Inquiry Screen for Prometra Clinician Programmers (REF 12828 and REF 13828). Contact Flowonix Technical Solutions at 855-356-9665 if you require access to a Flowonix Clinician Programmer with upgraded software.

Pump Compatibility with Clinician Programmer Software Versions		
	Clinician Programmer software version 2.01.5	Clinician Programmer software versions 1.02.1, 1.03.2, 1.04.10, 2.00.29, 2.00.30
Prometra 20 mL (REF 11827	✓	✓
Prometra II 20mL (REF 13827)	✓	✓
Prometra II 40 mL (REF 16827)	✓	Not compatible, programmer displays “Communication Failed. Please try again”

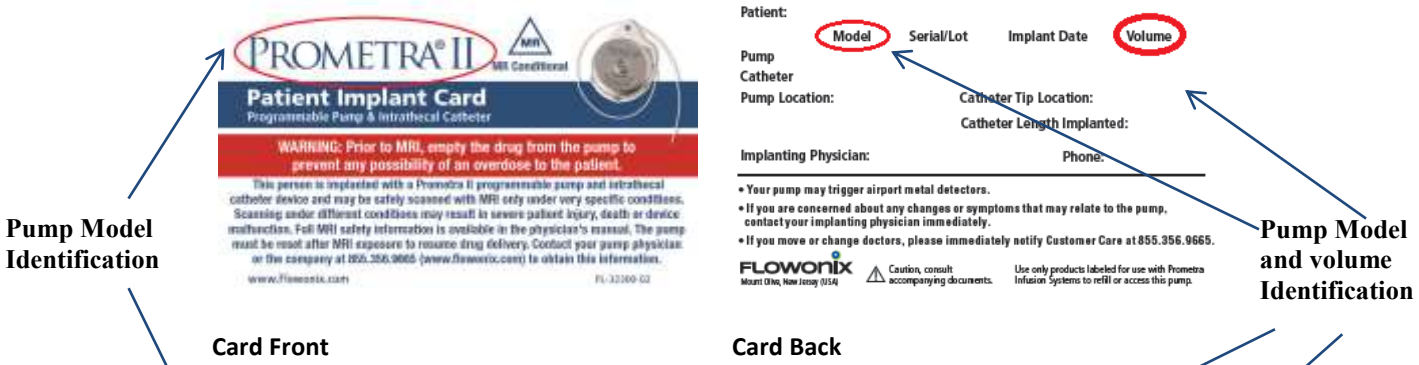
“Pump Model” Information Displayed on Inquiry Screen for Clinician Programmer Software Versions		
	Clinician Programmer software version 2.01.5	Clinician Programmer software versions 1.02.1, 1.03.2, 1.04.10, 2.00.29, 2.00.30
Prometra 20 mL (REF 11827	Prometra 20 mL	Prometra
Prometra II 20 mL (REF 13827)	Prometra II 20 mL	Prometra II
Prometra II 40 mL (REF 16827)	Prometra II 40 mL	Programmer displays “Communication Failed. Please try again.” The Inquiry Screen is not displayed.

Patient ID Card: : Identifies the pump model as **Prometra®** (Model # **11827, 20 mL Volume**), **Prometra® II** (Model # **13827, 20 mL Volume**) or **Prometra® II** (Model # **16827, 40 mL Volume**) as noted in the examples on the following page.

- **Note:** Patients with **Prometra® 20 mL (REF 11827), Prometra® II 20 mL (REF 13827) and Prometra® II 40 mL (REF 16827) Pumps** also have Medical Alert bracelets that indicate that the pump must be emptied prior to an MRI.

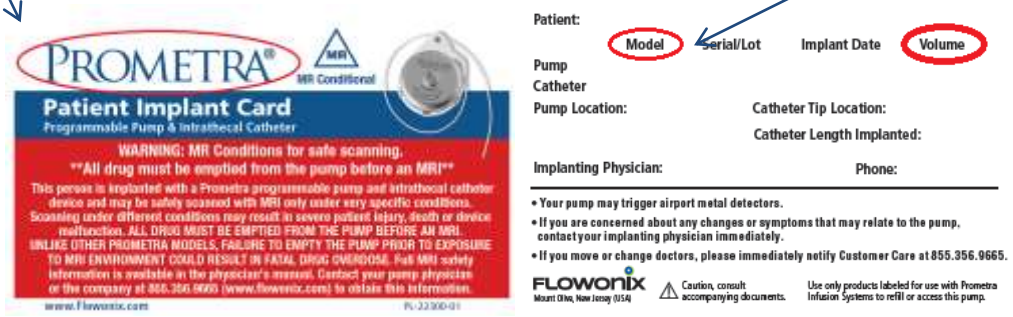
- **Contact patient's pump management physician:** The patient's medical records indicate the pump model and serial number implanted. **Flowonix provides medical chart labels to facilitate patient record documentation.**
- **Pump serial number:** There is a distinct difference in the serial numbers for the Prometra® 20 mL (REF 11827) Pump versus the Prometra® II 20 mL (REF 13827) and Prometra® II 40 mL (REF 16827) Pumps. The Prometra® II 20 mL (REF 13827) and Prometra® II 40 mL (REF 16827) pumps' serial number ends with an X, while the Prometra® 20 mL (REF 11827) Pump's serial number ends with a number.
- **Contact Flowonix Technical Solutions at 855-356-9665:** Pump information may be determined from our patient registration system. **This number is staffed 24 hours a day.**
- **Perform an X-ray of the pump:** The Prometra® II 20 mL (REF 13827) and the Prometra® II 40 mL (REF 16827) pumps can be differentiated from the Prometra® 20 mL (REF 11827) Pump via X-rays as shown on the following page. The image of the Prometra® II 20 mL (REF 13827) and Prometra® II 40 mL (REF 16827) Pumps shows the addition of the flow-activated valve (FAV) within the Catheter Access Port.

Prometra® II Pump Patient ID Card

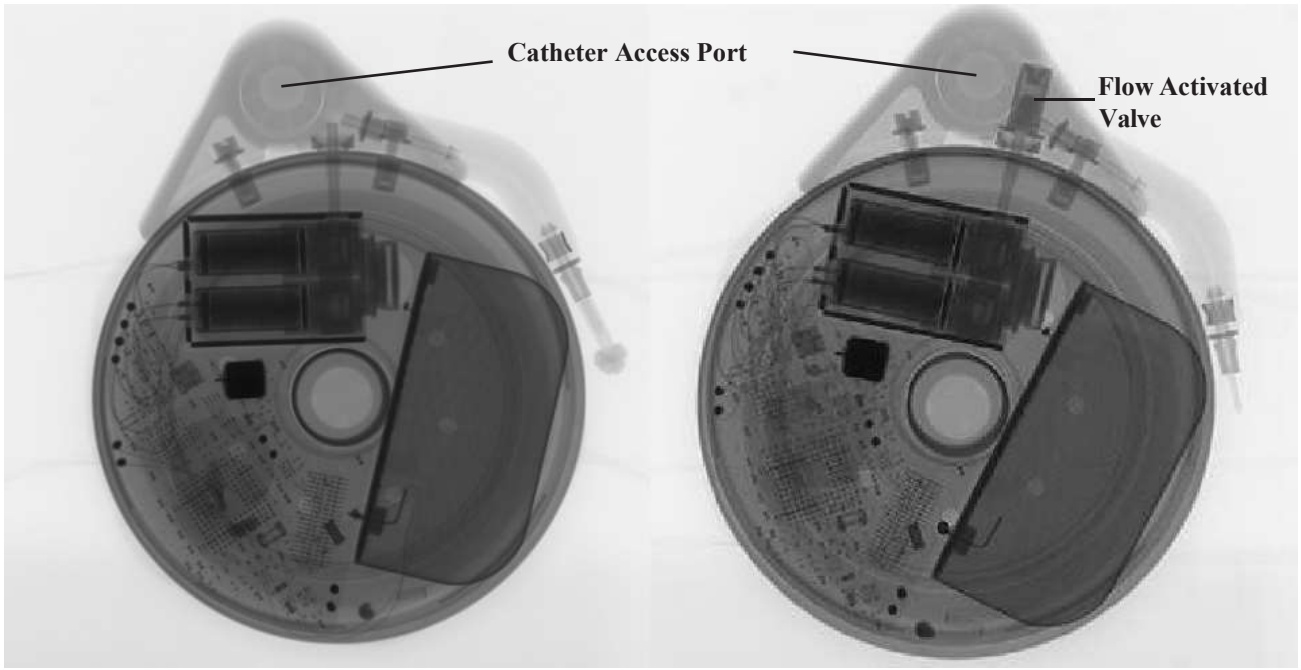


Card Front **Card Back**

Prometra® Pump Patient ID Card



Card Front **Card Back**



Prometra® 20 mL (REF 11827) Pump X-ray **Prometra® II 20 mL (REF 13827) Pump X-ray**

Precautions

- Carefully read and follow all instructions prior to use. Follow all instructions.
- Do not inject contrast media into the drug refill/reservoir septum as this may impair or damage the pump operation.
- Pain on injection that was not noted during previous injections may be an early sign of infection.
- 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.
- Use of this device should only be conducted by qualified medical personnel specifically trained in its use. 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.

Potential Adverse Events

The use of implanted pumps provides an important means of treating patients. However, the potential exists for serious complications. Please refer to the appropriate Prometra Programmable Pump instructions for a complete list.

Equipment

- Prometra Refill Kit
- Prometra Programmer (not sterile)

The following items may be needed and are not included:

- Sterile programmer sleeve
- 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
- Sterile preservative-free 0.9% saline
- Sterile pen
- Printer (not sterile)
- Programmer printer cable (not sterile)

Refill Template

Instructions

Before refilling or suspending drug therapy of the Programmable Pump, the drug refill reservoir must be emptied.

WARNING: DETERMINE THE PUMP NAME, MODEL NUMBER, AND MAXIMUM PUMP VOLUME PRIOR TO EMPTYING AND/OR REFILLING THE DRUG REFILL/RESERVOIR.

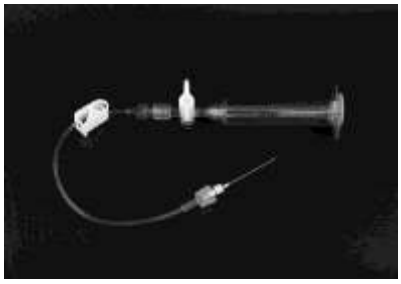
WARNING: IF SUSPENDING INTRATHECAL DRUG THERAPY, ALTERNATIVE DRUG THERAPY ADMINISTRATION ROUTES (E.G., ORAL OR INTRAVENOUS) MAY BE NECESSARY. AN ALTERNATIVE ORAL OR PARENTERAL DOSE "EQUIVALENT" TO THE INTRATHECAL DOSE MAY RESULT IN SIDE EFFECTS THAT WARRANT TEMPORARY MONITORING IN AN EMERGENCY DEPARTMENT OR INPATIENT FACILITY.

Emptying the Drug Refill/Reservoir

1. Turn the Programmer ON and select Inquiry. Place the Prometra Programmer over the pump. An audible tone sounds during inquiry of the pump. Check the **Inquiry** screen and note the **Reservoir Volume**. The Reservoir Volume is the expected volume of fluid remaining in the pump.
   Note: Prometra® II 40 mL (Model # 16827) Programmable Pumps are not compatible with Prometra Programmers (Model #12828 and Model # 13828) with software versions prior to 2.01.5. If a user attempts to inquire the 40 mL pump, the programmer will display a "Communication Failed. Please try again" message. Contact Flowonix Technical Solutions at 855-356-9665 if you require access to a Flowonix Programmer.
2. **USE STERILE TECHNIQUE.** Always inspect and aseptically prepare the site according to standard practice.
3. Locate the drug refill/reservoir septum with palpation and by placing the refill access template over the pump and aligning the edges of the template with the edges of the pump. You may use a sterile pen to mark the site for needle entry and set template aside.

   Warning: Always use the Prometra Refill Access Template to ensure proper access to the drug refill/reservoir septum. Using the incorrect template may result in drug overdose or infusate delivery into the pump pocket. If you are unsure of the proper access, use image guidance to verify proper needle placement.

4. Attach one of the 22G non-coring needles to the extension tubing.
   Warning: Use only the 22G non-coring needle supplied in the Refill Kit to access the drug refill/reservoir septum.
5. Slide the extension tubing clamp as far as possible toward the loose end of the tubing and close the clamp.
6. Attach the stopcock to the extension tubing. Turn the stopcock to the OFF position**,** perpendicular to the extension tubing.
7. Attach the syringe barrel to the stopcock. Place the syringe cap on the open end of the syringe barrel.
   Warning: Use only the calibrated syringe barrel supplied in the Refill Kit to collect infusate from the drug reservoir.
   Caution: Always make sure all connections are secure before addressing needle to skin. This will prevent leaks.



Emptying Setup

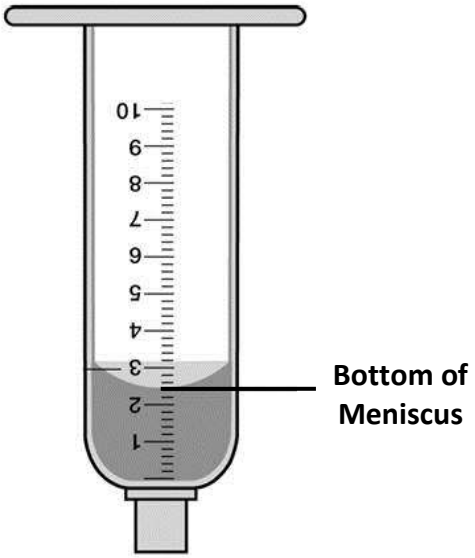
8. Insert the needle through the center of the drug refill/reservoir access septum, perpendicular to the skin and the pump. Advance the needle until the needle tip resides completely inside the refill chamber.
   Caution: Do not force the needle. Excessive force on the needle may damage the needle tip. Do not rock the needle sideways as this may damage the septum or cause drug to leak into the pump pocket.

Emptying Setup in Pump

9. Always carefully measure and record empty volume. The measurement of this volume is important to ensure that the pump is working properly.
10. *If the **Reservoir Volume** is less than 10 mL*, open the clamp on the extension tubing. Slowly turn the stopcock from perpendicular to inline with the extension tubing to open the stopcock. Allow the internal pump pressure to push the contents of the pump into the syringe barrel. This is the **Empty Volume**. Close the clamp on the extension tubing and disconnect the stopcock with its attached capped syringe barrel from the extension tubing. Set the stopcock aside and discard the syringe barrel.
11. *If the **Reservoir Volume** is greater than 10 mL*, then the Empty Volume must be collected in two to four steps (depending on the **Reservoir Volume**) using the same emptying setup.

<u>Collection of infusate:</u>

11.1. Open the clamp on the extension tubing. Slowly turn the stopcock from perpendicular to inline with the extension tubing to open the stopcock. Allow the internal pump pressure to push the contents of the pump into the syringe barrel.
11.2. Using the stopcock valve as a volume control device, collect up to 10 mL in the syringe barrel. Turn the stopcock valve to the OFF position and close the clamp on the extension tubing.
11.3. Disconnect the stopcock with its attached syringe barrel from the extension tubing. Holding the syringe barrel vertical and at eye level, read the **bottom of the meniscus** formed by the fluid to the nearest 0.2 mL. Record the syringe barrel volume.



11.4. Place the stopcock-syringe barrel assembly over the sterile Refill Kit Tray.

11.5. Turn the stopcock valve to the ON position to discard the Step One Empty Volume. When the syringe barrel and stopcock are empty, turn the stopcock valve to the OFF position.

If infusate remains in the reservoir:

11.6. Reattach the stopcock-syringe barrel assembly to the extension tubing. Repeat steps 11.1 – 11.5 until the reservoir is empty.

12. Once the reservoir is empty, close the clamp on the extension tubing and disconnect the stopcock with its attached capped syringe barrel from the extension tubing. Set the stopcock aside and discard the syringe barrel.

Calculating Empty Volume

13. If multiple syringe barrel volumes were collected, the **Empty Volume** is the sum of the syringe volume(s) minus the correction factor as shown in Table 1.

Note: The syringe barrel takes into account the 0.3mL stopcock volume and the 0.3mL tubing volume. By design, the markings on the Flowonix Refill Kit syringe barrel are offset and include the volume of infusate in the stopcock and tubing as well as the volume in the syringe barrel. There is no need to adjust the volume measured on the syringe barrel for the first emptying, because the syringe barrel already takes this volume into account. However, upon each additional emptying, the tubing volume must be subtracted because the extension tubing is not emptied between steps.

Table 1. Calculating Empty Volume				
-	***< 10 mL***	***10mL to 20 mL***	***20 mL to 30 mL***	***> 30 mL***
1st Syringe	All volume	Up to 10 mL	Up to 10mL	Up to 10 mL
2nd Syringe		Remaining Volume	Up to 10mL	Up to 10mL
3rd Syringe			Remaining Volume	Up to 10mL
4th Syringe				Remaining Volume
Correction Factor (Tubing Volume)	0.0 mL	0.3 mL	0.6 mL	0.9 mL
EMPTY VOLUME = TOTAL SYRINGE VOLUME(S) - CORRECTION FACTOR				

Example 1. *Two syringe barrel volumes collected*
Syringe Barrel Volume 1: 10 mL
Syringe Barrel Volume 2: 3.6 mL
Empty Volume = 10 mL + 3.6mL – 0.3 mL = 13.3 mL

Example 2. *Three syringe barrel volumes collected*
Syringe Barrel Volume 1: 10 mL
Syringe Barrel Volume 2: 10 mL
Syringe Barrel Volume 3: 5.2 mL
Empty Volume = 10 mL + 10 mL + 5.2 mL – 0.6 mL = 24.6 mL

14. Compare the **Empty Volume** to the **Reservoir Volume** to confirm that the pump is flowing properly.

WARNING: DETERMINE THE PUMP NAME, MODEL NUMBER, AND MAXIMUM PUMP VOLUME PRIOR TO EMPTYING AND/OR REFILLING THE DRUG REFILL/RESERVOIR.

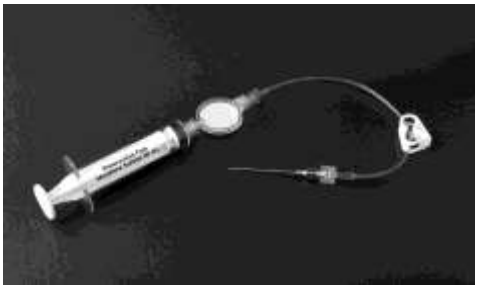
WARNING: IF SUSPENDING INTRATHECAL DRUG THERAPY, ALTERNATIVE DRUG THERAPY ADMINISTRATION ROUTES (E.G., ORAL OR INTRAVENOUS) MAY BE NECESSARY. AN ALTERNATIVE ORAL OR PARENTERAL DOSE "EQUIVALENT" TO THE INTRATHECAL DOSE MAY RESULT IN SIDE EFFECTS THAT WARRANT TEMPORARY MONITORING IN AN EMERGENCY DEPARTMENT OR INPATIENT FACILITY.

Filling the Drug Refill/Reservoir

A refill procedure should be scheduled to avoid interruption of drug therapy. Please refer to the **Calculations Guide** for any needed formulas or calculations.

1. **USE STERILE TECHNIQUE**. Always inspect and aseptically prepare the site according to standard practice.
2. Before refilling or suspending drug therapy of the Programmable Pump, the drug refill/reservoir must be emptied. Refer to Emptying instructions.
3. *If changing drug concentration*, refer to the supplementary **Calculations Guide** to determine the refill syringe concentration.
   Warning: If changing drug concentration, always adjust the concentration in the refill syringe to account for the residual current drug concentration and volume in the drug reservoir.
4. Obtain one refill syringe with 20 mL or less of the prescribed drug solution for pumps with 20 mL reservoir capacities and two refill syringes with 20 mL or less of the prescribed drug solution for pumps with 40 mL reservoir capacities. Confirm that the volume of the infusate in each syringe does not exceed 20 mL. For pumps with 40 mL reservoir capacities, proceed through steps 5-8 with the first syringe. The second syringe is used starting with step 9.
5. Attach 0.22 micron filter to the refill syringe containing the prescribed infusate. Prime filter with infusate to remove air. Confirm and record the volume of infusate remaining in the syringe, accounting for any that was lost when priming the filter.

6. Attach the filter-syringe assembly to the extension tubing already attached to the needle in the pump to create the refill setup. Verify that there is no air in the system.



Refill Setup

7. If the needle is not already in the septum from the emptying procedure, insert the needle through the center of the drug refill/reservoir access septum, perpendicular to the skin and the pump. Advance the needle until the needle tip resides completely inside the refill chamber.
Caution: Do not force the needle. Excessive force on the needle may damage the needle tip. Do not rock the needle sideways as this may damage the pump or cause drug to leak into the pump pocket.

Refill Setup in Pump

8. Keeping downward pressure on the syringe plunger, open the extension tubing clamp. To verify that the needle is in the correct position in the reservoir, begin slowly infusing 0.5 mL to 1 mL ONLY of the refill solution into the drug reservoir. Slowly release pressure on the syringe plunger to allow approximately half the volume of infusate back into the syringe, confirming the needle is correctly seated in the reservoir.
   Caution: If the infusate does not return back into the syringe when pressure to the syringe plunger is released, do not continue to infuse until proper placement of the needle has been verified.
   After confirming correct needle position, continue to slowly infuse 2 mL of refill solution into the drug reservoir then slowly release the pressure on the syringe to allow 1 mL to infusate back into the syringe. At every 5 mL increment, release pressure on the syringe plunger to allow 1 mL of infusate back into the syringe. This will verify that the needle is in the correct position and the drug refill reservoir is being filled.
   Caution: If the infusate does not return back into the syringe when pressure to the syringe plunger is released, do not continue to infuse until proper placement of the needle has been verified.
9. When all of the refill solution has been infused from the syringe into the drug reservoir, if another syringe is required for the refill procedure, maintain downward pressure on the syringe plunger, clamp the extension tubing, and disconnect the filter-syringe assembly from the extension tubing already attached to the needle in the pump. Repeat **Steps 5** through **8** to refill the pump reservoir with another 20 mL of refill solution.
10. When refill of the drug reservoir is completed, maintain downward pressure on the syringe plunger, clamp the extension tubing, and remove the needle from the refill septum. Discard the tubing, syringe and the needle.
    Caution: Do not rock the needle sideways as this may damage the pump or cause drug to leak into the pump pocket.
11. Using the Prometra Programmer, program the refill information into the pump. If the drug dose has been changed, program the new drug dose.
    Caution: Always program a flow rate of 0.1 mL/day or greater to maintain catheter patency.
12. If you have changed drug concentration, you must calculate and program a bridge bolus to deliver the residual drug in the pump and implanted catheter at the new rate. Refer to the supplementary **Calculations Guide** to make this calculation and to the Catheter Access Kit instructions for use to perform the bridge bolus(es).
13. Once the bridge bolus(es) is completed, the new drug regimen starts, using the new drug concentration in the reservoir.

Suspending Drug Therapy - Pump Rinse

Always empty then flush the pump twice with sterile preservative-free 0.9% saline when suspending drug therapy. Use two 20 mL volumes for pumps with reservoir volumes of 20 mL and four 20 mL volumes for pumps with reservoir volumes of 40 mL. It is important to empty and flush the pump twice to dilute residual drug left in the pump to non-therapeutic levels.

1. **USE STERILE TECHNIQUE**. Always inspect and aseptically prepare the site according to standard practice.
2. Before refilling or suspending drug therapy of the Programmable Pump, the drug refill/reservoir must be emptied. Refer to Emptying instructions.
3. If required, drug remaining in Intrathecal Catheter and Catheter Fluid Pathway can be removed via aspiration. Refer to the Catheter Access Kit instructions for use to perform the aspiration.
   Warning: If the Catheter Access chamber is not aspirated the drug in the pump fluid pathway and catheter will be administered to the patient at the flow rate programmed after the pump rinse.
   Warning: After aspiration, the pump fluid pathway still contains drug (approximately 0.137mL for Prometra, 0.153mL for Prometra II) at the concentration previously in the reservoir. This volume of

drug will be administered to the patient at the drug flow rate programmed into the pump after pump rinse. Refer to the Calculations Guide for more information.

4. Fill a 20 mL syringe with sterile preservative-free 0.9% saline solution.
5. Attach 0.22 micron filter to the saline-filled syringe and prime the filter with saline to remove air. Confirm that the syringe still contains 20 mL or fill with sterile preservative-free 0.9% saline solution to 20 mL.
6. Attach the filter-syringe assembly to the extension tubing already attached to the needle in the pump. Verify that there is no air in the system. Set aside this Pump Rinse setup.
7. Open the extension tubing clamp. Keep downward pressure on the needle and begin slowly infusing the saline solution into the drug reservoir. At every 5 mL increment, release pressure on the syringe plunger to allow 1 mL of saline back into the syringe. This will verify that the needle is in the correct position and drug reservoir is being filled.
   Caution: If the sterile saline solution does not return back into the syringe when pressure to the syringe plunger is released, do not continue to infuse until proper placement of the needle has been verified.
8. For pumps with a 20 mL reservoir capacity: When all of the saline solution is in the pump reservoir, allow the contents of the pump to empty back into the 20 mL syringe. When the pump is empty, clamp the extension tubing. Disconnect the syringe and discard the saline.
   For pumps with a 40 mL reservoir capacity: When all of the saline solution is in the pump reservoir, clamp the extension tubing and disconnect the filter-syringe assembly from the extension tubing already attached to the needle in the pump. Repeat **Steps 4** through **7** to refill the pump reservoir with another 20 mL sterile saline solution. When all of the saline solution is in the pump reservoir, allow the contents of the pump to empty back into the 20 mL syringe. When the syringe is full, clamp the extension tubing, disconnect the syringe, and discard the saline. Reconnect the syringe. Open the extension tubing clamp to allow the contents of the pump to empty back into the 20 mL syringe. When the syringe is full, clamp the extension tubing, disconnect the syringe, and discard the saline.
9. Repeat **Steps 4** through **8** for the second pump rinse.
10. After the second rinse, repeat **Steps 6** and **7** to refill the pump reservoir with 20 mL sterile saline solution.
11. When the pump refill is completed, clamp the extension tubing and remove the needle from the refill septum. Discard the tubing, syringe and the needle.
12. Program the refill using the Prometra Programmer:

Calculations

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

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

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