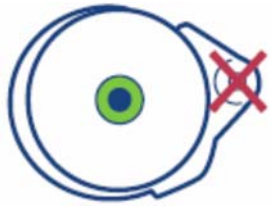
PROMETRA®

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.

Table of Contents

Refer to the Prometra and Prometra II Programmable Pump MRI Scan Instructions Guide (PL-21604) for important MRI procedures, warnings and related information.

Refer to the indications, drug stability, and emergency procedures manual (PL-39701) for indications and related information.

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 SUCH AS SEVERE UNDERDOSE, OVERDOSE OR DEATH.

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

- Prior to infusion of approved drug into the pump system, medical personnel should be familiar with and observe all warnings, cautions, contraindications, and instructions as specified by the drug manufacturer.
- 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.
- Physicians must be familiar with the drug stability information in the product insert and must understand the dose relationship to drug concentration and pump flow rate before prescribing pump infusion.
- Inform patients of the signs and symptoms of drug under- or overdose, appropriate drug warnings and precautions regarding drug interactions, potential side effects, and signs and symptoms that require medical attention.
- If suspected that all or part of the drug was injected into the pocket during the refill procedure, monitor the patient closely for signs and symptoms of overdose.
- After use, this product is a potential biohazard. Handle and dispose of in accordance with accepted hospital practice and all applicable laws and regulations.
- The patient should be monitored closely following adjustment of the dosing rate of the pump and/or concentration of baclofen injection (intrathecal).

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 drug 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-medication. In the event of over-dosage, refer to the approved drug 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.

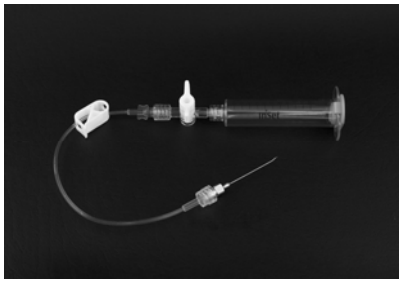
WARNING: IF SUSPENDING INTRATHECAL DRUG THERAPY, ALTERNATIVE DRUG THERAPY ADMINISTRATION ROUTES (E.G., ORAL OR INTRAVENOUS) MAY BE NECESSARY. AN ALTERNATIVE ORAL OR PARENTERAL DOSE "EQUIVALENT" TO THE INTRATHECAL DOSE MAY RESULT IN SIDE EFFECTS THAT WARRANT TEMPORARY MONITORING IN AN EMERGENCY DEPARTMENT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

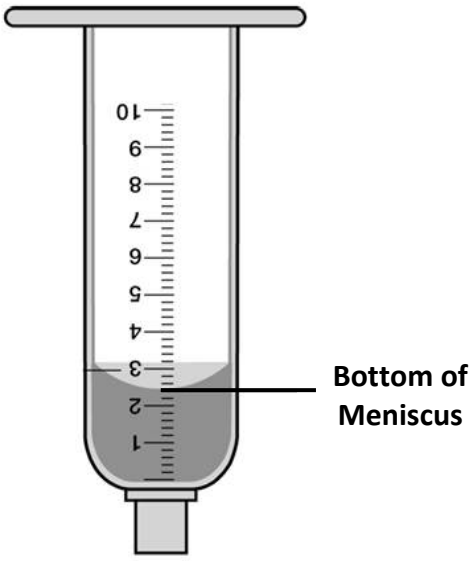
11. *If the **Reservoir Volume** is greater than 10 mL*, then the Empty Volume must be collected in two to four steps (depending on the **Reservoir Volume**) using the same emptying setup.

Collection of infusate:

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.

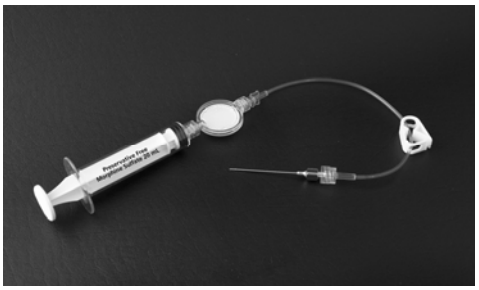
WARNING: IF SUSPENDING INTRATHECAL DRUG THERAPY, ALTERNATIVE DRUG THERAPY ADMINISTRATION ROUTES (E.G., ORAL OR INTRAVENOUS) MAY BE NECESSARY. AN ALTERNATIVE ORAL OR PARENTERAL DOSE "EQUIVALENT" TO THE INTRATHECAL DOSE MAY RESULT IN SIDE EFFECTS THAT WARRANT TEMPORARY MONITORING IN AN EMERGENCY DEPARTMENT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

Warning: Extreme caution must be used when filling a Prometra implantable pump, following strict aseptic technique and ensuring refill directly into the reservoir and not the catheter access port.

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

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.

8. 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.
9. 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.
10. 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.
11. 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).
12. 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 mLor 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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Issue Date: January 2022
PL-21607-03