

CODMAN NEURO

 DePuySynthes

MedStream™ Refill Kit
(Catalog No. 91-4287 & 91-4288)

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ENGLISH

IMPORTANT INFORMATION

Please Read Before Use

MedStream™ Refill Kit (Catalog No. 91-4287 & 91-4288)

STERILE EO

 Only

Become thoroughly familiar with the information contained in this user manual prior to refilling a MedStream Programmable Infusion Pump. Failure to follow these instructions can result in patient complications ranging from a failure of the intended therapy to a drug under- or overdose.

For additional information, refer to the user manual packaged with the infusion pump.

Indications

The MedStream Refill Kit is used only to empty and refill the drug reservoir of a MedStream Pump. The pump is indicated for the chronic intrathecal infusion of

- Baclofen injection sterile solution (5.0–7.0 pH) for treatment of severe spasticity

Use preservative-free sterile solution of 0.9% sodium chloride (4.5–7.0 pH) to achieve the physician-prescribed drug concentration.

WARNING: Use only the drug and diluent listed above with the MedStream pump. Using incompatible or contaminated (out of specification) drug solutions can damage the pump flow-restrictor chip and cause an increase or decrease in flow rate. This can lead to serious complications, including overdose and death.

WARNING: Refer to the appropriate drug labeling for a complete list of drug indications, contraindications, warnings, precautions, adverse reactions, dosage and administration information, screening procedures, and overdose procedures. Physicians prescribing a MedStream Pump for use with this drug must be familiar with the drug stability information listed in *Drug Stability Information*.

Contraindications

There are no known contraindications for the use of the MedStream Refill Kit.

Observe all contraindications relating to the use of the prescribed drug.

WARNINGS

Improper use of an implanted infusion pump can result in drug under- or overdose. Users must comply with product instructions for initial filling and refilling of the pump.

Only qualified medical personnel must perform these procedures.

Do not mix drugs. The effects of mixing drugs in the pump are not known.

Use only the drug and diluent listed in *Indications* with the MedStream pump. Using incompatible or contaminated (out of specification) drug solutions can damage the pump flow restrictor chip and cause an increase in flow rate. This can lead to serious complications, including overdose and death.

Consider the drug concentration, dose and rate relationships before selecting the pump volume and programming the flow rate. Failure to consider these factors can lead to under- or overdose.

Air in the pump reservoir may cause the infusion rate to exceed the programmed rate, leading to drug overdose. Care should be taken to remove all air from the drug syringes and the filling assembly prior to filling the pump reservoir. Ensure that all filling components are primed with fluid and visually verify that there are no air bubbles in the filling assembly prior to filling the pump reservoir.

Do not overfill the drug reservoir. Always identify the pump size (capacity of the drug reservoir) before performing a filling procedure. Always follow the instructions for removing the remaining drug solution before refilling the drug reservoir. Failure to remove the remaining drug solution can result in overfilling the drug reservoir. Overfilling can result in overinfusion, which can lead to a drug overdose or cause damage to the pump.

It is very important to access the central port during refill procedures. An error in accessing the central port can result in tissue damage or a drug under- or overdose, or drug withdrawal symptoms.

Do not inject into the pump catheter or the intraspinal catheter; a drug under- or overdose or damage to the catheter can result.

Do not use the filling needle provided with the refill kit for accessing the bolus port.

Injection in the bolus port or into the pump pocket can result in drug overdose. To prevent injection errors:

- identify the location of the pump central port;
- use only the filling needle provided in the Refill Kit for accessing the central port;
- confirm the reflux of drug into the syringe barrel several times during the filling procedure.

Precautions

Use sterile technique in all phases of handling this product.

Inspect the sterile package carefully. Do not use if:

- the package or seal appears damaged;
- the contents appear damaged; or
- the expiry date has passed.

The refill kit is for **single use only**. **Do not reuse**.

If local or systemic infection is suspected, use extreme caution when emptying and/or refilling the drug reservoir. If infection is suspected perform appropriate diagnostic procedures and intervention.

Use only the filling needles provided with MedStream Refill Kits for refilling the MedStream Pump. These needles are designed specifically for use with the pump. The use of other needles can damage the central port and/or result in a failure to administer solution appropriately.

Use only preservative-free solutions for intrathecal applications.

Adverse Events

Adverse events related to emptying, filling, or refilling the drug reservoir include:

- Contamination of the drug reservoir resulting in infection, such as meningitis;
- Injection errors, which can lead to tissue damage or a drug under- or overdose; or
- Overfilling of the drug reservoir, which can lead to drug overdose or damage to the pump.
- Air in the pump reservoir may cause the infusion rate to exceed the programmed rate, leading to drug overdose.

Complications relating to the drug therapy, such as:

- drug toxicity (local and systemic) and its related side effects;
- complications due to the use of a drug that is not approved for intrathecal administration;
- complications due to the use of drugs that are not approved for use with the system;
- complications due to use of an approved drug or diluent that is out of specification;
- extravasation.

Drug Stability Information

Drug stability has been tested for the drug and concentration listed in Table 2.

Table 2 Drug Stability information		
Drug Name	Drug Concentration	Stability Duration
LIORESAL INTRATHECAL (baclofen injection)	2000 µg/mL	120 days

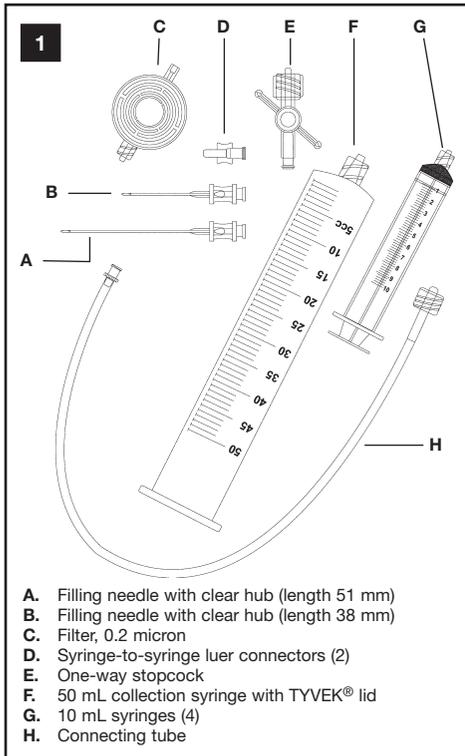
For patients who require concentrations less than 2000 µg/mL, LIORESAL INTRATHECAL **must be diluted** with preservative-free sterile solution of 0.9% Sodium Chloride. Concentrations of LIORESAL INTRATHECAL, other than those listed in Table 2, have not been tested in this device. Drug stability for concentrations of intrathecal baclofen greater than 2000 µg/mL are not approved and have not been tested in this device.

Refer to the drug labeling for complete prescribing information, indications, contraindications, warnings, precautions, and adverse events.

When filling the drug reservoir, verify that the “Use By” date of the drug will not occur before the patient’s next refill.

Product Description

The MedStream Refill Kit contains the following components, provided sterile (please see Figure 1):



Additional sterile components that are not shown in the illustration:

- Gauze pads (6)
- Self-adhesive bandages (2)
- Fenestrated drape

The following component is packaged outside the sterile package:

- Instruction manual (1 per package)

Reorder information:

Catalog Number	Description
91-4287	MedStream Refill Kit (1 unit)
91-4288	MedStream Refill Kit (6 units)

How Supplied



This product is for **SINGLE USE ONLY**; DO NOT RESTERILIZE. Codman Single Use devices have not been designed to undergo or withstand any form of alteration, such as

disassembly, cleaning or resterilization, after a single patient use. Reuse can potentially compromise device performance and any usage beyond the design intent of this single-use device may result in unpredictable loss of functionality.

Codman & Shurtleff will not be responsible for any product that is reesterilized, nor accept for credit or exchange any product that has been opened but not used.

As long as the inner unit is not opened or damaged, the product is sterile.

The following components have been tested and were determined to be nonpyrogenic:

- Filling Needles
- Syringe-to-syringe luer connectors
- Connecting tube

The following components have been tested and were determined to have a nonpyrogenic fluid pathway:

- 10 mL syringes
- Filter
- Stopcock

INSTRUCTIONS FOR USE

These instructions do not address the procedure for initial filling of the drug reservoir in preparation for implantation. Follow the instruction manual that is packaged with the MedStream Pump.

Refilling the Implanted Pump

Perform the steps listed in Sections A through I to refill a MedStream pump. These sections include all procedures needed for refilling with the same drug concentration or with a different concentration of the same drug.

PRECAUTIONS

Ensure that all luer-lock connections are secure.

Never overfill the drug reservoir. Always be sure to identify the pump size before performing a refilling procedure.

Use only the filling needles provided with the MedStream Refill Kit to access the central port. The use of other needles can damage the central port and/or result in a failure to administer solution appropriately.

Always follow the instructions for removing the remaining drug solution before refilling the drug reservoir. Failure to remove the remaining drug solution can result in overfilling the reservoir. Overfilling can result in overinfusion, which can lead to drug overdose and cause damage to the pump.

The 10 mL syringes are packaged with the plungers partially pulled out. Push in the plungers before filling the syringes.

Do not aspirate during emptying of the drug reservoir. Allow pump pressure to evacuate the drug reservoir during the emptying procedure. Aspiration of the reservoir can damage the pump's drive system.

The drug reservoir contents are under significant pressure. To prevent the reservoir contents from being ejected, do not use an open syringe when emptying the drug reservoir.

Always ensure proper needle placement (needle held perpendicular to the pump and inserted completely to the needle stop) before refilling the reservoir.

Use of excessive force when inserting the filling needle into the central port can damage the needle tip. Never use a filling needle if the tip is bent; use the second filling needle provided. Using a bent filling needle will cause damage to the central port, and can result in a failure to administer solution appropriately.

A. Preparing Materials for Pump Refill

- Gather the following items:
 - MedStream Control Unit
 - MedStream Refill Kit
 - Appropriate amount of drug solution (volume to be determined by the pump size)
 - Sterile gloves (2 pair)
 - Optional:** An additional 1 mL of drug solution for priming the filter.
- If changing the drug concentration, gather these additional materials:
 - 10 mL syringes, sterile, with luer-lock connectors (2) suitable for intrathecal injection
 - 10 mL of preservative-free sterile 0.9% saline solution
 - Optional:** an additional 3–10 mL of new drug solution for rinsing to offset dilution (see Step 7i in *F. Emptying the Reservoir*).

B. Interrogating the Pump

Use the MedStream Control Unit to interrogate the pump. Check the status of the pump, the pump size (reservoir capacity), the drug name, and drug concentration. (Refer to the instructions in the MedStream Implantable Infusion System Programming Guide.)

C. Starting the Control Unit Refill Sequence

- Select “Pump Menu” on the Control Unit. Select the “Refill Pump” icon and follow the prompts to stop the pump. This puts the pump in the Refill mode and the Refill Pump menu will appear on the screen.
- If changes are not needed in the drug concentration or the program, select “Accept” on the Control Unit and go to *D. Preparing the Refill Assembly*.
- If changes are needed to the drug concentration or program, use the MedStream Control Unit and follow the instructions in the Programming Guide to make the changes needed.
- When all changes have been made, set the Control Unit aside until the refill is complete. Go to *D. Preparing the Refill Assembly*.

Note: If the Control Unit is in the Power Saver Mode, it will automatically turn off after 25 minutes of inactivity. This will cause the loss of changes made to the drug concentration and drug delivery program. Take appropriate steps, such as deactivating the Power Saver Mode, prior to the refill if necessary.

D. Preparing the Refill Assembly

- Open the sterile outer package and deliver the CSR-wrapped kit to an appropriate surface. Open the CSR wrap.
- Put on sterile gloves. Confirm the drug name and the concentration. Confirm that the amount of drug solution does not exceed the pump size.

- Push in the plunger of each syringe before filling it with drug solution. (**Note:** The 10 mL syringes are provided with their plungers pulled back approximately 2 mL to facilitate sterilization.) Transfer 10 mL of the drug solution into one of the 10 mL syringes provided, using the syringe-to-syringe luer connector, if needed. Expel the air from the syringe. Visually verify that there is no air bubble remaining in the syringe.
- Repeat Step 3 with the remainder of the drug solution and the 10 mL syringes provided.
- If you are rinsing the pump reservoir with saline (that is, if the drug concentration is being changed), go to *E. Preparing the Patient*.
- If you are not rinsing the pump reservoir with saline, attach the filter to one of the drug-filled syringes and prime the filter. Go to *E. Preparing the Patient*.

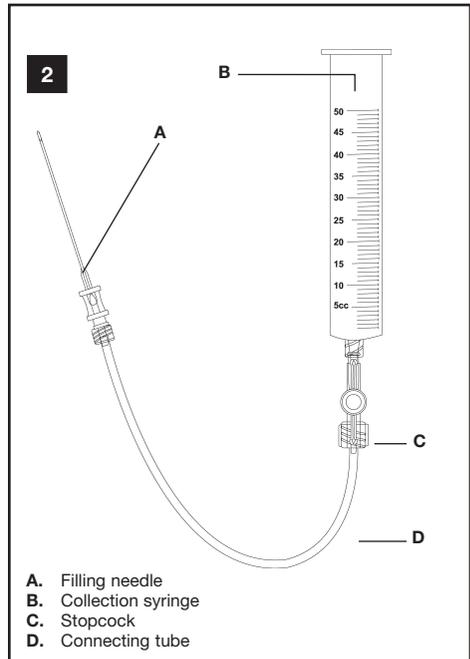
E. Preparing the Patient

- Follow your facility’s procedure to disinfect a wide area of skin over and around the central port of the pump.
- Discard the gloves and put on a new pair of sterile gloves. Place the fenestrated drape over the prepared pump site.
- Go to *F. Emptying the Reservoir*.

F. Emptying the Reservoir

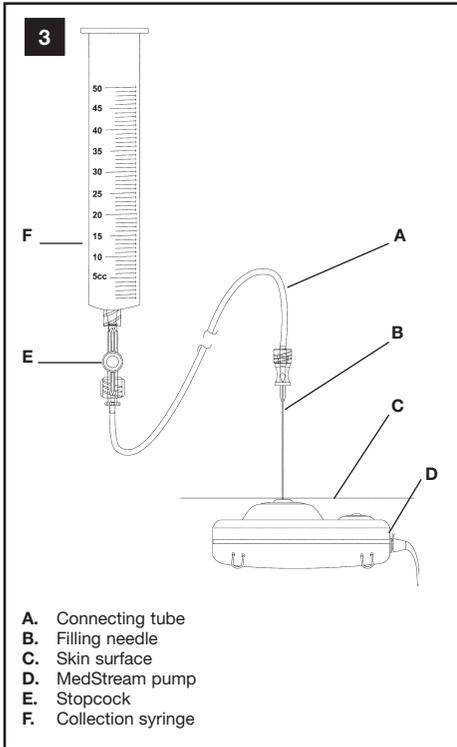
(see Figures 2 and 3)

- Select the shorter or longer filling needle, as desired. Attach the filling needle, connecting tube, stopcock, and collection syringe together. See Figure 2. Make sure the stopcock is closed.



- Palpate the pump to locate the central port, the pump outlet, and the bolus port. Hold the filling needle perpendicular to the pump and puncture the central port. Insert the needle with a twisting motion until it contacts the needle stop. See Figure 3.

CAUTION: If the needle does not contact the needle stop, it will not be possible to remove drug from the pump.



- Open the stopcock. The contents of the reservoir will reflux into the collection syringe. If reflux does not appear, check the position of the filling needle. If needed, twist the needle to ensure that it penetrates the central port (refer to *Troubleshooting*). **If no reflux is present after checking the needle position, consult the MedStream Therapy Maintenance Guide.**
- When the reflux of drug has stopped, wait an additional 30 seconds to ensure that the pump is empty. Close the stopcock.
- Turn the collection syringe upside down and remove it from the stopcock. (This will help prevent dripping.) Discard the collection syringe and the refluxed drug solution in an appropriate manner. The filling needle remains in place in the central port; the connecting tube and stopcock remain attached to the needle.

- If there will be a change to the drug concentration, proceed to Step 7. If there will be no change to the concentration, proceed to *G. Refilling the Reservoir*.
- If changing the drug concentration, rinse the pump as shown in Steps 7a through 7h. **Optional:** for users who wish to limit the affects of dilution from the saline rinse, perform Step 7i.

WARNING: Use caution to prevent drug overdose when changing concentrations in the drug reservoir. Before changing the concentration of the drug solution, first empty the drug reservoir, then rinse the reservoir twice with sterile 0.9% saline solution as instructed in Steps a through h.

Visually verify that no air bubbles are present in the connecting tube. If air is present, remove the needle from the central port. Attach a saline-filled 10 mL syringe to the filter and attach this to the filling assembly. Prime the assembly to remove the air. Visually verify that there is no air bubble remaining in the filling assembly. Palpate the pump and reinsert the needle into the central port, as previously performed.

- Fill two additional 10 mL syringes that are suitable for intrathecal injection with 5 mL of saline in each. Expel the air from the syringes.
- Attach one saline-filled syringe to the filter. Prime the filter with saline. Attach the syringe and filter to the stopcock.
- Open the stopcock. Slowly inject the saline into the reservoir. Remove pressure from the syringe plunger and allow the saline to reflux into the syringe.
- Close the stopcock. Remove and discard the syringe and the refluxed solution appropriately.
- Attach the second saline-filled syringe to the filter.
- Open the stopcock. Slowly inject the saline into the reservoir. Remove pressure from the syringe plunger and allow the saline to reflux into the syringe. Wait 30 seconds after reflux has stopped.
- Close the stopcock. Remove and discard the syringe and the refluxed solution appropriately.
- Leave the filling needle in place in the central port.
- Optional:** Because approximately 2 mL of the saline rinse will remain in the “dead space” of the reservoir, the refilled drug solution will be diluted to a concentration of 90% in the 20 mL pump and 95% in the 40 mL pump. If this is a concern, rinse the pump with a small amount of drug solution to decrease the dilution. Refer to Table 1 to select the amount of new drug solution for rinsing. Fill a 10 mL syringe with the appropriate amount of solution and follow steps 7e through 7h above to rinse the reservoir.
- Proceed to *G. Refilling the Reservoir*.

Table 1
Rinsing Quantities
(New Drug Concentration)

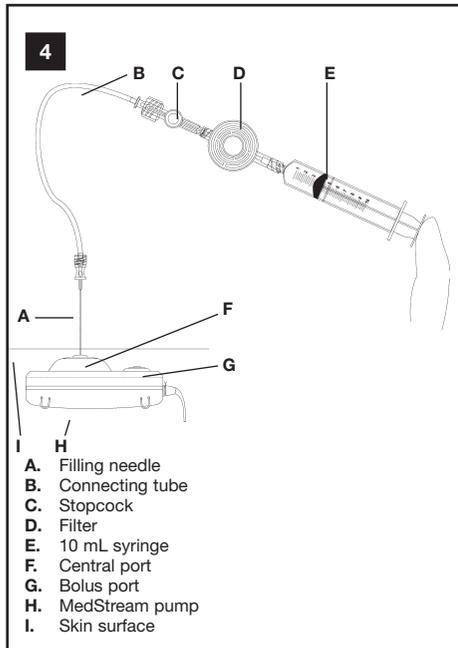
If reservoir volume is...	Then rinse with this amount of new drug solution...	To achieve this concentration of new drug solution (when changing drug concentration)
20 mL	3 mL	96%
20 mL	10 mL	98%
40 mL	3 mL	98%
40 mL	10 mL	99%

G. Refilling the Reservoir

(see Figure 4)

CAUTION: The contents of the pump are under pressure. Use your thumb to keep the syringe plunger under control. Failure to control the plunger may cause drug solution to spill.

1. Visually verify that no air bubbles are present in the connecting tube. If air is present, remove the needle from the central port. Attach a drug-filled 10 mL syringe to the filter and attach this to the filling assembly. Prime the assembly to remove the air. Visually verify that there is no air bubble remaining in the filling assembly. Palpate the pump and reinsert the needle into the central port, as previously performed.



2. While keeping your thumb on the plunger of the syringe to counteract the reflux pressure of the pump, open the stopcock. Begin to inject drug solution into the reservoir.
3. Release the pressure from the plunger of the 10 mL syringe at 5 mL increments and allow 1 mL of drug solution to return to the syringe to verify correct needle placement. Reflux **must** appear in the syringe. In this manner, inject the remainder of the contents of the 10 mL syringe.
4. While controlling the syringe plunger with your thumb, close the stopcock. Remove the empty syringe.
5. Attach the next drug-filled syringe to the filter. Follow Steps 2 through 4 to deliver the drug to the reservoir. Repeat with all filled syringes until the prescribed amount of drug has been injected.
6. Remove the filling needle from the central port and, if necessary, cover the injection site with a self-adhesive sterile bandage.
7. Discard all refill kit components.
8. Proceed to *H. Completing the Programming/Writing Data to the Pump.*

H. Completing the Programming/Writing Data to the Pump

1. Use the Control Unit and follow the steps in the MedStream Programming Guide to indicate that you have emptied and refilled the pump.
2. If you have changed **ONLY** the drug concentration, the control unit screen will prompt you to program a bridge bolus. A bridge bolus will ensure that the old drug concentration that remains in the catheter will be delivered at the appropriate rate to mimic the dosage of the new concentration. Follow the prompts on the control unit screen.
3. As instructed in the Programming Guide, "Write to Pump." This will communicate any changes you have made and will restart the pump.
4. **If you have changed the unit of measure or have altered the drug name**, you will not be able to program a bridge bolus. Therefore, the old drug remaining in the catheter will continue to be delivered. The rate of delivery of the old drug will adhere to any changes you made to the Program. If this is not appropriate for the patient, remove the contents of the catheter and manually deliver a bolus of new drug to replace the catheter contents.
 - Use the control unit to determine the volume of the catheter. This information appears on the second page of the Summary Sheet that appears when you communicate with the pump.
 - Use a MedStream Bolus Kit (REF 91-4284US) to remove and replace the catheter contents. Refer to the instructions for use packaged with the bolus kit.
5. Proceed to *I. Interrogating the Pump/Printing the Report.*
6. **Interrogating the Pump/Printing the Report**
 1. Use the Control Unit to interrogate the pump to confirm that key refill parameters have been written to the pump.
 2. Review the "Next Refill" date on the summary screen and schedule the patient's next appointment on or before that date.
 3. Follow the instructions in the Programming Guide to print the transaction report for your records.
 4. The refill procedure is complete.

Discontinuing Drug Therapy

CAUTION: If the drug therapy is to be discontinued for a prolonged period of time, empty the pump of the drug solution and refill it with sterile preservative-free 0.9% saline solution, following the prescribed refill schedule to maintain a patent fluid pathway.

To discontinue drug therapy, follow the instructions for *Refilling the Implanted Pump*, Sections A through I, using preservative-free sterile 0.9% saline solution in place of drug solution.

Troubleshooting

If unable to empty the pump or inject into the central port:

1. Check the pump status with the control unit. If the "Next Refill" date has passed, the pump might be empty. If a "Pump Hardware Error" message is displayed, follow the instructions in the Activated Alarms chapter of the MedStream Programming Guide.
2. Check that the stopcock is open.
3. Check that the correct filling needle is used. Use only the needles packaged in the MedStream Refill Kit.
4. Check the needle for damage to the tip. If it appears bent or damaged, use the second filling needle provided in the kit.
5. Check the position of the needle. Hold the needle perpendicular to the central port. Twist the needle as it pierces the port to ensure penetration. Make sure to insert the needle until it contacts the needle stop.
6. Check the position of the pump with radiography.

Warranty

Codman & Shurtleff, Inc. warrants that this medical device is free from defects in both materials and workmanship.

Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. Suitability for use of this medical device for any particular surgical procedure should be determined by the user in conformance with the manufacturer's instructions for use. There are no warranties that extend beyond the description on the face hereof.

TM MedStream is a trademark of Codman & Shurtleff, Inc.

® TYVEK is a registered trademark of

E. I. du Pont de Nemours and Company

Appendix A: Emergency Procedures

Drug Overdose

WARNING: Refer to the appropriate drug labeling for a complete list of drug indications, contraindications, warnings, precautions, adverse reactions, dosage and administration information, screening procedures, and overdose procedures contained in the prescribed drug labeling.

1. Use the MedStream Control Unit to interrogate the pump and confirm the drug and drug concentration on the summary screen.
2. In the event of a suspected overdose:
3. Empty the pump of the remaining drug. Refer to *F. Emptying the Reservoir* Steps 1 through 5.
4. Use a MedStream Bolus Kit (REF 91-4284US) to aspirate the catheter contents, if appropriate.

5. After stabilizing the patient, rinse the pump with saline, as instructed in *F. Emptying the Reservoir*, Steps 7a through 7h.
6. Once the pump is rinsed, refill it with preservative-free sterile 0.9% saline solution to keep the pathway patent, or refill it with the correct prescription.



Do not resterilize



Do not use if package is damaged



Rx Only



Manufacturer



Nonpyrogenic, see instructions for use



Quantity



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* For recognized manufacturer, refer to product label.