

### KIT CONTENTS

MEDSTREAM Refill Kit (REF 91-4287 and 91-4288) contains the following components, provided sterile:

- Filling Needle with clear hub: 38 mm and 51 mm
- Filter, 0.2 micron
- Syringe-to-Syringe luer connectors (2)
- One-way stopcock
- 50 mL collection syringe with Tyvek® lid
- 10 mL syringes (4)
- Connecting tube
- Fenestrated drape
- Gauze pads (6)
- Self-adhesive bandages (2)

Not provided in the Refill Kit:

- Isopropyl alcohol swabs (3)
- MEDSTREAM Control Unit
- Syringe with appropriate amount of drug solution (the volume of solution no greater than pump reservoir size: 20 or 40 mL)
- Skin disinfectant
- Sterile gloves (2 pair)
- OPTIONAL: 1 mL of drug solution for priming the filter

### IMPORTANT: PLEASE READ BEFORE USE

Please refer to the **MEDSTREAM Refill Kit Instructions for Use** for complete information on refilling the MEDSTREAM pump and for Indications, Contraindications, Warnings, Precautions, and Adverse Events.

Please 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 for the prescribed drug.

**PLEASE NOTE:** These instructions do not address the procedure for initial filling of the drug reservoir in preparation for implantation. Follow the instructions in the user manual packaged with the MEDSTREAM Pump.

### WARNINGS

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.

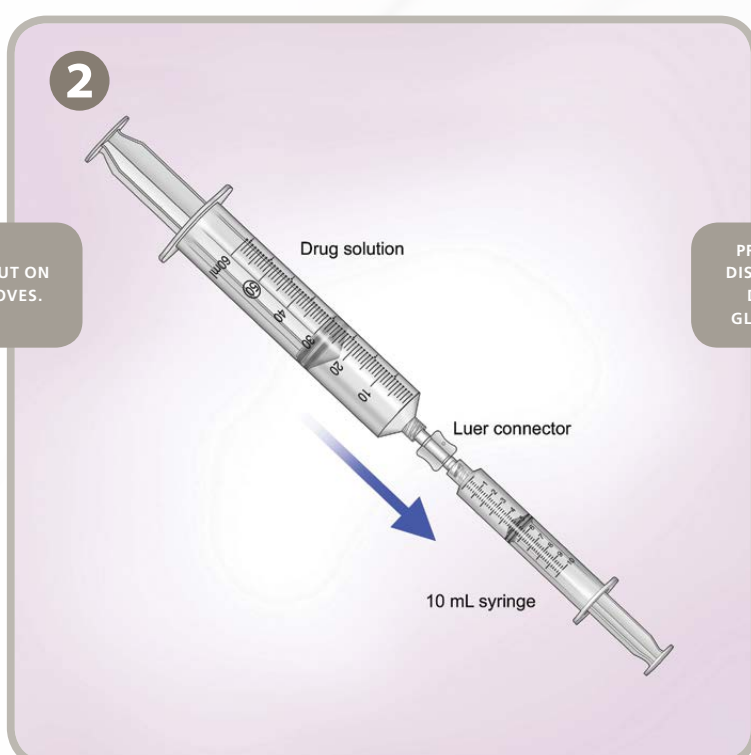
Never overfill the drug reservoir. Always be sure to identify the pump size before performing a refilling procedure. Overfilling can result in over infusion, which can lead to drug overdose or cause damage to the pump.

## COMMUNICATE

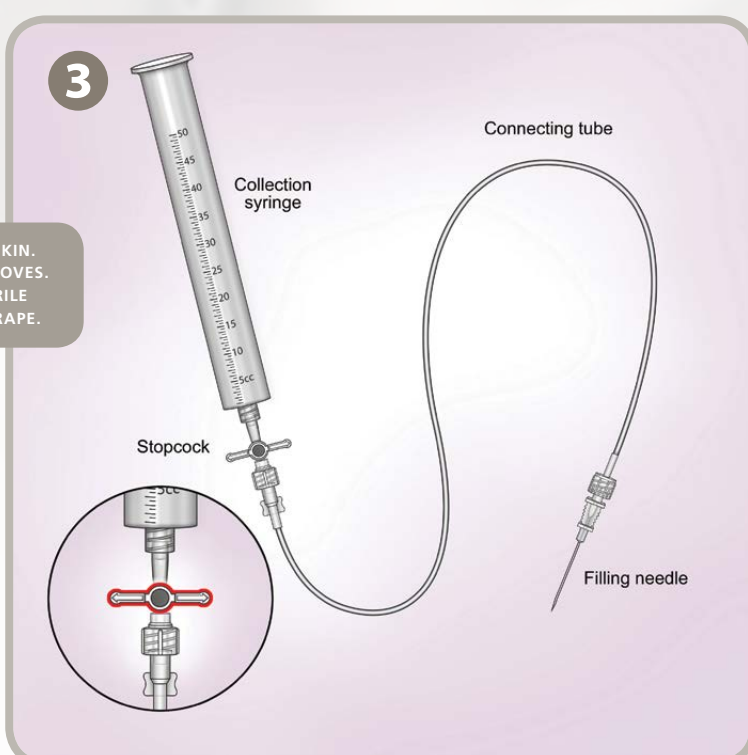


Perform initial refill programming. Check pump status, pump size, drug name and concentration.

## PREPARATION

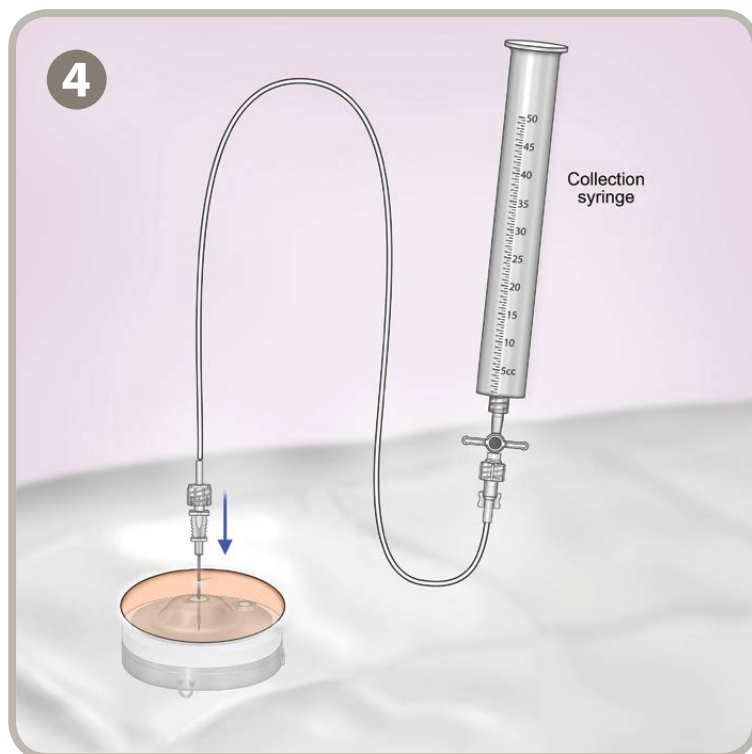


Transfer the drug to the 10 mL Syringes. Push in the plunger of each syringe before filling it with drug solution. Transfer the drug to the 10 mL syringes. Expel the air from the syringe. Visually verify that there is no air bubble remaining in the syringe.

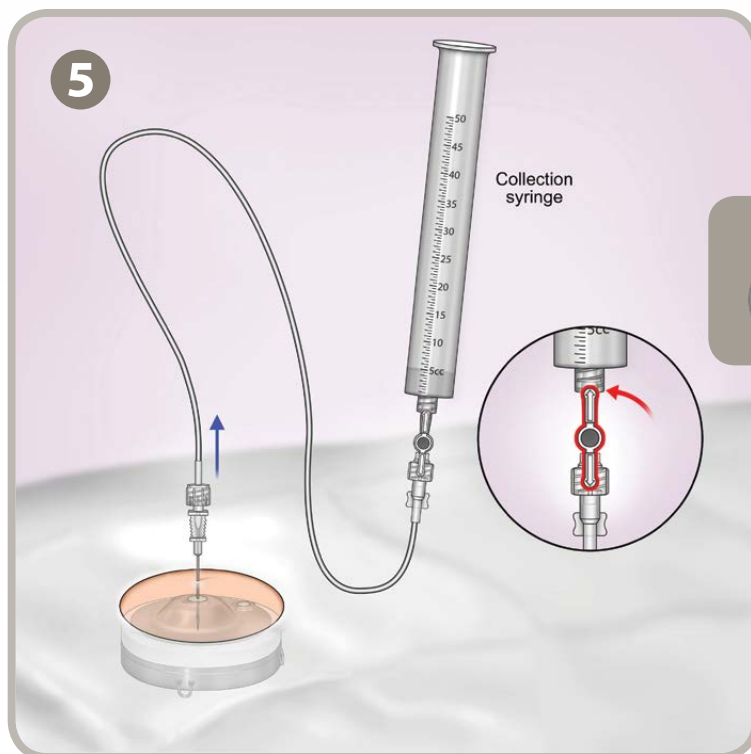


Prepare the tubing assembly.

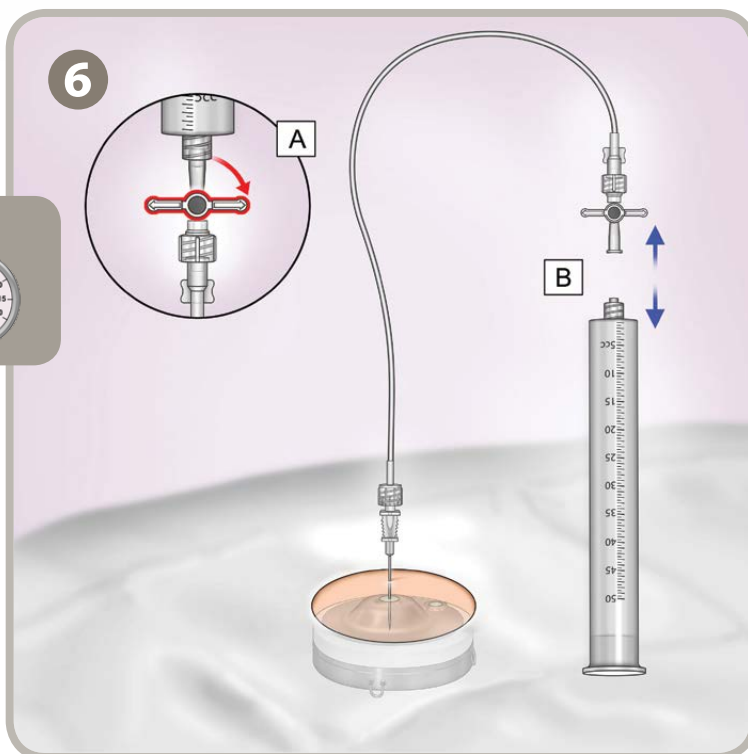
## EMPTY PUMP



Insert filling needle into central port.



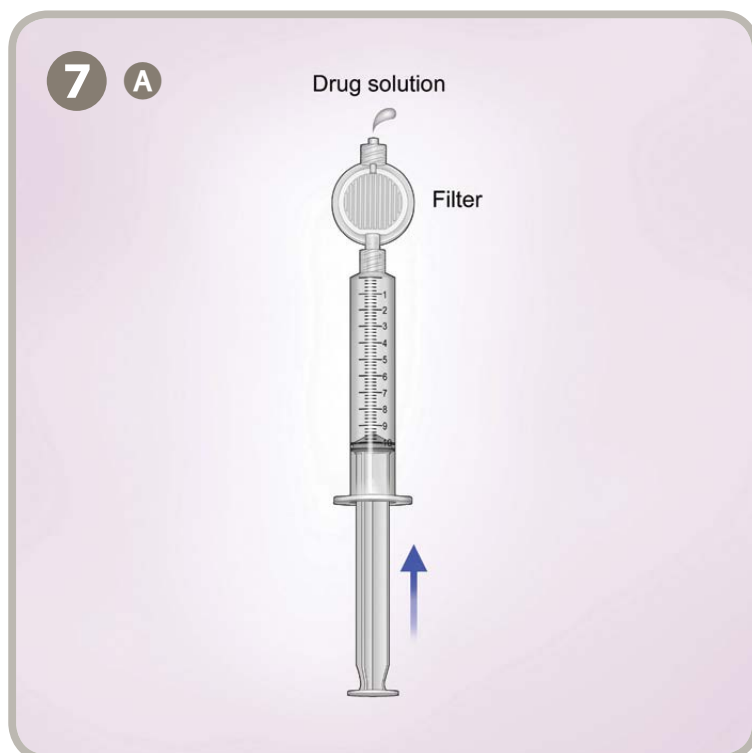
Open stopcock. Pump reservoir contents will reflux into collection syringe. When reflux has stopped, wait 30 seconds to ensure pump is empty. If no reflux appears, check position of needle and consult Troubleshooting section.



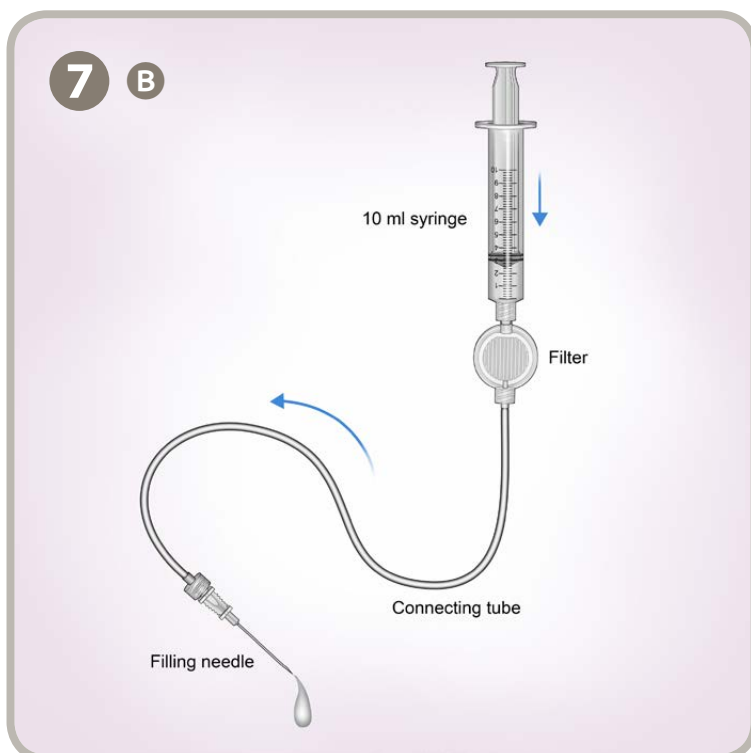
- A Close stopcock.
- B Invert and remove collection syringe from tubing assembly.

Note: If there will be a change to the drug concentration, the pump should be rinsed twice at this time with saline and, if desired, with the new concentration of drug, as outlined in the MEDSTREAM Refill Kit Instructions for Use.

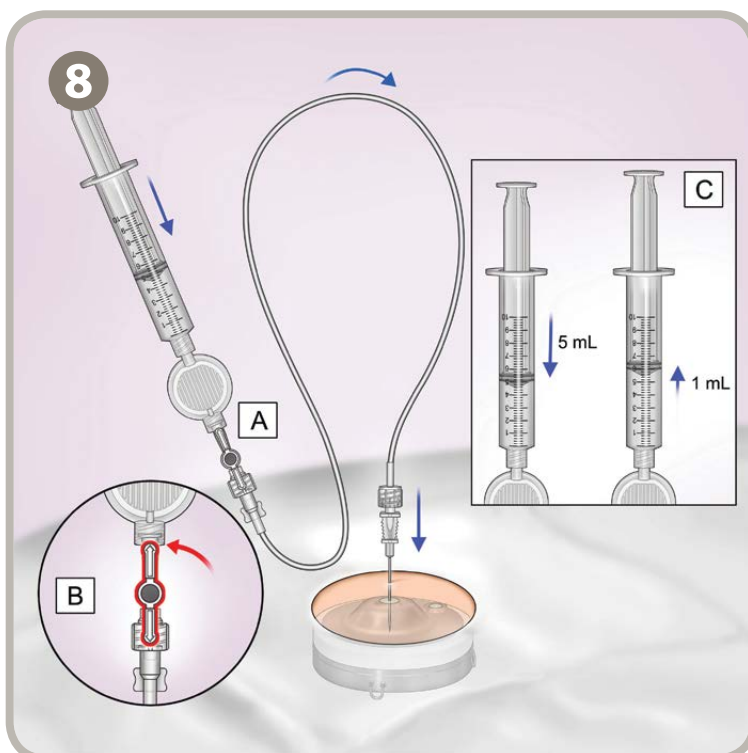
## REFILL PUMP



Prime the filter.

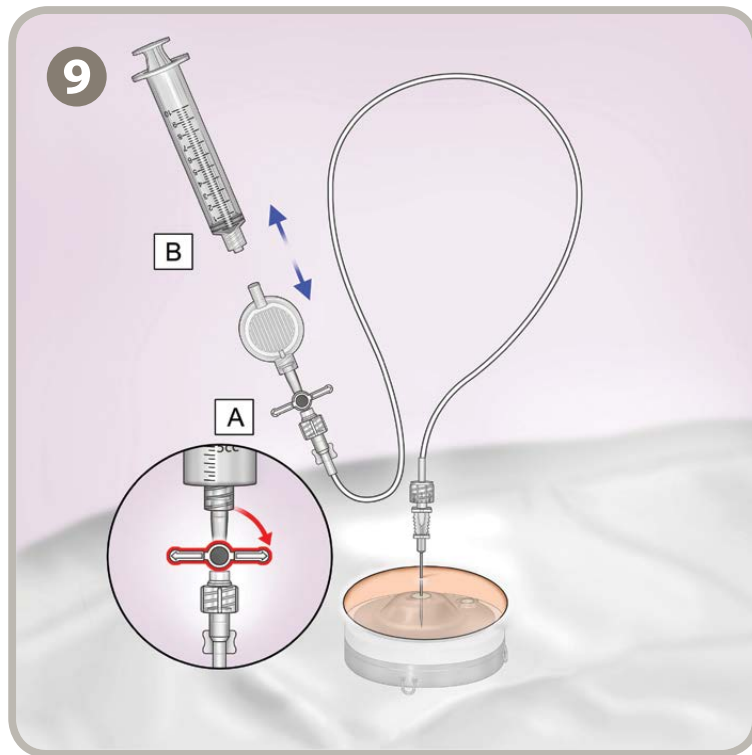


Visually verify that no air bubbles are present in the tubing assembly. If no air is present, go to Step 8. If air is present, remove the needle from the central port. Attach the drug-filled syringe and filter to the tubing assembly. Prime the assembly to remove the air. Visually verify that there is no air bubble remaining in the filling assembly.



- A Assemble parts as shown. If needed, reinsert the needle into the central port, as previously performed.
- B Open stopcock, keeping thumb pressure on plunger.
- C Inject 5 mL drug solution, then allow 1 mL to reflux. Repeat until syringe is empty.

## COMMUNICATE



- A Close stopcock.
- B Remove empty syringe.

Repeat pump refill steps 8 and 9 with drug filled syringes as needed until pump reservoir is filled. Remove filling needle and tubing assembly from central port. SEE WARNINGS ABOVE.



Communicate the refill information to the pump and interrogate the pump.

## 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 correct needle is used. Use only the needles packaged in the MEDSTREAM Refill Kit.
3. Check the needle for damage to the tip. If it appears bent or damaged, use the second needle provided in the kit.
4. 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.
5. Check the position of the pump with radiography.
6. Contact Codman for 24-Hour Technical Assistance at 800-660-2660.

# MEDSTREAM™ Refill Procedure



## MEDSTREAM PROGRAMMABLE INFUSION SYSTEM ESSENTIAL PRESCRIBING INFORMATION

Product instructions for use and appropriate drug labeling must be reviewed prior to use for detailed disclosure.

**INDICATIONS**  
The MEDSTREAM Programmable Infusion System is indicated for the chronic intrathecal infusion of Bacterin injection sterile solution (5.0 pH to 7.0 pH) in the treatment of severe spasticity.

**CONTRAINDICATIONS**  
The pump is contraindicated under the following conditions: in the presence of active or incompletely treated infection; if the top surface of the implanted pump will be more than 2.5 cm from the surface of the skin; if the patient's body size is insufficient to accept the bulk and weight of the pump; when conservative treatment is appropriate; and in the presence of spinal anomalies that might complicate the implantation and fixation of an intraspinal catheter. In addition, observe all contraindications relating to the use of the prescribed drug.

Thoroughly review product instructions for use for a detailed listing of indications, contraindications, Warnings, Precautions and Adverse Events.

**LIMITED WARRANTY AND DISCLAIMER**  
Codman products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

**CAUTION**  
This device is restricted to sale by or on the order of a physician (or properly licensed practitioner) who has appropriate training or experience.

## KEY CONTACTS

USA  
Codman & Shurtleff, Inc.  
325 Paramount Drive  
Rayham, MA 02767  
Technical Assistance: 800-660-2660  
Ordering: 800-255-2500

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