Refill Kit–Model 3000 Series
CONSTANT FLOW IMPLANTABLE PUMPS

WARNING
The Pump should be implanted and refilled only by qualified medical personnel, knowledgeable in the surgical use and servicing of implantable devices and catheters, and trained specifically to implant or refill the Pump. Use of the Pump by personnel not properly trained in its implantation and/or servicing may lead to serious complications including either under or over-delivery of drug to the patient, to the extent of an irreversible drug overdose.

Boils access and Pump refill procedures must be performed using the correct access needle. Never attempt to refill the Pump using a Special Bolus Needle. This use will result in a bolus injection to the patient and may cause a fatal drug overdose.

The Model 3000 Series Constant Flow Implantable Pumps contain a safety valve in-line with the bolus pathway to prevent a bolus procedure can only be performed when using a properly positioned Special Bolus Needle.

PRECAUTION 1. A non-coring needle is provided in this kit. It is critical to the safe functioning of the Pump that no other needle be used to puncture the septum.

PRECAUTION 2. Do not aspirate fluid from the Pump. Aspiration may cause blood to be drawn into the catheter and result in occlusion.

PRECAUTION 3. It is important to precisely follow the Pump refill instructions as detailed in this pamphlet in order to successfully complete the Pump refill procedure. If the needle is not properly positioned, and verified as detailed in the Pump Refill Procedures, there is a possibility that a drug extravasation will occur.

PRECAUTION 4. If no fluid returns to the syringe upon release of the plunger, DO NOT CONTINUE TO INJECT REFILL SOLUTION UNTIL YOU HAVE VERIFIED THE NEEDLE PLACEMENT PER THE PROCEDURE (step 8 to 10).

REVIEW ALL INSTRUCTIONS BEFORE PROCEEDING:

1. Attach the Needle and Stopcock to the tubing set. Stopcock and clamp are in the OPEN position. Next attach the 5 mL calibrated syringe barrel to the Stopcock. Tighten all connections.

2. Re-position the Pump site and locate the raised septum. Insert the non-coring needle PERPENDICULAR to the Pump septum.

3. Advance needle until it is in contact with the needle stop. Keep downward pressure on the needle and inject 5 mL of saline solution into the Pump.

4. Allow the Pump reservoir to empty. Release downward pressure on the needle and allow 1 mL of solution to return to syringe. This will verify that the needle is in the correct position and the Pump reservoir is being filled. Continue to inject and check needle placement until the syringe is empty.

5. Close STOPCOCK. Note return volume (mL) and record on refill data sticker provided. Discard syringe barrel and stopcock leaving the 5 mL saline solution in the syringe barrel.

6. Expel air from the 10 mL syringe of saline. Attach the syringe to the proximal end of the refill set and confirm that the needle is still in contact with the needle stop. Keep downward pressure on the needle and inject 5 mL of saline into the Pump.

7. Release pressure on the plunger and allow the 5 mL to return to the syringe. The procedure establishes correct positioning of the needle in the needle stop. Refer to Troubleshooting Guide for assistance. Discard the syringe from the refill set.

8. Expel air from refill syringes. Attach syringe to proximal end of refill set. Confirm that the needle is still in contact with the needle stop.

9. Keep downward pressure on the needle and begin to inject refill solution into the Pump. Release pressure on syringe at 5 mL increments and allow 1 mL of solution to return to syringe. This will verify that the needle is in the correct position and the Pump reservoir is being filled. Continue to inject and check needle placement until the syringe is empty.

Refill Volume: Model 3000-16.... 16 mL
Model 3000.... 30 mL
Model 3000-50.... 50 mL

10. After injecting the entire contents of the refill syringe, close the clamp on the tubing set and pull needle out of Pump septum. Remove drape and iodine. Apply adhesive bandage to access site.

KIT CONTENTS
[1] Data Sticker
[2] Alcohol Swabsticks
[3] INSTRUCTIONS FOR USE
[5] Suture Grommets and Syringes
[6] STOPCOCK
[7] TUBING SET
[8] STOPCOCK
[9] 50 mL CALIBRATED SYRINGE BARREL
[10] ALCOHOL SWABSTICK
[12] SUTURE GROMMETS
[13] TUBING SET
[14] STOPCOCK
[15] 50 mL CALIBRATED SYRINGE BARREL
[16] ALCOHOL SWABSTICK
[17] Gauze Pads
[18] SUTURE GROMMETS

For a complete list of kit contents, see Instructions for Use. KIT CONTENTS are intended for use with Codman & Shurtleff, Inc. pumps. They are not to be used with incompatible pumps from other manufacturers.

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For 24-Hour Technical Assistance or to arrange an in-service Training Program, contact Codman & Shurtleff, Inc. at [phone number].

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1. Attach Needle and Stopcock to tubing set. Stopcock and clamp are in the OPEN position. Next attach the 5 mL calibrated syringe barrel to the Stopcock. Tighten all connections.

2. Re-position the Pump site and locate the raised septum. Insert the non-coring needle PERPENDICULAR to the Pump septum.

3. Advance needle until it is in contact with the needle stop.

4. Allow the Pump reservoir to empty. Release downward pressure on the needle and allow 1 mL of solution to return to syringe. This will verify that the needle is in the correct position and the Pump reservoir is being filled. Continue to inject and check needle placement until the syringe is empty.

5. Close STOPCOCK. Note return volume (mL) and record on refill data sticker provided. Discard syringe barrel and stopcock leaving the 5 mL saline solution in the syringe barrel.

6. Expel air from the 10 mL syringe of saline. Attach the syringe to the proximal end of the refill set and confirm that the needle is still in contact with the needle stop. Keep downward pressure on the needle and inject 5 mL of saline into the Pump.

7. Release pressure on the plunger and allow the 5 mL to return to the syringe. The procedure establishes correct positioning of the needle in the needle stop. Refer to Troubleshooting Guide for assistance. Discard the syringe from the refill set.

8. Expel air from refill syringes. Attach syringe to proximal end of refill set. Confirm that the needle is still in contact with the needle stop.

9. Keep downward pressure on the needle and begin to inject refill solution into the Pump. Release pressure on syringe at 5 mL increments and allow 1 mL of solution to return to syringe. This will verify that the needle is in the correct position and the Pump reservoir is being filled. Continue to inject and check needle placement until the syringe is empty.

Refill Volume: Model 3000-16.... 16 mL
Model 3000.... 30 mL
Model 3000-50.... 50 mL

10. After injecting the entire contents of the refill syringe, close the clamp on the tubing set and pull needle out of Pump septum. Remove drape and iodine. Apply adhesive bandage to access site.

Precaution: If no fluid returns to the syringe upon release of the plunger, DO NOT CONTINUE TO INJECT REFILL SOLUTION UNTIL YOU HAVE VERIFIED THE NEEDLE PLACEMENT PER THE PROCEDURE (step 8 to 10).

If there is still no fluid return after injection of the 5 mL of saline, remove needle and refill tubing set. Flush the refill set to confirm that the system is patent. Re-insert the needle perpendicular to the Pump septum until it is in contact with the needlestop. Repeat step C.

Contact Codman & Shurtleff, Inc. at 1-800-860-1122 or 1-800-880-2600.
Institutional Use

CONSTANT FLOW IMPLANTABLE PUMPS

Refill Kit - Model 3000 Series

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