

Refill Kit – Intera 3000

HEPATIC ARTERY INFUSION PUMP

Indications for Use Statement

The Intera 3000 Refill Kit is indicated for use with the Intera implanted infusion pumps to administer infusate solutions. The Refill Kit is indicated for emptying and refilling the reservoir of an Intera 3000 Hepatic Artery Infusion Pump or CODMAN® 3000 Series Pump.

For Indications for Use of the Intera 3000 Hepatic Artery Infusion Pump or CODMAN® 3000 Series Pump, please find a digital copy of the associated IFU at: www.interaoncology.com/providers/resource-library/usa-library

WARNINGS

The pump must 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 can lead to serious consequences involving either under or over-delivery of drug to the patient. In the event of an over-delivery of drug refer to the approved drug labeling for appropriate action.

Utilization of the pump requires the proper handling (filling, storage and dispensing) of a significant volume/dosage of drug. This amount of drug can be extremely harmful to the patient if delivered suddenly or inappropriately.

Bolus 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 giving a bolus injection to the patient and can cause a fatal drug overdose.

The Intera 3000 Hepatic Artery Infusion Pump contain a safety valve in-line with the bolus pathway to insure that a bolus procedure can only be performed when using a properly positioned Special Bolus Needle (REF AP-04013-5 or AP-04032-5).

REVIEW ALL INSTRUCTIONS BEFORE PROCEEDING:

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 penetrate the septum.

PRECAUTION 2. Do not aspirate fluid from the Pump. Aspiration can 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.

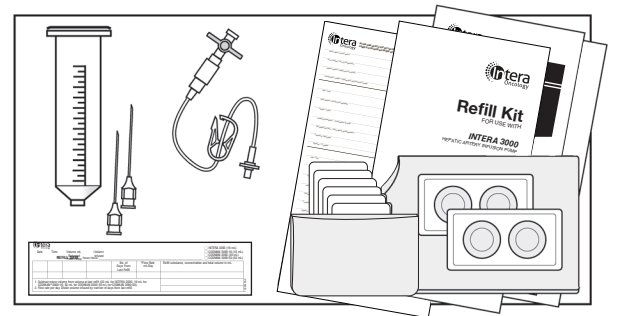
PRECAUTION 4. If the patient is traveling to a different altitude during the refill interval, refer to detailed Refill Kit IFU for flow rate adjustment.

PRECAUTION 5. If the refill is using glycerin, refer to the Intera Glycerin IFU, available at www.interaoncology.com.

Use the refill data sticker provided in this kit to maintain accurate Pump refill records.

Place patient in a supine position. Expose Pump pocket site. Palpate the Pump site and locate the raised septum. Fill a syringe with appropriate refill solution (16 mL for the CODMAN® 3000-16, 30 mL for the CODMAN® 3000-30, 50mL for the CODMAN® 3000-50 and 30mL for the Intera 3000) and a 10mL syringe with saline solution. Using sterile technique, expose kit contents.

Don sterile gloves. Use a disinfecting agent to prep the Pump site. Allow prepped area to dry. Place fenestrated drape over Pump site.



KIT CONTENTS

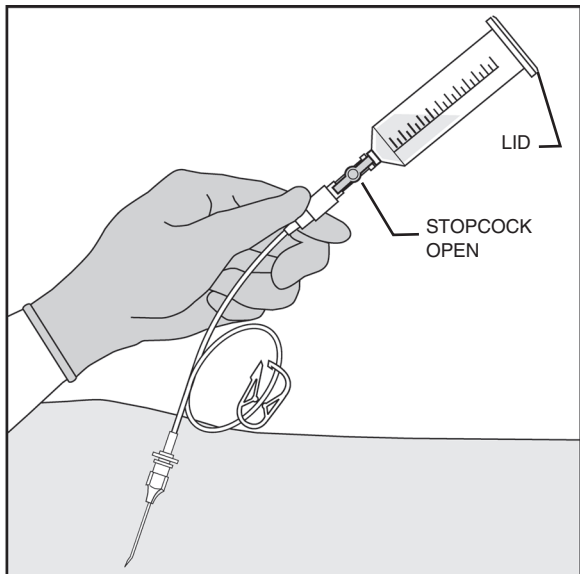
- [2] Huber Needles, 22 Gauge, 1.5" Length (3.8 cm)
- [1] Empty Syringe Barrel (50 mL) with Lid
- [1] 17.5" (44.5 cm) Microbore Tubing Set with Clamp
- [1] Stopcock
- [6] Gauze Pads
- [2] Adhesive Bandages

[1] Fenestrated Drape

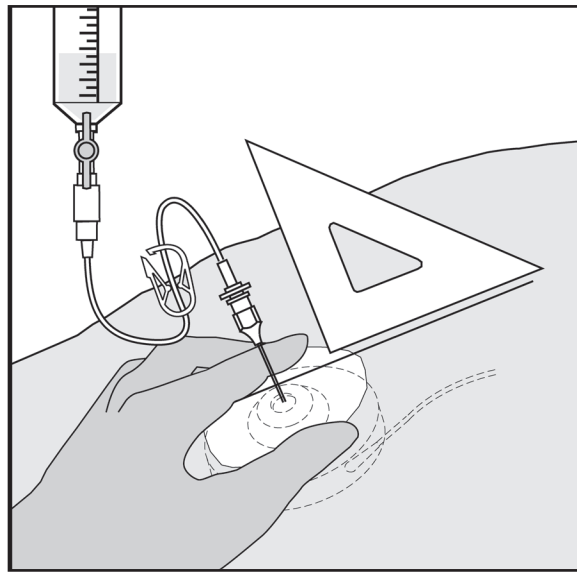
- [1] Data Sticker
- [1] Refill Worksheet
- [1] Instructions for Use
- [1] Instructions Poster

ITEMS NOT PROVIDED IN KIT:
Sterile gloves and syringes required for procedure and disinfecting agent to prep the pump site.

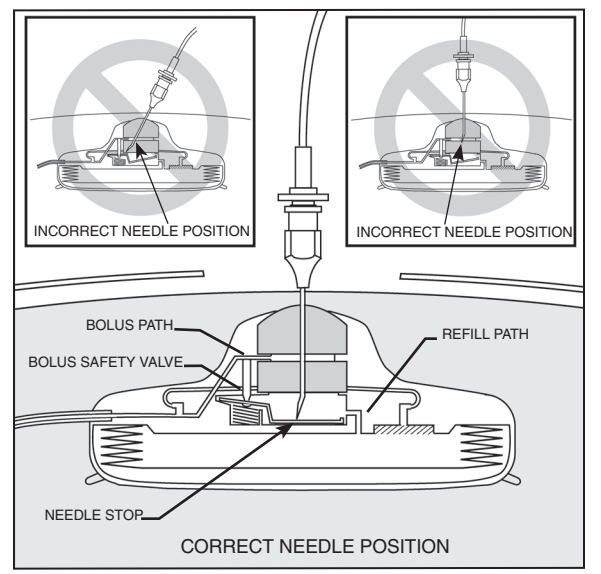
For 24-Hour Technical Assistance or to arrange an in-service Training Program, contact: **Intera Oncology, Inc.**
800-660-2660.



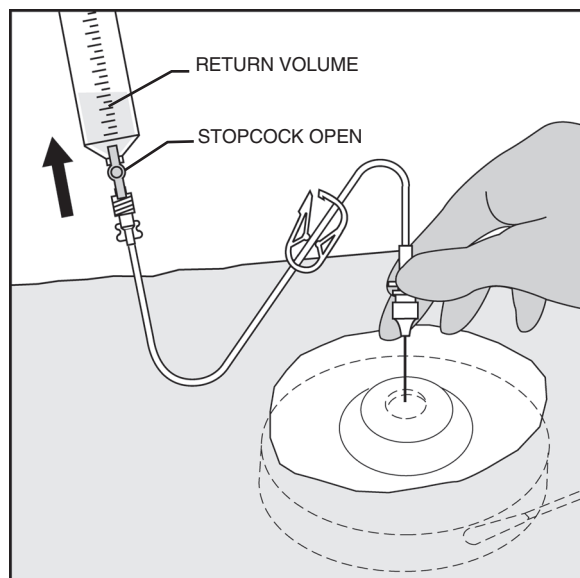
1. Attach the Needle and Stopcock to the tubing set. Stopcock and clamp are in the OPEN position. Next attach the 50 mL syringe barrel to the Stopcock. Tighten all connections.



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

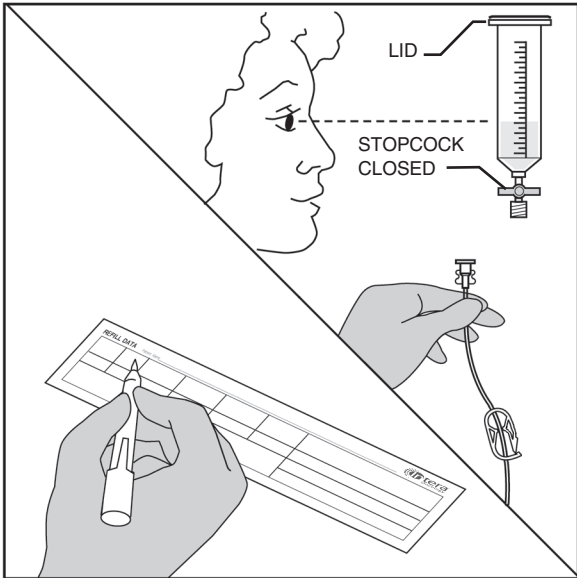


3. Advance needle until it is in contact with the needlestop.

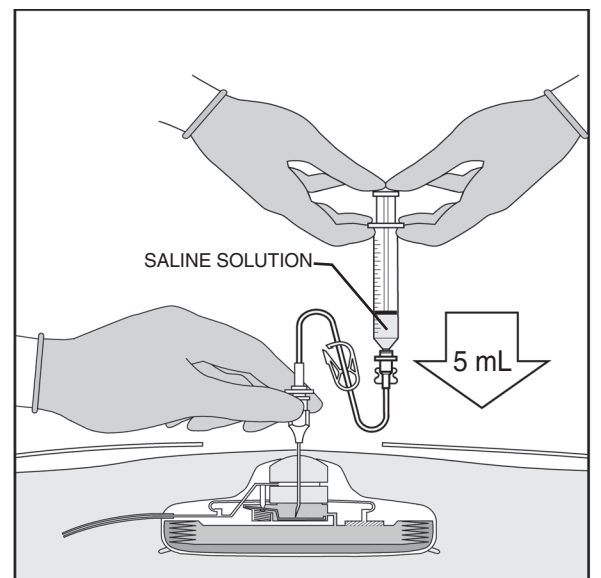


4. Allow the Pump reservoir to empty. Keep downward pressure on the needle throughout the procedure. **If no fluid returns to the syringe, refer to Troubleshooting Guide for assistance.**

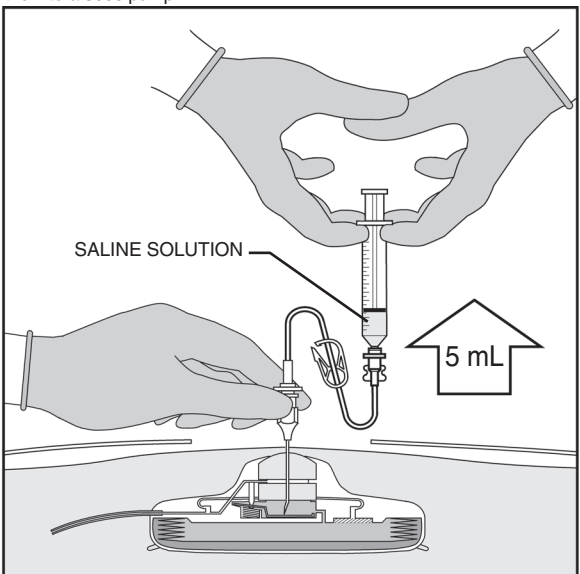
NOTE: After allowing the Pump to "empty" into the syringe barrel, fluid from the previous refill will remain in the Pump. This residual volume is 2.33mL for the CODMAN 3000-16 pump, 2.72mL for the CODMAN 3000-30 pump, 2.86mL for the CODMAN 3000-50 pump and 2.72mL for the Intera 3000 pump.



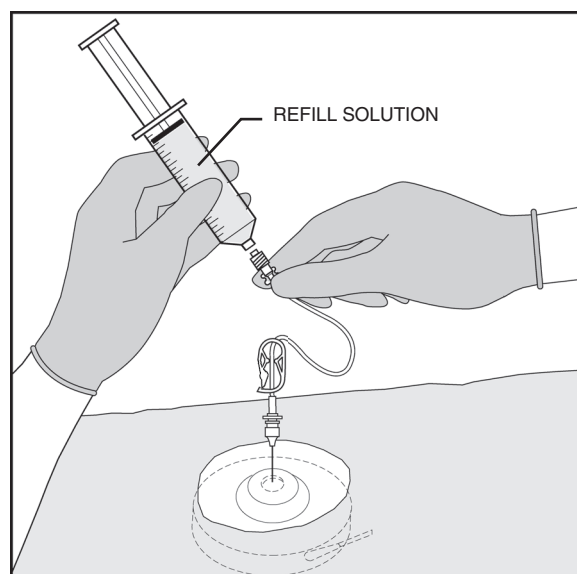
5. CLOSE STOPCOCK and clamp on tubing set. Note return volume (mL) and record on refill data sticker provided. Discard syringe barrel and stopcock leaving the needle and refill set in place.



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. Open the clamp on the tubing set while keeping downward pressure on the needle. Inject 5 mL of saline into the Pump.

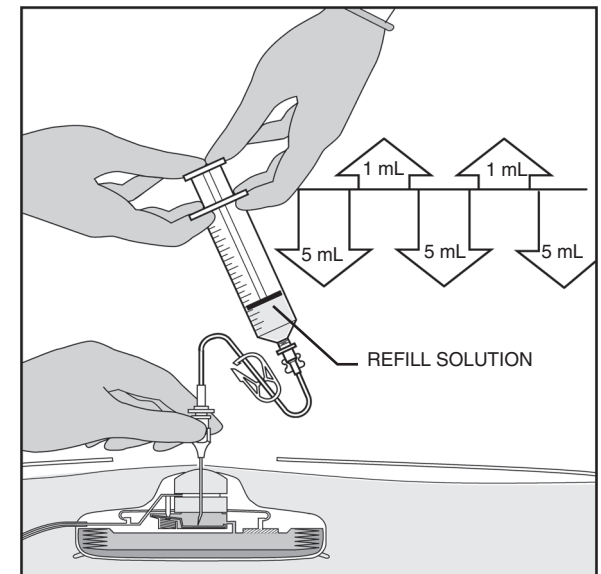


7. Release pressure on the plunger and allow the 5 mL injected to return to the syringe. This procedure reconfirms correct positioning of the needle. If no fluid returns, refer to Troubleshooting Guide for assistance. Close the clamp on the tubing set and disconnect the syringe from the refill set.



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

Refill Volume: INTERA 3000 30 mL
CODMAN 3000-16 16 mL
CODMAN 3000-30 30 mL
CODMAN 3000-50 50mL



9. Open the clamp on the tubing set while keeping downward pressure on the needle and begin to inject refill solution into the Pump. Release pressure on the plunger 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 emptied.

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 IN THE TROUBLESHOOTING GUIDE.

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

Troubleshooting Guide: If no fluid returns during Pump emptying, or during the Refill Injection Procedure, proceed as follows:

A. Confirm needle position and that a 22 gauge, non-coring needle is being used. Check that the needle is PERPENDICULAR to the Pump septum and is fully depressed and in contact with the needlestop. If no volume returns proceed with steps B, C, D.

B. Attach a 10 mL syringe containing normal saline solution to the refill tubing set.

C. Keep downward pressure on the needle and inject 5 mL of saline into the Pump. Release pressure on the syringe plunger and allow the fluid to return to the syringe. If fluid returns then the needle is in the proper position and indicates that the Pump was empty at the start of the refill procedure. Replace the 10 mL syringe with a syringe containing the Pump refill solution and continue with the refill procedure (steps 8 to 10).

D. 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.

E. Contact Intera Oncology, Inc. for 24-Hour Technical Assistance at 800-660-2660.