



Refill Kit

FOR USE WITH

INTERA 3000

HEPATIC ARTERY INFUSION PUMP

and


CODMAN 3000 Series

CONSTANT FLOW IMPLANTABLE PUMPS

REF AP-07014US

LCN 208545-001-X Rev. E

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Refill Kit – INTERA 3000

HEPATIC ARTERY INFUSION PUMP

Description

The Refill Kit is designed for use with the INTERA 3000 and CODMAN 3000 Series Pumps.

The Refill Kit contains:

- [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

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

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

IMPORTANT INFORMATION

Please Read Before Use

The Codman 3000 Series Constant Flow Infusion Pump has been rebranded as the Intera 3000 Hepatic Artery Infusion Pump. The Refill Kit is compatible with both the Intera 3000 and Codman 3000 infusion pumps.

For additional information, refer to the user manuals packaged with the Intera 3000 Hepatic Artery Infusion Pump.

For questions about Refill Kits or to submit a complaint, please call Intera Oncology Customer Service at 1-800-660-2660.

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 contains 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-040135 or AP-040325).

REVIEW ALL INSTRUCTIONS BEFORE PROCEEDING

PRECAUTIONS

CAUTION: Inspect the sterile package carefully. Do not use if:

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

A 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.

Do not aspirate fluid through the Bolus Pathway. Aspiration will cause blood to be drawn into catheter and result in occlusion.

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.

HOW SUPPLIED



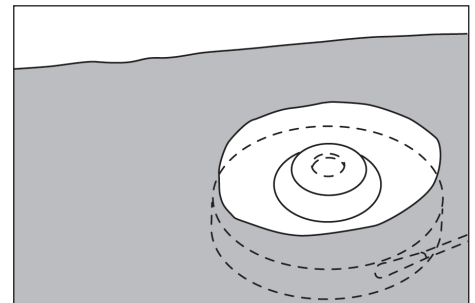
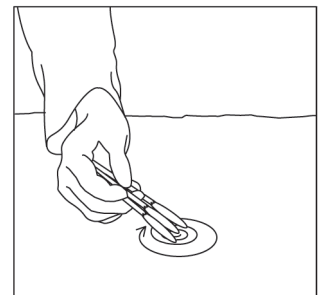
The INTERA Refill Kit is intended for SINGLE USE ONLY; DO NOT RESTERILIZE. Use aseptic technique in all phases of handling. Intera Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or resterilization, after a single patient use. Reuse can potentially compromise device performance and any usage beyond the design intent of this single use device may result in unpredictable loss of functionality.

Intera Oncology, Inc. will not be responsible for any product that is resterilized, 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.

REFILL PROCEDURE:

Place patient in a supine position. Expose the pump pocket site. Palpate the pump site and locate the raised septum.

1. Fill a syringe with appropriate refill solution (refer to model for proper volume) and a 10 mL syringe with saline solution.
2. Using sterile technique, open refill kit and expose kit components.
3. Don sterile gloves. Use a disinfecting agent to prep the pump site in a circular fashion extending the prepped area beyond the periphery of the pump. Allow prepped area to dry. Place fenestrated drape over pump site.



STERILE EO

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

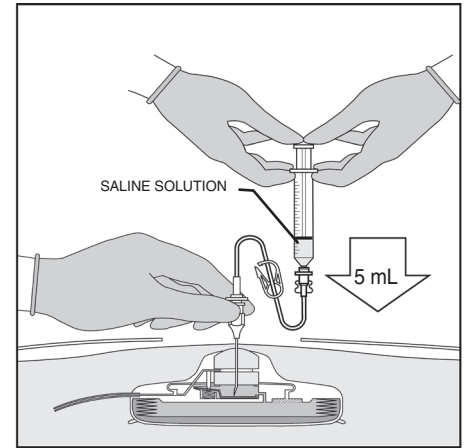
INTERA 3000 (30 mL)
 CODMAN 3000-16 (16 mL)
 CODMAN 3000 (30 mL)
 CODMAN 3000-50 (50 mL)

REFILL DATA Patient Name: _____

Date	Time	Volume mL Returned From Pump	¹ Volume Infused	No. of Days From Last Refill	² Flow Rate mL/Day	Refill substance, concentration and total volume in mL.
1. Subtract return volume from volume at last refill: (30 mL for INTERA 3000, 16 mL for CODMAN® 3000-16; 30 mL for CODMAN 3000; 50 mL for CODMAN 3000-50). 2. Flow rate per day. Divide volume infused by number of days from last refill.						

EXAMPLE:
INTERA 3000
30 mL Reservoir

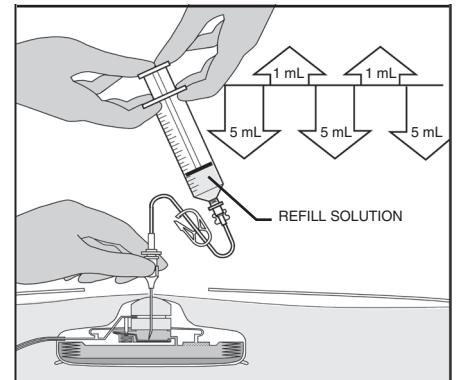
A	B	C	D
Volume Returned From Pump 10.5 mL	Volume Infused 30 mL – A 30 – 10.5 = 19.5 mL	No. of Days from Last Refill 15 days	Flow Rate B/C 19.5 mL/15 days = 1.3 mL/day



10. 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.

11. Expel air from the refill syringe. Attach the appropriate volume syringe to the proximal end of the refill set and confirm that the needle is still in contact with the needle stop.

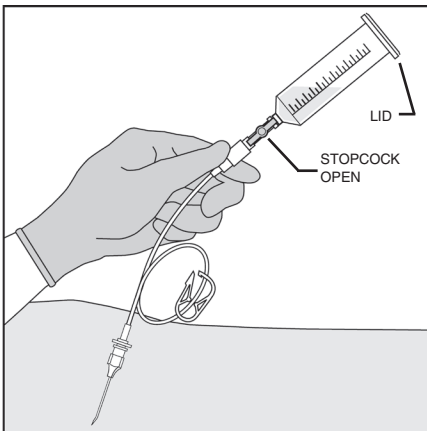
12. Open the clamp on the tubing set while keeping downward pressure on the needle and begin to inject refill solution into the pump. Release pressure on the plunger at 5 mL increments and allow 1 mL of solution to return to the syringe. This will verify that the needle is in the correct position and 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.** Follow steps A, B, C, D per the *Troubleshooting Guide*.

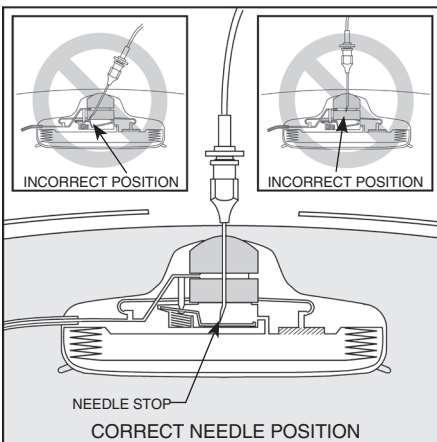
13. After injecting the entire contents of the refill syringe, maintain pressure on the syringe plunger and close the clamp on the tubing set and pull the needle out of the pump septum. Remove drape and apply adhesive bandage to access site.

4. Attach the Needle and Stopcock to the Tubing Set. Stopcock and clamp are in the OPEN position. Next attach 50 mL syringe barrel to the Stopcock. Tighten all connections.

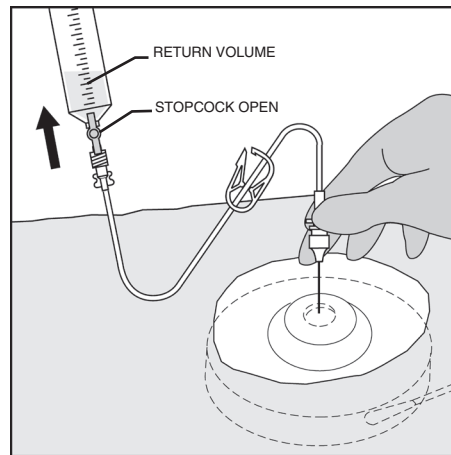


5. Re-palpate the pump site and locate the raised septum.

6. Insert the non-coring needle PERPENDICULAR to the pump septum. Advance the needle until it is in contact with the needle stop.

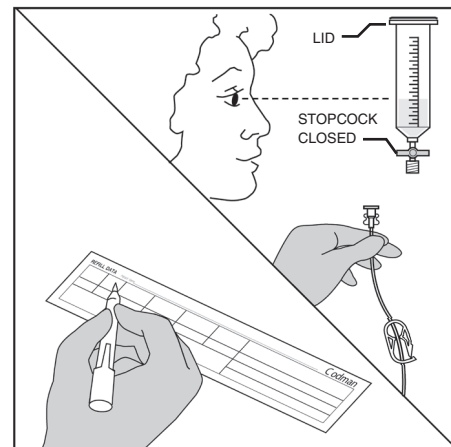


7. Allow pump reservoir to empty (Figure 5). Keep downward pressure on the needle throughout the procedure. If no fluid returns to the syringe, refer to *Troubleshooting Guide* for assistance.



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

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



9. 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 and inject 5 mL of saline into the pump.

Special Note:
Inform patient of date, time and place for next pump refill.

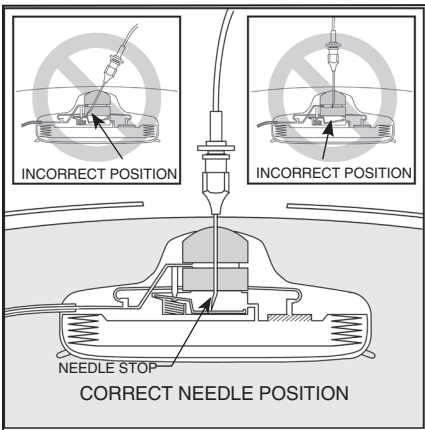
Refill Volume:
INTERA 3000 30 mL
CODMAN 3000-16 16 mL
CODMAN 3000-30 30 mL
CODMAN 3000-50 50 mL

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 needle stop. If no volume returns proceed with steps B, C, D.

B. Attach a 10 mL syringe containing 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 the syringe containing the pump refill solution and continue with the refill procedure (steps 12 and 13).

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 into the pump septum until it is in contact with the needle stop. Repeat step C.

E. If there is still no fluid return after injection of the 5 mL of saline, contact Intera Oncology, Inc. for 24-hour technical assistance at 860-660-2660.

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Symbols Glossary



Do not resterilize



Do not reuse



Sterile



Sterilized using ethylene oxide



Sterilized using steam



Do not use if package is damaged



Keep dry



Nonpyrogenic, see instructions for use



Consult Instructions for Use



Prescription device only (USA)



Use by date



Serial number



Date of manufacture



Made in



Quantity



Store product between 15°C (59°F) and 30°C (86°F)

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