



# Refill Kit

FOR USE WITH

***INTERA 3000***

HEPATIC ARTERY INFUSION PUMP

and


***CODMAN 3000 Series***

CONSTANT FLOW IMPLANTABLE PUMPS

**REF AP-07014US**

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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. These pumps are indicated for the continuous regional delivery of the following infusates with the associated route of administration indicated below:

Infusate	Indicated Route of Administration
2-Deoxy 5-Flourouridine (FUDR)	Arterial
Heparinized Saline	Arterial
Saline	Arterial
Bacteriostatic Water	Arterial
Glycerin Injection	Arterial

In addition to the above, Codman 3000 Series Pumps are also indicated for the continuous regional delivery of the following infusates with the associated route of administration indicated below:

Infusate	Indicated Route of Administration
Preservative Free Morphine Sulfate	Intraspinal
Baclofen	Intraspinal
Saline	Intraspinal

The approved labelling for FUDR stipulates the indications, contraindications, and warnings for use of the drug in the pump.

The use of preservative-free morphine sulfate is indicated for patients with intractable chronic pain.

Bacteriostatic water or saline must be used to achieve the desired concentration of FUDR. Heparinized saline can be used during an interruption of FUDR therapy to maintain catheter patency.

Use saline to achieve the desired concentration of preservative-free morphine sulfate and during an interruption of morphine therapy to maintain catheter patency. Glycerin infusion is indicated for patients who are receiving continuous Hepatic Arterial FUDR Chemotherapy. Glycerin infusion is employed as a placebo to keep the catheter patent or to extend the refill interval for patients who require therapy interruption or withdrawal.

The INTERA 3000 Pump is indicated for use in the adult population only.

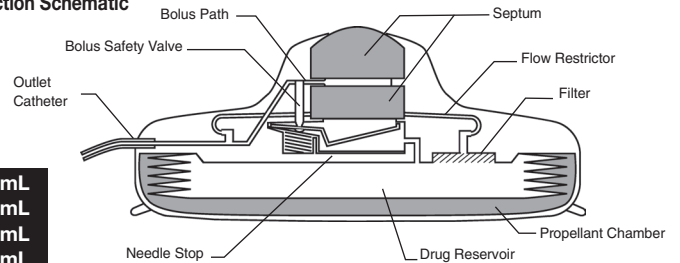
**The Refill Kit contains:**

- [1] 50 mL Calibrated Syringe Barrel
- [1] Tubing Set
- [1] Stopcock
- [2] Huber Point Needles; 22 Gauge x 1.5" (3.8cm)
- [6] Gauze Pads
- [1] Fenestrated Drape
- [1] Data Sticker
- [2] Adhesive Bandages
- [1] Refill Worksheet
- [1] INSTRUCTIONS FOR USE
- [2] INSTRUCTION POSTERS

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

**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.

**INTERA 3000 SERIES Cross Section Schematic**


INTERA 3000 .....	30 mL
CODMAN® 3000-16 .....	16 mL
CODMAN® 3000-30 .....	30 mL
CODMAN® 3000-50 .....	50 mL

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

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-04013-5 or AP-04032-5).

**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.

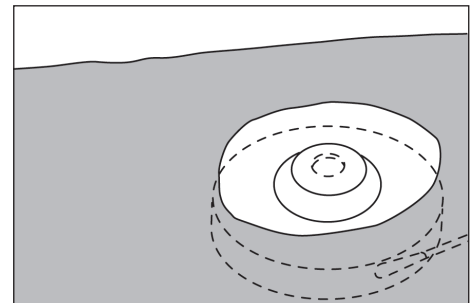
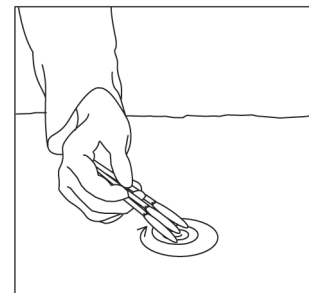
Intera Oncology, Inc. will not be responsible for any product that is resterilized, nor accept for credit or exchange any product that has been opened but not used.

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.



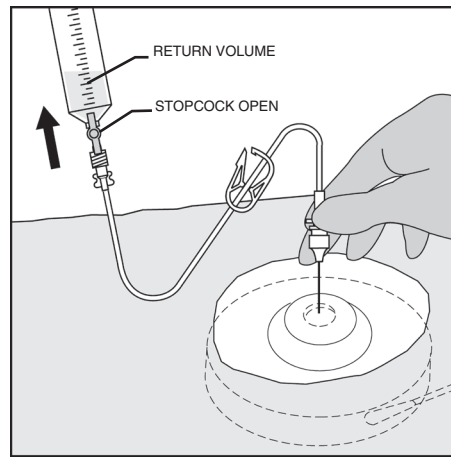
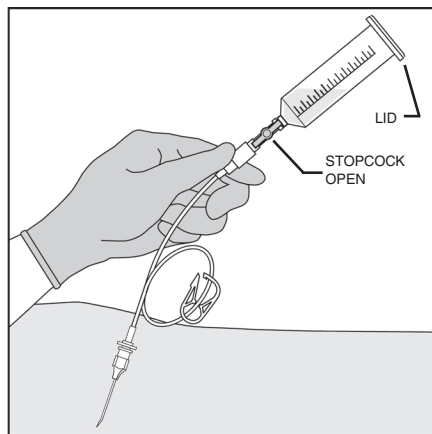
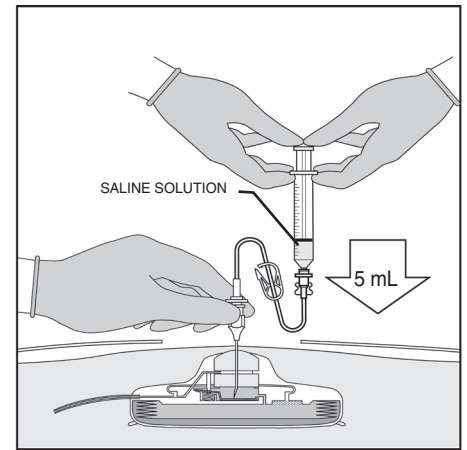
4. Attach the Needle and Stopcock to the Tubing Set. Stopcock and clamp are in the OPEN position. Next attach 50 mL calibrated syringe barrel to the Stopcock. Tighten all connections.

REFILL DATA						Patient Name: _____
Date	Time	Volume mL Returned From Pump	<sup>1</sup> Volume Infused	No. of Days From Last Refill	<sup>2</sup> 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.						

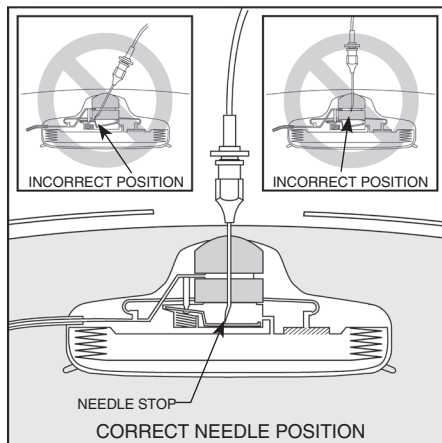
**EXAMPLE:**

**INTERA 3000  
30 mL Reservoir**

A	B	C	D
Volume Returned From Pump	Volume Infused 30 mL – A	No. of Days from Last Refill	Flow Rate B/C
2 mL	30 – 2 = 28 mL	28 days	28 mL/28 days = 1 mL/day



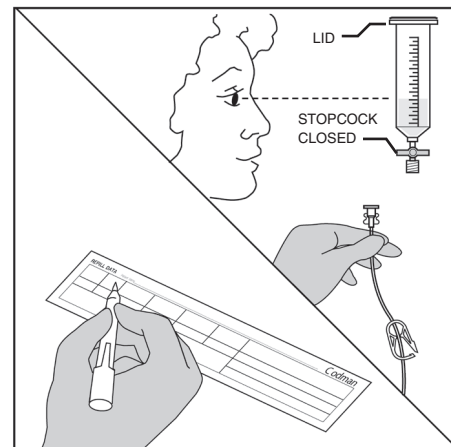
5. Re-palpate the pump site and locate the raised septum.
6. Insert the non-coring needle PERPENDICULAR to the pump septum. Advance the needle until it is in contact with the needle stop.



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 refill 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. 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.

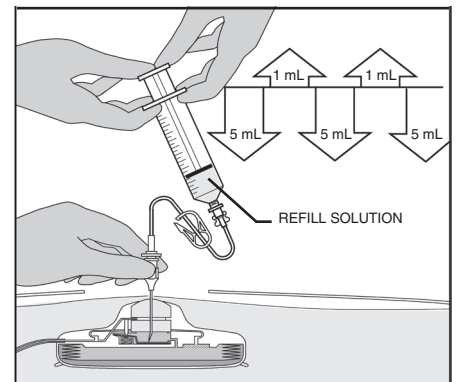


9. Expel air from the 10 mL syringe of saline. Attach the syringe to the proximal end of the refill set and confirm that the needle is still in contact with the needle stop. Keep downward pressure on the needle and inject 5 mL of saline into the pump.

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. 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. Keep downward pressure on the needle and begin to inject refill solution into the pump. Release pressure on 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*. Follow steps A, B, C, D per the *Troubleshooting Guide*.

13. After injecting the entire contents of the refill syringe, 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.

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

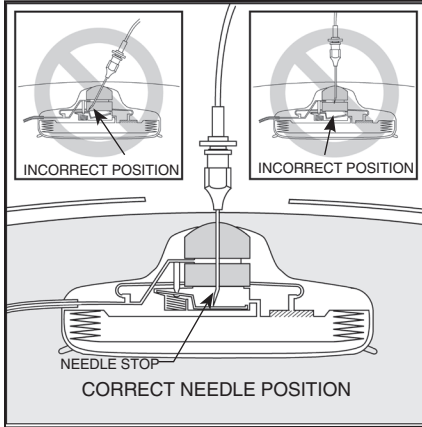
Refill Volume:	
INTERA 3000	30 mL
CODMAN 3000-16	16 mL
CODMAN 3000-30	30 mL
CODMAN 3000-50	50 mL

**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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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