

## **Intera 3000 Hepatic Artery Infusion (HAI) Pump**

For Hepatic Artery Infusion  
Liver Directed Therapy

THE ONLY FDA-APPROVED   
HEPATIC ARTERY INFUSION PUMP

PATIENT EDUCATION BROCHURE

**Intera**<sup>®</sup>  
Oncology  
Liver Directed Therapy



# INTERA 3000 HAI PUMP

“ After initially being told the tumors in my liver couldn't be removed, I received four rounds of HAI Pump therapy which shrank my tumors so they could be removed surgically. ”



-Mike F, patient

(Individual results may vary. Please consult your doctor.)

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# INTERA 3000 HAI PUMP

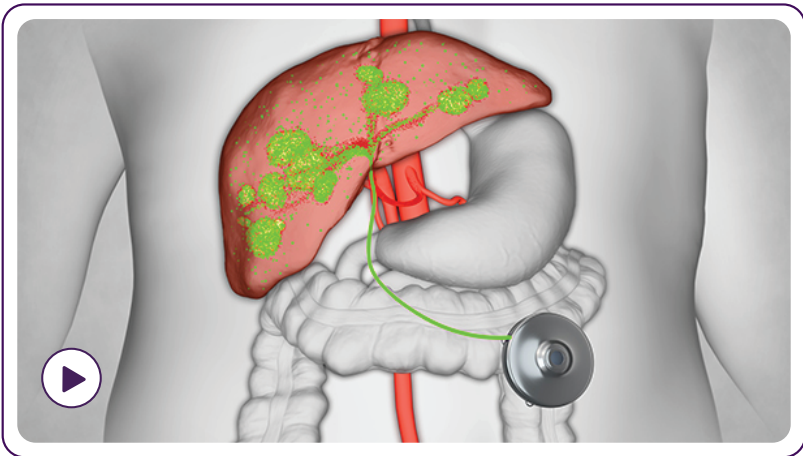


## WHAT IS HEPATIC ARTERY INFUSION THERAPY AND HOW DOES IT WORK?

Hepatic Artery Infusion (HAI) therapy is a treatment for colorectal or bile duct cancer (intrahepatic cholangiocarcinoma) that has spread to the liver. Chemotherapy is delivered to the liver using a pump that is implanted in the abdomen. This precise, localized delivery mechanism provides up to 400 times higher drug concentration to the tumors compared to systemic chemotherapy.

Traditional systemic chemotherapy is usually delivered through a patient's vein, requiring the drug to travel through the body's bloodstream to reach the liver. Only a small portion of the chemotherapy ultimately reaches the tumors in the liver.

With HAI therapy, the drug is administered through the hepatic artery directly to the liver, delivering therapy to the tumors and limiting potential side effects elsewhere.



Watch the animation video to see how the therapy works by visiting [www.interaoncology.com](http://www.interaoncology.com) or scanning the QR code.



# INTERA 3000 HAI PUMP

## USES OF HAI THERAPY

**Note:** This information is provided for educational purposes only. No claims are made for these products. Individual experience may vary. Please talk with your doctor to know whether HAI therapy is an option for you.

HAI therapy is a treatment option for patients with colorectal cancer or bile duct cancer (intrahepatic cholangiocarcinoma) that has spread to the liver. Your doctor may recommend HAI therapy in the following situations:

- **Following surgical removal of liver tumors from colorectal cancer (adjuvant therapy)**

Sometimes, after the tumors are removed from the liver, clusters of cancerous cells that are too small for a surgeon to see may remain. Doctors may use HAI therapy to treat these cancer cells before they can grow into tumors.

- **For colorectal cancer patients with liver tumors (metastases) that cannot be surgically removed**

HAI may shrink the tumors to the point they can be surgically removed or disappear altogether.

- **For bile duct cancer (intrahepatic cholangiocarcinoma) patients with liver tumors that cannot be surgically removed**

HAI may shrink the tumors to the point they can be surgically removed or disappear altogether.

# INTERA 3000 HAI PUMP



## HOW DOES THE INTERA 3000 HAI PUMP WORK?

The Intera 3000 HAI Pump contains a drug reservoir which is attached to a catheter (a long tube) that connects to the hepatic artery, the blood vessel that supplies blood to tumors in the liver. The pump is made of titanium and has smooth contours and measures approximately 3 inches in diameter, 1 inch in thickness and weighs 5 ounces.

The Intera 3000 HAI Pump is surgically implanted just below the skin in the abdomen. The HAI Pump implantation procedure can be performed as a standalone surgery or during other scheduled surgeries such as the removal of existing tumors.

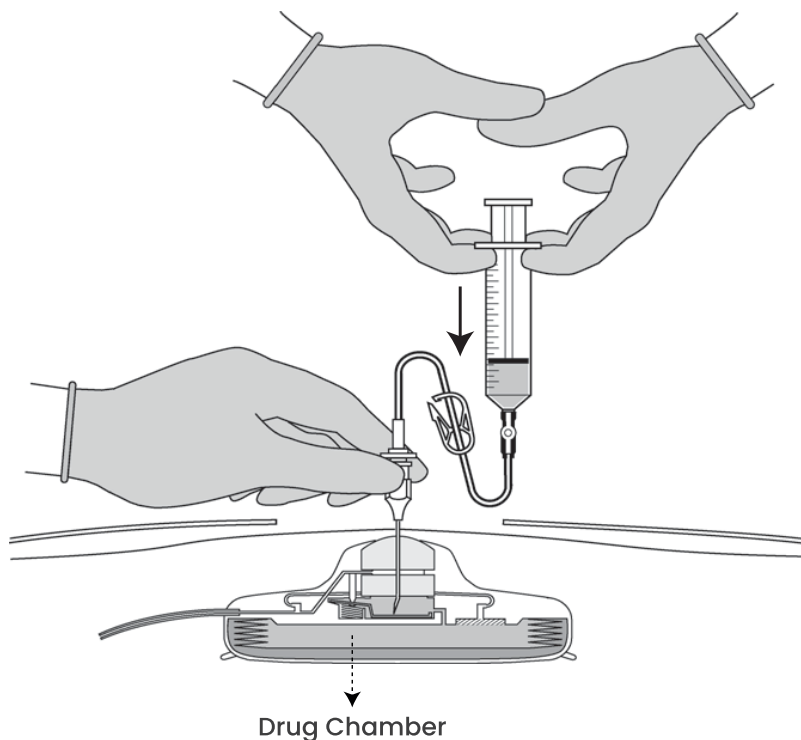
Once implanted, heat from the body activates the pump to deliver medicine. There are no batteries, motors, or gears that can stall or fail. The pump will not run out of power, as it is powered by the patient's body heat. The medication flows from the pump's inner chamber through the catheter, into the hepatic artery, and is delivered directly to the liver.

The pump will need to be periodically refilled. Patients can expect to visit the doctor's office every 14 days to refill the pump while receiving therapy. Refilling the pump is done in the doctor's office using a needle that is inserted into the pump. You may feel a mild pinprick as the needle passes through the skin to the pump. The doctor or nurse will then use a syringe to refill the pump. Patients report experiencing minimal discomfort while the pump is refilled. The refill procedure takes about 10–15 minutes. When not receiving therapy, visits can be extended to every six to eight weeks.



# INTERA 3000 HAI PUMP

## Intera 3000 HAI Pump being refilled with medication



### How long is the pump implantation procedure?

A standalone surgery can take one and half to two hours to complete, but if combined with other procedures, total surgery time will vary. After surgery, you may stay in the hospital for monitoring for one to three days, or as your doctor advises. After a few weeks of recovery, you can return to most of your usual daily routine with some limitations. There are some activities you should avoid, and your doctor will discuss these with you.

# INTERA 3000 HAI PUMP



## INTERA 3000 HAI PUMP – FEATURES

### Designed and approved for hepatic artery infusion

- Delivers chemotherapy directly to the blood vessel that supplies the tumors in the liver.
- The only FDA-approved implantable pump for HAI therapy.

### Designed for reliable, accurate drug administration

- Simple continuous flow pump.
- Inexhaustible power supply using body heat to power the pump.
- Refill cycles are predictable and reliable.

### Designed for simple long-term maintenance and support

- Easy for doctors and nurses to refill the pump.
- Extended refill periods of 6 to 8 weeks when not on active treatment.
- No motors, rotors, or gears that could stall or fail.

**The HAI Pump has been used for over 25 years and has an established safety profile**

Please see Important Safety Information for Intera 3000 HAI Pump on pages 11–12 of this brochure.

**Note:** The Intera 3000 Hepatic Artery Infusion Pump was previously marketed as the Model 3000 Series Pump and Codman® Series 3000 Pump. CODMAN is a registered trademark of Integra LifeSciences Corporation. Intera Oncology is not endorsed by, affiliated with, or sponsored by Integra LifeSciences Corporation.





# INTERA 3000 HAI PUMP

## LIVING WITH THE INTERA 3000 HAI PUMP

### Who is an appropriate candidate for HAI therapy?

HAI therapy is indicated for patients with colorectal cancer or bile duct cancer (intrahepatic cholangiocarcinoma) that has spread to the liver. The tumors (metastases) must be predominantly in the liver to be eligible for HAI therapy.

### How long will I have the pump?

The pump will remain in place for the duration of your therapy. In some cases, the pump remains implanted in patients for several years. Consult your doctor about your individual treatment plan.

### Will people notice the pump?

You will notice a slight bulge where the pump is implanted. At first it may take some time to get used to the pump. However, many patients report they eventually don't even realize it is there.

### Do I have to limit my activities?

Once you have recovered from surgery, you will be able to continue most of the activities you enjoyed before surgery. Your doctor or nurse will be able to give you guidelines; however, there are a few specific things to consider:

- Avoid rough physical activity including contact sports to protect the pump site.
- Avoid deep sea and scuba diving. Increased pressure will affect the flow rate of the pump. Snorkeling and swimming will have no effect on the flow rate, so you may continue with these activities.
- Do not place heating pads and/or hot water bottles directly over the pump implant site. This will increase the local temperature, thereby causing the pump to flow slightly faster.

# INTERA 3000 HAI PUMP



- Avoid saunas, long periods in hot tubs, as well as prolonged direct sun exposure because your pump will flow faster if your body temperature is elevated.
- Change in elevation can impact the pump flow rate. Let your doctor know if you plan to travel by air or spend time at another location as your medication may need to be adjusted.

## How often will I need to see my doctor?

Initially and during active treatment, you will need to see your doctor every two weeks. During those visits, your doctor will refill the pump with medication. After treatment is completed, the frequency of pump refills and appointments can be reduced to every six to eight weeks.

## What happens if I miss an appointment?

It is very important for you to keep your refill appointments, so the pump does not run dry. If you cannot keep an appointment, be sure to call your doctor or nurse for alternate arrangements as soon as possible.

If the pump is not refilled on a regular basis and runs dry, it may be impossible to continue HAI therapy.

## Does higher elevation impact my pump?

The Intera 3000 Pump is designed to be used at any elevation. However, the pump's flow rate will be affected while at high altitude. If you live or plan to spend time at locations 1000 feet above sea level or higher, or you are traveling by air, it is important you share this information with your doctor as your therapy may need to be adjusted.

## Can I safely have an MRI procedure with the pump?


The Intera 3000 Pump is classified as MRI Conditional, which means that certain conditions must be met to safely have an MRI. Before you have an MRI examination, please contact your doctor.





# INTERA 3000 HAI PUMP

## What is Intera 3000 patient identification (ID) card?

After your surgery, your doctor or nurse will give you an ID card that you should always carry with you.

 <b>INTERA 3000</b>	
<b>HEPATIC ARTERY INFUSION PUMP</b>	
PATIENT NAME	PUMP SERIAL NO.
<input type="text"/>	<input type="text"/>
PHYSICIAN	IMPLANT DATE
<input type="text"/>	<input type="text"/>
PHYSICIAN PHONE NO.	DRUG DELIVERED
<input type="text"/>	<input type="text"/>
<b>RESERVOIR VOLUME 30 mL</b>	
<small>NOTE: For Bolus Injection or Infusion Procedures Use Special Bolus Needle, ONLY.</small>	
<small>0883-20081 Rev. B</small>	

Front

	<b>Patient Medical Alert Card</b>
<b>Identification Information</b>	
This Patient has an INTERA 3000 Hepatic Artery Infusion Pump. Please carry this card at all times and show it to any medical personnel who may be treating you.	
 MR Conditional	
<b>Magnetic Resonance Imaging (MRI) Information</b>	
The INTERA 3000 Hepatic Artery Infusion Pump has been shown to be MR Conditional in MR systems operating under the following conditions: static magnetic field of 1.5 Tesla or 3 Tesla only, maximum spatial gradient magnetic field of 4,000 G/cm (40 T/m), maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg, and maximum gradient slew-rate (SR) of 150T/m/s per axis.	
<b>Before you have an MRI examination, please contact your physician.</b>	
<small>Manufactured for: Intera Oncology™, Inc. 65 William St., Suite 200, Wellesley, MA 02481 USA 800-660-2660 www.interaoncology.com</small>	

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## Why should I carry the Intera 3000 patient ID card with me?

It may be useful in case:

- You are traveling and need to receive medical care
- To show to your radiologist prior to MRI
- To show to airport security while traveling

## Can I travel with my Intera 3000 HAI Pump?

Your Intera 3000 Pump should not stop you from enjoying travel. Let your doctor know before you travel to confirm that you will not miss a refill appointment. It is unlikely that airport security systems will detect such a small amount of metal. If this does occur, present your patient ID card to security.

# INTERA 3000 HAI PUMP



## IMPORTANT SAFETY INFORMATION

### INTERA 3000 HAI PUMP

**Important:** Information in this booklet is not meant as medical advice and should not be used as a substitute for talking with your doctor. Always talk with your doctor about diagnosis and treatment information.

#### INDICATIONS

The Intera 3000 HAI Pump is indicated for the continuous regional delivery of the following infusates with arterial administration: 2-deoxy 5-fluorouridine (floxuridine), heparinized saline, saline, bacteriostatic water, glycerin injection.

The approved labeling for floxuridine stipulates the indications, contraindications, and warnings for use of the drug in the pump. Bacteriostatic water or saline must be used to achieve the desired concentration of floxuridine. Heparinized saline can be used during an interruption of floxuridine therapy to maintain catheter patency.

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

#### CONTRAINDICATIONS

The Intera 3000 HAI Pump is contraindicated for use in patients with:

- Known or suspected infection, bacteremia, septicemia, or peritonitis.
- Known allergic reaction or other signs of intolerance to implanted devices.
- Certain emotional or psychiatric problems.
- Insufficient body size to accommodate the physical size of the pump.
- Floxuridine should be used with added caution in patients with impaired hepatic or renal function.



# INTERA 3000 HAI PUMP

- Patients with known disease extending beyond an area capable of infusion must be considered for systemic therapy with other chemotherapeutic agents.

**Drug leakage can result if the instructions for use are not followed correctly during a pump refill or bolus procedure.**

It is important that a Refill Kit be used for pump refill and that the refill procedure be carried out in accordance with the instructions provided in this pamphlet and in the Refill Kit. A special bolus needle must be used to successfully perform a bolus procedure.

## **ADVERSE EVENTS**

Possible adverse events associated with the pump are those potential risks associated with any implanted drug delivery device and include catheter thrombosis, bolus path occlusion, vessel thrombosis, pump dislodgement, seroma or recurrent hematoma, infection, extravasation, catheter shear, dislodgement or leakage and migration, arterial pseudoaneurysm, arterial dissection, and extrahepatic perfusion.

**Caution:** Federal law (USA) restricts this device to sale by or on the order of a doctor.



# INTERA 3000 HAI PUMP



## Glossary

**Adjuvant therapy:** Additional cancer treatment given after the primary treatment to lower the risk of cancer coming back.

**Artery:** A blood vessel that takes blood away from the heart to one or more parts of the body.

**Bacteremia:** Presence of bacteria in the bloodstream.

**Bacteriostatic water:** Water that has an additive to inhibit the growth of most types of bacteria.

**Bile:** Fluid that is made and released by the liver and stored in the gallbladder.

**Bloodstream:** Blood that flows through arteries and veins around your body.

**Blood vessel:** An artery or vein through which the blood circulates in the body.

**Bolus:** The pump has a separate fluid pathway that allows your doctor to administer drugs and fluids more quickly through the pump catheter and into the hepatic artery. This is useful if the catheter becomes occluded and when performing special scans of flow of blood in the liver.

**Catheter thrombosis:** A blood clot that forms within or at the tip of the catheter.

**Chemotherapy:** A treatment that uses powerful drugs to kill fast-growing cancer cells in the body.

**Contraindication:** Anything (including a symptom or medical condition) that is a reason for a person to not receive a particular treatment or procedure because it may be harmful.

**Drug concentration:** The amount of drug in a given volume of liquid.

**Extravasation:** Leakage of blood, lymph, or other fluid, such as an anticancer drug, from a blood vessel or tube into the tissue around it.

**Floxuridine:** Belongs to a group of medicines known as antimetabolites. It is used to treat some kinds of cancer.

**Hematoma:** Collection of pooled blood under the skin.

**Heparinized saline:** An anticoagulant to decrease the clotting ability of your blood and help stop clots from forming at the tip of the catheter where it is inserted in the hepatic artery.

**Hepatic:** Relating to the liver.

**Infusate:** A fluid or drug given intravenously over a period of time for medication or diagnostic purposes.

**Liver metastases:** Cancerous tumors that have spread (metastasized) to the liver from another part of the body.

**Occlusion:** The blockage of a blood vessel or a tube.

**Peritonitis:** Inflammation or infection of the peritoneum — a membrane that lines inner abdominal wall and covers the organs within the abdomen — that is usually due to a bacterial or fungal infection.

**Saline:** A liquid mixture of salt and pure water.

**Septicemia:** Blood poisoning by bacteria.

**Seroma:** Build-up of clear fluid inside the body.

**Systemic chemotherapy:** Anti-cancer drugs that are injected into a vein or given by mouth. These drugs travel through the bloodstream to all parts of the body.

**Thrombosis:** The formation of a blood clot inside a blood vessel, or tube such as a catheter, obstructing the flow of blood or fluid.

**Tumor:** A solid mass of tissue that forms when abnormal cells group together.

**Vein:** A blood vessel that carries blood from the body and toward the heart.



# INTERA 3000 HAI PUMP

MY NOTES

# INTERA 3000 HAI PUMP



MY NOTES

## ABOUT INTERA ONCOLOGY

We are a Boston-based medical device company whose mission is personal. We have close friends and family members who have been diagnosed with colon cancer or cholangiocarcinoma and have directly benefited from HAI therapy. When the founders learned that the only FDA-approved pump for HAI treatment was being discontinued, they formed Intera Oncology to make sure that as many patients as possible who have tumors in the liver from colorectal cancer and cholangiocarcinoma have access to HAI therapy.



For further queries, please contact

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🌐 [www.interaoncology.com](http://www.interaoncology.com)

