

INTERA 3000

HEPATIC ARTERY INFUSION PUMP

Patient Education Booklet

Your doctor has prescribed an Implantable Pump for you because your treatment plan requires administration of medication on a continuous basis directly into a specific body site.

Your therapy requires the administration of

| | MEDICATION |
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| | |
| to the | |
| | |
| | |
| | BODY SITE |

Your pump holds 30 mL's when filled.

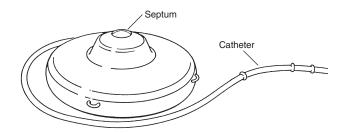
The information contained within this booklet will help you understand how the Pump will be used in your treatment.

What is an Implantable Pump?

An Implantable Pump is a small drug delivery system that is completely implanted beneath the skin. The pump is approximately two to three inches in diameter, 3/4 to one inch thick and weighs four to six ounces. The titanium pump is circular in shape with a small raised area in the center called a septum.

The septum is where the special needle is inserted when the pump is filled with medication. The medication flows from the drug chamber into the selected body site through a small flexible tube called a catheter.

The pump holds medication which is continuously released while you are going about your daily activities



Implantable Pump

How is the Pump implanted?

Your surgeon will place the Pump under your skin in a pocket made between the skin and muscle in your lower abdomen or upper chest cavity.

The catheter will be placed into a selected body site. The pump will be filled at the time of your operation and will begin working immediately.

The surgical procedure to implant the Pump is usually performed under general anesthesia and normally takes two to three hours. If needed, any additional surgery may be performed at this time. If this is the case, your surgery may take longer.

Your stay in the hospital after surgery will depend on the amount of surgery performed at the time of your pump implant. You will usually have a bandage over the incision site. Your doctor or nurse will provide you with instructions for care of the implant site. Once the incision has healed the site will no longer require any special care.

After your surgery, your doctor or nurse will give you an Identification Card that you should carry with you at all times



Patient Medical Alert Card

Identification Information

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 MR Conditional

Magnetic Resonance Imaging (MRI) Information

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.

Before you have an MRI examination, please contact your physician.

Manufactured for: Intera Oncology™, Inc.

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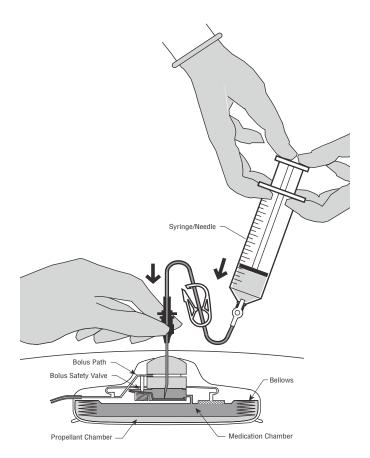
www.interaoncology.com

How does the Pump work?

The inside of the Pump is divided into inner and outer chambers by an accordion-like bellows. The inner chamber contains the medication to be infused. The outer chamber contains a propellant permanently sealed inside. The temperature of your body warms the propellant.

The warmed propellant exerts a constant pressure on the bellows causing the medication to flow out of the inner chamber, through a filter and flow restrictor, and then slowly out the catheter.

Refilling the pump with medication expands the bellows and starts the pump on the next cycle of drug infusion. The pump may be refilled as many times as is necessary for your therapy.



Refilling the Pump

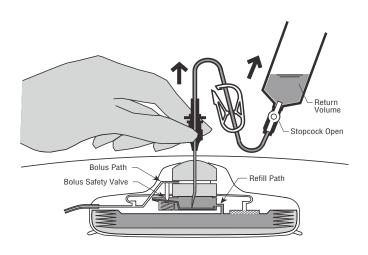
Using the pump for treatments:

The Pump can be used to deliver medication in two ways. One method is CONTINUOUS INFUSION and the other is BOLUS INJECTION.

CONTINUOUS INFUSION:

Continuous infusion is used from the time the Pump is implanted in surgery. Your doctor or nurse will refill the pump every two to eight weeks.

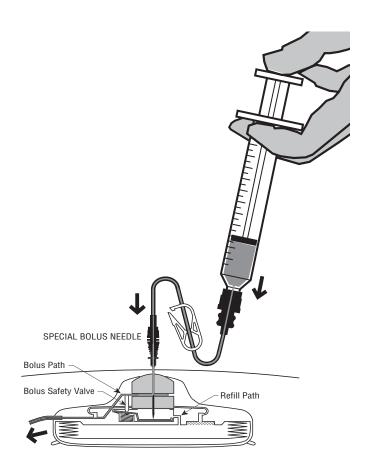
After cleaning your skin at the pump site, a special needle with a syringe attached will be inserted into the septum in the top of the pump. You will feel a mild "pinprick" sensation as the needle passes through the skin into the septum. This will allow all the medication which remains in the pump to flow out of the pump into the syringe. The amount of fluid removed will be measured so your doctor will be sure you receive the proper amount of medication. Next, a syringe containing the refill medication will be attached to the needle already in place and the pump will be refilled. The refill procedure takes 10–15 minutes and you should not feel pain other than the "pinprick" sensation.



Emptying the Pump

Bolus Injection:

There may be times when your doctor may want to flush the catheter or give you an injection of medication directly into your body through the catheter. This is done through the septum in the top of your pump using a Special Bolus Needle. This needle is designed with a special opening which when inserted into the septum allows the drug or fluids to be injected directly into the catheter. This procedure can be done for several reasons, which will be explained by your doctor or nurse. As in the pump refill procedure, you will only feel a "pinprick" as your pump is accessed.



Bolus Injection

MRI Safety Information



MR Conditional

You may encounter occasions when there is a need for Magnetic Resonance Imaging (MRI) to diagnose you or determine a treatment plan. Your Intera 3000 pump can only be scanned under very specific conditions at a facility that is qualified to image implanted pumps. Your doctor or radiologist can obtain full MRI safety information in the MRI section of the Intera 3000 manual, which can be obtained at www.interaoncology.com or by calling 1-800-660-2660.

Activities after the pump is implanted:

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

- 1. Avoid rough physical activity like contact sports which might cause a blow to the pump site.
- Avoid deep sea and scuba diving. Increased pressures will affect the flow rate of the pump. Snorkeling and swimming will have no effect on the flow rate, so you may continue these activities.
- 3. Do not place heating pads and/or water bottles directly over the pump implant site. Direct contact of the heating pad or water bottle over the pump pocket site will increase the local temperature, thereby causing the pump to flow faster.
- Avoid saunas, long periods in hot tubs, and prolonged direct sun exposure because your pump will flow faster if your body temperature is elevated.
- Let your doctor know if you plan to travel by air or move to another location as your medication may need to be adjusted.
- **6.** Call your doctor or nurse if you have a fever.

Common questions patients have about an Implantable Pump:

Q: What happens if I miss a scheduled appointment?

It is very important for you to keep your appointments because the pump may run dry. If you cannot keep an appointment, be sure to call your doctor or nurse for alternate arrangements.

Q: Can I travel with my Pump?

Your Pump should not stop you from enjoying travel. Let your doctor know if you plan to be away for longer than your scheduled refill period. Your doctor can refer you to a physician in another area while you are on vacation.

Q: Will the Pump activate airport security systems? It is highly unlikely that the airport security systems will detect such a small amount of metal. If this does occur, present your Patient Identification Card to security.

Q: Will my insurance company pay for the Pump? Insurance coverage differs from company to company. However, most insurance companies will provide financial support for the placement and care of the pump. To be sure, check with your insurance carrier to determine the extent of your coverage.

Q: What if I need an MRI (Magnetic Resonance Imaging)?

Your pump is classified as MR Conditional, which means that certain conditions must be met to safely have an MRI. Before you have an MRI examination, please contact your physician or Intera Oncology at 1-800-660-2660.

Q: 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 any time at locations 1,000 feet above sea level or higher, including travel by air, it is important you share this information with your physician as your therapy may need to be adjusted.

| Notes: | | |
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