



Patient Information Guide

Understanding Your Treatment

TheraSphere™ Yttrium-90 Glass Microspheres

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A Patient's Guide to TheraSphere™

Your physician has prescribed TheraSphere as a treatment for your liver tumor. This booklet contains details on what to expect from typical treatment activities and possible side effects. It also contains some helpful information such as common medical terms (found in the Glossary).

Read this booklet carefully before your TheraSphere treatment.

- Keep this booklet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you have questions about any of the side effects listed, or you experience a side effect that is not listed in this booklet, please consult with your doctor.

Glossary

Angiography: a medical imaging procedure performed by a doctor (Interventional Radiologist (IR)). By inserting dye via a needle and catheter, your doctor can see and study blood vessels and their branches which are not visible by standard non-invasive means like X-ray or CT scan.

Artery: any blood vessel that carries blood from the heart to the organs.

Catheter: a thin, flexible tube introduced through a blood vessel used to access the treatment region, to inject fluids or to implant TheraSphere glass microspheres.

TheraSphere™: a liver cancer treatment that is made up of microscopic glass spheres containing a radioactive element yttrium-90.

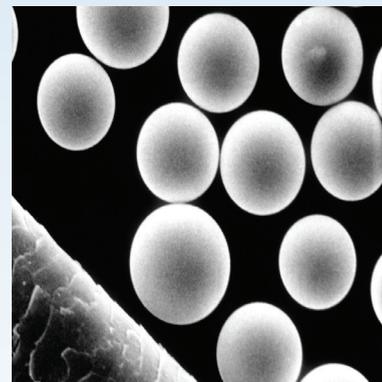
Yttrium-90: a radioactive element that emits radiation while transitioning from yttrium-90 (unstable element) to Zirconium-90 (stable element).

What is TheraSphere™ used for?

TheraSphere is used to treat malignant tumors in the liver. Your doctor has determined that TheraSphere is the most appropriate treatment for your disease. TheraSphere treatment is commonly referred to as selective internal radiation therapy (SIRT), transarterial radioembolization (TARE), or simply radioembolization.

How does TheraSphere work?

- TheraSphere is made of many microscopic glass spheres containing yttrium-90. Yttrium-90 emits radiation into the tissue within 0.5 inches of the glass spheres.
- The radioactive glass spheres are delivered to the tumor through a catheter. The selective delivery of the spheres into the blood vessels within the tumor will minimize the effect of radiation on the rest of the liver surrounding the tumor.
- Most of the radiation from the glass spheres (approximately 95%) will be absorbed in the liver tissue within 12 days of the treatment.
- The glass microspheres stay permanently in the liver.



**TheraSphere microspheres
next to human hair.**

What should I tell my doctor before being treated with TheraSphere™?

Before your treatment with TheraSphere, tell your doctor if you:

- are pregnant or may be pregnant
- have slow or irregular blood clotting or a bleeding condition
- have any liver conditions besides cancer
- have heart or lung conditions

Your doctor will determine if TheraSphere is an appropriate treatment for you by determining how well your liver works. Your doctor will look at your medical history, your previous treatments and the current medication you take. If you have any questions, ask your doctor about the tests they will perform.

How can I benefit from TheraSphere™ treatment?

Since every patient is different, it is difficult to know if, and by how much, TheraSphere may control your liver cancer (stabilize or shrink the tumor).

The procedure targets the liver tumor; therefore, there is minimal impact to the liver outside the treatment area or to other parts of your body not exposed to TheraSphere.

How could a treatment with TheraSphere affect me?

The yttrium-90 in TheraSphere emits radiation into the liver tissue, within 0.5 inches of the microspheres. Because the radiation produced by the glass spheres has a very small range of action, the radioactive energy outside your body is very low and is not a safety issue. Your hospital may give instructions when you leave the hospital, as a precaution. No safety restrictions are required for visitors, family, or caregivers.

If you plan to travel in the months following treatment, the security screening equipment at some airports may detect radiation from your TheraSphere. Ask your doctor if you need a letter explaining the treatment.

Please note: Although the radioactive energy continues to go down over time, the microspheres will remain permanently in your liver. Special liver handling may be required soon after your TheraSphere treatment if you have a liver surgery, or transplantation. In the case of death, disclosure of radioactive implants is normally required to funeral homes and crematoriums, and these institutions set their own policies.

What will be my treatment plan?

Your doctor will describe your treatment and follow-up appointments. All the procedures can be done on an outpatient basis and do not require hospitalization, allowing you to go home later that day. The procedures will require several visits to the hospital and your follow-up treatments will span several months. If you are currently taking other therapies, your doctor may temporarily stop these therapies during your treatment with TheraSphere™.

Your doctor will first do some testing (blood samples and imaging) and an angiography procedure before the TheraSphere treatment to investigate the liver blood flow. This pre-treatment “work-up” is to determine if TheraSphere can be administered to you safely. These tests will detect if TheraSphere could go unintentionally to other organs such as the stomach or lungs and whether it could cause side effects.

For the “work-up” angiography, your doctor will numb the area where they will be inserting the catheter into a blood vessel, either in your groin area or on your forearm. After numbing and disinfecting the area, they will make a small cut the size of a pencil tip to insert a thin, flexible catheter into an artery. They will steer the catheter through the arteries to reach the treatment location in the liver and inject a diagnostic imaging agent. This process may take around 15 – 20 minutes.

Your doctor may then order a scan of the just placed diagnostic imaging agent. After this work up, your doctor will know precisely how to best treat your disease. If you are a candidate, you will return 1 – 2 weeks later for your treatment with TheraSphere.

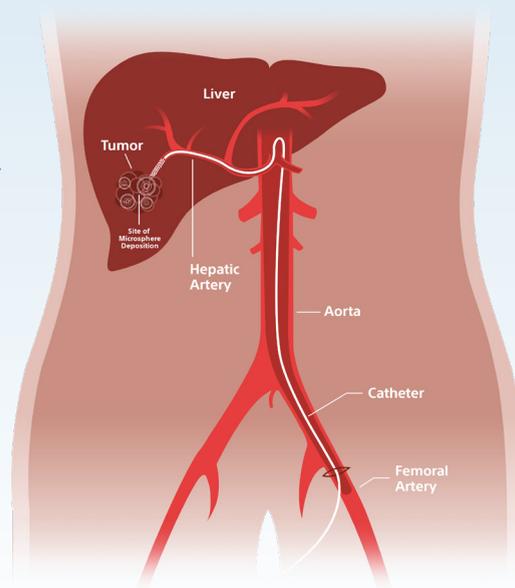
TheraSphere™ Treatment Day

Your doctor will inject TheraSphere into your liver during another angiography procedure:

- The doctor will position a catheter as described on the previous page.
- Your doctor will connect the catheter to the TheraSphere treatment system and will then inject TheraSphere with a salt-water solution into your liver through the catheter. This process will take approximately 5 minutes and you will not feel anything happening.
- The glass spheres deposit in the microscopic arteries of the tumor and remain permanently there. The radiation emitted by the yttrium-90 begins to treat the tumor.
- The catheter used to deliver TheraSphere is taken out after the procedure, and the insertion site is closed. Usually pressure is applied to the insertion site to prevent bleeding.

During the angiography procedures for work-up and TheraSphere treatment, your doctor may give you medication to help you relax and to prevent potential side effects such as nausea or pain. You will be sleepy but able to talk with your doctor and the medical team during the procedure if you choose.

The angiographies for work-up and TheraSphere treatment generally take less than an hour each. You may need to stay a few hours in the hospital after each angiography. Your doctor will explain any tests they may need to do after your treatment with TheraSphere.



What can I do after the procedures?

Each patient is unique and there may be medical reasons for restricting activity. Be sure to discuss with your doctor what level of activity is most appropriate for you following the procedure.

Limit your activities after the angiographies for work-up and TheraSphere™ treatment to avoid pain or bleeding at the puncture site:

- No exercise or lifting (more than 10 pounds) for the next 3 days
- Do not drive for 24 hours after the procedure

You may resume all other daily activities 24 hours after the procedure

Your doctor or pharmacist may review all prescriptions with you after your TheraSphere treatment. Please take your medications as prescribed. The following prescription medications may be given to you:

- A sedative and pain medication
- An anti-ulcer medication to help protect your stomach
- An antibiotic to reduce potential for infection

What side effects may I have?

Before the treatment, your doctor may prescribe additional medications to prevent or minimize the most frequent treatment side effects such as abdominal pain and nausea.

TheraSphere™ releases radiation energy that affects liver tissue. As a result, your doctor will routinely test your blood to monitor liver function and identify any potential risks that might occur.

After the angiographies for work-up and TheraSphere treatment, there may be some redness and a small bump at the site of the catheter insertion. Tell your doctor if you see bleeding or swelling at the site.

All medical treatments have risks or discomfort and may cause side effects. You should discuss the possible adverse effects of the angiography procedure with your doctor. Common side effects that may occur throughout the first week after the TheraSphere treatment are generally mild to moderate and include:

- fatigue
- mild stomach discomfort
- nausea
- vomiting
- fever

Doctors describe these symptoms as like those of the common flu. You may experience loss of appetite and temporary changes in liver blood tests that may or may not be associated with symptoms. Many side effects disappear shortly and completely within one week of treatment. Tell your doctor if these symptoms continue or worsen. Be aware that some side effects may last longer or, rarely, become permanent.

More severe side effects are rare but possible, and most of them are completely reversible. Very rarely there may be deterioration of the liver function that could lead to death.

Even after safety screening, there is still a small risk that some of the microspheres could go to other organs, resulting in injuries such as:

- radiation damage to the lungs
- fluid collection around the lungs
- injury or radiation to the gallbladder
- stomach or intestinal ulcer
- bleeding from the stomach or intestines
- kidney damage

Everyone responds differently to their treatment. These are not all the possible side effects you may feel. Contact your doctor if you experience any side effects.

What should I do if I experience a side effect?

Contact your doctor if you experience a side effect. Your doctor may prescribe medications to ease any discomfort. For information on TheraSphere™, please refer to the website:

www.bostonscientific.com

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300 Boston Scientific Way
Marlborough, MA 01752-1234

www.bostonscientific.com

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Manufacturer:

Biocompatibles UK Ltd
Chapman House, Farnham Business Park
Weydon Lane, Farnham, Surrey, GU9 8QL, UK

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