

A Patient's Guide to TheraSphere™

Important Information for People with Liver Cancer



A Patient's Guide to TheraSphere

Your physician has prescribed TheraSphere as a treatment. 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).



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Introduction

What is TheraSphere?

TheraSphere is a targeted liver cancer therapy with low toxicity, consisting of millions of tiny glass beads containing radioactive Yttrium-90. The glass beads (20–30 micrometers in diameter – about a third of the width of a human hair) are delivered directly to the liver tumors. TheraSphere treatment is commonly referred to as selective internal radiation therapy (SIRT), transarterial radioembolization (TARE), or simply radioembolization.

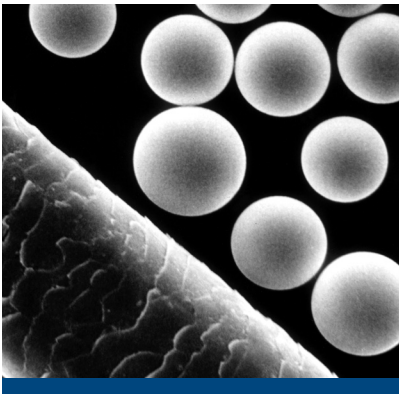


How does TheraSphere work?

- Your doctor injects TheraSphere into the hepatic artery of your liver through a small flexible tube known as a catheter.
- The tiny radioactive glass beads flow directly into the liver tumor via its own blood vessels and become permanently lodged in the small blood vessels.
- The radiation destroys the tumor cells from within the tumor, with minimal impact to the surrounding healthy liver tissue.
- The tiny glass beads will deliver most of the radiation (>95%) to the tumor in the first two weeks following the TheraSphere treatment.

TheraSphere treatment can be an outpatient procedure that does not require hospitalization.

- It is well tolerated by patients, with side effects that are normally milder than many other liver cancer treatments.
- Because the procedure is directed within the liver tumor, there is minimal impact to non-targeted liver tissue. After treatment, most TheraSphere patients are eligible for further therapeutic options because the procedure does not block the vessels of the liver.



TheraSphere microspheres next to a human hair

TheraSphere treatment has some common side effects, including mild to moderate fatigue, and abdominal discomfort and nausea for about a week. Doctors describe these symptoms as similar to those of the common flu. Some patients may experience loss of appetite.

For details on side effects, please refer to What side effects may I have? (page 15).

Tens of thousands of patients around the world have benefited from TheraSphere — in both liver cancer treatment hospitals and research centers of excellence.



TheraSphere dose vial



When can my doctor use TheraSphere?

TheraSphere is approved for the treatment of liver neoplasia or any cancer in the liver. TheraSphere™ is a medical device for treating cancer that started in your liver, such as hepatocellular carcinoma (HCC), or migrated to the liver from another location. These are also referred to as primary and secondary liver cancers.

- Your doctor may use TheraSphere™ to treat your primary or secondary liver cancer if you are not eligible for surgery.
- TheraSphere™ can also be used to treat liver cancer when there is portal vein thrombosis (PVT).
- If you are currently taking chemotherapy or systemic therapy, your doctor will indicate whether this treatment will continue or be temporarily stopped in order to receive TheraSphere™.



Who is TheraSphere suitable for?

TheraSphere is suitable for patients where the liver is the only site of disease or the liver is the major site of disease. TheraSphere has no effect on tumors outside the liver.

In prescribing TheraSphere as a treatment, your doctor has taken into consideration several factors such as liver performance status, medical history, previous therapy and the liver blood flow to minimize side effects and optimize therapy to your liver. Please ask your doctor or nurse about the tests they will perform prior to your TheraSphere treatment.



How can I benefit from TheraSphere treatment?

Since every patient is different, it is difficult to know how much you may benefit from TheraSphere. If your doctor thinks TheraSphere may be suitable for you, your doctor can treat your liver cancer with TheraSphere, possibly stabilizing your liver cancer or increasing your chance of having surgery to remove the tumor or getting a liver transplant.

A Practical Guide to TheraSphere Treatment

At Boston Scientific, we care about the lives and families our products touch. We hope you will be reassured by the information that is provided for your consideration.

What to expect with a typical TheraSphere treatment

You can expect different types of doctors to be involved with TheraSphere treatment, such as:

- Interventional radiologists,
- Radiation oncologists, and
- Nuclear medicine physicians.

Typically, you will continue seeing your referring doctor while undergoing treatment.

The actual TheraSphere administration is performed by an interventional radiologist.

Although all of the procedures can be done on an outpatient basis, they require several visits to the hospital and your follow-up treatments will span several months.

Will I have to stop my other therapy treatments to receive TheraSphere?

Generally, most patients' therapy is stopped before receiving TheraSphere. However, your oncologist will determine if your therapy needs to be stopped during the treatment period.

TheraSphere Treatment Summary



Start



Preplanning angiography

Week 2



TheraSphere treatment within
2 weeks after preplanning angiography

Week 6



Repeat CT/MRI, PET scan if needed,
lab tests and office visit with your doctor
4–6 weeks after TheraSphere treatment

If a second TheraSphere treatment is needed, the same schedule may be repeated. To maximize the safety of TheraSphere treatment, sometimes only one side of the liver is treated at a time. Therefore, if you have tumors in both sides of your liver, you may need a second treatment. These steps are described on the following page. See Follow-Up Appointments (page 18).

Preparation and Preplanning Angiography

This is the first step to prepare you for your treatment (this is not the radiation treatment). The angiography helps determine if you are a candidate for TheraSphere. If you are a candidate, you will return 1–2 weeks later for your radiation treatment. Once you are in the procedure room, the following steps occur:

The area will be numbed with a numbing medicine injection and a sedative is given to help you relax.



A small incision the size of a pencil tip will be made to an area of your upper leg (femoral artery) or left wrist (left radial artery) in order to insert a catheter into your artery to deliver the treatment.



The catheter is guided to the hepatic artery of your liver using an x-ray method (fluoroscopy) to position the catheter.



Three important steps
are then performed:

1

Mapping the arteries of your liver to identify any blood vessels that may be feeding your tumor.

2

Possible insertion of coils into small blood vessels going to your stomach or intestines. This is a simple procedure that prevents any radioactive microspheres from traveling to your stomach and potentially causing side effects. Not every patient needs this portion of the procedure.

3

Finally, some diagnostic imaging spheres are injected into your liver. These diagnostic imaging spheres consist of harmless proteins that are similar in size to the TheraSphere yttrium-90 microspheres and will provide the treating physician with information regarding blood flow within your liver and to the lungs. By using these diagnostic imaging spheres, the doctor is able to ensure that TheraSphere will stay in your liver and does not travel to other organs that could cause side effects. This may be referred to as safety screening.



There may be some redness, and a small bump at the puncture site, where the catheter was inserted.

You should notify your doctor if you notice any bleeding or additional swelling at the site.

The angiography takes up to 2 hours. You will then be transferred to the Nuclear Medicine Department for a scan to see the location of the diagnostic imaging spheres. This takes approximately 2 hours. Following your Nuclear Medicine scan you will typically be discharged.

Discharge Instructions

Clear discharge instructions will be provided by your Doctor.

TheraSphere Treatment Day

Typically, your treatment day will be 1–2 weeks following your preplanning angiography. You will be at the hospital for approximately 4–6 hours. The treatment requires another angiography, but you typically will not need to have another scan in the Nuclear Medicine Department.

What will TheraSphere treatment be like?

Once you are taken into the procedure room, the following steps occur:

1

Pain medication and a sedative may be given to help you relax. You will be sleepy but able to communicate with your doctor and the team if you choose.

2

A numbing medicine injection will numb an area of your upper leg (femoral artery) or left wrist (left radial artery), a small incision will be made and the catheter inserted into your femoral artery or left radial artery.

3

The catheter is guided to the hepatic artery using an x-ray method (fluoroscopy) to position the catheter.

4

TheraSphere is infused, the blood flow carries TheraSphere to the targeted tumor and radiation is emitted from the glass beads. TheraSphere infusion takes several minutes but due to catheter placement time, you will typically be in the room for about 1–1.5 hours.

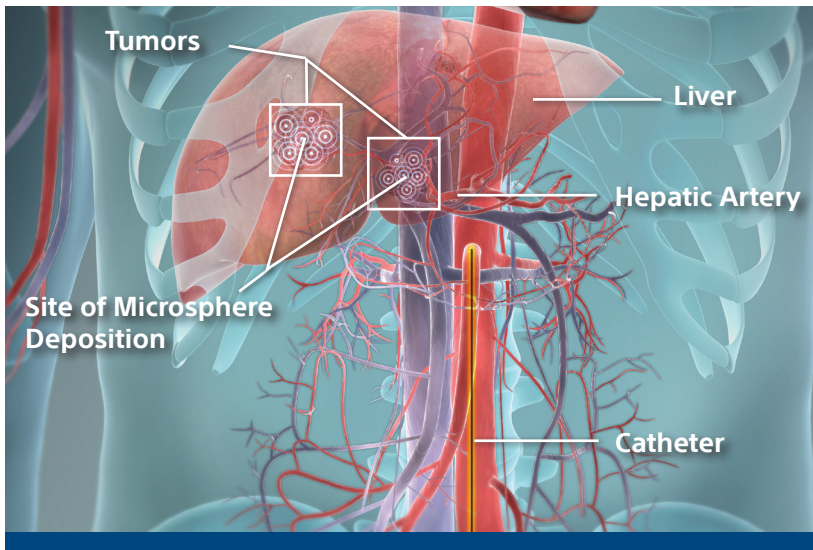
5

The catheter is removed and you are taken to the recovery area or Nuclear Medicine Department for approximately 2–6 hours.



Will the incision site be different from the angiography?

No, the incision site is generally the same. The procedure for inserting the catheter is similar for both TheraSphere infusion and the preplanning angiography. Please refer to Preparation and Preplanning Angiography for information (page 10).



Typical liver tumor being treated with TheraSphere



Prescription Medications

All prescriptions will be reviewed with you prior to discharge. The following prescription medications **may** be given to you the day of treatment:

- An anti-ulcer medication is given to help protect your stomach.
- An antibiotic to take for 5 days to reduce potential for infection.

Please take your medications as prescribed.

You may be discharged with an information packet containing items such as:

- Your scheduled follow-up appointments,
- Prescriptions, and
- Emergency contact phone numbers.

Please put these in a safe place, as you may need to bring them with you to your follow-up appointments.

Post treatment Discharge Instructions

Discharge instructions will be similar to the preplanning angiography. Any additional considerations may be provided by your treating doctor.



Do I need to do anything differently when I go home after treatment?

Clear instructions will be provided by your Doctor.



When can I return to work?

Every patient has different recuperative needs. Generally, patients that have no symptoms prior to the procedure recover more quickly. The type of work you do should also be taken into consideration before returning to work (e.g., physical exercise and heavy lifting greater than 10 pounds/4.5 kilos). Consult your physician if you have any questions.



What side effects may I have?

Typical side effects are mild to moderate after TheraSphere treatment. These may include: **fatigue, mild abdominal/stomach discomfort, nausea and/or vomiting, fever** and generally resolve within 48 hours. If these signs and symptoms persist, tell your doctor. You may receive additional medications with your treatment to minimize these side effects.



How does the procedure affect my liver?

TheraSphere releases radiation that may affect liver tissue. As a result, your doctor will routinely test your blood to monitor liver function and identify any potential risks that might occur. Rarely there may be loss of liver function that could lead to death. Many side effects disappear shortly after the delivery of treatment. Other side effects may last longer or become permanent.



Even after safety screening, there is still a small risk that some of the TheraSphere delivered could have gone to your lungs and/or digestive tract, possibly resulting in some lung damage or gastrointestinal irritation.

As is possible with every treatment, rare, serious side effects may occur. Since every patient is different, your doctor can best describe any possible side effects you may experience.

Further information is also described in the TheraSphere Package Insert (available at www.TheraSphere.com).

What should I do if I experience a side effect?

It is important that you contact your doctor or nurse if you experience a side effect. Your doctor may prescribe medications to ease any discomfort. Although it is rare that side effects become life threatening, it is important to tell your doctor as soon as you experience any side effects.

What will my ongoing care be like?



Your doctor may follow up with you 2 weeks after your treatment to evaluate how you are feeling after the procedure.



Approximately 4–6 weeks after your treatment, you will return to your hospital for a repeat CT/MRI or PET scan if needed (depending on whether the other side of your liver requires treatment). You will then have a posttreatment visit with your doctor to review your scans and blood tests.



At your appointment, 4–6 weeks after your treatment, it will typically be determined if you need a second treatment. To maximize the safety of TheraSphere treatment, we recommend only one side of the liver is treated at a time. Therefore, if you have tumors in both sides of your liver, you may need a second treatment. Within a month of the CT/MRI or PET scan, treatment of the second side of the liver will be performed if it is needed. The sequence of steps will be similar to the first treatment.



If the treatment of the second side of the liver is not needed, your doctor or nurse will advise you about your specific follow-up appointments or routine monitoring. Typically they will occur at 3-month intervals.

Radiation Safety Precautions

Radiation safety may be a concern for many patients being discharged from the hospital following TheraSphere treatment; however, no special safety precautions are required.

It has been established that patients leaving the hospital are not at risk to those around them; the radiation field outside their body is sufficiently low to be deemed not a radiation safety issue. As a precaution, many hospitals have general instructions *as recommended guidelines for discharge from the hospital.* You will be provided with further information on these precautions when you leave the hospital.

If you anticipate traveling, the security screening equipment may detect low radiation levels as a result of your TheraSphere treatment. Your doctor can provide you with a letter explaining the circumstances—it is available upon request.

Please note: Although TheraSphere radioactivity continues to diminish over time, TheraSphere will remain permanently implanted in the liver tissue. Special liver tissue handling may be required at the time of surgery.*

** This may also be required if cremation is considered.*



Important Contacts

These resources may help you find information and support:

Health Care Team

Name: _____

Position: _____

Address: _____

Home #: _____

Cell #: _____

Email: _____

Name: _____

Position: _____

Address: _____

Home #: _____

Cell #: _____

Email: _____

Name: _____

Position: _____

Address: _____

Home #: _____

Cell #: _____

Email: _____

Support Team/Other

Name: _____

Position: _____

Address: _____

Home #: _____

Cell #: _____

Email: _____

Name: _____

Position: _____

Address: _____

Home #: _____

Cell #: _____

Email: _____

Name: _____

Position: _____

Address: _____

Home #: _____

Cell #: _____

Email: _____



Glossary

Please note that the terms defined in this glossary are commonly used terms for the treatment of liver cancer with TheraSphere.

Albumin is a serum protein that is mostly produced by the liver. Decreases in albumin levels can be an indication of advanced liver disease.

ALT stands for alanine amino-transferase which is an enzyme found in large amounts in the liver. High levels of both ALT and AST are a sign of viral hepatitis or liver damage caused by drugs.

Angiography is a medical imaging technique used to visualize the inside of blood vessels and organs of the body.

An **Artery** is any blood vessel that carries blood from the heart to the body.

AST stands for aspartate amino-transferase which is an enzyme found in large amounts in the liver. High levels of both ALT and AST are a sign of viral hepatitis or liver damage caused by drugs.

Bilirubin is the major pigment of bile and is removed from the blood by the liver. Bilirubin levels in the blood rise when the liver is unable to metabolize it. Rises in serum bilirubin levels are usually a sign of liver disease.

A **Catheter** is a flexible tube used to deliver or withdraw fluids from the body.

A **Coil** is a small twisted wire that is inserted into a vessel to block blood flow.

Downstaging is a situation in which a patient with a previously inoperable tumor or large number of tumors is now eligible for surgery or liver transplant following treatment.

The **Femoral Artery** is the chief artery of the thigh supplying blood to the groin and legs.

Fluoroscopy is an x-ray procedure that takes continuous pictures to study moving structures within the body.

The **Hepatic Artery** is a blood vessel to the liver, stomach, small intestine and pancreas.

Hepatocellular Carcinoma (HCC)

(or Primary Liver Cancer) is a type of liver cancer which has started in the liver.

An **Infiltrative Tumor** is a type of tumor that has grown into the surrounding tissue so much that there are no clear edges.

A **Micrometer** is a unit of measurement of length. One micrometer is equal to one millionth of a meter (approximately one twenty-five thousandth of an inch).

Portal Vein Thrombosis (PVT) is a blockage, by a blood clot, of the portal vein, or tumor growth against the vein which brings blood to the liver.

The **Radial Artery** is one of the main arteries in the forearm supplying blood to the forearm and hand.

Radioembolization is the injection of micron-sized embolic particles loaded with a radioisotope that are infused through arteries.

TheraSphere is a liver cancer treatment that is made up of microscopic glass beads containing radioactive yttrium-90.

TheraSphere Package Insert

is a document directed towards treating doctors which fully describes the TheraSphere product, its indication, contraindications, precautions/warnings, adverse events and other important product-related information.

ULN is a short form for Upper Limit of Normal and is the largest value of a test result before the result is considered high.

Yttrium-90 is a radioactive isotope that emits energy in the form of beta radiation as it decays to stable zirconium-90.

Zirconium-90 is a stable element that is produced from the decay of yttrium-90.



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