

**PATIENT
INFORMED
CONSENT**

- Legacy Emanuel Hospital
- Legacy Good Samaritan Hospital
- Legacy Meridian Park Hospital
- Legacy Mount Hood Medical Center
- Legacy Salmon Creek Hospital
- _____

Full Name of Patient:

(Place patient identification label in this box.)

Name of Procedure(s):

SIR-SPHERES FOR THE TREATMENT OF UNRESECTABLE LIVER TUMORS

- Single Treatment Only
- Multiple Treatments

DESCRIPTION

SIR-Spheres® consists of biocompatible microspheres containing yttrium-90 with a size between 20 and 40 microns in diameter. Yttrium-90 is a high-energy pure beta-emitting isotope with no primary gamma emission. The maximum energy of the beta particles is 2.27MeV with a mean of 0.93MeV. The maximum range of emissions in tissue is 11mm with a mean of 2.5mm. The half-life is 64.1 hours (approx 2½ days). In therapeutic use, requiring the isotope to decay to infinity, 94% of the radiation is delivered in 11 days. The average number of particles implanted is 30 to 60 million. SIR-Spheres® is a permanent implant.

SIR-Spheres® is implanted into the hepatic tumors by injection. The Interventional Radiologist who injects into either the common hepatic artery or the right or left hepatic artery via a femoral catheter performs this in a special image guided procedure suite. SIR-Spheres® distributes non-uniformly in the liver, primarily due to the unique physiological characteristics of the hepatic arterial flow, the tumor to normal liver ratio of the tissue vascularity, and the size of the tumors. The tumor will therefore receive a higher density per unit distribution of SIR-Spheres® than the normal liver. The density of SIR-Spheres® in the tumor can be as high as 5 to 6 times that of the normal liver tissue. Once SIR-Spheres® is implanted into the liver, it is not metabolized or excreted and it stays permanently in the liver.

SIR-Sphere® is approved for use in the treatment of unresectable liver tumors from primary colorectal cancer. Over 4500 treatments have been performed world wide.

PROCEDURE

Before the day of therapy, your Interventional Radiologist will have reviewed your medical history, laboratory information, imaging, and will have performed an angiogram to ensure you are a candidate for therapy.

On the day of treatment, you will have a small tube (catheter) placed into a blood vessel leading to the liver by your Interventional Radiologist. This process will be identical to your planning angiogram that occurs several weeks prior. This catheter will be used to deliver SIR-Spheres® to the liver. Once this catheter is in place, the SIR-Spheres® will be injected through the catheter. After treatment, you will remain at the hospital until your doctor determines that you have sufficiently recovered to return home, usually 24-48 hours. The radiation emitted by SIR-Spheres® is confined within your body and is relatively short lived.

When you leave the hospital, you will be provided with a telephone number that will reach a physician at any time of the day or night, if you experience any problems after the procedure.

Dr. _____ will perform the procedure(s). Other practitioners may assist with the procedure(s) as necessary. The following practitioner(s) will perform the following specific significant surgical tasks (if any): _____

The practitioner(s) listed above may change due to unforeseen circumstances.

Mark the following as applicable:

- Right-side procedure _____ Left-side procedure _____ Not applicable
- A blood transfusion may be required during or after the procedure(s) and I consent to receive blood or blood products as deemed necessary and appropriate by the physician.
- Sedation managed by the physician performing the procedure(s).

Risks/Side Effects: Participation in this treatment involves some known risks, discomforts or inconvenience. There also may be risks that are unknown or unforeseeable.

Risks of Catheter Placement: The possible side effects include pain at the insertion site, possible risk of clotting of the artery, bleeding or infection around the catheter insertion site. There is a very small chance (3%) that the hepatic artery might develop an obstructing clot that would temporarily result in pain in the liver and increased abnormalities in liver function blood tests.

Risks of SIR-Spheres® Treatment: Before any treatment is given, you will undergo a special liver x-ray study to find out whether SIR-Spheres® can be delivered safely to the affected areas of your liver with minimal risk of exposure of other body organs to the radioactivity released from SIR-Spheres®. If there is evidence of blood circulation from the liver to other organs outside the liver that is not correctable and that could result in exposure of these organs to unnecessary radiation, you will not be given treatment with SIR-Spheres®. Even after this safety screening evaluation, there is still a small risk that radiation could potentially be delivered to your lungs and/or digestive tract, resulting in either lung damage, which could include fluid retention (edema), scarring (fibrosis), and could result in shortness of breath, infection, or even death (3% risk of death); or irritation of the gastrointestinal tract, which could result in chronic pain, nausea, vomiting, ulceration, and bleeding. Patients known to be at risk for blood clots or who had them before can develop new blood clots after SIR-Spheres® treatment to major organs, like brain or lungs.

After SIR-Spheres® treatment, you may experience some abdominal pain and/or bleeding, nausea, vomiting, and/or occasional fever. Treatment for abdominal bleeding would consist of medications and possible blood transfusions and/or hospitalization. Treatment of nausea and vomiting would consist of antacids or anti-vomiting medications. Treatment for fever would include use of anti-fever drugs, such as Tylenol or Ibuprofen. SIR-Spheres® release radiation that affects both cancerous and non-cancerous liver tissue. As a result, there may be changes in your liver function blood tests for 2 to 3 weeks after treatment.

Your physician will be checking you closely to see if any of these side effects are occurring. Post-treatment follow-up visits will be scheduled to monitor any side effects that occur. Many side effects disappear shortly after the delivery of treatment. Other side effects may be longer lasting or permanent. Your doctor may prescribe medication to minimize these side effects.

Fertility/Reproductive Issues: If you are a woman capable of childbearing, you should undergo a pregnancy test prior to receiving SIR-Spheres® treatment. The results will be made known to you. You should not become pregnant while being treated with SIR-Spheres®, and you are asked to use a medically accepted form of birth control while under treatment, until you are at least 30 days past your last SIR-Spheres® treatment. Women who are pregnant must not receive this treatment, and if you find that you have become pregnant while participating, you agree to notify your doctor immediately.

If you are a man, you agree to use a means of birth control while you are undergoing this treatment, because the effect of the SIR-Spheres® treatment on your sperm or upon the development of an unborn child is unknown. You are asked to agree not to father any children while under this treatment.

Unanticipated side effects may occur which have not been reported. If you have any unusual symptoms, report them immediately to your physician. Your physician may decide to discontinue treatment without your consent if the treatment is judged to be too toxic or harmful.

RADIATION RISKS

This procedure uses radioactive materials (x-rays) and you will receive a radiation exposure. There is a risk associated with this exposure that is justified by your disease. The dose of ionizing radiation in SIR-Spheres® is designed to be lethal to the cancer cells in your liver. If part of this dose accidentally goes to your lungs, stomach or intestine, it could result tissue injury and ulceration possible requiring surgery and may result in death. The specific dose you will receive will be carefully calculated to be the minimum dose required, based on the extent of your tumor (as measured from CT images). Every effort will be made to prevent flow of the radioactive material to other organs of the body. The type of radioactive material (Yttrium-90) used in SIR-Spheres® minimally penetrates tissue and becomes minimally active in the body within 7 days after treatment due to physical decay.

Risk of Radiation Hepatitis: The risk of death from radiation hepatitis is minimal, less than 1%. Your treating physician will decide how frequently blood tests are needed to evaluate the effects of SIR-Spheres® on your blood counts and liver function.

The potential long-term risk from this radiation is uncertain, however, as long as the radiation is confined to your liver and lungs, the side effects are mild to moderate. Radiation exposure has potential to cause secondary malignancies. Any additional risk of this radiation procedure is very small compared to the seriousness of your disease.

Alternative Procedures or Treatment: There are alternative forms of therapy for liver cancer, which you may or may not have received. Other treatments for your disease include supportive care only or other forms of liver-directed therapy. Other forms of liver-directed therapy, using embolization (blockage of blood supply to the tumor) alone, or embolization in combination with other anti-cancer drugs or toxic chemicals (chemoembolization or CE) is one alternative form of treatment and can be used before or after SIR-Spheres® treatment. CE also requires the placement of a catheter. Other risks of CE include pain, nausea and vomiting, and severe liver failure. There is no radiation risk with CE. Tumor response rates to CE vary widely and have been reported to range from 40-90%.

External radiation therapy to the liver may reduce symptoms, but only approximately 20% of patients experience significant tumor shrinkage. Systemic chemotherapy has historically poor response rates in liver cancer, ranging from 6-19%. Liver transplantation has curative potential for hepatocellular carcinoma, but is limited by stringent requirements for organ recipients and limited donor organ availability. If you have metastatic cancer to the liver you will not be considered for a liver transplant. A final alternative is no therapy at all. Your doctor will explain the advantages and disadvantages of alternative treatments that are being used for this disease.

ADDITIONAL THERAPY

Based on the type of metastatic disease and distribution of disease your Interventional Radiologist may decide to treat a part of your liver more than once or may treat a lobe of your liver on separate treatment days usually one month apart. This strategy is typically employed in order to minimize the chance of liver failure.

FOLLOW-UP/ IMAGING

In order to determine a course of treatment and response to therapy, we will ask you to follow-up with your medical or surgical oncologist. As well, a follow-up appointment will be scheduled within two weeks in the Interventional Radiology Clinic.

Follow-up CAT scan and PET imaging will be requested at 3,6,9, and 12 months. This imaging is vital to our ability to determine treatment.

The procedure(s), risks and alternatives listed above were explained to me. I had the opportunity to ask questions and all of my questions about the procedure(s), risks and alternatives were answered to my

satisfaction. I understand that, during the course of the procedure(s), unforeseen conditions may necessitate additional or different procedures than those listed above or discussed with me. I authorize the physician/credentialed provider and other practitioners to perform such other procedures as are, in their judgment, necessary and appropriate. I acknowledge that no warranty or guarantee was made to me as to result or cure.

I CONSENT TO THE ABOVE PROCEDURE(S).

(Patient's Signature*) (Printed Name) Date and Time)

*Patient is unable to consent because: _____. I therefore consent for the patient.

(Authorized Consenter's Signature) (Printed Name) (Relationship to Patient) (Date and Time)

(Witness' Signature - Only required for telephone consent) (Printed Name)

I EXPLAINED THE ABOVE PROCEDURE(S) TO THE PATIENT OR AUTHORIZED CONSENTER.

(Physician's/Credentialed Provider's Signature) (Printed Name)

Rev. 8/07

Place original form in chart. For procedures performed in Washington, provide a signed copy to the patient.