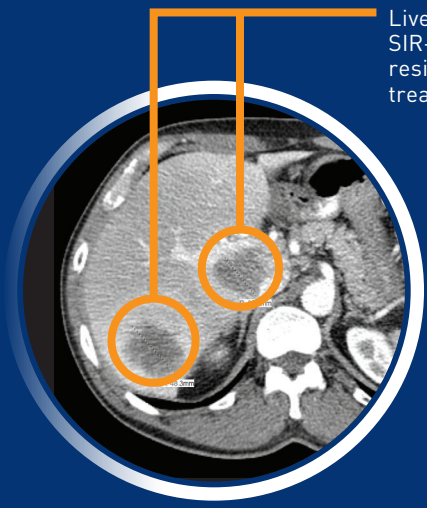
SIRTeX | SIR-Spheres® Y-90 resin microspheres

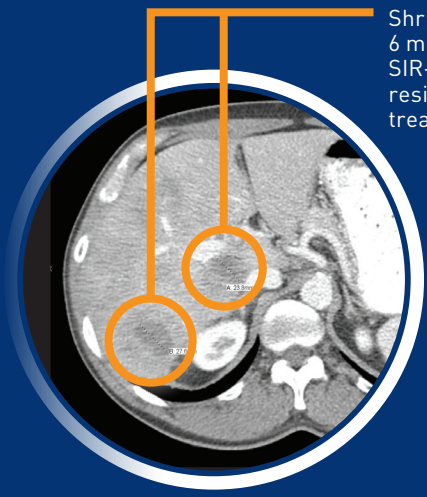
A Patient's Guide

Selective Internal Radiation Therapy (SIRT) for liver tumors using SIR-Spheres® Y-90 resin microspheres

The information within this document is for educational purposes only and is not a substitute for professional medical advice. Please consult your doctor for more information.



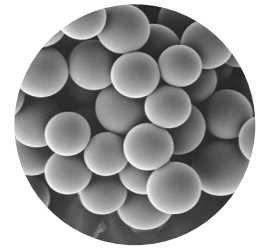
Liver tumors before SIR-Spheres® Y-90 resin microspheres treatment*



Shrinkage of tumors 6 months after SIR-Spheres Y-90 resin microspheres treatment

*The CT images above are an example case; individual responses may vary

Introduction



Electron micrograph of SIR-Spheres® Y-90 resin microspheres

This brochure has been developed for patients being offered or considered for Selective Internal Radiation Therapy (SIRT, also called Radioembolization) using SIR-Spheres Y-90 resin microspheres. It is intended to provide you with information about SIR-Spheres Y-90 resin microspheres and the SIRT procedure, possible side effects, and answer some questions you may have about this innovative treatment. As you review your medical condition with your healthcare providers, they can answer any further questions you may have about the SIRT procedure.

What is SIRT and what are SIR-Spheres Y-90 resin microspheres?

SIRT is a targeted treatment that delivers millions of tiny radioactive beads called SIR-Spheres Y-90 resin microspheres directly to liver tumors.

The development of SIR-Spheres Y-90 resin microspheres started in Australia in the 1980s, with regulatory approval being granted in the United States in 2002. More than 100,000 doses have been delivered to treat patients with liver cancer at more than 1,000 medical centers in over 40 countries.

SIR-Spheres® Y-90 resin microspheres is the only Y-90 treatment in the United States approved for local tumor control in both Hepatocellular Carcinoma (HCC) and Metastatic Colorectal Cancer (mCRC).

This therapy is indicated for Hepatocellular Carcinoma (HCC) in patients with no macrovascular invasion, Child Pugh-A cirrhosis, well-compensated liver function, and good performance status[1]. They are also indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant

intra-hepatic artery chemotherapy (IHAC) of FUDR (Floxuridine)[1].

Who is SIRT suitable for?

SIRT is only suitable for patients with liver tumors when the liver is either the only site or the major site of disease.

Before SIRT can be offered as a treatment option, your doctor must determine if you are eligible. Importantly, you need to have a sufficiently healthy liver. This is usually determined by a blood test.

Who performs the SIRT procedure?

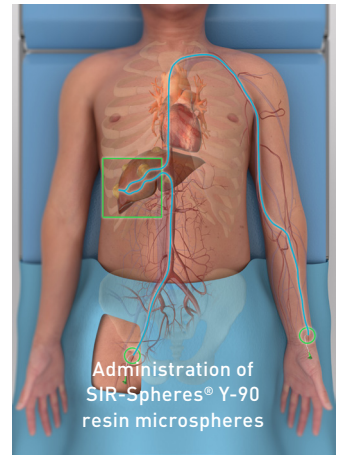
The SIRT procedure is conducted by a medical team of specialists, including intervention radiologist and others who are trained to work with radiation.

What will my treatment team do before administering SIRT?

Your treatment team will want to know about your previous cancer history and any other medical conditions. They will then conduct a number of initial tests to ensure that it is possible for you to receive SIRT safely. Normally patients will undergo two procedures either under conscious sedation or general anesthesia. Both procedures include a radiology procedure known as an angiogram.

The purpose of the first angiogram or mapping is to prepare your liver for SIRT treatment. During the mapping procedure your treatment team may block (embolize) the vessels to minimize the potential for the microspheres to travel to areas outside your liver (e.g. stomach or intestine). You will also receive a small amount of radioactive dye or "test beads" to check the amount of blood that flows from the liver to the lungs.

Assuming that the results of these initial tests are acceptable, the prescribed dose of SIR-Spheres Y-90 resin microspheres will be determined. The SIR-Spheres Y-90 resin microspheres will then be administered during a second procedure which is typically conducted one or two weeks after the initial angiogram is completed.


Administration of SIR-Spheres® Y-90 resin microspheres

How are SIR-Spheres Y-90 resin microspheres administered?

The interventional radiologist makes a small puncture, usually into the femoral artery near the groin or the radial artery near the wrist. Your physician will determine which approach is best for your treatment plan. A small flexible tube, known as a catheter, is then guided through the artery into the liver. The SIR-Spheres Y-90 resin microspheres are administered through this catheter. The whole procedure may take about 90 minutes. Your doctor will discuss with you any medications that may be used during the procedure.

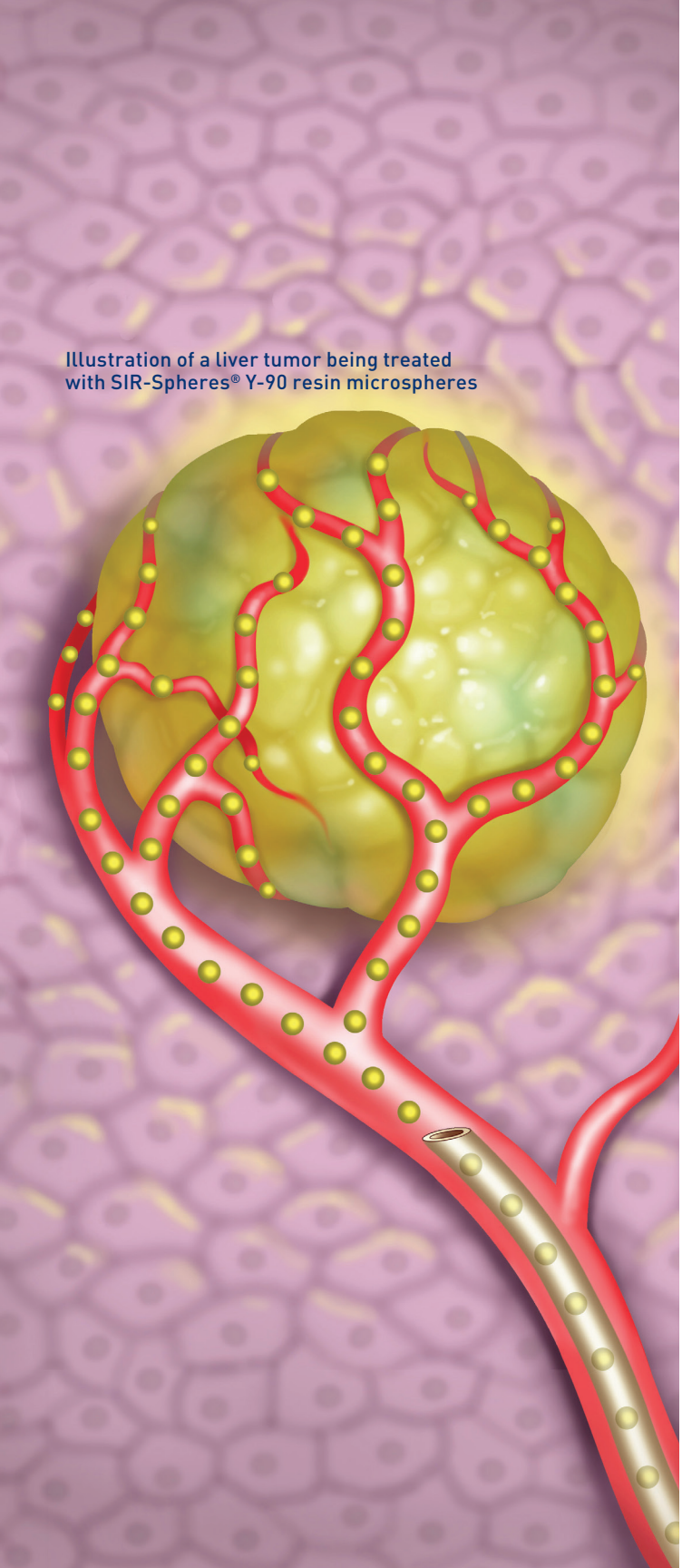


Illustration of a liver tumor being treated with SIR-Spheres® Y-90 resin microspheres

How do SIR-Spheres® Y-90 resin microspheres work?

The SIRT procedure enables radiation – which is often used to treat cancer – to be administered directly to liver tumors using the tumor's blood supply. The liver has two blood supplies.[2] Most healthy liver cells are fed by the portal vein.[2] Liver cancer cells are mainly fed by the hepatic artery.[2] SIR-Spheres Y-90 resin microspheres target liver tumors directly via the hepatic artery, so exposure to the remaining healthy liver tissue is minimized.

SIR-Spheres Y-90 resin microspheres range from 20–60 microns in diameter.[1] The microspheres are small enough to flow through the hepatic arteries, but too large to pass through the small blood vessels within the tumor, where they become permanently lodged in the tumor bed.

SIR-Spheres Y-90 resin microspheres contain the radioactive element yttrium-90, which delivers beta radiation over a relatively short distance in human tissue.

Since SIR-Spheres Y-90 resin microspheres are delivered directly to the tumors, this allows a larger dose of radiation to be implanted locally than is possible with conventional external beam radiotherapy.

What are the potential benefits of SIR-Spheres® Y-90 resin microspheres?

Clinical data in patients with unresectable colorectal cancer liver metastases show that, when used in combination with chemotherapy, SIR-Spheres Y-90 resin microspheres can extend patients' survival.[3] There are many publications demonstrating the safety and effectiveness of SIR-Spheres Y-90 resin microspheres in the treatment of patients with colorectal cancer liver metastases and hepatocelluar carcinoma.[4-7]

Will I have to stop my chemotherapy treatments to receive SIRT?

Generally, most patients' chemotherapy is stopped before the SIRT procedure. However, your oncologist will determine if your chemotherapy needs to be stopped during the treatment period.

What will happen after I receive treatment?

Immediately following the SIRT procedure, you may be taken for a scan to confirm that the SIR-Spheres Y-90 resin microspheres were infused into your liver. The treatment team will monitor you for a few hours after the procedure to determine if you have any side effects or complications that require additional medication.

Since you will have received a radioactive treatment, there are some simple precautions that need to be taken during the first 24 hours following the SIRT procedure. These precautions include: thorough washing of your hands after going to the toilet; cleaning up any spills of body fluids such as blood, urine, or stools and disposing of them in the toilet. You will be provided further information on these precautions when you leave hospital. Your treatment team will also monitor your progress using blood tests and radiography scans at periodic intervals.

How soon can I go home after treatment?

Normally, you can be discharged 4-6 hours after the procedure. Most patients can resume their normal daily activities two to three days after the treatment. In rare instances, some patients may need to stay overnight in the hospital for observation.

What side effects are associated with treatment?

Almost all treatments and drugs can produce unwanted side effects. Some side effects can be minor, making you feel uncomfortable, but a small number can be serious. Everyone reacts differently to a treatment.

The most common adverse events are fever, a temporary decrease in hemoglobin, mild to moderate abnormality of liver function tests, abdominal pain, nausea, vomiting and diarrhea.[1] As a precaution, you may receive additional medications (e.g., pain relievers, anti-inflammatory, anti-emetics, antacids) to help prevent or minimize these side effects.

What are the potential complications?

In rare instances and even in experienced hands, there is the possibility that a small number of microspheres may inadvertently reach other organs in the body, such as the gall bladder, stomach, intestine, pancreas, or lung. Inflammation may occur if SIR-Spheres® Y-90 resin microspheres reach these organs. Potential side effects due to high radiation include cholecystitis, gastritis, duodenitis, and pneumonitis. These complications are rare, but normally require additional treatment. Your treatment team is trained to minimize these risks.

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 might prescribe medications to ease any discomfort. While side effects are rarely life threatening, it is important to tell your doctor as soon as you experience any unwanted reactions.

Will I lose my hair?

Hair loss (alopecia) has never been reported following treatment with SIR-Spheres® Y-90 resin microspheres. Hair loss may be caused by chemotherapy, but SIR-Spheres Y-90 resin microspheres will not make this worse.

Is there anything I must avoid?

You must not receive SIRT treatment if you are pregnant and you must not become pregnant within two months of being treated as this may cause irreversible harm to the unborn baby. Effective contraception must therefore be used at all times during this period. You must not breastfeed for two weeks following treatment and must not use any milk expressed during this period for bottle feeding of your baby.

Will I have to change what I eat or drink?

No. You can and should continue to eat and drink as normal. Adequate levels of food and, in particular, fluids will help your return to normal daily activities. Your doctor is the best person to advise you regarding alcohol consumption.

Where can I get treatment?

You can request details of your nearest treatment center on the Sirtex website at www.sirtex.com or call 888.4.SIRTEX.

How can I find out about other patients' experiences?

In addition to the many patient organizations providing advice and assistance to people living with specific types of cancer, there is a US-based patient group dedicated to sharing information and enabling choices regarding the treatment and recovery from SIRT.

Their contact details are:

Yttrium 90 Microspheres Education & Support (YES)
Web: www.SayYEStoHope.org
Email: slindley@sayyestohope.org

Tel: 877.937.7478 (toll-free only in the US)

The opinions expressed by Yttrium 90 Microspheres Education & Support (YES) group are not necessarily those of Sirtex and the link is provided as a service and should not been seen as an endorsement.

Sirtex is committed to the development of innovative therapies for liver cancer in order to improve patient survival and quality of life. Please contact us at info@sirtex.com for more information.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. **Indications for Use:** SIR-Spheres® Y-90 resin microspheres are indicated for the local tumor control of unresectable hepatocellular carcinoma (HCC) in patients with no macrovascular invasion, Child Pugh-A cirrhosis, well-compensated liver function, and good performance status. They are also indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intra-hepatic artery chemotherapy (IHAC) of FUDR (Floxuridine). **Side Effects:** Common side effects are fever, transient decrease of hemoglobin, mild to moderate abnormality of liver function tests, abdominal pain, nausea, vomiting, and diarrhea. Potential serious effects due to exposure to high radiation include acute pancreatitis, radiation pneumonitis, acute gastritis, acute cholecystitis and radioembolization induced liver disease (REILD). **Consult the Instructions for Use (www.sirtex.com/sir-spheres/risks_adverse-events) for a complete listing of indications, contraindications, side effects, warnings, and precautions.**

References:

1. SIR-Spheres Y-90 resin microspheres Instructions for Use (SSL-US-18 SIR-Spheres microspheres IFU-US).
2. Embolization Therapy for Liver Cancer. American Cancer Society.Last Revised: April 1, 2019. Accessed March 19, 2024. https://www.cancer.org/cancer/types/liver-cancer/treating/embolization-therapy.html
3. Gray, B et al. Annals of Oncology 12: 1711-1120. Randomised trial of SIR-Spheres plus chemotherapy vs. chemotherapy alone for treating patients with liver metastases from prmary large bowel cancer. 2021.
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For more patient information, scan here

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