

SIRTeX

SIR-Spheres®
Y-90 resin microspheres

A Patient's Guide

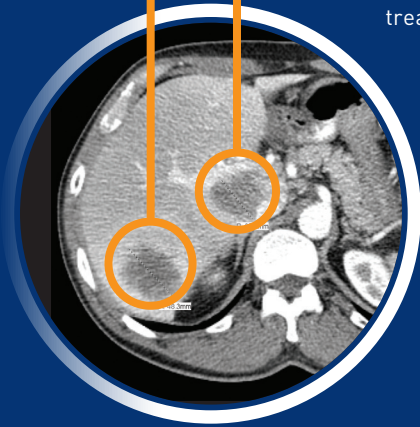


**Selective Internal Radiation
Therapy (SIRT) for liver tumors
using SIR-Spheres® Y-90
resin microspheres**

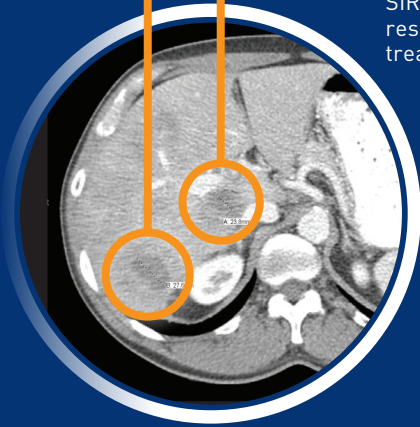
Advancing to the next level.



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



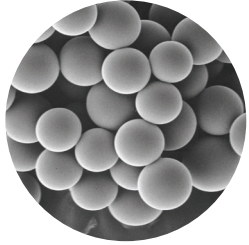
Shrinkage of tumors 6 months after SIR-Spheres Y-90 resin microspheres treatment



*The image above is an example case; individual responses may vary

Introduction

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



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

microspheres. It is intended to provide you with information about SIR-Spheres Y-90 resin microspheres and the SIRT procedure, possible side effects, and to answer some of the questions you may have about this innovative treatment. If you have further questions about the SIRT procedure, please speak to your doctor or nurse. Your doctor can address any specific concerns you may have about your medical condition.

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

SIRT is a targeted treatment for liver tumors that delivers millions of tiny radioactive beads called SIR-Spheres Y-90 resin microspheres directly to the 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 are approved in the United States for the treatment of inoperable colorectal liver metastases in combination with hepatic arterial chemotherapy using FUDR (floxuridine). These liver tumors are also known as secondary liver metastases because the cancer cells have spread to the liver from the primary colon or rectal tumor.

Who is SIRT suitable for?

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

Before SIRT can be offered as a treatment option for patients, there are a number of other factors that have to be considered by your doctor. Most importantly, you need to have a sufficiently healthy liver that is working satisfactorily. This is usually determined by a simple blood test.

Who performs the SIRT procedure?

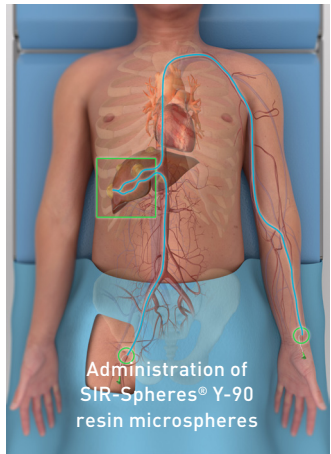
The SIRT procedure is conducted by a medical team that includes a specialist known as an interventional radiologist, together with other specialists trained to work with radiation.

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 anesthetic. Both procedures include a radiology procedure known as an angiogram.

The purpose of the first angiogram or mapping is to prepare your liver for the SIRT treatment. During the mapping procedure your interventional radiologists may block (embolize) the vessels to minimize the potential for the microspheres to travel to areas outside your liver (e.g. the 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.

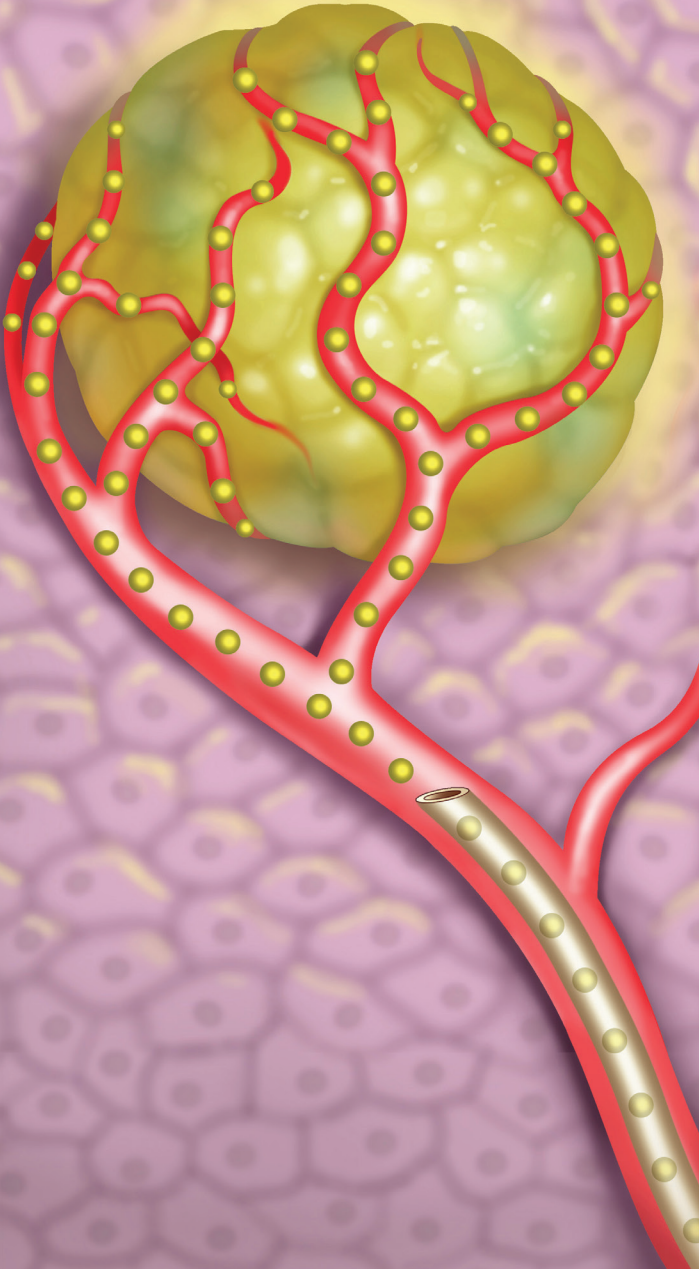
Assuming that the results of these initial tests are acceptable, the prescribed dose of SIR-Spheres Y-90 resin microspheres will be determined. The SIR-Spheres Y-90 resin microspheres will then be administered during a second procedure which is typically conducted one or two weeks after the initial angiogram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



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 medication and anesthesia that may be used during the procedure.

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 sent directly into the liver tumors by using the tumor’s blood supply. The liver is special in that it has two blood supplies.¹ Most normal liver cells are fed by the portal vein.¹ Liver cancer cells are mainly fed by the hepatic artery.¹ SIR-Spheres Y-90 resin microspheres are targeted directly at the liver tumors via the hepatic artery, so exposure to the remaining healthy liver tissue is minimized.

SIR-Spheres Y-90 resin microspheres range in size between 20–60 microns in diameter.² In comparison, the average diameter of a human hair can range from 51–83 microns.³ The microspheres are small enough to flow through the hepatic arteries, but they are 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 shows that when used in combination with chemotherapy, SIR-Spheres Y-90 resin microspheres may shrink patients' liver tumors more than chemotherapy alone.³⁻⁷ For a small number of patients, treatment can cause sufficient shrinkage of the liver tumor to permit its removal by surgery at a later date.³⁻⁷ In patients whose liver tumors are no longer responding to chemotherapy, SIR-Spheres Y-90 resin microspheres have also been used successfully to shrink these tumors and extend patients' survival. There are many publications in the scientific literature on the use of SIR-Spheres Y-90 resin microspheres in the treatment of patients with liver metastases.^{6, 8-10}

Will my health insurance cover the procedure?

Most insurance companies generally cover the cost of SIR-Spheres Y-90 resin microspheres for the treatment of metastatic colorectal cancer. Under the terms of the Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003, Medicare, for the most part, reimburses hospitals for the full cost of outpatient treatment with SIR-Spheres Y-90 resin microspheres.

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 have received treatment?

Immediately following the SIRT procedure, you may be taken for a scan to confirm that the SIR-Spheres Y-90 resin microspheres have been infused into your liver. You will also be monitored for a few hours after the procedure to enable the treatment team 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 with 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 is different in how he or she reacts to a treatment.

The most common adverse events are fever, a decrease in hemoglobin, mild to moderate abnormality of liver function tests, abdominal pain, nausea, vomiting and diarrhea.² As a precaution, you may receive additional medications such as pain-killers, anti-inflammatory, anti-nausea and anti-ulcer drugs with your treatment with the aim of preventing or minimizing 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 or pancreas. If SIR-Spheres® Y-90 resin microspheres reach these organs, they may cause inflammation of the gall bladder (cholecystitis), stomach (gastritis) or intestine (duodenitis). These complications are rare, but if one of these occurs, they normally require additional treatment. Your treatment team will have received special training to minimize these risks and to prevent them from happening.



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. Although it is rare that side effects become 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. If you are receiving chemotherapy this may cause hair loss; however 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 during the first two weeks after 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 be 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.

Notes

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 treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intrahepatic artery chemotherapy (IHAC) of FUDR (Flouxuridine). **Warnings / Precautions:** Inadvertent delivery of the microspheres to locations other than the intended hepatic tumor may result in local radiation damage. Due to the radioactivity and the significant consequences of misplacing the microspheres in situ, this product must be implanted by physicians who have completed the Sirtex TEC training program. A SPECT scan of the upper abdomen immediately after implantation is recommended. Patients may experience abdominal pain immediately after administration and pain relief may be required. H-2 blocking agents may be administered the day before implantation and continued as needed to reduce gastric complications. **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, radiation hepatitis, and acute cholecystitis. **Contraindications:** SIR-Spheres Y-90 resin microspheres should not be implanted in patients who have either had previous external beam radiation therapy to the liver; ascites or are in clinical liver failure. This device is contraindicated in patients with markedly abnormal synthetic and excretory liver function tests; greater than 20% lung shunting of the hepatic artery blood flow, or >30 Gy radiation absorbed dose to the lungs, as determined by the ^{99m}Tc MAA scan; disseminated extra-hepatic malignant disease, and portal vein thrombosis. This device should not be implanted in patients determined via angiogram to have an abnormal vascular anatomy that would result in significant reflux of the hepatic arterial blood flow to the stomach, pancreas, or bowel. **General Information:** SIR-Spheres Y-90 resin microspheres may only be distributed to a duly licensed or accredited facility capable of handling therapeutic medical isotopes. This product is radioactive and should thus be handled in accordance with all applicable standards and regulations.

Consult the Instructions for Use (www.sirtex.com) for a complete listing of indications, contraindications, side effects, warnings, and precautions.

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Manufacturer

Sirtex Medical Pty Ltd
Shop 6, 207 Pacific Highway
St Leonards, NSW 2065
Australia
Tel: +61 2 9964 8400
Fax: +61 2 9964 8410

Americas

Sirtex Medical Inc.
300 Unicorn Park Drive
Woburn, MA 01801
USA
Tel: +1 888 474 7839

www.sirtex.com



@SirtexMedical



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