

SIRTeX

SIR-Spheres®  
Y-90 resin microspheres

# A Patient's Guide



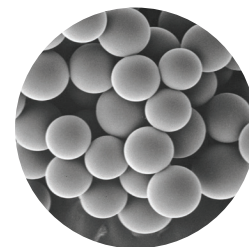
Selective Internal Radiation  
Therapy (SIRT) for liver tumours  
using SIR-Spheres® Y-90  
resin microspheres

*Advancing to the next level.*



## 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 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.



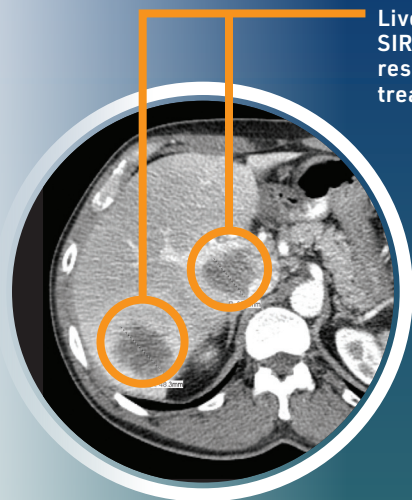
**Electron micrograph of  
SIR-Spheres® Y-90  
resin microspheres**

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

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

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.

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



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



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

## Who is SIRT suitable for?

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

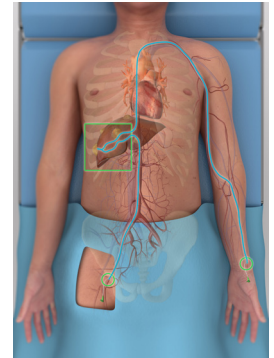
The SIRT procedure is conducted by a medical team that includes a specialist known as an interventional radiologist, together with other specialists trained to work with radiation.

## 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.



**Administration of  
SIR-Spheres® Y-90  
resin microspheres**

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 medication and anesthesia that may be used during the procedure.

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

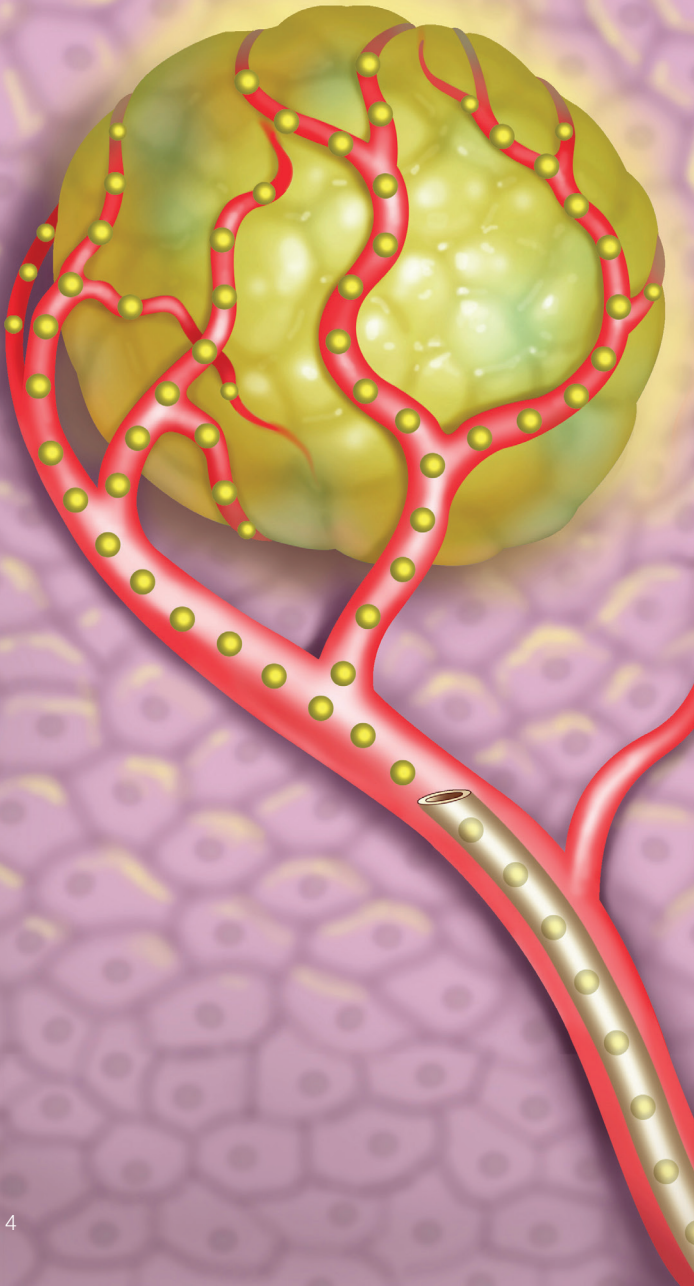
The SIRT procedure enables radiation – which is often used to treat cancer – to be sent directly into the liver tumours by using the tumour's blood supply. The normal liver tissue takes about 90% of its blood supply from the portal vein that flows from the intestine while liver tumours receive about 90% of their blood supply from the hepatic artery. SIR-Spheres Y-90 resin microspheres are targeted directly at the liver tumours via the hepatic artery, so exposure to the remaining healthy liver tissue is minimized.

The majority of microspheres are approximately 32 microns in diameter, about a third of the width of a human hair. 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 tumour, where they become permanently lodged in the tumour 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. Yttrium-90 has a half-life of approximately 2.5 days; therefore most of the radiation (over 97%) is delivered to the tumour in the first two weeks following treatment.

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

**Liver tumour being treated with  
SIR-Spheres® Y-90 resin microspheres**



## 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 tumours more than chemotherapy alone, improve quality of life and increase life expectancy. For a small number of patients, treatment can cause sufficient shrinkage of the liver tumour to permit its removal by surgery at a later date. In patients whose liver tumours are no longer responding to chemotherapy, SIR-Spheres Y-90 resin microspheres have also been used successfully to shrink these tumours 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 tumours.

## 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?

Depending on the treatment center protocol, you may be discharged 4-6 hours after the procedure or the following day. Most patients can resume their normal daily activities two to three days after the treatment.



## 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.

Many patients experience abdominal pain and/or nausea which normally subside after a short time and/or with routine medication. Many patients also develop a mild fever that may last for up to a week and fatigue which may last for several weeks. 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.

## 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.y90support.org](http://www.y90support.org)

Email: [info@y90support.org](mailto:info@y90support.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.  
*Contact us at [info-ap@sirtex.com](mailto:info-ap@sirtex.com) for more information.*

Notes \_\_\_\_\_

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**Caution:** 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. SIR-Spheres® Y-90 resin microspheres are supplied for use in Singapore, Malaysia, Thailand, Vietnam, Hong Kong, Taiwan, South Korea, India, Australia and New Zealand. **Intended Use / Indications For Use:** This product is indicated for the treatment of patients with advanced non-operable liver cancer.

**Warnings / Precautions:** Inadvertent delivery of the microspheres to locations other than the intended hepatic tumour may result in local radiation damage and serious side effects. 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. Gastric acid blocking agents may be administered the day before implantation and continued as needed to reduce gastric complications. **Side effects:** Common side effects are fever, mild to moderate abnormality of liver function tests, abdominal pain, nausea, vomiting, and diarrhoea. 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 are 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 estimated by the 99mTc MAA scan. 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.

**Reference the Package Insert for each country for a complete listing of indications, contraindications, side effects, warnings and precautions.**





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

Email: [info-au@sirtex.com](mailto:info-au@sirtex.com)

Sirtex Medical Singapore Pte Ltd.

50 Science Park Road,

#01-01, The Kendall

Singapore Science Park II,

Singapore 117406

Tel: +65 6800 6500

Email: [info-ap@sirtex.com](mailto:info-ap@sirtex.com)

**[www.sirtex.com](http://www.sirtex.com)**

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Y-90 resin microspheres

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