

SIRTeX

SIR-Spheres®
Y-90 resin microspheres

A Patient's Guide



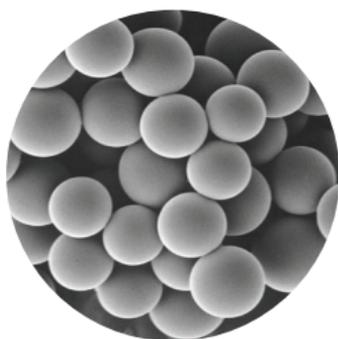
**Selective Internal Radiation
Therapy (SIRT) for liver tumors
using SIR-Spheres® Y-90
resin microspheres**

Advancing to the next level.



Introduction

This brochure has been developed for patients being offered or considered for Selective Internal Radiation Therapy (SIRT, also called Radioembolisation) using SIR-Spheres Y-90 resin microspheres. It is intended to provide you with information about SIR-Spheres 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 directly to the liver tumours.

The development of SIR-Spheres started in Australia in the 1980s, with regulatory approval being granted in the United States and Europe in 2002.

SIR-Spheres are approved for the treatment of liver tumours that cannot be removed by surgery. These may be tumours that start in the liver (also known as primary liver cancer)*, or they may be tumours that have spread to the liver from the primary colon or rectal tumor (also known as secondary liver cancer or metastases).

*hepatocellular carcinoma

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 75% 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 are targeted directly at the liver tumours via the hepatic artery, so exposure to the remaining healthy liver tissue is minimised.

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 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 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.

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.

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.

What will my treatment team do before administering SIRT?

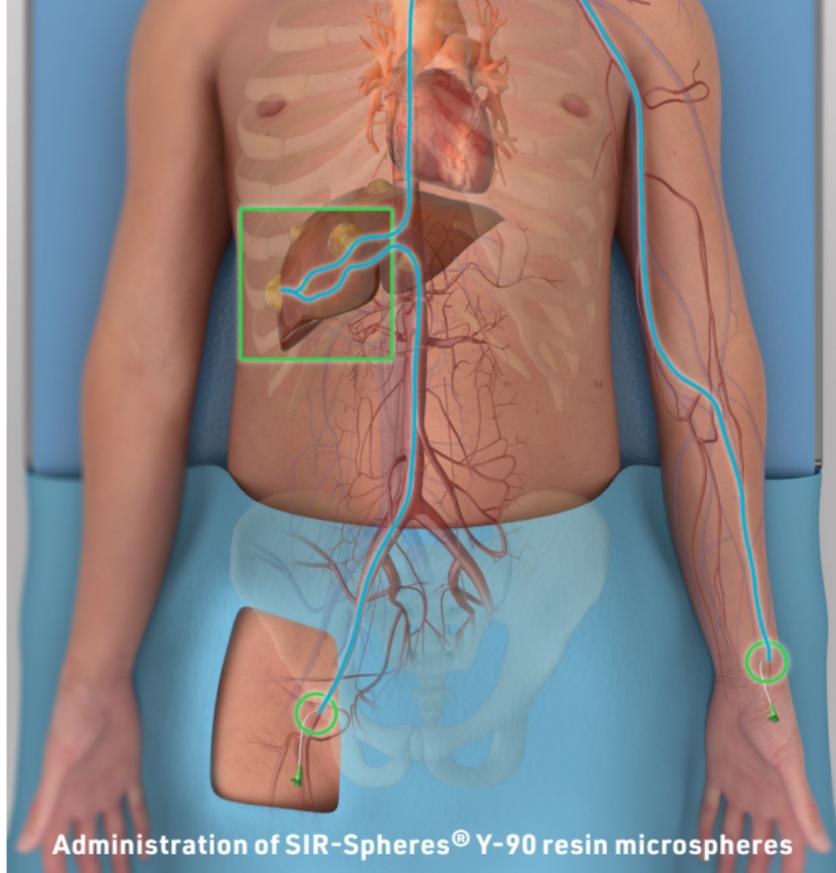
Your treatment team will want to know about your previous cancer history and any other medical conditions. They will then conduct a number of initial tests to ensure that it is possible for you to receive SIRT safely. Normally patients will undergo two procedures under conscious sedation. Both procedures 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 radiologist may block (embolise) some 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 "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 dose of SIR-Spheres will be determined.

The SIR-Spheres will then be administered during a

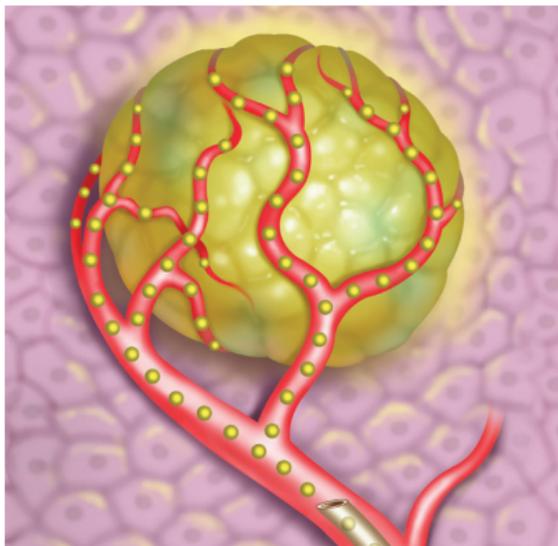


second procedure which is typically conducted one or two weeks after the initial angiogram is completed.

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



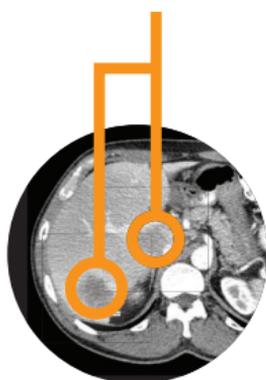
Will I have to stop my chemotherapy treatments to receive SIRT?

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.

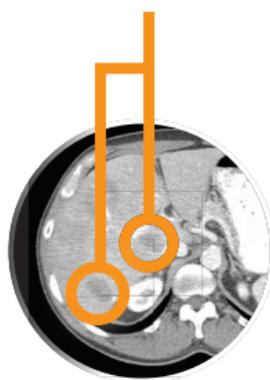
What are the potential benefits of SIR-Spheres Y-90 resin microspheres?

Clinical data show that when used in combination with chemotherapy, SIR-Spheres 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 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 in the treatment of patients with liver metastases or with primary liver cancer.

Liver tumours before SIR-Spheres microspheres treatment*



Shrinkage of tumours 6 months after SIR-Spheres treatment



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

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 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?

When you can go home after the treatment depends upon local regulations. You can be discharged 4-6 hours after the procedure. Your doctor may also keep you in hospital for one or two nights to ensure you do not develop any complications following treatment. Usually patients who have received SIRT can most soon resume their normal daily activities.

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 minimising 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 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 minimise 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. If you are receiving chemotherapy this may cause hair loss; however SIR-Spheres 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.

Will the National Health Service cover the procedure?

The National Institute for Health and Care Excellence (NICE) has recommended the use of SIRT with SIR-Spheres in England and Wales as a fully funded option for adult patients with hepatocellular carcinoma (HCC). NHS England also fully fund the use of SIRT with SIR-Spheres for certain adult patients with metastatic colorectal cancer (mCRC). Please do speak to your clinician for further information.

Where can I get treatment?

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

How can I find out about other patients' experiences?

There are many patient organisations providing advice and assistance to people living with specific types of cancer in UK. The British Liver Trust is supporting the education and sharing of information regarding potential treatment and recovery from SIRT.

Their contact details are:

British Liver Trust

Web: www.britishlivertrust.org
www.britishlivertrust.org.uk

Email: helpline@britishlivertrust.org.uk

Helpline: 0800 6527 330

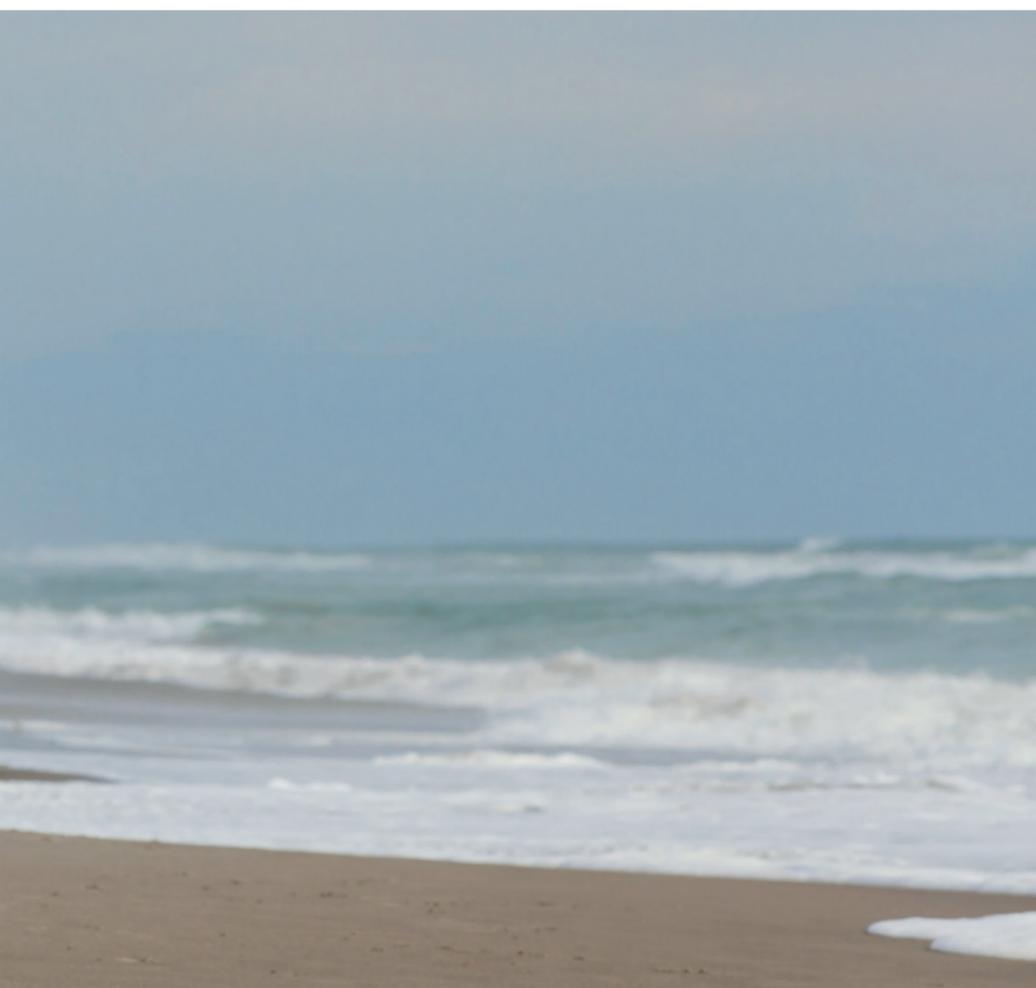


The opinions expressed the British Liver Trust are not necessarily those of Sirtex and the link is provided as a service and should not be seen as an endorsement.

Sirtex is committed to the development of innovative therapies for liver cancer in order to improve patient survival and quality of life.

For more information please visit us at www.sirtex.com.

Notes



Intended Use: SIR-Spheres Y-90 resin microspheres are intended for implantation into hepatic tumors via the hepatic artery.

Indications For Use: SIR-Spheres Y-90 resin microspheres are indicated for the treatment of unresectable hepatocellular carcinoma (HCC) or unresectable metastatic liver tumors from primary colorectal cancer in patients refractory to or intolerant of chemotherapy. **Consult the Instructions for Use 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

Sirtex Medical Europe GmbH
Joseph-Schumpeter-Allee 33
53227 Bonn, Germany
Tel: +49 228 18407 30
Fax: +49 228 18407 35

www.sirtex.com

SIRTeX



twitter.com/SirtexMedical



www.linkedin.com/company/sirtex-medical-limited/

SIR-Spheres® is a registered trademark of
Sirtex SIR-Spheres Pty. Ltd.
©2021 Sirtex Medical Europe GmbH

APM-UK-001-06-21 V2