

Frequently Asked Questions

1. What are SIR-Spheres?

SIR-Spheres are tiny polymer (plastic) beads (about one third the diameter of a strand of hair) that are combined with yttrium-90, a radioisotope that emits pure beta radiation. Y^{90} (yttrium-90) has a “half life” of about 64 hours, that is, every 64 hours the level of radiation falls by one half until it is effectively gone after 2 weeks. The radiation from Y^{90} penetrates an average of only 2.5 mm (approximately 1/16 of an inch) in tissue. After injection into the artery supplying blood to the tumors, the spheres are trapped in the tumor’s vascular bed, where they destroy the tumor cells by delivering the beta radiation. The radiation is targeted to the tumor and after 14 days the majority of the radiation effect has occurred. SIR-Spheres are considered a regional treatment as the radiation is directed to the liver and does not affect other organs in the body.

2. What happens to SIR-Spheres once they are inside the liver?

After lodging in the tumors, SIR-Spheres continuously deliver radiation for approximately 14 days. Since the SIR-Spheres are biocompatible they can remain in the liver without posing any danger to the patient.

3. How soon after the procedure can I go home?

Usually, patients treated with SIR-Spheres can go home the same day of treatment and resume normal activity. However, your doctor might keep you in hospital for observation to ensure that you do not develop any complications resulting from the treatment with SIR-Spheres. Your doctor will decide what is best for you.

(continued on back)

4. Are there any special precautions that family members will need to take as a result of the internal radiation delivered by SIR-Spheres?

After treatment it is important that the precautions mentioned elsewhere in the brochure are observed. There should be no travel on public transportation (including airlines) where the patient is sitting next to a fellow passenger for more than 2 hours for the first week after treatment; the patient should not sleep in the same bed as his/her partner for a week; there should be no close contact with children or pregnant women for one week and adults may approach the patient for a few minutes at a time, but for prolonged periods they should stay more than 6 feet away for the first three days.

5. How will my doctor monitor my progress?

Your doctor will be able to track your progress by special blood tests and radiographic studies. These studies are usually ordered at periodic intervals and will be determined by your physician.

6. Will my insurance cover this procedure?

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

7. How can I find treatment centers in my area?

There is a list of treatment centers on the Sirtex Medical website. Go to www.sirtex.com to find the center closest to you.



Sirtex Medical is committed to the development of innovative therapies for the treatment of liver cancer. For more information about Sirtex, contact us at www.sirtex.com.

Sirtex Medical, Inc | 1401 N. Western Avenue Suite 100 | Lake Forest, IL 60045
Phone – 847-482-9023 | Fax – 847-482-9103 | www.sirtex.com

Sirtex Medical Europe GmbH | Friedrich-Ebert-Allee 67 | 53113 Bonn Germany
Postfach 12 03 80 | Phone +49 (228) 18 40 7- 30 | Fax +49 (228) 18 40 7- 35

Sirtex Medical Products Pty Ltd | PO Box 760 | North Ryde NSW 1670
Australia | Phone + 61 2 9856 0400 | Fax + 61 2 9856 0404

09/09/04

SIR-Spheres® Learning the Answers

Patient Information about SIR-Spheres
Yttrium-90 Microspheres
A New Treatment for Non-Resectable Liver Tumors

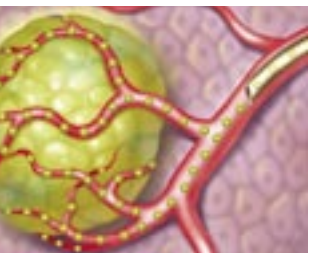


INNOVATORS IN ONCOLOGY

This brochure is intended to provide patients and family members with an overview of what to expect with a SIR-Spheres treatment. Specific concerns related to your medical condition should be addressed by your attending physician.

SIR-Spheres: What's Being Discussed

SIR-Spheres is an innovative product to treat liver cancer. In cases where it is not possible to surgically remove liver tumors, SIR-Spheres can be used to deliver targeted, internal radiation therapy directly to the tumor. This new therapy is called **Selective Internal Radiation Therapy**, also known as **SIRT**. This technique uses millions of tiny polymer (plastic) beads or microspheres which contain a radioactive element



Liver tumor being treated with SIR-Spheres.

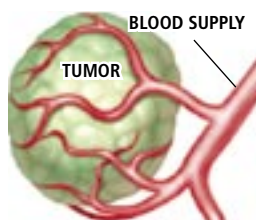
yttrium-90. SIR-Spheres are very small, approximately 32 microns in size or about one-third the diameter of a strand of hair. SIRT is usually administered as an outpatient procedure by a specially trained physician. A small catheter is guided into the liver and the SIR-Spheres are infused through the catheter. The microspheres with the radioactive Y^{90} are carried by the bloodstream directly to the tumors in the liver where they preferentially lodge in the small vessels

feeding the tumor and deliver their dose of radiation for a period of approximately 2 weeks. Unlike conventional external beam radiation, which can only be applied to limited areas of the body, SIR-Spheres selectively irradiate the tumors and therefore have the ability to deliver more potent doses of radiation directly to the cancer cells over a longer period of time.

SIR-Spheres were developed in 1987 at the Cancer Research Institute in Perth, Western Australia, and since then, the product and the procedure have been refined in collaboration with Sirtex Medical and over a thousand patients have been treated. SIR-Spheres received approval by the United States Food and Drug Administration (FDA) in 2002.

SIR-Spheres At Work

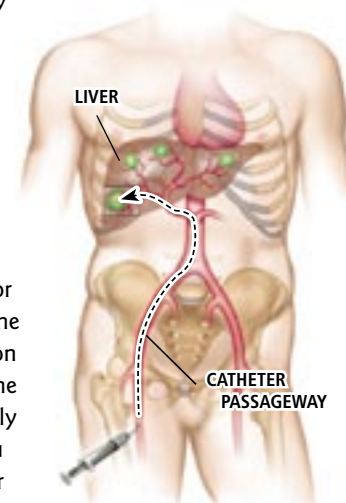
Radiation is an effective agent for destroying tumors and is widely used in cancer treatment. However, organs in the body are sensitive to radiation and high doses can seriously affect or injure a patient. SIR-Spheres and the SIRT technique enable specific targeting and destruction of the tumors within the liver, while sparing the normal healthy tissue. Because liver tumors are hypervascular and derive most of their blood supply from the hepatic artery while healthy liver tissue is fed predominantly by the portal vein, by injecting the SIR-Spheres into the hepatic artery they are carried preferentially to the tumor, where they become lodged. The dose of radiation from the SIR-Spheres, in



conjunction with their proximity to the tumor, destroys the tumor and preserves the healthy liver tissue. The SIRT procedure allows a more pin-pointed delivery of radiation to liver tumors than other radiotherapy techniques, making it more effective in killing the cancer.

How Are They Administered?

SIR-Spheres are administered by specially trained physicians experienced in the treatment of liver tumors. The procedure is usually performed as an outpatient procedure under local sedation in the radiology suite. A small incision is made in the groin and a flexible catheter positioned in the liver under x-ray guidance by an interventional radiologist to allow for targeted infusion of the SIR-Spheres to the liver tumors. SIR-Spheres administration takes about 15-20 minutes and the entire procedure lasts approximately one hour from beginning to end. You will be monitored for a few hours after the procedure and most patients are discharged within 24 hours.



SIR-Spheres administration procedure.

There are a few precautions that you and your family need to keep in mind after treatment with SIR-Spheres: there should be no travel on public transportation (including airlines) where the patient is sitting next to a fellow passenger for more than 2 hours for the first week after treatment; the patient should not sleep in the same bed as his/her partner for a week; there should be no close contact with children or pregnant women for one week and adults may approach the patient for a few minutes at a time, but for prolonged periods they should stay more than 6 feet away for the first three days.

Treatment Information

SIR-Spheres therapy is regarded as a regional treatment; that is, the anti-cancer effect is concentrated in the liver and there is no effect on the cancer at other sites. SIR-Spheres are used to treat secondary liver cancer where the cancer originates in the bowel (colon or rectum) and then spreads to the liver. This type of cancer is called metastatic colorectal cancer.

SIR-Spheres is generally not regarded as a cure, but has been shown to shrink the tumors more than chemotherapy alone. Quality of life can improve, and life expectancy may increase. For a small number of patients, treatment with SIR-Spheres can cause marked shrinkage of the liver tumor allowing for surgical removal at a later date.

How Do I Qualify?

Patients suitable for treatment with SIR-Spheres need to establish that:

- they have non-resectable metastatic colorectal cancer; that is, cancer that originated in the bowel or rectum and has spread to the liver;
- they have the liver as the major site of disease;
- they have sufficient remaining healthy liver still functioning satisfactorily (this can be determined by a simple blood test)
- they meet the pre-selection criteria established by their doctor's pre-treatment testing

If you meet the criteria above then you may be a candidate for treatment and you can contact one of the treatment centers that specialize in SIR-Spheres therapy. You will find the list of treatment centers on our website: www.sirtex.com. A cancer specialist will then make a decision on your suitability for treatment. In addition, you can take this brochure plus other information from our web site to your doctor and have him or her contact us.

What Are The Side Effects?

Patients should not have any serious side effects when SIR-Spheres are correctly administered. However, during the infusion of the SIR-Spheres you may experience some pain. If you do, your doctor will provide medication to help alleviate any discomfort during the infusion. Sometimes patients develop pain in the abdomen that may last for a few hours after the administration of SIR-Spheres, but this can also be treated with medication. Most frequently, patients develop a fever and may experience nausea but these symptoms subside with time and medication. Patients are often placed on medication for the first month after treatment with SIR-Spheres to alleviate any symptoms of gastritis (stomach upset) and peptic ulceration. Many patients complain of feeling lethargic with loss of appetite for several days after the treatment, but this also subsides with time.

There is the potential of more serious side effects if the SIR-Spheres are incorrectly delivered into the artery supplying blood to the liver. In this case, the SIR-Spheres could be inadvertently supplied to the stomach, duodenum (intestine), pancreas or other organs, resulting in severe side effects. Interventional Radiologists delivering SIR-Spheres are given special training to inform them of this risk and to prevent this from happening. The dose of radiation is individually prescribed for each patient. If the normal liver tissue receives too high a dose, some patients may develop long-term damage to the normal liver. Because everyone is unique, it is not possible to predict what side effects you may experience. It is always important to discuss SIR-Spheres treatment benefits and potential risks with your doctor and to have realistic expectations of your SIRT treatment. If you have questions about any side effects discussed in this brochure consult your doctor or a member of your health care team.