



New Device Approvals

SIR-Spheres® - P990065

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: SIR-Spheres®
Manufacturer: Sirtex Medical Inc.
Address: Centrecourt Business Park, Unit D4, 25-27 Paul Street North, P.O. Box 760,
North Ryde, NSW, 1670, Australia
Approval Date: March 5, 2002
Approval Letter: <http://www.fda.gov/cdrh/pdf/p990065a.pdf>

What is it? SIR-Spheres® consists of tiny spheres of yttrium-90, a radioactive substance, that are injected into the liver to treat cancer.

How does it work? The physician injects the small spheres into the liver tumor through the common hepatic (liver) artery, or through the right or left hepatic artery. The spheres lodge in the area of the tumor, where the radiation helps slow the growth of the cancer cells. The radioactivity disappears within 11 days, but the spheres remain in the liver permanently. For a drawing of the whole digestive system go to: <http://www.niddk.nih.gov/health/digest/pubs/digesyst/newdiges.htm>

When is it used? SIR-Spheres ®is for the treatment of inoperable tumors from primary colorectal cancer that have spread to the liver.

What will it accomplish? For patients with advanced colorectal cancer that has spread to the liver, the addition of a single treatment of SIR-Spheres® , along with chemotherapy, acts to slow down the progress of the disease.

When should it not be used? SIR-Spheres ®should not be used in patients who:

- have had previous external radiation therapy to the liver,
- have fluid accumulations or have liver failure,
- have markedly abnormal liver function test results,

- have abnormal blood circulation resulting in abnormal return of blood from the liver to the stomach, pancreas or bowel,
- have cancer that has spread to other areas of the body,
- have been treated with the drug capecitabine within the two previous months,
- will be treated with capecitabine at any time following treatment with SIR-Spheres , or
- who have a blood clot in the portal vein.

Additional information: Summary of Safety and Effectiveness and labeling are available at: <http://www.fda.gov/cdrh/pdf/p990065.html>

Information from the National Institutes of Health

- NCI ongoing study on colorectal hepatic liver cancer, patient recruitment
http://clinicalstudies.info.nih.gov/detail/A_2001-C-0093.html
- General information on colorectal cancer
<http://medlineplus.nlm.nih.gov/medlineplus/colorectalcancer.html>
- General information on colonic diseases
<http://medlineplus.nlm.nih.gov/medlineplus/colonicdiseasesgeneral.html>

(Updated 4/18/2002)