

SIROS™

Control your Y-90 delivery with confidence



Locking cover

Shields and safely contains the Y-90 during delivery.

Needleless vial

The D-Vial is designed to eliminate touch points and allow more controlled delivery options that may result in a more even distribution of spheres exiting the vial.



Delivery Set

The peel and place tubing set is designed for quick and simple set-up and disposal.



Simple Set-up. As easy as 1-2-3

- 1 Position**
tubing set on base
- 2 Place**
needleless D-Vial holder
- 3 Snap**
on cover to lock and secure SIR-Spheres


Part Number	Part Name	Description
SIR-10100	SIROS Delivery Dome	Reusable Delivery Dome designed to facilitate the SIR-Spheres administration process and provide beta radiation shielding.
SIR-10300	SIROS Delivery Set	Sterile disposable tubing designed to provide proper routing of dose and contrast media, and connections between the syringes, D-Vial, and the microcatheter set.
SIR-10200	SIROS D-Vial Prep Set	SIROS D-Vial Prep Set is disposable and includes: <ol style="list-style-type: none"> 1. Sterile D-Vial designed to hold the SIR-Spheres. Supplied with: (1) Sterile D-Vial, (1) D-Vial holder, (1) transport base, (2) vent needles, (2) filters, (1) 21 G drawing up needle, (2) blue cap. 2. D-Vial holder designed to hold the D-Vial. A removable transport base is provided to support the holder during priming, loading and transport.

Additional hospital accessories required:

- Two 20 mL luer lock syringes filled with non-ionic solution, either 5% dextrose/glucose solution (D5W/G5) or water for injection
- Two 20 mL luer lock syringes filled with non-ionic contrast

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. 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.

Indications For Use: In the US, SIR-Spheres Y-90 resin microspheres have a Pre-Market Approval (PMA) from the FDA and are indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intra-hepatic 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, 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. **Reference the Instructions for Use (www.sirtex.com) for a complete listing of indications, contraindications, side effects, warnings, and precautions.**

 **Manufacturer**
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