SIROS™
Activity Preparation Poster

The information and steps described below are recommended for the preparation of the SIR-Spheres® Y-90 resin microspheres within a Nuclear Medicine department. Read the SIR-Spheres Y-90 resin microspheres Instructions for Use and Training Manual before preparing SIR-Spheres Y-90 resin microspheres hereinafter referred to as SIR-Spheres.

⚠ **PRECAUTIONS**:
- Time, distance and shielding considerations should be used to minimize exposure to radiation.
- Ensure that the distance between any puncture holes in the septum of the D-Vial are at least 2 mm apart.

SIR-Y001
SIR-SPHERES Y-90 RESIN MICROSPHERES

SIR-Spheres Y-90 resin microspheres glass vial in Lead Pot

SIR-10200
SIROS D-VIAL PREP SET

SIROS D-Vial Prep Set Consists of:
- D-Vial transport base
- D-Vial holder
- D-Vial
- 21G drawing up needle
- Two 25G vent needles
- Two 0.22 micron needle filters
- Two blue caps

Additional hospital accessories required:
- Forceps
- Alcohol swabs
- One 20 mL luer lock syringe
- One 5 mL luer lock syringe
- 20 mL of 5% dextrose / glucose solution (D5W/G5) or water for injection
- Syringe shield

1. UNPACKING PROCESS

A. Unpack SIR-Spheres lead pot from the plastic shipping pail and place it on the bench top.

B. Insert the D-Vial holder into the transport base and place it on the prep surface area.

C. Remove D-Vial from pouch and place in D-Vial holder.

D. Remove the aluminum seal from the center of the D-Vial with forceps and wipe the rubber septum with an alcohol swab.

2. PRIMING PROCESS

A. Connect the 0.22 micron filter to the 25 G vent needle. Insert it through the rubber septum of the D-Vial to create a vent.

B. Ensure vent needle tip is above the upper fill level mark.

C. Remove the blue cap from D line

D. Attach a syringe filled with at least 10 mL of D5W or sterile water for injection to prime the D line. Fill D-Vial to fill level mark. Ensure there is no air in the D line.

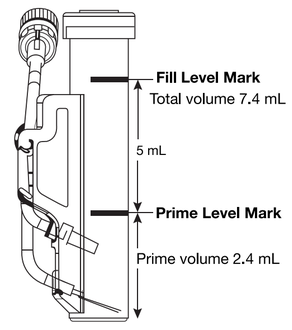
E. Disconnect priming syringe from D line; attach a new blue cap to the D line connector.

F. Remove blue cap from C line.

G. Connect same priming syringe to the C line.

H. Slowly draw fluid into the syringe from the vial to prime the C line until fluid is at the prime level mark. Ensure here is no air in the C line. **Do not draw below the prime level mark.**

I. Disconnect syringe from the C line; attach a new blue cap to the C line connector.



3. DOSE DRAW PROCESS

A. Invert the lead pot and shake vigorously before opening to re-suspend the SIR-Spheres, which will have settled during shipping.

B. Quickly open the lead pot and remove the glass shipping vial using forceps.

C. Determine the total activity of SIR-Spheres microspheres in the glass shipping vial using an appropriate ion chamber (dose calibrator) and then return the glass shipping vial to the lead pot.

D. Determine the volume of SIR-Spheres suspension that needs to be withdrawn from the glass shipping vial to provide the intended patient-specific activity of SIR-Spheres.

E. Partially peel back the aluminum seal of the SIR-Spheres glass shipping vial and wipe the septum with an alcohol swab.

F. Connect the 0.22 micron filter to the 25 G vent needle. Insert it through the rubber septum of the shipping vial to create a vent. Ensure that the tip of the needle is well clear of the contents.

G. Attach the 21 G drawing up needle to a 5 mL Luer lock syringe and place it in the acrylic syringe shield.

H. Using the shielded syringe and 21 G needle, puncture the septum of the glass shipping vial and quickly draw back and forth at least six times in order to resuspend the SIR-Spheres thoroughly.

I. Quickly withdraw the determined volume of SIR-Spheres suspension that will provide the intended patient specific activity. Prior to removing syringe needle from the shipping vial, draw some air through needle into syringe to draw spheres within needle up into syringe.

J. Withdraw the needle from the septum and re-cap the needle using forceps. Set aside on the bench top.

K. Using forceps, swirl the glass shipping vial to re-suspend the microspheres and measure the activity remaining in the shipping vial with the dose calibrator.

L. Replace the glass shipping vial into the lead pot.

M. Subtract the activity remaining in the shipping vial from the starting total activity, to determine the amount of activity that has been drawn up into the 5 mL syringe.

N. If the amount of activity that has been drawn up into the 5 mL syringe is not correct, transfer the SIR-Spheres suspension back into the glass shipping vial and repeat the steps above to obtain the prescribed level of activity.

O. Once the correct activity has been obtained, remove the vent needle from the shipping vial, and secure the lead pot cover.

P. Transfer the SIR-Spheres from the 5 mL syringe into the vented D-Vial.

Q. If the volume of fluid in the D-Vial does not reach the fill level mark, use a 25 G needle to add D5W or sterile water for injection until the fluid reaches the fill level mark. The volume between the prime level mark and fill level mark is 5 mL. **Do not exceed the fill level mark.**

R. Remove all needles from the D-Vial septum.

S. Tightly screw on the D-Vial Holder cap.

T. The patient-specific activity of SIR-Spheres is now ready for transport to the angiography suite in which the implantation will be performed.

4. SYMBOLS GLOSSARY DEFINITIONS

Symbol	Definition	Symbol	Definition	Symbol	Definition
	Manufacturer	LOT	Lot or batch code	LATEX	Product is not made with natural rubber latex
	Date of Manufacture		Use by date		Do not use if package is damaged
	Consult instructions for use	STERILE R	Sterilized using irradiation		Keep dry
	Caution	STERILE	Sterilized using steam	15°C 25°C	Temperature limit
QTY	Quantity		Single Use Only. Indicates a medical device that is intended for use on a single patient during a single procedure.	RADIOACTIVE	Ionizing radiation
REF	Catalog number	STERILE	Do not re-sterilize	Rx ONLY	Caution: Federal Law (US) restricts this device to sale by or on the order of a physician or licensed healthcare practitioner.

Manufacturer
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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 (Floxuridine). **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.**