

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, Training Manual and Technical Descriptions 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-S001 SYRINGE SHIELD

Syringe Shield (Non-sterile, re-usable device)



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

1. UNPACKING PROCESS

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



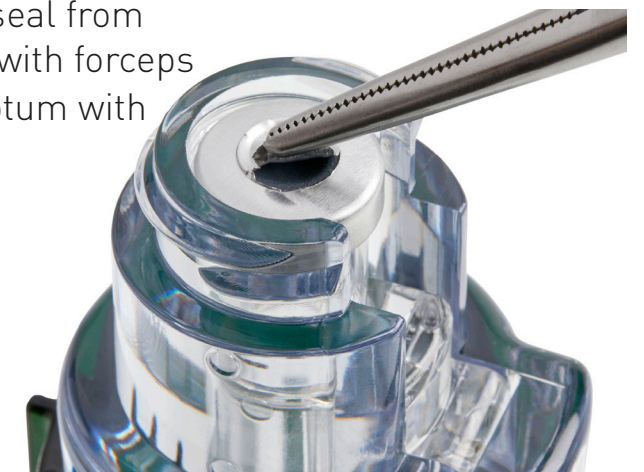
B. Insert the D-Vial holder into the transport base and place it on the prep surface area.



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.

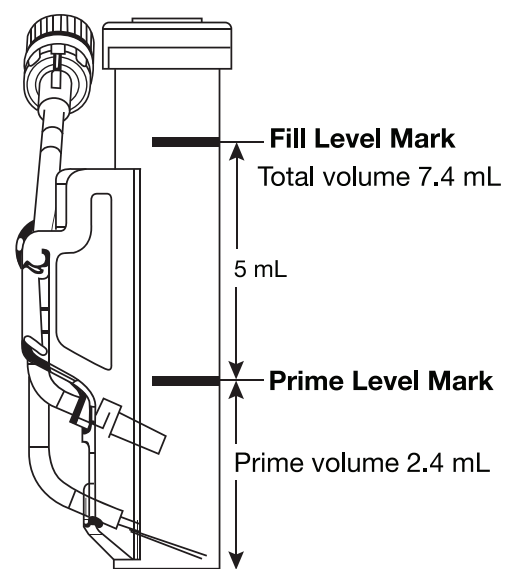
F. Remove blue cap from C line.



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 there 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	Symbol	Definition
	Manufacturer		Lot or batch code		Product is not made with natural rubber latex		Unique Device Identifier
	Date of Manufacture		Use by date		Do not use if package is damaged		Authorized representative in Switzerland
	Consult instructions for use		Sterilized using irradiation		Keep dry		Authorized representative in the European Community
	Caution		Sterilized using steam		Temperature limit		CE mark + Notified Body identification number
	Quantity		Single Use Only. Indicates a medical device that is intended for use on a single patient during a single procedure.		Ionizing radiation		MR Safe
	Catalog number		Do not re-sterilize		Sterilized using Ethylene Oxide		Medical Device
	Importer		Protective Barrier		Serial number		
	Sterile Barrier		Non-Sterile		Relative Humidity Limit		