

Dose Preparation Guide

SIR-Spheres® Y-90 resin microspheres



SIRTeX

SIR-Spheres®
Y-90 resin microspheres

Advancing to the next level.




GUIDANCE	3
SUPPLIES PROVIDED BY SIRTEX	4
ANCILLARY SUPPLIES RECOMMENDED	5
ACTIVITY MEASUREMENT	6
PREPARATION OF THE V-VIAL	6
SYRINGE PREPARATION	7
PREPARATION OF THE SHIPPING VIAL	7
DOSE DRAW	8
ACTIVITY MEASUREMENT	8
FILLING OF THE V-VIAL	9
WASTE MANAGEMENT	10











- All handling of SIR-Spheres Y-90 resin microspheres must be performed by personnel trained and authorized to handle SIR-Spheres Y-90 resin microspheres.
- All handling of SIR-Spheres Y-90 resin microspheres must be performed using standard aseptic technique, standard equipment and radiation protection methods.
- The nuclear medicine technician must verify the activity of the dose shipped with the facility's dose calibrator.
- The required quantity of SIR-Spheres Y-90 resin microspheres is withdrawn from the shipping vial and placed in the shielded V-Vial.
- When inserting a needle into the shielded V-Vial, watch the beveled end of the needle to avoid scratching the vial walls and ensure that the distance between the punctures is not smaller than 2 mm.
- The activity of the Y-90 to be transferred to the V-Vial is confirmed by measuring the Shipping Vial and subtracting the residual activity after dose draw is complete.
- If necessary, add sterile water for injection or dextrose 5% water to bring the volume of the V-Vial to the minimum of 3 mL.
- The V-Vial is placed in the V-Vial holder, which is a dedicated acrylic shield.
- The shipping vial should always remain in the lead container when being manipulated.
- Dose preparation should be performed in a controlled area, behind an acrylic or lead-shield.





	Component	Comment
	Lead shipping container	
	Shipping Vial SIR-Spheres	ca. 5 mL total volume
	Acrylic Syringe Shield	Reusable
	V-Vial	
	V-Vial holder	
	Sampling Needle	Length: 70 mm Diameter: 21 G



	Material	Recommendation
	2 forceps and/or tweezers	Length: approximately 15 cm
	Spatula or blade for opening the shipping container	Optional, to lift the aluminium cover
	3 or 5 mL Luer-Lock syringe	To be inserted into the syringe shield and used for activity manipulation
	Dose calibrator	Calibrated for SIR-Spheres
	Vent needle for the shipping vial and the V-vial	Diameter: 25 G Length max. : 16 mm
	Vent Filter	0.22 micron
	Swabs	
	2 pairs of nitrile gloves or similar	No Latex
	Alcohol for disinfection, or alcohol swabs	70% minimum, isopropyl
	Water for Injection or dextrose 5% water (D5W)	5 or 10 mL
	Appropriate radiation shielded area	
	Appropriate beta waste container	
	Survey meters : a) contamination b) exposure	For contamination and exposure

- Invert the lead pig and shake vigorously to re-suspend SIR-Spheres Y-90 resin microspheres
- Quickly open the lead container and remove the shipping vial with forceps and measure the total activity with a dose calibrator (calibrated for SIR-Spheres)



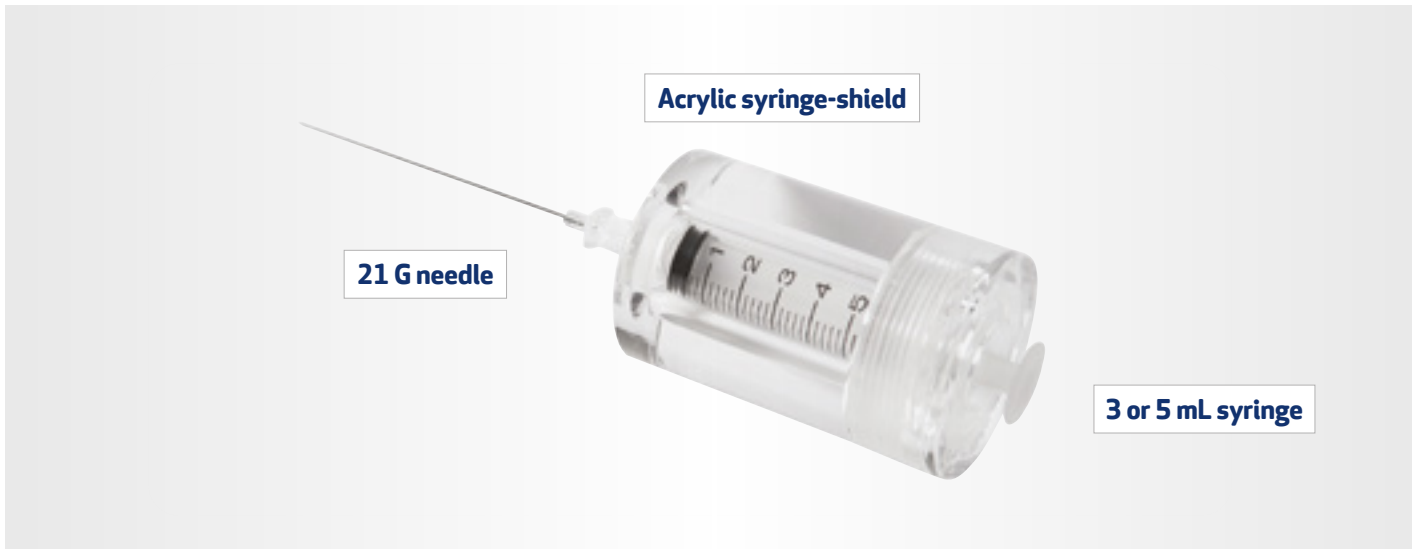
- Return the shipping vial to the lead container and place it in the shielded work area. Replace the lid on the lead container
- Determine the volume of SIR-Spheres Y-90 resin microspheres to be withdrawn from the shipping vial to deliver the required radiation dose to the patient
 - Ensure to account for decay and residual

Preparation of the V-Vial

- Remove the aluminum seal from the sterile V-Vial with forceps and wipe it off with an alcohol swab
 - Mark two opposite positions on the aluminium top of the V-Vial
- Place the sterile V-Vial in the acrylic V-Vial holder and screw the lid on
- Insert a short 25 G vent needle (with filter, if appropriate) near one of the marked positions into the septum of the V-Vial until it pierces the septum to create an airway



- Attach the provided 70 mm, 21 G lubricated sampling needle to the Luer Lock syringe
- Place a Luer-Lock syringe in the provided acrylic syringe shield and screw on the lid

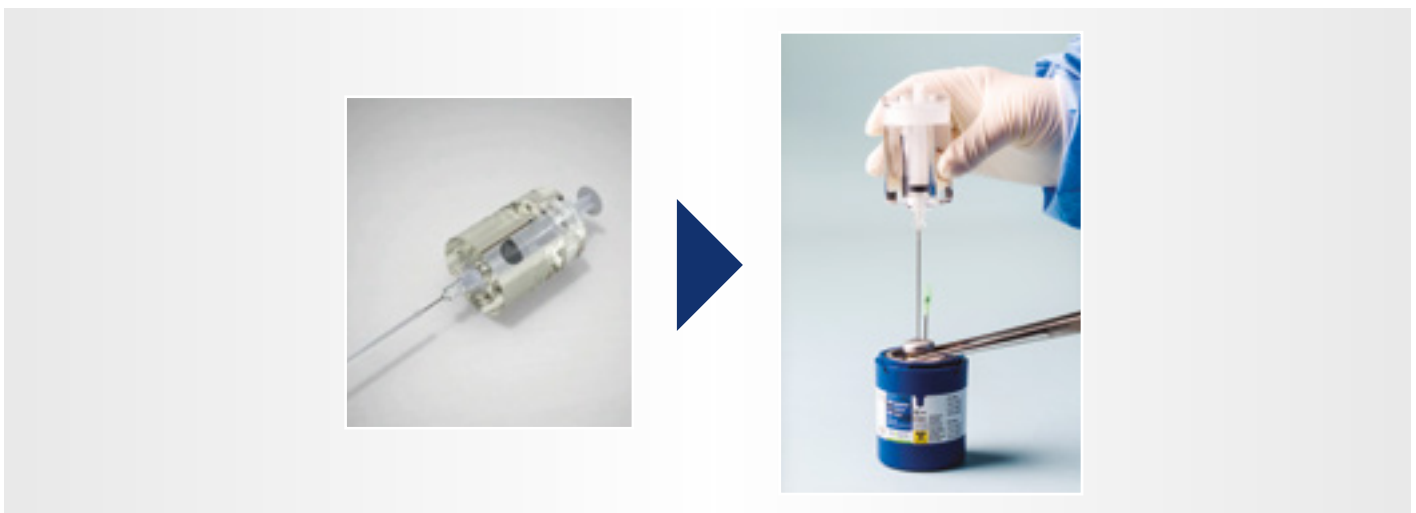


Preparation of the Shipping Vial

- Remove the aluminum seal from the shipping vial with forceps
- Clean the septum with an alcohol swab held in place with forceps
- Insert a 25 G vent needle into the septum of the shipping vial to create an air vent, ensuring that the needle does not touch the contents of the shipping vial



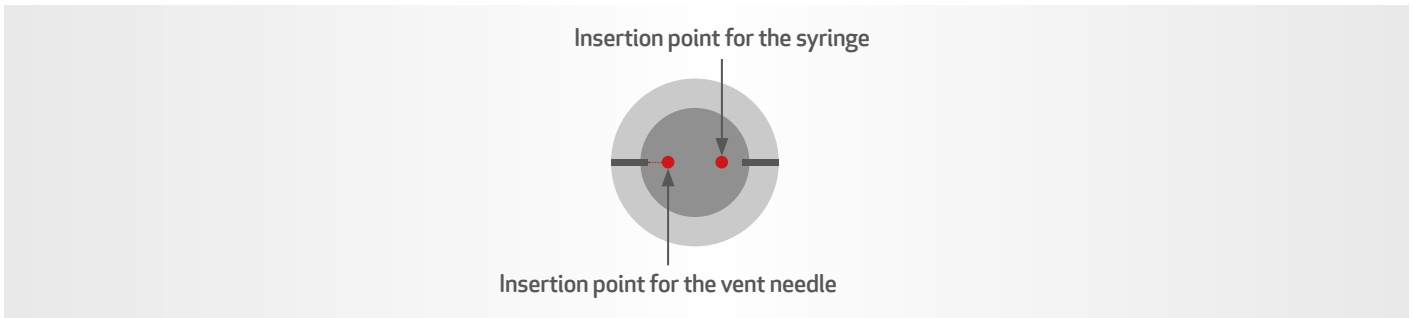
- Remove the needle cover from the shielded syringe
- Gently insert the needle into the shipping vial perpendicular to the septum so as not to twist the needle
- Withdraw and expel the microspheres vigorously six times to suspend the SIR-Spheres® Y-90 resin microspheres. **The suspension should be completely homogeneous**
- Rapidly withdraw the calculated volume of SIR-Spheres Y-90 resin microspheres
- Carefully raise the sampling needle out of the meniscus of the SIR-Spheres® Y-90 resin microspheres solution
- Before removing the sampling needle from the septum of the shipping vial, pull a small volume of air into the needle
- Remove sampling needle from the septum of the shipping vial
- Replace the protective cover on the sampling needle



Activity Measurement

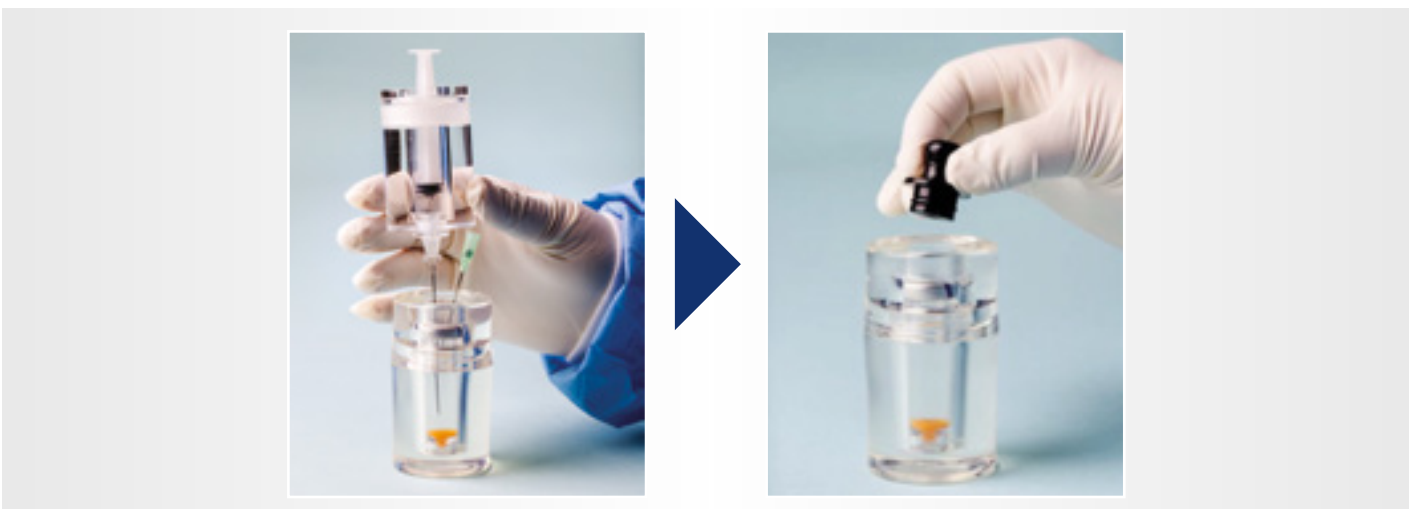
- To check the activity of the syringe place the shipping vial back into the dose calibrator and measure the difference
- If additional activity is required or deviation is not acceptable, repeat the previous steps until the correct activity is achieved
- Once the correct activity is achieved, remove the vent needle from the shipping vial and replace the lid on the lead container

- If the volume of the sample is less than 3 mL, add sterile water for injection or D5W to the syringe to achieve a total volume of approximately 3 mL
- Ensure that the distance between the holes in the septum is at least 2 mm and that the walls of the septum are not scratched
- Insert the 21 G sampling needle perpendicularly into the septum of the V-Vial



- Gently inject the SIR-Spheres Y-90 resin microspheres into the V-Vial, checking that no fluid remains in the syringe
- Carefully raise the sampling needle out of the meniscus of the SIR-Spheres Y-90 resin microspheres solution
- Before removing the sampling needle from the septum of the V-Vial, pull a small volume of air into the needle
- Remove sampling needle from the septum of the V-Vial
- Replace the protective cover on the sampling needle.
- Remove the vent needle from the V-Vial
- Ensure the lid of the V-Vial holder is tightly closed and the black plug is in place

NOTE: This step only needs to be performed ONCE.





- Open the syringe holder and dispose of the syringe and the needle in the appropriate container.
 - If needed, detach the sampling needle with forceps and dispose of it in the appropriate container.
- Perform a survey of the dose preparation area and any personnel present in the controlled area
- Collect all contaminated material into the radioactive waste container
- Ensure waste container is labeled and treated as radioactive
- Store waste in appropriately designated secure area

Intended Use: SIR-Spheres Y-90 resin microspheres are intended for implantation into hepatic tumors via the hepatic artery. **Indication For Use:** SIR-Spheres Y-90 resin microspheres are indicated for the treatment of unresectable hepatocellular carcinoma (HCC) or unresectable metastatic liver tumors from primary colorectal cancer in patients refractory to or intolerant of chemotherapy. **Warnings :** 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. **Precautions:** A SPECT scan of the upper abdomen may be performed immediately after implantation to confirm placement of the microspheres in the liver. Patients may experience abdominal pain immediately after implantation. Gastric acid blocking agents may be administered the day before implantation and continued as needed to reduce gastric complications. Safety and effectiveness of this device in pregnant women, nursing mothers or children has not been established. SIR-Spheres microspheres demonstrated a mild sensitization potential when tested dermally in an animal model. **Adverse Events:** The common side effects include fever, transient decrease of hemoglobin, transient thrombocytopenia, mild to moderate abnormality of liver function tests, abdominal pain, nausea, vomiting, and diarrhea. Potential serious adverse events due to exposure to high radiation include acute pancreatitis, radiation pneumonitis, acute gastritis, acute cholecystitis, and radioembolization induced liver disease (REILD). **Contraindications:** SIR-Spheres Y-90 resin microspheres are contraindicated and must not be implanted in patients who are pregnant, or patients that have either had previous external beam radiation therapy to the liver; ascites or are in clinical liver failure. This device is also contraindicated in patients with markedly abnormal synthetic and excretory liver function tests, ≥ 30 Gy absorbed radiation dose to the lungs and pre-assessment angiogram that demonstrates potential pathways for deposition of microspheres to non-target organs. **General Information:** SIR-Spheres Y-90 resin microspheres are radioactive and should thus be handled in accordance with all applicable standards and regulations.

Consult the Instructions for Use for a complete listing of indications, contraindications, side effects, warnings, and precautions.



A series of horizontal dashed lines spanning the width of the page, intended for handwritten notes.



Manufacturer

Sirtex Medical Pty Ltd
Shop 6, 207 Pacific Highway
St Leonards, NSW 2065
Australia
Tel: +61 2 9964 8400
Fax: +61 2 9964 8410

Europe, Middle East & Africa

Sirtex Medical Europe GmbH
Joseph-Schumpeter-Allee 33
53227 Bonn
Germany
Tel: +49 228 1840 730

www.sirtex.com

SIR-Spheres® is a registered trademark of Sirtex SIR-Spheres Pty Ltd. ©2020 Sirtex Medical Pty Ltd APM-EMEA-005-10-20 V5

SIRTeX