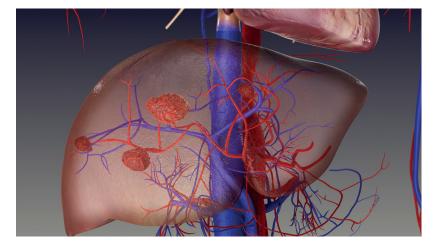


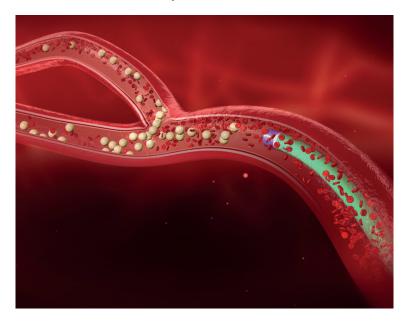
Advancing to the next level.

What is SIRT?

- Selective Internal Radiation Therapy (SIRT), also known as Radioembolisation, is a liver-directed therapy for inoperable liver tumours.
- SIRT is performed by specially trained physicians, called Interventional Radiologists and Nuclear Medicine Physicians.
- A microcatheter is used to deliver millions of microspheres with the radioactive isotope yttrium-90 (Y-90) into the liver through the hepatic arterial system, where they lodge in the tumour microvasculature and target liver tumours directly.



What are SIR-Spheres Y-90 resin microspheres?



- The high number of microspheres provide a more uniform radiation distribution, enabling treatment of solitary and multifocal liver tumours.¹⁻³
- With a specific density close to that of red-blood cells,¹ they are carried by the blood flow, penetrating deep into the tumour microvasculature.
- Tumour vasculature allows a targeted, high dose of radioactivity whilst sparing healthy liver tissue..
- Alternating injections of SIR-Spheres and contrast allow improved visualisation and control, at any time during the procedure.
- Injections can be interrupted and restarted, and the catheter position can be verified and adjusted easily.
- Administration is done using a specially designed acrylic box and a V-Vial holder for beta-radiation shielding.

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V-Vials with prepared activity, shipping vial and lead pot for shipment



Advancing to the next level.

Product information

Product features

| Manufacturer | Sirtex Medical Pty Ltd |
|------------------------------------|--|
| Approval | CE mark since 2002 |
| Indication | Treatment of unresectable hepatocellular carcinoma (HCC) or unresectable metastatic liver tumors from primary colorectal cancer in patients refractory to or intolerant of chemotherapy. |
| lsotope | Yttrium-90 |
| Decay product | Zirconium-90 |
| Composition | Resin |
| Specific density | 1.125-1.6 g/ml (comparable to red blood cells) |
| Diameter | 32.5 μm ± 2.5 μm (range 20-60 microns) |
| T _{1/2} | 64.1 h (94% within 11 days, about 1% decay/hour) |
| β-energy (max.) | 2.27 MeV (I _B = 100%) |
| Activity-to-dose conversion factor | 49.67 Gy/ (GBq x Kg) |
| Penetration in tissue | 2.5 mm (mean) |
| Radioactivity per sphere | 68 Bq ± 10% at calibration date & time* |
| Presentation of activity | Single dose size containing 3.0 GBq ± 10% of Y-90 at calibration date & time in 5 ml water for injection, moist sterilised |
| No. of microspheres per 3 GBq vial | 44 million* |

Treatment features

| Bilobar disease: Whole liver, sequential |
|---|
| Unilobar disease: Single lobe selectively |
| Segmental disease: Segmental, super-selective |
| Flow-directed, slow and controlled with full visibility |
| Shipping vial can be divided into multiple treatment vials for a single patient |
| |

Services

Training TEC** Programme, Workshops, Ongoing support

Ordering information

Item number Item

| SIR-Y001 | SIR-Spheres Y-90 resin microspheres (available in various activities at time of delivery) Each dose shipment includes one accessory pack (SIR-K002) |
|----------|--|
| SIR-K002 | Accessories Pack (includes 1 Delivery Set, 1 V-Vial and 1 V-Vial Holder) |
| SIR-V001 | V-Vial |
| SIR-D001 | Delivery Set |
| SIR-H001 | V-Vial Holder |
| SIR-S001 | Syringe Shield |
| SIR-B001 | Delivery Box |

References:

1. Sirtex internal data

2. Burrill J *et al.* J Nucl Med Radiat Ther 2011; 2:107. doi:10.4172/2155-9619.1000107. 3. Chiesa *et al.* J Nuc Med Molmaging 2011; 55: 168–197.

* On average there are 44 million microspheres in each SIR Spheres Y-90 resin microsphere delivery vial with a standard deviation of 2.6 million. Engineering test results on file

**Training, Education & Certification

APM-EMEA-007-05-21-V2

 $\mathsf{SIR}\text{-}\mathsf{Spheres}^{\circledast}$ is a registered trademark of Sirtex SIR-Spheres Pty Ltd

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