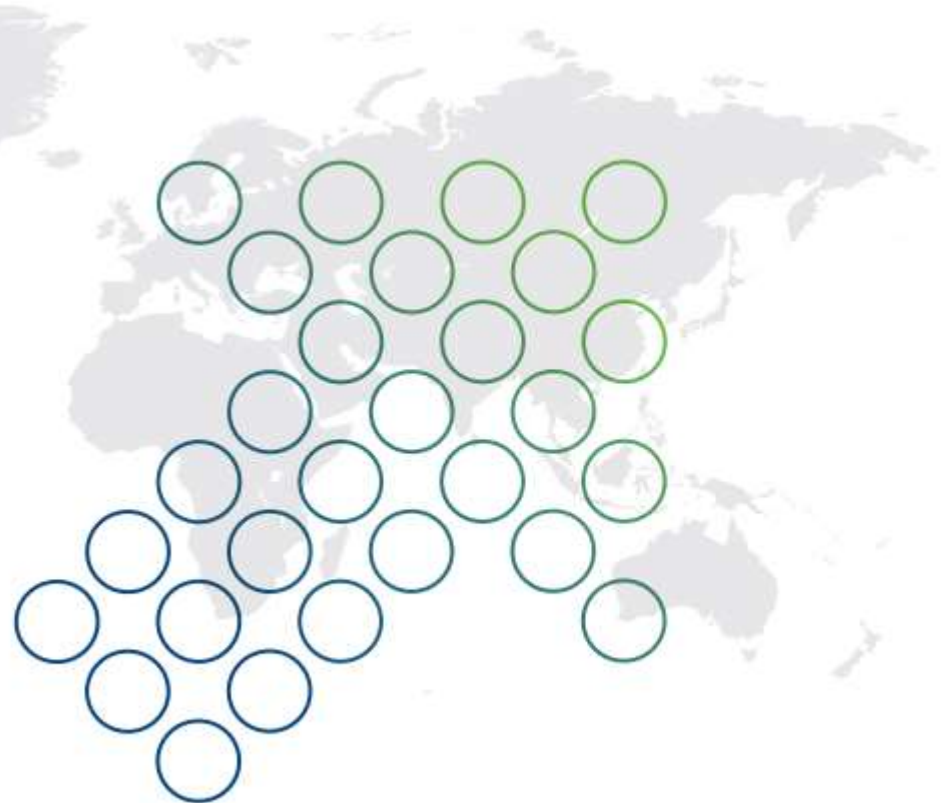




SIR-Spheres® Y-90 Resin Microspheres

Next Generation Sirtex Delivery System

Diana Thompson, MS, CHP, RRPT



Disclosure

Financial Disclosure

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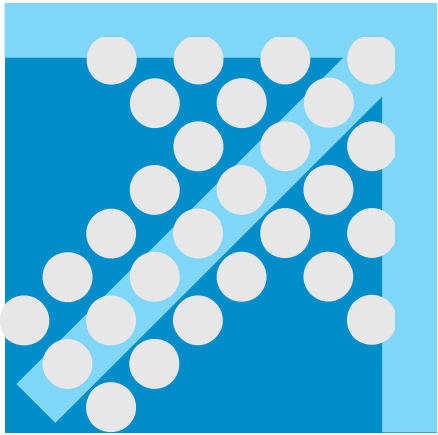
are indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intrahepatic artery chemotherapy (IHAC) of FUDR (Floxuridine).



Overview

- Sirtex SIR-Spheres Overview
- Current Delivery System
- New Delivery System
- Commonalities
- Differences





SIR-Spheres Overview

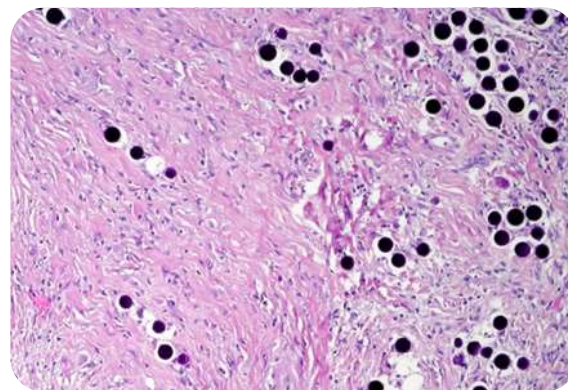
SIR-Spheres Overview

- Licensed under 35.1000 or state specific medical emerging technologies category.
- Compliance is required with NRC licensing guidance available in the medical licensee toolkit, or state specific (Illinois).
- Compliance is required with license specific conditions.
- NRC guidance is currently under revision, but 2016 version is still enforceable.



SIR-Spheres Overview

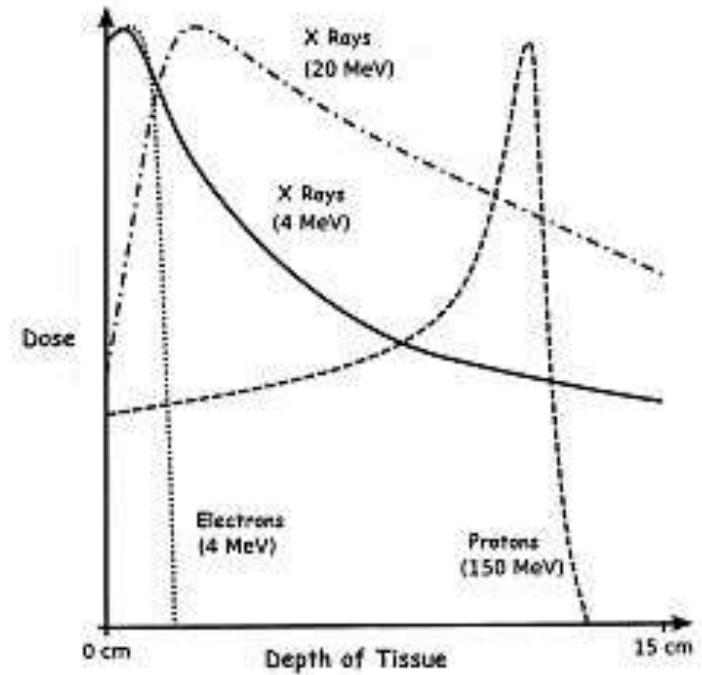
- Y-90 emits pure beta radiation with limited penetration range in tissue
- The half-life of Y-90 is 64 hours
- The delivered radiation is largely confined to a distance of 2-3 mm from the microsphere



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SIR-Spheres Overview



External Beam Image Source: National Cancer Institute (NCI) Creator: NIH Medical Arts ; Depth Dose Graph: Wikipedia

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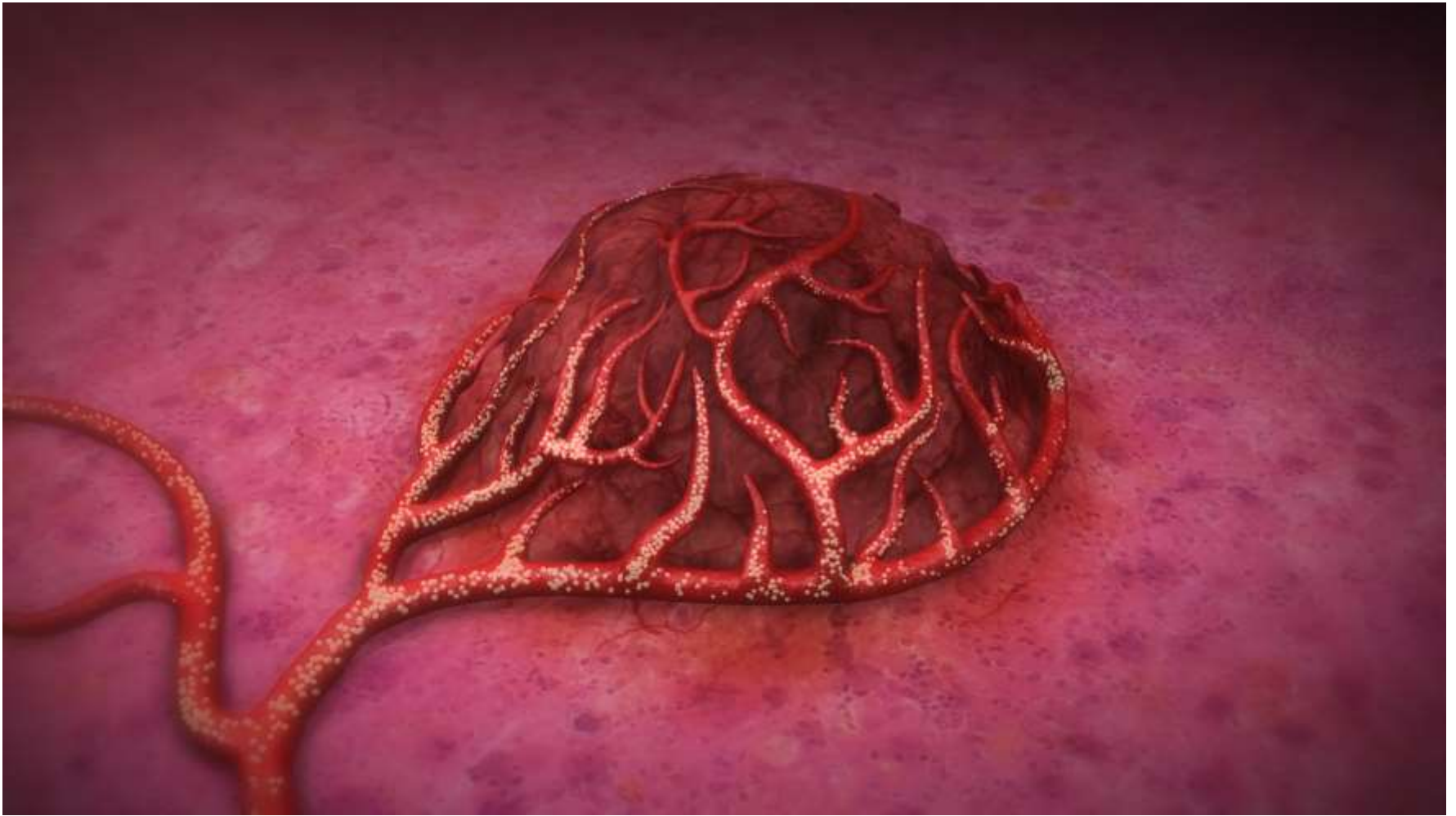
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SIR-Spheres Overview

- Treatment is delivered as an outpatient procedure in the interventional radiology suite.
- Interventional Radiologists position a catheter under fluoroscopic guidance to the delivery location.
- Using the liver's unique blood supply, millions of tiny resin microspheres loaded with yttrium-90 (Y-90) are released into the liver blood circulation. The radioactive microspheres lodge in the blood supply of the tumor, where they emit radiation used for treatment.
- The procedure normally takes about 60 to 90 minutes, with most patients returning home four to six hours later.
- The most commonly reported side effects are flu-like symptoms over one to three weeks.



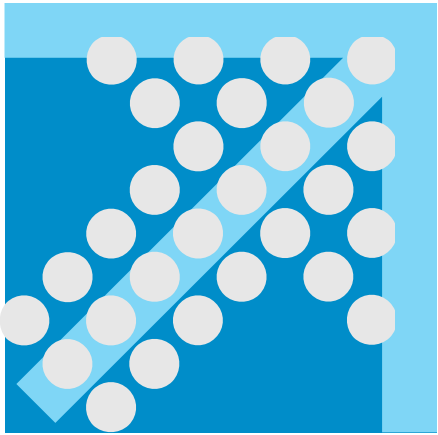
SIR-Spheres Overview



SIR-Spheres Overview

- Once SIR-spheres Y-90 resin microspheres are permanently implanted in a patient, only a small amount of bremsstrahlung radiation is detected outside of the patient (low energy x-rays).
- Patients are released as less than 100 mrem to members of the public.
- Betas are shielded with low “Z” material such as acrylic to lessen bremsstrahlung radiation





Current Delivery System

Current Delivery System



Current Delivery System

v – vial holder

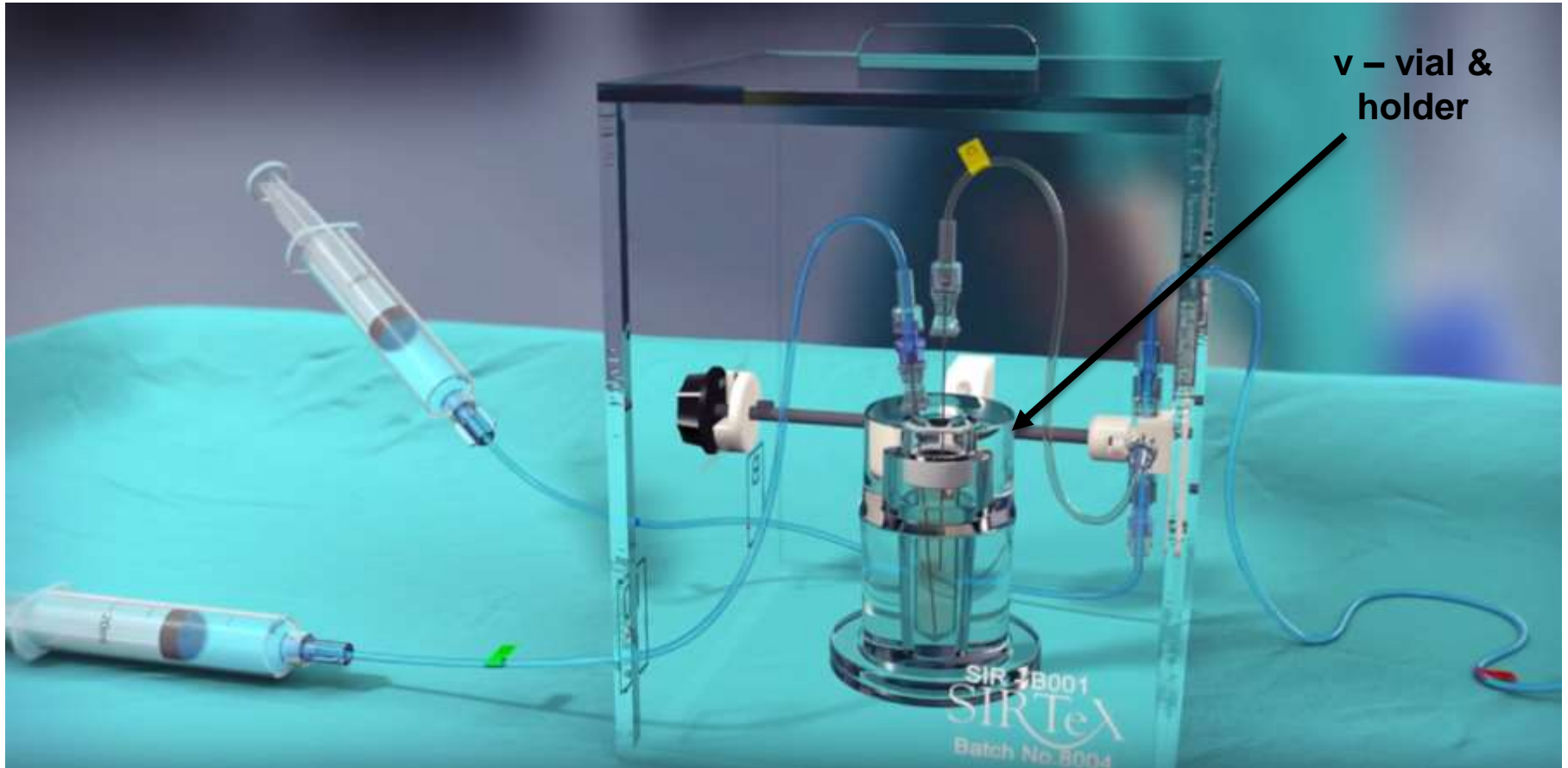
syringe shield

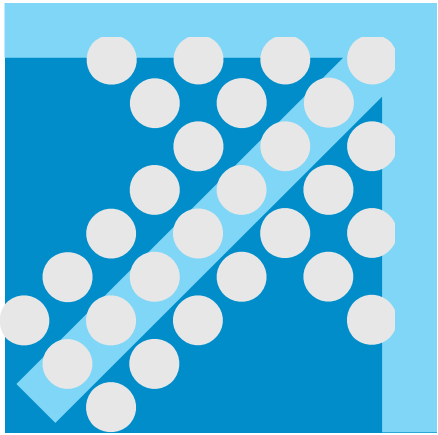
delivery box

delivery set



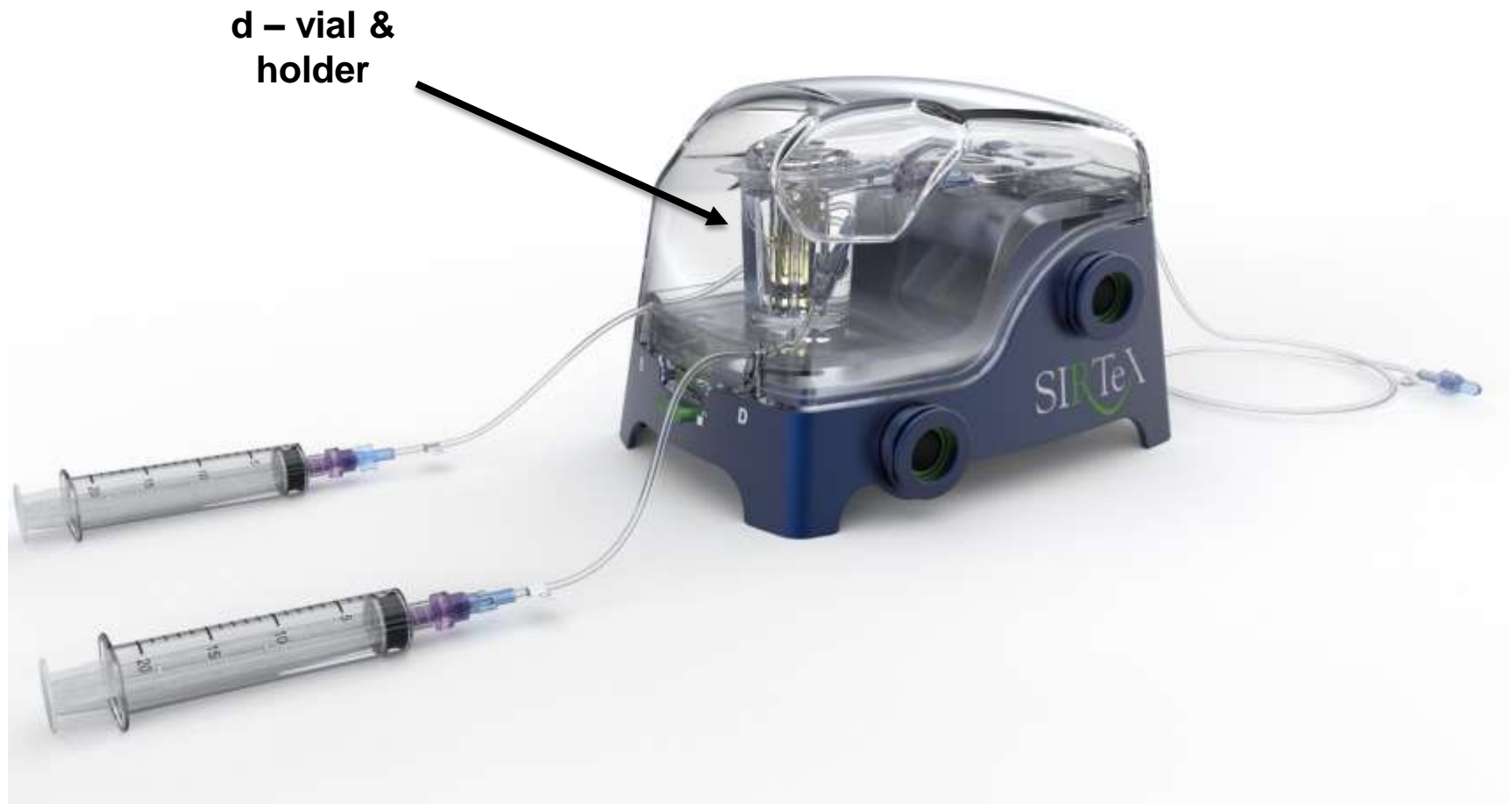
Current Delivery System





New Delivery System

New Delivery System



d - vial &
holder



New Delivery System

d - vial



Shipping vial

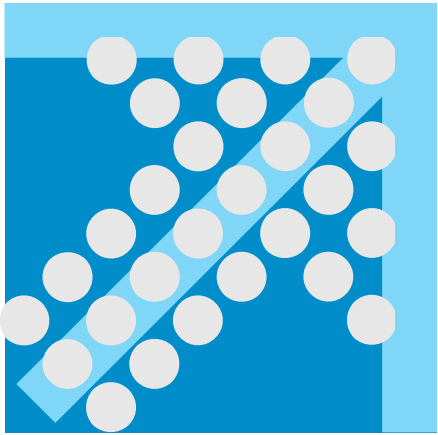


Lead pot



Lead pot cap





Commonalities

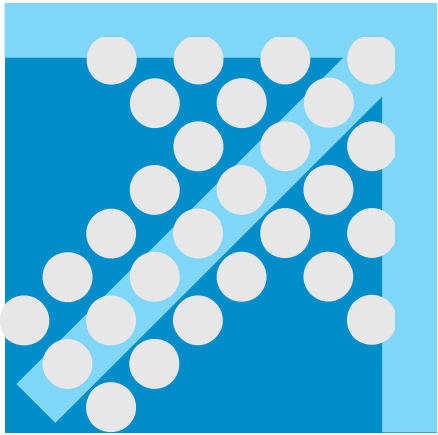
Commonalities

- SIR-Spheres
- Shipped Packaging
- Shipping Vial
- Dose Draw
- Syringe Shield
- Patient Selection
- Patient Side Effects
- Treatment Planning
- Patient Dosimetry
- Delivery Location
- Delivery Principle
- Shielding Afforded
- Decontamination Requirements
- Surveys Needed
- Medical Event Criteria



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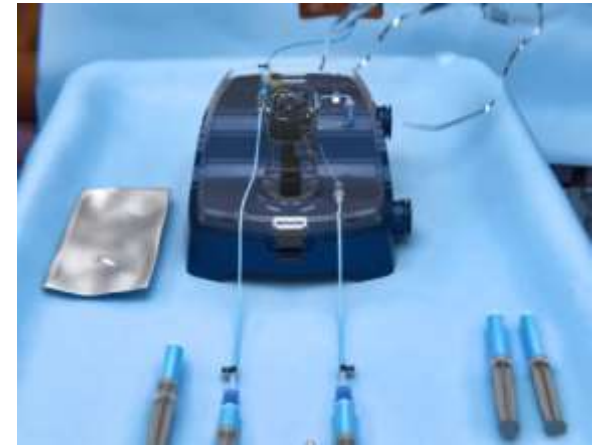
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Differences

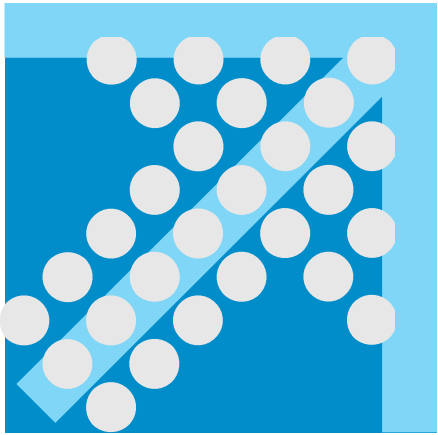
Differences

- Needleless in the Interventional Radiology Suite
- No Knob to Switch Between Syringes
- Accommodates a light to visualize SIR-Spheres
- Designed with ease of use in mind and attention of SIR-Sphere Delivery
- Accommodates a mounted dosimeter
- Modern aesthetic appearance
- Quick and simple placement of tubing



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Conclusions

Conclusions

- Sirtex is committed to providing optimal patient treatment and supporting radiation worker safety
- Questions?

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