Next Generation Sirtex Delivery System

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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
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

- 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

v - vial  Shipping vial  Lead pot  Lead pot cap
Current Delivery System

- v – vial holder
- syringe shield
- delivery box
- delivery set
Current Delivery System

v – vial & holder
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
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
Conclusions
Conclusions

• Sirtex is committed to providing optimal patient treatment and supporting radiation worker safety

• Questions?

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