

Employee Training

Y-90 Microspheres

Principles & Radiation Safety

CARDINAL RULE

- **DEMAND STRICT ATTENTION TO DETAIL FOR ALL ASPECTS OF THESE PROCEDURES !!!**

GENERAL PRINCIPLE

- Selective Internal Radiation Therapy – (SIRT) - to selectively target a very high radiation dose to all tumors within the liver, regardless of their cell of origin, number, size or location. While at the same time, maintaining a low radiation dose to the normal liver tissue.
- Blood supply to the “normal” liver is primarily from the portal vein and a small component is from the hepatic artery.
- Liver tumors however receive most of their blood supply from the hepatic artery
- Therefore it is desired that Y-90 microspheres are “perfused” into malignant hepatic tumors via a micro-catheter (ID>0.5 mm) placed into the hepatic artery using the tumor’s own blood supply.
- Yttrium-90 is a pure beta emitter with a maximum energy of 2.27 MeV and average energy of 0.93 MeV with a range in tissue of 11 mm maximum and a mean range of 2.5 mm. It is therefore an excellent internal therapeutic radiation source.
- Microspheres themselves are biocompatible not biodegradable and localize in the tumor via capillary blockage.

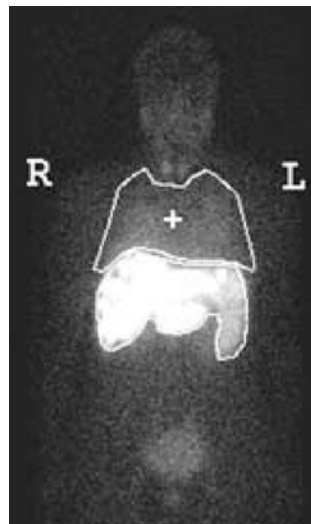
Commercial Y-90 Microsphere Products

- SIR-Spheres® (Sirtex Medical)
 - Resin microspheres
 - Y-90 embedded in resin
 - ~5.0 ml sterile water
 - 20-60 μm
 - 40-70 Bq per sphere
 - 3 GBq = 30-60 $\times 10^6$ spheres
 - Density (g/cm^3) – 1.6
- TheraSphere® (MDS Nordion)
 - Glass microspheres
 - Y-90 incorporated into glass
 - 0.6 ml sterile water
 - 20-30 μm
 - 2,400-2,700 Bq per sphere
 - 3 GBq = 1.2 $\times 10^6$ spheres
 - Density (g/cm^3) – 3.29

Y-90 Microsphere Therapy

RADIOLOGY WORK-UP

- CT – to assess liver volume and tumor burden
- Hepatic Angiogram – to evaluate hepatic vasculature
 - a. Embolization (coiling) of extrahepatic vessels to prevent gastroduodenal ulceration from errant microsphere deposition
 - b. Micro-catheter placement
- Tc-99m – MAA Scan to assess lung shunting



- Lung shunting limited to <20% or an absorbed dose of 25 – 30 Gy

RADIATION SAFETY – IR SUITE

NO ONE Leaves the IR Suite Exit – Without Being Surveyed for Contamination !!!

- Acrylic Delivery Box - Shields against bremsstrahlung X-ray radiation
- Absorbent Pads on Floor / Device Tray - “Catch” possible loose contamination
- Sterile Drapes from Device to Patient - “Catch” possible loose contamination
- Lead Aprons / Glass and Distance - Shields for Fluoroscopy Use
- “in-Line” RADOS Radiation Monitor of Activity Delivery - TheraSpheres Only
- Door Postings / NMT Entrance Monitor / Gatekeeper - Traffic / Contamination Control
- GM meters – Live contamination surveys of Hands Bottom of Feet, Ant & Post Body Surfaces - **PRIOR TO ROOM EXIT**
- Spill Kit - Immediate Response
- Waste Containers - Collect / Segregate contaminated Items
- Protective Clothing - Gowns, Double Gloves, Masks, Double Shoe Covers
- Personnel Monitoring Devices

Y-90 Microsphere Therapy

RADIATION SAFETY - CONTAMINATION POTENTIAL

- Contamination Potential is EXTREMELY HIGH
- Microspheres are approximately $\frac{1}{4}$ the diameter of a human hair
- A single TheraSphere contains approximately 2500 Bq (67nCi)
- A single SIRSpheres contains approximately 50 Bq (1.35 nCi)
- Microspheres do Roll and can Bounce
- Microspheres can become Airborne if allowed to dry.
- Survey Procedures are unchanged from other radioactive solutions

RADIATION SAFETY - CONTAMINATION REMEDIAL ACTIONS

- Microspheres can easily fall into cracks and crevices
- Strategic placement of plastic backed absorbent pads and surgical towels is mandatory
- Masking or Duct Tape can be employed to “pick up” microspheres
- Dampened paper towels can be used
- The following “household cleaning” items should be considered:
- “Scrubbing Bubbles” to “lift” contamination and / or “Swiffer Wet Jet” with removable moistened pad.



Y-90 Microsphere Therapy

Y-90 MICROSPHERE - NRC ISSUES

- Specifically licensed under 10 CFR 35.1000 – Written Directive Required
- No Leak Test Required
- Licensing Guidance – TheraSphere and SIR-Spheres Y-90 Microspheres (June 2012)
 - a. Training and Experience Requirements for Authorized Users (AU's)
 - b. License Commitments for Written Directives, Inventories, Patient Release, Labeling and Medical Event Reporting

Y-90 MICROSPHERES – WRITTEN DIRECTIVE

- Properly ID the patient prior to Tc-99m MAA or Y-90 Microsphere administration
- Signed and Dated by an AU **PRIOR** to administration – noting either total dose (rad or Gy) or prescribed activity (mCi or GBq) which is preferred
- Written Directive **SHALL** record the administered activity (or dose) delivered to the primary treatment site and to other specified site(s).
- Written Directive **SHOULD** specify the maximum activity (or dose) that would be acceptable to the specified site(s) outside the primary treatment site due to shunting (e.g. lung and gastrointestinal tract).
- If appropriate for the type of microsphere used, the statement “or dose / activity delivered at stasis.” Is to be noted as the dose / activity administered when stasis occurred.
- A notation of stasis must include the name of the individual who made the “stasis” assessment, the date and the signature of the AU.
- A Medical Event has **NOT** occurred if stasis is documented as a treatment endpoint in the written directive

Y-90 MICROSPHERE – SEALED SOURCE INVENTORY AND WASTE

- Semiannual sealed source inventory is required and must include
 - a. Radionuclide and physical form
 - b. Unique identification of each vial
 - c. Total activity contained in each vial(s)
 - d. Location of vials
- A separate form for waste storage and disposal is required.

ACTIVITY DELIVERED - ASSURANCE WRITTEN DIRECTIVE FOLLOWED

- Follow manufacturer's instructions for Pre-administration assay / monitoring



- Follow manufacturer's instructions for Post-Administration assay / monitoring to confirm agreement with written directive prescribed activity



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Y-90 MICROSPHERE - PATIENT RELEASE

- The patients' own tissues will provide sufficient attenuation of the beta emissions such that patients can be immediately released in accordance with NRC criteria under 10 CFR 35.75.
- This release criteria limits total effective dose to others to 500 mrem at one(1) meter. It has been estimated that an administration of 38.5 Ci of Y-90 would be required to exceed this limit.

Y-90 MICROSPHERE - PATIENT INSTRUCTIONS

- Written Discharge Instruction May Include:
 - a. No travel on public transport, including air travel lasting more than two(2) hours for one(1) week
 - b. Avoid crowded public places for one(1) week
 - c. Do not sleep in the same bed as your partner for one(1) week
 - d. No contact with children or pregnant individuals for one(1) week
 - e. Adult visitors should stay more than six(6) feet away for one(1) week (if for a prolonged period of time).
 - f. There is no need to make special arrangements for bodily fluids (urine, stool, blood, vomit).

POST – ADMINISTRATION NURSING CARE

- The patient is moved from the IR suite to a recovery room
- The following guidelines are suggested:
 - a. Non-pregnant nursing staff only
 - b. Pregnant visitors or children should not visit
 - c. Nursing care should be delivered from the LEFT side of the patient
 - d. Collection of bed linen, rubbish or clothing NOT necessary
 - e. Universal Precautions should be stressed

Y-90 MICROSPHERE – POST ADMINISTRATION PATIENT DEATH

- The following residual activity limits are suggested for handling deceased patients administered Y-90 microspheres
 - a. Necropsy 150 MBq (4.05 mCi)
 - b. Cremation / Burial 1 GBq (27 mCi)
 - c. Embalming 150 MBq (4.05 mCi)

Y-90 Microsphere Therapy

I have read and reviewed the enclosed Y-90 Microsphere workbook with regards to general principles and radiation safety instruction. All questions and concerns have been answered in accordance with my duties and responsibilities for this procedure:

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Radiation Safety Officer_____
Management

Date: _____

Date: _____