Minimizing Unnecessary Radiation Exposure to Healthcare Professionals and Patients

TheraSphere®

Imagine where we can go.
The use of radiation for beneficial purposes in medical procedures is a major contributor to improved human health. However, the benefits of treatment need to be balanced with the risks of radiation exposure.

ALARA is a radiation safety principle of keeping unnecessary radiation exposure and release of radioactive materials to the environment as low as can be achieved by employing all reasonable methods.¹

ALARA is also a regulatory requirement for all radiation safety programs.

ALARA is based on the assumption that exposure to radiation of any dose increases the probability of detrimental biological effects such as genetic mutations and cancer.

ALARA can be achieved using three key factors:

1. **TIME**
   - Reducing exposure time reduces radiation risk.

2. **DISTANCE**
   - Doubling the distance reduces radiation exposure four-fold.

3. **SHIELDING**
   - Shielding material absorbs radiation between the source and the individual.

Adapted from Brateman L, 1999.²
ALARA = As Low As Reasonably Achievable
TheraSphere® was designed with ALARA in mind to reduce radiation exposure to both healthcare professionals and patients to ‘As Low As Reasonably Achievable’ levels.

- **Dose vials are ready to use**: Both the shipping vial and the administration vial are ONE AND THE SAME. NO dose preparation or manipulation is required.
- **Rapid infusion** means that delivery is quick, with an infusion time of less than 5 minutes.
- NO continuous fluoroscopy or contrast is needed during administration.
- Preparation (priming) of the administration system tubing is performed independent of the dose vial.
- Protection is provided by acrylic and lead shielding around the dose vial during shipping AND patient treatment. Acrylic shield blocks 100% of the beta radiation. Lead pot reduces Bremsstrahlung radiation exposure to 1/7th of levels without lead shielding.
- NO significant amount of free ⁹⁰Y present in the treatment vial.

**Minimizing radiation exposure to patients and others:**
- NO significant amount of ⁹⁰Y leaches from the glass matrix.
- Secondary radiation exposure to others is well below regulatory limits.
- Body fluid radioactivity is NOT an issue for TheraSphere® patients. There is NO need for special precautions regarding body fluids (urine, stool, blood, or vomit). Patient hygiene instructions are NOT necessary.
- High delivery efficiency means less ⁹⁰Y in waste materials that need to be handled after patient treatment.

⁹⁰Y = yttrium-90
The TheraSphere® Administration Accessory Kit is designed and constructed to SHIELD healthcare professionals and patients from radiation exposure to ‘As Low As Reasonably Achievable’ levels.

TheraSphere® Administration Accessory Kit:
- Provides 100% beta shielding to the user through the acrylic shield
- Is supplied with a 2 L waste jar beta shield for handling and storing post-treatment waste
- Is designed to contain any potential leaks from the dose vial (although leaks are exceedingly rare)

How Does the Administration Accessory Kit Conform to ALARA?

- Acrylic shield
- Dosimeter
- Lead pot containing dose vial
- 2 L waste jar with beta shield
- Administration Accessory Kit

Adapted from the TheraSphere® website: www.therasphere.com
What is TheraSphere®?

TheraSphere® is indicated for radiation treatment or as a neoadjuvant to surgery or transplantation in patients with unresectable hepatocellular carcinoma (HCC) who can have placement of appropriately positioned hepatic arterial catheters. The device is also indicated for HCC patients with partial or branch portal vein thrombosis/occlusion, when clinical evaluation warrants the treatment.

TheraSphere®:

- Consists of insoluble glass microspheres where yttrium-90 (⁹⁰Y) is an integral constituent of the glass
- Has a mean microsphere diameter of 20 to 30 μm
- Is a pure beta emitter with an average energy of 0.9367 MeV and physical half-life of 64.1 hours (2.67 days)
- Is calibrated to National Institute of Standards and Technology (NIST) standards

The recommended dose for TheraSphere® administered to the liver is between 80–150 Gy (8000–15,000 rad).

Radiation exposure to the healthcare professional during TheraSphere® treatment is well below the amount of exposure from a US coast-to-coast flight.

* Please refer to “Instructions for Use” in the TheraSphere® U.S. package insert for complete dosing calculations and administration instructions.
Important Safety Information

Caution

Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training and experience.1

Warnings

A retrospective study of 121 patients from five clinical trials has shown that the following five Pre-treatment High Risk Factors have been associated with at least 48% of all serious adverse events that were possibly related to use of the device and with 11 of the 12 deaths that were possibly related to use of the device:

- Infiltrative tumor type
- “Bulk disease” (tumor volume >70% of the target liver volume, or tumor nodules too numerous to count)
- AST or ALT >5 × ULN
- Bilirubin >2 mg/dL
- Tumor volume >50% combined with an albumin <3 g/dL.

The physician should always take the above-noted Pre-treatment High Risk Factors into consideration for each patient when making decisions regarding the use of TheraSphere® for treatment.2

Contraindications

The use of TheraSphere® is contraindicated in patients:3
- whose Tc-99m MAA hepatic arterial perfusion scintigraphy shows any deposition to the gastrointestinal tract that may not be corrected by angiographic techniques
- who show shunting of blood to the lungs that could result in delivery of greater than 16.5 mCi of yttrium-90 to the lungs. Radiation pneumonitis has been seen in patients receiving doses to the lungs greater than 30 Gy in a single treatment
- in whom hepatic artery catheterization is contraindicated; such as patients with vascular abnormalities or bleeding diathesis
- who have severe liver dysfunction or pulmonary insufficiency
- who are pregnant

Adverse Events

The most common adverse events (≥5%) include elevated bilirubin (23.1%), ascites (8.3%), abdominal pain (6.6%), and elevated AST/ALT (5.8%).3

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References:


ALT = alanine aminotransferase; AST = aspartate aminotransferase; HCC = hepatocellular carcinoma; MAA = macroaggregated albumin; Tc-99m = technetium-99m; ULN = upper limit of normal

TheraSphere®

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