Imagine where we can go.
What is ALARA?  
**As Low As Reasonably Achievable**

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. **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.

**What is TheraSphere®?**

**TheraSphere®** is used in the treatment of hepatic neoplasia. **TheraSphere®**:
- Consists of insoluble glass microspheres where yttrium-90 ($^{90}$Y) 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 four-hour airline flight.

*Please refer to the **TheraSphere®** Instructions for Use for complete dosing calculations and administration instructions.*
**What is ALARA?**
**As Low As Reasonably Achievable**

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.

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.

**How Does the BETA™ Dose Vial Conform to ALARA?**

BETA™ 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**

Minimising 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 BETA™ 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**

**How Does the Administration Accessory Kit Conform to ALARA?**

The BETA™ 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 with 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)

*Dosimeter*®

**Administration Accessory Kit**

**Lead pot containing dose vial**

**2 L waste jar with beta shield**

**Acrylic shield**

Adapted from Brateman L, 1999

ALARA = As Low As Reasonably Achievable
In the UK, ALARA is referred to as ALARP (As Low As Reasonably Practicable)
Indication for Use
TheraSphere® is used in the treatment of hepatic neoplasia.3

Important Safety Information

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 tumour type
• “Bulk disease” (tumour volume >70% of the target liver volume, or tumour nodules too numerous to count)
• AST or ALT >5 × ULN
• Bilirubin >2 mg/dL
• Tumour 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.3

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 catheterisation is contraindicated; such as patients with vascular abnormalities or bleeding diathesis
• who have severe liver dysfunction or pulmonary insufficiency
• who are pregnant

Please see the full TheraSphere® Instructions for Use available at www.TheraSphere.com for complete important safety information, including BOXED WARNINGS.


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