

*Preparing for a clinical dose of Y-90 TheraSphere™
A Hazmat Tech's perspective.*

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The University of Louisville Hospital is a 400+ bed facility that provides a full range of diagnostic, therapeutic, emergency and surgical services, including the region's only Level I Adult Trauma Center. Their knowledge of the latest medical treatments and techniques means a patient at the University of Louisville Hospital will receive the most up-to-date treatment in the region. One such treatment is TheraSphere™.

TheraSphere™ is a therapeutic treatment that delivers radiation directly to tumors in the liver using glass Micro-Spheres. The tiny beads (or intra-hepatic micro-spheres) measure one third the diameter of a human hair, and are embedded with a radioactive element called Yttrium90 (Y-90), a Beta emitter. Millions of these micro-spheres are injected into the blood stream through a guided catheter into the hepatic artery, the liver's main blood supply. When they arrive in the liver, the radiation-laden spheres get lodged within the smaller blood capillaries that sustain tumors. Because they are lodged in the tumor, the spheres Y-90 component radioactively decays within the tumor mass. This feature allows for a much more targeted treatment of the tumor and significantly reduces damage to the surrounding tissue.

While this treatment is very beneficial to the patient, it can hold considerable Hazmat consequences. From the Hazmat Tech's perspective, extra caution is warranted in the set up of the operating suite and the delivery device due to the EXTREME contamination problems facing personnel and the facility if the product gets loose.

The vial containing the spheres is infused with IV saline under pressure during the delivery of the treatment. The delivery pressure varies, but our Radiation Safety Office uses 12 to 20 psi. If a leak occurs during the procedure, the radioactive micro-sphere saline solution may be sprayed about in any direction and the evaporation of the saline will cause the micro-spheres to have the ability to become airborne and readily distributed in air currents. They may then become lodged in small cracks, floor seams,

clothing, and may possibly be inhaled. The consequences of a leak consist of contamination of personnel and the closure of the procedure room for decontamination. Most hospitals have 1 to 3 Cardiac Catheter or Interventional Radiology suites. Therefore, the revenue loss from having to close the suite while the decontamination is underway could be enormous.

Y-90 is a pure Beta emitter with an average energy of 0.94 MeV and has a half-life of 64.1 hours. The average number of micro-spheres per dose is seen in the following chart.

DOSE ACTIVITY (GBq \pm 10%) (mCi)		MASS IN MILLIGRAMS	MILLIONS OF SPHERES
3	81	27	1.2
5	135	45	2.0
7	189	63	2.8
10	270	90	4.0
15	405	135	6.0
20	540	180	8.0

* Provided by MDS Nordian

The first step in contamination control is to prepare the room. The staff should start by removing all unnecessary tables, carts, equipment and any other items that may become contaminated if a spill occurs on the floor. Next, completely cover an approximately 6ft area on the floor around the operating table with a textured absorbent paper with a polyethylene backing. The paper is duct taped in place and all overlapping seams are taped. This type of paper has proven to hold up under the foot traffic and cart traffic of the operating suite. Also, due to the texture of the paper, if a spill were to occur it would absorb the liquid and keep the micro-spheres contained in the textures.

The TheraSphere™ equipment set consist of the delivery device, administration tubing, needles, meters, waste vial, dose vial, waste container, and setup directions / procedures. This equipment is arranged on a separate table from the operating equipment. Both tables are draped with sterile sheets and several sterile absorbent towels are placed on each for use during the procedure. Ensure the table used is sturdy enough to handle the equipment and the pressure of the dose delivery.

The delivery device is then assembled in consultation with the detailed instructions. The first possible leak or spill could occur during this procedure. To prevent contamination of personnel during this step, lab coats, shoe covers, and gloves are mandated and worn.

The delivery fixture consists of four main components, a stainless steel base, 2 Rad60R dosimeters, a lower acrylic box, and an upper acrylic shield. Other parts include an IV bag post, wrench, locking pin and supplied waste container. Once this system is assembled the administration tubing is ready to be connected and the dose vial is ready for infusion. The next step involves connecting the tubing from the IV bag to the syringe, and then to the red stopcock which controls the saline into the inlet line. The dosimeters are placed in their holders at the dose vial and the blue stopcock. The dosimeters allow the flow of the micro-spheres to be followed.

The tamper seal is removed from the dose vial and the plug is removed by applying surgical tape to it and lifting it out. The dose vial septum is cleaned with an alcohol swab using long forceps or tweezers. Then needle guides are placed on the septum and the inlet and outlet needles are placed into the guides, piercing the septum. Extra care is taken when piercing the septum due to the possible release of the micro-spheres. An additional line from the blue stopcock is then placed into the waste vial.

Once this procedure is complete, the lines to the blue stopcock, and only to the blue stopcock, may be primed. The technician watches for leaks at each of the Luer lock hubs, inlet and outlet needle connections, and septum. A reading on both dosimeters should now be present.

If there is leaking or the pressure reading on the syringe exceeds 30psi, then abort the procedure. The administration tubing set-up as a whole unit should then be disposed of into the waste container.

The needle guides are now removed and the needles are inserted the rest of the way into the dose vial. Careful attention is required not to dislodge the needles from the lines and from the septum causing a spill. The needle hubs should be taped down to the vial. The tape will hold the needles in place under the pressure of the delivery and help to prevent them from coming out of the septum.

Once all of these procedures are completed, the device is ready to be hooked up to the patient.

Before connecting the line to the patient, a sterile towel is placed under the catheter connection and in the space between the patient and the delivery device. This will help catch any possible leakage.

Once the catheter is connected, the position of the catheter is once again verified and the administration of the dose can begin.

During the administration, check for leaks at each Luer lock hub, the vial septum, and needle connections. If a leak occurs, the procedure should be aborted. After the first flush, most of the spheres are delivered and the reading on the dosimeter next to the vial should be close to background. The dosimeter near the blue stopcock may have a reading due to spheres lodged in the connection fittings or due to the close proximity to the patient. Additional flushes and light tapping on the fittings should remove all spheres and bring this reading down. Remember only tap lightly, if the fittings come loose this will cause a leak.

Once the dose has been delivered, the doctor will remove the catheter and place it in the waste jar. There may be some residual spheres in the end of the catheter. Make sure to inform the doctor not to pull the catheter out in such a motion that will cause slinging of blood or excessive dripping off the protected areas. The residual spheres at the end of the catheter are still a contamination hazard. The delivery device table can now be moved away from the patient and the clean up can begin.

The tubing should not be disconnected. The IV bag, tubing, and both vials should be placed as a whole unit into the waste jar. The towels, draping, and any surgical supplies used should be checked for contamination with a survey instrument. If these are determined to be contaminated, they should be placed in the jar as well.

Someone should be posted at the entry and exit point of the room with a survey instrument to ensure all personnel involved with the procedure are not contaminated. For extra precaution, place a sticky mat at the door to catch any possible shoe covering contamination. In addition, the wheels of the bed need to be checked for contamination before they roll the patient out. Finally, the floor covering and remaining areas are monitored to ensure no residual contamination is present.

If the procedure was a success, only the catheter, the delivery device tubing unit, doctor's gloves and the towel underneath the connection would be required to be placed in the jar. The lid should be placed on the waste jar and the recommended checks per MDS Nordian should be completed. The waste jar would then be ready to be moved to a radioactive waste accumulation area.

The floor covering and remaining supplies can be disposed of in the normal refuse and the room can be turned back over to the suite staff.

If the procedure was not a success and a spill occurred, a decontamination kit should be located nearby. Our kit consists of a garbage can with a liner to hold all the towels, sheets and floor coverings that would be contaminated. If the contamination was not contained and it reached the

unprotected floor, our staff would use a Swiffer Wet Jet™. This system sprays a liquid cleaner that would keep the spheres from becoming dry and the absorbent pad would contain the suspended spheres. All personnel involved would be thoroughly checked with a survey instrument and a complete decontamination of the room would be done. Additional equipment in our kit consists of gloves, tyvex suits, absorbent paper, tape, and various survey instruments.

The room can not be returned to service until it is thoroughly surveyed and decontaminated.

As you can see, there are many steps involved with the TheraSphere treatment that could cause a possible Hazmat incident. But, with the proper training provided by MDS Nordian, the standard and effective operating procedures, and a prepared Hazmat Tech on staff, the risk can be greatly minimized.

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