

13 December 2017

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*Submitted to
LAF 12/18/17*

RE: MidState Medical Center	NRC Materials License No.: 06-05686-02
	Docket No.: 030-01257
	Mail Control: 601467

In response to your questions with respect to MidState Medical Center's amendment requests dated 08/02/17 and 09/29/17

Please confirm that Pamela Lyons is authorized to sign such requests on behalf of senior management.

Gary Havican, FACHE, Senior Vice President and President, Central Region, Hartford HealthCare, will be authorizing our amendment requests going forward.

Please submit your procedures for termination of treatment due to stasis.

Presently, according to the manufacturer, BTG, there are no reported instances of stasis in the administration of TheraSphere® Y-90 Glass microspheres, other than those due to catheter failure-related events. BTG emphasizes the very small diameter of the TheraSphere® microspheres (mean diameter 25 microns) and the relatively smaller volume of product slurry delivered to the treatment site. The attached reference manual, page 59, details these advantages that minimize the incidence of stasis.

However, if stasis were to occur during infusion of TheraSphere® microspheres, we would use the protocol presented in the attached TheraSphere® procedure checklist (see items 6 and 7 on the checklist).

Personnel calculate infusion efficiency and residual activity from pre and post treatment measurements of the dose vial and any item associated with microsphere delivery, recorded on a procedural template as instructed by the procedure checklist. Personnel will follow NRC notification rules when, for whatever reason, a reportable event arises during or following the treatment.

Please confirm that you have appropriate instrumentation available to adequately survey for the presence of radioactive contaminants in the waste stream.

We confirm we possess a variety of suitably calibrated survey meters appropriate for monitoring all aspects of this procedure, including the patient, involved personnel, suite and waste. These instruments include the following:

Ludlum Model 14C, with Ludlum model 44-7 probe;

Ludlum Model 2, with Ludlum model 44-38 probe.

We reserve the right to replace these instruments with survey meters of comparable specifications. Further, we commit to maintaining these instruments or the equivalent replacement survey meters. A qualified individual will calibrate these instruments or the replacement instruments.

Please contact me if you have any questions. I may be reached at 574-339-1134 or at Jennifer.Fisher@hhchealth.org.

Regards,
Jennifer Hann Fisher, MS, DABR

601467

NRC/REGION1 MATERIALS-002

TheraSphere® Checklist

Patient Name _____ Number _____

Date of Treatment _____

TheraSphere® Lot Number _____ Labeled Quantity (GBq) _____

Catheter Information:
 (Place catheter sticker in the space provided below)

*This is an
 exempt for the
 180 page
 TheraSphere
 Brochure
 Submitted w/
 12/13/17
 letter*

1. Items Required for TheraSphere® Administration:

- Patient prescription for TheraSphere® (signed Written Directive)
- Ionization survey meter
- Geiger-Mueller (GM) contamination meter
- Spill kit
- A floor drape applied under the cart in the angiography suite
- A sterile drape placed on the cart

Place the following items on the draped cart:

Sterile side of cart:	Non-sterile side of cart:
<ul style="list-style-type: none"> <input type="checkbox"/> Hemostat <input type="checkbox"/> Scissors <input type="checkbox"/> Sterile adhesive strips <input type="checkbox"/> Towels <input type="checkbox"/> Gauze 	<ul style="list-style-type: none"> <input type="checkbox"/> Administration Set (in packaging) Lot # _____ <ul style="list-style-type: none"> o Verify the expiry date <input type="checkbox"/> TheraSphere® Administration Accessory Kit (acrylic box) <ul style="list-style-type: none"> o Remove the top shield o Fully extend the stainless steel arm o Install the bag hook <input type="checkbox"/> Electronic dosimeter (RADOS RAD 60R or equivalent) <ul style="list-style-type: none"> o Turn the dosimeter on and set to mR/h o Clip the dosimeter to its bracket on the acrylic box <input type="checkbox"/> Saline bag (in packaging) or bottle (minimum 100 mL) <input type="checkbox"/> Alcohol swabs <input type="checkbox"/> 2L Nalgene waste container with beta shield <input type="checkbox"/> TheraSphere® dose vial, in lead pot

TheraSphere® Checklist

2. Administration Set Priming

- Open the Administration Set packaging and remove the Administration Set and 20 mL empty vial.
- Insert the white non-vented spike (CLEAR CAP) into the saline bag. Hang the saline bag on the hook.
- Insert the white vented spike (BLUE CAP) into the empty 20 mL vial.
- Remove the (RED RUBBER) shield cap from the needle injector assembly. Place the needle injector assembly on a sterile surface.
- If the 20 mL syringe is marked 'VacLok', turn the syringe plunger fully clockwise to ensure it is unlocked. (This step may not be required for alternate syringe.)
- Slowly fill and discharge the syringe to remove air from the Administration Set tubing and syringe. Continue priming vigorously with full pressure until there are no bubbles in the lines and there are continuous streams of saline flowing out of both needle holes in the needle injector assembly.
- Fill the syringe when priming is complete.

3. Dose Vial Preparation

- Lift the TheraSphere® dose vial in its lead pot and tilt the lead pot back and forth to 90 degrees to wet any microspheres on the vial septum. Tap the bottom of the lead pot firmly on a hard surface. Place the lead pot into the pot holder in the acrylic box base.
- Remove the lead pot lid and place it upside down on a non-sterile surface.
- Use a hemostat to remove the purple seal from the top of the dose vial acrylic shield. Discard the seal in the Nalgene waste container.
- Use a sterile adhesive strip to remove the dose vial acrylic shield plug. Discard the plug and sterile adhesive strip in the Nalgene waste container.
- Use an alcohol swab and a hemostat to swab the dose vial septum. Discard the swab in the Nalgene waste container.
- Record the dosimeter initial reading from the dose vial (mR/h).

Dose Vial (mR/h)

- Measure and record the initial radiation field for the patient, using an ionization survey meter.

4. Final Assembly

- Close the pinch clamp on the outlet tubing near label 'E.'
- Place the empty 20 mL vial in the holder on the acrylic box and push the relief valve tube into gripper clip 'A.'
- Insert the needle injector assembly into the acrylic dose vial shield. Press on the GREEN cap to lock it in place. You will hear or feel a click or snap.
- Place the inlet tubing through slot 'B' in the acrylic box. Place the outlet tubing through slot 'D' in the acrylic box. Loop the tubing around the side and place the fitting into the holder at 'C.'
- Clamp the priming line at label 'C' with a hemostat (or equivalent).
- Push the YELLOW tabs on the needle injector assembly all the way down, locking the needles into the dose vial. You will hear or feel a click or snap at the bottom of travel.
- Ensure that the side shield is installed on the acrylic box. Place the top shield on the acrylic box with the sloped shield towards slot 'D.' Ensure that the tubing is not pinched or kinked.
- Move the cart close to the patient. Lower the bed to lowest position.
- Place a sterile towel under the extension arm holder 'E,' and under holder 'C.'
- Place a sterile towel across the gap between the acrylic box and the patient.

TheraSphere® Checklist

- The Interventional Radiologist (IR) will flush the infusion catheter to ensure flow. Replace the infusion catheter if it is damaged or does not have satisfactory flow. Do not use a catheter extension or extra fittings. Replace the catheter if it is too short.
- Disconnect the outlet tubing labeled 'E' from the priming tubing at holder 'C.' Firmly connect the outlet tubing 'E' to the catheter.
- Place the catheter connection into the slotted holder 'E' at the end of the extended arm. Outlet tubing 'E' must be above the holder, with the infusion catheter hanging vertically below.
- The IR will verify the infusion catheter position. Release the pinch clamp from the outlet tubing. Dents in the tubing may be reduced by rolling outlet tubing with fingers.

5. TheraSphere® Administration

ATTENTION: BETA RADIATION FIELDS CAN BE VERY HIGH DURING MICROSPHERE TRANSFER. STAND BEHIND BETA SHIELDING OR MAINTAIN DISTANCE.

- Record the starting time of the administration: _____
- Infuse TheraSphere® Y-90 glass microspheres using steady pressure on the syringe plunger. Infuse continuously until syringe is empty (≥ 20 cc per minute).

NOTE: If the infusion pressure is over 30 psi, excess fluid will drip into the vented 20 mL vial. If this occurs, reduce the pressure being applied on syringe until no flow is seen going into the vented vial. If the syringe flow is <20 cc per minute (i.e. appropriate to the flow of the native vessel), this may decrease the delivery efficiency of the administration system and result in higher residual waste.

- Observe the outlet line and catheter for proper operation. If a problem is observed, inform the team and take corrective action.
- Re-fill syringe for subsequent flushes by pulling back the syringe plunger. A minimum of 3 flushes (60 cc total) are recommended. Continue flushes until the desired dosimeter reading is achieved.
- Record the number of flushes completed: _____
- Record the time that administration was completed: _____
- Record the dosimeter final reading: _____

Dose Vial (mR/h)

- Measure and record the final radiation field for the patient using an ionization survey meter.

TheraSphere® Checklist

6. Disassembly

- Cut the inlet line at indicated position.
- Remove the acrylic box top shield and side shield.
- The IR will remove the infusion catheter from the patient and lift the catheter connection out of the extended holder 'E.' Do not disconnect the catheter from the outlet tubing. Use care to control the tip of the infusion catheter and guide catheter as these may be contaminated with microspheres. Use gauze, a small towel, or hemostat to handle the catheters for radiation protection. Any item that has come in contact with microspheres is considered contaminated.
- Place all contaminated waste into the Nalgene waste container (in its beta shield), including the following:
 - Infusion and guide catheters with attached tubing and towels/gauze
 - Dose vial with attached Needle Injector Assembly
 - Lift the lead pot and dump out the dose vial
 - Contaminated items such as gauze, towels, and gloves
- Cap the Nalgene waste container and place the acrylic lid on the beta shield. Remove for measurements to determine percent delivery and for disposal.
- Use a GM contamination meter to check IR's hands for contamination.
- Survey all staff leaving the room with the GM contamination meter.

7. Cleanup and Waste Disposal

- Use GM contamination meter to check for contamination on the cart, lead pot, equipment, and the areas under the catheter connection and cart.

NOTE: Radiation from fluoroscopy, the patient, and the waste container will affect the ability to detect and measure contamination.

- Decontaminate and/or dispose of items as appropriate.
- As required, clean the TheraSphere® acrylic box with water, mild soap and a clean soft cloth. Alcohol wipes may be used (minimize alcohol contact with glued joints – alcohol degrades the glue over an extended time). Chlorine (bleach) disinfectants are also acceptable. Always use a clean soft cloth. Do not use industrial cleaner wipes, ammonia or abrasives to clean the acrylic parts of the acrylic box.
- Replace the top and side shields on the acrylic box. Retract the extension arm and remove the bag hook. Turn off the dosimeter. Store the kit.