



Medical Device Product Advisory - Action Required
TheraSphere™ Administration Sets

July 23, 2021

Dear Materials Manager / Field Action Contact:

Boston Scientific is initiating a Product Advisory for specific lots of TheraSphere™ Administration Sets to reinforce the existing administration set assembly instructions within the instructions for use (IFU), which state to firmly connect the outlet luer to the patient catheter as detailed in Appendix A. This Product Advisory will also inform users of the potential for leaks at this connection.

Boston Scientific has received complaints of leaks and loosening at the patient catheter connection. Our investigation has determined that, for the affected Administration Sets detailed in Table 1, the outlet luer could loosen after being fastened to the patient catheter. This could result in an unsecure connection to the patient catheter, which may result in the leakage of Yttrium-90 (Y-90) microspheres from this connection. To date, no patient harm has occurred.

If leakage of Y-90 microspheres occurs, the patient may receive a lower than intended TheraSphere dose. No patient harm is expected from a potential underdose. TheraSphere (Y-90) leakage might expose the patient and users to radiation. The level of radiation exposure to the skin is estimated to be within regulatory limits and no serious harm is anticipated. An unlikely and prolonged skin exposure could result in reddening or sunburn-type symptoms of the skin which would resolve without medical intervention.

Users are advised to continue to follow the IFU to ensure a firm connection is made between the outlet luer and the patient catheter prior to, and during, TheraSphere administration.

This advisory impacts only the UPN and Lot numbers listed in Table 1 below. No other UPN or Lot numbers are impacted by this advisory. These products shipped to customers prior to March 1, 2021.

Boston Scientific is not removing any TheraSphere devices from the field; devices remain available for clinical use as all devices continue to perform as intended when used in accordance with the IFU.

Table 1: Product Listing

Product Description	Product Code	GTIN	Lot #	Expiration Date Range
TheraSphere™ Administration Set	OTT-SPE-FP-226 (990226.SPE)	05060116920253	001E	August 5, 2021 – December 15, 2021
			002E	
			004E	
			005E	
			006E	
			007E	
			114E	
			690E	
692E				

TheraSphere™ Administration Set	OTT-SPE-FP- 001 (990264.SPE)	05060116920635	61673698	August 21, 2021 – November 30, 2021
			61673699	
			61673700	
			61673702	
			61694124	
			61705932	
			61706656	
			61705933	
			61732176	

Please complete and return the acknowledgement form to indicate receipt of this letter.

If you are a distributor, please follow the attached instructions and also forward this notification to your customers.

If you are a facility that has sent products to another hospital within your network, please follow the attached instructions and also ensure that this notification is forwarded to them.

Sincerely,



Brendan Smith
 Boston Scientific Quality Systems
 763-494-1133
BSCFieldActionCenter@BSCI.com

Encl: Advisory Instructions
 Acknowledgement Form

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to Boston Scientific by calling 1-866-868-4004 and to the FDA’s MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

Online: www.fda.gov/MedWatch/report.htm
 Regular Mail: use postage-paid FDA form 3500 available at www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, 5600 Fishers Lane, Rockville, MD, 20852-9787
 Fax: (800) FDA-0178
 Phone: (800) FDA-1088

Medical Device Product Advisory – Instructions

The Acknowledgement Form enclosed with this Notice must be completed and returned **even if you do not have any affected units.**

1. Complete and return the Acknowledgement Form.

- Complete the enclosed Acknowledgement Form even if you do not have any affected product, following the directions on this page and on the Acknowledgement Form.
- Return the Acknowledgement Form as described below:

Email: BSCFieldActionCenter@bsci.com

or

Fax to: Field Action Center 1-866-213-1806

Please email or fax your Acknowledgement Form(s) immediately.

Appendix A – US IFU Excerpt



11.2 PREPARATION FOR THERASPHERE ADMINISTRATION

- Confirm patient identity and prescription for TheraSphere against measured dose and treatment location (e.g., signed Written Directive)
- Prepare the treatment room with appropriate equipment (e.g., radiation meter, spill kit) and signage
- Prepare a moveable cart with the following items:
 - Small sterile towels/drapes
 - Saline bag or bottle – one per dose vial, minimum 200 mL size
 - Hemostat/Kelly forceps or similar
 - Adhesive strips
 - Alcohol disinfectant
 - Scissors
 - TheraSphere Administration Set(s) – one tubing set per dose vial
 - TheraSphere Administration Accessory Kit, including electronic dosimeter (RADOS RAD 60 or equivalent) clipped onto Administration Accessory Kit and set to dose rate (mR/h)
 - Waste container with beta shield (e.g., 2 L wide-mouth plastic jar with screw lid, with acrylic beta shield)
 - TheraSphere dose vial(s), in lead pot
- Ensure the packaging for the TheraSphere Administration Set is intact before use. If package integrity has been breached prior to use, discard the item and obtain a new one. Do not use expired TheraSphere Administration Sets.

11.3 ADMINISTRATION SET PRIMING

- Open the Administration Set packaging
- Connect the fluid spike into the saline, and hang saline on the bag hook
- Connect the vented spike to the empty overflow vial
- Remove the cap from the needle injector assembly. Follow standard sharps precautions – two needles are located inside injector assembly. The yellow tabs should be fully retracted to lock needles in enclosed position. Place the needle injector assembly on a sterile surface.
- Prime the Administration Set with saline until bubbles are removed and saline flows continuously out of both needle injector assembly holes
- Fill the syringe when priming is complete

11.4 DOSE VIAL PREPARATION AND ASSEMBLY WITH ADMINISTRATION SET

- Tilt the TheraSphere dose vial (in its lead pot) back and forth to 90° and tap it sharply on a hard surface
- Put the dose vial (in its lead pot) into the acrylic box and remove the lead pot lid
- Remove the dose vial security seal and dose vial access plug from the acrylic shield and put into waste container. The dose vial access plug can be removed using an adhesive strip as required.
- Disinfect the dose vial septum with alcohol
- Place the overflow vial and tubing 'A' into the overflow vial holder and gripper clip on the acrylic box
- Connect the Administration Set needle injector assembly to the dose vial
- Place tubing through slots 'B' and 'D', and slide fitting into the holder at 'C'
- Pinch or clamp to close the tubing at label 'C'

11.5 FINAL ASSEMBLY (IMMEDIATELY BEFORE ADMINISTRATION)

- Close the white pinch clamp on tubing near label 'E'
- Push down on both yellow tabs to fully insert needles into dose vial
- Put the lid on the acrylic box
- Interventional Radiologist (IR) to verify microcatheter position and flush it with saline to ensure flow
- Disconnect the outlet luer 'E' from the holder at 'C' and firmly connect to the microcatheter
- Place the microcatheter connection in the holder on the extension arm (fully extended) with the microcatheter hanging vertically below
- Ensure the tubing and microcatheter are free of kinks

Appendix A – EU English IFU Excerpt

- Insert the white non-vented spike into the saline bag (or bottle). Hang the saline bag on the bag hook.
- Insert the white vented spike into the empty 20mL vial.
- Remove the RED RUBBER cap from the needle injector assembly. Place the needle injector assembly on a sterile surface.
- 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 for the dose vial (mR/h).
- Measure and record the initial radiation field for the patient, using an ionization survey meter.

4. **Final Assembly**

- Close the white pinch clamp on the outlet tubing between labels 'D' and 'E'.
- Place the empty 20 mL vial in the holder on the acrylic box and push the pressure 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 the blue pinch clamp. For sets with no blue pinch clamp, clamp the priming line with hemostats (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.
- 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 white pinch clamp from the outlet tubing. Dents in 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 the 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 oc-

Troubleshooting

Problem	Action
1. Difficulty priming the Administration Set.	<p>Verify that the tubing in the Administration Set is not pinched or kinked. Verify that the pinch clamp is not closed.</p> <p>The first priming flush should be performed very slowly to prevent small bubbles from forming in tubing and fittings. Subsequent priming flushes should be vigorous with full pressure.</p> <p>If saline leakage is observed, ensure connections are tight.</p> <p>If the issue cannot be identified and corrected, replace the Administration Set with a new one. Notify the manufacturer of the problem.</p>
2. Leakage that may contain microspheres	<p>Attention: Any leakage from the dose vial, injector assembly, tubing 'D' through 'E', or the catheter connection at 'E' is likely to contain microspheres.</p> <p>Assess the extent of the leak. Ensure that the needle injector is properly inserted into the dose vial. If warranted, abort the infusion, disassemble the Administration Set and commence decontamination procedures. During decontamination, investigate the cause of the leak.</p>
3. Leakage of saline during infusion	<p>Leakage observed from the syringe, the saline bag/bottle, or tubing lines 'A', 'B' and 'C' will only contain saline. If saline leakage is observed during TheraSphere™ Administration, maintain steady pressure on the syringe.</p> <p>Do not stop the flush. At the end of the flush, address the saline leakage. Ensure that priming tube 'C' is clamped. Ensure connection to the syringe is tight. Adjust the saline bag or bottle connection.</p>
4. Blood begins to flow back to the TheraSphere™ dose vial, when the catheter is connected and the syringe is not being pushed.	<p>This indicates that one of the fittings or the TheraSphere™ dose vial septum is compromised. The procedure should be aborted if the issue cannot be identified and corrected. If issue has been identified and corrected, continue with administrations and observe the system for possible leaks (see Problem 2).</p>
5. Excessive fluid flow resistance is experienced during infusion or Difficulty achieving the desired dosimeter reading.	<p>Verify that the white pinch clamp is open. Verify that the tubing between the syringe and dose vial are not pinched or kinked. Verify that the tubing between the dose vial and catheter are not pinched or kinked. Verify that the yellow tabs are pushed all the way down.</p> <p>Apply sufficient pressure on the syringe to cause fluid to flow into the pressure relief vial.</p> <p>Apply and release pressure on the syringe several times rapidly. This may clear a collection of microspheres at the tip of the outlet needle.</p> <p><u>Close the white pinch clamp</u> before performing any actions with the catheter. Verify that there is no blood coagulation or damage in the catheter.</p> <p>Attention: There may be microspheres in the outlet line and catheter. Use standard radiation safety methods to assess the components before handling. Use remote handling tools as appropriate.</p>



CUSTOMER ACKNOWLEDGEMENT FORM

TheraSphere™ Administration Set

Instructions: This form must be completed and returned in all cases even if you do not have any affected product.

Immediately complete form and Scan/e-mail to: BSCFieldActionCenter@bsci.com OR Fax to #: 763-415-7708

Account #: _____	Customer Name: _____
Contact Name: Material Manager	
Address: _____	State: _____
City: _____	Country: USA Postal Code: _____

PLEASE COMPLETE, SIGN AND RETURN THIS FORM AS A CONFIRMATION THAT YOU RECEIVED THIS NOTICE FROM BOSTON SCIENTIFIC (even if you do not have any of the referenced product on the enclosed product listing in your current inventory).

My signature below acknowledges receipt of the Boston Scientific Notice regarding:

TheraSphere™ Administration Set

Field Action # 92641385-FA

Section to be filled out by Customer:

1. Please Indicate:

Are you a Distributor? No Yes, and we have notified all customers that have been shipped/sold affected product

2. Sign and Date to acknowledge this Field Action Notification (must be completed):

Print Name: _____ Signature: _____ Date _____

Phone: _____ Fax: _____ E-mail: _____

Customer Name: _____

Date: _____

Account #: _____

Field Action # 92641385-FA

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