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«Hospital_Name»
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«Customer_Address»
«Zip_Code» «City»
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<Reference: 92641385-FA> 29 July 2021

Urgent Field Safety Notice - Product Advisory TheraSphere™ Administration Sets

Dear «Users_Name»,

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.

Our records indicate that your facility received some of the concerned product. Th**e table below provides a complete list of all affected products**, including Product Description, Product Code, GTIN number, Lot number and expiry date. Please note that **only the devices listed below are affected. No other Boston Scientific product is involved in this Field Safety Notice**. **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.

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	

INSTRUCTIONS:

1- Please read this notice.

2- **Please complete the attached Acknowledgement Form** even if you do not have any affected product.

3- **When completed, please return the Acknowledgement Form to your Boston Scientific office** for the attention of «Customer_Service_Fax_Number» on or before **10 September 2021**.

4- Please pass on this notice to any healthcare professional from your organization that need to be aware and to any organization where the potentially affected devices have been transferred (If appropriate). Please provide Boston Scientific with details of any affected devices that have been transferred to other organizations (if appropriate).

Although Boston Scientific is not physically recalling any product, your Competent Authority is being notified of this Field Safety Notice.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.
Yours sincerely,

Marie Pierre Barlangua
Quality Department
Boston Scientific International S.A.

Attachment: Acknowledgement Form

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.	Verify that the tubing in the Administration Set is not pinched or kinked. Verify that the pinch clamp is not closed. 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. If saline leakage is observed, ensure connections are tight. If the issue cannot be identified and corrected, replace the Administration Set with a new one. Notify the manufacturer of the problem.
2. Leakage that may contain microspheres	**Attention:** Any leakage from the dose vial, injector assembly, tubing 'D' through 'E', or the catheter connection at 'E' is likely to contain microspheres. 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.
3. Leakage of saline during infusion	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. **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.
4. Blood begins to flow back to the TheraSphere™ dose vial, when the catheter is connected and the syringe is not being pushed.	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).
5. Excessive fluid flow resistance is experienced during infusion or Difficulty achieving the desired dosimeter reading.	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. Apply sufficient pressure on the syringe to cause fluid to flow into the pressure relief vial. Apply and release pressure on the syringe several times rapidly. This may clear a collection of microspheres at the tip of the outlet needle. Close the white pinch clamp before performing any actions with the catheter. Verify that there is no blood coagulation or damage in the catheter. **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.

Please complete the form & Send it to:
«Customer_Service_Fax_Number»

«Sold_to» - «Hospital_Name» - «City» - «Country»

Acknowledgement Form – Product Advisory
TheraSphere™ Administration Sets
92641385-FA

By signing this form, I confirm that

I have read and understood
the Boston Scientific Field Safety Notice

dated 29 July 2021 for the

TheraSphere™ Administration Sets devices.

NAME* _____Title _____

Telephone _____ Department _____

SIGNATURE* _____ **DATE*** _____
* Required field dd/mm/yyyy