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<Reference: 92823993-FA>

24 February 2022

Urgent Field Safety Notice - PRODUCT ADVISORY SpaceOAR™ System and SpaceOAR Vue™ System

Subject: Field Safety Notice – Instructions for Use (IFU) Update for SpaceOAR and SpaceOAR Vue Systems, Boston Scientific Field Action Reference 92823993-FA.

Dear «Users_Name»,

This Field Safety Notice (FSN) provides important information regarding updates being made to the IFU and to highlight existing warnings and instructions in the IFU for SpaceOAR and SpaceOAR Vue Systems, as detailed in Appendix 1.

Product Name	Material Number (UPN)	GTIN	Lot numbers	Expiration Date Range
SpaceOAR System (EU)	SO-1010	00864661000157	All	All
SpaceOAR Vue System (EU)	SV-1010	00850009803009	All	All

Summary

- Since commercialization of the SpaceOAR System in March 2010 and the SpaceOAR Vue System in May 2020 embolism related to misplacement of the needle intravascularly has been a known adverse event included in the IFUs for both products.

- Boston Scientific has recently received three reports of venous and arterial embolism to the abdominal viscera and lower extremities; this occurred as a result of inadvertent placement of SpaceOAR gel into a blood vessel and subsequent migration of the hydrogel outside of the pelvis. There have been no reported deaths associated with these events.
- The overall rate of reported embolism events for both products remains very low (< 0.006% or 1 in 45,000 cases), and the rate continues to remain within expected thresholds.
- A comprehensive investigation has identified updates to be made to the product IFUs (please see summary of IFU updates in Appendix 1). The purpose of the updates is to raise awareness of embolism as an existing adverse event and provide new procedural instructions, warnings and precautions that describe steps to verify correct placement of the hydrogel following implantation, as well as technique recommendations for the proper placement of SpaceOAR and SpaceOAR Vue to potentially reduce hydrogel misplacements.
- **Boston Scientific is not removing any SpaceOAR or SpaceOAR Vue devices from the field; devices remain available for use.** The risk to patients associated with use of the SpaceOAR and SpaceOAR Vue Systems remains unchanged.
- **As per the IFU, SpaceOAR and SpaceOAR Vue System procedures should only be performed by physicians who have received appropriate training for proper hydrogel spacer deployment technique.**
- There are no changes to the management of patients who have already been treated with SpaceOAR and SpaceOAR Vue Systems.
- The updated IFUs will be packaged with SpaceOAR and SpaceOAR Vue Systems after all applicable regulatory approvals are obtained for the IFU updates.

Description

Embolism is a known adverse event related to the placement of SpaceOAR and has been listed in the IFUs for both SpaceOAR and SpaceOAR Vue Systems since commercial introduction of the products in March 2010 and May 2020, respectively.

Recently, Boston Scientific received three reports of embolism that occurred outside of the pelvis; these events have included both venous and arterial embolism in blood vessels to organs in the GI tract and lower extremities. Treatment was tailored to each specific patient depending on the location of the hydrogel embolism. The most serious adverse outcome resulting from an embolism due to vascular misplacement has been determined to be life-threatening. However, there have been no reported deaths associated with these events and based on the current available data, a life-threatening event or death resulting from embolism would be a rare event. In general, hydrogel embolism of any severity is rare (< 0.006%, or 1 in 45,000 cases) and the most common type of hydrogel embolism reported has not resulted in any serious complications for the patient.

As a result of these three reports, Boston Scientific conducted a comprehensive investigation of all SpaceOAR and SpaceOAR Vue embolism complaints received where patient harm was reported. As part of these investigation efforts, Boston Scientific identified potential contributing factors and best practices regarding hydrogel placement during all SpaceOAR procedures that we are incorporating into the IFU. These updates are aimed at reinforcing and expanding on current IFU content that may potentially reduce inadvertent hydrogel misplacements, as well as steps to verify the correct placement of the hydrogel following implantation. In addition, clarification of embolism as an adverse event is being included in these updates to raise the awareness of the remote possibility that embolisms may present outside of the pelvis in the venous or arterial systems.

Recommendations

1- Review the content of the IFU Updates detailed in Appendix 1.

2- Share this information as appropriate to provide awareness of this information, particularly with clinicians in your hospital that use the SpaceOAR and SpaceOAR Vue Systems. Also share this information with any other organization to which these devices may have been transferred.

3-Immediately post this information in a visible location near the product to ensure this information is easily accessible to all users of the device.

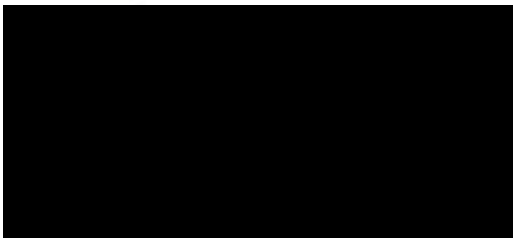
4- Maintain a copy of this notice in your records.

5- Continue to report all adverse events or quality concerns experienced with the use of these devices to Boston Scientific (in accordance with all applicable local regulations).

6- Complete the attached Acknowledgement Form and return it to **to your local Boston Scientific office** for the attention of «Customer_Service_Fax_Number» **by 18 March 2022.**

Patient safety remains our highest priority. Although we recognize the impact of advisory communications on both you and your patients, we are committed to transparent communication with physicians and healthcare professionals to ensure you have timely, relevant information for managing your patients. If you have additional questions regarding this information or would like to report a clinical event, please contact your Boston Scientific representative.

Sincerely,



Attachments: - Appendix 1: IFU updates
- Acknowledgement Form

APPENDIX 1 – Updates to SpaceOAR and SpaceOAR Vue Instructions for Use

Table 1 below provides the updates to the IFU highlighted in blue.

Table 1: Updates to Instructions for Use

IFU Section	Labeling Updates
<p>Adverse Event</p> <p>NOTE: Embolism as an adverse event was already present in the IFUs but has been clarified (see blue text).</p>	<p>Embolism (venous or arterial embolism is possible and may present outside of the pelvis, potentially impacting vital organs or extremities)</p>
<p>Warnings</p>	<ul style="list-style-type: none"> • If SpaceOAR hydrogel is not seen in the perirectal space during injection, discontinue the procedure immediately. This could potentially indicate gel is in an unintended location (blood vessel). Do not inject additional SpaceOAR. • Injection of air, fluid, or SpaceOAR hydrogel intravascularly could potentially lead to arterial or venous embolism. Always aspirate with the saline syringe to verify the needle tip is not in a blood vessel. If blood is aspirated, discontinue the procedure.
<p>Precautions</p>	<ul style="list-style-type: none"> • Maintain visualization of the SpaceOAR needle tip at all times to prevent injecting SpaceOAR into an unintended location, including the rectal wall, prostate, blood vessels, or other tissues. If needle tip visibility is distorted or compromised, do not inject SpaceOAR. • Excessive resistance experienced during hydrodissection or SpaceOAR injection may indicate the needle tip is in an unintended location. Reassess needle position. • Limit needle movement after hydrodissection and during SpaceOAR injection to avoid perforating unintended organs, such as the rectal wall, prostate, or blood vessels.
<p>Detailed Procedural Instructions</p>	<ul style="list-style-type: none"> • <i>Note: various existing and new Warnings and Precautions subject to this Product Advisory have also been incorporated (where deemed pertinent) into this section for emphasis</i> • Note: Patient movement during the procedure should be minimized for best hydrogel placement. • Ensure the perirectal space opens before proceeding with hydrogel injection. • Verify hydrogel is in intended location on ultrasound imaging. SpaceOAR may take up to 30 seconds to form a gel following injection. If uncertain about hydrogel location, follow up CT or MRI is recommended.



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

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

Acknowledgement Form – Field Safety Notice

SpaceOAR and SpaceOAR Vue Systems

92823993-FA

By signing this form, I confirm that

**I have read and understood
the Boston Scientific Field Safety Notice**

dated 24 February 2022 for the

SpaceOAR and SpaceOAR Vue Systems devices.

NAME* _____ **Title** _____

Telephone _____ **Department** _____

SIGNATURE* _____ **DATE*** _____

* Required field

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