Boston Scientific International S.A.
EMEA Headquarters
Siège social : Parc du Val Saint Quentin – 2 rue René Caudron
78960 Voisins le Bretonneux – France
Tel 33 (0)1 39 30 97 00
Fax 33 (0)1 39 30 97 99
www.bostonscientific.com

«Hospital_Name»
«Users_Name»
«Department»
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<Reference: 97610227-FA> 11 June 2026
SRN: US-MF-000004702

Urgent Field Safety Notice
FARADRIVE™ Steerable Sheath IFU update

Dear Materials Manager or Healthcare Professional,

Boston Scientific is communicating to customers of a forthcoming update to the FARADRIVE™ Steerable Sheath Instructions for Use (IFU). This notification applies to the products listed in Attachment 1.

Air embolism is a known procedural risk associated with left atrial ablation procedures utilizing transseptal sheaths and catheter exchanges and is addressed within the device labeling. Boston Scientific continuously monitors product performance and customer feedback as part of its quality system and ongoing product improvement activities. Ongoing product performance monitoring confirms that the FARADRIVE sheath continues to perform within established design, safety, and anticipated product performance expectations. The observed rate of air embolism events remains very low at 0.0134%, consistent with the air embolism incidence of less than 1% reported in medical society expert consensus statements[1].

Notwithstanding the low event rate, Boston Scientific's complaint investigations have identified that a subset of air ingress complaints are associated with hemostatic valve damage related to dilator insertion orientation during device preparation. Valve damage may result in air ingress, potential air embolism, and associated patient harm. This risk can be mitigated by inserting the dilator straight through the center of the valve and fully advancing it into the sheath body.

Although FARADRIVE is performing within performance expectations and published guidance, Boston Scientific has implemented manufacturing updates and is enhancing the FARADRIVE Sheath IFU as part of Boston Scientific's commitment to continuous improvement. The IFU enhancement provides additional guidance regarding dilator insertion methodology that may mitigate the potential for air ingress and potential subsequent air embolism during procedural use. Revised IFU content is provided in Appendix 1.

[1] Most recent consensus statement providing a specific incidence estimate for air embolism during atrial fibrillation ablation: Calkins H, Hindricks G, Cappato R, Kim YH, Saad EB, Aguinaga L, et al. 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. Heart Rhythm. 2017;14(10):e275-e444. doi:10.1016/j.hrthm.2017.05.012.

Instructions:

1- **Post a copy of the appropriate IFU provided near each FARADRIVE™ Steerable Sheath devices,** replacing any previous versions currently in use and **follow the revised IFU** provided in Appendix 1.

2-. Forward this notice to relevant personnel and any facilities to which the product was transferred

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

4- **When completed, please return the Acknowledgement Form to your Boston Scientific office for the attention of «Customer_Service_Fax_Number»** on or before **29 June 2026**.

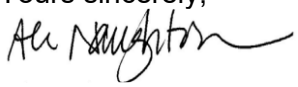
5- **Share this communication** with any healthcare professionals in your facility that use the product and with any other organization to which this product may have been transferred.

Please note that this is an informational notice to you. **No** product is being recalled.

Your national Competent Authority has been informed of this communication. Any adverse events or quality concerns associated with use of these devices should be reported to Boston Scientific and Competent Authorities if appropriate.

Patient safety is Boston Scientific's highest priority. We are committed to transparent communication with physicians and healthcare professionals to ensure you have timely, relevant information for managing your patients. If you require additional assistance or more information regarding this communication, please contact your local Boston Scientific representative.

Yours sincerely,



Alexandra Naugton
Vice President, Quality Assurance

Attachment: - Acknowledgement Form

FOR BOSTON SCIENTIFIC INTERNAL USE ONLY
Account Email: «Contact_Email»
Language: «Languages»
LFAC Team: «LFAC_Distribution_Email_Address»
Country Code-Sold to: «Country_Code»-«Sold_To»

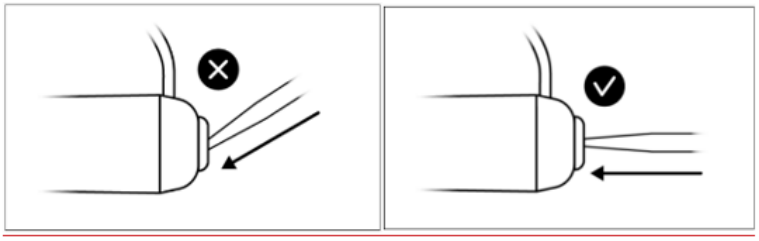
Attachment 1 Affected Products

Description	Material Number/UPN	GTIN No.

Appendix 1 Updates to FARADRIVE Steerable Sheath Instructions for Use (IFU)

Note: Table 2 provides additional warnings and procedural instruction updates to various sections of the IFU for FARADRIVE Steerable Sheaths. The updated wording is provided in red text.

Table 1 Updates to FARADRIVE Steerable Sheath IFU

Section	Labeling Updates
OPERATIONAL INSTRUCTIONS - Preparation	Insert the dilator into the valve and fully into the FARADRIVE Sheath. Ensure that the distal tip of the dilator is inserted in a straight orientation through the center of the FARADRIVE Sheath valve and that the dilator is advanced into the sheath until the hub snaps into the sheath hub. Remove the flush syringe from the hub of the dilator.  Figure 2. FARADRIVE Dilator insertion
Warnings	Insert the distal tip of the dilator in a straight orientation through the center of the FARADRIVE Sheath valve in order to avoid valve damage. Failure to do so may result in air embolism.

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

«Sold_To» - «Hospital_Name» - «City» - «Country_name»

Acknowledgement Form
FARADRIVE™ Steerable Sheath IFU update
97610227-FA

By signing this form, I confirm that

I have read and understood the Boston Scientific Field Safety Notice

dated 11 June 2026 for the

FARADRIVE™ Steerable Sheath IFU update

NAME* _____ Title _____

Telephone _____ Email _____

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