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<Reference: 97661064-FA> 22 October 2026
SRN: IL-MF-000004702

Urgent Field Safety Notice - Product Advisory
OptiCross™ Intravascular Ultrasound (IVUS) Imaging Catheters

Dear «Users_Name»,

Boston Scientific is providing this advisory regarding the OptiCross™ family of intravascular ultrasound (IVUS) imaging catheters to communicate an update to the flushing instructions, reinforce device preparation and air-management practices, and inform users of upcoming updates to the Instructions for Use (IFU). This advisory applies only to the products listed in Attachment 1.

The updated IFU will remove instructions permitting flushing while the catheter is positioned within the patient when entrapped air is suspected and will further clarify device preparation and air management instructions.

OptiCross IVUS catheters remain available for use. Until the updated IFU is available, continue to follow the existing IFU except where updated instructions are included in this communication.

Device Description

Air embolism is a known risk of percutaneous coronary and peripheral vascular procedures and is identified as a potential adverse event in the OptiCross IFUs. Over the past three years, the worldwide observed complaint rate for air embolism associated with OptiCross IVUS catheters was approximately 0.002%; the rate involving a reported patient death was approximately 0.0001%. No air embolism complaints were identified for the peripheral OptiCross 18 or OptiCross 35 catheters. These devices are nevertheless included in this communication because their preparation and air-management practices are similar.

Boston Scientific is implementing these IFU updates in response to reports of air embolism events and reports of repeated flushing to restore image quality while the catheter was positioned within the patient.

Investigation concluded that the reported air embolism events are not associated with the OptiCross IVUS catheter design or manufacture. Device testing demonstrated that completing all three flushing steps currently specified in the IFU prior to use reduces residual air within the catheter.

Clinical Impact
The risk of air embolism is a known risk inherent to percutaneous procedures, including procedures involving intravascular imaging with the OptiCross catheter, and is identified in the current IFU.

Intravascular air may cause air embolism, resulting in clinical consequences of varying severity, including ST-segment changes, reduced blood flow, arrhythmia, myocardial infarction, cardiac arrest, and other serious injury.

Based on the investigation, the most commonly reported patient harm of residual entrapped air was procedure prolongation. In these cases, air was identified following initial use of the device in the patient, prompting additional actions such as repetition of device preparation steps and/or device exchange.

Patients previously treated with an OptiCross IVUS catheter do not require additional patient management as a result of this communication and should continue to receive standard clinical care at the discretion of their physician.

Instructions:
1- **Review IFU updates related to air embolism** as detailed in Appendix 1.
2- **Follow these steps** when using OptiCross IVUS catheters:
- Complete all device preparation and flushing instructions before inserting the catheter into the patient. This includes clearing air from all accessories and then the catheter by completing all three IFU-prescribed flushing steps.
- Do not flush the OptiCross IVUS catheter while it is positioned within the patient if entrapped air is suspected. If additional flushing is required, remove the catheter from the patient before flushing.

3- 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).
4- **Post this information in a visible location** near the affected products to ensure it is readily available to all users of the device.
5- **Please complete the attached Acknowledgement Form even if you do not have any affected product**.
6- When completed, please return the Acknowledgement Form to your Boston Scientific office for the attention of «Customer_Service_Fax_Number» on or before 10 November 2026.

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 Regulatory Authorities if appropriate.

Safety is our highest priority. We are providing this notice to ensure you have the necessary information to support safe use of these systems during servicing. If you need additional assistance or have questions about this notice, please contact your local Boston Scientific representative.
Yours sincerely,



Brandon Erickson
Vice President, Global Quality
Boston Scientific

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 Product

Description	Material Number/UPN	GTIN
OptiCross™ Intravascular Ultrasound (IVUS) Imaging Catheters	H749518100	08714729890393
	H749518110	08714729847878
	H749518120	08714729841531
	H749518080120	08714729938415
	H749518130	00191506035396
	H749518140	00191506035402
	H7495181160	08714729904762
	H7495181260	08714729904779
	H7495181360	00191506035433
	H7495181460	00191506035440
	H74939352010	08714729960744
	H74939352020	08714729960751
	H74939352030	08714729960768
	H74939352040	08714729960737
	H74939352050	00191506035419
	H74939352060	00191506035426
	H74939354050	08714729960782
	H74939354060	08714729960799
	H74939354080	08714729960775
	H74939354090	00191506035457
	H74939354100	00191506035464
	H749305900180	08714729904809
	H7493932700180	08714729904748
	H7493932800180	08714729904366
	H7493932800350	08714729984542
	H7493932801350	08714729997153
	H7493932802350	08714729997160

<u>Appendix 1</u>: Pending Updates to OptiCross™ Intravascular Ultrasound (IVUS) Imaging Catheter Instructions for Use (IFU)

These are the planned revisions to the applicable sections of the OptiCross IVUS Imaging Catheter IFU.

Warnings:

- Air entrapped in the catheter and flushing accessories may cause serious injury or death (air embolism) if flushed inside of the vasculature. Always verify that the catheter and flushing accessories have been properly cleared of air prior to inserting the catheter into the vasculature. Do not flush the system with the catheter inserted into the patient if entrapped air is suspected.

[all other warnings remain the same]

Instructions for Use: Preparation for Catheter Use:

[steps 1-2 remain the same, outside of minor wording changes/clarification]

3- Fill the 3 cm3 (3 cc) and 10 cm3 (10 cc) syringes with heparinized saline. Connect the 3 cm3 (3 cc) and 10 cm3 (10 cc) syringes to the 4-way stopcock, with the 3 cm3 (3 cc) syringe connected to the inline port of the 4-way stopcock. Then connect the assembly to the extension tube. Ensure that all air is expelled from the assembly (syringes, stopcock, and extension tubing) by flushing, using heparinized saline in syringes. Connect the extension tube to the flush port with one-way check valve on the catheter hub. The 10 cm3 (10 cc) syringe is to be used as a reservoir for refilling the 3 cm3 (3 cc) flushing syringe.

4- Flush the imaging catheter TWICE on the prep table continuously with 3 cm3 (3 cc) volume each time. Move the imaging catheter over to the procedure table.

[steps 5-8 remain the same, outside of minor wording changes/clarification]

9- Refill the 3 cm3 (3 cc) syringe with the 10 cm3 (10 cc) syringe and flush the imaging catheter once with the 3 cm3 (3 cc) syringe with the telescope closed.

Note: Refill the 10 cm3 (10 cc) syringe as needed and reattach to the stopcock without introducing air into the line.

Note: To prevent air from being introduced into the catheter lumen, DO NOT retract the imaging core (i.e., open the telescope) prior to catheter placement. Any amount of retraction of the imaging core prior to catheter placement could draw in air and will require additional flushing per Step 9.

Note: If flushing is difficult with the imaging core in the full distal position, then manually retract the imaging core 3 mm - 5 mm and re-flush. Then, manually advance the imaging core to the original full distal position.

Instructions for Use: Catheter Placement and Imaging

[step 1 remains the same]

2- Keeping the catheter body and guidewire fixed, turn MDU5 PLUS “ON” and retract the imaging core slowly along its length of travel (up to maximum of 15 cm) either using the Automatic Pullback Sled or manually to image the region of interest. Retract and advance the imaging core (i.e., open and close the telescope) as desired.

Note: If the image is flickering or fades during use, the distal imaging window lumen may contain air bubbles. Remove catheter and repeat flushing procedure in Section B, Preparation for Catheter Use, step 9.

Note: If the image cannot be recovered after flushing outside the body, a drive cable failure or MDU5 PLUS disconnection may have occurred. Prior to reinserting the catheter, ensure the MDU5 PLUS is “OFF” and verify that the hub is fully seated in the MDU5 PLUS. If the hub is fully seated, turn the MDU5 PLUS “ON”. If the condition persists, visually inspect for rotation of the imaging core. If it is not rotating, return the catheter to your Boston Scientific representative for analysis.

Note: Before advancing or retracting the imaging core (i.e., opening or closing the telescope) within the catheter, always turn the MDU5 PLUS “ON”.

[step 3 remains the same, outside of minor wording changes/clarification]

4- If the imaging catheter is to be re-inserted, flush once with 3 cm3 (3 cc) volume syringe and coil the catheter and set aside the MDU5 PLUS and Automatic Pullback Sled, if used.

Note: If multiple insertions are required, the catheter should not be disconnected from the MDU5 PLUS to prevent breach of catheter sterility.

5- When ready to reinsert the imaging catheter, flush one more time with 3 cm3 (3 cc) volume syringe with the telescope closed.

Troubleshooting:

Section removed; content incorporated into the applicable sections of the IFU.

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

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

Acknowledgement Form – Product Advisory

OptiCross™ Intravascular Ultrasound (IVUS) Imaging Catheters

97661064-FA

By signing this form, I confirm that

I have read and understood
the Boston Scientific Field Safety Notice

dated 22 October 2026 for the

OptiCross™ Intravascular Ultrasound (IVUS) Imaging Catheters

NAME* _____ Title _____

Telephone _____ Email _____

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