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«Hospital_Name»
«Users_Name»
«Department»
«Customer_Address»
«Zip_Code» «City»
«Country»

<Reference: 97245720-FA> 5 September 2024

Urgent Field Safety Notice – Product Advisory
AVVIGO™ + Multi-Modality Guidance System when used with OptiCross™ 18 Peripheral Imaging Catheter

Dear «Users_Name»,

Boston Scientific is writing to inform you of a software anomaly that occurs **only** when the AVVIGO™+ Multi-Modality Guidance System is connected to the OptiCross™ 18 Peripheral Imaging Catheter **and** either Live or Record mode is in use. This software anomaly affects only the products listed in the attached Affected Product Table and does not impact previous AVVIGO System generations or other imaging catheters used with the AVVIGO + Multi-Modality Guidance Systems.

This product advisory serves to reinforce the methods for ensuring accurate vessel sizing, including use of the measurement tools available in Review mode, when using AVVIGO+ Multi-Modality Guidance System with OptiCross 18 Peripheral Imaging Catheters.

Description:
Boston Scientific has received reports indicating the grid mark overlay on the cross-sectional view did not present correctly when an OptiCross 18 Peripheral Imaging Catheter was connected to the AVVIGO+ Multi-Modality Guidance System while in either Live or Record mode. The Boston Scientific investigation determined that, due to a software anomaly, a 9-grid mark overlay is incorrectly displayed during Live mode when AVVIGO+ is connected to an OptiCross 18 Peripheral Imaging Catheter. Note that the correct overlay display for this catheter is the 15-grid mark overlay, which allows for a reference depth setting of 14.9mm for peripheral catheters.

This software anomaly is limited to Live or Record mode. In Review mode, the correct 15-grid mark overlay is displayed, and the vessel image is correctly scaled to the appropriate size.

Clinical Impact:
The most common outcome associated with this software anomaly is a procedure delay due to the potential need for a physician to troubleshoot and confirm an accurate measurement. The most serious outcome as a result of an inaccurate assessment of vessel sizing is additional intervention to address stent migration or embolism.

In the reported events, the difference in grid mark overlays were detected during the procedure while in Review mode. No patient complications were reported as a result of any of these events.

Recommendations
Boston Scientific recommends using the measurement tools, available in Review mode only, to take vessel measurements (refer to detailed instructions included within the AVVIGO+ Multi-Modality Guidance System Instructions for Use, IFU). If measuring using grid mark overlay is preferred, it should only be performed in Review mode. Additionally, a physician can manually adjust the depth settings through the 'Case Settings' menu or elect to remove the grid marks from the display at time of use.

Boston Scientific is developing a software update to address this anomaly.

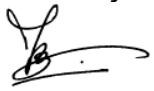
Instructions:

- Please read carefully this Field Safety Notice and immediately post it in a visible location near the AVVIGO+ Multi-Modality Guidance System to ensure this information is easily accessible to users. Also, share this product advisory with any health care professional within your organization that needs to be aware and/or with any organization where the affected devices have been transferred (if appropriate).
- No product is being recalled and you are not required to return product to Boston Scientific.
- Please **complete the enclosed Acknowledgment Form** and **send it to Boston Scientific at «Customer_Service_Fax_Number» by 25 September 2024.**
- Any adverse events or quality concerns associated with use of this product should be reported to Boston Scientific.

Additional Information:
Your Competent Authority is being notified of this Field Safety Notice.

Patient safety is our highest priority. As such, we are committed to transparent communication to ensure that 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.

Sincerely,



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

Attachment: Acknowledgment Form

Attachment 1 - Affected Product Table

Product Description	Material Number (UPN)	GTIN/UDI	Batch / Serial Number	Expiry date Range
AVVIGO + MOB SYSTEM EU + ROW	H7492493320C0	00191506033309	103189853, 103416434, 103416437, 103416600, 103416629, 103416630, 103416690, 103469208, 103552000, 103552353, 103645606, 103645607, 103667250, 103710560, 103711075, 103799547, 104033389, 104035234, 104042507, 104112099, 104112181, 104113877, 104119696, 104124626, 104124634, 104125281, 104125291, 104185271, 104185745, 104196585, 104210922, 104212968, 104338136, 104340593, 104523528, 104535237, 104535289, 104548777, 104573317, 104586006, 104586008, 104586060, 104596504, 104597121, 104597142, 104877669, 104884458, 104889669, 104890938, 104890985, 104902736, 105072735, 105092091, 105092230, 105092231, 105471081, 105491421, 105542133	01/04/2051 to 03/12/2051
AVVIGO + MOB SYSTEM EVAL EU + ROW	H7492493320D0	00191506033330	103874922	22/06/2051
AVVIGO + INT SYSTEM EU + ROW	H7492493320I0	00191506033354	103810801, 103811529, 103824292, 103826195, 103882483, 103961608, 103961637, 104098361, 104098367, 104108403, 104927614, 104927862, 104930144, 104931985, 105342419	15/06/2051 to 17/11/2051
AVVIGO II TO AVVIGO MOB UPGRADE EU ROW	H7492493321C0	00191506033385	104159021	17/07/2051

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

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

Acknowledgement Form – Urgent Field Safety Notice

AVVIGO™ + Multi-Modality Guidance System when used with OptiCross™ 18 Peripheral Imaging Catheter

97245720-FA

By signing this form, I confirm that

I have read and understood the Boston Scientific Field Safety Notice

dated 5 September 2024 for

AVVIGO™ + Multi-Modality Guidance System when used with OptiCross™ 18 Peripheral Imaging Catheter

NAME* _____ Title _____

Telephone _____ Email _____

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