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<Reference: 92912936-FA> 15 September 2022

Urgent Field Safety Notice – Product Advisory
FARAWAVE™ Pulsed Field Ablation Catheter
FARASTAR™ Pulsed Field Ablation Generator

Subject: Field Safety Notice (Boston Scientific Field Action Reference: 92912936-FA) – Instructions for Use (IFU) Update for FARAWAVE™ Pulsed Field Ablation (PFA) Catheter (REF/UPN 41M401 and 41M402) and FARASTAR™ PFA Generator (REF/UPN 61M401).

Dear «Users_Name»,

This Field Safety Notice (FSN) provides important information regarding planned updates to the IFU for the FARAWAVE PFA Catheter (REF/UPN 41M401 and 41M402) and FARASTAR PFA Generator (REF/UPN 61M401), as detailed in Appendix 1. The affected device information is listed below.

Product Description	Material # (REF/UPN)	GTIN #	Lot/Batch #	Expiration Date (or range)
FARAWAVE PFA Catheter 31 mm	41M401	00810087180096	All	All
FARAWAVE PFA Catheter 35 mm	41M402	00810087180102	All	All
FARASTAR PFA Generator	61M401	00810087180126	All	All

Summary

- Farapulse, Inc. is a subsidiary of Boston Scientific Corporation and was acquired on 6 August 2021.

- Since launch of the FARAPULSE™ PFA System, Boston Scientific has received a limited number of reports of coronary artery vasospasm following off-label use of the FARAWAVE PFA catheter for ablation of the cavotricuspid isthmus or the mitral isthmus. All reported events resolved with treatment, including one instance where the patient experienced cardiac arrest and was successfully resuscitated.

- The FARAWAVE PFA catheter is intended for use in the pulmonary veins for the treatment of paroxysmal atrial fibrillation. The safety and efficacy of the FARAWAVE PFA catheter has not been evaluated in other locations. Off-label use in locations adjacent to the coronary arteries could lead to complications, such as coronary artery vasospasm/injury. Pending regulatory approval, Boston Scientific will update the FARAWAVE PFA Catheter and FARASTAR PFA Generator IFUs to include relevant warnings for this off-label use (Appendix 1).

- Boston Scientific is not removing FARAWAVE PFA Catheters or FARASTAR PFA Generators from the field; all devices remain available for clinical use.

- There are no changes required for the management of patients who have been or will be ablated with the FARAPULSE PFA System.

Description

The FARAPULSE PFA System is designed/intended for use in pulmonary vein isolation during ablation of paroxysmal atrial fibrillation. However, since introducing the FARAPULSE PFA System in 2021[1], Boston Scientific has received a limited number of reports associated with coronary artery vasospasm occurring during off-label catheter use. These cases involved ablations of the cavotricuspid isthmus or the mitral isthmus with the FARAWAVE PFA catheter. All reported events resolved with treatment including one instance where the patient experienced cardiac arrest and was successfully resuscitated. Coronary artery vasospasm is a known procedural complication of cardiac ablation. This potential risk is listed as coronary injury within FARAPULSE PFA System labeling and associated product risk documentation.

Currently, there is no clinical data to support safe use of the FARAWAVE PFA Catheter in areas adjacent to coronary arteries (e.g., the cavotricuspid isthmus or the mitral isthmus). As such, Boston Scientific will revise the IFU for the FARAWAVE PFA Catheter and FARASTAR PFA Generator to further emphasize the intended use and include additional relevant warnings (Appendix 1). These planned updates are aimed at further reducing the potential for procedural complications and off-label use of the FARAPULSE PFA System. Boston Scientific is not removing FARAWAVE PFA Catheters or FARASTAR PFA Generators from the field; all devices remain available for clinical use. All relevant regulatory authorities are being notified of this FSN, as required.

[1] Farapulse, Inc. is a subsidiary of Boston Scientific Corporation and was acquired on 6 August 2021.

Recommendations

1- Review the content of the planned IFU updates detailed in **Appendix 1**, related to the intended use and additional warnings.

2- Share this information as appropriate, particularly with clinicians in your hospital that use the FARAPULSE PFA System (including the FARAWAVE PFA Catheter and FARASTAR PFA Generator), as well as any other organization to which these devices may have been transferred. Post this information in a visible location near the product to ensure it is easily accessible to all users of the device.

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

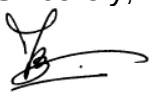
4- There are no changes required for the management of patients who have been or will be ablated with the FARAPULSE PFA System.

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

6- Complete the attached Acknowledgement Form and return it **to your local Boston Scientific office** for the attention of «Customer_Service_Fax_Number» **by 4 October 2022**.

Patient safety remains our highest priority and we are committed to transparent communication with our physician customers to ensure you have timely, relevant information for managing your patients. If you have additional questions regarding this information, please contact your local Boston Scientific sales representative.

Sincerely,



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

Attachments: - Appendix 1: IFU updates
- Acknowledgement Form

APPENDIX 1 – Planned Updates to FARAWAVE™ and FARASTAR™ Instructions for Use

Tables 1 and 2 (below) provide updates for two sections of the Instructions For Use (IFU) for the FARAWAVE Pulsed Field Ablation (PFA) Catheter (REF/UPN 41M401 and 41M402) and the FARASTAR PFA Generator (REF/UPN 61M401). These planned updates (in red bolded text) include a clarification for the intended use of the FARAWAVE PFA Catheter, as well as additional relevant warnings for both devices.

Table 1: FARAWAVE PFA Catheter IFU

Section	IFU Updates
Intended Use	The FARAWAVE Pulsed Field Ablation (PFA) Catheter is indicated for the **isolation of pulmonary veins** in the treatment of paroxysmal atrial fibrillation**.**
Warnings	**Cardiac ablation has the potential of causing unintended myocardial injury. Clinical indications of myocardial ischemia should be closely monitored during the procedure (e.g., ECG changes).**
	The FARAWAVE PFA Catheter has not been studied clinically in the mitral isthmus or cavotricuspid isthmus areas. Ablations in areas adjacent to coronary arteries may lead to coronary artery spasm and/or injury, and the resulting myocardial injury can be fatal.

Table 2: FARASTAR PFA Generator IFU

Section	IFU Updates
Warnings	**Cardiac ablation has the potential of causing unintended myocardial injury. Clinical indications of myocardial ischemia should be closely monitored during the procedure (e.g., ECG changes).**
	The FARAWAVE PFA Catheter has not been studied clinically in the mitral isthmus or cavotricuspid isthmus areas. Ablations in areas adjacent to coronary arteries may lead to coronary artery spasm and/or injury may occur, and the resulting myocardial injury can be fatal.

Please complete the form & Send it to:
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«Sold_to» - «Hospital_Name» - «City» - «Country»

Acknowledgement Form – Field Safety Notice

FARAWAVE™ Pulsed Field Ablation Catheter
FARASTAR™ Pulsed Field Ablation Generator

92912936-FA

By signing this form, I confirm that

I have read and understood
the Boston Scientific Field Safety Notice

dated 15 September 2022 for

FARAWAVE™ Pulsed Field Ablation Catheter
FARASTAR™ Pulsed Field Ablation Generator

NAME* _____Title _____

Telephone _____ Email _____

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