Boston Scientific

Electrophysiology

Urgent Medical Device Removal - Immediate Action Required

FARAWAVE™ Pulsed Field Ablation Catheter

June 2025

Dear Materials Manager:

Boston Scientific is initiating a removal of a limited number of lots of the first generation FARAWAVE™ Pulsed Field Ablation Catheter (Attachment 1) related to a potential issue identified by Boston Scientific during standard internal manufacturing process evaluation. These lots comprise approximately 500 total units, built between May 19 and May 26 of this year (2025) and distributed in the United States, of which a subset of devices are potentially affected. The potentially impacted units were manufactured using specific equipment that may have caused cracks in the electrode bands on the catheter's distal end. The manufacturing equipment issue that could lead to a cracked electrode band has been resolved and currently built products are not susceptible to this issue nor in scope of this removal.

If an electrode band cracks (Figure 1), there is a theoretical risk that the band may become loose and/or detached from the catheter spline during catheter deployment, ablation or general manipulation of the device. A cracked electrode band may also result in a sharp edge. Boston Scientific's investigation, which included rigorous cyclic testing of finished catheters, did not lead to band detachment or impairment of electrical performance.

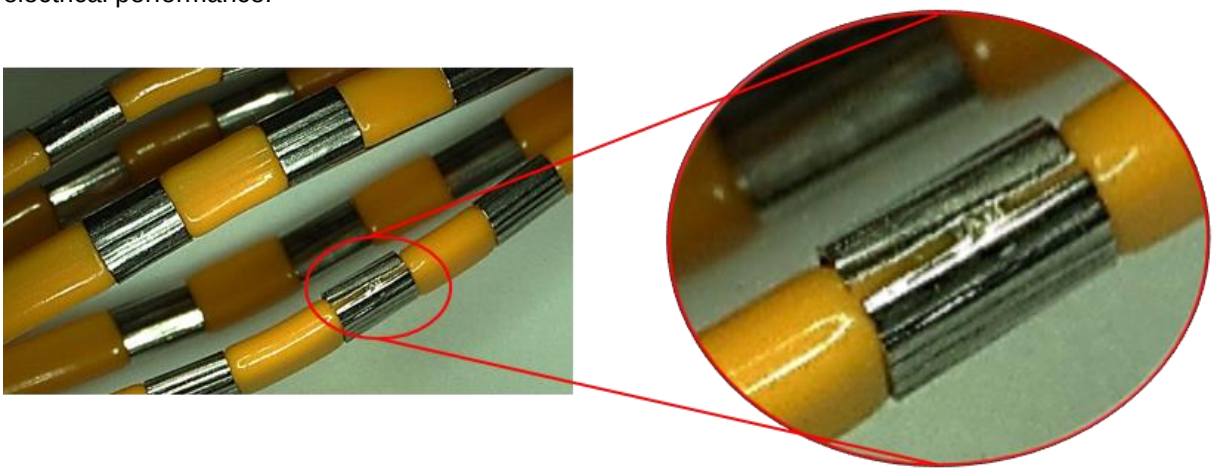

Figure 1. Cracked electrode band

Clinical Impact

Boston Scientific has not received any complaints or reports of patient harm relating to this issue. The most serious hypothetical risk would be that the ring electrode could potentially detach during deployment, ablation, or general manipulation and embolize during an ablation procedure. The metal composition of the electrode is highly radiopaque and would be readily detectable with standard fluoroscopy imaging. However, detachment leading to embolism is considered unlikely based on the detachment testing conducted during the investigation.

Another hypothetical clinical consequence would be that if the electrode band remains attached to the spline and the crack is on the external aspect of the catheter, it may result in a sharp edge that could lead to tissue trauma. Systemic anticoagulation routinely used during ablation procedures as well as post-procedure anticoagulation mitigates the potential risk of thrombus formation at a site of tissue trauma.

For patients in whom an impacted product has been used, there are no specific recommendations beyond the local standard of care for post-procedure monitoring/reporting.

Actions

1. **Do NOT use affected product (Attachment 1)**, remove affected devices from your facility's inventory, segregate the units in a secure place until they can be returned to Boston Scientific.
2. **Immediately post** this information in a visible location near the affected products to ensure this information is readily accessible to all handlers and users of the device.
3. **Forward this notice** to any healthcare professional from your organization for awareness and to any organization where affected devices have been transferred.
4. **Complete and return the enclosed Reply Verification Tracking Form** per the enclosed instructions on page five.
5. **Return affected product**.

This removal affects only the products, and lots listed in Attachment 1 (Affected Products). No other material numbers or lots are impacted by this removal. If you are a facility that has sent products to another hospital or a facility within your network, ensure this notification is forwarded to them.

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,

Alexandra Naughton
Vice President, Global Quality

Encl: Removal Instructions
Reply Verification Tracking Form

Healthcare professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to Boston Scientific by calling 1-800-811-3211 and to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

Online: www.fda.gov/MedWatch/report.htm
Regular Mail: use postage-paid FDA form 3500 available at www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, 5600 Fishers Lane, Rockville, MD, 20852-9787
Fax: (800) FDA-0178
Phone: (800) FDA-1088

Attachment 1

Affected Product

Product Description	Material Number (UPN)	GTIN	Lot	Expiration Date
FARAWAVE™ Pulsed Field Ablation Catheter	M004PF41M401	00191506043148	36543581	05/17/2027
			36543644	05/17/2027
			36543646	05/17/2027
			36568553	05/21/2027
			36572565	05/21/2027
			36572568	05/21/2027
			36572571	05/21/2027
			36572576	05/21/2027
			36578308	05/21/2027
			36578314	05/21/2027
			36579110	05/21/2027
			36598352	05/23/2027
			36598809	05/23/2027
			36599402	05/23/2027
			36600406	05/24/2027
			36600543	05/24/2027
			36600544	05/24/2027
			36600545	05/24/2027
			36600578	05/24/2027

Urgent Medical Device Removal - Instructions

The Reply Verification Tracking Form (RVTF) enclosed with this Removal Notice must be completed and returned even if you do not have any affected product.

1. Immediately discontinue use and segregate affected product.
2. Complete and return the RVTF to get a Return Goods Authorization (RGA) number.
    - Indicate the quantity of SINGLE units you will be returning for credit
    - If you have product that is listed in Attachment 1 (Affected Products) that is not included on your RVTF, provide the material number, lot number, and quantity you intend to return on your RVTF
    - Return the RVTF via:
        Email: BSCFieldActionCenter@bsci.com
        or
        Fax: BSC Field Action Center 1-763-415-7708
3. Once Boston Scientific receives your completed RVTF, you will be contacted within 2 business days and provided an RGA number for product return.
4. Package and ship affected product:
    - Write the RGA number in large print on the enclosed (red/white) return address label
    - Affix the return address label to the outside of box
    - Use our Federal Express account number: 9205-2515-6 to return package via second-day delivery
    - Seal box and return to:
        Boston Scientific Corporation
        US Distribution Center
        500 Commander Shea Blvd
        Quincy, MA 02171
        RGA: _____
5. If you have sent a response to this Removal Notice to anyone other than Boston Scientific, we would not have received your response. Please ensure response is sent to email or fax indicated above.
6. Credit will be issued for all returned affected product once received and confirmed by Boston Scientific.

Reach out to your local Boston Scientific representative with any questions.