Important U.S. Medical Device Removal

Rhythm Management
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Facilities within the United States: Return affected/original EMBLEM S-ICD[1] Subcutaneous Electrode inventory (see Table 1) when the enhanced version of EMBLEM Electrode is available within your facility. The enhanced electrode addresses the potential for electrode body fractures distal to the proximal sense ring.

- In December 2020, Boston Scientific voluntarily notified users of the EMBLEM Electrode (Model 3501) about the potential for electrode body fractures at a location just distal to the proximal sense ring.
- The EMBLEM Electrode has demonstrated a low overall malfunction rate, within industry standards, and therefore has continued to be available while a design enhancement was pursued.
- Performance data about the affected/original EMBLEM Electrode advisory population will continue to be published in our Product Performance Report[2]. Since the December 2020 physician communication:
  - There is no change in management recommendations.
  - The cumulative occurrence rate for electrode body fractures distal to the proximal sense ring is 0.2% at 48 months, slightly lower than the rate reported in December 2020[3].
  - There is no change in the potential for life-threatening harm of 1 in 25,000 at 10 years.
  - There have been no patient deaths related to this behavior since the December 2020 communication.
  - Routine prophylactic replacement of an electrode without evidence of fracture is not recommended.
- Facilities located within the United States are to return remaining inventory of the affected/original Electrodes (Table 1) to Boston Scientific when the enhanced version of the Electrode is available within your facility. Boston Scientific sales professionals are actively supporting this removal.
  - See Appendix A to identify affected/original electrodes based on part number and packaging.
  - If your facility has inventory to return, please review the instructions in Appendix B. Forward this notification to other facilities within your network with original/affected electrode inventory.

Table 1. Identify affected/original EMBLEM Electrode inventory based on the part number on the packaging.

Product	Model	Part Number	GTIN
EMBLEM Subcutaneous S-ICD Electrode	3501	643501-100 643501-101	00802526599101 00802526599200

- The enhanced EMBLEM Electrode is pending approval in countries outside the United States. In those geographies, all affected/original EMBLEM Electrode inventory may remain in place until the respective approvals are received and the enhanced electrode is subsequently available.

[1]Subcutaneous Implantable Cardioverter Defibrillator (S-ICD)
[2]Available online at www.BostonScientific.com/ppr
[3]The reported cumulative occurrence rate in December 2020 notification was 0.2% at 41 months.

Enhanced EMBLEM Electrode

The root cause of body fracture for an affected/original EMBLEM Electrode is associated with the adhesive backfilled notch at a location distal to the proximal sense ring. This revealed notch facilitates connection of the sense conductor to the proximal sense ring. The enhanced electrode design has moved the connection of the sense conductor, notch, and adhesive to a centered location entirely under the sense ring. An accelerated, extreme laboratory test method was developed to assess electrode body fatigue around the sense ring using implant X-rays and body motion assessments. Based on this accelerated, extreme laboratory test, the enhanced EMBLEM Electrode design has demonstrated statistical survival of the electrode body around the sense ring to 10 implant years.

Additional Information

Up-to-date product performance information, including this topic, the original December 2020 letter, and a device lookup tool is available within our Product Performance Resource Center at www.bostonscientific.com/ppr. Patient safety remains our highest priority. If you have additional questions or would like to report a clinical event, please contact your Boston Scientific representative or our Technical Services team.

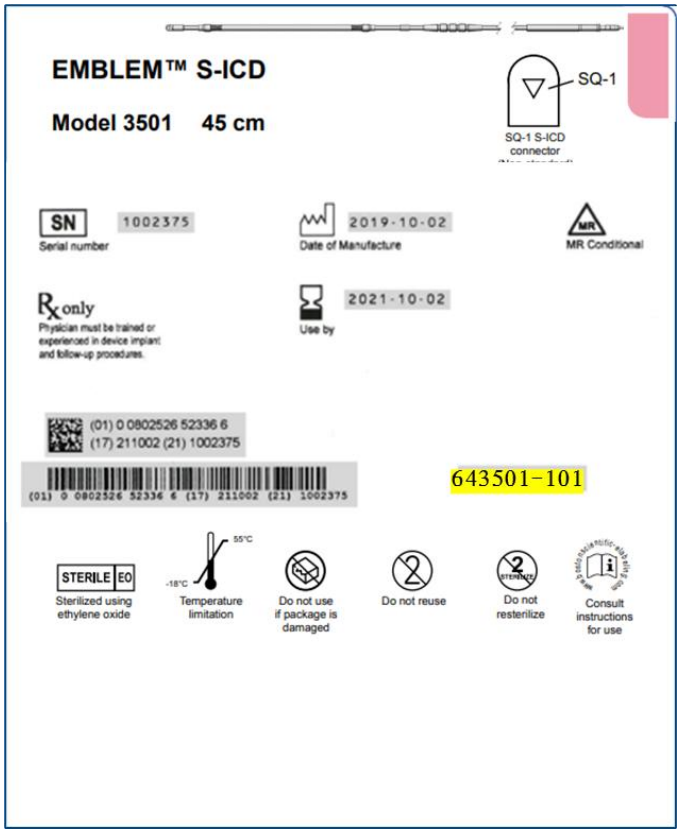
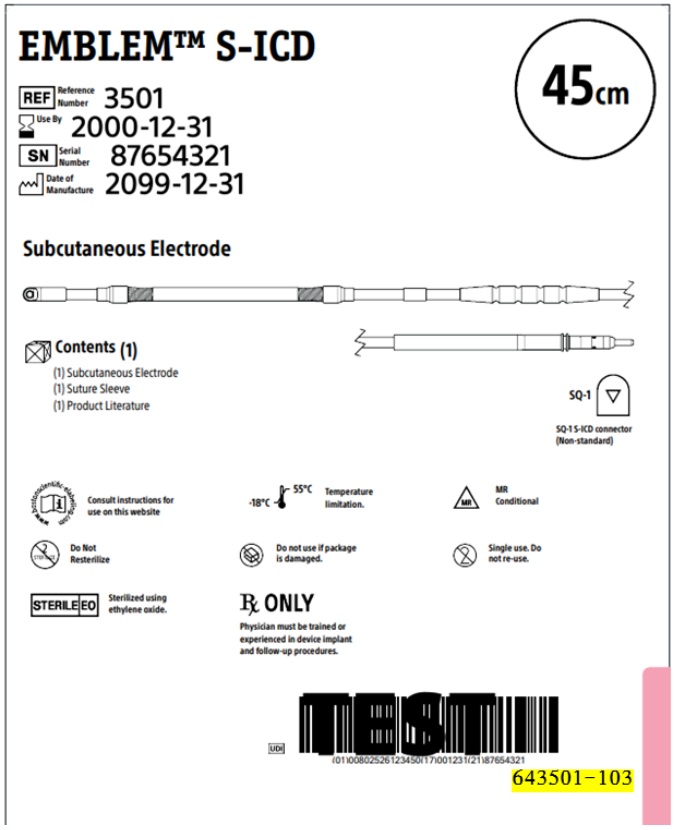
Sincerely,

Alexandra Naughton
Vice President, Quality Assurance

APPENDIX A – EMBLEM Electrode Packaging Description

This Appendix is intended to assist users in distinguishing between affected/original EMBLEM Electrode inventory and enhanced EMBLEM Electrode inventory.

Table 2. Users may distinguish affected/original EMBLEM Electrodes and the enhanced EMBELM Electrodes through part number and packaging.

Remove and Return **Affected/Original EMBLEM Electrode**	**In Service** **Enhanced EMBLEM Electrode**
When enhanced electrodes are available at your facility, return EMBLEM Electrodes with 9-digit part numbers ending in <u>0 or 1</u> (e.g., 643501-10**<u>1</u>** ends in **<u>1</u>** and is to be returned).	Enhanced EMBLEM Electrodes include 9-digit part number ending in <u>3 or higher</u> may be placed in service (e.g. 643501-10**<u>3</u>**, ends in **<u>3</u>**).
	
The affected/original EMBLEM Electrode is potentially susceptible to electrode body fractures distal to the proximal sense ring. This packaging may also include literature describing the electrode body fracture behavior described in Dec 2020.	The enhanced version of the EMBLEM S-ICD Subcutaneous Electrode includes design enhancements to the proximal sense ring to address electrode body fractures distal to that location and changes to packaging for continued conformance with labeling requirements.

APPENDIX B – U.S. Removal Instructions

The Customer Acknowledgement Form enclosed with this letter must be completed and returned **even if you no longer have any of the affected/original version of the product.**

1. Return the affected/original EMBLEM Electrodes once the enhanced electrode is available.
   - Segregate this product in a secure location for return to BSC.
   - Use Appendix A to identify any affected/original product that may not be listed on the device list enclosed with this notification to ensure all affected/original EMBLEM electrodes are returned.

2. You must complete and email or fax your Acknowledgement Form(s) to one of these addresses:
   - Email: BSCFieldActionCenter@bsci.com
   - Fax to: Field Action Center 1-763-415-7708

NOTE: If a response to this removal has been provided to anyone other than Boston Scientific your response will not be forwarded to us. Please respond using the Email/Fax information provided above.

3. Package/Ship the affected/original product.
   - Package any product that is being returned in an appropriate shipping box.
   - Feel free to use our Federal Express Number 9205-2515-6 to return this package via second day delivery.
   - Seal the box, and return to: **Boston Scientific Corporation**
     CRM Non-Complaint Returns
     4100 Hamline Ave N – Dock 9
     Arden Hills, MN 55112

Note: Credits will be issued for all product that is removed and returned to Boston Scientific.

If you are a distributor, please forward this notification to your customers. If you are a facility that has sent products to another hospital within your network, please ensure that this notification is forwarded to them.