

## Farouk Maamoun Tamer & Co

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<Reference: 92384167E-FA>

26 July 2021

## Urgent Field Safety Notice – Urgent Medical Device Recall EMBLEM™ S-ICD Subcutaneous Electrode (Model 3501) with Reply Form/Product List

Dear Distributor,

Please find attached:

- Distributor Return Verification Tracking Form (RVTF)
- Customer package: Cover Letter, Field Safety Notice and blank RVTF form

### **You are kindly requested to follow the below instructions:**

1- Please read the Cover Letter and Field Safety Notice. After you have received new/Enhanced Electrodes please segregate and do not distribute any original/affected electrodes from your inventory.

2- **Please notify all your Customers that have Original/Affected Electrodes** that they should return them after the Enhanced version of the Electrode is available at your customers' facilities. To effectively manage this removal, your accounts are to communicate and return products directly with you, not Boston Scientific. If any of your customers are distributors, please notify them that they must communicate this Field Action to the medical facility level.

Note that customers who have programmers only should also be notified about this removal of original/affected electrodes and the availability of new/Enhanced Electrodes. While the programmer is not affected by this removal, programmer locations are being used to identify locations where patients may be followed. Following Physician customers with a programmer only should follow instructions on the form Step 2 and check the box "We do not have any affected product."

3- Have **all original/affected Electrodes returned to your facility** and held in quarantine for reconciliation.

4- **Please complete the attached Distributor RVTF Form**. Return the form to Boston Scientific via email at [ComplaintsMiddleEast@bsci.com](mailto:ComplaintsMiddleEast@bsci.com) by **13 August 2021**.

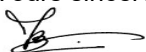
5- **If you have products to return**, please package them in an appropriate shipping box and **contact** Export Services mail address: [BDCEXportServicesCusSerIC@bsci.com](mailto:BDCEXportServicesCusSerIC@bsci.com) of **your local Boston Scientific office**, to arrange return.

Your Competent Authority is being notified of this Field Safety Notice, unless per local regulation, this task is to be performed by you as a Distributor.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,



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

Attachment: - Distributor's RVTF Form  
- Customer package: Cover Letter/FSN/Form

Please Complete the form even if you do not have any affected product & send it to Your Local Office:  
ComplaintsMiddleEast@bsci.com

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**Distributor Verification Form – Urgent Medical Device Recall  
EMBLEM™ S-ICD Subcutaneous Electrode (Model 3501)  
92384167E-FA**

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1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated 26 July 2021.
2. **Boston Scientific records indicate you have received the following affected product** (*additionally please check inventory against complete list of affected product provided*)  
For your convenience, Appendix A of the Field Safety Notice Letter contains example labeling for affected product.  
**Note:** If you are a Following Physician and do not perform implant procedures at your facility, your product list will be empty. Please check “We do not have any affected product.” in #4 below.

Material N° (UPN)	Lot / Batch N° / Serial N°	Customer PO	Qty Sent	Qty to return
643501-250	199559		1	
643501-250	199627		1	
643501-250	199740		1	
643501-550	114492		1	
643501-550	114570		1	
643501-550	114818		1	
643501-550	114980		1	
643501-550	115008		1	
643501-550	115050		1	
643501-550	115191		1	
643501-550	115351		1	
643501-550	115399		1	
643501-550	115753		1	
643501-550	115904		1	
643501-550	116473		1	
643501-550	116605		1	
643501-550	116712		1	
643501-550	116715		1	
643501-550	116730		1	
643501-550	116739		1	
643501-550	116837		1	
643501-550	116906		1	
643501-550	116920		1	
643501-550	118399		1	
643501-550	118578		1	
643501-550	119022		1	
643501-550	119127		1	
643501-550	119129		1	
643501-550	119166		1	
643501-550	119170		1	
643501-550	119314		1	
643501-550	119336		1	
643501-550	119360		1	
643501-550	119380		1	
643501-550	119392		1	
643501-550	119426		1	
643501-550	119437		1	
643501-550	119457		1	
643501-550	119467		1	
643501-550	119475		1	
643501-550	119526		1	
643501-550	119535		1	
643501-550	119538		1	
643501-550	119549		1	
643501-550	119678		1	
643501-550	119733		1	
643501-550	119815		1	
643501-550	119840		1	
643501-550	119851		1	
643501-550	119864		1	
643501-550	119865		1	
643501-550	119883		1	
643501-550	119914		1	
643501-550	119915		1	
643501-550	119916		1	
643501-550	119933		1	
643501-550	119963		1	
643501-550	119978		1	
643501-550	119991		1	
643501-550	119998		1	
643501-550	119999		1	
643501-550	120021		1	
643501-550	120026		1	
643501-550	120033		1	

643501-550	120039		1	
643501-550	120153		1	
643501-550	120245		1	
643501-550	120296		1	
643501-550	120331		1	
643501-550	120398		1	
643501-550	120411		1	
643501-550	120591		1	
643501-550	120602		1	
643501-550	123051		1	
643501-550	127779		1	
643501-550	131775		1	
643501-550	132450		1	
643501-550	132462		1	
643501-550	132557		1	
643501-550	132630		1	
643501-550	132690		1	
643501-550	132764		1	
643501-550	135055		1	
643501-550	161022		1	
643501-550	161786		1	
643501-550	162103		1	
643501-550	162781		1	
643501-550	162818		1	
643501-550	162824		1	
643501-550	162853		1	
643501-550	163133		1	
643501-550	163158		1	
643501-550	163225		1	
643501-550	163239		1	
643501-550	163252		1	
643501-550	163256		1	
643501-550	163262		1	
643501-550	163294		1	
643501-550	163296		1	
643501-550	163299		1	
643501-550	164432		1	
643501-550	166064		1	
643501-550	166408		1	
643501-550	166417		1	
643501-550	166422		1	
643501-550	166438		1	
643501-550	166483		1	
643501-550	166491		1	
643501-550	166500		1	
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643501-550	166538		1	
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643501-550	166614		1	
643501-550	166697		1	
643501-550	167667		1	
643501-550	168213		1	
643501-550	169316		1	
643501-550	169401		1	
643501-550	169421		1	
643501-550	169604		1	
643501-550	169701		1	
643501-550	169745		1	
643501-550	169766		1	
643501-550	169792		1	
643501-550	169884		1	
643501-550	169900		1	
643501-550	169906		1	
643501-550	169943		1	

643501-550	169946		1	
643501-550	169966		1	
643501-550	170020		1	
643501-550	170021		1	
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643501-550	170182		1	
643501-550	170242		1	
643501-550	170261		1	
643501-550	170280		1	
643501-550	170343		1	
643501-550	170359		1	
643501-550	170382		1	
643501-550	170396		1	
643501-550	170398		1	
643501-550	170399		1	
643501-550	170404		1	
643501-550	170410		1	
643501-550	170412		1	
643501-550	170422		1	
643501-550	170426		1	
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643501-550	170428		1	
643501-550	170450		1	
643501-550	170464		1	
643501-550	170515		1	
643501-550	170548		1	
643501-550	171178		1	
643501-550	171192		1	
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643501-550	171294		1	
643501-550	171305		1	
643501-550	171310		1	
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643501-550	171401		1	
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643501-550	171464		1	
643501-550	171530		1	
643501-550	171541		1	
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643501-550	171639		1	
643501-550	171664		1	
643501-550	171716		1	
643501-550	171717		1	
643501-550	171721		1	
643501-550	171791		1	
643501-550	171793		1	
643501-550	171812		1	
643501-550	172839		1	
643501-550	173182		1	
643501-550	173505		1	
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643501-550	175446		1	
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643501-550	179256		1	

643501-550	180071		1	
643501-550	181401		1	
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643501-550	182422		1	
643501-550	184748		1	
643501-550	184878		1	
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643501-550	185718		1	
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643501-550	187742		1	
643501-550	187827		1	
643501-550	187829		1	
643501-550	187843		1	
643501-550	187952		1	
643501-550	187965		1	
643501-550	188205		1	
643501-550	189549		1	
643501-550	189598		1	
643501-550	189600		1	
643501-550	189623		1	
643501-550	189642		1	
643501-550	189668		1	
643501-550	189681		1	
643501-550	189682		1	
643501-550	189691		1	
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643501-550	189724		1	
643501-550	189741		1	
643501-550	189742		1	
643501-550	189776		1	
643501-550	189780		1	
643501-550	189798		1	
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643501-550	189835		1	
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643501-550	190374		1	
643501-550	190377		1	
643501-550	190378		1	
643501-550	190379		1	
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643501-550	190409		1	
643501-550	190420		1	
643501-550	190464		1	
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643501-550	190568		1	
643501-550	190627		1	
643501-550	190672		1	
643501-550	190724		1	
643501-550	190839		1	

643501-550	191127		1	
643501-550	191474		1	
643501-550	194587		1	

3. We confirm that all areas where affected product could be located have been checked. , **including at our customers' location**, have been checked.

4. **TICK ONE OF THESE STATEMENTS\***, **SIGN THIS FORM**

- We do not have any affected product.
- We have found affected product(s): Please confirm the quantity to return above. *If you are returning product not listed above, please **add the UPN, Lot/Batch/Serial number and the quantity to return.***

**5- When completed, please return the Verification Form to your local Boston Scientific office** for the attention of ComplaintsMiddleEast@bsci.com on or before **13 August 2021**.

**TO RETURN PRODUCTS:**

1. Contact Export Services mail address: BDCExportServicesCusSerLC@bsci.com of your Local Office to arrange return of any affected product
2. Prepare the package
3. Follow the instructions given by your Local Office about collection of the package

**NAME\*** \_\_\_\_\_ **Title** \_\_\_\_\_

**Telephone** \_\_\_\_\_ **Email** \_\_\_\_\_

**Customer' SIGNATURE\*** \_\_\_\_\_ **DATE\*** \_\_\_\_\_

\* Required field