Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

URGENT: FIELD SAFETY NOTICE RECALL (REMOVAL)

Part Number	Part Description	Lot Number	UDI	Mfg. SRN
D-1412-01	VARIPULSE Bi-Directional Ablation Catheters	See the list below	10846835025460	US-MF-000014219

April 26, 2024

Dear Valued Customer,

Biosense Webster, Inc. (BWI) is initiating a voluntary recall (removal) of specific lots of VARIPULSE Catheters, part number D141201. You are receiving this letter because our records indicate that you have received one or more VARIPULSE Bi-Directional Ablation Catheters (Catalog Number: D-1412-01) Lot Numbers (see the list below).

Affected Lot Numbers
31192375L 31203363L 31203365L

The VARIPULSE Catheter is indicated for use in catheter-based cardiac electrophysiological mapping (stimulating and recording) and, when used with a TRUPULSE Generator, for cardiac ablation. The catheter provides location information when used with the CARTO 3 System. The VARIPULSE Catheter and TRUPULSE Generator are only available for sale in Europe and Japan.

Reason For Removal:

As part of an investigation Biosense Webster found that a polymer used to bind the catheter electrodes to the catheter (Polyurethane; “PU”) had overrun over the electrodes. PU overrun can increase the potential for:

- Blocked irrigation holes
- Reduction in electrode surface area
- PU extending beyond the electrode outside diameter.

Potential Patient Impact:

PU overrun that reduces the electrode surface area or blocks the irrigation holes may increase the risk of a cerebrovascular event. Having PU extending beyond the electrode’s outside diameter may cause interference with the sheath and variability in catheter performance or procedural delays.

As part of our procedures for all of our devices, we investigate all reports of patient adverse events associated with procedures using a VARIPULSE Catheter to determine the root cause. To date, five complaints reported

patients presenting symptoms following ablation procedures. In all cases the ablation procedures were completed successfully, and the patients were discharged home. All potential complaints received for the VARIPULSE Catheter are being investigated to determine if they are related to this issue. Healthcare providers who have treated patients using the specific lots subject to this removal should continue to follow those patients pursuant to their standard of care.

What Actions Are Required:

1. Examine your inventory immediately to determine if you have the subject products and quarantine the subject products. **DO NOT USE THE SUBJECT PRODUCTS.**
2. Carefully review the information contained in this Medical Device Recall and ensure that anyone in your facility who needs to be aware of this notification reads the attached letter carefully.
3. Locate the lot number of the affected VARIPULSE Catheter and verify whether it matches the lot numbers referenced at the top of this letter and the attached Business Reply Form (BRF).
4. If you have any affected VARIPULSE Catheters, please complete, and sign the BRF on page 3 of this notification and email it to *jnjmedical-ch@its.jnj.com.*
   Please make sure to include your facility name, address, account number, name of person completing the form, title, email address, telephone number and signature in the spaces provided.
5. If you do not have a subject VARIPULSE Catheter, please complete all appropriate fields of the attached BRF, select the check box "We have no products subject to this removal for return," and email it to *jnjmedical-ch@its.jnj.com.*
6. Return the subject VARIPULSE Catheter(s) immediately to

   Johnson & Johnson AG
   c/o Postlogistik
   Stichwort: VARIPULSE
   Allmendstrasse 8
   5612 Villmergen

7. Upon receipt of the completed BRF and returned product, Biosense Webster will provide a credit for the quantities received. Incomplete BRFs cannot be processed.
8. If any of the subject VARIPULSE Catheter have been forwarded to another facility, contact *jnjmedical-ch@its.jnj.com,* and provide a copy of this to the relevant personnel.
9. Maintain a copy of this communication where the product identified in this letter is located until all products have been consumed.

If you have additional questions about this medical device recall (removal), please contact *jnjmedical-ch@its.jnj.com.*

Sincerely,

Biosense Webster

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BUSINESS REPLY FORM

Please complete this Business Reply Form (BRF) and return it to *jnjmedical-ch@its.jnj.com* **within 5 business days upon receipt of this letter**.

Affected Lot Numbers
31192375L 31203363L 31203365L

Please check and complete the following box to acknowledge receipt of notification:

☐ I have read and understand the notification.

Your Name/Title:	Facility/Business Name:
Sign*:	Date:
Facility/Business or shipping Address, City:	
Biosense Webster Sales Representative (if applicable):	
Date the notification was received:	
Telephone Number:	
**Your signature provides confirmation that you have received and understood this notification.*	

Please check one of the following boxes:

☐ We have no products subject to this removal for return

☐ We have products subject to this removal and are returning the following devices:

Please complete the table below and attach this BRF with your product return. Remember to keep a copy of your completed BRF for your records.

Lot No.	Qty to be returned	Lot No.	Qty to be returned

☐ We have products subject to this removal that have moved/transferred to the following facility/location.

List the serial numbers and facility/location name & address: _____