

**URGENT FIELD SAFETY NOTICE  
MEDICAL DEVICE – VOLUNTARY FIELD RECALL**

Biosense Webster, a division of Johnson & Johnson Medical NV/SV PENTARAY® Catheter Family  
Product Names: PENTARAY® NAV Catheter and PENTARAY® NAV ECO Catheter

Catalog No: D128201, D128202, D128204, D128205, D128207, D128208, D128210, D128211  
Lot Numbers: All Lots

May 1, 2014

Dear Valued Customer,

The purpose of this communication is to inform you Biosense Webster, a division of Johnson & Johnson Medical NV/SV (“Biosense Webster”) is expanding a previously initiated voluntary field removal on February 18, 2014 to now include all product lots of the PENTARAY® NAV Catheter and the PENTARAY® NAV ECO Catheter (Catalog No: D128201, D128202, D128204, D128205, D128207, D128208, D128210, D128211). This letter provides important information about the affected products and instructions on how you can return the affected products to Biosense Webster.

**Overview:**

At Biosense Webster, we have an ongoing commitment to patient safety and continuously monitoring the performance of our products. Despite the fact that there have been no adverse events reported, after a recent analysis of increased reports of partial tip separation from the shaft, we have decided to expand the initial voluntary field removal to now include all lots of the PENTARAY® Catheters (see above for specific Catalog Numbers). Biosense Webster has identified an issue in the production process of the PENTARAY® NAV Catheter and the PENTARAY® NAV ECO Catheter that can lead to an insufficient bond of the distal tip to the catheter shaft. The PENTARAY® NAV Catheter and the PENTARAY® NAV ECO Catheter are designed with a safety puller wire that prevents any complete tip separation and this design has demonstrated to function properly in the units of the affected products. To date, with regard to the affected products, Biosense Webster has not received any reports of: (i) a complete tip separation from the shaft; or (ii) patient injuries or adverse events as a result of a partial tip separation from the shaft. There is no concern for patients who have already been successfully mapped with the affected products.

**Details on Affected Products:**

Indications for Use:

Biosense Webster’s PENTARAY® NAV and PENTARAY® NAV ECO High-Density Mapping Catheters are indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart.

**Actions Requested on Your Part:**

- Read the "Description of the Problem" section below carefully.
- Immediately identify and set aside all lots of the affected products in a manner that ensures the affected product will not be used.
- Maintain a copy of this letter with the affected PENTARAY® NAV and PENTARAY® NAV ECO Catheters until all units are returned to Biosense Webster.
- Sign and return the attached Voluntary Field Removal Certification Form in accordance with the instructions listed on the form.
- Arrange for return of all affected units of PENTARAY® NAV and PENTARAY® NAV ECO Catheters that you may have in your inventory per the instructions on the Voluntary Field Removal Certification Form.
- Pass on this notice to anyone in your facility that needs to be informed.
- Maintain awareness of this notice until all affected products have been returned to Biosense Webster.
- If any of the affected PENTARAY® NAV and PENTARAY® NAV ECO Catheters have been forwarded to another facility, contact that facility and arrange for the return.

**Description of the Problem:**

Biosense Webster has identified an increase in reports of partial tip separation for the PENTARAY® NAV and PENTARAY® NAV ECO Catheters. After conducting a root cause analysis resulting from increased reports of partial tip separation from the shaft, Biosense Webster has identified an issue in the production process of the PENTARAY® NAV and PENTARAY® NAV ECO Catheters that can lead to an insufficient bond of the distal tip to the catheter shaft.

To date, there have been no patient injuries or adverse events reported as a result of this defect. However, a partial tip separation of the catheter could pose a safety risk to the patient. For this reason, Biosense Webster is voluntarily removing all PENTARAY® Catheter product lots from the field. Please return all affected units of PENTARAY® NAV and PENTARAY® NAV ECO Catheters to Biosense Webster. First, complete and sign the attached Voluntary Field Removal Certification Form. Then, return the completed document along with the devices to Biosense Webster according to the instructions at the bottom of the form.

**Available Assistance:**


For questions related to this issue, product return, and the Voluntary Field Removal Certification Form please contact your Biosense Webster sales representative.

**Additional Information:**

The relevant national regulatory agencies have been notified as appropriate and are aware that Biosense Webster is voluntarily taking this action.

Biosense Webster regrets any inconvenience that this communication may cause. The health and safety of our patients is our first priority. We know that you place high value in our products and we appreciate your cooperation in this matter.

Sincerely,

  
  
Vice President, Worldwide Quality and Regulatory Compliance  
Biosense Webster, Inc.

**VOLUNTARY FIELD REMOVAL CERTIFICATION FORM**  
**FOR PENTARAY® NAV AND PENTARAY® NAV ECO CATHETERS**  
**(CATALOG NUMBERS: D128201, D128202, D128204, D128205, D128207, D128208, D128210, D128211)**



All units (all lot numbers) for PENTARAY® NAV and PENTARAY® NAV ECO Catheters must be removed from inventory and returned to Biosense Webster, a division of Johnson & Johnson Medical NV/SA.

Please check one of the following:

- Affected product is no longer in our possession because:
  - All inventory has been previously used in procedures
  - Previously returned
  - Previously disposed
  - Other, please explain: \_\_\_\_\_

- Affected product has been segregated and the following catheters are being returned.

Catalog Number	Lot Number	Quantity

*(continue on reverse, if necessary)*

I have read and understand the May 1, 2014 Field Safety Notice for Voluntary Field Recall, have appropriately disseminated this information within my institution, and have taken the requested actions.

**Name** \_\_\_\_\_  
 (Please print)

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

**Contact Info** \_\_\_\_\_  
 (email or phone #)

**Facility Name** \_\_\_\_\_

**Facility Address** \_\_\_\_\_

\_\_\_\_\_ City State Postal Code

Please return this completed Certification Form by mail, fax or e-mail as soon as possible to the Field Action Coordinator below. Upon receipt, a Biosense Webster representative will contact you with a Return Goods Authorization number and instructions on how to return the product. Please inform the representative if you require a box to return the product in and one will be provided for you.

Biosense Webster, a division of Johnson & Johnson Medical NV/SA  
 Attn: Field Action Coordinator Name: \_\_\_\_\_

Mailing Address: \_\_\_\_\_

Fax Number: \_\_\_\_\_ e-Mail Address: \_\_\_\_\_