URGENT FIELD SAFETY NOTICE

April 18, 2016

PENTARAY® NAV Catheters, PENTARAY® NAV eco Catheters hereafter "PENTARAY® Catheters"
Catalog Numbers: D128201, D128202, D128203, D128204, D128205, D128206, D128207, D128208, D128209, D128210, D128211, D128212
Lot Numbers: All

NOTE: This is additional labeling. Retain this letter with affected product.

Please distribute this information to appropriate personnel at your facility.

Dear Valued Customers,

The purpose of this communication is to inform you that Biosense Webster, a division of Johnson & Johnson Medical NV/SA ("Biosense Webster"), is initiating a Field Safety Notice for all PENTARAY® Catheters, Catalog Numbers: D128201, D128202, D128203, D128204, D128205, D128206, D128207, D128208, D128209, D128210, D128211, and D128212.

At Biosense Webster, we have an ongoing commitment to patient safety and we continuously monitor the performance of our products to ensure we meet customer expectations. Biosense Webster is clarifying the contraindication language in the Instructions For Use (IFU) and product labeling for this catheter relative to patients with prosthetic valves. The current language in the IFU provides a precaution against use of the PENTARAY® Catheter in patients with prosthetic valves under the contraindication section stating: "[The] use of this catheter may not be appropriate for use in patients with prosthetic valves." We are updating the IFU to clarify the contraindication statement as follows: **"Do not use PENTARAY® Catheters in patients with prosthetic valves".**

This action is **NOT a product removal**, and you may continue to use PENTARAY® Catheters in accordance with the updated contraindication as stated in this letter. We kindly request you to review this Field Safety Notice and return the attached acknowledgement form.

Indications for Use
PENTARAY® 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. The PENTARAY® Catheter provides location information when used with compatible CARTO® 3 EP Navigation Systems.

Overview
The use of the PENTARAY® Catheter is contraindicated for patients with prosthetic valves. The Instructions For Use also include a precaution against using excessive force when

Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
No. 2 International Business Park, #07-01, Tower One, The Strategy, Singapore 609930
Tel: +65 6827 6000 Fax: +65 6720 0750
Business Reg No. 52836279L Company Reg No. 197402104W

advancing or withdrawing the catheter through the sheath. When used in patients with prosthetic valves, the splines of the PENTARAY® Catheter may become entangled in the valves. If this happens, the physician could have difficulty withdrawing the catheter from the patient and may apply excessive force against the resistance, which may cause a part of the catheter spline to detach and potentially embolize inside the patient's body. Surgical intervention may be required in order to retrieve the detached part. Between January 2014 and March 2016, Biosense Webster received four (4) customer complaints for PENTARAY® Catheter spline entanglement and, in 3 of the cases, subsequent embolization of catheter parts when used in patients with prosthetic valves.

Based on the medical assessment, there is a high risk of catheter spline entanglement when using PENTARAY® Catheters in patients with prosthetic valves. If excessive force is applied on the entangled catheter spline, there is a potential for parts to detach and embolize inside the patient's body, which may lead to serious complications like stroke, transient ischemic attack, myocardial infarction or pulmonary embolism. The likelihood of these serious complications remains low.

Available Assistance
For questions related to this Field Safety Notice, please contact your Biosense Webster sales representative.

The Regulatory Agencies and Notified bodies, have been notified and are aware that Biosense Webster is voluntarily taking this action.

ACTIONS REQUIRED FROM YOU

1. Read this Field Safety Notice carefully.
2. Pass on this notice to anyone in your facility that needs to be informed
3. Maintain a copy of this letter with the product.
4. Complete the **Customer Acknowledgement Form** and pass it to your Biosense Webster Representative or fax it to **6720 0750 within 2 business days.**
5. Maintain awareness of this Field Safety Notice.

Thank you for your cooperation and patience.

Yours sincerely,

[redacted]

Lee Ching Hwee

Associate Manager, Regulatory Affairs

Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
No. 2 International Business Park, #07-01, Tower One, The Strategy, Singapore 609930
Tel: +65 6827 6000 Fax: +65 6720 0750
Business Reg No. 52836279L Company Reg No. 197402104W

VOLUNTARY FIELD SAFETY NOTICE ACKNOWLEDGEMENT FORM

PENTARAY® NAV Catheters, PENTARAY® NAV eco Catheters hereafter "PENTARAY® Catheters"
Catalog No: D128201, D128202, D128203, D128204, D128205, D128206, D128207, D128208, D128209, D128210, D128211, D128212

Apr 18, 2016

Please distribute this information to appropriate personnel at your facility.

Customer Acknowledgement Form

Please complete this Customer Acknowledgement Form and return to your local BW Representative or fax it to +65 6720 0750 within two (2) business days of receipts of the Field Safety Notice, even if you do not have any product to return.

Please check (√) all that apply:

☐ Yes, I have received the Field Safety Notice regarding the PENTARAY® NAV Catheters, PENTARAY® NAV eco Catheters hereafter "PENTARAY® Catheters" from Johnson & Johnson Medical Singapore, a division of Johnson & Johnson Pte Ltd ("JJMS"). We have passed on the Notice to all those who need to be aware within our organization, or to any organization where potentially affected devices may have been transferred.

Please sign, date and stamp below. Your signature provides confirmation that you have received and understood this notification.

_____ Customer Name

_____ Title

_____ Signature & Date

_____ Stamp *(Stamp shall bear facility name)*

Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
No. 2 International Business Park, #07-01, Tower One, The Strategy, Singapore 609930
Tel: +65 6827 6000 Fax: +65 6720 0750
Business Reg No. 52836279L Company Reg No. 197402104W