Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

URGENT FIELD SAFETY NOTICE

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.

April 14, 2016

Dear Valued Customer,

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.

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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 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.

Actions Requested on Your Part:

- Read and follow this Field Safety Notice carefully.
- Pass on this notice to anyone in your facility that needs to be informed.
- Maintain a copy of this letter with the PENTARAY® Catheters.
- **Sign and return the attached Acknowledgement Form in accordance with instructions on the form.**
- Maintain awareness of this Field Safety Notice

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.

Respectfully yours,

Vadim Kastin
Sr. Director, Quality & Compliance

Ahmed Abdelaal, MD, PhD
Director, Medical Affairs

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