Biosense Webster
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

URGENT FIELD SAFETY NOTICE

Biosense Webster, a division of Johnson & Johnson Medical NV/SA
CARTOSOUND® Module in conjunction with SOUNDSTAR® eco 8F and eco10F Catheters
Catalog No: C3SOUND, 10439236, 10439072, 10439011 & 10438577

September 21, 2015

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 the CARTOSOUND® Module of the CARTO® 3 EP Navigation System, Catalog No. C3SOUND, when used with the SOUNDSTAR® eco 8F and eco 10F Diagnostic Ultrasound Catheter, Catalog No. 10439236, 10439072, 10439011 & 10438577. This letter is not a product removal and it is not necessary for you to return any catheters.

Indications for Use:
The Biosense Webster SOUNDSTAR® eco 8F and eco 10F Diagnostic Ultrasound Catheters and related accessory devices are indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with compatible CARTO® 3 EP Navigation Systems, the SOUNDSTAR® eco 8Fand eco 10F Catheters provide location information.

The CARTOSOUND® Image Integration Module (CARTOSOUND® Module) is an add-on to the CARTO® 3 System. This module enables viewing of real-time ultrasound images during a CARTO® 3 Study, and adding 3D anatomical information derived from selected ultrasound frames to your maps.

Overview:
At Biosense Webster, we have an ongoing commitment to patient safety and continuously monitor the performance of our products to ensure we meet customer expectations. We have received one complaint of image disappearance from the cardiac ultrasound system when the CARTO® 3 EP Navigation System needed restarting. This occurred while the patient was experiencing pericardial effusion.

Based on medical evaluation of the health risk profile, Biosense Webster believes that the likelihood of harm to the patient is generally low if the ultrasound imaging is not available. However, if the intra-cardiac ultrasound is used to actively monitor an ongoing effusion, the lack of imaging may present a safety issue due to the delay in procuring the resources/equipment to use another imaging modality. Further to the reported complaint where this concomitant event occurred, Biosense Webster decided to initiate this Field Safety Notice to inform you about this occurrence.

Precautionary Safety Measures
We would like to emphasize the following statement: "The intra-cardiac ultrasound image will disappear if the CARTO® 3 EP Navigation System power is disrupted and this may present a

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safety issue if the electrophysiologist is using the ultrasound imaging to monitor the patient during the electrophysiology procedure. The ultrasound image will not reappear until the CARTO® 3 System is restored."

Biosense Webster will be updating the product labeling to include and further reinforce this precautionary safety information.

Actions Requested on Your Part:

- Read this Field Safety Notice carefully.
- Pass on this notice to anyone in your facility that needs to be informed of this issue, including appropriate clinical personnel involved in the use of SOUNDSTAR® eco Catheters.
- Review, complete, sign and return the attached Acknowledgement Form in accordance with the instructions on the form.
- Maintain a copy of this letter with the product.
- 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 European Regulatory Agencies and Notified Body have been notified and are aware that Biosense Webster is voluntarily providing this information. Other regulatory agencies are being notified as applicable.

Respectfully yours,

Vadim Kastin, M.Sc.
Sr. Director, Quality and Compliance

Ahmed Abdelaal, MD, PhD
Director, Medical Affairs

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