Biosense Webster, Inc.
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Biosense Webster
a Johnson & Johnson company

URGENT FIELD SAFETY CORRECTIVE ACTION
MEDICAL DEVICE – VOLUNTARY FIELD REMOVAL

Biosense Webster, Inc. MOBICATH™ Bi-Directional Guiding Sheath
Small Curve Catalog No: D140010
Large Curve Catalog No: D140011

November 12, 2012

Dear Valued Customer,

The purpose of this communication is to inform you that a voluntary field removal of the MOBICATH™ Bi-Directional Guiding Sheath Small Curve (D140010) and MOBICATH™ Bi-Directional Guiding Sheath Large Curve (D140011) has been issued. The affected products are manufactured by Greatbatch, Ltd., and Biosense Webster, Inc., as the authorized distributor of the affected products in your area, has been asked by Greatbatch, Ltd. to work with you to implement a field removal.

Overview:
This letter provides important information concerning the potential for defective product and instructions for returning product you may have at your facility.

Details on Affected Devices:

Indications for Use:

The MOBICATH™ Bi-Directional Guiding Sheath is intended for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum. The bi-directional guiding sheath system is intended for single use only.

Actions requested on your part:

- Read the "Description of the Problem" section below carefully.
- Sign and return the attached Voluntary Field Removal Certification Form in accordance with the instructions listed on the form.
- Arrange for return of any units of MOBICATH™ Bi-Directional Guiding Sheath Small Curve (D140010) and MOBICATH™ Bi-Directional Guiding Sheath Large Curve (D140011) 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 a copy of this letter with the affected MOBICATH™ Bi-Directional Guiding Sheath Small Curve (D140010) and MOBICATH™ Bi-Directional Guiding Sheath Large Curve (D140011) product.
- If any of the affected MOBICATH™ Bi-Directional Guiding Sheath Small Curve (D140010) and MOBICATH™ Bi-Directional Guiding Sheath Large Curve (D140011) product has been forwarded to another facility, contact that facility and arrange for the return.

Description of the Problem:
Recently, Biosense Webster, Inc. was informed by Greatbatch Medical, the manufacturer of the MOBICATH™ sheath, that they had observed some anomalies of the inner lumen of these products and upon implementation of a new inspection tool during visual inspection. The anomalies may include loose, string-like liner material, liner abrasion (fraying), and/or attached string-like liner material (from scratches or damage on the inner wall of sheath lumen).

To date, there have been no patient injuries or adverse events reported as a result of this issue and there have been no reported complaints for this type of defect. However, the severity of a potential patient adverse event could be high, since under the worst case scenario, a loose piece of the liner could be introduced into a patient during a procedure and potentially lead to a patient embolic event.

For these reasons, Biosense Webster, Inc and Greatbatch, Ltd are voluntarily recalling all lots of the MOBICATH™ Bi-Directional Guiding Sheath Small Curve (D140010) and MOBICATH™ Bi-Directional Guiding Sheath Large Curve (D140011).

Please return all lots of MOBICATH™ Bi-Directional Guiding Sheaths (including those that are expired if they are still within your possession) to Biosense Webster immediately by completing and signing the attached Voluntary Field Removal Certification Form. 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, Inc. and Greatbatch, Ltd. are 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,

Mina Ghajar
Vice President, Worldwide Quality and Compliance
Biosense Webster, Inc.

This confirms that this notice has been communicated to the appropriate Regulatory Agencies.

Enclosures