REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٥١/٢٥
رقم الصادر: ١٢/١/٢٢٢٥
بيروت، في: ٣ شرين الثاني ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Therapy tissue ablation, cardiac ablation system.
Thermocool SmartTouch catheter.

الجهاز المعني بالمتابعة:

- Therapy tissue ablation, cardiac ablation system. Thermocool SmartTouch catheter.
- Trade Mark: Biosense Webster Inc.
- Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الصنف الوارد أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

الجمهورية اللبنانية
وزارة الصحة العامة

مدير عام الصحة
د. وليد عمار

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Biosense Webster, Inc. a division of
Johnson & Johnson Medical NV/SV
Leonardo Da Vincilaan 15
BE – 1831 Diegem – Belgium

Biosense Webster

URGENT FIELD SAFETY NOTICE
MEDICAL DEVICE – VOLUNTARY FIELD REMOVAL

Biosense Webster, Inc. THERMOCOOL® SMARTTOUCH™ Catheter
Catalog No: D132701, D132702, D132703, D132704, D132705, D133601, D133602, D133603
Lot Numbers: All

September 3, 2013

Dear Valued Customer,

The purpose of this communication is to inform you that Biosense Webster, Inc., a division of Johnson & Johnson Medical NV/SA ("Biosense Webster") is initiating a voluntary field removal of the THERMOCOOL®SMARTTOUCH™ Catheter (All catalog numbers). This letter provides important information about the affected products and instructions on how you can return the product to Biosense Webster.

Overview:
After conducting a root cause analysis resulting from increased reports of irrigation fluid flow interruption, Biosense Webster has identified an issue in the production process of the THERMOCOOL® SMARTTOUCH™ Catheter, which can lead to occlusion of the irrigation fluid lumen. As a result, Biosense Webster is initiating a voluntary field removal of all affected products. To date, there have been no patient injuries or adverse events reported as a result of this defect. There is no concern for patients who have already been successfully treated with the device.

Details on Affected Devices:

Indications for Use:
The THERMOCOOL® SMARTTOUCH™ Catheter and related accessories are indicated for catheter-based cardiac electrophysiological mapping (stimulating and recording) and, when used in conjunction with a radiofrequency generator, for cardiac ablation.

Actions Requested on Your Part:

- Read the "Description of the Problem" section below carefully.
- Immediately identify and set aside all affected products in a manner that ensures the product will not be used. Maintain a copy of this letter with the affected THERMOCOOL® SMARTTOUCH™ Catheter 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 units of the THERMOCOOL® SMARTTOUCH™ Catheter 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 THERMOCOOL® SMARTTOUCH™ Catheters have been forwarded to another facility, contact that facility and arrange for the return.

Description of the Problem: Recently, Biosense Webster has seen an increase in reports of irrigation flow interruption. An Internal investigation identified a defect in the production process, which can lead to occlusion of the irrigation lumen.

To date, there have been no patient injuries or adverse events reported as a result of this defect. However, an irrigation fluid flow interruption has the potential to lead to overheating of the ablation tip and formation of char or thrombus, which in turn could pose a thromboembolic risk to the patient. For this reason, Biosense Webster is voluntarily removing all lots of the THERMOCOOL® SMARTTOUCH™ Catheter from the field. Please return all units of THERMOCOOL® SMARTTOUCH™ Catheter 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,

Mina Ghajar
Vice President, Worldwide Quality and Regulatory Compliance
Cardiovascular Care & Specialty Surgery Group