

URGENT FIELD SAFETY NOTICE
MEDICAL DEVICE – VOLUNTARY FIELD REMOVAL

Biosense Webster, a division of Johnson & Johnson Medical NV/SA
nMARQ® Circular Irrigated Catheter
Catalog No: D132214

June 24, 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 voluntary field removal of the nMARQ® Circular Irrigated Catheter, Catalog No. D132214. This letter provides important information about the affected products and instructions on how you can return them to Biosense Webster.

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. As a part of this commitment, we have decided to conduct a removal for all lots of the nMARQ® Circular Irrigated Catheter distributed since February 2, 2015.

This removal is due to an increased number of complaints related to low temperature issues due to thermocouple malfunction of the nMARQ® Circular Irrigated Catheter, which occurred during the same time period as reports of three (3) deaths. Two (2) of these deaths have been confirmed to be due to Atrio-Esophageal Fistula (AEF).

Details on Affected Devices:

Indications for Use:

The nMARQ® Circular Irrigated Catheter is indicated for use in catheter-based cardiac electrophysiological mapping (stimulating and recording) and, when used with the nMARQ® Multi-Channel RF Generator, for cardiac ablation. The nMARQ® Circular Irrigated Catheter provides location information when used with the CARTO® 3 EP Navigation System.

Cause of the Reported Complaints:

Biosense Webster has recently received an increased number of complaints related to a low temperature measurement anomaly at electrodes of the nMARQ® Circular Irrigated Catheter. During the same time period, we have also received three reports of deaths of patients who were treated with the nMARQ® Circular Irrigated Catheter. Two of these cases were confirmed to be caused by Atrio-Esophageal Fistula (AEF). Extensive ablation on the left atrial posterior wall may have been the main contributing factor to the AEFs in these two cases of persistent atrial fibrillation that were treated by pulmonary vein isolation and left atrial posterior wall ablation.

No direct link could be confirmed between the low temperature issue and the AEF as it was detected in only one of the two confirmed AEF cases. Therefore, the low temperature issue may be a secondary risk factor as it may affect power titration and delivery during radio frequency ablation.

As a result of these issues, Biosense Webster is voluntarily recalling the nMARQ[®] Circular Irrigated Catheter and is conducting a full investigation.

Actions Requested on Your Part:

- Read the “Overview” and “Cause of the Reported Complaints” section above 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 nMARQ[®] Circular Irrigated Catheters until all affected 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 affected units of the nMARQ[®] Circular Irrigated Catheters that you may have in your inventory per the instructions on the Voluntary Field Removal Certification Form.
- Pass this notice on 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 nMARQ[®] Circular Irrigated Catheters have been forwarded to another facility, contact that facility and arrange for their return.

Atrio-Esophageal Fistula is a rare, but known complication of cardiac ablation procedures. As part of regular clinical practice, physicians perform a follow up with their patients for any sign or symptom of esophageal injury.

Available Assistance:

For questions related to this issue, product return, and the Voluntary Field Removal Certification Form 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.

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.

Respectfully yours,



Vadim Kastin
Worldwide Director
Quality Assurance



Dr. Ahmed Abdelaal, MD, PhD
Director
WW Medical Affairs & Science