

URGENT: FIELD SAFETY NOTICE
SMARTABLATE™ RF GENERATOR SYSTEM Manufactured BY STOCKERT GmbH
(CATALOG NUMBER: M4900106, AND M4900107)

Note: This is additional labeling. Retain this letter with affected product.

July 27, 2017

Dear Doctor,

The purpose of this communication is to provide you with additional information for the safe and effective use of the SMARTABLATE™ System in a Stereotaxis™ RMT Lab. This information will be included in an updated labeling. The SMARTABLATE™ System is manufactured by Stockert GmbH and distributed by Biosense Webster, a division of Johnson & Johnson Medical NV/SA. This is not a product removal and it is not necessary for you to return any SMARTABLATE™ Systems.

Indications for Use:

The use of the SMARTABLATE™ RF Generator and all accessories is indicated in combination with compatible therapeutic catheters for use in conventional intracardiac RF ablation procedures.

The SMARTABLATE™ System's Foot Pedal has been designed to initiate or discontinue operation of the SMARTABLATE™ System. The Foot Pedal can be connected to the SMARTABLATE™ RF Generator, SMARTABLATE™ Irrigation Pump, or SMARTABLATE™ Remote Control.

Overview:

Biosense Webster received 2 complaints reporting that during an RMT procedure the SMARTABLATE™ RF Generator inadvertently delivered RF energy. None of the reported complaints resulted in adverse events or patient injury. Biosense Webster's investigation determined that if the SMARTABLATE™ System Foot Pedal is placed in close proximity and oriented toward the Stereotaxis™ magnets, the SMARTABLATE™ RF Generator may inadvertently deliver RF energy.

The error mode is easily recognized by a constant high-pitched tone and the red color of the ablation catheter tip on the CARTO® 3 System. The delivery of RF energy can be stopped immediately using the "Stop" button on the generator and/or the generator remote control. If the delivery of RF energy is not stopped there is potential risk to patients when the catheter is in use. To date, there has been no adverse event or patient injury associated with inadvertent ablation of the SMARTABLATE™ RF Generator in the Stereotaxis™ RMT lab.

Precautionary Safety Measures:

We would like to reinforce the following statement from the Warnings in the Instructions for Use (IFU) for the SMARTABLATE™ System Foot Pedal:

- Warnings: Magnetically conducting materials are to be kept away from the immediate foot pedal area.

In addition, we will be updating the Warnings in the IFU of the SMARTABLATE™ System Foot Pedal as follows:

- **Do not use the SMARTABLATE™ System Foot Pedal in the Stereotaxis™ RMT lab.** Using the Foot Pedal in RMT lab may inadvertently trigger the pedal to start delivering RF energy.

If you utilize the SMARTABLATE™ RF Generator in a Stereotaxis™ RMT lab ensure that the SMARTABLATE™ System Foot Pedal is not located within the Stereotaxis™ RMT lab. As indicated in the user manual, the SMARTABLATE™ RF Generator is able to be operated using the controls directly on the generator or the remote control for the system.

Based on Biosense Webster's investigation, including a medical evaluation of the health risk profile from the post-market reports, Biosense Webster believes the overall benefit risk profile of these RF generators remains in an acceptable range when used as directed in the indicated populations.

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 the SMARTABLATE™ RF Generator.
- Ensure that the SMARTABLATE™ System Foot Pedal is not located within your Stereotaxis™ RMT lab.
- Review, complete, sign and return the attached Acknowledgement Forms in accordance with the instructions on the form.
- Maintain a copy of this letter with the product.
- Maintain awareness of this Field Safety Notice.

Cause of the reported complaints:

The design of the SMARTABLATE™ Generator foot pedal has two magnetic switches. If the foot pedal is too close to the Stereotaxis™ RMT magnets and oriented toward the magnets, the magnetic field of the Stereotaxis™ RMT System can inadvertently activate the foot pedal, which begins ablation with the SMARTABLATE™ RF Generator.

Biosense Webster is committed to addressing this issue via this Field Safety Notification to all physicians using the SMARTABLATE™ RF Generator in a Stereotaxis™ RMT lab and updating the Instructions for Use to reflect the precautionary safety measures in this letter.

Available Assistance:

For questions related to this Field Safety Notice, please contact your Biosense Webster sales representative.

The relevant European Regulatory Agencies and Notified Bodies have been notified and are aware that Biosense Webster is voluntarily providing this information to customers. 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.

Yours sincerely,



Lee Ching Hwee
Regulatory Affairs Manager

cc: Chairman Medical Board
Relevant Head of Departments