Customer Communication

THERMOCOOL SMARTTOUCH® SF Uni-Directional Navigation Catheter &
THERMOCOOL SMARTTOUCH® SF Bi-Directional Navigation Catheter
Catalog No: D1347XX, D1348XX, D1347XXIL, D1348XXIL

October 31, 2018

Dear Valued Customer,

Through the post-market surveillance process, Biosense Webster, Inc. has observed a higher than expected reported rate of char formation for the THERMOCOOL SMARTTOUCH® SF Uni-Directional Navigation Catheter and the THERMOCOOL SMARTTOUCH® SF Bi-Directional Navigation Catheter (collectively, the "THERMOCOOL SMARTTOUCH® SF Catheters"). Although char formation by itself is not a patient adverse event, in rare circumstances it has the potential to contribute to patient adverse events. Despite the higher rate of char complaints, Biosense Webster has not received a commensurate higher rate of reports of patient adverse events for the THERMOCOOL SMARTTOUCH® SF Catheters than for other Biosense Webster irrigated catheters.

Multiple factors are related to the potential for excessive temperature and char formation at the ablation site. Biosense Webster has conducted an analysis of cases reporting char formation, including a detailed analysis of available CARTO® 3 EP Navigation System files. This analysis identified specific workflow practices and ablation parameters that may result in excessive heat generation at the site of ablation, leading to an increased risk for the formation of char. Any of these practices independently or in combination may result in the formation of char. These practices and parameters include:

1. Duration of ablation for greater than 60 seconds.
2. Contact force that exceeds 40 grams during ablation.
3. Narrow CARTO VISITAG™ Module settings on the CARTO® 3 System.
4. Use of lower than prescribed irrigation rates for specified power settings.
5. Elimination of pre-ablation high flow irrigation prior to onset of radiofrequency (RF) energy delivery.
6. Use of dilute irrigation fluid (i.e., half-normal saline).

For this reason, Biosense Webster is providing the following recommendations to reduce the potential for excessive temperature and char occurrence when using THERMOCOOL

SMARTTOUCH® SF Catheters. Workflow recommendations are summarized below to optimize the performance of the device:

1. Reduce ablation duration.
2. Reduce contact force to 5-25 grams.
3. Use only prescribed irrigation rate for a specified power output.
    - For power levels up to 30 W, a high flow rate of 8 mL/min should be used
    - For power levels 31W and above, a high flow rate of 15 mL/min should be used
4. Increase the irrigation to high flow rate starting up to 5 seconds before the onset of RF energy delivery. The application of RF energy must not be initiated until the increase in irrigation flow rate is confirmed by a minimum of 2^0C decrease in tip electrode temperature.
5. When using the CARTO VISITAG™ Module, the following settings are recommended:
    - Stability Distance: Maximum Change 2-3 mm
    - Stability Time: Minimum 3 seconds
    - VISITAG Module settings: Tag size of 3 mm
    - Force Over Time: 25% over 3grams
6. The combination of reduced stability range, extended stability time, or elevated threshold for force over time, may result in excessive temperature at ablation site.
7. Do not rely on the catheter tip temperature response to guide ablation. If temperature increases rapidly, stop RF application immediately. Monitoring the temperature behavior from the electrode during the application of RF energy ensures that the irrigation flow rate is being maintained.
8. Connect the irrigation tubing to a room temperature, heparinized (1 IU heparin/mL) normal saline bag using standard safe hospital practices. The use of dilute irrigation fluid (i.e., half-normal saline) has not been evaluated.

Next Steps:

1. Please maintain awareness of this letter and pass it on to anyone in your facility that needs to be informed.
2. Please complete, sign, and ***return the Business Reply Form.***

Thank you for your attention to this important matter. If you have any questions about the information in this letter, please contact your Biosense Webster field representative.

Notification of this FSN has been provided to the appropriate Regulatory Agency.

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Yours sincerely,

[redacted]

Lee Ching Hwee
Manager, Regulatory Affairs

cc: Chairman Medical Board
Relevant Head of Departments

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Business Reply Form

Medical Device - Customer Communication

Product Name/Code	Description of the Notification
THERMOCOOL SMARTTOUCH® SF Uni-Directional Navigation Catheter D1347XX, D1347XXIL (China Only) THERMOCOOL SMARTTOUCH® SF Bi-Directional Navigation Catheter D1348XX, D1348XXIL (China Only)	Customer Communication

Please return this completed Business Reply Form **within three (3) business days** to the Biosense Webster field representative or email to RA-ITSUS-JJMSingapo@its.jnj.com.

Please check and complete the following box to acknowledge receipt of notification:

☐ **I have read and understand the notification**

Name	Signature	Date
Healthcare Facility Details (Name, Address, Telephone, Email and Company Stamp)		

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