# URGENT Field Safety Notice: MEDICAL DEVICE PRODUCT REMOVAL

THERMOCOOL SMARTTOUCH™

Products Subject to this Removal

| Part Number (Catalog Number) | Part Description | Lot Numbers | UDI | Mfg. SRN |
|---|---|---|---|---|
| D134805 | THERMOCOOL SMARTTOUCH™catheter | 30779056L and 30779172L | 08468350a0010EQ | US-MF-000014219 |

September 2nd, 2022

Dear Valued Customer,

Biosense Webster Inc. is initiating a voluntary product removal of THERMOCOOL SMARTTOUCH™ Catheters (Catalog Number: D134805), Lot Numbers: 30779056L and 30779172L.You are receiving this letter because our records indicate that you have received one or more THERMOCOOL SMARTTOUCH™ that are included in this voluntary removal. This letter provides important information about the products subject to removal and instructions for returning the products.

**Reason For Removal**: We identified a manufacturing error that occurred to the specific lots of THERMOCOOL SMARTTOUCH™ catheters included in this field action that resulted in the potential contamination of the catheter irrigation path with foreign matter (cellulose fibers). No patient adverse events have been reported related to this issue.

**Potential Patient Impact:**
In most cases, due to the size of the cellulose material and the size of the irrigation holes, no significant amount of material will accumulate at the dome and the catheter will perform as expected. If the contamination is sufficient to cause irrigation issues, the catheter may fail initial flushing inspection by the user or, during the procedure, the catheter tip temperature will increase and provide an indication of occlusion limiting the ability to deliver ablation leading to a catheter exchange. Insufficient irrigation causes the temperature to rise to the generator cutoff limit (Refer to IFU for more information).
Due to the small volume of the cellulose in the dome (<0.12 ml) that can potentially enter the patient and the small diameter of the irrigation holes in relation to the cellulose fibers the probability of some particles being flushed through the irrigation of the catheter during the procedure is extremely rare. This material may have a thrombogenic or toxic effect for *the patient in very rare circumstances. To date, no complaints or patient adverse events have been reported related to* this issue.

**What Actions Are Required:** Do not use the product subject to this recall.
We are requesting that you segregate this product from your inventory and follow the instructions below.

1. Carefully review the information contained in this Medical Device Correction/Removal letter.
2. Ensure that anyone in your facility who needs to be aware of this notification reads the attached letter carefully.
3. Evaluate if you have inventory of THERMOCOOL SMARTTOUCH™ Catheters, lot numbers ***30779056L and 30779172L*** and segregate the product.
4. Return the above product immediately to your Biosense Webster representative.
5. Complete all fields of the attached Business Response Form and return it to *[Enter Local Affiliate Information].*

If you have additional questions about this letter, please contact your Biosense Webster representative.

Sincerely,

Maria Jose Arana

Digitally signed by Maria Jose Arana
DN: c=US, o=JNJ, ou=Subscribers, 0.9.2342.19200300.100.1.1=1055552, cn=Maria Jose Arana
Reason: I am approving this document
Date: 2022.09.02 11:49:31 -07'00'
Adobe Acrobat Reader version: 2020.013.20064

Maria Jose Arana
Sr. Director, Quality & Compliance Biosense Webster, Inc
31 Technology Drive, Suite 200 Irvine, CA 92618 USA

# BUSINESS REPLY FORM

**URGENT Field Safety Notice: MEDICAL DEVICE PRODUCT REMOVAL**

THERMOCOOL SMARTTOUCH™

**Catalog Numbe**r: D134805

**Lot Numbers**: 30779056L and 30779172L

Please complete this Business Reply Form (BRF) and return it to *[Enter Local Affiliate Information]* **within 3 business days upon receipt of this letter**.

**Biosense Webster, a division of Johnson & Johnson Medical NV/SA**
**Attn:** *[Affiliate to Enter Representative or Recall Coordinator Name here]*
**Mailing Address:** *[Affiliate to Enter contact information here]*
**e-Mail Address:** *[Affiliate to Enter contact information here]*
*Fax Number (If applicable), affiliate could enter here.*

**Part 1. Please check and complete the following box to acknowledge receipt of notification:**

☐ I have read and understand the notification

| | |
|---|---|
| Your Name/Title: | Facility/Business Name: |
| Signed*: | Date: |
| Facility/Business or shipping Address, City: | |
| Biosense Webster Sales Representative (if applicable): | |
| **Date the notification was received:** | |
| Telephone Number: | |
| **Your signature provides confirmation that you have received and understood this notification.* | |

**Please check one of the following boxes:**

☐ We do not have products subject to this recall
*There is no need to complete the table below*

☐ We have products subject to this recall and are returning the following devices:

*Please complete the table below and attach this BRF with your product return.*
*Remember to keep a copy of your completed BRF for your records.*
*Upon receipt, credit will be issued for the quantity of the devices that were returned (contact your local Biosense Webster Representative if you have any questions).*

| Serial No. | Qty to be returned | Serial No. | Qty to be returned |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |