

URGENT FIELD SAFETY NOTICE

MEDICAL DEVICE - RECALL

Biosense Webster, Inc.'s THERMOCOOL® SF NAV Diagnostic/Ablation Deflectable Tip Catheter, THERMOCOOL SMARTTOUCH® SF Uni-Directional Navigation Catheter, THERMOCOOL SMARTTOUCH® SF Bi-Directional Navigation Catheter, THERMOCOOL SMARTTOUCH® Uni-Directional Navigation Catheter, THERMOCOOL SMARTTOUCH® Bi-Directional Navigation Catheter

Catalog No: D134701, D134702, D134703, D134801, D134804, D134805, D133602, D133604IL, D133605IL, D132704, D132705, BNI35FJCT, BNI35DFCT, D131503, D131504

September 6, 2017

Dear Valued Customer,

The purpose of this communication is to inform you that Biosense Webster, Inc. ("Biosense Webster") is initiating a voluntary recall of some lots of the following devices:

- THERMOCOOL SMARTTOUCH® SF Uni-Directional Navigation Catheter (D134701, D134702, D134703)
- THERMOCOOL SMARTTOUCH® SF Bi-Directional Navigation Catheter (D134801, D134804, D134805)
- THERMOCOOL SMARTTOUCH® Uni-Directional Navigation Catheter (D133602, D133604IL, D133605IL)
- THERMOCOOL SMARTTOUCH® Bi-Directional Navigation Catheters (D132704, D132705)
- THERMOCOOL® SF NAV Diagnostic/Ablation Deflectable Tip Catheter (BNI35FJCT, BNI35DFCT, D131503, D131504)

This letter provides important information about the products subject to this recall and instructions on returning 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. We have recently received an increased number of complaints related to the display of Alert 402 on the CARTO® 3 System for certain lots of THERMOCOOL brand catheters.

Alert 402 implies a 'Map: magnetic distortion' when connected to CARTO® 3 System. Magnetic distortion may result in inaccurate catheter tip location information on the CARTO® 3 System. This issue may subsequently lead the physician to ablate in an unintended area when delivering RF energy. The CARTO® 3 System User Manual provides steps for resolving this alert, but for the catheters subject to this recall those steps are not effective. Severe complications (e.g. AV block, vascular injury, cardiac perforation) are highly unlikely but may occur due to the physician selecting higher than required power settings for a given anatomical area. When the alert message is displayed, it is recommended to verify the location of the catheter using fluoroscopy, as well as using ECG signals. These steps minimize the risk of potential harm to the patient.

One adverse event of pericardial effusion requiring pericardiocentesis with no further patient consequences was reported to be potentially associated with this issue. Due to the potential safety risk associated with inaccurate catheter tip location, we decided to conduct a voluntary recall (removal) for all devices within these specific lots. **This recall does not apply to all THERMOCOOL® catheters, but only to the lots identified in this letter.**

Biosense Webster, Inc.
33 Technology Drive,
Irvine, CA 92618
www.biosensewebster.com
TEL: 1-800-729-9010

Lots Subject to Removal:

Please refer to Appendix I attached.

Why Are You Being Contacted

You are receiving this letter because our records indicate you have received devices subject to this recall.

What Actions Are Required

- Complete Business Reply Form (BRF) and return it to local field action coordinator.
- Evaluate your current inventory of catheters with the identified lot numbers. If you have inventory from these lots, remove and return products immediately.
- To return the products, complete the BRF and follow the product return instructions contained within. Contact your local Sales Representative if further assistance is needed to complete the BRF or if you have questions on product return.
- Complete the BRF within three (3) business days even if you no longer have inventory of the identified products.
- Ensure that anyone in your facility who needs to be aware of this notification reads this letter carefully.
- Maintain a copy of this communication where the inventory of lots identified in this letter is located until all products are returned.

Available Assistance:

For questions related to this issue and product recall please contact your Biosense Webster sales representative.

The appropriate Health Authorities have been notified and are aware that Biosense Webster is voluntarily recalling this product.

Biosense Webster regrets any inconvenience that this field action may cause. Patient health and safety is our first priority. We know that you place high value in our products and we appreciate your cooperation in this matter.

Respectfully yours,

Atenea Cenicerros
Atenea Cenicerros
Director, Quality Systems (Escalation & Field Action)
Biosense Webster, Inc

Appendix 1

1. THERMOCOOL SMARTTOUCH® SF Uni-Directional Navigation Catheter (D134701, D134702, D134703)

17682851L	17682730L	17685880L	17685740L
17685692L	17680131L	17685811L	17685897L
17685789L	17676998L	17685889L	17685896L
17685792L	17685741L	17685758L	17685846L
17689428L	17689420L	17685881L	17680081L
17689454L	17682788L	17685853L	17685750L
17692068L	17689430L	17680080L	17682787L
17692069L	17689463L	17689421L	17685691L

2. THERMOCOOL SMARTTOUCH® SF Bi-Directional Navigation Catheter (D134801, D134804, D134805)

17673851L	17685693L	17689360L	17689462L	17689532L	17690548L	17692070L	17692193L	17695495L	17698306L	17698457L
17676952L	17685715L	17689361L	17689477L	17689533L	17690549L	17692099L	17692194L	17695519L	17698307L	17698458L
17677062L	17685742L	17689369L	17689479L	17689534L	17690550L	17692101L	17692196L	17695520L	17698308L	17698460L
17677144L	17685763L	17689370L	17689485L	17689535L	17690551L	17692102L	17692197L	17695522L	17698339L	17698461L
17680082L	17685770L	17689371L	17689486L	17689536L	17692025L	17692104L	17692205L	17695523L	17698340L	17701761L
17680149L	17685772L	17689372L	17689487L	17689537L	17692026L	17692105L	17692209L	17695524L	17698341L	17701765L
17680198L	17685795L	17689380L	17689488L	17689538L	17692027L	17692107L	17692226L	17695525L	17698343L	17701766L
17680199L	17685805L	17689381L	17689489L	17689539L	17692028L	17692109L	17692228L	17695526L	17698344L	17701769L
17682731L	17685806L	17689387L	17689490L	17689540L	17692037L	17692110L	17692229L	17695564L	17698347L	17701771L
17682732L	17685816L	17689390L	17689491L	17689541L	17692053L	17692116L	17692230L	17695565L	17698348L	17701773L
17682733L	17685843L	17689392L	17689492L	17690527L	17692054L	17692139L	17692231L	17695623L	17698378L	17701774L
17682789L	17685844L	17689396L	17689493L	17690528L	17692057L	17692140L	17692237L	17695626L	17698382L	17701775L
17682790L	17685859L	17689403L	17689494L	17690529L	17692058L	17692142L	17692238L	17695628L	17698383L	17701798L
17682820L	17685883L	17689405L	17689496L	17690530L	17692059L	17692149L	17695427L	17695633L	17698384L	17701799L
17682853L	17685885L	17689413L	17689497L	17690531L	17692060L	17692150L	17695453L	17697886L	17698385L	17701801L
17682854L	17685886L	17689444L	17689505L	17690533L	17692061L	17692151L	17695455L	17697887L	17698417L	17701802L
17682855L	17685887L	17689445L	17689506L	17690537L	17692062L	17692155L	17695456L	17697888L	17698418L	17701806L
17682858L	17685901L	17689447L	17689512L	17690539L	17692063L	17692159L	17695458L	17698298L	17698420L	17701810L
17682910L	17685902L	17689449L	17689529L	17690540L	17692064L	17692186L	17695489L	17698299L	17698423L	17701812L
17682911L	17689355L	17689451L	17689530L	17690541L	17692065L	17692189L	17695491L	17698302L	17698425L	17701834L
17682912L	17689358L	17689461L	17689531L	17690542L	17692066L	17692191L	17695492L	17698303L	17698454L	17701842L

3. THERMOCOOL SMARTTOUCH® Bi-Directional Navigation Catheter (D132704, D132705)

17445775M	17694994M	17697951M
17685286M	17697907M	17697991M
17691864M	17697910M	17697994M

4. THERMOCOOL SMARTTOUCH® Uni-Directional Navigation Catheter (D133602, D133604IL, D133605IL)

17688816M	17697930M	17697966M
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5. THERMOCOOL® SF NAV Catheters (BNI35FJCT, BNI35DFCT, D131503, D131504)

17637495L	17638389L	17640039L	17640494L	17640952L
17638118L	17639706L	17640040L	17640742L	17640953L
17638387L	17639707L	17640041L	17640743L	17640954L
17638388L	17639708L	17640490L	17640744L	17643130L