FDA Home<sup>3</sup> Medical Devices<sup>4</sup> Databases<sup>5</sup>

Class 2 Device Recall THERMOCOOL SMARTTOUCH NAVIGATION Catheter
510(k)<sup>7</sup>|DeNovo<sup>8</sup>|Registration & Listing<sup>9</sup>|Adverse Events<sup>10</sup>|Recalls<sup>11</sup>|PMA<sup>12</sup>|Classification<sup>13</sup>|Standards<sup>14</sup>

21<sup>15</sup>

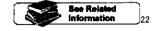
CFR Title Radiation-Emitting Products<sup>16</sup>

X-Ray Medsun Assembler<sup>17</sup> Reports<sup>18</sup> |CLIA<sup>19</sup>|TPLC<sup>20</sup>|Inspections<sup>21</sup>

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Class 2 Recall THERMOCOOL SMARTTOUCH **NAVIGATION Catheter** 



**Date Posted** 

October 27, 2014

Recall Status<sup>1</sup>

Open

**Recall Number** 

Z-0139-2015

Recall Event ID

69532<sup>23</sup>

Premarket Approval **PMA Numbers** 

P03003124 P04003625

**Product Classification** 

Cardiac Ablation Percutaneous Catheter<sup>26</sup> - Product Code LPB<sup>27</sup>

**Product** 

ThermoCool SmartTouch Navigation Catheters, Catalog No. D132701, D132702,

D132703, D132704, D132705, D133601, D133602, D133603.

Code Information

Catalog No. D132701, D132702, D132703, D132704, D132705, D133601, D133602,

D133603 All Lots manufactured from launch (Dec 2010)

Recalling Firm/ Manufacturer

Biosense Webster, Inc.

15715 Arrow Hwy

Irwindale, California 91706-2006

Manufacturer Reason

for Recall

The recall was initiated because Biosense Webster is providing additional labeling for the

safe and effective use of the ThermoCool SmartTouch Catheter.

**FDA Determined** 

Cause 2

TRAINING: Use Error

Action

A customer notification letter dated October 19, 2014, will be sent to all customers who purchased the Biosense Webster's ThermoCool SmartTouch Catheter Family. The letter informs the customers of the additional information for the safe and effective use of the ThermoCool SmartTouch Catheter, which will be included in the updated labeling. The letter informs the customers of the problems identified and the actions to be taken. Customers with questions related to the recall letter are instructed to contact their Biosense Webster sales representative or call (866) 473-7823, Monday through Friday from 7am to 8pm EST.

**Quantity in Commerce** 

173,329 units total (21,812 units in US)

Distribution

Nationwide Distribution

Total Product Life Cycle TPLC Device Report<sup>28</sup>

PMA Database

PMAs with Product Code = LPB and Applicant = BIOSENSE WEBSTER, INC.30

## Links on this page:

- 1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
- 2. http://www.addthis.com/bookmark.php

For details about termination of a recall see <u>Code of Federal Regulations (CFR) Title 21 §7.55</u><sup>29</sup>

<sup>&</sup>lt;sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.