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Class 2 Device Recall THERMOCOOL SMARTTOUCH NAVIGATION Catheter



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Class 2 Recall THERMOCOOL SMARTTOUCH NAVIGATION Catheter



Date Posted	October 27, 2014
Recall Status¹	Open
Recall Number	Z-0139-2015
Recall Event ID	69532 ²³
Premarket Approval PMA Numbers	P030031 ²⁴ P040036 ²⁵
Product Classification	Cardiac Ablation Percutaneous Catheter ²⁶ - Product Code LPB ²⁷
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 Cause²	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 ²⁸

¹ For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55](#)²⁹

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

PMA Database [PMAs with Product Code = LPB and Applicant = BIOSENSE WEBSTER, INC.](#)³⁰

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