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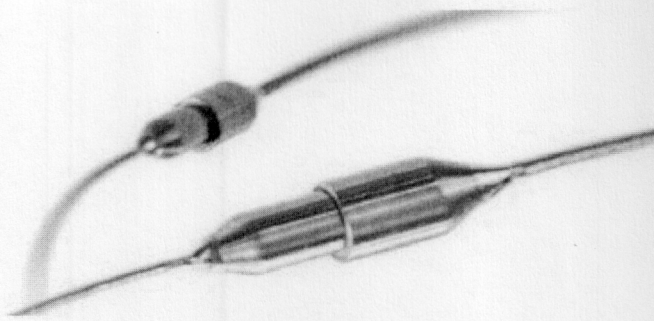
SentreHeart Recalls FindrWIRZ Guidewire System due to Coating Separation

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The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product:

- FindrWIRZ Guidewire System
- Lot Numbers: 01160568, 02160586, (no products shipped from this lot) 07160639-150
- Distribution Dates: June 1, 2016 to September 26, 2016
- Manufacturing Dates: January 4, 2016 to July 22, 2016
- Devices Recalled in the U.S.: 98



Device Use

The FindrWIRZ Guidewire System is intended for use during minimally invasive procedures in the cerebrovascular, cardiovascular and peripheral vascular systems. The system helps the positioning of over-the-wire catheters through the insertion of a thin flexible tube into arteries of the leg or wrist. This device has a hydrophilic lubricious coating, polytetrafluoroethylene (PTFE), to reduce friction between the device and blood vessels.

Reason for Recall

SentreHeart is recalling the FindrWIRZ Guidewire System because the PTFE coating may separate (e.g., peel, flake, shed, delaminate, slough off) from the packaging and potentially cause serious injuries to patients. Coating separation may be caused by issues with the device design or manufacturing processes. Small pieces of the coating could break away and travel elsewhere in the body, or the exposed wire beneath the coating could cause dangerous blood clots in the patient's bloodstream and can lead to serious adverse health consequences including embolism, stroke, or death.

Who May be Affected

- Health care providers using this device during vascular procedures
- All patient groups undergoing procedures involving the FindrWIRZ Guidewire System

What to Do

On September 29, 2016, SentreHeart sent an Urgent Medical Device Voluntary Recall letter to all affected customers. The letter asked customers to:

- Identify and stop using the affected products
- Return the affected products to SentreHEART immediately
- Complete and return the response form via fax 650-354-1204 or email to customerservice@sentreheart.com

Contact Information

Health care professionals and consumers with questions are instructed to contact SentreHeart at (650)-241-6008 with any questions related to this recall.

Date Recall Initiated

September 29, 2016

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) either online, by regular mail or by FAX to 1-800-FDA-0178.

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