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**Subject:** Medical Device Recall - Boston Scientific Corp. - RotoWire Elite core wires  
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# RotaWire Elite Guidewire and wireClip Torquer Guidewire by Boston Scientific: Recall - Wires May Break and Separate from the Rotablator System

AUDIENCE: Risk Manager, Biomedical Engineering, Cardiology, Pharmacy

ISSUE: Boston Scientific Corp is recalling RotaWire 'Elite' core wires because they may crack and separate from the rest of the Rotablator Rotational Atherectomy System and cause serious injury such as tamponade (blood in the sac around the heart causing decreased heart function), myocardial infarction (heart attack), and migration of wire fragments elsewhere in the body. The company has received three reports of this issue occurring, including one patient death following medical intervention to remove the broken wire. Other interventions have included purposefully blocking off (occluding) the affected artery, placing stents into the affected artery, and emergency heart surgery.

The use of affected product may cause serious adverse health consequences, including death.

BACKGROUND: The RotaWire Elite Guidewire and wireClip Torquer Guidewire are components of the Rotablator Rotational Atherectomy System. The device is used to open narrowed arteries and improve blood flow to the heart by cutting plaque from the artery wall (atherectomy).

RECOMMENDATION: Boston Scientific sent an Urgent Medical Device Recall Removal - Immediate Action Required letter to customers beginning October 9, 2015. The letter listed the following instructions:

- Stop distributing and using these devices immediately.
- Return all affected products to Boston Scientific following the recall instructions in the letter.
- Distributors should notify any customer who may have received the product.
- Return the Recall Removal Reply Verification Tracking Form to Boston Scientific via email: [maplegrovesfieldactioncenter@bsci.com](mailto:maplegrovesfieldactioncenter@bsci.com), or fax: 1-866-213-1806.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report](http://www.fda.gov/MedWatch/report)
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including links to the recall notice, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm474632.htm>

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