Boston Scientific

# Voluntary Recall of Fetch™ 2 Aspiration Catheter

MARLBOROUGH, Mass., April 8, 2016 /PRNewswire/ -- Boston Scientific (NYSE: BSX) has initiated a global, voluntary recall of all models of its Fetch™ 2 Aspiration Catheter, a thrombectomy catheter used during procedures to remove small blood clots from coronary arteries. The Fetch 2 catheters were recalled on March 22, 2016, due to complaints of shaft breakage. The U.S. Food and Drug Administration (FDA) classified the action as a Class 1 recall. This recall designation means that the use of the device exposes the patient to a reasonable chance of a serious adverse health consequence or death.

There have been no reports of patient injury or death, and there is no risk to patients who previously underwent a thrombectomy procedure with the Fetch 2 catheter. All reports of shaft breakage happened during the procedure, and the broken section was either removed while still partially attached to the catheter shaft or retrieved with a snare, without further patient complications. While unreported, the most severe potential outcome of this breakage is embolism of device fragments, which could lead to obstruction of blood flow or additional intervention to remove a device fragment surgically.

As part of the recall, all affected healthcare facilities were advised to discontinue use of all Fetch 2 catheters immediately and return unused product to Boston Scientific. Because Boston Scientific acquired the Fetch 2 catheter product line from Bayer Medical Care Inc., all recalled inventory is packaged and labeled as Bayer product. This device was manufactured between June 11, 2014 and February 19, 2016. There are currently 21,155 devices on the market subject to this recall.

**Fetch 2 Catheter UPNs**

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| FETCH2 US<br>109400-001 |
| FETCH2 OUS<br>109400-002 |
| FETCH2 Canada<br>109400-003 |
| FETCH2 Japan<br>109400-004 |
| FETCH2 EU<br>109400-005 |

Physicians and healthcare facilities can direct questions to their Boston Scientific representative or, call 1-800-811-3211. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm 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

or

- Health care professionals and consumers may report serious adverse events or product quality problems with the use of this product to Boston Scientific by calling 1-800-811-3211 and to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

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