U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Boston Scientific Corporation Recalls Fetch 2 Aspiration Catheter Due to Shaft Breakage

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

Recalled Product:

- Fetch 2 Aspiration Catheter
- Model number: 109400-001
- Lot numbers: **See list below**
- Manufacturing dates: June 11, 2014 to February 19, 2016
- Distribution dates: June 24, 2014 to March 11, 2016
- Devices recalled in the U.S.: 17,455 nationwide, including D.C. and the Virgin Islands

Device Use

The Fetch 2 Aspiration Catheter is intended to remove small blood clots from peripheral veins and coronary arteries (thrombectomy) to restore blood flow to the heart.

Reason for Recall

Boston Scientific Corporation is recalling the Fetch 2 Aspiration Catheter because the catheter shaft may break at various points along the device, before or during procedures. If breakage occurs while the device is in a patient, pieces of the catheter may block blood supply to the heart or blood vessels. This could result in the need for additional medical procedures, patient injury, or death.

Who May be Affected

- Patient groups undergoing a thrombectomy procedure using this device
- Health care professionals using this device to conduct thrombectomy procedures

What to Do

On April 8, 2016, Boston Scientific Corporation issued a **news release (http://news.bostonscientific.com/2016-04-08-Voluntary-Recall-of-Fetch-2-Aspiration-Catheter) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** advising all affected customers to:

- Discontinue the use of all affected products immediately
- Return unused products to Boston Scientific Corporation
- Contact a Boston Scientific Corporation representative at 1-800-811-3211 for questions

Date Recall Initiated:

March 22, 2016

Additional Resources

- **Boston Scientific Corporation News Release (http://news.bostonscientific.com/2016-04-08-Voluntary-Recall-of-Fetch-2-Aspiration-Catheter) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**

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.

Lot Numbers:

129496, 130473, 139577, 141089, 141570, 142212, 145520, 145783, 148859, 149263, 153368, 153847, 154650, 154786, 155675, 155908, 156690, 156822, 158009, 158494, 158598, 159368, 159902, 160530, 161209, 162814, 162893, 162943, 163987, 164148, 166281, 166646, 168472, 169484, 169638, 170169, 170464, 170471, 171178, 171385, 171800, 172254, 172375, 172518, 172831, 173151, 173398, 173897, 173902, 174153, 174431, 174617, 174619, 174721, 174722, 174727, 174728, 174804, 174805, 175189, 175190, 175782, 175783, 176048, 176221, 176385, 176437, 176438, 176843, 177414, 177415, 177970, 177971, 178252, 178253, 178254, 178764, 178848, 178849, 178894, 178935, 178936, 180305, 180306, 180367, 180368, 180370, 180747, 181168, 181169, 181285, 181933, 181934, 182257, 182258, 182259, 182927, 183220, 183221, 183451, 183452, 183539, 183540, 183974, 184091, 184092, 184093, 184244, 184245, 184478, 184479, 184531, 184532, 184633, 184634, 185180, 185182, 185354, 185355, 185395, 185396, 185397, 185632, 185633, 185958, 185959,

185960, 186145, 186146, 186147, 186148, 186149, 186150, 186151, 186152, 186153, 186154, 186326, 186338, 186498, 186553, 186554, 186555, 186556, 186557, 186558, 186559, 186732, 186733, 186765, 186766, 186767, 186768, 186769, 186839, 186876, 186877, 186938, 186939, 186940, 187157, 187158, 187238, 187239, 187778, 187779, 187811, 187812, 188206, 188207, 188208, 188758, 188759, 189082, 189230, 189231, 189232, 189233, 189234, 189235, 189236, 189237, 189238, 189239, 189240, 189241, 189242, 189243, 189244, 189245, 189273, 189274, 189374, 191401, 191402, 191403, 191404, 191405, 191406, 191407, 191408, 191409, 191802, 191803, 192256, 192257, 192355, 192356, 192466, 192467, 192468, 192469, 192470, 192471, 192483, 192484, 192485, 192486, 192777, 192778, 192779, 192780, 192784, 192785, 192786, 192914, 192915, 192916, 192917, 192918, 192919, 192921, 192922, 192923, 192925, 192926, 192927, 192928, 192929, 192930, 192931, 192932, 192933, 193146, 193147, 193148, 193149, 193150, 193151, 193152, 193153, 193154, 193155, 193156, 193158, 193159, 193160, 193161, 193162, 193356, 193357, 193358, 193360, 193361, 193362, 193363, 193364, 193449, 193450, 193451, 193952, 193953, 193954, 193955, 193956, 193957, 193958, 193959, 193960, 193961, 193962, 193963, 193964, 193965, 193966, 193967, 193968, 193969, 193970, 18737680, 18760027, 18760028, 18844376, 18881248, 18939879

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)

2015 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm429489.htm)

2014 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm384921.htm)