



Urgent Medical Device Recall Notice - Immediate Action Required

Fetch™ 2 Aspiration Catheter

March 22, 2016

Dear Materials Manager / Field Action Contact:

Boston Scientific is voluntarily implementing a Medical Device Recall for all models of the Fetch™ 2 Aspiration Catheter as a result of receiving reports from the field of catheter shaft breaks; including cases requiring the use of a snare or other intervention to retrieve the broken shaft from the patient. No serious patient injuries have been reported.

This recall affects all models and batches of Fetch2 Aspiration Catheters manufactured to date. Because Boston Scientific acquired the Fetch2 Aspiration Catheter product line from Bayer Medical Care Inc., all recalled inventory is packaged and labeled as Bayer product.

All affected Fetch2 products are listed within the enclosed **Affected Product Listing**. If affected product is identified within your inventory, please segregate the product immediately and return it to Boston Scientific in accordance with the enclosed **Urgent Medical Device Recall Instructions**. You will receive a credit for all affected product that is returned to Boston Scientific.

Affected Product Listing

Product Description	Material Number (UPN)	Batch	Batch Expiration Date Range
Fetch™ 2 Aspiration Catheter	109400-002 109400-003 109400-004 109400-005	See Attached Affected Product Listing	March 2016 – June 2017

Further distribution or use of any remaining product affected by this recall should cease immediately.

If you are a distributor, please note that this recall is to the hospital level and this notification should be forwarded to all of your customers.

We are also notifying regulatory authorities in affected geographies of this recall as required.

Boston Scientific is committed to continuing to offer products that meet the highest quality standards and we appreciate your understanding as action is taken to ensure patient safety and customer satisfaction. If you have additional questions regarding this communication, please contact your local Boston Scientific Sales Representative or the Boston Scientific Field Action Center.

Sincerely,

[Contact]

[Title]

[Phone]

[Email]

Encl: Affected Product Listing
Recall Instructions
Account Reply Verification Tracking Form

Affected Product Listing
Fetch™ 2 Aspiration Catheters

UPN: 109400-002									
Batch	Batch	Batch	Batch	Batch	Batch	Batch	Batch	Batch	Batch
154901	172256	174383	176473	181497	182925	185644	186333	192478	193972
155010	174316	176146	180748	181498	183830	186329	186334	192479	
158949	174358	176324	180841	182438	183977	186330	186335	192480	
160734	174381	176441	180842	182439	183978	186331	189612	192481	
161256	174382	176442	180843	182923	185398	186332	189613	192482	

UPN: 109400-003									
Batch	Batch	Batch	Batch	Batch	Batch	Batch	Batch	Batch	Batch
171807	174834	178152	180301	181688	185645	186327	187539	190073	193444
171869									

UPN: 109400-004									
Batch	Batch	Batch	Batch	Batch	Batch	Batch	Batch	Batch	Batch
176327	186328	188803	188805	188807	188809	188811	188813	188815	188817
186144	186734	188804	188806	188808	188810	188812	188814	188816	

UPN: 109400-005									
Batch	Batch	Batch	Batch	Batch	Batch	Batch	Batch	Batch	Batch
187150	187509	190463	190465	190982	190984	192782	193447	193973	194039
187505	187510	190464	190466	190983	192781	192783			

Urgent Medical Device Recall Instructions

The Reply Verification Tracking Form enclosed with this Recall Notice must be completed and returned by **22nd April, 2016** **even if you do not have any of the devices from the affected batches.**

1. **Immediately discontinue use of and segregate affected product.**
 - Immediately remove all affected product from your inventory.
 - Segregate this product in a secure location for return to Boston Scientific.
2. **Complete and return the Reply Verification Tracking Form (RVTF).**
 - Complete the enclosed Reply Verification Tracking Form (even if you do not have any product to return) by following the directions on this page and the Reply Verification Tracking Form.
 - Return the Account Reply Verification Tracking Form:

Email:

or

Fax:

Please email or fax your Account Reply Verification Tracking Form(s) immediately. You will be contacted by Boston Scientific and provided a Returned Goods Authorization (RGA) Number after your RVTF is received. When returning the product, place the original form with returned products.

3. **Package/Ship the Affected Product.**
 - Package any product that is being returned in an appropriate shipping box.
 - Affix a shipping label to the outside of the shipping box.
 - Write the **RGA number** in large print on the outside of the box, either on or near the shipping label.
 - Seal the box, and return it to: [Address]