Boston Scientific

Urgent Medical Device Product Removal - Immediate Action Required
SpyScope™ DS Access and Delivery Catheter

21 December 2017

Dear Doctor,

Boston Scientific is initiating a voluntary removal of certain batches of SpyScope DS Catheters. An internal investigation found that the working channel sleeve may not be adequately bonded inside of these devices. This may result in the working channel sleeve protruding from the camera cap located at the distal tip of the catheter.

The most common injury reported has been minor tissue damage caused by the protruding working channel sleeve scraping along the duct walls during the procedure. The most serious injury that has been reported is significant bleeding resulting in medical or surgical intervention, including hospital admission and additional procedures.

This removal affects only the UPN and batches listed in the table below and Attachment 1. No other UPNs or batches are impacted by this notification.

Affected Product Listing

Product Description	Material Number (UPN)	Batch	Expiration Date Range
SpyScope™ DS *Access and Delivery Catheter*	M00546600	See Attachment 1	See Attachment 1

If you identify any product from the affected batches within your inventory, please segregate the affected product immediately and return it to Boston Scientific in accordance with the enclosed instructions. You will receive replacements for all removed product returned to Boston Scientific.

If you are a distributor, please note that this removal is to the customer level. Please notify any customer who has received affected product.

Boston Scientific is notifying worldwide regulatory authorities of this removal as required.

Please read carefully through the enclosed instructions. Your local Sales Representative can answer any questions that you may have regarding this removal. Please pass this notice to any healthcare professional from your organization that needs to be aware and to any organization where the potentially affected devices have been transferred (if appropriate). Please provide Boston Scientific with details of any affected devices that have been transferred to other organizations (if appropriate).

We regret any inconvenience that this action may cause, and we appreciate your understanding as we take action to ensure patient safety and customer satisfaction. We are committed to continuing to offer products that meet the highest quality standards that you expect from Boston Scientific.

Sincerely,

[redacted]

Elaine Seak
Senior Territory Manager, Endoscopy

Encl: Removal Instructions
Reply Form

Copy: Chairman Medical Board and relevant Head of Departments

Urgent Medical Device Removal - Instructions

The Reply Verification Tracking Form enclosed with this Notice must be completed and returned **even if you do not have any remaining removed units**.

1. **Immediately discontinue use of and segregate removed product.**
   - Immediately remove all affected removed product from your inventory.
   - Segregate this product in a secure location for return to Boston Scientific.
   - If you are a distributor, please note that the removal depth is to the hospital level and the removal notification should be forwarded to your customers.

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, following the directions on this page and on the Reply Verification Tracking Form.
   - Verify by product batch/lot number in product table to determine if the batch within your inventory is affected. If so, indicate on your Verification Form the quantity of units from each batch that you will be returning.
   - Return the Reply Verification Tracking Form as Boston Scientific Sale Representative.

Attachment 1 – Affected Product Listing

UPN	Batch				Expiration Date Range
SpyScope™ DS *Access and Delivery Catheter* M00546600	21071349	21186002	21264281	21339969	August 29, 2019 To November 21, 2019
	21072506	21186199	21264826	21346857	
	21097205	21186874	21268628	21348369	
	21099913	21189216	21269880	21348655	
	21101809	21192332	21275009	21351508	
	21104860	21194784	21279183	21354138	
	21106212	21196427	21280166	21355128	
	21111667	21196815	21282419	21356067	
	21112353	21197475	21284302	21359495	
	21120166	21198355	21285174	21360857	
	21121467	21201164	21285708	21361914	
	21125598	21203598	21287283	21366469	
	21129863	21204762	21291325	21368941	
	21134585	21207916	21291903	21372468	
	21136699	21210287	21295990	21373463	
	21139834	21212151	21301969	21373946	
	21143014	21215249	21302617	21377827	
	21150144	21216252	21305351	21380698	
	21150932	21218379	21307321	21381638	
	21156170	21220903	21308963	21385327	
	21159396	21221247	21310860	21387164	
	21160496	21226282	21311361	21387745	
	21163684	21227147	21313025	21391319	
	21164861	21233949	21313392	21393249	
	21165772	21235402	21315518	21393900	
	21168729	21237929	21316968	21395015	
	21169977	21240546	21317017	21395016	
	21170814	21241587	21322828	21401047	
	21174026	21245984	21324197	21401048	
	21175845	21246770	21324851	21401049	
	21176842	21249893	21329021	21413940	
	21180343	21251968	21329708	21414750	
	21181148	21253001	21332229	21420240	
	21181151	21254244	21334848		
	21181253	21257214	21335787		
	21181677	21260915	21338493		

Boston Scientific

RECALL REMOVAL REPLY VERIFICATION TRACKING FORM
PRODUCT NAME: 92196708-FA – SpyScope Working Channel Sleeve (WCS) Protrusion

Instructions: This form must be completed and returned in all cases even if you do not have any affected product.
Immediately complete form and Scan/e-mail to: OR Fax to #:

Account #:	Customer Name:

Contact Name:
Address:
City: State: Province: Postal Code:
Country:

Our records indicate you have received the following affected product:

UPN/Material Number	Lot/Batch/Serial Number	Quantity Shipped	Shipment Date	P.O. Number	Quantity Single Units to be Returned

Section to be filled out by Customer:

1. Please Indicate:

☐ We have checked all areas where affected product could be located and have determined we do not have any affected product.

OR

☐ We have found affected product and have quarantined as instructed in this Recall Notification. Please indicate the quantity to be returned (in single units) in the above table. To return affected product, follow the instructions provided within this notification or from your (country) local office.

Please also indicate:

Are you a Distributor? ☐ Yes, and we have notified all customers that have been shipped/sold affected product
☐ No

2. Sign and Date to acknowledge this Field Action Notification (must be completed):

Print Name:_____ Signature:_____ Date:_____

Phone:_____ Fax:_____ E-mail:_____