



Urgent Medical Device Removal - Immediate Action Required
Extractor™ Pro RX-S
Retrieval Balloon Catheter

DATE

Dear Materials Manager / Field Action Contact:

Boston Scientific is implementing a voluntary Medical Device Removal on two lots of Extractor Pro RX-S Retrieval Balloon Catheters. The labeling on the affected devices incorrectly identifies the injection location as “above” the balloon when it should be below the balloon and “below” the balloon when it should be above the balloon.

If the injection location is above or below where labeled, then the user will see contrast emerge from the other location, but still within the lumen. This may result in a minor procedure delay due to the need for device exchange.

This removal affects only the UPNs and batches listed in the table below. **Further distribution or use of any remaining product affected by this removal should cease immediately.**

Affected Product Listing

Product Description	Material Number (UPN)	Batch	Batch Expiration Date
Extractor™ Pro RX-S Injects Above 9-12mm	M00547300	19343203	6/30/2018
Extractor™ Pro RX-S Injects Below 12-15mm	M00547340	19343209	6/30/2018

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 a replacement 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 affected worldwide regulatory authorities of this removal.

Please read carefully through the enclosed instructions. Your local Sales Representative can answer any questions that you may have regarding this removal.

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,



Brendan Smith
Boston Scientific Quality Systems
763-494-1133
BSCFieldActionCenter@bsci.com

Encl: Removal Instructions
Reply Verification Tracking Form

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to Boston Scientific by calling 1-866-868-4004 and to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

Online: www.fda.gov/MedWatch/report.htm

Regular Mail: use postage-paid FDA form 3500 available at www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, 5600 Fishers Lane, Rockville, MD, 20852-9787

Fax: (800) FDA-0178

Phone: (800) FDA-1088

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 described below:

Email: BSCFieldActionCenter@bsci.com

or

Fax to: **Field Action Center 1-866-213-1806**

Please email or fax your 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 Removed 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.
- Feel free to use our Federal Express Number 0554-0315-5 to return this package via second day delivery.
- Seal the box, and return it to:

**Boston Scientific Corporation
US Distribution Center
Boston Scientific Marina Bay
Customer Fulfillment Center
500 Commander Shea Blvd.
Quincy, Massachusetts 02171
RGA: _____**