Boston Scientific

Market Withdrawal - Immediate Action Required
Extender Cable for Autolith™ Touch
Bipolar Electrohydraulic Lithotripter

February 2019

Dear Materials Manager / Field Action Contact:

Boston Scientific, a distributor of the Autolith™ Touch Bipolar Electrohydraulic Lithotripter (EHL) Generators and Extender Cables, is notifying you that Northgate Technologies, Inc., is initiating a voluntary market withdrawal of mislabeled extender cables that were packaged with certain generators. The flag label on these cables did not include the Unique Device Identification number (UDI) required by the US FDA.

This market withdrawal does not include Autolith Touch EHL Extender Cables that were sold individually. The labeling issue has no impact on product performance and there is no risk to patient safety. The generator is not impacted and should not be returned or replaced.

This market withdrawal affects only two Extender Cable Lot numbers listed in the table below and in Attachment 1. No other Lot numbers are impacted by this notification. The Generator Serial Number is listed for your reference.

Affected Product Listing

Product Description	Extender Cable UPN	Affected Lot Numbers	Extender Cable GTIN	Generator Serial Number
Autolith Touch EHL Extender Cable	M00546750	13400 13401	00817183020455	See attachment 1

Please complete the enclosed reply verification tracking form and return to Boston Scientific in accordance with the enclosed instructions.

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

Regulatory authorities affected by this market withdrawal will be notified as required.

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

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]

Shannon Stanek
Boston Scientific Quality Systems
763-494-1133
BSCFieldActionCenter@bsci.com

Encl: Removal Instructions
Reply 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 Market Withdrawal - Instructions

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

1. **Immediately verify the UPN and serial number on your generator(s) and the lot number of your extender cable(s).**
   - Verify by product UPN and serial number in product table to determine if the generator(s) in your inventory is affected.
   - If your generator is affected, check the lot number on your cable to see if it is one of the two lots listed in the Affected Product Table on page 1 of the letter.
   - 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 RVTF even if you do not have any affected product, following the directions on this page and on the RVTF.
   - Indicate on your RVTF the quantity of cables in your inventory.
   - 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. We will also process your replacement at that time for the number of cables indicated on your form.

3. **Package/Ship the Removed Product.**
   - In order to avoid interruptions in use, please return your extender cable after you have received your replacement.
   - 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 920525156 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: _____