

«Hospital_Name»
«Users_Name»
«Department»
«Customer_Address»
«Zip_Code» «City»
«Country_name»

<Reference: 92801018-FA>

9 December 2021

Urgent Field Safety Notice - Product Advisory AUTOLITH®* TOUCH Bipolar Electrohydraulic Lithotripter

Dear «Users_Name»,

Boston Scientific Corporation (BSC), a distributor of the AUTOLITH® TOUCH Bipolar Electrohydraulic Lithotripter (EHL) Generators, is notifying you that Northgate Technologies, Inc. (NTI), is voluntarily initiating a product advisory due to a recently identified discrepancy in some languages. You are receiving this letter because you have been identified as a customer having received one or more of these devices.

When the following languages are selected, the device text will indicate high power (but operate in low power) and the text will indicate low power (but operate on high power): Russian, Romanian, Slovak, and Czech. The differences between high and low power does not impact patient safety.

The text displays as intended in all other languages and there have been no reported adverse events associated with this issue.

The most common potential consequence as well as the most serious potential consequence that is reasonably foreseeable to occur is a prolonged procedure while the EHL probe is exchanged. If a prolonged procedure were to occur it is not anticipated to result in a clinically significant delay in the procedure.

Our records indicate that your facility received some of the concerned product. **The table below provides a complete list of all affected products**, including Product Description, Material Number (UPN), GTIN number and Serial numbers. Please note that **only the devices listed below are affected. No other Boston Scientific product is involved in this Field Safety Notice.**

Product Description	UPN	GTIN/UDI	Serial Numbers
AUTOLITH TOUCH® EHL	M005466800	00817183020493	All distributed prior to 15-November-2021

NO product is being recalled and you are NOT required to return product to Boston Scientific.

INSTRUCTIONS:

- 1- Please read this notice.
- 2- **Please complete the attached Acknowledgement Form even if you do not have any affected product.**
- 3- **When completed, please return the Acknowledgement Form to your Boston Scientific office** for the attention of «Customer_Service_Fax_Number» on or before **24 December 2021.**
- 4- Please pass on this notice to any healthcare professional from your organization that need 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).

Although Boston Scientific is not physically recalling any product, NTI and BSC are notifying regulatory authorities of this advisory as required.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,



Marie Pierre Barlangua
Quality Department
Boston Scientific International S.A.

Attachment: Acknowledgement Form

*Autolith is a registered trademark of Northgate Technologies, Inc.



Please complete the form & Send it to:
«Customer_Service_Fax_Number»

«Sold_to» - «Hospital_Name» - «City» - «Country_name»

Acknowledgement Form – Product Advisory
AUTOLITH® TOUCH Bipolar Electrohydraulic Lithotripter
92801018-FA

By signing this form, I confirm that
I have read and understood
the Boston Scientific Field Safety Notice
dated 9 December 2021

for AUTOLITH® TOUCH Bipolar Electrohydraulic Lithotripter.

NAME* _____ **Title** _____

Telephone _____ **Email** _____ - _____

Customer' SIGNATURE* _____ **DATE*** _____
* Required field dd/mm/yyyy