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<Hospital_Name>
<Users_Name>
<Department>
<Customer_Address>
<Zip_Code> <City>
<Country_Name>

<Reference: 97334102-FA> xx January 2025

Urgent Field Safety Notice - Urgent Medical Device Recall
Lumenis Pulse™ 120H Holmium Laser System

Dear <Users_Name>,

Boston Scientific is initiating a recall on certain Serial numbers of Lumenis Pulse™ Holmium Laser Systems. Investigation has revealed the initial current in certain chargers may lead to overheating and damage to the power resistors on the Alternating Current (AC) controller during the power-on sequence of the laser system.

Once the AC controller is damaged, there is the potential for the laser system to not power on:
- At initial start-up.
- If restarting is necessary due to power loss during the procedure.
- If restart is necessary to clear an error code or notification.
- If laser emission is interrupted during the procedure.

This may impact the ability to start or complete the procedure. If this issue is detected during setup and testing of the laser system, the most reasonably foreseeable outcome is no harm. If this issue occurs during the procedure the most reasonably foreseeable outcome is conversion to an alternative procedure or a prolonged procedure to exchange the laser for another.

Boston Scientific has received no reports of this issue or patient harm to date.

Our records indicate that your facility has received some of the concerned product. Th**e table below provides a complete list of all affected products**, including Product Description, Material Number (UPN), GTIN and Lot/Batch numbers. Please note that **only the devices listed below are affected. No other Boston Scientific product is involved in this Field Safety Notice**.
Further distribution or use of any remaining product affected by this action should cease immediately.

Product Description	UPN	GTIN	Serial #
Lumenis Pulse™ 120H Holmium Laser System	GA-0006802	07290109145525	1803
	GA-2009996	07290109145518	1791
	GA-0008700	07290109145464	1818

INSTRUCTIONS:

1- **Please immediately discontinue use of the Boston Scientific product reported in the list and remove all of the affected units from your inventory**, regardless of where these units are stored in your facility. Segregate the units in a secure place, pending return to Boston Scientific.

2- **Please complete the attached Verification Form** even if you do not have any product to return

3- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of <Customer_Service_Fax_Number> on or before **17 February 2025**.

4- **If you have products to return,** please package them in an appropriate shipping box and **contact** <Customer_Service_Tel> **of your local Boston Scientific office,** to arrange return.

5- Immediately post this information in a visible location near the affected products to ensure this information is readily accessible to all handlers and users of the device. Please pass this notice to any health 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).

Your Competent Authority is being notified of this Field Safety Notice.

We appreciate your understanding as we take action to address this issue. At Boston Scientific, patient safety and customer satisfaction are our priority. We are committed to continuing to offer products that meet the quality standards that you expect from Boston Scientific.

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

Yours sincerely,

Brandon Erickson
Vice President, Global Quality
Boston Scientific International S.A.

Attachment: Verification Form

FOR BOSTON SCIENTIFIC INTERNAL USE ONLY
Account Email: <ContactEmail>
Language: <Language(s)>
LFAC Team: <LFAC_Distribution_Email_Address>
Country Code-Sold to: <Country_Code>-<Sold_to_b>

<Sold_to> - <Hospital_Name> - <City> - <Country_Name>

Please Complete the form even if you do not have any affected product & send it to your Local Office:
<Customer_Service_Fax_Number>

Verification Form – Urgent Medical Device Recall
Lumenis Pulse™ 120H Holmium Laser System
97334102-FA

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1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated xx January 2025.

2. **Boston Scientific records indicate you have received the following affected product** *(additionally please check inventory against complete list of affected product provided)*

Material N° (UPN)	Lot / Batch N° / Serial N°	Customer PO	Qty Sent (Units)	Qty to return (Units)

3. We confirm that all areas where affected product could be located have been checked.

4. **TICK ONE OF THESE STATEMENTS***, **SIGN THIS FORM** and send it to <Customer_Service_Fax_Number>

- ❑ We do not have any affected product.
- ❑ We have found affected product(s): Please confirm the quantity to return above. *If you are returning product not listed above, please* ***add the UPN, Lot/Batch/Serial number and the quantity to return.***

TO RETURN PRODUCTS:
1. Contact <Customer_Service_Tel> of your Local Office to arrange return of any affected product.
2. Prepare the package
3. Follow the instructions given by your Local Office about collection of the package

NAME* _____Title _____

Telephone _____ Email _____

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