

**Boston Scientific International S.A.**

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«Hospital\_Name»

«Users\_Name»- «Department»

«Customer\_Address»

«Zip\_Code» «City» -«Country\_name»

**Reference: 92154313-FA**

xx September 2017

## **Urgent Field Safety Notice - Urgent Medical Device Correction Auriga™ 30 and Auriga™ XL 4007 Laser System**

Dear «Users\_Name»,

Boston Scientific is initiating a Field Correction on certain Auriga 30 and Auriga XL 4007 Laser System Consoles, which may have an incorrectly assembled trigger wire.

The trigger wire functions in the start-up of the console. An incorrectly assembled trigger wire may result in error codes or failure to start the console.

Should the console fail to start, the most common consequence would be a delay of the procedure while the affected console is swapped for another. If a substitute console or immediate alternative treatment is not available, this issue may result in moderate risk to the patient related to repeat anesthesia for the re-intervention at a later date.

This correction affects only the UPNs and serial numbers listed in the table below. **If you possess a console listed in the table below, stop using the affected console. Boston Scientific certified engineers will begin contacting customers to schedule correction of affected consoles within two weeks of this communication.**

<b>Product Description</b>	<b>Material Number (UPN)</b>	<b>Serial Number</b>
Auriga™ XL 4007 Laser System	M0068FS4007G0	20503137
		20541967
		20546219
		20546440
		20575518
Auriga™ 30 Laser System	M0068S30G0	20413941

## **INSTRUCTIONS:**

- 1- **Check your Inventory for the products affected by this Field safety Notice.**
- 2- **Please segregate any of the affected products found in your inventory, until correction is made.**
- 3- **Please complete the attached Verification Form, even if you do not have any affected product.**
- 4- **When completed, please return the Verification Form to your local Boston Scientific office for the attention of «Customer\_Service\_Fax» by **DATE.****
- 5- 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).

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

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act 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.

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

Yours sincerely,

  
Boston Scientific International S.A.

Attachment: Verification Form

Please complete the form even if you do not have any affected product  
& send it to: «Customer\_Service\_Fax\_Number»

«Sold\_to» - «Hospital\_Name» - «City» - «Country\_Name»

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**Verification Form – Urgent Medical Device Field Correction**  
**"Name of the Product"**  
**92154313-FA**  
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1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated «Date\_notif\_sent».
2. **Boston Scientific records indicate you have received the following affected product** (additionally please check inventory against complete list of affected product provided)

Product Description	Material N° (UPN)	Lot / Batch / Serial N°	Customer PO	Qty Sent (Unit)	Qty To be corrected (Units)
«DESCRIPTION»					

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 and have quarantined as instructed in this Field Correction Notification. Please indicate the quantity to be corrected (in single units) in the above table
5. If you have any questions or would like assistance with this Field Safety Notice, please contact «Customer\_Service\_Tel».

NAME\* \_\_\_\_\_ Title \_\_\_\_\_

Telephone \_\_\_\_\_ Email \_\_\_\_\_

Customer' SIGNATURE\* \_\_\_\_\_ DATE\* \_\_\_\_\_

\* Required field

dd/mm/yyyy