

Boston Scientific International S.A.

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«Hospital_Name»

«Users_Name»- «Department»

«Customer_Address»

«Zip_Code» «City» -«Country_name»

Reference: 92169170-FA

07 November 2017

Field Safety Notice - Urgent Medical Device Recall Eluvia™ 150mm and Innova™ 180mm & 200mm Stent Systems

Dear «Users_Name»,

Boston Scientific is initiating a voluntary removal of the 150mm Eluvia™ Drug-Eluting Vascular Stent System and the 180mm and 200mm Innova™ Self-Expanding Stent System due to elevated complaint rates for partial stent deployment.

No other Eluvia™ or Innova™ stent system sizes are included in this voluntary removal. In addition, this action does not include previously implanted devices.

Partial deployment occurs when the stent is unable to be fully released from the delivery system. Part of the stent can become anchored in the vessel while the rest of the stent remains within the delivery system. The most common reported injury has been additional medical or minor surgical intervention, vessel trauma or prolongation of the implant procedure. However, in certain cases Boston Scientific has received reports of major surgery to retrieve the stent/delivery system or to correct vascular compromise.

Our records indicate that your facility received some of the concerned product.

The **table below (Attachment 1) provides a complete list of all affected products**, including Product Description and Material Number (UPN). 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 affected product should cease immediately.

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 Cas Sherrard - Fax: 01442 411816 - Email: UK-Quality@bsci.com; on or before **21 November 2017.**
- 4- **If you have products to return**, please package them in an appropriate shipping box and **contact Cas Sherrard - Tel: 01442 411731 of your local Boston Scientific office**, to arrange return.
- 5- Please pass this notice to any healthcare 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 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: Verification Form

Attachment 1 : Affected Product Listing
Eluvia™ 150mm and Innova™ 180mm & 200mm Stent Systems

All batches for the UPN's listed below are affected

Innova 180mm, 200mm - EU	
Product Description	Material Number (UPN)
Innova EU 5x180x75	H74939180051870
Innova EU 5x200x75	H74939180052070
Innova EU 6x180x75	H74939180061870
Innova EU 6x200x75	H74939180062070
Innova EU 7x180x75	H74939180071870
Innova EU 7x200x75	H74939180072070
Innova EU 8x180x75	H74939180081870
Innova EU 8x200x75	H74939180082070
Innova EU 5x180x130	H74939181051830
Innova EU 5x200x130	H74939181052030
Innova EU 6x180x130	H74939181061830
Innova EU 6x200x130	H74939181062030
Innova EU 7x180x130	H74939181071830
Innova EU 7x200x130	H74939181072030
Innova EU 8x180x130	H74939181081830
Innova EU 8x200x130	H74939181082030

Eluvia 150mm- OUS	
Product Description	Material Number (UPN)
EU DES SFA, 6X150, 75 cm	H74939295601570
EU DES SFA, 6X150, 130 cm	H74939295601510
EU DES SFA, 7X150, 75 cm	H74939295701570
EU DES SFA, 7X150, 130 cm	H74939295701510