



Urgent Medical Device Removal - Immediate Action Required

Eluvia™ 150mm and Innova™ 180mm & 200mm Stent Systems

07 November 2017

Dear Valued Customer:

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.

Enclosed with this notification is a listing of all product codes, Attachment 1 within the scope of this removal. **Further distribution or use of any remaining product affected by this removal should cease immediately.** This removal does not include any product other than the specified affected batches/lots listed below.

Affected worldwide regulatory authorities are being notified of this removal as required.

Please read carefully through the removal instructions included with this notification. Please direct any questions that you may have regarding this notification to your local Sales Representative.

We regret the inconvenience that this action will 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,

Shannon M. Stanek
Sr. Project Lead, Field Action Team
651-582-5150
Shannon.Stanek@bsci.com

Encl: Removal Instructions
Reply Verification Tracking Form

cc: Chairman Medical Board and relevant Head of Departments

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 representatives.

Removal Instructions

The Reply Verification Tracking Form enclosed with this letter must be completed and returned **even if you do not have any of the units from the recalled batches/lots.**

1. **Immediately discontinue use of and segregate recalled product.**
 - Immediately remove all affected recalled product from your inventory.
 - Segregate this product in a secure location for return to Boston Scientific.

2. **Complete and return the Reply Verification Tracking Form.**
 - Complete the enclosed Reply Verification Tracking Form (even if you do not have any product to return), following the directions on this page and the Reply Verification Tracking Form.
 - Report all inventory to be returned and report in single-unit quantity(ies), not boxes.
 - Return the Reply Verification Tracking Form to Boston Scientific Representatives

Attachment 1 - Affected Product Listing
All batches for the UPN's listed below are affected

Innova 180mm, 200mm – US, Japan	
Product Description	Material Number (UPN)
Innova 5 x 180 x 75	H74939293051870
Innova 5 x 200 x 75	H74939293052070
Innova 6 x 180 x 75	H74939293061870
Innova 6 x 200 x 75	H74939293062070
Innova 7 x 180 x 75	H74939293071870
Innova 7 x 200 x 75	H74939293072070
Innova 8 x 180 x 75	H74939293081870
Innova 8 x 200 x 75	H74939293082070
Innova 5 x 180 x 130	H74939293051830
Innova 5 x 200 x 130	H74939293052030
Innova 6 x 180 x 130	H74939293061830
Innova 6 x 200 x 130	H74939293062030
Innova 7 x 180 x 130	H74939293071830
Innova 7 x 200 x 130	H74939293072030
Innova 8 x 180 x 130	H74939293081830
Innova 8 x 200 x 130	H74939293082030

Innova 180mm, 200mm - China	
Product Description	Material Number (UPN)
Innova-China 5 x 180 x 75	H74939259051870
Innova-China 5 x 200 x 75	H74939259052070
Innova-China 6 x 180 x 75	H74939259061870
Innova-China 6 x 200 x 75	H74939259062070
Innova-China 7 x 180 x 75	H74939259071870
Innova-China 7 x 200 x 75	H74939259072070
Innova-China 8 x 180 x 75	H74939259081870
Innova-China 8 x 200 x 75	H74939259082070
Innova-China 5 x 180 x 130	H74939259051830
Innova-China 5 x 200 x 130	H74939259052030
Innova-China 6 x 180 x 130	H74939259061830
Innova-China 6 x 200 x 130	H74939259062030
Innova-China 7 x 180 x 130	H74939259071830
Innova-China 7 x 200 x 130	H74939259072030
Innova-China 8 x 180 x 130	H74939259081830
Innova-China 8 x 200 x 130	H74939259082030

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



CUSTOMER ACKNOWLEDGEMENT FORM
PRODUCT NAME: Boston Scientific Eluvia™ 150mm and Innova™
180mm & 200mm Stent Systems

Instructions: This form must be completed and returned in all cases even if you do not have any affected product.
Immediately complete form and Scan/e-mail to: Boston Scientific Sales Rep OR Fax to #: 64188899

Account #:		Customer Name:	
Contact Name:			
Address:			
City:	State:	Province:	Postal Code:
Country:			

***PLEASE COMPLETE, SIGN AND RETURN THIS FORM AS A
CONFIRMATION THAT YOU RECEIVED THIS NOTICE FROM BOSTON
SCIENTIFIC (even if you do not have any of the referenced product on the
enclosed product listing in your current inventory).***

**My signature below acknowledges receipt of the Boston Scientific Eluvia™ 150mm and
Innova™ 180mm & 200mm Stent Systems Urgent Medical Device Removal Notification**

Section to be filled out by Customer:

1. Please Indicate:	
Are you a Distributor?	
<input type="checkbox"/>	Yes, and we have notified all customers that have been shipped/sold affected product
<input type="checkbox"/>	No
2. Sign and Date to acknowledge this Field Action Notification (must be completed):	
Print Name: _____ Signature: _____ Date: _____	
Phone: _____ Fax: _____ E-mail: _____	

Customer Name:

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Date: 07-Nov-2017

Account #:

Field Action #: Eluvia 150mm & Innova 180mm & 200mm

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Boston Scientific
Customer Acknowledgement RVTF
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