



Field Safety Notice -Important Medical Device Information
Lotus™ Valve System

12 April 2016

Dear Dr,

Boston Scientific (BSC) is voluntarily initiating this Field Safety Notice to reinforce the training requirements associated with the use of the Lotus Valve System. Refer to Table 1 below for product information.

A recent investigation identified a number of sites that had performed Lotus Valve cases without the mandatory support of a BSC Field Clinical Specialist (FCS). All Lotus Valve cases must be supported by a BSC FCS until the site is designated as “Independent” by Boston Scientific.

In order for a site to be designated as Independent, the following must be complete:

- Two (2) physicians must be certified, i.e. they must have
 - Attended face to face training;
 - Performed a minimum of 6 Lotus Valve cases with a Proctor and a BSC FCS and
 - Performed a minimum of 4 additional Lotus Valve cases with a BSC FCS
- Two (2) cath lab staff must be certified to prepare the Lotus Valve
- Certified physicians must be trained on Advanced Techniques by BSC

Your site is not yet Independent; therefore, you must not perform Lotus Valve cases without the support of a BSC FCS.

No product is being recalled and you are not required to return product to Boston Scientific. There is no impact to previously implanted devices.

As always, your FCS is available to answer any questions you may have regarding the current mandatory training program and associated materials.

Table 1: Product Information

Product Description	Material Number (UPN)	Catalog Number	Lot/Batch Number
Lotus TAVR 23mm	H749LTV230	LTV23	All Batches
Lotus TAVR 25mm	H749LTV250	LTV25	All Batches
Lotus TAVR 27mm	H749LTV270	LTV27	All Batches

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

We appreciate your understanding to ensure patient safety and customer satisfaction. We are committed to continuing to offer products and training that meet the highest quality standards that you expect from Boston Scientific.

Sincerely,



Encl: Field Safety Notice Instructions
Customer Acknowledgement Form

Field Safety Notice Instructions

The Acknowledgment Form enclosed with this Field Safety Notice must be completed and returned.

1. **Read the Field Safety Notice information contained in the above letter.**
2. **Complete the Acknowledgment Form.**
 - Complete the enclosed Acknowledgment Form.
 - Return the Acknowledgment Form to your FCS or Boston Scientific as soon as possible.