

«Hospital\_Name»

«Users\_Name» - «Department»

«Customer\_Address»

«Zip\_Code» «City» - «Country\_name»

Reference: 90973990-FA

Date, 2014

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

Dear «Users\_Name»,

This letter is to provide additional clarification on the step-by-step instructions for implanting the Lotus Valve. Specifically, during the valve release phase, it is important to maintain a neutral catheter position and avoid pushing forward on the valve. This will avoid interaction between the valve and the catheter after the valve is detached from the delivery system. This clarification is intended to reduce the risk of a valve becoming unlocked due to interaction with the catheter during the release phase.

The Lotus training materials for the procedure have recently been updated to clarify the optimal technique for valve release described above. If you have recently implanted the Lotus Valve, your Boston Scientific Field Clinical Specialist (FCS) or proctor will have already explained the updates. If not, your FCS will do so at the time of this notification.

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

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


**INSTRUCTIONS:**

1. Please read carefully the Field Safety Notice.
2. Complete the attached Acknowledgement Form (even if you have previously attended the updated training)
3. Once completed, please return immediately the Acknowledgement Form to your FCS

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.

Yours sincerely,

  
Quality Department  
Boston Scientific International S.A.

Attachment: Acknowledgement Form