

«Customer_Address»

«Zip_Code» «City» - «Country_name»

Reference: 92069759-FA

xx February 2017

Field Safety Notice (for Distributor) - Important Medical Device Information Foot Switch - AngioJet™ Ultra 5000A Console

Dear «Users_Name»,

At Boston Scientific (BSC), we are dedicated to providing high quality medical devices to help advance the care of patients. As part of our efforts to support to our customers, we are providing this notification to you regarding the AngioJet™ Ultra 5000A Console foot switch.

Why Are You Receiving This Letter?

Boston Scientific has received field reports regarding the AngioJet Ultra 5000A Console foot switch sticking during use resulting in an undesired continued operation of the device. If this situation occurs, perform the troubleshooting steps per the operator's manual. An attempt can be made to manually release the footswitch, or turn the console off to deactivate the catheter. The complaint review shows that this issue results in a prolongation of the procedure in order to perform troubleshooting steps and remove the catheter. The most serious consequence from this issue could be the need to abort a procedure if the situation has not been resolved and alternative options are not available. To date, there have been no reported patient adverse events as a result of these complaints.

What Should You Do?

Please continue to follow the operator's manual for service and maintenance for the AngioJet Ultra 5000A Console.

If you have noticed this issue with the AngioJet Ultra 5000A Console foot switch at your facility, please discontinue use and contact BSC's Technical Support at the contact information below. If the foot switch is operating correctly, no action is necessary on your part.

«TAC_associated»

Please notify all your customers that have received affected product of this Field Safety Notice. To effectively manage this Field Safety Notice, your accounts are to communicate directly with you, not Boston Scientific. If any of your customers are distributors, please notify them that they must communicate this recall to the medical facility level.

Your local Sales Representative can answer any questions that you may have regarding this notification. We regret any inconvenience that this notification may cause, and we appreciate your understanding as we take action to ensure continued customer satisfaction. We are committed to continuing to offer products that meet the highest quality standards that you expect from Boston Scientific.

Yours sincerely,



Marie Pierre Barlangua
Quality Department
Boston Scientific International S.A.

Picture of the AngioJet™ Ultra 5000A Console:

Note: it may be possible that some consoles still have a “Possis” or “Bayer” labelling instead of “Boston Scientific”

