



**Urgent Medical Device Correction - Immediate Action Required**  
**AngioJet™ Ultra Consoles**

November 11, 2019

Dear Doctor,

Cc: Chairman Medical Board and relevant Head of Department

Boston Scientific Corporation is conducting a Medical Device Correction of certain AngioJet Ultra Consoles which were shipped to customers without the required Operator’s Manual. These products meet design specifications and are expected to perform as intended. While we have determined that correct use of the device should not be impacted due to the interactive nature of the Console, there could be a potential delay to the procedure while the Operator’s Manual is located. No adverse health consequences have been reported or are expected to occur as a result of this issue.

Included with this notification is the AngioJet Ultra Console Operator’s Manual. Please place the manual in a location that is accessible to the device’s operator while the console is in use.

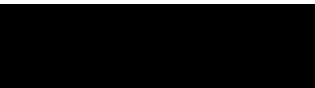
**Affected Product Listing**

Product Description	Material Number (UPN)	Serial	GTIN
AngioJet™ Ultra Consoles	See Attachment 1		

*Please complete and return the acknowledgement form to indicate receipt of this letter.*

Please read carefully through the enclosed instructions. Your local Sales Representative can answer any questions that you may have regarding this correction. Please pass this notice to any healthcare professional from your organization who needs to be aware and to any organization where these devices have been transferred (if appropriate). Please provide Boston Scientific with details of any listed devices that have been transferred to other organizations (if appropriate).

Sincerely,



Brendan Smith  
Boston Scientific Quality Systems



[BSCFieldActionCenter@bsci.com](mailto:BSCFieldActionCenter@bsci.com)

Encl: Correction Instructions  
Reply Form

## **Urgent Medical Device Correction – Instructions**

The Acknowledgement Form enclosed with this Notice must be completed and returned **even if you do not have any affected units.**

1. **Complete and return the Acknowledgement Form.**

- Complete the enclosed Acknowledgement Form even if you do not have any affected product, following the directions on this page and on the Acknowledgement Form.
- Return the Acknowledgement Form as described below:

**Angela Ye, Boston Scientific Representative**

**Please email or fax your Acknowledgement Form(s) immediately.**

## Attachment 1 – Product List

UPN	GTIN	Serial				
105650-001D	08714729892182	U5058				
105650-001H	08714729890591	U2259	U2262	U2379	U2552	U2613
		U2851	U2976	U3460	U3535	U3611
		U3819	U3939	U6400		
105650-001R	08714729890607	U2003	U2007	U2066	U2092	U2149
		U2185	U2192	U2206	U2219	U2260
		U2282	U2285	U2313	U2336	U2337
		U2370	U2419	U2458	U2492	U2525
		U2527	U2535	U2611	U2638	U2648
		U2649	U2666	U2691	U2788	U2789
		U2804	U2937	U2956	U3032	U3092
		U3096	U3138	U3140	U3143	U3229
		U3231	U3232	U3235	U3241	U3284
		U3286	U3332	U3358	U3365	U3379
		U3409	U3433	U3461	U3466	U3504
		U3516	U3572	U3597	U3609	U3769
		U3904	U4144	U4322	U4351	U4363
		U4369	U4371	U4389	U4428	U4437
		U4442	U4444	U4520	U5024	U5050
		U5093	U5094	U5126	U5189	U5198
		U6056	U6072	U6084	U6089	U6098
		U6104	U6129	U6130	U6131	U6154
		U6164	U6172	U6192	U6301	U6310
		U6332	U6357	U6358	U6364	U6369
U6370	U6372	U6379	U6451	U6457		
U6460	U6468	U6476	U6518	U6669		
105650-001Z	08714729892199	U5029	U5096			
105650-004H	08714729890683	U5073				
105650-024Z	08714729892656	U8808				
105650-025	08714729891307	U8047				
105650-025R	08714729891321	U3278	U3858	U8041	U8049	U8050
		U8052	U8054	U8059	U8060	U8062
		U8073	U8074	U8080	U8081	U8089
		U8148	U8153	U8195	U8197	U8214
		U8564	U8594	U8802	U8803	U8804
		U8854	U8872	U8879	U8883	U8885
		U8907	U8919	U8942	U8980	U8985
		U8993	U9047	U9048	U9078	
105650-026R	08714729891352	U8260				



**CUSTOMER ACKNOWLEDGEMENT FORM  
(92441532-FA) AngioJet Console DFU Field Correction**

**Instructions:** This form must be completed and returned in all cases even if you do not have any affected product. Immediately complete form and hand it to Boston Scientific Representative.

<b>Account #:</b>		<b>Customer Name:</b>		
<b>Contact Name:</b>				
<b>Address:</b>				
<b>City:</b>	<b>State:</b>	<b>Province:</b>	<b>Postal Code:</b>	
<b>Country:</b>				

***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 Notice regarding the AngioJet™ Ultra Console Correction and that the included operator’s manual has been placed with the impacted product at my facility.**

**Section to be filled out by Customer:**

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

**Date:** 11 Nov 2019

**Field Action #:** 92441532-FA

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