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«Hospital_Name»
«Users_Name» - «Department»
«Customer_Address»
«Zip_Code» «City» - «Country_name»

Reference: 92441532-FA 12 November 2019

Urgent Field Safety Notice (for Distributor) - Medical Device Correction AngioJet™ Ultra Consoles

Dear «Users_Name»,

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.

Our records indicate that your facility received some of the concerned product.
The table on attachment 1 provides a complete list of all products shipped without the Operator's Manual, including Product Description, Material Number (UPN), Serial Numbers and GTIN. Please note that **only the devices listed in table on attachment 1 were shipped without the required manual. No other Boston Scientific product is involved in this Field Safety Notice**.

Please note that this is an informational notice to you. **NO** product is being recalled.

INSTRUCTIONS:

1- **Please read carefully the Field Safety Notice letter and immediately post this information in a visible location near the product to ensure this information is easily accessible to all users of the device.**

2- **Please place the enclosed Operator's Manual with any listed products found in your inventory.**

3- **Please notify all your customers that have received listed 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 Medical Device Correction to the medical facility level.

4- **Please complete the attached Acknowledgement Form** even if you do not have any affected product.

5- **When completed, please return the Acknowledgement Form to your local Boston Scientific office** for the attention of «Customer_Service_Fax_Number» by **25 November 2019.**

6- Please pass on this notice to any employee from your organization that need to be aware and to any organization where the potentially affected devices have been transferred (If appropriate). Please provide Boston Scientific with details of any affected devices that have been transferred to other organizations (if appropriate).

Although Boston Scientific is not physically recalling any product, your Competent Authority is being notified of this Field Safety Notice.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,

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

Attachments: - Acknowledgement Form
- Operator's Manual

Boston Scientific

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				

Boston Scientific

Please complete the form & Send it to:
«Customer_Service_Fax_Number»

«Sold_to» - «Hospital_Name» - «City» - «Country_name»

Distributor Acknowledgement Form – Urgent Medical Device Correction
AngioJet™ Ultra Consoles
92441532-FA

By signing this form, I confirm that I have read and understood the Boston Scientific Field Safety Notice dated 12 November 2019 for the AngioJet™ Ultra Consoles, and will place the enclosed Operator's Manual with any listed products found in our inventory, if applicable.

Also, we will disseminate this information to our customers.

Distributor Acknowledgement:

NAME* _____ **TITLE** _____

Telephone _____ Email _____

SIGNATURE* _____ **DATE*** _____
* Required field (dd/mm/yyyy)