

«Hospital_Name»

«Users_Name»- «Department»

«Customer_Address»

«Zip_Code» «City» -«Country_name»

Reference: 92358366-FA

24 April 2019

Urgent Field Safety Notice - Urgent Medical Device Recall
Precision™ Spinal Cord Stimulator Systems leads, lead extensions, adapters, and
Vercise™ Deep Brain Stimulation Systems lead extensions
Artisan™ 70cm 2x8 Surgical Lead Kit
35cm and 55cm 8 Contact Extension Kits
Linear™ 3-4 50cm and 70cm 8 Contact Lead Kit
Precision™ M8 Adapter, 15cm

Dear «Users_Name»,

Boston Scientific is initiating a voluntary removal of certain Precision™ Spinal Cord Stimulator Systems leads, lead extensions, adapters, and Vercise™ Deep Brain Stimulation Systems lead extensions due to the actual “Use by Date” being later than the correct “Use by Date” displayed on the label of these products. While the “Use by Date” (UBD) is incorrect, to date, none of the affected products have reached the allowed product shelf life and the earliest instance of these devices reaching their actual expiration date is September 2019. While no adverse events related to use of the affected devices are expected to occur, Boston Scientific has not performed testing beyond the UBD timeframe.

Our records indicate that your facility received some of the concerned product.

The table below provides a complete list of all affected products, including Product Description, Material Number (UPN), GTIN and Serial numbers. Please note that **only the devices listed below are affected. No other Boston Scientific product is involved in this Field Safety Notice.**

Further distribution or use of any remaining affected product should cease immediately.

Product Description	Part Number (UPN)	GTIN	Serial Numbers			
Vercise™ Deep Brain Stimulation Systems						
55cm 8 Contact Extension Kit	M365NM3138550	8714729820765	1049357	1057225	3010769	3014616
			1053194	1057232	3012324	3014631
Precision™ Spinal Cord Stimulator Systems						
Artisan™ 70cm 2x8 Surgical Lead Kit	M365SC8216700	8714729779919	632107		645608	
35cm 8 Contact Extension Kit	M365SC3138350	8714729760559	1041034	1054299	1058015	3000564
			1041380	1054304	1058017	3001907
			1053375	1055172	1062660	3007457
			1053695	1056806	1064590	3008119
			1053700	1058008	3000549	
Linear™ 3-4 50cm 8 Contact Lead Kit	M365SC2352500	8714729789550	1039736	1039779	1042340	
Linear™ 3-4 70cm 8 Contact Lead Kit	M365SC2352700	8714729789581	1042757			
Precision™ M8 Adapter, 15cm	M365SC9218150	8714729888734	1043743		1051329	
55cm 8 Contact Extension Kit	M365SC3138550	8714729760566	1044463	1063798	3002561	3010114
			1044464	1063801	3002817	3012781
			1044466	1066182	3003040	3013204
			1061554	1066242	3003042	3013267
			1062766	1068589	3003047	3018105
			1062770	1068602	3003048	3018106
			1062787	1068606	3003060	3018866
			1063430	1068608	3006620	3036973
			1063632	1068611	3009041	
			1063650	3001046	3009045	
			1063749	3002547	3009050	

INSTRUCTIONS:

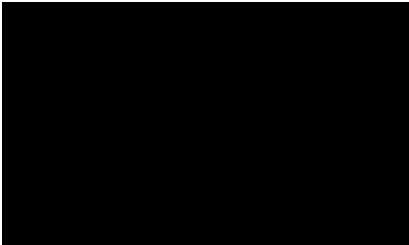
- 1- Please immediately discontinue use of the Boston Scientific product reported in the list and remove all of the affected units from your inventory, regardless of where these units are stored in your facility. Segregate the units in a secure place, pending return to Boston Scientific.
- 2- Please complete the attached Verification Form even if you do not have any product to return.
- 3- When completed, please return the Verification Form to your local Boston Scientific office for the attention of «Customer_Service_Fax_Number» on or before **10 May 2019**.
- 4- If you have products to return, please package them in an appropriate shipping box and contact «Customer_Service_Tel» of your local Boston Scientific office, to arrange return.
- 5- Please pass this notice to any healthcare professional from your organization that needs 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).

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,



Attachment: Verification Form

Boston Scientific International S.A.