



Urgent Field Safety Notice **6F Sherpa NX Active Catheters**

Recall

April 2019

Medtronic reference: FA864

Dear Physician or Health Care Professional,

In March 2019, Medtronic initiated a verbal communication about an Urgent Field Safety Notice for a subset of 6F Sherpa NX Active Catheters. After continued investigation, it has been determined that the scope of this Field Safety Notice should be expanded to include all model numbers that are listed in Appendix A.

Medtronic determined that the listed catheters were assessed to have an unacceptable potential for a failure mode of extensive loss of the distal segment outer material, with resulting exposure of the underlying stainless-steel braid wires after insertion into the body. The potential patient risks related to this issue include surgical intervention, dissection, non-occluding embolism, occlusion, prolonged procedure, and cerebrovascular accident. As the loss of material is experienced at the time of product use, there is no additional action related to this recall for patients who have previously been treated with potentially affected product. These patients should continue to be monitored in accordance with each facility's standard care protocols.

Medtronic initiated this Urgent Field Safety Notice in response to receiving four (4) complaints related to this issue in the relatively short time period between 29 January 2019 and 13 March 2019. There have been no patient harms reported with these complaints.

Customer Instructions

Medtronic requests that you immediately take the following actions:

1. Quarantine all unused potentially affected product that remains in your inventory.
2. Return all unused affected product in your inventory to Medtronic. Your Medtronic Representative can assist you in the return and replacement of this product as necessary.

The Competent Authority of your country has been notified of this action.

Please share this notification with others in your organization as appropriate.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions, please contact your Medtronic Representative.

Sincerely,

Medtronic Saudi Arabia

Appendix A: Model and Lot Numbers

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Model Number	Lot Number	Model Number	Lot Number
SA6IMAK*	All Lot Numbers	SA6IMA	All Lot Numbers
SA6RDND1K*		SA6IMASH	
SA6RBU35		SA6PK1W	
SA6HSI		SA6JR40K	
SA63DRCSH		SA6CHAMP05	
SA6AR10		SA6EBU40A	
SA6AR20		SA6RCBSHD	
SA6LCBD		SA6RCBD	
SA63DRC		SA6LCBSHD	
SA6RBU35SH		SA6CHAMP20K	
SA6AR10SH		SA6EBU35D	
SA6RDCK		SA6JCR40	
SA6JL40D		SA6NOTO	
SA6FL40		SA6AL10D	
SA6AR20SH		SA6SR40SH	
SA6IMAD		SA6SR40	
SA6MPHK		SA6CHAMP05SH	
SA6HSISH		SA6AL30A	
SA6FL40SH		SA6MP1K	
SA6JR40D		SA6JL50A	
SA6AL10A		SA6JR40A	
SA6AL20A		SA6JL35A	
SA6EBU35A		SA6AL75A	
SA6NOTOSH		SA6MB1D	
SA6SR30		SA6IMASHJ	
SA6JL40A			

*Part of the March 2019 notification scope.