

Updated Urgent Field Safety Notice

6F Sherpa NX Active Catheters

Recall

June 2019

Medtronic reference: FA864 Phase II

Dear Physician or Health Care Professional,

This letter is to inform you of a recall affecting 6F Sherpa NX Active Catheters distributed through 15 March 2019. Medtronic has determined that the 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.

Medtronic has received a total of five (5) complaints related to this issue between 29 January 2019 and 30 May 2019. There have been zero (0) patient harms reported with these complaints. 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.

Background

In April 2019, Medtronic initiated an Urgent Field Safety Notice for fifty-one (51) models of 6F Sherpa NX Active Catheters.

Current Recall

On May 14th, 2019, Medtronic received one (1) complaint related to this issue for a model number of 6F Sherpa NX Active Catheter that was not previously part of the recall. As a result, Medtronic has determined that the recall should be expanded to all model numbers and all lot numbers of 6F Sherpa NX Active Catheters. No other Medtronic products are affected by this recall.

Customer Instructions

Your facility has been identified as having received one or more of the potentially affected products in scope of the recall. 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 regarding this communication, please contact your Medtronic Field Representative directly or via Tel No: 01 511 1400.

Sincerely,



Keith Taverner: Regulatory Affairs Manager UK & Ireland

Appendix A: Model and Lot Numbers

Please see below.

Appendix A: Model and Lot Numbers

Product Number (CFN) All non-expired lot numbers of the below models are affected					
SA63DRC	SA6CHAMP15	SA6ERADR	SA6JL45SH	SA6MAC35SH	SA6RCBSHD
SA63DRCSH	SA6CHAMP15SH	SA6ERADRST	SA6JL50	SA6MAC375	SA6RDCK
SA63DRIGHT	SA6CHAMP20	SA6FL40	SA6JL50A	SA6MAC375SH	SA6RDND1K
SA63DRIGHTSH	SA6CHAMP20K	SA6FL40SH	SA6JL50SH	SA6MAC40	SA6RMHSII
SA6AL10	SA6CHAMP20SH	SA6FR35	SA6JL60	SA6MAC40SH	SA6RRAD
SA6AL10A	SA6CHAMP30	SA6FR40	SA6JL60SH	SA6MAC45	SA6SAL10
SA6AL10D	SA6CHAMP35	SA6HSI	SA6JR30	SA6MAC50	SA6SAL10SH
SA6AL10SH	SA6EBU30	SA6HSII	SA6JR30SH	SA6MB1	SA6SAL15
SA6AL15	SA6EBU30SH	SA6HSIII	SA6JR35	SA6MB1D	SA6SAL15SH
SA6AL15SH	SA6EBU35	SA6HSIIISH	SA6JR35SH	SA6MB1SH	SA6SAL20
SA6AL20	SA6EBU35A	SA6HSIISH	SA6JR40	SA6MB2	SA6SAL20SH
SA6AL205	SA6EBU35D	SA6HSISH	SA6JR405	SA6MB2SH	SA6SAL30
SA6AL20A	SA6EBU35SH	SA6IMA	SA6JR40A	SA6MP1	SA6SAL75
SA6AL20SH	SA6EBU375	SA6IMAD	SA6JR40D	SA6MP1K	SA6SAL75SH
SA6AL25	SA6EBU375SH	SA6IMAK	SA6JR40K	SA6MP1SH	SA6SAR10
SA6AL30	SA6EBU40	SA6IMASH	SA6JR40SH	SA6MP2	SA6SAR20
SA6AL30A	SA6EBU40A	SA6IMASHJ	SA6JR40SHA	SA6MPHK	SA6SCR35
SA6AL30SH	SA6EBU40SH	SA6JCL35	SA6JR45	SA6MPST	SA6SCR35SH
SA6AL40	SA6EBU45	SA6JCL40	SA6JR45SH	SA6MRADIAL	SA6SCR40
SA6AL75	SA6EBU45SH	SA6JCR40	SA6JR50	SA6MRESS	SA6SCR40SH
SA6AL75A	SA6EBU50	SA6JL30	SA6JR50SH	SA6NOTO	SA6SCR50
SA6AL75SH	SA6EBU50SH	SA6JL30SH	SA6JR60	SA6NOTOSH	SA6SL30
SA6ALR12	SA6ECR35	SA6JL35	SA6JR60SH	SA6PK1W	SA6SL35
SA6ALR12SH	SA6ECR35SH	SA6JL355	SA6LARA	SA6RBU35	SA6SL40
SA6AR10	SA6ECR40	SA6JL35A	SA6LCB	SA6RBU35SH	SA6SL45
SA6AR10SH	SA6ECR40SH	SA6JL35SH	SA6LCBD	SA6RBU40	SA6SL50
SA6AR20	SA6ELGAMAL	SA6JL40	SA6LCBSH	SA6RBU40SH	SA6SR30
SA6AR20SH	SA6ELGAMALSH	SA6JL405	SA6LCBSHD	SA6RBU45	SA6SR35
SA6CHAMP05	SA6ERADL	SA6JL40A	SA6MAC30	SA6RCB	SA6SR35SH
SA6CHAMP05SH	SA6ERADLLT	SA6JL40D	SA6MAC3030	SA6RCBD	SA6SR40
SA6CHAMP10	SA6ERADLSH	SA6JL40SH	SA6MAC30SH	SA6RCBII	SA6SR40SH
SA6CHAMP10SH	SA6ERADLST	SA6JL45	SA6MAC35	SA6RCBSH	