Medtronic
8200 Coral Sea St. NE
Mounds View, MN 55112
www.medtronic.com

URGENT MEDICAL DEVICE RECALL

6F Sherpa NX Active Catheters

See Appendix A for Models/Lot Numbers

April 2019

Dear Risk Manager or Health Care Professional:

In March 2019, Medtronic initiated an Urgent Medical Device Recall for a subset of 6F Sherpa NX Active Catheters <(see Appendix B)>. After continued investigation, it has been determined that the scope of this recall 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 recall 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. Contact <Medtronic Customer Service at 1-888-283-7868> to initiate a product return. Your local Medtronic Representative can assist you in the return of this product.
3. Complete the attached Customer Confirmation Certificate <and email to RS.CFQFCA@Medtronic.com>.

<Note: If you have already taken action as a result of the previous notification, please ensure you are now taking action on the expanded scope (additional models as indicated in Appendix A).>

Per your facility's standard medical device complaint procedures, report any adverse reactions or quality problems if the quality issue described above has been observed. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Medtronic will notify all applicable regulatory agencies about this matter.

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.

Sincerely,

<Eliezer De Jesus Hernandez
Vice President, Quality
Coronary & Structural Heart
Medtronic>

Appendix A: Model and Lot Numbers
<Appendix B: March 2019 Notification>

Appendix A: Model and Lot Numbers

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.

Appendix B: March 2019 Notification

Medtronic
8200 Coral Sea St. NE
Mounds View, MN 55112
www.medtronic.com

URGENT MEDICAL DEVICE RECALL
Sherpa 6F Active Catheters

Model Number	Lot Number
SA6IMAK	All lot numbers
SA6RDND1K	All lot numbers

March 2019

Dear Risk Manager or Health Care Professional,

Medtronic has identified a potential quality issue with a specific subset of lot numbers of the Medtronic Sherpa 6F Active Catheters. As a result, we are recalling the subset of catheters, from the specific model numbers and lot numbers as noted in the table above, for engineering evaluation. Further information regarding this issue will be provided at a later date.

Medtronic requests you immediately take the following actions:

1. Remove and quarantine all unused potentially affected product that remains in your inventory.
2. Return all unused affected product in your inventory to Medtronic. Contact <Medtronic Customer Service at 1-888-283-7868> to initiate a product return. Your local Medtronic Representative can assist you in the return of this product.
3. Complete the attached Customer Confirmation Certificate <and email to RS.CFQFCA@Medtronic.com>.

Medtronic has taken the necessary steps to prevent any future shipment of the potentially affected product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

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.

Sincerely,

<Eliezer De Jesus Hernandez
Vice President, Quality
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Medtronic>