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

URGENT: MEDICAL DEVICE RECALL

Heli-FX™ Guide Device

Model	Lot Number
HG-18-90-42	0008674156
HG-18-90-22	0008674157

September 2017

Dear Risk Manager or Health Care Professional:

The purpose of this letter is to advise you that Medtronic is voluntarily recalling two specific lot numbers of the Heli-FX™ Guide Devices per the table above. There is a total of 39 affected devices. There are no other model numbers or lot numbers of Medtronic devices affected by this issue.

Issue Description:

Medtronic has determined the deflection length indicated on the Guide catheter handle does not match the label on the box and sterile packaging for these affected devices.

As a result of the mislabeling, a patient could be exposed to a delivery system of identical length and diameter as intended but with a different deflection length when manipulated to deploy Heli-FX™ EndoAnchor™ implants. This could occur if the inconsistency between the packaging labeling and the deflection length on the Heli-FX Guide is undetected, or if the physician notices the inconsistency, and elects to use the device anyway.

While unlikely, the potential patient harms for using a guide with deflection that is too small or too large are vessel occlusion, leaks, migration of device, mis-deployed EndoAnchor, renal failure, CVA, Ischemia, Emboli, broken EndoAnchor, Type A dissection.

As of September 7, 2017, one (1) complaint has been received involving two (2) mislabeled Heli-FX Guide devices. **There were no adverse events or harms associated with the complaint.**

There are no actions required for patients already treated with use of this device as the potential for harm only occurs acutely at implant. These patients should continue to be monitored in accordance with your standard practice.

Actions:

Medtronic's records indicate that your facility has received product potentially affected by this issue. As a result, Medtronic requests that you immediately take the following actions:

1. Identify and quarantine all unused affected product as listed in your inventory.
2. Return all unused affected listed product in your inventory to Medtronic. Contact Medtronic Customer Service at 1-800-854-3570 to initiate a product return and credit. Your local Medtronic Representative can assist you in the return and replacement of this product as necessary.

3. Complete the enclosed Customer Confirmation Certificate and fax it to Medtronic at 651-367-0612 to the attention of Customer Focused Quality or scan and email to RS.CFQFCA@medtronic.com.

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please maintain a copy of this notice in your records.

Medtronic is communicating this information to the FDA.

Adverse reactions or quality problems experienced with this product should be reported to FDA and Medtronic:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or
- Call FDA (800) FDA-1088

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,

Jonathan Morris
Vice President, Quality
Aortic & Peripheral Vascular
Medtronic