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

URGENT MEDICAL DEVICE RECALL

SpiderFX™ Embolic Protection Devices

Model	Lot Number
SPD2-070-320	A464416
SPD2-030-320	A497831
SPD2-030-320	A504402
SPD2-050-320	A576053

March 2019

Dear Risk Manager or Health Care Professional:

The purpose of this letter is to advise you that Medtronic is voluntarily recalling a specific subset of SpiderFX™ Embolic Protection Devices in the United States (US). Medtronic has determined a total of 12 SpiderFX devices intended for sale outside of the United States, were shipped to facilities within the US. The devices were from the lots listed above. This issue does not pose any additional risk to the patient as there is no impact to device form, fit or function. The only difference is in the Instructions for Use (IFU).

There are no other model numbers or lot numbers of Medtronic devices affected by this issue.

Through Mar 14, 2019 Medtronic has received one (1) complaint involving this issue. There were no adverse events or harms associated with these complaints.

There are no actions required for patients already treated with this device. These patients should continue to be monitored in accordance with your standard practice.

Customer 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, from the affected lot number indicated in the table above, as listed in your inventory.
2. Return all unused affected listed product in your inventory to Medtronic. Contact Medtronic Customer Service at rs.cvspecialtyaccounts@medtronic.com or call 1-888-283-7868 or 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 return via email to RS.CFQFCA@medtronic.com.

This notice must be passed to all those who need to be aware within your organization or to any organization where potentially affected devices have been transferred. Please maintain a copy of this notice in your records.

Medtronic will notify all applicable regulatory agencies about this matter.

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,

Jonathan Morris
Vice President, Quality
Aortic & Peripheral Vascular
Medtronic

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Customer Confirmation Form
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<Account Name>
Account Number:<Insert Number>
<Address
City, State, Zip>
Sales Representative: *<Rep Name>* Representative Phone: *<Rep phone number>*

For completion by Medtronic Customers Only – Please complete all fields below and return immediately, even if you do not have any product to return.

By signing this form, I confirm that I have read the Urgent Medical Device Recall Notification Letter, dated March 2019, from Medtronic regarding SpiderFX™ Embolic Protection Devices, and taken appropriate action.

Please complete and sign the form as indicated below and email to **RS.CFQFCA@Medtronic.com**.

Customer Name (Print): _____ Date: _____
(First Name, Last Name)

Customer Title (Print): _____

Customer Signature (ink): _____

Telephone: _____

For questions, contact your Medtronic Field Representative.
Note: The addressee may continue to receive reminders of this notice until a response is received.

Please fill-in below the quantity of product that you have in your existing stock and will be returning.

Qty On-hand to return (units)	

Return Instructions:

- Identify and quarantine all unused affected product as listed in your inventory.
- Return all unused affected listed product in your inventory to Medtronic. Contact Medtronic Customer Service at rs.cvspecialtyaccounts@medtronic.com or call 1-888-283-7868 to initiate a product return and credit. Your local Medtronic Representative can assist you in the return and replacement of this product as necessary.
- Complete this provided Customer Confirmation Certificate and email to RS.CFQFCA@medtronic.com

Product Return Address:

Medtronic Logistics
4340 Swinnea Road, Building A - Returns
Memphis, TN 38118
ATTN: RGR # (provided by Customer Service)