

**URGENT: MEDICAL DEVICE RECALL**  
**Pipeline™ Flex Embolization Device**  
**Pipeline Flex Embolization Device with Shield Technology**  
**All Product Models**

July 13, 2021

Dear Healthcare Professional:

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific production lots of **Pipeline™ Flex Embolization Devices, including Pipeline™ Flex Embolization Device with Shield Technology.**

**Issue Description:**

Medtronic has received reports of serious injuries and deaths in connection with delivery pushwire fracture at the distal section of the Pipeline Flex™ delivery system during use. Through investigation, we have established that the root cause impacts production lots described in the Product Scope section below. Corrective actions have been implemented to address the underlying issue. This recall action is limited to the specific production lots listed on Attachment 1.

**Risk to Health:**

As of July 2, 2021, Medtronic has received reports of 71 confirmed and unconfirmed fractures. These events include reports of ten (10) serious injuries and two (2) deaths.

Use of impacted product may result in unintended fracture, where the distal portion of the pushwire separates from the device delivery system during delivery and deployment. If separation occurs, it may result in significant patient injury, including a prolonged procedure, foreign body, ischemic stroke, intracranial hemorrhage, neurological deficit, and/or death.

The risk of fracture presents only intra-operatively. If a Pipeline™ Flex embolization device has already been implanted successfully, there is no increased risk to patients due to the issue. Those patients with an implanted device should continue with their normal course of treatment.

**Product Scope:**

All models of the Pipeline™ Flex Embolization Device and Pipeline Flex Embolization Device with Shield Technology production lots manufactured between April-October 2019 (Expiry Dates: April 2022 – October 2022) and April-May 2020 (Expiry Dates: April 2023 – May 2023) are impacted by the issue. Refer to Attachment 1 – Product List for specific impacted production lot numbers.

Product Names, Unique Device Identifier (if applicable)	Manufacturer's Product Number/Catalog Number
Pipeline™ Flex Embolization Device	PED-250-XX, PED-275-XX, PED-300-XX, PED-325-XX, PED-350-XX, PED-375-XX, PED-400-XX, PED-425-XX, PED-450-XX, PED-475-XX, PED-500-XX

Pipeline™ Flex Embolization Device with Shield Technology™	PED2-250-XX, PED2-275-XX, PED2-300-XX, PED2-325-XX, PED2-350-XX, PED2-375-XX, PED2-400-XX, PED2-425-XX, PED2-450-XX, PED2-475-XX, PED2-500-XX
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**Required Actions:**

Our records show that your facility has received one or more lots of the impacted products. Lot Numbers of the affected product are listed in Attachment 1. Consequently, Medtronic requires that you immediately take the following actions:

1. Do NOT use any impacted product. Remove and quarantine all unused impacted products in your inventory.
2. Return the impacted products to Medtronic. Your Medtronic representative can assist in facilitating the return of product as necessary. If alternative product is needed, your Medtronic representative can assist you with identifying suitable replacement product.
3. Complete the attached Customer Confirmation Form, see Attachment 2, and fax it to Medtronic at 1-651-367-7075 to the attention of Neurovascular Quality or email it to [rs.navfca@medtronic.com](mailto:rs.navfca@medtronic.com).

Medtronic has taken the necessary steps to prevent future shipment of the impacted product.

**Transmission of this Communication:**

Please share this communication within your organization, with other organizations where impacted devices have been transferred, and any other associated organizations that may be impacted by this action.

Please maintain a copy of this letter for your records.

**Regulatory notification:**

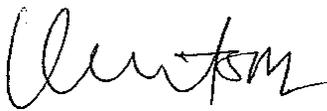
Medtronic is communicating this information to the appropriate regulatory agency in your country.

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

- E-mail Medtronic Quality Assurance at [rs.nvcomplaints@medtronic.com](mailto:rs.nvcomplaints@medtronic.com) or call at 1(800) 633-8766 (US Toll free) or (763)514-4000 (Worldwide)

We are committed to patient safety and appreciate your prompt attention to this matter. We regret any inconvenience this may cause. If you have any questions regarding this communication, please contact your Medtronic representative or email the Office of Medical Affairs at [rs.nvoma@medtronic.com](mailto:rs.nvoma@medtronic.com).

Sincerely,



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*Enclosure: Customer Confirmation Form*