

Medtronic Recalls Pipeline Flex Embolization Devices Due to Risk of Device Fracture

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- Pipeline Flex Embolization Device (Available in the US) and Pipeline Flex Embolization Device with Shield Technology (Not Available in the US)
- Product Codes:
 - Pipeline Flex Embolization Device: PED-250-XX, PED-275-XX, PED-300-XX, PED-325-XX, PED-350-XX, PED-375-XX, PED-400-X
 - 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
- Manufacturing Dates: October 22, 2019 to February 1, 2020
- Distribution Dates: November 6, 2019 to February 7, 2020
- Devices Recalled in the U.S.: 822
- Date Initiated by Firm: February 14, 2020

Device Use

The Pipeline Flex Embolization Device ("Pipeline Flex") is a permanent mesh cylinder (stent) braided from platinum and tungsten and cobalt-chromium-nickel alloy wires intended for the treatment of brain aneurysms (<https://medlineplus.gov/brainaneurysm.html>) that bulge or balloon out the sides of the blood vessel (wide-neck and fusiform). The Pipeline Flex also includes a guidewire-based delivery system used to place the implant inside the patient.

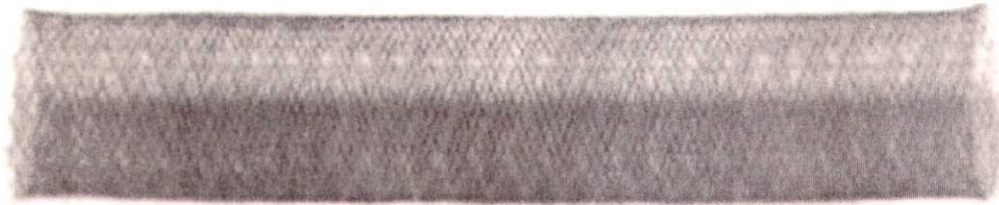


Figure 1. Pipeline™ Flex Embolization Device Implant

Reason for Recall

Medtronic is recalling their Pipeline Flex Embolization Device and Pipeline Flex Embolization Device with Shield Technology because there is a risk the delivery system could fracture while placing the stent inside the patient.

Fractured pieces of the delivery system could be left inside the patient's brain bloodstream, and this or the attempts made to retrieve the fractured pieces, can make the patient's condition worse. This can also cause other serious adverse health consequences such as continued blockage of blood vessels, stroke, and death.

If a Pipeline Flex Embolization Device (the permanent flow diverting stent) has already been implanted successfully, there is no increased risk to patients due to this issue.

The FDA has received 50 Medical Device Reports, with 10 injuries and 1 death, from November 1, 2019 to March 1, 2020.

Who May be Affected

- Health care providers using the device during the treatment of brain aneurysms
- All patient groups undergoing procedures involving the Pipeline Flex Embolization and Pipeline Flex Embolization Device with Shield Technology

What to Do

On February 14, 2020, Medtronic sent an Urgent Medical Device Recall Notice to their customers advising them of the product issue and provided the following instructions:

- Do NOT use any affected product. Remove and quarantine all unused affected products in your inventory.
- Return the affected 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.
- Complete the Customer Confirmation Form (Attachment 2) and fax it to Medtronic at 1-949-434-5020 to the attention of Neurovascular Quality.

- Share the notice with other organizations where affected devices have been transferred, and any other associated organizations that may be impacted by this action.
- Be aware that Medtronic has taken the necessary steps to prevent future shipment of the affected product.

Contact Information

Customers with questions may contact Medtronic Quality Assurance at 1(800) 633-8766 (US Toll free) or (763)514-4000 (Worldwide). Questions may also be emailed to rs.nvcomplaints@medtronic.com (<mailto:rs.nvcomplaints@medtronic.com>).

Additional Resources:

- Medical Device Recall Database Entry: Pipeline Flex Embolization Device (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=180023>)
- Medical Device Recall Database Entry: Pipeline Flex Embolization Device with Shield Technology (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=180025>)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.