Medtronic

Urgent Field Safety Notice

Pipeline™ Flex Embolization Device

Recall

February 2020

Medtronic reference: FA906

Dear Healthcare Professional or Risk Manager,

At 18 February 2020, Medtronic initiated a verbal communication about an Urgent Field Safety Notice for specific production lots of Pipeline™ Flex embolization devices (including Pipeline™ Flex with Shield technology). This notice is a follow-up to that verbal notification provided to your facility, where Medtronic requested that you put unused affected products in quarantine.

Issue Description:

Medtronic has identified the potential for device fracture at the distal section during use due to a weakened bond in a subset of devices that have been recently manufactured. Use of affected product may result in unintended separation, where the distal portion of the device delivery system remains in the patient. If this occurs, it may result in significant patient injury, including a prolonged procedure, ischemic stroke, intracranial hemorrhage, neurological deficit, and/or death.

No complaints related to the issue have been confirmed within the affected population at this time. However, due to the increased potential for device fracture, Medtronic is recalling these production lots listed below.

This is a peri-procedural risk. 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 lots with a Use-Before date on or after 21OCT2022 are affected by the issue. Refer to Attachment 1 for specific affected product 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

Required Actions:

Our records show that your facility has received one or more lots of the affected 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 affected product. Remove and quarantine all unused affected products in your inventory.**
2. **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.**

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

Please share this communication within your organization, with other organizations where affected 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.

The Competent Authority of your country has been notified of this action.

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 representative at <XXX>.

Sincerely,

Local /BU Manager

Enclosure: Attachment 1: Affected Product Model Numbers and Lot Information

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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

Product Lots Impacted					
A918616	A920071	A922016	A922688	A924194	A925293
A918617	A920072	A922017	A922690	A924197	A925295
A918618	A920073	A922018	A922691	A924198	A925296
A918619	A920074	A922020	A922692	A924199	A925297
A918620	A920075	A922021	A922693	A924638	A925298
A918621	A920076	A922022	A922694	A924640	A925299
A918622	A920078	A922480	A922695	A924641	A925300
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A918624	A920902	A922483	A922698	A924643	A925914
A918625	A921354	A922484	A922699	A924644	A925915
A918626	A921355	A922571	A923951	A924645	A925917
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