

## Urgent Field Safety Notice

### Pipeline™ Flex Embolization Device and Pipeline™ Flex with Shield Technology All Product Models Recall

July 2021

Medtronic Reference: FA985

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. One (1) additional serious injury originated from Europe (Finland), however all the other serious injuries and 2 deaths occurred outside Europe, Middle East and Africa.

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:**

Specific lot numbers of all models of the Pipeline™ Flex Embolization Device and Pipeline Flex Embolization Device with Shield Technology that have been 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

**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. The impacted list of products is grouped by 3-month expiry date windows to assist in inventory review.

Consequently, Medtronic requires that you immediately take the following actions:

1. Based on the product in your control, please review the expiry window as compared to the expiration date on the Pipeline devices. (See sample labels in Attachment 1 for an example of where the expiry date can be found on Pipeline labels).
2. If any device is within the following expiry windows – April 2022 – October 2022 or April 2023 – May 2023, please review Attachment 1 to identify the expiry group and review the lot number on your device.
3. Devices observed to have any of the lot numbers in Attachment 1, are considered within scope of the Recall notice.
4. Do NOT use any impacted product. Remove and quarantine all unused impacted products in your inventory.
5. 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.

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.

**Additional Information:**

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

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, please contact your Medtronic Representative.

Sincerely,


Medtronic


## Attachment 1 – Affected Product Lots

**ev3™**

Contents

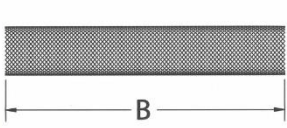
202 cm

1x 

1x 

**Pipeline™ Flex Embolization Device**

US and Foreign Patents: Pending




**A** 2.50 mm

**B** 10 mm

**REF** PED-250-10

**LOT** A123456

 2019-06-10

**Pipeline™ Flex Embolization Device**

**REF** PED-250-10 **LOT** A123456

(01)00763000276379 (17)190610(10)A123456

**Pipeline™ Flex Embolization Device**

**REF** PED-250-10 **LOT** A123456

(01)00763000276379(17)190610(10)A123456

**Pipeline™ Flex Embolization Device**























**REF** PED-250-10 **LOT** A123456

(01)00763000276379(17)190610(10)A123456

**REF** PED-250-10 **LOT** A123456 **2.50 mm / 10 mm** **Pipeline™ Flex Embolization Device**

**2019-06-10**

Micro Therapeutics, Inc.  
d/b/a ev3 Neurovascular  
9775 Toledo Way  
Irvine, CA 92618 USA  
Tel: +1-949-837-3700

STERILE EO                        

Affected Product Lots: Expiry Date Range 2022-04-01 to 2022-06-30										
A810945	A810946	A811477	A811479	A811480	A812095	A812097	A812119	A812724	A812725	A812726
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Affected Product Lots: Expiry Date Range 2022-04-01 to 2022-06-30										
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Affected Product Lots: Expiry Date Range 2022-07-01 to 2022-09-30										
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Affected Product Lots: Expiry Date Range 2022-07-01 to 2022-09-30										
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A894397	A894398	A894400	A894401	A894402	A894404	A894405	A894406	A894597	A894599	A894600
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A895293	A895294	A895295	A895296	A895302	A895303	A895304	A895305	A895306	A895307	A895308
A895309	A895310	A895312	A895313	A895314	A895315	A896153	A896154	A896155	A896157	A896158
A896159	A896160	A896161	A896162	A896163	A896936	A896937	A896938	A896941	A896942	A896944
A896945	A896946	A896947	A896948	A897345	A897347	A897348	A897350	A897354	A897358	A897361
A897363	A897365	A897367	A897369	A897371	A897373	A897375	A897377	A897378	A897379	A898544
A898545	A898546	A898549	A898551	A898552	A898555	A898557	A898558	A898559	A898562	A898564
A899357	A899360	A899361	A899362	A899364	A899366	A899368	A899369	A899370	A899372	A899373
A899375	A899376	A900253	A900254	A900255	A900256	A900258	A900260	A900262	A900263	A900265
A900266	A900736	A900739	A900740	A900741	A900742	A900744	A900745	A900746	A900747	A900749
A900750	A900752	A900753	A900754	A900755	A900756	A900757	A900758	A900759	A902089	A902090
A902091	A902092	A902093	A902094	A902095	A902096	A902097	A902098	A902100	A902101	A902102
A902103	A902104	A902106	A902107	A902751	A902753	A902755	A902756	A902758	A902759	A902760
A902761	A902762	A902764	A902767	A902772	A903537	A903538	A903540	A903541	A903543	A903544
A903545	A903560	A903561	A903562	A903563	A903564	A903565	A903566	A903567	A904230	A904232
A904234	A904237	A904239	A904241	A904243	A904246	A904252	A904253	A904254	A904255	A904256
A904257	A904258	A904870	A904871	A904873	A904875	A904876	A904906	A906053	A906054	A906055
A906057	A906062	A906063	A906064	A906065	A906066	A906067	A906068	A906069	A906070	A906071
A906072	A906073	A906074	A906076	A906077	A906079	A906080	A906724	A906725	A906726	A906727
A906728	A906729	A906730	A906731	A906733	A906734	A906735	A906736	A906737	A907480	A907481
A907482	A907483	A907484	A907490	A907491	A907496	A907497	A907498	A907499	A907500	A908288
A908291	A908292	A908295	A908296	A908626	A908627	A908628	A908629	A908631	A908633	A908634
A908635	A908636	A909350	A909351	A909353	A909354	A909355	A909356	A909357	A909358	A909360
A909361	A909362	A909363	A909370	A909371	A909372	A909373	A909375	A909377	A909378	A910385
A910387	A910389	A910390	A910392	A910393	A910394	A910395	A910396	A910397	A910398	A910918
A910919	A910920	A910922	A910924	A910925	A910926	A910927	A910928	A910929	A911793	A911794
A911795	A911797	A911798	A911799	A911800	A911801	A911802	A912441		A912447	

Affected Product Lots: Expiry Date Range 2022-10-01 to 2022-10-31										
A909374	A910391	A910923	A910930	A911796	A911803	A912440	A912442	A912443	A912444	A912445
A912449	A912451	A913140	A913143	A913144	A913145	A913148	A913149	A913155	A913156	A913157
A913158	A913160	A913162	A914075	A914076	A914077	A914141	A914142	A914143	A914144	A914206
A914207	A914208	A914209	A914210	A914211	A914212	A914214	A914804	A914805	A914806	A914808
A914809	A914810	A914811	A914812	A914814	A914815	A914816	A914817	A915508	A915516	A915518
A915520	A915521	A915523	A915524	A915527	A915529	A915537	A915539	A915540	A915541	A915542
A916289	A916290	A916291	A916292	A916293	A916294	A916295	A916296	A916297	A916298	A916299
A916300	A917147	A917148	A917150	A917152	A917154	A917155	A917157	A917159	A917160	A917837
A917839	A918056	A918057	A918058	A918061	A918062	A918063	A918065	A918066	A918068	A918069
A918070										

Affected Product Lots: Expiry Date Range 2023-04-01 to 2023-05-31										
B002744	B002749	B002757	B005837	B005838	B005839	B005840	B005844	B005846	B005848	B005849
B005850	B005851	B005852	B005853	B005855	B005859	B005860	B005862	B005863	B005864	B005865
B005867	B007366	B007367	B007368	B007369	B007370	B007371	B007372	B007373	B007374	B007375
B007376	B007377	B007378	B007400	B007401	B007402	B007403	B007404	B007405	B007406	B007407
B007408	B008202	B008203	B008204	B008206	B008207	B008208	B008215	B008216	B008217	B008219
B013889	B015360	B016955	B016957	B016960	B016962	B016964	B016966	B017057	B017058	B017059
B017067	B017069	B017070	B017071	B017072	B017073	B017074	B017075	B017076	B017077	B017078
B017079	B017080	B017082	B017083	B017084	B017085	B018619	B018620	B018621	B018622	B018624
B018625	B018627	B018628	B018629	B018630	B018631	B018632	B019181	B019182	B019184	B019186
B027513	B027921	B031111								