

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 at <XXXX>.

Sincerely,

Local / BU Manager

Attachment 1 – Affected Product Lots

ev3™

Contents

202 cm

1x

1x

Pipeline™ Flex Embolization Device

A 2.50 mm

B 10 mm

REF PED-250-10

LOT A123456

2019-06-10

US and Foreign Patents: Pending

Micro Therapeutics, Inc.
d/b/a ev3 Neurovascular
9775 Toledo Way
Irvine, CA 92618 USA
Tel: +1.949.837.3700

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REF PED-250-10

LOT A123456

2019-06-10

2.50 mm / 10 mm Pipeline™ Flex Embolization Device

ev3™

Contents

202 cm

1x

1x

Pipeline™ Flex Embolization Device with Shield Technology™

Dispositif d'embolisation Pipeline™ Flex avec Shield Technology™
Pipeline™ Flex Embolisation Instrument mit Shield Technology™
Dispositivo di embolizzazione Pipeline™ Flex con Shield Technology™
Dispositivo de embolización Pipeline™ Flex con Shield Technology™
Pipeline™ Flex embolizációs eszköz Shield Technology™
Pipeline™ Flex embolizációs szerkezet Shield Technology™
Pipeline™ Flex-embolizációs segédeszköz Shield Technology™
Dispositiv de embolizare Pipeline™ Flex cu Shield Technology™
Shield Technology™ - teknička značka Pipeline™ Flex - embolizacijski alat
Pipeline™ Flex-embolizációs szerkezet Shield Technology™
Устройство за емболизација Pipeline™ Flex со Shield Technology™
Εμβολισιακή συσκευή Pipeline™ Flex со Shield Technology™
Embolizációs készülék Pipeline™ Flex со Shield Technology™

Pipeline™ Flex embolizációs eszköz Shield Technology™
Устройство за емболизација Pipeline™ Flex со Shield Technology™
Uzariadenie do embolizácie Pipeline™ Flex s Shield Technology™
Embolizációs szerkezet Pipeline™ Flex s Shield Technology™
Embolizációs segédeszköz Pipeline™ Flex s Shield Technology™
Dispositiv de embolizare Pipeline™ Flex cu Shield Technology™
Устройство за емболизација Pipeline™ Flex со Shield Technology™
Embolizációs készülék Pipeline™ Flex со Shield Technology™

A 2.50 mm

B 10 mm

REF PED2-250-10

LOT A123456

2019-07-16

US and Foreign Patents: Pending

Micro Therapeutics, Inc.
d/b/a ev3 Neurovascular
9775 Toledo Way
Irvine, CA 92618 USA
Tel: +1.949.837.3700

EC REP
Medtronic B.V.
Earf Bakkerstraat 10
6422 PJ Mierden
The Netherlands

Country of Origin: United States of America

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REF PED2-250-10

LOT A123456

2019-07-16

REF PED2-250-10

LOT A123456

2019-07-16

2.50 mm / 10 mm Pipeline™ Flex Embolization Device with Shield Technology™

Legend:

LOT = Lot Number  = Expiry Date

Affected Product Lots: Expiry Date Range 2022-04-01 to 2022-06-30

A810945	A810946	A811477	A811479	A811480	A812095	A812097	A812119	A812724	A812725	A812726
A812727	A812728	A812729	A812730	A812731	A812732	A812733	A812734	A813318	A813319	A813320
A813321	A813323	A813324	A813325	A813326	A813327	A813329	A813907	A813908	A813909	A813912
A813913	A813915	A813916	A813917	A813920	A813921	A815062	A815063	A815064	A815065	A815066
A815067	A815068	A815069	A815071	A815073	A815074	A815075	A815076	A815077	A815078	A815079
A815080	A815691	A815692	A815693	A815694	A815695	A815696	A815697	A815698	A815699	A815702
A816329	A816330	A816334	A816335	A816338	A816341	A816342	A816343	A816345	A816346	A816347
A816348	A816349	A817106	A817107	A817108	A817109	A817110	A817111	A817112	A817113	A817115
A817116	A817117	A817119	A817123	A817126	A817130	A817751	A817753	A817754	A817756	A817758
A817759	A817761	A817762	A817763	A817764	A817765	A817766	A817767	A817769	A818290	A818291
A818292	A818295	A818296	A818297	A818298	A818299	A818300	A818301	A818459	A818460	A818461
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A819171	A819172	A819203	A819204	A819205	A819208	A819209	A820989	A821009	A821010	A821011
A821012	A821013	A821014	A821016	A821017	A821018	A821019	A821020	A821029	A821504	A821505
A821506	A821507	A821508	A821511	A821512	A821514	A821515	A821517	A821519	A821521	A822208
A822209	A822210	A822211	A822212	A822213	A822215	A822627	A822630	A822664	A822666	A822667
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A827607	A827608	A827609	A828614	A828615	A828616	A828617	A828618	A829030	A829031	A829033
A829034	A829036	A829037	A829039	A829042	A829043	A829044	A829045	A829047	A829048	A829744
A829745	A829746	A829747	A829748	A829750	A829751	A830302	A830303	A830304	A830766	A830768
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A833115	A833117	A833119	A833120	A833121	A833122	A833123	A833700	A833701	A833702	A833703
A833704	A833706	A833707	A833709	A833710	A833711	A833712	A833713	A833714	A833715	A834386

Affected Product Lots: Expiry Date Range 2022-04-01 to 2022-06-30

A834388	A834389	A834390	A834391	A834393	A834396	A834397	A834398	A835004	A835005	A835008
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A835659	A835660	A835661	A835662	A835663	A835664	A836543	A836546	A836549	A836550	A836551
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A837021	A837022	A837024	A837026	A837027	A837028	A837029	A837030	A838062	A838063	A838064
A838065	A838084	A838085	A838086	A838089	A838092	A838095	A838097	A838100	A838102	A838104
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A850791	A850792	A850793	A850795	A850796	A851427	A851428	A851429	A851431	A851432	A851433
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A852557	A852711	A852712	A852713	A852714	A852715	A852716	A852717	A852718	A852720	A852721
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A854608	A854822	A854823	A854824	A854825	A854826	A854827	A854828	A854829	A854832	A854833
A854834	A855375	A855377	A855378	A855382	A855383	A855384	A855386	A855387	A855388	A855389
A855391	A855392	A855393	A855394	A855395	A856680	A856681	A856682	A856683	A856684	A856685
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A858337	A858340	A858341	A858342	A858343	A858345	A859165	A859166	A859167	A859168	A859169
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A859757	A859761	A859762	A859763	A859764	A859765	A859766	A859774	A859777	A859780	A861603

Affected Product Lots: Expiry Date Range 2022-07-01 to 2022-09-30

A859164	A859758	A859759	A859760	A859767	A859768	A859769	A859770	A859771	A859772	A859773
A859775	A859776	A859778	A859779	A861600	A861601	A861602	A861604	A861605	A861606	A861607
A861608	A861609	A861756	A861757	A861758	A861759	A861761	A861763	A861764	A861765	A861766
A861767	A861768	A861769	A861771	A862900	A862901	A862902	A862904	A862905	A862906	A862907
A862908	A862909	A862910	A862911	A862912	A862914	A862916	A862917	A862918	A862919	A862920
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A864456	A864457	A864459	A864460	A864462	A864463	A864469	A864470	A864472	A864474	A864475
A864476	A864477	A864480	A864482	A864484	A864485	A864487	A865228	A865229	A865230	A865231
A865232	A865233	A865234	A865235	A865236	A865239	A865240	A865241	A865242	A866003	A866004
A866005	A866006	A866008	A866009	A866010	A866011	A866012	A866014	A866016	A866017	A866018
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A867723	A867838	A867839	A867840	A867841	A867843	A867844	A867845	A867846	A867847	A867848
A867849	A868552	A868555	A868564	A868565	A868566	A868567	A868568	A868571	A868572	A868573
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A869098	A869101	A869102	A869105	A869897	A869898	A869899	A869900	A869901	A869902	A869903
A869904	A869905	A869906	A869907	A869908	A870618	A870621	A870625	A870630	A870631	A870632
A871380	A871382	A871384	A871386	A871390	A871391	A871392	A871393	A871636	A871637	A871639
A871640	A871933	A871934	A871935	A871936	A871937	A871938	A871941	A871943	A871944	A871947
A871949	A871951	A871952	A871953	A871954	A871955	A873187	A873188	A873189	A873190	A873191
A873192	A873193	A873194	A873195	A873197	A873198	A873200	A873201	A873204	A873205	A874035
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A878850	A878851	A878853	A878854	A878855	A878856	A879717	A879718	A879719	A879720	A879721
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A880355	A880357	A880359	A880361	A880362	A880363	A880365	A880366	A880367	A880368	A880369
A880370	A880371	A880372	A880373	A881403	A881405	A881406	A881407	A881408	A881409	A881410
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A883593	A884540	A884541	A884542	A884543	A884544	A884546	A884549	A884551	A884552	A884576
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A886638	A886640	A886642	A886644	A886647	A886649	A886650	A886651	A886652	A886653	A886654

Affected Product Lots: Expiry Date Range 2022-07-01 to 2022-09-30										
A886655	A886656	A887300	A887301	A887302	A887303	A887304	A887306	A887308	A887311	A887314
A887316	A887317	A887318	A887319	A887320	A887321	A887928	A887929	A887930	A887931	A887932
A887933	A887934	A887937	A887938	A887940	A887941	A888378	A888379	A888380	A888381	A888383
A889026	A889027	A889028	A889029	A889033	A889034	A889035	A889037	A889039	A889041	A890031
A890034	A890035	A890036	A890037	A890038	A890039	A890041	A890605	A890606	A890609	A890612
A890613	A890614	A890615	A890619	A890623	A890625	A890626	A890627	A890628	A890629	A890630
A890631	A894159	A894160	A894161	A894162	A894163	A894164	A894165	A894393	A894394	A894396
A894397	A894398	A894400	A894401	A894402	A894404	A894405	A894406	A894597	A894599	A894600
A894601	A894602	A894603	A894604	A894605	A894606	A894607	A894609	A894611	A894613	A894614
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								