

Dringende veiligheidskennisgeving

**Pipeline™ Flex-embolisatiehulpmiddel en Pipeline™ Flex met Shield Technology
Alle productmodellen
Recall**

Juli 2021

Medtronic-referentienr: FA985

Geachte zorgverlener,

Het doel van deze brief is u te informeren dat Medtronic vrijwillig specifieke productiepartijen van **Pipeline™ Flex-embolisatiehulpmiddelen**, inclusief de **Pipeline™ Flex-embolisatiehulpmiddel met Shield Technology** terugroept.

Beschrijving van het probleem:

Medtronic heeft meldingen ontvangen van ernstige letsels en sterfgevallen, in verband met een breuk van de duwdraad aan het distale deel van het Pipeline Flex™ plaatsingssysteem tijdens gebruik. Na onderzoek hebben we vastgesteld dat de hoofdoorzaak de productiepartijen in de hieronder beschreven scope beïnvloedt. Corrigerende acties zijn geïmplementeerd om het onderliggende probleem op te lossen. Deze recall is beperkt tot de specifieke productiepartijen vermeld in Bijlage 1.

Risico voor gezondheid:

Tot 2 juli 2021 heeft Medtronic meldingen van 71 bevestigde en onbevestigde breuken ontvangen. Deze voorvallen omvatten meldingen van tien (10) ernstige letsels en twee (2) sterfgevallen. Een (1) additionele melding van ernstig letsel kwam uit Europa (Finland), echter alle overige meldingen van ernstig letsel en de 2 sterfgevallen vonden plaats buiten Europa, het Midden-Oosten en Afrika.

Het gebruik van het betreffende product kan resulteren in onbedoelde breuk, waarbij het distale deel van de duwdraad wordt afgezonderd van het plaatsingssysteem tijdens plaatsing. Als dit plaatsvindt, kan dit resulteren in aanzienlijk letsel voor de patiënt, waaronder een langer durende ingreep, 'vreemd lichaam', ischemische beroerte, intracraniale bloeding, neurologische uitval en/of overlijden.

Het risico van breuk treedt alleen tijdens de operatie op. Als een Pipeline™ Flex-embolisatiehulpmiddel reeds is geïmplant, is er geen verhoogd risico voor patiënten wegens dit probleem. Bij patiënten met een geïmplant hulpmiddel moeten hun normale behandeling gecontinueerd worden.

Scope

Het probleem treedt op bij specifieke partijnummers van alle modellen van het Pipeline™ Flex-embolisatiehulpmiddel en Pipeline™ Flex-embolisatiehulpmiddel met Shield Technology die zijn geproduceerd tussen april en oktober 2019 (vervaldata: april 2022 – oktober 2022) en april-mei 2020 (vervaldata: april 2023 – mei 2023). Zie bijlage 1 - Productlijst voor specifieke desbetreffende productiepartijnummers.

Productnamen, Unieke apparaat-id (indien toepasselijk)	Productnummer/catalogusnummer fabrikant
Pipeline™ Flex-embolisatiehulpmiddel	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-embolisatiehulpmiddel met 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

Vereiste acties:

In onze dossiers staat aangegeven dat uw organisatie een of meer partijen van het betreffende product heeft ontvangen. Partijnummers van het desbetreffende product zijn vermeld in Bijlage 1. De betreffende lijst van de producten is gegroepeerd in vervaldatumvensters van 3 maanden om te helpen bij het controleren van de voorraad.

Medtronic verzoekt u onmiddellijk de volgende acties uit te voeren:

1. Controleer, op basis van het product waarover u beschikt, het vervaldatumvenster en vergelijk het met de vervaldatum op de Pipeline-hulpmiddelen. (Zie de voorbeeldetiketten in Bijlage 1 voor de plaats waar u de vervaldatum kunt vinden op Pipeline-etiketten).
2. Indien een hulpmiddel binnen de volgende vervaldatumvensters – april 2022 – oktober 2022 of april 2023 – mei 2023 valt, zoek dan in Bijlage 1 de vervaldatumgroep en controleer het partijnummer op uw hulpmiddel.
3. Hulpmiddelen waarop een van de partijnummers uit Bijlage 1 wordt aangetroffen, worden geacht binnen de scope van deze recall te vallen.
4. Gebruik het desbetreffende product NIET. Plaats alle ongebruikte betrokken producten in uw voorraad in quarantaine.
5. Retourneer de betrokken producten aan Medtronic. Uw Medtronic-vertegenwoordiger zal - indien nodig - helpen om de producten terug te sturen. Als een ander product is vereist, kan uw lokale Medtronic-vertegenwoordiger u helpen met het identificeren van een geschikt vervangingsproduct.

Medtronic heeft de nodige stappen genomen om verdere verzending van het desbetreffende product te voorkomen.

Verzending van dit bericht:

Deel dit bericht binnen uw organisatie, met andere organisaties waarnaar de betrokken producten zijn gedistribueerd en alle andere verbonden organisaties die mogelijk getroffen worden door deze actie.

Bewaar een kopie van deze brief voor uw administratie.

Aanvullende informatie:

De bevoegde autoriteit (IGJ) in uw land is van deze actie op de hoogte gesteld.


De veiligheid van de patiënt staat bij ons voorop en we waarderen uw snelle afhandeling van deze zaak. Onze excuses voor het ongemak dat door deze kwestie kan zijn veroorzaakt. Als u vragen hebt, kunt u contact opnemen met uw Medtronic-vertegenwoordiger op zijn/haar mobiele telefoonnummer of via 040-7117555.

Met vriendelijke groet,

...


**LET'S TAKE HEALTHCARE
FURTHER, TOGETHER**


Bijlage 1 - Betrokken productpartijen



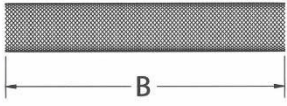
Contents

202 cm

1x 

1x 


Pipeline™ Flex Embolization Device




A

B


US and Foreign Patents: Pending



(01)00763000276376




(17)190716(10)A123456

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
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(01)00763000276376(17)190716(10)A123456

Pipeline™ Flex Embolization Device







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(01)00763000276376(17)190716(10)A123456

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d/b/a ev3 Neurovascular
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Irvine, CA 92618 USA
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www.medtronic.com/manuals


REF PED-250-10

LOT A123456

2019-06-10


2.50 mm / 10 mm


Pipeline™ Flex Embolization Device



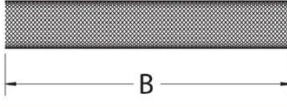
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202 cm

1x 

1x 


Pipeline™ Flex Embolization Device with Shield Technology™



A


B

US and Foreign Patents: Pending

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B	10 mm
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Pipeline™ Flex Embolization Device with Shield Technology™


REF PED2-250-10	LOT A123456
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Pipeline™ Flex Embolization Device with Shield Technology™







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(01)00763000283834(17)190716(10)A123456

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REF PED2-250-10

LOT A123456

2019-07-16

2.50 mm / 10 mm

Pipeline™ Flex Embolization Device with Shield Technology™

Legenda:

LOT = Partijnummer



= Vervaldatum

Betrokken productpartijen: vervaldatumvenster 2022-04-01 tot 2022-06-30										
A810945	A810946	A811477	A811479	A811480	A812095	A812097	A812119	A812724	A812725	A812726
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Betrokken productpartijen: vervaldatumvenster 2022-04-01 tot 2022-06-30										
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Betrokken productpartijen: vervaldatumvenster 2022-07-01 tot 2022-09-30										
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A874036	A874039	A874042	A874045	A874046	A874049	A874050	A874053	A874057	A874059	A874062
A874064	A875013	A875015	A875017	A875022	A875030	A875033	A875034	A875035	A875036	A875037
A875039	A875042	A875048	A875051	A875056	A875062	A876738	A876740	A876741	A876742	A876743
A876744	A876745	A876746	A876747	A876748	A876749	A877514	A877516	A877517	A877518	A877519
A877520	A877521	A877523	A877524	A877525	A877526	A877527	A877532	A877533	A877534	A878414
A878417	A878418	A878419	A878420	A878840	A878842	A878844	A878845	A878846	A878848	A878849
A878850	A878851	A878853	A878854	A878855	A878856	A879717	A879718	A879719	A879720	A879721
A879723	A879724	A879725	A879726	A879727	A879728	A879731	A879732	A879733	A879734	A879735
A880355	A880357	A880359	A880361	A880362	A880363	A880365	A880366	A880367	A880368	A880369
A880370	A880371	A880372	A880373	A881403	A881405	A881406	A881407	A881408	A881409	A881410
A881412	A881414	A881415	A881416	A881417	A881418	A881419	A881420	A882122	A882134	A882135
A882136	A882137	A882138	A882139	A882141	A882143	A882146	A882147	A882796	A882797	A882798
A882799	A882800	A882801	A882802	A882804	A882805	A882806	A883575	A883576	A883577	A883578
A883579	A883581	A883582	A883583	A883585	A883586	A883587	A883588	A883589	A883590	A883591
A883593	A884540	A884541	A884542	A884543	A884544	A884546	A884549	A884551	A884552	A884576
A884579	A884580	A884581	A884583	A884585	A884589	A884594	A884598	A885863	A885864	A885865
A885866	A885867	A885868	A885869	A885870	A885871	A885872	A885873	A885874	A885877	A885880
A886638	A886640	A886642	A886644	A886647	A886649	A886650	A886651	A886652	A886653	A886654

Betrokken productpartijen: vervaldatumvenster 2022-07-01 tot 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		

Betrokken productpartijen: vervaldatumvenster 2022-10-01 tot 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										

Betrokken productpartijen: vervaldatumvenster 2023-04-01 tot 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								