

URGENTE: RECALL (RECOLHIMENTO) DE DISPOSITIVO MÉDICO

Dispositivo de Embolização Pipeline™ Flex Anexo 1 – Lotes dos Produtos Afetados

Instruções:

1. A lista dos produtos afetados (conforme páginas a seguir) está agrupada por intervalos com datas de vencimento de 3 (três) em 3 (três) meses para facilitar a verificação do produto no inventário.
2. Verifique a data de vencimento do dispositivo Pipeline em seu controle (Ver amostras de etiquetas abaixo para verificar um exemplo de onde a data de vencimento pode ser localizada nas etiquetas do Pipeline).
3. Se algum dispositivo estiver dentro do intervalo do vencimento: **Abril de 2022 – Outubro de 2022 ou Abril de 2023 – Maio de 2023**, utilize este documento para identificar o grupo das datas de vencimento e verifique o número do lote em seu dispositivo.
4. Os dispositivos pertencentes a qualquer um dos números dos lotes indicados neste documento estão dentro do escopo do Aviso de Recolhimento e devem ser devolvidos de acordo com as instruções na carta ao cliente e no formulário de confirmação do cliente.

Pipeline™ Flex Embolization Device

Contents: 1x [Device], 1x [Accessories], 202 cm

Dimensions: 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

STERILE EO, Rx ONLY, CE 0297

www.medtronic.com/manuals

REF PED-250-10
LOT A123456
2019-06-10

2.50 mm / 10 mm Pipeline™ Flex Embolization Device

Pipeline™ Flex Embolization Device with Shield Technology™

Contents: 1x [Device], 1x [Accessories], 202 cm

Dimensions: 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.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

Country of Origin: United States of America

STERILE EO, Rx ONLY, CE 0297

www.medtronic.com/manuals

REF PED2-250-10
LOT A123456
2019-07-16

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

Legenda:

LOT = Número do Lote



= Data de Vencimento

**Lotes dos Produtos Afetados: Intervalo das Datas de Vencimento:
2022-04-01 a 2022-06-30**

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**Lotes dos Produtos Afetados: Intervalo das Datas de Vencimento:
2022-04-01 a 2022-06-30**

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**Lotes dos Produtos Afetados: Intervalo das Datas de Vencimento:
2022-07-01 a 2022-09-30**

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**Lotes dos Produtos Afetados: Intervalo das Datas de Vencimento:
2022-07-01 a 2022-09-30**

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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	

**Lotes dos Produtos Afetados: Intervalo das Datas de Vencimento:
2022-10-01 a 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										

**Lotes dos Produtos Afetados: Intervalo das Datas de Vencimento:
2023-04-01 a 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								