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Urgent Field Safety Notice

Pipeline™ Vantage Embolization Device with Shield™ Technology

Recall of 027 Compatible Devices (PED3-027-XXX-XX)

IFU Update to 021 Compatible Devices (PED3-021-XXX-XX)

January 2025

Medtronic Reference: FA1466

EU Manufacturer Single Registration Number (SRN): US-MF-000019796

Dear Healthcare Professional,

The purpose of this letter is to advise you that Medtronic is taking the following actions on the Pipeline™ Vantage Embolization Device with Shield Technology™ ("Pipeline Vantage") product family. Medtronic is initiating a recall of Pipeline Vantage devices with the part numbers PED3-027-XXX-XX, which represents compatibility to 0.027 inch (0.69 mm) inner diameter (ID) microcatheters ["Pipeline Vantage 027"]. Additionally, Medtronic is issuing a correction to the IFU of Pipeline Vantage devices with the part number PED3-021-XXX-XX, which represents compatibility to 0.021 inch (0.53 mm) inner diameter (ID) microcatheters ["Pipeline Vantage 021"].

You are receiving this notice because our records indicate that you have used or purchased either a Pipeline Vantage 027 or Pipeline Vantage 021 in the past.

Note: This notification does not apply to the Pipeline™ Flex Embolization Device ("Pipeline Flex") or the Pipeline Flex Embolization Device with Shield Technology™ ("Pipeline Shield").

Issue Summary and Risk to Patient Health

Medtronic has received reports of incomplete wall apposition and/or braid deformation noted during the procedure and post-procedure involving the Pipeline Vantage 027 and Pipeline Vantage 021 devices. Braid deformation (sometimes termed "fish-mouthing", "braid narrowing", or "braid collapse") and incomplete wall apposition are known risks that potentially can lead to thrombosis and/or serious adverse events including stroke or death.

Up until 31 December 2024, Medtronic has received reports of incomplete wall apposition and/or braid deformation, including 3 patient deaths and 13 ischemic strokes (from 416 complaints out of approximately 18,200 Pipeline Vantage 027 units distributed worldwide). As observed in the INSPIRE-A registry (Appendix A), Pipeline Vantage 027 devices (diameters ≥4mm) appear to exhibit a higher incidence stent braid deformation compared to the Pipeline Shield. Additionally, the risk of braid deformation was higher in females, especially females ≤45 years of age. The risk of braid deformation presents either intra-operatively or post-procedurally, with braid deformations typically noted at 6–12-month imaging follow-up.

Comparatively, for Pipeline Vantage 021 devices, fewer reports were received for incomplete wall apposition and/or braid deformation with 0 deaths and 4 strokes (from 57 complaints out of approximately 7,400 units distributed). The Pipeline Vantage 021 compatible sizes are similar to the Pipeline Shield product family in design characteristics. As shown in Appendix A, the rate of braid deformation for the Pipeline Vantage 021 is lower than that observed for Pipeline Vantage 027. Based on this information, the retrieval is only isolated to unused inventory of the Pipeline Vantage 027 devices.

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As part of this field action, Medtronic will correct the IFU of the Pipeline Vantage 021 to provide instructions to users on mitigating the risk of incomplete wall apposition and/or braid deformation.
Medtronic is committed to further analyzing the occurrence of braid deformation, including evaluation of longer-term clinical evidence from ongoing registries and post-market studies.

Patient Management Considerations:

The need for follow up imaging and/or changes in medical management should be made by the treating physician according to accepted guidelines, taking into consideration the patient's overall health. The risks of dual antiplatelet therapy (DAPT) should be weighed against the potential risk posed by braid deformation.

Product Scope:

The unused product removal portion of this notification applies to the following models and sizes of Pipeline™ Vantage devices.

Product Name	**Model Number**
Pipeline Vantage Embolization Device with Shield Technology	PED3-027-350-XX, PED3-027-400-XX, PED3-027-450-XX, PED3-027-500-XX, PED3-027-550-XX, PED3-027-600-XX

The product correction (IFU Update) portion of this notification applies to the following models and sizes of the Pipeline Vantage devices.

Product Name	**Model Number**
Pipeline Vantage Embolization Device with Shield Technology	PED3-021-250-XX, PED3-021-275-XX, PED3-021-300-XX, PED3-021-325-XX, PED3-021-350-XX

Required Actions for Impacted Product:

Our records show that your facility has received one or more lots of the impacted products which includes all units with model number PED3-027-XXX-XX and PED3-021-XXX-XX. Consequently, Medtronic requires that you immediately take the following actions:

1. Do NOT use any impacted Pipeline Vantage 027 product listed above. Remove and quarantine all unused impacted products listed in Appendix C from your inventory.
2. Return the impacted products to Medtronic as per the instructions outlined in the Customer Acknowledgment form. 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 Pipeline Vantage 027 product.

3. Medtronic is implementing changes to the IFU for the Pipeline Vantage 021 with part numbers PED3-021-XXX-XX. The purpose of these changes is to help achieve optimal size selection and stent braid deployment to reduce the risk of complications and patient harms. The key updates are:
    - Appropriate device diameter and length selection to account for complex anatomy.

- Techniques to deploy Pipeline Vantage compared to Pipeline Shield using a balance of device tension and compression to achieve adequate wall apposition and landing around curves.
- Warnings about the consequences of incomplete wall apposition and suboptimal deployment and the increased risk of braid deformation in females, especially in females ≤45 years.

A copy of the IFU changes is enclosed with this letter. We strongly recommend following the redlined/proposed IFU language while we work through the regulatory approval process to make changes to IFU permanently. Please ensure the updated IFU is used when completing any future procedure with the Pipeline Vantage device.

- Complete the enclosed Customer Acknowledgement Form and email to rs.ranordic@medtronic.com

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 and the records of your patients with Pipeline Vantage.

Regulatory notification:

Medtronic has notified the Competent Authority of your country 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 regarding this communication, please contact your Medtronic representative.

Sincerely,

Local / OU manager

Enclosures: *Customer Acknowledgement Form*
Appendix A: Pipeline™ Vantage post-market clinical performance information from Inspire-A Registry
Appendix B: Proposed IFU changes for device selection, device sizing, and device deployment of Pipeline™ Vantage:
Appendix C: List of affected pipeline vantage devices for retrieval

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Appendix A: Pipeline™ Vantage post-market clinical performance information from Inspire-A Registry

INSPIRE-A is a prospective, single-arm, multi-center, global registry for the real-world use of the Pipeline Embolization Device. INSPIRE-A includes monitored data on 423 patients treated with the Pipeline Vantage Embolization Device with Shield Technology ("Pipeline Vantage") and 530 patients treated with the Pipeline Flex Embolization Device with Shield Technology ("Pipeline Shield"). For this registry, safety oversight of reported adverse events is conducted by an independent, third-party Clinical Events Committee and effectiveness oversight of follow-up imaging is conducted by an independent Core Lab. The below tables are based on data as of Aug. 19, 2024.

Table 1: INSPIRE-A: Analysis of Procedural, Safety, And Effectiveness Outcome

Outcomes		**Vantage 021 (N=110)**	**Vantage 027 (N=306)**	**Shield < 4 mm (N=187)**	**P-value < 0.05?[£]**
Procedure Outcomes	Device Deployment Success – Patient Level[¥]	100.0% (110)	99.3% (304)	98.9% (185)	No
Effectiveness	Complete Aneurysm* Occlusion*	75.3% (58)	71.4% (167)	79.0% (109)	No
	Retreatment (through 1-year)[#]	1.54% (1)	0.47% (1)	1.69% (3)	No
Safety Events in Patients					
Death		0.9% (1)	1.3% (4)	1.6% (3)	No
All Stroke		8.2% (9)	5.9% (18)	5.9% (11)	No
Major Stroke		1.8% (2)	2.6% (8)	2.7% (5)	No
Minor Stroke		4.5% (5)	2.6% (8)	3.2% (6)	No
Indeterminate Stroke		1.8% (2)	0.7% (2)	0.0% (0)	No
Parent Artery Stenosis (> 25-50%) (DSA only)*		9.1% (7)	9.8% (23)	8.7% (12)	No
Parent Artery Stenosis (> 50-75%) (DSA only)*		0.0% (0)	2.1% (5)	2.2% (3)	No
Parent Artery Stenosis (> 75-100%) (DSA only)*		1.3% (1)	1.7% (4)	1.4% (2)	No

Categorical measures: % (n); n corresponds to the number of patients with events.

Median clinical follow-up months (lower-upper quartile): Vantage 021: 21 months (13-26); Vantage 027: 22 months (15-27); Shield < 4 mm: 18 months (9-24).

[¥] Based on available data (N = 110 for Vantage 021 models, 306 for Vantage 027 models, 187 for Shield models).

*Last available DSA imaging (N = 77 for Vantage 021 models, 234 for Vantage 027 models, 138 for Shield < 4 mm models).

[#]Based on the available imaging follow-up through 1 year (N=65 for Vantage 021 models, N=215 for Vantage 027 models, and N=178 for Shield < 4 mm models.

[£] Two comparisons to assess statistically significant difference between respective groups: Vantage 021 vs. Vantage 027 and Vantage 021 vs. Shield < 4 mm.

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Table 2A: Braid Deformation - Pipeline Vantage 021 vs. Pipeline Vantage 027; Pipeline Vantage 021 vs. Pipeline Shield < 4 mm

Braid Deformation (and Types)	Pipeline Vantage 021 (N=110)	Pipeline Vantage 027 (N=306)	Shield < 4 mm (N=183)	P-value < 0.05? [£]
Any Braid Deformation	**3.64% (4)**	**12.09% (37)**	**5.46% (10)**	**Yes****
Foreshortening Rate	0.00% (0)	0.33% (1)	1.64% (3)	No
Fish-Mouthing (25-50%) Proximal	1.82% (2)	2.29% (7)	0.00% (0)	No
Fish-Mouthing (> 50%) Proximal	0.00% (0)	0.00% (0)	0.00% (0)	--
Fish-Mouthing (25-50%) Distal	0.91% (1)	7.84% (24)	1.09% (2)	Yes**
Fish-Mouthing (> 50%) Distal	0.00% (0)	0.33% (1)	0.00% (0)	No
Braid Collapse (Reduced Lumen)	0.00% (0)	1.31% (4)	0.00% (0)	No
Braid Hump	1.82% (2)	2.29% (7)	3.28% (6)	No

% (n); n corresponds to the number of patients with events.

[£] Two comparisons to assess statistically significant difference between respective groups: Vantage 021 vs. Vantage 027 and Vantage 021 vs. Shield < 4 mm.

** p value < 0.05 only for the Vantage 021 vs. Vantage 027 comparison.

Table 2B: Braid Deformation Subgroups - Gender

Sub-groups	Pipeline Vantage	Pipeline Shield	P-value < 0.05?
Male	3.5% (3/85)	7.4% (9/121)	No
Female	11.2% (38/338)	5.4% (22/409)	Yes
Females ≤ 45	22.6% (14/62)	10.1% (10/99)	Yes
Females > 45-60	11.9% (14/118)	4.7% (8/170)	Yes
Females > 60	6.3% (10/158)	2.9% (4/140)	No

% (n/N); n corresponds to the number of patients with events.

N corresponds to the total number of patients in that group.

Appendix B: Proposed IFU changes for device selection, device sizing, and device deployment of Pipeline™ Vantage:

Appendix C: List of Pipeline Vantage 027 devices for retrieval