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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.
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 highlighted IFU changes. Please ensure the updated IFU is used when completing any future procedure with the Pipeline Vantage device.

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,

Medtronic (Schweiz) AG

Enclosures:
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

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.

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.

Medtronic

Instructions for use

Pipeline™ Vantage Embolization Device with Shield Technology™

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Instructions for Use

Pipeline™ Vantage Embolization Device with Shield Technology™

CAUTION

- This device should be used only by physicians with a thorough understanding of angiography and/or percutaneous neurointerventional procedures.

DESCRIPTION

The Pipeline™ Vantage Embolization Device with Shield Technology™ consists of a permanent implant combined with a guidewire-based delivery system. The Pipeline™ Vantage Embolization Device with Shield Technology™ implant is a braided, multi-alloy, mesh cylinder woven with cobalt-chromium-nickel and platinum wires. An image of the Pipeline™ Vantage Embolization Device with Shield Technology™ implant is shown in Figure 1 and the design of the device is shown in Figure 2. The woven wires of the device provide approximately 30% metal coverage of the arterial wall surface area. The implant is designed for placement in a parent vessel across the neck of an intracranial aneurysm (IA). The expanded or unconstrained diameter is 0.25 mm larger than the labeled diameter. Shield Technology™ is a surface-modification that is not derived from any animal or human sources.

The Pipeline™ Vantage Embolization Device with Shield Technology™ implant is assembled on a guide-wire based delivery system that consists of a 304-stainless steel core wire and a 304L stainless steel hypotube. The implant is assembled over 304 stainless steel resheathing components. A Platinum-Iridium Restraint is distal to the resheathing components and is termed the Resheathing Marker. Refer to Figure ~~3~~ 6 for the Resheathing Marker position.

The tip coil is made of platinum-tungsten alloy. The tip, distal, and proximal solder joints are a tin-silver. The ePTFE protective sleeves cover and protect the distal portion of the braid while the Pipeline™ Vantage Embolization Device with Shield Technology™ implant is advanced through the micro catheter. The Resheathing components allow the user to resheath the implant back into the micro catheter. The Resheathing Marker provides the user fluoroscopic visualization for the limit of resheathing the implant.

The Pipeline™ Vantage Embolization Device with Shield Technology™ implant is compressed inside an introducer sheath. The Pipeline™ Vantage Embolization Device with Shield Technology™ implant is designed to be delivered through a compatible micro catheter of ~~either~~ 0.021 inch (0.53 mm) ~~or 0.027 inch (0.69 mm)~~ inner diameter and minimum 135 cm in length. Refer to Table 1 for micro catheter compatibility for each device size.

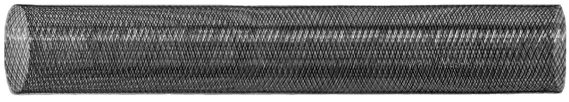


Figure 1. The Pipeline™ Vantage Embolization Device with Shield Technology™

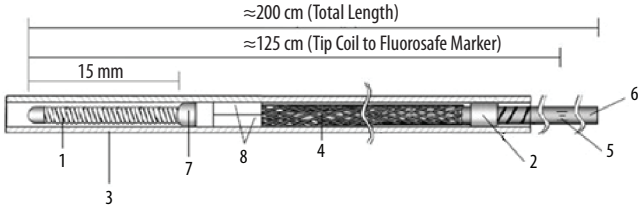


Figure 2. The Pipeline™ Vantage Embolization Device with Shield Technology™ delivery system and implant (not to scale)

1. Tip Coil
2. Proximal Bumper
3. Introducer Sheath
4. Braid
5. Fluorosafe Marker
6. Delivery Wire
7. Distal Marker
8. ePTFE Sleeves

Table 1. Size Ranges: Pipeline™ Vantage Embolization Device with Shield Technology™		
Labeled Diameter (mm)	**Compatible catheter inner diameter**	**Labeled Lengths (mm)**
2.50	0.021 inch (0.53 mm)	10, 12, 14, 16, 18, 20
2.75		10, 12, 14, 16, 18, 20
3.00		10, 12, 14, 16, 18, 20, 25
3.25		10, 12, 14, 16, 18, 20, 25
3.50		10, 12, 14, 16, 18, 20, 25
	~~0.027 inch (0.69 mm)~~	~~10, 12, 14, 16, 18, 20, 25, 30, 35~~
~~4.00~~		~~10, 12, 14, 16, 18, 20, 25, 30, 35, 40~~
~~4.50~~		~~10, 12, 14, 16, 18, 20, 25, 30, 35, 40~~
~~5.00~~		~~10, 12, 14, 16, 18, 20, 25, 30, 35, 40~~
~~5.50~~		~~10, 12, 14, 16, 18, 20, 25, 30, 35, 40, 45, 50~~
~~6.00~~		~~10, 12, 14, 16, 18, 20, 25, 30, 35, 40, 45, 50~~

DEVICE COMPATIBILITY

Micro catheter compatibility is defined on the product label:

The Pipeline™ Vantage 021 system is designed to be delivered through a compatible micro catheter of 0.021 inch (0.53 mm) inner diameter at least 135 cm in length. Compatibility testing has been performed with the Phenom 21 Catheter.

~~The Pipeline™ Vantage 027 system is designed to be delivered through a compatible micro catheter of 0.027 inch (0.69 mm) inner diameter at least 135 cm in length. Compatibility testing has been performed with the Phenom 27 Catheter.~~

INTENDED PURPOSE / INDICATIONS FOR USE

The Pipeline™ Vantage Embolization Device with Shield Technology™ is intended for endovascular embolization of cerebral aneurysms.

CONTRAINDICATIONS

- Patients with active bacterial infection.
- Patients in whom antiplatelet therapy (i.e. aspirin and clopidogrel) is contraindicated.
- Patients who have not received antiplatelet agents prior to the procedure.
- The Pipeline™ Vantage Embolization device with Shield Technology™ should not be used alone as sole therapy for acutely ruptured aneurysms.

PREPARATION FOR USE

1. Choose a Pipeline™ Vantage device with a labeled diameter that is the approximately ~~size of the largest equivalent to the~~ target vessel landing zone diameter. Ensure that the ends of the device are not deployed in a vessel that is larger than the labeled diameter of the selected size.
   - ~~Select an appropriately sized Pipeline™ Vantage device such that its fully expanded diameter is equivalent to that of the largest target vessel diameter.~~ An incorrectly sized Pipeline™ Vantage device may result in inadequate device placement, incomplete opening, ~~or~~ migration, or stent braid deformation.
   - Select a Pipeline™ Vantage device that allows for distal deployment and proximal landing in a straight vessel segment and/or in a location that allows for complete wall apposition on the distal and proximal ends. Adjusting the device length selected may be necessary to ensure that the distal and proximal segments land in a straight vessel. Landing on a curve can result in poor wall apposition, increasing the risk of braid deformation, thrombosis and stroke.
2. Choose a Pipeline™ Vantage device with labeled length that is at least 6 mm longer than the aneurysm neck and ≥ 3 mm landing zone on both sides of the aneurysm neck, see Figure 3.
   - Take device foreshortening into account when deploying the Pipeline™ Vantage device. The Pipeline™ Vantage device foreshortens 47 - 58% during deployment.
   - Adjusting the device length selected and landing zone length may be necessary to ensure that the segments distal and proximal to the aneurysm are positioned and anchored to avoid unanticipated post-procedure foreshortening, device movement, device deformation, and herniation, especially in curved vessels, and with large aneurysm necks.

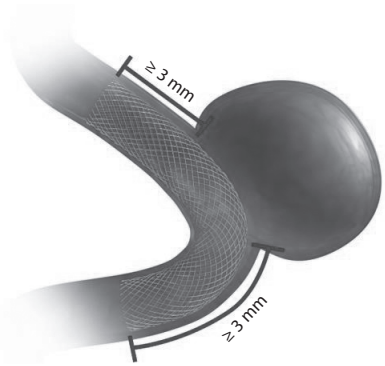


Figure 3. Illustration of landing zone and aneurysm neck

3. Remove packaging hoop from the pouch and pull the distal end of the introducer sheath from the blue clip on the packaging hoop.
4. Carefully remove device from the packaging hoop until the delivery wire is exposed.

WARNING

- Pre-deploying the distal end of the device prior to introduction into the micro catheter may cause damage to the distal end of the braid

5. Partially insert introducer sheath into the rotating hemostatic valve (RHV) at the micro catheter hub and close the RHV. Use a minimum flush pressure of 250 mmHg and confirm back flush of the saline at the proximal end of the introducer sheath prior to advancing the Pipeline™ Vantage device into the micro catheter.
6. Advance introducer sheath into the RHV; visually confirm the tip of the sheath is seated deeply in the hub of the micro catheter.

DIRECTIONS FOR USE

1. Using standard interventional radiographic technique, place the micro catheter tip at least 20 mm past the distal edge of the aneurysm. Gently retract the micro catheter to reduce slack in the micro catheter prior to inserting the Pipeline™ Vantage device.

   NOTE: It is recommended to use a heparinized saline drip to continuously flush micro catheter during Pipeline™ Vantage device use.
2. Secure introducer sheath to the hub by locking down the RHV tightly.

   CAUTION: Avoid deploying the device prior to introduction into the micro catheter.
3. Advance the proximal end of the delivery wire until it aligns with the proximal end of the introducer sheath.
4. Remove the introducer sheath.

   NOTE: The delivery wire has a fluorosafe marker no further than 125 cm from the distal end.

   CAUTION: The fluorosafe marker is only compatible with micro catheters with a minimum length of 135 cm.
5. Advance the Pipeline™ Vantage device into the micro catheter by pushing the delivery wire until the tip of the delivery wire aligns with the tip of the micro catheter.

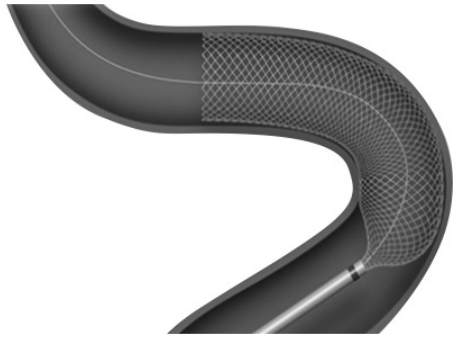
   CAUTION: If high forces or excessive friction are encountered during delivery, discontinue delivery of the device and identify the cause of the resistance, remove device and micro catheter simultaneously. Advancement of the Pipeline™ Vantage device against resistance may result in device damage or patient injury.

   CAUTION: The presence of other indwelling endovascular stents may interfere with proper deployment and function of the Pipeline™ Vantage device.
6. Once the tip of delivery wire and micro catheter are aligned, verify that the Pipeline™ Vantage implant is in the desired location. The distal end of Pipeline™ Vantage implant should be placed at least 3 mm past the distal edge of the aneurysm neck.

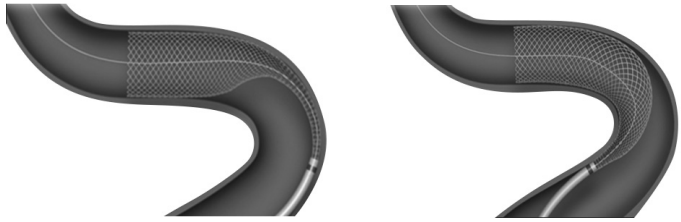
Device Deployment

7. Begin to deliver the Pipeline™ Vantage implant using a combination of unsheathing the Pipeline™ Vantage implant and pushing the delivery wire simultaneously.

   NOTE: When deploying within tortuous anatomy (particularly around a curve), attempt to keep the micro catheter tip centered to allow for forces to be evenly transferred to the implant, see Figure 4. Avoid uneven application of force to the implant, such as pushing it to one side, as this may lead to incomplete device opening, poor wall apposition, ribboning, and twisting. Gently push or pull on the device and catheter system to maintain alignment within the center of the vessel.

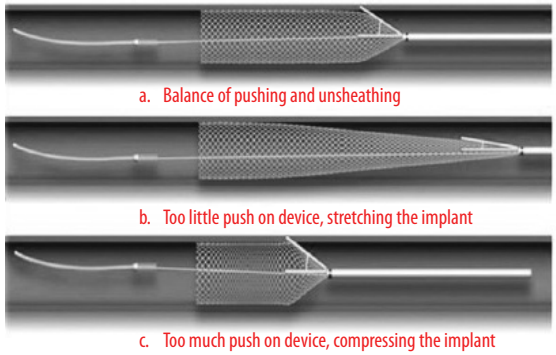


a. Micro catheter tip centered in vessel, even transfer of forces



b. Micro catheter tip not centered in vessel, uneven transfer of forces

Figure 4. Micro catheter tip centered in tortuous vessel



a. Balance of pushing and unsheathing

b. Too little push on device, stretching the implant

c. Too much push on device, compressing the implant

Figure 5. Illustration of combination of implant unsheathing and push on delivery wires

WARNING

- Pushing delivery wire without retracting the micro catheter at the same time will cause the open-end of the braid to move distally in the vessel. This may cause damage to the braid or vessel.
- Use in anatomy with severe tortuosity, stenosis or parent vessel narrowing may result in difficulty or inability to deploy the Pipeline™ Vantage device and can lead to damage to the Pipeline™ Vantage device and micro catheter. To mitigate potential problems as a result of increased delivery forces, reduce the load in the system by:
  - Unloading the micro catheter to the inner curves of vessel by pulling back on the system (i.e., the micro catheter and delivery wire together).
  - Continue unloading the system until advancement of the device (inside of micro catheter) is observed, while minimizing the distal tip movement to prevent loss of position.
  - Begin to re-advance the delivery wire while maintaining reduced load in the micro catheter. This process should be repeated until the device passes through tortuous area and the delivery force is decreased.
- Following distal deployment and device anchoring:
  - Avoid stretching and/or creating tension in the implant before unsheathing the proximal end.
  - Avoid deploying the implant if kinking or twisting is observed.

  Fully deploying the device under the conditions above may lead to poor wall apposition,unanticipated device foreshortening, device migration, thromboembolic risk, and impaired aneurysm occlusion. Device kinking, twisting, or stretching may be resolved with appropriate positioning of the micro catheter or by resheathing the entire implant and repeating distal deployment, adjusting the technique combination of unsheathing the implant and pushing the deliver wire. If it cannot be resolved, consider replacing the device.

8. **Resheathing Instructions:**

   During deployment of the Pipeline™ Vantage device resheathing can be performed by either:
   - Advancing the micro catheter while pinning the delivery wire
   - Advancing the micro catheter while applying tension on the delivery wire
   - Advancing the micro catheter while gently pulling the delivery wire proximally

- During deployment, the point of no return/Resheathing limit is reached when the Resheathing marker aligns with the Distal marker of the micro catheter (see Figure ~~3~~ 6). The Resheathing limit is the maximum length of the implant that can be deployed while maintaining the ability to fully resheath the device.
- The Pipeline™ Vantage device implant is fully resheathed when the distal marker is retracted completely inside the micro catheter. The system is designed to allow for a 2 full cycles of resheathing of the Pipeline™ Vantage device.

WARNING

- Avoid deploying the implant if kinking or twisting is observed.

9. After the distal end of the implant has successfully expanded, deploy the middle segments of the implant ~~continue to deploy~~ using a balanced combination of unsheathing the implant by pulling the micro catheter back and pushing the delivery wire simultaneously. Manipulation of the micro catheter by locking down the delivery wire and moving both as a system may facilitate expansion of the implant, See Figure 5. Adjust tension on the device by pushing more or less on the device wire or system.

   Deploy the proximal segment of the device ~~It is recommended to perform proximal deployment~~ by simultaneously unsheathing ~~of~~ the implant by pulling the micro catheter back with minimal forward pressure or tension on the delivery wire to achieve optimal opening.

   Prior to releasing the proximal end of the device, ensure that the proximal end of the device, will land ≥3mm proximal to the edge of the aneurysm neck without stretching the implant. If this cannot be achieved, consider fully resheathing and respositioning or replacing with a longer device.

   NOTE: Ensure complete wall apposition along the full Pipeline™ Vantage device during the course of device deployment before final release of the device. If adequate apposition cannot be achieved, consider resheathing the implant up to the resheathing marker or removing and replacing the device.

   CAUTION: Avoid using excessive push to the implant. Using excessive push may result in braid deformation (such as braid narrowing, braid collapse) and/or insufficient opening at the time of deployment. Avoid repositioning the distal end of device under tension after device distal end is open and fully opposed to the vessel wall.

   CAUTION: Under fluoroscopy, carefully monitor the tip coil position during deployment of the Pipeline™ Vantage device.

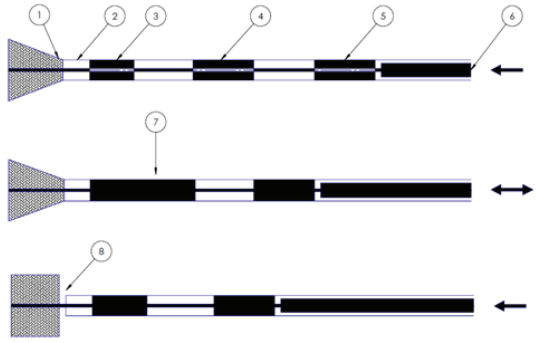
   CAUTION: Avoid applying excessive tension to the implant during final deployment. Excessive tension may result in delayed device migration, herniation into the aneurysm neck, thromboembolic risk, and stroke.

   CAUTION: For lack of adequate wall apposition in the medial section after device deployment, attempt addressing the lack of apposition in the medial section of the implant with a guidewire. If unsuccessful, adjunctive balloon angioplasty may be used to address the apposition issue, however, once both ends of the device are anchored, adjunctive device use may be temporary or ineffective. Placement of another flow diverter is not recommended to attempt opening of a narrowed medial section of the device. Be careful to maintain access while attempting adjunctive device use.

WARNING

- Avoid deploying the implant if kinking or twisting is observed.
- Incomplete wall apposition can result unanticipated device foreshortening, device migration, and/or device deformation which can lead to thromboembolic risks, elevated neointimal hyperplasia formation and/or reduced intracranial aneurysm occlusion.
- Resheathing the Pipeline™ Vantage device more than 2 full cycles may cause damage to the distal or proximal ends of the braid.
- Resheathing the Pipeline™ Vantage device past the distal marker of the delivery system may cause damage to the distal end of the braid.

Figure ~~3~~ 6. Pipeline™ Vantage Embolization Device with Shield Technology™ (Resheathing schematic as seen under fluoroscopy, image not to scale).



1. Proximal End of device
2. Micro Catheter
3. Micro Catheter Distal Marker
4. Resheathing Marker
5. Proximal Bumper
6. Delivery Wire
7. Resheathing Limit
8. Device Detached

10. After the entire implant is deployed, advance the micro catheter through the implant making sure not to dislodge the braid. When the micro catheter tip is distal to the implant, retract the delivery wire into the micro catheter tip.

    CAUTION: Avoid advancing or retracting the Resheathing Marker within the implant without coverage of the micro catheter.

    CAUTION: If the catheter cannot be advanced through the Pipeline™ Vantage implant, carefully withdraw the delivery wire through the implant.

    CAUTION: If the delivery wire cannot be retracted into the micro catheter, carefully remove the delivery wire and micro catheter simultaneously as a system.

11. ~~Carefully inspect the deployed implant under fluoroscopy to confirm it is completely apposed to the vessel wall and not kinked/twisted. If the device is not fully apposed or is kinked/twisted, consider using a balloon catheter, micro catheter, or guidewire to fully open it.~~ Carefully inspect the deployed implant under fluoroscopy to confirm it is completely apposed to the vessel wall and the braid is not deformed (e g kinking, twisting, or fishmouthing).

    If poor wall apposition or significant braid deformation are observed, in the distal or proximal ends of the implant, attempt to resolve the malapposition utilizing an adjunctive device such as a guidewire, an angioplasty balloon, or another stent.

    Verify that the distal and proximal landing zones are both ≥3 mm and not under tension, see Figure 3. If less than 3 mm or under tension such that the device may foreshorten in a way that the landing zone is less than 3 mm, consider deployment of an additional device in a telescoping manner, such as an overlapping Pipeline™ or other neurovascular flow-diverting stent to ensure adequate securement of the ends of the implant.

    CAUTION: In order to place another stent, the existing Pipeline™ Vantage device must be traversed, this may lead to foreshortening and prolapse of the original stent into the intracrancial aneurysm. Consider adjusting the access system to ensure maximum stability while attempting to cross the Pipeline™ Vantage and deploy another device.

CAUTION: It is not recommended to use the Pipeline™ Vantage delivery wire to influence apposition of the implant. Additional interaction between components on delivery wire and braid may lead to braid damage.

CAUTION: Avoid using the micro catheter or intermediate/support catheter to modify the position or wall apposition of the proximal end of the implant as this may lead to implant deformation, thromboembolic risk, and elevated neointimal hyperplasia.

CAUTION: Excessive manipulation of the device using adjunctive devices such as balloons and secondary stents may lead to adverse events such as device herniation, stroke and death. Modification of the device with excessive manipulation may not be maintained post procedure.

WARNING

- Malapposition to the vessel wall at the proximal end of the implant may lead to stenosis, stroke or death.

POTENTIAL COMPLICATIONS

Potential complications of the device and the endovascular procedure include or are synonymous with, but may not be limited to the following:

- Adverse reaction to antiplatelet/anticoagulation agents, anesthesia reactions such as pain, nausea, aspiration, or to contrast media such as burn sensation and organ damage or failure or due to radiation exposure such as alopecia, burns, skin reddening, ulcers, skin discoloration, cataracts, delayed neoplasia
- Access site complications such as edema, abscess, bleeding including retroperitoneal hemorrhage, tissues damage, hematoma, hemorrhage, and nerve damage
- Vascular complications such as vasospasm, hyperplasia, stenosis, dissection, perforation, rupture, AV fistula formation, pseudo aneurysm, occlusion, thromboembolic complications including ischemia, occlusion, embolism (to unintended territory)
- Device malfunctions such as kink, stretching, friction, fracture, breakage, foreign body, misplacement, migration, inadequate deployment, premature deployment, non-detachment, braid deformation, reaction to device materials (such as hypersensitivity, hemolysis, fever, mutagenic effects, inflammation, granuloma, toxicity)
- Systemic complications such as infection, discomfort, pain, fever, shock, allergic reactions, organ damage, organ failure, hypertension, hypotension, arrhythmia, angina, myocardial infarction.
- Neurological deficits or dysfunctions including stroke, infarction, visual deficits, loss of vision, seizures, motor function, transient ischemic attack, headache, cranial neuropathy, confusion, emotional changes, coma
- Bleeding/ hemorrhagic complications.
- Visual complications include but are not limited to Amaurosis fugax/transient blindness, Blindness, Diplopia, Reduced visual acuity/field, Retinal artery occlusion, Retinal ischemia, Retinal infarction, Vision impairment including scintillations, blurred vision, eye floaters
- Decreased therapeutic response including need for target aneurysm retreatment
- Intra-cranial hemorrhage (including from aneurysm rupture), mass effect, brain edema, hydrocephalus
- Death

* Consult instructions for use for other therapy devices and medications for additional potential complication information.

WARNING

- Person with known allergy to cobalt/chromium alloy (including major elements cobalt, chromium, nickel, molybdenum) or platinum may suffer an allergic reaction to the Pipeline™ Vantage device implant.
- Person with known allergy to platinum alloy (including major elements platinum, tungsten, iridium), tin, silver, stainless steel or silicone elastomer may suffer an allergic reaction to the Pipeline™ Vantage device delivery system.
- Do not reprocess or resterilize. Reprocessing and resterilization increase the risk of patient infection and compromised device performance.
- Placement of multiple Pipeline™ Vantage devices may increase the risk of ischemic complications.
- Do not attempt to reposition the device after full deployment.

PRECAUTIONS

- Physicians should undergo appropriate training prior to using the Pipeline™ Vantage device in patients.
- The Pipeline™ Vantage device is intended for single use only. Carefully inspect the sterile package and device components prior to use. Do not use if sterile package or device components are damaged.
- Use the Pipeline™ Vantage device system prior to the "Use-By-date" printed on the package.
- Do not use the Pipeline™ Vantage device in patients in whom angiography demonstrates inappropriate anatomy for endovascular treatment, such as severe pre- or post-aneurysmal narrowing or severe intracranial vessel tortuosity.
- The appropriate anti-platelet and anti-coagulation therapy should be administered in accordance with standard medical practice.
- A thrombosing aneurysm may aggravate pre-existing, or cause new, symptoms of mass effect and may require medical therapy.
- Use of implants with labeled diameter larger than the parent vessel diameter may result in decreased effectiveness and additional safety risk due to incomplete foreshortening resulting in an implant longer than anticipated.
- Take all necessary precautions with patients in whom a pre-existing stent is in place in the parent artery at the target aneurysm location.
- Take all necessary precautions to limit X-ray radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors where possible.
- Carefully weigh the benefits of treatment vs. the risks associated with treatment using the device for each individual patient based on their medical health status and risks factors for intracranial aneurysm rupture during their expected life time such as age, medical comorbidities, history of smoking, intracranial aneurysm size, location, and morphology, family history, history of prior asymptomatic subarachnoid hemorrhage (aSAH), documented growth of intracranial aneurysm on serial imaging, presence of multiple intracranial aneurysms, and presence of concurrent pathology. The benefits of device use may not outweigh the risks associated with the device in certain patients; therefore, judicious patient selection is recommended.
  - In the INSPIRE-A registry, there was an observation of increased braid deformity in female patients, especially in female patients less than 45 years of age.

HOW SUPPLIED

This device is supplied STERILE using ethylene oxide. This device is Non-pyrogenic.

STORAGE AND DISPOSAL

- This device should be stored in a dry place, away from sunlight.
- Dispose of device in accordance with hospital, administrative, and/or local government policy.

DIAGNOSTIC MAGNETIC RESONANCE (MR) IMAGING

Non-clinical testing has demonstrated that the Pipeline™ Vantage device is MR Conditional for single and overlapping stents up to 70 mm in length. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla, only.
- Maximum spatial gradient magnetic field of 3000 Gauss/cm or less.
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 2-W/kg (Normal Operating Mode of Operation for the MR system).
- Maximum head SAR of 3.2 W/kg.

After 15-minutes of continuous scanning the Pipeline™ Vantage device is expected to produce a maximum temperature rise up to 4.15°C.

Artifact Information

In non-clinical testing, the image artifact caused by the Pipeline™ Vantage device extends approximately 20.2 mm from this implant when imaged using a T1-weighted spin echo pulse sequence and a 3-Tesla MR system.

Multilayer implant configuration of the Pipeline™ Vantage device does not affect its MRI compatibility, including temperature rise, torque, displacement, and artifact.

Symbol Glossary

STERILE EO	Sterilized using ethylene oxide		Keep away from sunlight
	Do not re-use		Keep dry
Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician	EC REP	Authorized representative in the European Community / European Union
STERILIZE	Do not resterilize	REF	Catalogue number
www.medtronic.com/manuals	Consult electronic instructions for use		Manufacturer
	Caution		Use-by date
	Do not use if package is damaged and consult instructions for use	LOT	**en** Batch code
MR	MR Conditional	CONTENTS	**en** Contents of Package
	Non-pyrogenic	CE 0297	**en** Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union Acts

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EC REP

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CE
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~~M050938CDOC2 Rev. B (01/2024)~~
M069725CDOC2 Rev. A (01/2025)

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Anhang C: Liste der in der Schweiz vom Rückruf betroffenen Pipeline Vantage Produkte

Produktbeschreibung	Modell Nr.	Chargen Nr.			
STENT PED3-027-350-12	PED3-027-350-12	B700548			
STENT PED3-027-350-14	PED3-027-350-14	B700550			
STENT PED3-027-350-16	PED3-027-350-16	B409692	B700551	B795136	B795142
STENT PED3-027-350-20	PED3-027-350-20	B700552	B777630		
STENT PED3-027-350-25	PED3-027-350-25	B771934			
STENT PED3-027-400-12	PED3-027-400-12	B594119	B321585	B336094	B437740
		B612514	B655648	B720634	B744619
STENT PED3-027-400-14	PED3-027-400-14	B339540	B350391	B375523	B438538
		B459694	B608852	B622657	B625453
		B629552	B698756		
STENT PED3-027-400-16	PED3-027-400-16	B402034	B423257	B426548	B439156
		B449149	B449591	B459846	B465307
		B474417	B560503	B608221	B615571
		B623135	B625944	B738422	B739914
		B744860			
STENT PED3-027-400-20	PED3-027-400-20	B381434	B391816	B575122	B576711
		B636674	B657799	B692916	B705994
		B739972			
STENT PED3-027-400-30	PED3-027-400-30	B475566	B594121	B731515	
STENT PED3-027-450-12	PED3-027-450-12	B322748	B471328	B486866	B575963
		B601277	B750794		
STENT PED3-027-450-14	PED3-027-450-14	B320465	B336565	B462206	B637191
		B669563	B719084	B741791	
STENT PED3-027-450-16	PED3-027-450-16	B395007	B450972	B483899	B535234
		B626044	B666589		
STENT PED3-027-450-20	PED3-027-450-20	B389289	B397986	B423116	B440859
		B550980	B569276	B651312	B652220
		B696501	B696960	B700714	B760821
STENT PED3-027-450-25	PED3-027-450-25	B395978	B463202	B471895	B604474
		B604478	B611115	B645444	B693373
		B699762	B752452	B759553	
STENT PED3-027-450-30	PED3-027-450-30	B436536	B574352	B651451	B658656
STENT PED3-027-450-40	PED3-027-450-40	B448343	B615408	B684783	
STENT PED3-027-500-14	PED3-027-500-14	B432210	B606137	B651443	B674478
STENT PED3-027-500-16	PED3-027-500-16	B320910	B432683	B441009	B536475
		B638485	B655727	B704999	B729572

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PRODUCT DESCRIPTON	CFN	Lot Serial #			
STENT PED3-027-500-20	PED3-027-500-20	B331608	B396652	B466125	B645491
		B650050	B651347	B677890	B678959
		B695686	B737927	B779633	
STENT PED3-027-500-25	PED3-027-500-25	B536229	B648039	B688975	B694374
STENT PED3-027-500-30	PED3-027-500-30	B342643	B606136	B655034	B663561
		B750658			
STENT PED3-027-500-40	PED3-027-500-40	B464764	B590192	B693594	
STENT PED3-027-550-16	PED3-027-550-16	B575962	B689577	B707045	B749920
STENT PED3-027-550-20	PED3-027-550-20	B454303	B560727	B623137	B690738
		B713205	B717726	B766393	B780554
STENT PED3-027-550-30	PED3-027-550-30	B473971	B611882	B695406	B783566
STENT PED3-027-550-40	PED3-027-550-40	B433336	B615604	B704973	
STENT PED3-027-550-50	PED3-027-550-50	B431531	B616028	B658014	B717320
STENT PED3-027-600-16	PED3-027-600-16	B607478	B611280	B693533	
STENT PED3-027-600-20	PED3-027-600-20	B491096	B608223	B681791	B708642
STENT PED3-027-600-30	PED3-027-600-30	B467222	B489389	B652141	
STENT PED3-027-600-40	PED3-027-600-40	B655601	B655798		
STENT PED3-027-600-50	PED3-027-600-50	B429330	B434230	B653261	B653391
		B768841			