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URGENT: MEDICAL DEVICE RECALL

Pipeline™ Vantage Embolization Device with Shield™ Technology
Recall of 027 Compatible Devices (PED3-027-XXX-XX)
Correction (IFU Update) to 021 Compatible Devices (PED3-021-XXX-XX)

02 February 2025 | 21:32 SGT

Attention: Risk Management Director and O.R Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

Dear Healthcare Professional:

The purpose of this letter is to advise you that Medtronic is taking the following voluntary 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.

As of 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 removal (retrieval) is only isolated unused inventory of the Pipeline Vantage 027 devices.

As part of this recall, 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	Manufacturer's Product Number/Catalog 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. 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.
4. Complete the attached Consignee Confirmation Form and hand or scan then email back to your local Medtronic representative.

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 communicated this information to the appropriate regulatory authorities.

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 local Medtronic representative.

Sincerely,

Signed by:

Signer Name: Chloe Tan
Signing Reason: I approve this document
Signing Time: 02 February 2025 | 21:29 SGT
90D0724C9B1C402A99B286449A1644B8

Quality and Regulatory Affairs Director

Southeast Asia

Enclosure: Customer Confirmation 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

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.

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

Medtronic

Instructions for use

Pipeline™ Vantage Embolization Device with Shield Technology™

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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) inside~~ inner diameter and minimum 135 cm in length. Refer to Table 1 for micro catheter compatibility for each device size.

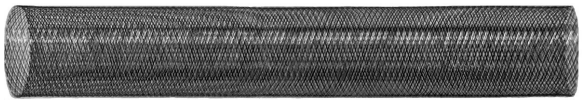


Figure 1. The Pipeline™ Vantage Embolization Device with Shield Technology™

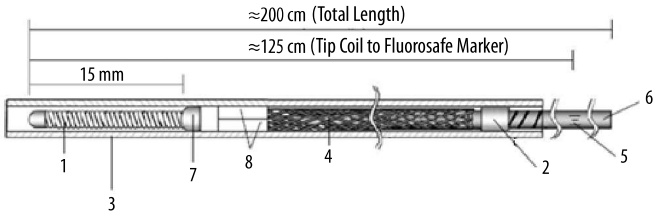


Figure 2. The Pipeline™ Vantage Embolization Device with Shield Technology™ delivery system and implant (not to scale)

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
~~4.00~~	~~0.027 inch (0.69 mm)~~	~~10, 12, 14, 16, 18, 20, 25, 30, 35~~
~~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 microcatheter of 0.021 inch (0.53 mm) ~~inside~~ 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) inside 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.

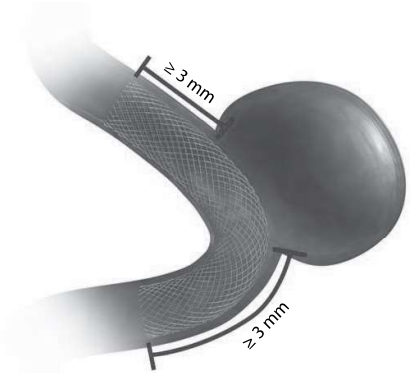


Figure 3. Illustration of landing zone and aneurysm neck

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 microcatheters 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.

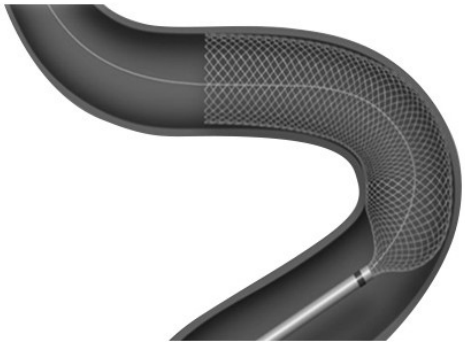
   CAUTION: If high forces or excessive friction are encountered during delivery, discontinue delivery of the device and identify the cause of the resistance, remove device and micro catheter simultaneously. Advancement of the Pipeline™ Vantage device against resistance may result in device damage or patient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

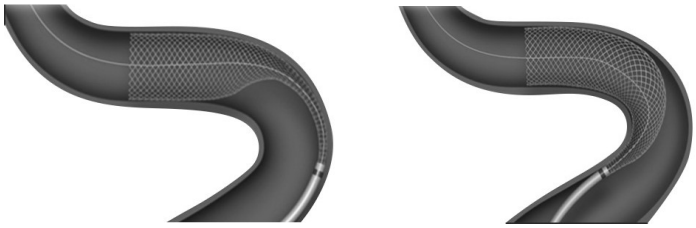
Device Deployment

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 microcatheter 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.

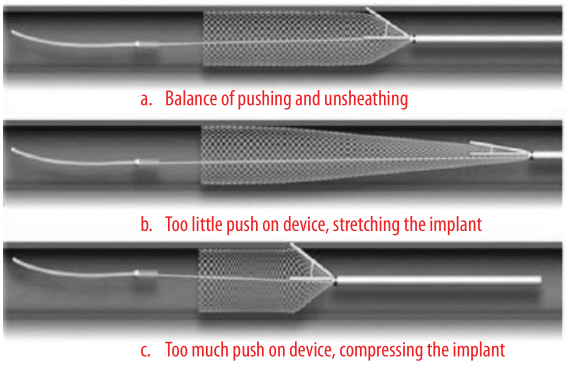


a. Micro catheter tip centered in vessel, even transfer of forces



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 microcatheter. To mitigate potential problems as a result of increased delivery forces, reduce the load in the system by:
  - Unloading the microcatheter to the inner curves of vessel by pulling back on the system (i.e., the microcatheter and delivery wire together).
  - Continue unloading the system until advancement of the device (inside of microcatheter) 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 microcatheter. 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 microcatheter or by resheathing the entire implant and repeating distal deployment, adjusting the technique combination of unsheathing the implant and pushing the delivery 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 remainder of the implant~~ deploy the middle segments of the implant using a balanced combination of unsheathing the implant by pulling the micro catheter back and pushing the delivery wire simultaneously ~~by pushing and/or unsheathing the delivery wire~~. 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 by simultaneously unsheathing 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 ≥3 mm proximal to the edge of the aneurysm neck without stretching the implant. If this cannot be achieved, consider fully resheathing and repositioning 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.

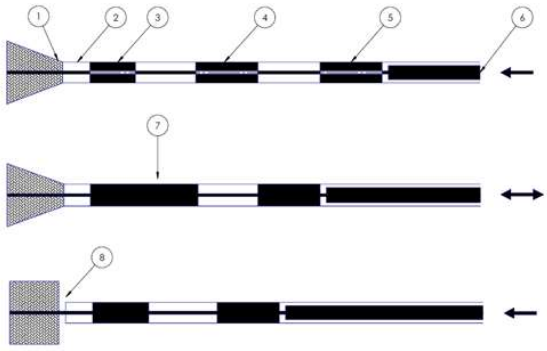
   CAUTION: Avoid applying excessive tension to the implant during final deployment. Excessive tension may result in delayed device migration, herniation into the aneurysm neck, thromboembolic risk, and stroke.

   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 microcatheter.

    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 intracranial 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, stenosis, dissection, perforation, rupture, AV fistula formation, pseudo aneurysm, occlusion, thromboembolic complications including ischemia, occlusion, embolism (to unintended territory), hyperplasia
- 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.

WARNINGS

- 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.

en Symbol Glossary

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

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CE
0297

~~M011974CDOC4 Rev. C (03/2021)~~
M069853CDOC2 Rev. A (01/2025)

Appendix C: List of Pipeline Vantage 027 devices for retrieval

PRODUCT DESCRIPTON	CFN	Lot Serial #			
STENT PED3-027-350-12	PED3-027-350-12	B409106			
		B637287			
		B700548			
STENT PED3-027-350-14	PED3-027-350-14	B409234			
		B700550			
		B794880			
STENT PED3-027-350-16	PED3-027-350-16	B409692			
		B697962			
		B700551			
		B795136			
		B795142			
		B809808			
STENT PED3-027-350-20	PED3-027-350-20	B410645			
		B558444			
		B623124			
		B672921			
		B700552			
		B777630			
STENT PED3-027-350-25	PED3-027-350-25	B410718			
		B672530			
		B700553			
		B771934			
		B771938			
STENT PED3-027-400-12	PED3-027-400-12	B321585	B612514	B671805	
		B336094	B616043	B720634	
		B349668	B616052	B720635	
		B371137	B647374	B744619	
		B409814	B649853	B744621	
		B414591	B655648	B756639	
		B437740	B658620	B765446	
		B482271	B658685	B765448	
		B594119	B666385	B780611	
		B597085	B666418	B786108	
		B598465			
STENT PED3-027-400-14	PED3-027-400-14	B318079	B556978	B691414	
		B335275	B601007	B698756	
		B339540	B608852	B714840	
		B350391	B616050	B715051	
		B364366	B622657	B721683	
		B372416	B625452	B745065	
		B375523	B625453	B753732	

		B410879	B629552	B763635	
		B415080	B683800	B763642	
		B422400	B689019	B802419	
		B438538			
		B448437			
		B459694			
		B460349			
		B464650			
		B469525			
		B474550			
STENT PED3-027-400-16	PED3-027-400-16	B326193	B445198	B608221	B730829
		B330879	B449040	B611268	B738422
		B330881	B449149	B615571	B738423
		B357080	B449591	B623135	B739914
		B401867	B453559	B623136	B744842
		B402034	B454843	B625944	B744860
		B403012	B459846	B625945	B766155
		B417737	B460523	B672865	B766701
		B419736	B465307	B678987	B769315
		B420127	B469682	B694225	B776922
		B422990	B474417	B694934	B776933
		B423257	B560503	B699098	B777378
		B426548	B575892	B715043	B791207
		B438677	B578340	B721778	
		B439156	B597083	B721782	
		B439301	B603196	B730828	
STENT PED3-027-400-18	PED3-027-400-18	B795091			
STENT PED3-027-400-20	PED3-027-400-20	B318459	B460915	B649884	B741664
		B329314	B461092	B654937	B741666
		B329316	B461510	B657799	B746709
		B338468	B465420	B658273	B752946
		B368540	B470193	B658540	B753532
		B374265	B475106	B659188	B756807
		B380481	B478030	B659211	B756808
		B381434	B485264	B666546	B763701
		B383600	B487677	B671140	B778174
		B384092	B557537	B679007	B778192
		B384233	B565556	B680109	B778193
		B388982	B571634	B692381	B778534
		B391816	B575122	B692536	B778535
		B420182	B576711	B692916	B781327
		B420318	B577356	B693469	B781347
		B423735	B578341	B705994	B791327
		B439714	B631830	B722574	B811796

		B441852	B632949	B722592	
		B449699	B635238	B730946	
		B450256	B636674	B739972	
STENT PED3-027-400-25	PED3-027-400-25	B322422	B481516	B675951	B747537
		B394134	B483308	B689989	B747541
		B400793	B568647	B704525	B754030
		B411501	B576712	B706229	B765519
		B415161	B577358	B706230	B776777
		B424676	B634985	B709931	B777166
		B432804	B636192	B712123	B780003
		B442338	B648012	B726423	B780520
		B470284	B649383	B741049	B786557
		B474964	B661189	B741051	
STENT PED3-027-400-30	PED3-027-400-30	B394830	B484529	B675952	B741809
		B401265	B594121	B681380	B764098
		B413855	B603201	B681596	B778206
		B415343	B608917	B711437	B778207
		B415743	B616555	B711438	B798796
		B444760	B622661	B723555	
		B470728	B623126	B731515	
		B475566	B637143	B731516	
STENT PED3-027-450-12	PED3-027-450-12	B322748	B637185	B750794	
		B456666	B666423	B751129	
		B471328	B703226	B758665	
		B486866	B706228	B758666	
		B575963	B708791	B758667	
		B601277	B711095	B794235	
STENT PED3-027-450-14	PED3-027-450-14	B320465	B470900	B669568	B719080
		B336565	B477408	B675953	B719084
		B340244	B481700	B692841	B741791
		B351032	B483148	B694794	B745142
		B374880	B601181	B696125	B745143
		B404541	B604476	B697448	B751967
		B425289	B617556	B704465	B753463
		B432042	B637191	B709288	B772618
		B462206	B669563	B711828	B814124
STENT PED3-027-450-16	PED3-027-450-16	B318562	B483899	B659718	B735829
		B331383	B485855	B660616	B735830
		B331528	B535234	B661809	B746751
		B340320	B552285	B666550	B746752
		B351038	B568744	B666589	B753483
		B374958	B571592	B668758	B757640
		B384705	B585330	B669369	B757645
		B385273	B596585	B675954	B762226

		B395007	B622035	B682011	B762228
		B405061	B625593	B698182	B764394
		B407737	B626044	B723071	B787789
		B424599	B628700	B723072	B789383
		B450972	B629503	B723787	B803301
		B465971	B643420	B723791	
		B471455	B659204	B735828	
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		B328709	B449796	B585331	B705508
		B355336	B450384	B594727	B728234
		B357077	B451092	B632801	B729519
		B357672	B452205	B635651	B732220
		B377120	B461652	B650035	B752592
		B381729	B462339	B651312	B758912
		B389289	B464094	B651584	B758914
		B390355	B480010	B652220	B760821
		B397986	B481041	B669427	B774880
		B419639	B487030	B673379	B776153
		B421094	B549631	B674005	B794615
		B423116	B550980	B681938	B794620
		B425691	B557508	B696501	B798765
		B440190	B569276	B696960	B810476
		B440356	B573461	B700714	B811668
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		B395978	B488714	B645874	B751210
		B403146	B558531	B646698	B751305
		B408241	B590206	B652027	B752452
		B419571	B596591	B654357	B759553
		B425960	B597131	B681223	B759554
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STENT PED3-027-450-30	PED3-027-450-30	B396144	B645276	B714798	
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		B436536	B658656	B731603	
		B535757	B659930	B784372	
		B561797	B675955	B785363	

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		B616037	B713232	B815818	
		B644866	B714797		
STENT PED3-027-450-40	PED3-027-450-40	B353358	B683288	B761386	
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		B448343	B699776	B778836	
		B549634	B704439	B786518	
		B559739	B710043		
		B615408	B710051		
		B623125	B733018		
		B637017	B761384		
		B675956	B761385		
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		B447358	B674478	B729531	
		B455035	B675957	B764751	
		B455951	B685652	B765289	
		B601160	B701387	B785958	
		B603379	B706116	B790520	
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		B375682	B622123	B655727	B785793
		B425116	B638485	B683524	B807437
		B426932	B638487	B703758	B809811
		B432683	B644714	B704315	
		B441009	B645376	B704999	
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		B536475	B649263	B729572	
		B558194	B652167	B730327	
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		B354635	B476324	B677890	B737927
		B370450	B479966	B678397	B737928
		B377872	B485115	B678959	B752681
		B381636	B566387	B679068	B763087
		B386124	B590194	B684999	B772659
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		B426418	B645491	B705610	B779449

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		B456058	B645962	B707606	B779633
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		B387287	B603199	B695076	B747332
		B396748	B646445	B700554	B751359
		B413971	B648039	B702913	B761968
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		B478679	B689445	B720231	
STENT PED3-027-500-30	PED3-027-500-30	B337320	B429875	B655004	B743037
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		B378426	B445405	B663561	B750658
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		B382844	B456544	B668512	B752314
		B401379	B596584	B669368	B752315
		B427074	B598708	B669370	B779538
		B428049	B606136	B707244	
		B428522	B623128	B728433	
STENT PED3-027-500-40	PED3-027-500-40	B319346	B464764	B693594	B749861
		B340946	B467126	B701050	B753183
		B373012	B473757	B703777	B753184
		B373062	B482175	B703949	B762889
		B374156	B567777	B707108	B773500
		B379194	B573469	B710395	
		B397871	B585305	B711021	
		B398496	B590192	B711022	
		B456742	B677757	B736159	
		B457215	B682747	B747948	
STENT PED3-027-550-16	PED3-027-550-16	B358321	B580922	B707045	B720913
		B369526	B622743	B707126	B739371
		B452971	B623127	B708154	B749920
		B497779	B686266	B708159	B782490
		B575962	B689577	B720912	B806751
STENT PED3-027-550-18	PED3-027-550-18	B803199			
STENT PED3-027-550-20	PED3-027-550-20	B412256	B615897	B713214	B766393
		B417797	B623137	B717726	B766406
		B446018	B623138	B731786	B780554
		B454303	B690738	B731789	B781697
		B496490	B691319	B740657	B800693
		B560727	B692483	B741946	B808083
		B565445	B695336	B764254	
		B578965	B713205	B764286	

STENT PED3-027-550-30	PED3-027-550-30	B397247	B494116	B696119	B738502
		B408458	B608410	B697734	B746449
		B414706	B611882	B709920	B783057
		B416571	B615380	B713734	B783239
		B473971	B663584	B713735	B783566
		B475784	B666410	B729710	
		B479273	B695406	B738501	
STENT PED3-027-550-40	PED3-027-550-40	B358931	B612534	B684986	B768849
		B378536	B615604	B704973	B771892
		B389916	B616547	B706035	B771893
		B409027	B652056	B707059	B773963
		B433336	B654234	B717259	B778320
		B437033	B655595	B717261	B778326
		B454059	B671064	B742095	B780176
		B493075	B672455	B750469	
		B494673	B672476	B761584	
STENT PED3-027-550-50	PED3-027-550-50	B397414	B616028	B717336	B745974
		B412119	B637697	B717341	B749926
		B431531	B658014	B724924	B785200
		B435644	B705133	B745389	B785874
		B437187	B717320	B745405	
STENT PED3-027-600-16	PED3-027-600-16	B368960	B611281	B720780	
		B454127	B690544	B732968	
		B603197	B691908	B762785	
		B607478	B693533	B801322	
		B611280	B709546		
STENT PED3-027-600-18	PED3-027-600-18	B801452			
STENT PED3-027-600-20	PED3-027-600-20	B317266	B608223	B708016	B747893
		B338536	B624427	B708642	B761449
		B376423	B624430	B709539	B769429
		B412355	B681791	B713242	B805791
		B446526	B682681	B720316	
		B491096	B698133	B720318	
		B596581	B701028	B747892	
STENT PED3-027-600-30	PED3-027-600-30	B339559	B611169	B682043	B728348
		B412787	B611170	B701346	B735171
		B457289	B626128	B711916	B748081
		B467222	B652141	B712145	B748545
		B489389	B653242	B719705	B748565
		B594600	B654415	B726352	B758585
		B597081	B681946	B726417	B808813
STENT PED3-027-600-40	PED3-027-600-40	B320318	B549767	B669603	B745966
		B337325	B552409	B694091	B758046
		B360226	B559740	B695569	B758050

		B369513	B567778	B699270	B760363
		B379020	B608855	B711618	B767594
		B419419	B618581	B716111	B790633
		B480964	B622005	B720752	B800873
		B485981	B655601	B721600	
		B485982	B655798	B742928	
STENT PED3-027-600-50	PED3-027-600-50	B327190	B617560	B673424	B746625
		B332681	B623582	B680095	B758339
		B342121	B626133	B695531	B758371
		B403885	B651590	B703875	B768841
		B415948	B652749	B713824	B783879
		B428706	B653261	B714234	B783888
		B429330	B653391	B726282	B788852
		B433507	B658476	B732261	B790033
		B434230	B658484	B732262	B794845
		B457419	B670055	B732459	
		B557587	B670398	B733700	

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Consignee Confirmation Form

URGENT: MEDICAL DEVICE RECALL

Pipeline™ Vantage Embolization Device with Shield™ Technology

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

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

For completion by Medtronic Customers Only – Please complete all fields below and return all pages immediately even if you do not have any product to return.

Customer Contact Details		Medtronic Contact Details
Distributor/Hospital/Clinic/Patient name:		**Name:**
		Contact:
Address:		**Email:**
Phone no:	**Email:**	

If you have no affected stock to be returned, please tick the appropriate box, and sign off the form.

Do you have remaining inventory of the affected units? (Please select only ONE):

☐ no, **NONE** of the affected inventory to be returned. I have examined our inventory for product/s covered by this and confirm that all affected was/were previously consumed.

☐ YES, affected inventory to be returned. I have examined our inventory and have the affected product/s listed in the following table that remain/s unconsumed and is to be returned.

CFN/ Product Number	Lot/Serial Number	Quantity to be returned (in units)

By signing this form, I confirm that I have read the Urgent Medical Device Recall Notification Letter, dated 02 February 2025 | 21:32 SGT **from Medtronic and taken appropriate actions for:**

- **The recall removal for *Pipeline™ Vantage Embolization Device with Shield™ Technology with part numbers PED3-027-XXX-XX and***
- ***The correction (IFU Update) for Pipeline™ Vantage Embolization Device with Shield Technology™ with part numbers PED3-021-XXX-XX***

Please complete all fields and sign the form as indicated below and hand or scan then email back to your local Medtronic representative.

Name (print): _____ Signature: _____ Stamp: _____ Date: ☐☐ ☐☐☐ ☐☐☐☐

Return Instructions:

1. Identify and quarantine all affected Pipeline™ Vantage with part numbers PED3-027-XXX-XX as listed in the letter.
2. Return all affected and unused Pipeline™ Vantage devices in your inventory to Medtronic. Your local Medtronic Representative can assist you as necessary in initiating the return of this product.
3. Complete the enclosed Customer Confirmation Form and hand or scan then email back to your local Medtronic representative.

Note: The addressee may continue to receive reminders of this notice until a response is received.

For questions, contact your Medtronic Representative

****Please fill out the previous table first** and list the remaining on this page.
This page must also be signed and dated.**

CFN/ Product Number	Lot/Serial Number	Quantity to be returned (in units)

Name (print): _____ Signature: _____ Stamp: _____ Date: dd Mmm yyyy