Date: December 18, 2019

To: Healthcare Providers

Re: WEB Embolization Device Update

Dear Healthcare Provider,

MicroVention (A Terumo Group Company located in Aliso Viejo, CA) is committed to communicating to the physician community as the commercial launch of the WEB Aneurysm Embolization System proceeds in the United States (US).

The WEB Aneurysm Embolization Device was approved by the US Food and Drug Administration (FDA) on December 31, 2018 and has been available to US patients and physicians for about a year. The WEB Aneurysm Embolization Device has been marketed in Europe since 2010. The WEB was commercially launched in the US on Jan 28th, 2019, and, through December 2019, ~1,100 WEB procedures were completed in the US in patients with, mostly, unruptured wide-neck bifurcation intracranial aneurysms. Due to the novelty of the device, MicroVention offered and continues to offer a comprehensive proctoring and training program to incorporate the best practices of using the device in clinical practice.

This communication is intended to update health care practitioners on product performance and reported adverse events and advise health care practitioners on best practices. Specifically, 6 intra-procedural, intracranial aneurysm ruptures caused by aneurysm wall perforation were reported to MicroVention in 2019 that resulted in patient deaths due to iatrogenic intra-procedural subarachnoid hemorrhage - 4 in the US and 2 outside of the US (OUS).

One death reported in the US describes perforation of the aneurysm wall by a guidewire and three reports describe intra-procedural movement of the WEB device during deployment. Of two mortalities reported to MicroVention from outside the US, one report describes intra-procedural perforation of the aneurysm wall by movement of the microcatheter and one by intra-procedural movement of the device during deployment. At this time, neither the root cause(s) nor the role of either the access devices (guidewire and microcatheter), the WEB device or the deployment / intervention technique in these deaths is known.

In the US WEB-IT trial results (Arthur et al. 2019), there was one incidence of intra-procedural perforation (0.67%, 1/150). The results of the 3 combined European GCP studies (WEBCAST, French Observatory, WEBCAST-2, 168 patients), reported a 1.2% intraprocedural perforation rate. The reported intraprocedural perforation reported in the US WEB-IT trial and the perforations reported in the 3 combined European GCP studies did result in subarachnoid hemorrhage but did not result in patient death.

MicroVention is strongly committed to patient safety and would like to take this opportunity to remind health care practitioners to carefully follow the instructions, warnings, indications for use, contraindications, precautions, and device selection procedures in the labeling.

MicroVention is working to better understand the procedural risk following intraprocedural complications and to ensure that the product labeling and training address this potential risk. Additional information and updates may be provided when available. MicroVention recommends that, as with other endovascular treatments, caution should be used while advancing microcatheters and guidewires intravascularly, and, especially into the intracranial aneurysm and in patients with severe tortuous anatomy. The use of the WEB device with compatible delivery microcatheters (i.e. the VIA microcatheter) and guidewires should be followed per the recommendations in the labeling.

The table below summarizes the 3-step procedure that was presented as part of your didactic training and proctored cases. We encourage you to review this procedure and continue to use it in your WEB procedures.

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3-Step Delivery Procedure of the WEB Device

Step	Sequence	Rationale
1	**VIA® Microcatheter in place** Once the VIA® Microcatheter has been positioned in the aneurysm	▪ Confirm catheter tip location ▪ Confirm support catheter position ▪ Secure new roadmap
2	**WEB® Device at distal tip of VIA® catheter** Once the WEB® Device has been delivered to the tip of VIA® catheter	▪ Confirm catheter tip location ▪ Confirm support catheter position ▪ Secure new roadmap
	WEB® Device Deployment	
3	**WEB® Device pre-detachment** Once the WEB® Device has been fully deployed, prior to detachment	▪ Assess device position within aneurysm ▪ Confirm device position at neck and daughter vessels ▪ Confirm that tension has been removed in the system

User facilities should report device-related deaths and serious injuries per 21 CFR Part 803.30 to MicroVention (the manufacturer), at fieldassurance@microvention.com. Device-related deaths should also be reported to the FDA. User facilities are encouraged, but are not required, to report malfunctions through FDA's MedWatch Adverse Event Reporting. Whenever possible, MicroVention kindly asks that the following patient-unidentified information be provided:

- If the device system was used for the treatment of an unruptured or ruptured intracranial aneurysm.
- Anatomical location, size, neck width, and morphology of the intracranial aneurysm.
- Vessel anatomical characteristics (e.g. tortuosity).
- Whether the adverse event occurred intra-procedurally or post-procedurally.
- A complete description of the adverse event and patient outcome, if available.

- The WEB device model names and numbers.
- Any ancillary devices used during the procedure such as the specific microcatheter, intermediate catheter, guide catheter, and guidewire.
- Unique device identifier (UDI).

Please contact your MicroVention Clinical Associate or Sales Associate with any questions at 800.990.8368.