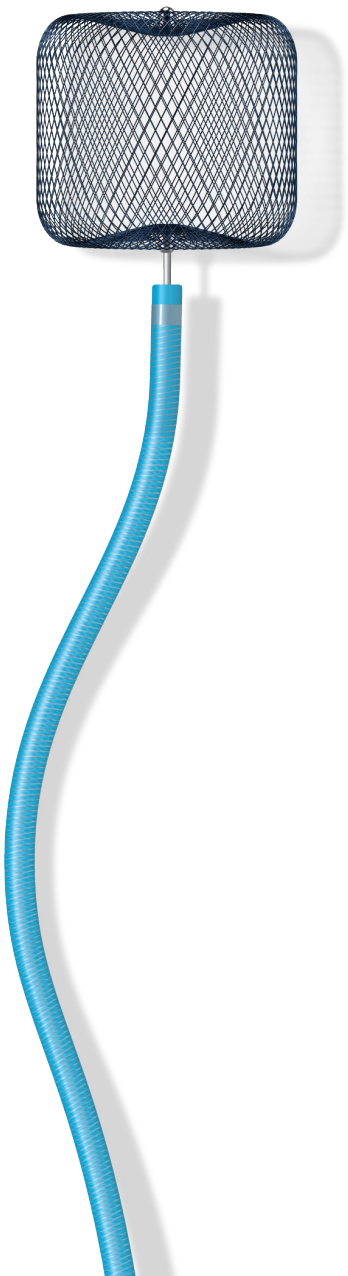
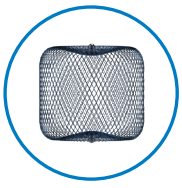
MicroVention™
TERUMO



CLINICALLY PROVEN. **ONE AND DONE TREATMENT.**

WEB™ Aneurysm Embolization System

Intrasaccular solution for wide neck bifurcation aneurysm treatment



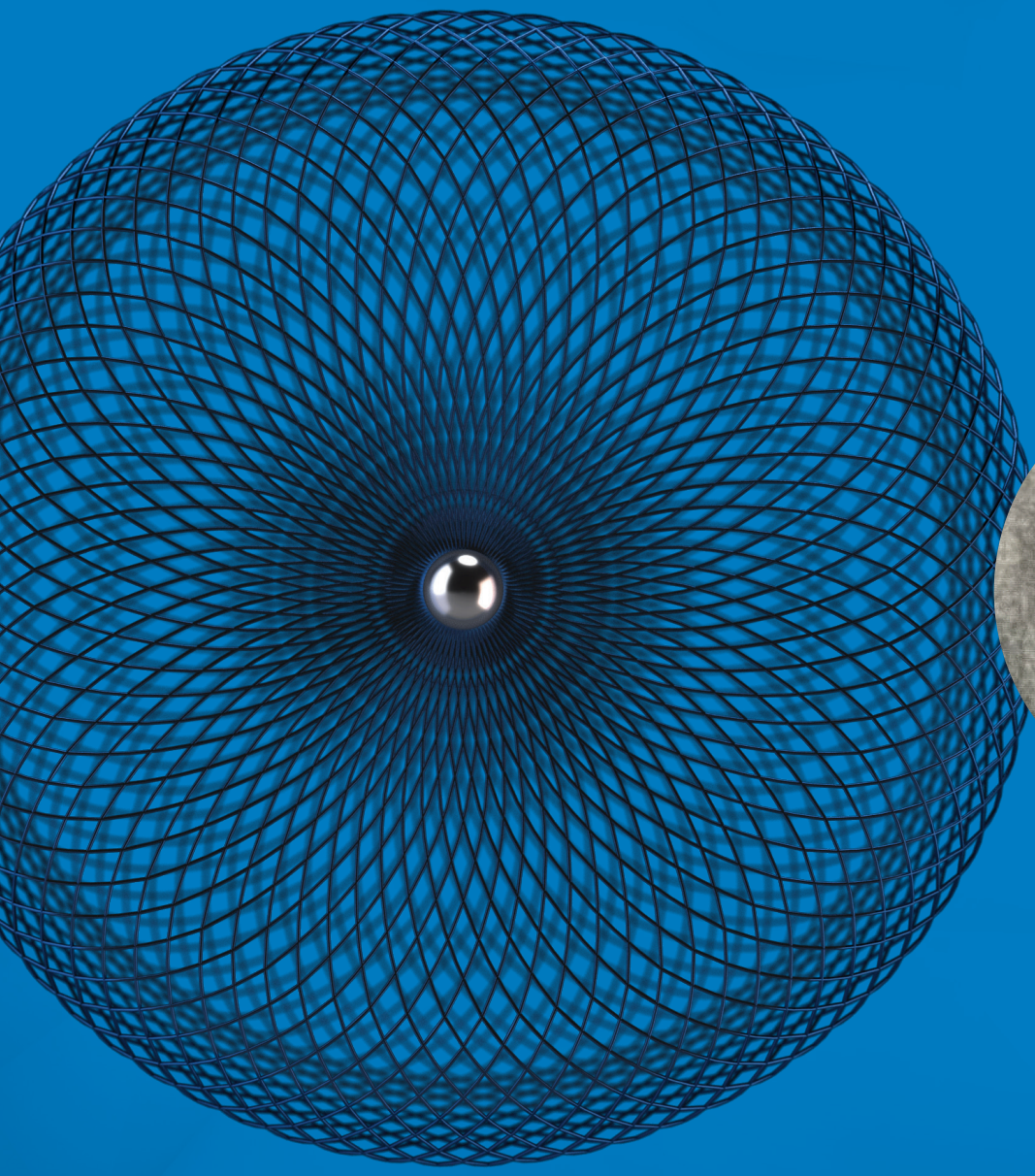
SL Device

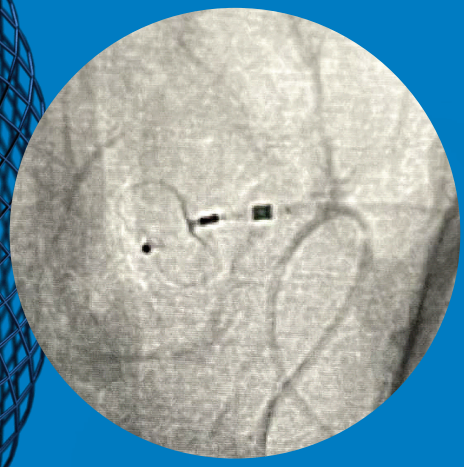
SLS Device

The power of one

Advances treatment of wide-neck bifurcation aneurysms with one intrasaccular device:

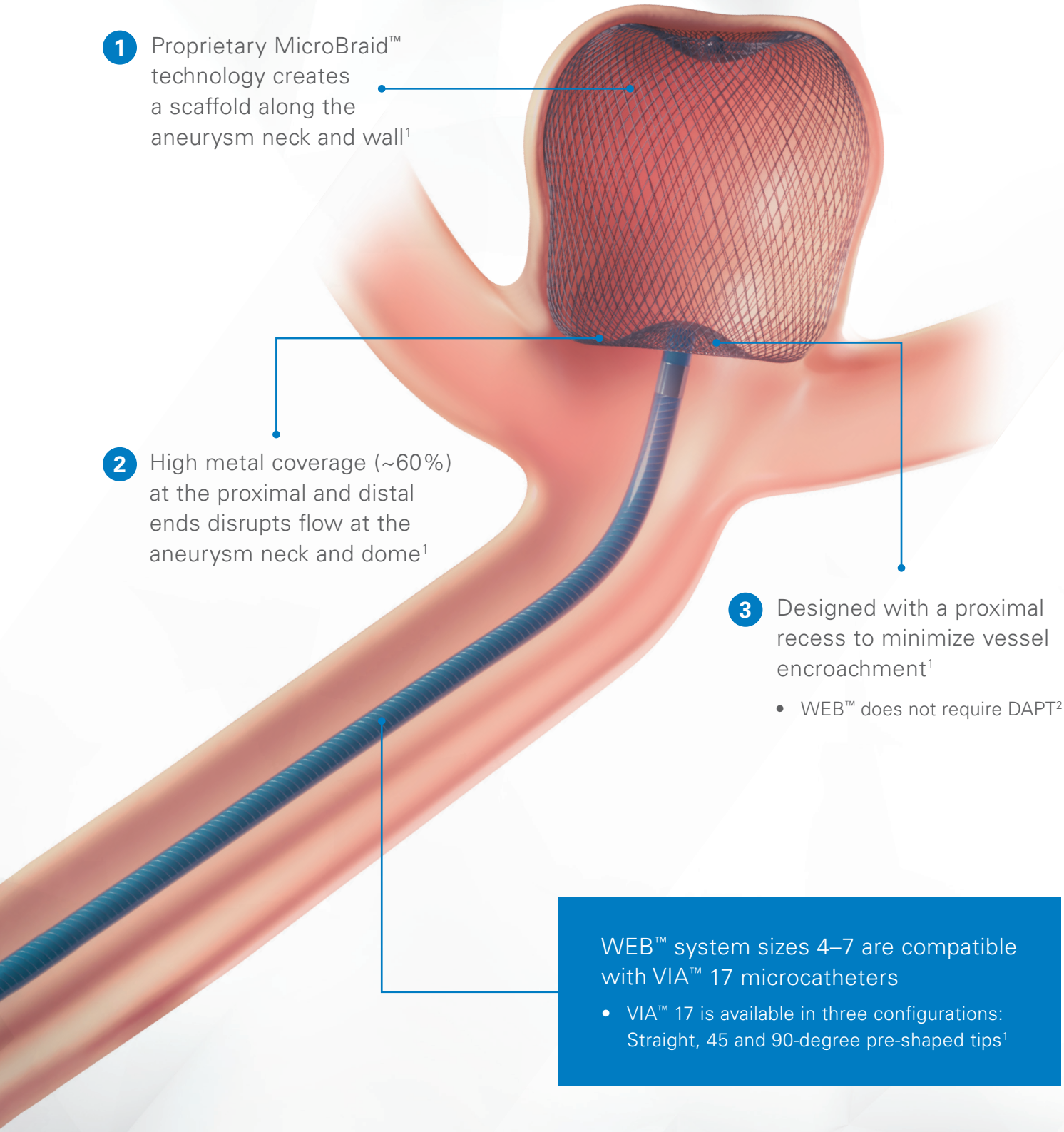
- The WEB System overcomes the challenges of multiple devices[3]
- Reduced procedure times with streamlined method and less radiation exposure[3–6]
- Seamless resheathing and repositioning for procedural control and effective outcomes[7]





Angulated Acomm bifurcation aneurysm treated with WEB SL 6x2 by David Altschul from Montefiore Medical Center

Designed to seal the neck and protect the dome



1. Proprietary MicroBraid™ technology creates a scaffold along the aneurysm neck and wall[1]

2. High metal coverage (~60%) at the proximal and distal ends disrupts flow at the aneurysm neck and dome[1]

3. Designed with a proximal recess to minimize vessel encroachment[1]
   - WEB™ does not require DAPT[2]

WEB™ system sizes 4–7 are compatible with VIA™ 17 microcatheters

- VIA™ 17 is available in three configurations: Straight, 45 and 90-degree pre-shaped tips[1]

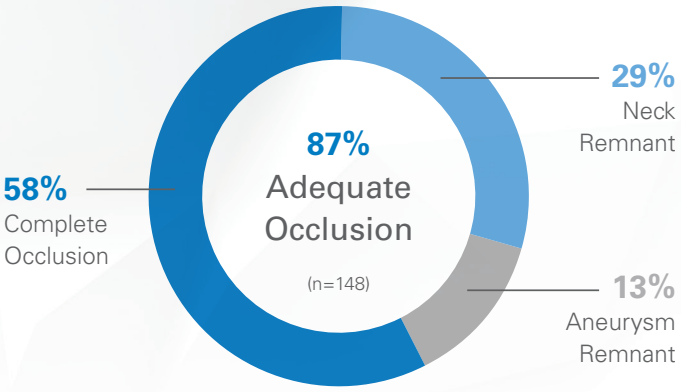
Proven long-term durability

Five-year follow-up results demonstrate long-term safety and efficacy.[8,9]

WEB-IT 5-year Follow-up[8*]

0%

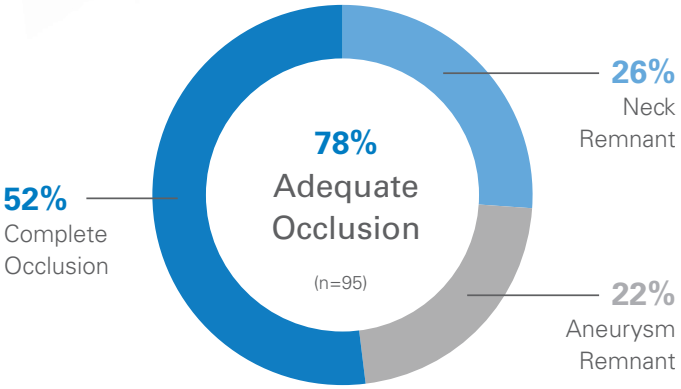
- Bleeding or rebleeding after initial procedure
- WEB™-related mortality



WEBCAST 1&2 5-year Follow-up[9*]

0%

- Bleeding or rebleeding after initial procedure
- WEB™-related morbidity and mortality



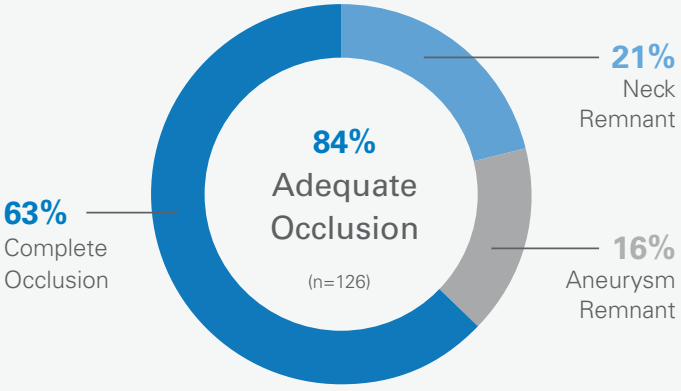
Proven low profile system[10]

The WEB™ 17 system demonstrates excellent safety and effectiveness at 1-year follow-up.

CLEVER Study of WEB™ 17 System[10**]

0%

- Bleeding or rebleeding after initial procedure
- WEB™-related morbidity and mortality

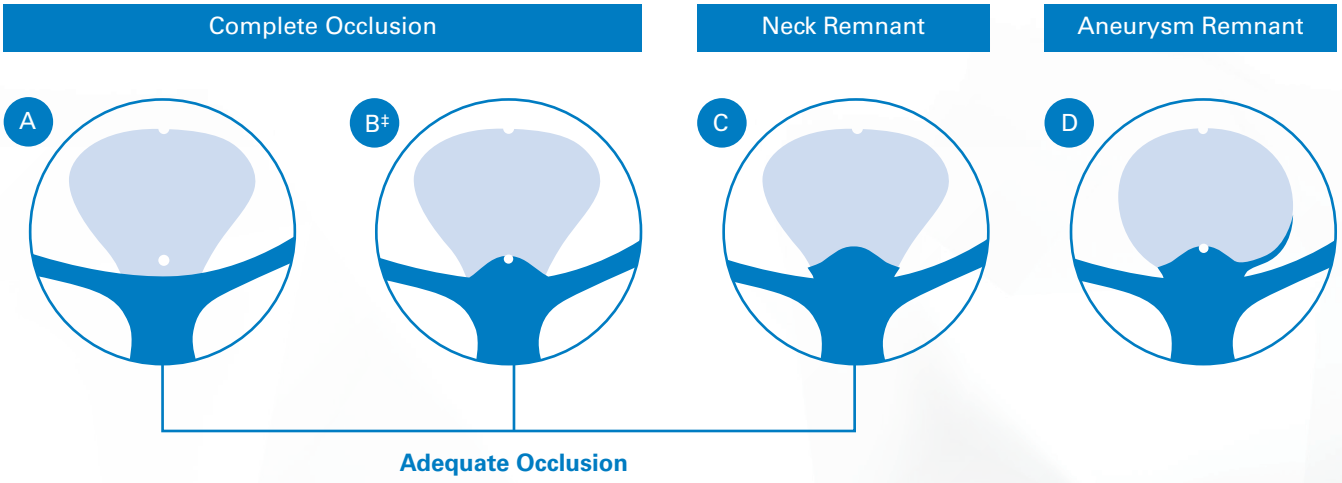


The most studied intrasaccular device

Seven Good Clinical Practice (GCP) Studies and hundreds of publications on its safety and effectiveness treating a variety of different aneurysms

	WEB-IT[8]	WEBCAST 1&2[9]	CLARYS[11]**	CLEVER[10]**
Study Description	US IDE – long term follow up	EU GCP – long term follow up	EU study of ruptured aneurysms	EU study of 17-system
Angiographic Follow-up	5 years	5 years	1 year	1 year
Ruptured Aneurysms Treated	6.0% (9/150)	7.4% (7/95)	100% (60/60)	36.8% (60/163)
Adequate Occlusion A B C	87.2% (129/148)	77.9% (74/95)	87.0% (40/46)	83.9% (120/143)
Bleed/Rebleed	0%	0%	0%	0%
Overall Morbidity†	NR	1.0%	9.6%	2.0%
Overall Mortality†	4.7%	7.0%	3.8%	0.6%

Not included: FROBS, WEB-IT China



*WEB-IT and WEBCAST 1&2 included WEB 21, 27, and 33 systems.
**The CLEVER and CLARYS studies were conducted in accordance with the European indications for use. Occlusion and safety findings do not necessarily correlate with WEB results in other geographies.
†All-cause morbidity and mortality. 0% WEB-related morbidity and mortality.
‡Contrast opacification in the proximal marker recess (image B).

Contact a MicroVention sales associate to learn more about integrating the WEB™ device into your practice.

REFERENCES:

1. Data on file.
2. Spelle L, Liebig T. *Neuroradiol J.* 2014;27:369.
3. Fiorella D, et al. Demographic, procedural and 30-day safety results from the WEB Intra-saccular Therapy Study (WEB-IT). *J Neurointerv Surg.* 2017;9:1191-6.
4. Miller TR, Jindal G, Krejza J, Gandhi D. Impact of Endovascular Technique on Fluoroscopy Usage: Stent-Assisted Coiling versus Flow Diversion for Paraclinoid Internal Carotid Artery Aneurysms. *Neuroradiol J.* 2014;27(6):725-731. doi:10.15274/NRJ-2014-10094
5. Cheung NK, Boutchard M, Carr MW, Froelich JJ. Radiation exposure, and procedure and fluoroscopy times in endovascular treatment of intracranial aneurysms: a methodological comparison. *J Neurointerv Surg.* 2018;10(9):902-906. doi:10.1136/neurintsurg-2017-013596
6. Chalouhi N, McMahon JF, Moukarzel LA, et al. Flow diversion versus traditional aneurysm embolization strategies: analysis of fluoroscopy and procedure times. *J Neurointerv Surg.* 2014;6(4):291-295. doi:10.1136/neurintsurg-2013-010777
7. Data on file. TR16-292-01
8. Fiorella D, Molyneux A, Coon A, et al. Safety and effectiveness of the Woven EndoBridge (WEB) system for the treatment of wide necked bifurcation aneurysms: final 5 year results of the pivotal WEB Intra-saccular Therapy study (WEB-IT) [published online ahead of print, 2023 Jun 24]. *J Neurointerv Surg.* 2023. doi:10.1136/jnis-2023-020611.
9. Pierot L, Szikora I, Barreau X, et al. Aneurysm treatment with the Woven EndoBridge (WEB) device in the combined population of two prospective, multicenter series: 5-year follow-up. *J Neurointerv Surg.* 2022
10. CLEVER: Clinical evaluation of WEB 0.017 device in intracranial aneurysms. Final results at 1 year. Observational post-market, prospective, multicenter GCP study. Conducted at 17 European sites with a minimum of 160 subjects. Data comes from information presented at ISC 2023.
11. Spelle L, Herbreteau D, Caroff J, et al. CLinical Assessment of WEB device in Ruptured aneurYSms (CLARYS): results of 1-month and 1-year assessment of rebleeding protection and clinical safety in a multicenter study. *J Neurointerv Surg.* 2022;14(8):807-814.

WEB INDICATIONS FOR USE:

The WEB Aneurysm Embolization System is intended for the endovascular embolization of ruptured and unruptured intracranial aneurysms and other neurovascular abnormalities such as arteriovenous fistulae (AVF). The WEB Aneurysm Embolization System is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

CAUTION: Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician. Indications, contraindications, warnings, instructions for use, pictures, and figures for the WEB™ Aneurysm Embolization System can be found in the Instructions for Use provided with the Device. Indications for use: The WEB Aneurysm Embolization System is indicated for use at the middle cerebral artery (MCA) bifurcation, internal carotid artery (ICA) terminus, anterior communicating artery (AComm) complex, or basilar artery apex for the endovascular treatment of adult patients with saccular, wide neck bifurcation intracranial aneurysms with dome diameter from 3 mm to 10 mm and either neck size 4 mm or greater or the dome-to-neck ratio is greater than 1 and less than 2. Contraindications: Patients with known active bacterial infection that may interfere with or negatively affect the implantation procedure. Patients with known hypersensitivity to nickel. Warnings: The WEB Aneurysm Embolization System (see Figure 1) is provided sterile and non-pyrogenic unless the unit package is opened or damaged. Do not use if the packaging is open or damaged. Use before expiration date noted on the product packaging. The WEB Aneurysm Embolization System is intended for single use only. The detachment control device is intended to be used for one patient. Do not resterilize and/or reuse the WEB embolization device. Reuse and/or resterilization can increase risk of infection, cause a pyrogenic response or other life-threatening complications. Reuse and/or resterilization can degrade product performance, leading to WEB embolization device malfunction. Dispose of all WEB embolization devices in accordance with applicable hospital, administrative and/or local government policy. The safety and effectiveness of the WEB embolization device in areas other than those identified in the Indications for Use has not been established. The safety and effectiveness of the WEB embolization device has not been established for ruptured intracranial aneurysms. The safety and effectiveness of the WEB embolization device has not been evaluated or established in intracranial aneurysms that were previously treated. High quality, digital subtraction fluoroscopic road mapping, with orthogonal views is recommended to achieve correct placement of the WEB embolization device. Do not allow an inappropriately sized or non-optimally positioned WEB embolization device to reside in the aneurysm significantly beyond the activated clotting time (ACT). Experience has shown that thrombus formation can also prevent the WEB embolization device from full deployment and recapture. To minimize the risks of potential complications, the status of the patient's anti-platelet medication regimen should be considered when deciding to remove the entire WEB embolization device from the aneurysm prior to deployment/detachment for replacement by a new WEB embolization device. Use of the WEB embolization device in anatomy with severe tortuosity, stenosis, or vessel narrowing may result in difficulty or inability to deploy the subject WEB embolization device and can lead to damage of the WEB embolization device or microcatheter. The safety and effectiveness of the WEB embolization device has not been established for patients taking anticoagulants or who have a known blood dyscrasia, coagulopathy, or hemoglobinopathy. The WEB embolization device must be delivered only through a compatible microcatheter with a PTFE inner surface coating. If an incompatible microcatheter is used, damage to the WEB embolization device and delivery device may occur and necessitate removal of both the WEB embolization device and microcatheter from the patient. Advance and retract the WEB embolization device slowly. Do not advance the delivery device with excessive force. Determine the cause of any unusual resistance. Remove the WEB embolization device if excessive friction is noted and check for damage. Do not rotate the delivery device during or after delivery of the WEB embolization device. Rotating the WEB embolization device may result in damage or premature detachment. The WEB embolization device cannot be detached with any other power source other than a WEB detachment control device. Ensure that at least two WEB detachment control devices are available before initiating an embolization procedure. Precautions: Large bore microcatheters may have a higher probability of developing a thromboembolic event in the parent vessel. The WEB embolization device should be used only by physicians trained in percutaneous, intravascular, and neurovascular techniques and procedures at medical facilities with the appropriate fluoroscopic equipment. The WEB embolization device should be used by physicians who have received appropriate training for this WEB embolization device. Carefully weigh the benefits of treatment vs. the risks associated with treatment using the WEB embolization 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 WEB embolization device use may not outweigh the risks associated with the WEB embolization device in certain patients; therefore, judicious patient selection is recommended. Limit the exposure to X-ray radiation doses to patients and physicians by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors when possible. The WEB embolization device may create local field inhomogeneity and susceptibility artifacts during magnetic resonance angiography (MRA), which may degrade the diagnostic quality to assess effective intracranial aneurysm treatment. Please only use digital subtraction angiography (DSA) or computed tomography angiography (CTA) to assess intracranial aneurysm occlusion for patient follow-up. Steam shaping 0.021" and greater microcatheters may result in improper WEB embolization device delivery and deployment, depending on the degree of shaping and catheter deflection during WEB embolization device delivery. If repositioning is required, take special care to retract or to advance the WEB embolization device under fluoroscopy, including new road map to confirm catheter position. If the WEB embolization device must be retrieved from the vasculature after detachment, retrieval devices (e.g. alligator and snare) should be used per their manufacturer's instructions. The pictures in (a) through (c) below illustrate WEB embolization device deployment. Initially, the distal implant marker band exits the microcatheter (a). As the implant is advanced, it begins to expand in diameter (b). When the distance between the catheter marker band and implant tip is about 1/3 of the total implant marker distance, the implant diameter is generally about 1/2 of its fully deployed diameter (b). When the implant distal marker band to catheter distal marker band distance is about 2/3 of the total implant marker-marker distance, the implant has reached about 4/5 of its fully deployed diameter and the distal marker band begins moving into the distal recess (c). VIA™ 17 Microcatheters have a proximal marker band not shown in the drawings or photos below. This proximal catheter marker band is not used for WEB delivery. The WEB embolization device foreshortens during delivery (~60%) (e.g. see Figure 2a, a 11mm x 9mm device will measure ~20mm in length when contained within a 0.032"-0.038" delivery microcatheter). When properly deployed, two radio-opaque markers should be separated and fluoroscopically visible (e.g. see Figure 2b, depending on working projection and placement in the aneurysm, the distance between the proximal to distal marker should approximate the labeled WEB embolization device length). WEB embolization device visibility may vary with diameter; larger sizes may be more visible than smaller sizes. Examples are shown in Figure 2c. If the radio-opaque markers are clustered (i.e. a shorter distance between markers than expected), retract WEB embolization device into the microcatheter and evaluate the microcatheter/aneurysm position with multiple fluoroscopic angles. Batteries are pre-loaded into the WEB detachment control device. Do not attempt to remove or replace the batteries. Potential complications: Include but are not limited to the following: vessel puncture site hematoma, aneurysm perforation or rupture, hemorrhage, edema, thromboemboli, transient ischemic attack, ischemic stroke, neurologic deficits, parent artery occlusion, ischemia, vessel dissection or perforation, vascular thrombosis, vasospasm, device migration or misplacement, premature detachment, headache, post-embolization syndrome, infection and death. The WEB embolization device requires the use of fluoroscopy. Potential complications related to angiographic and fluoroscopic radiation doses include, but are not limited to, alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia. The probability of occurrence of complications may increase as procedure time and number of procedures increase. Other procedural complications including but not limited to anesthetic and contrast media risks, hypotension, hypertension and access site complications.

VIA INDICATIONS FOR USE:

The VIA Microcatheter is intended for the introduction of interventional devices (such as the WEB device/stents/flow diverters) and infusion of diagnostic agents (such as contrast media) into the neuro, peripheral, and coronary vasculature.

CAUTION: Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

For Healthcare Professionals Intended Use Only

MicroVention Worldwide
Innovation Center
35 Enterprise
Aliso Viejo, CA 92656 USA
PH +1.714.247.8000
PH 1.800.990.8368
Website: microvention.com

Caution: Federal law restricts these devices to sale by or on the order of a physician

CE 0297
Class III Device

MicroVention™ TERUMO