LVIS™ EVO™

Intraluminal Support Device

TERUMO NEURO

Seeing is Believing

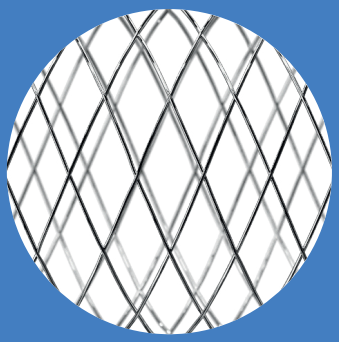
THE EVOLUTION IN STENT INNOVATION

EVO™ Enhanced Visualization & Opening

DFT Wire Construction

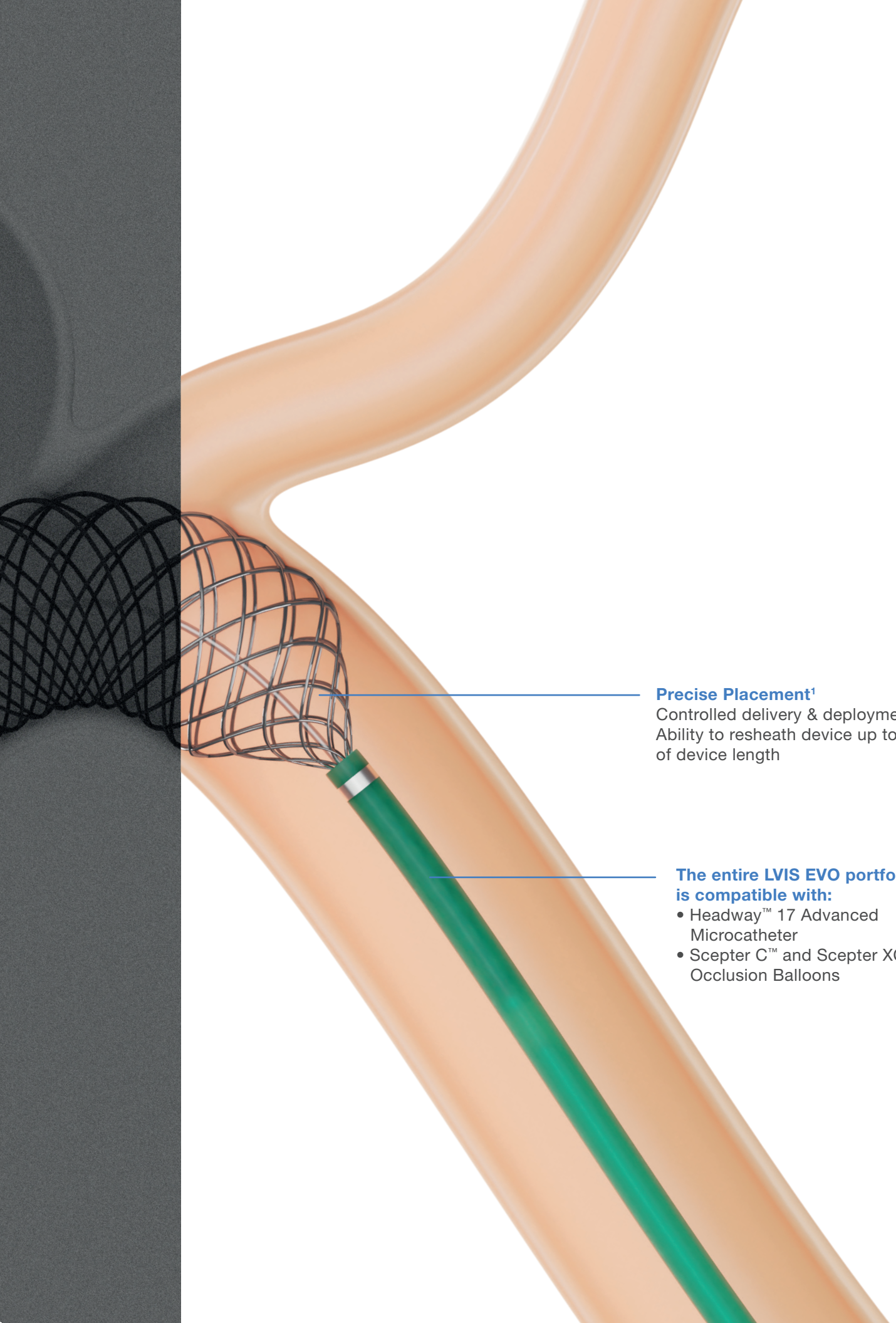
Every wire visible under fluoroscopy[1]

Advanced Braid Design



Enhanced Visualization[1]
Provides wall apposition confirmation

Optimized Opening[1]
Optimized braid angle allows for improved device opening along entire length of device



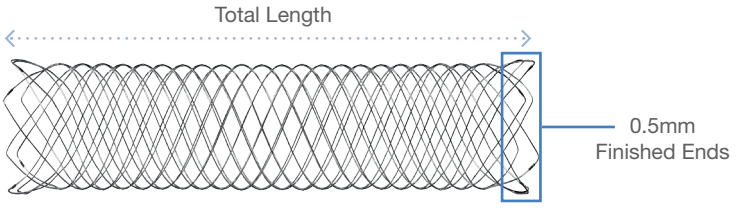
Precise Placement[1]
Controlled delivery & deployment
Ability to resheath device up to 80% of device length

The entire LVIS EVO portfolio is compatible with:

- Headway™ 17 Advanced Microcatheter
- Scepter C™ and Scepter XC™ Occlusion Balloons

LVIS™ EVO™

Intraluminal Support Device



Working Length = Total Length - 1 mm

Product Code	Labeled Diameter X Total Length (mm)	Undeployed Total Length (mm)	Total Length at Device Diameter (mm)				
			2.0mm	2.5mm	3.0mm	3.5mm	4.0mm
LEV2512	2.5 x 12	20	16	12			
LEV2517	2.5 x 17	29	23	17			
LEV2522	2.5 x 22	38	30	22			
LEV2527	2.5 x 27	47	36	27			
LEV3018	3.0 x 18	34	28	24	18		
LEV3024	3.0 x 24	44	37	32	24		
LEV3028	3.0 x 28	54	46	39	28		
LEV3032	3.0 x 32	60	50	43	32		
LEV3517	3.5 x 17	32	28	26	22	17	
LEV3522	3.5 x 22	44	39	35	30	22	
LEV3528	3.5 x 28	56	49	44	37	28	
LEV3534	3.5 x 34	67	60	53	45	34	
LEV4013	4.0 x 13	22		20	18	15	13
LEV4018	4.0 x 18	36		31	28	24	18
LEV4021	4.0 x 21	43		36	33	28	21
LEV4027	4.0 x 27	56		48	43	37	27
LEV4031	4.0 x 31	63		53	48	41	31

Delivery System

Compatible with Headway™ 17 Advanced Microcatheter, Scepter C™, and Scepter XC™ Balloons

[1]Data on file at Microvention. Data is derived from bench testing and may not be representative of clinical performance.

TERUMO NEURO

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Indications for Use: The LVIS device is indicated for use with neurovascular embolization coils in patients ≥ 18 years of age for the treatment of wide-neck (neck width ≥ 4 mm or dome to neck ratio < 2) saccular intracranial aneurysms arising from a parent vessel with a diameter ≥ 2.0 mm and ≤ 4.5 mm.

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 for the LVIS™ device can be viewed at https://microvention.com/products/product-use-and-safety. **Contraindications:** Use of the LVIS device is contraindicated under these circumstances: Patients in whom anticoagulant, anti-platelet therapy or thrombolytic drugs are contraindicated; Patients with known hypersensitivity to metal, such as nickel-titanium and metal jewelry; Patients with anatomy that does not permit passage or deployment of the LVIS device; Patients with an active bacterial infection; Patients with a pre-existing stent in place at the target aneurysm. **Warnings:** Do not use device for acutely ruptured intracranial aneurysms within a minimum of 30 days from intracranial aneurysm rupture. Should unusual resistance be felt at any time during access or removal, the introducer/microcatheter and LVIS device should be removed as a single unit. Applying excessive force during delivery or retrieval of the LVIS device can potentially result in loss or damage to the device and delivery components. The LVIS device should only be used by physicians trained in endovascular interventional neuroradiology, radiology, neurosurgery or interventional neurology on the treatment of intracranial aneurysms. Selection of the LVIS device size is important for proper product performance and patient safety and must be based on pretreatment angiograms for correct and accurate vessel measurements from multiple views. It is imperative to use the LVIS device with compatible microcatheters. If repeated friction is encountered during LVIS device delivery, verify microcatheter is not kinked or in extremely tortuous anatomy. Confirm that the microcatheter does not ovalize. Confirm that there is adequate sterile flush solution. Do not reposition the LVIS device in the parent vessel without fully retrieving the device. The LVIS device MUST be retrieved into the microcatheter and re-deployed at the desired target location or removed completely from the patient. Do not attempt to re-position the LVIS implant after detachment. Do not shape the tip of the delivery wire. Do not torque the delivery wire while advancing or retracting the LVIS device. A torque device should not be used. DO NOT FULLY DEPLOY LVIS device. If the device is deployed, DO NOT attempt to reload the device. Use a new device. DO NOT CONTINUE if any defect is observed; return the unit to MicroVention, Inc. Do not shape the tip of the delivery wire. Purge the LVIS device carefully to avoid the accidental introduction of air into the system. Confirm that there are no air bubbles trapped anywhere in the system. Do not torque the delivery wire while advancing or retracting the LVIS device. A torque device should not be used. Do not apply undue force. If resistance is encountered at any point during LVIS device delivery or manipulation, withdraw the unit and select a new LVIS device. Do not detach the LVIS device if it is not properly positioned in the parent vessel. Observe the delivery wire distal tip to assure it remains within the desired location of the parent vessel. The LVIS device delivery wire should not be utilized as a guidewire. Do not torque the LVIS device. A torque device should not be used. **Precautions:** The LVIS device is provided sterile for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Carefully inspect the sterile package and the LVIS device prior to use to verify that neither has been damaged during shipment. Do not use kinked or damaged components, or if the packaging is damaged. See the product label for the device shelf life. Do not use the device beyond the labeled use by date. Exercise caution when crossing the deployed/detached LVIS device with adjunctive devices such as guidewires, catheters, microcatheters or balloon catheters to avoid disrupting the device geometry and device placement. The LVIS device with neurovascular embolization coils 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. The safety and effectiveness of the device has not been established in the treatment of large and giant wide- neck intracranial aneurysms. The benefits may not outweigh the risks of treatment in patients with wide-neck intracranial aneurysms ≤ 5 mm in size, or reduced life expectancy, in the absence of additional risk factors for intracranial aneurysm rupture. The safety and effectiveness of the device has not been well established in the posterior circulation. Ensure that the specific embolization coil models and sizes used are indicated for the embolization of intracranial aneurysms. **Potential Complications:** The following potential risks and complications associated with general anesthesia, cerebral angiography, intracranial catheterization, intracranial stent placement or intra-saccular coil deployment have been identified below: Allergic reaction, including but not limited to: contrast dye, nitinol metal, and any other medications used during the procedure; Aphasia; Blindness; Cardiac Arrhythmia; Coil prolapsed or migration into normal vessel adjacent to aneurysm; Complications of arterial puncture including pain, local bleeding, local infection and injury to the artery, vein or adjacent nerves; Cranial neuropathy; Death; Device fracture, migration or misplacement; Dissection or perforation of the parent artery; Headache; Hemorrhage (i.e., intracerebral hemorrhage (ICH), subarachnoid hemorrhage (SAH), or retroperitoneal (or in other locations)); Hemiplegia; Hydrocephalus; Infection; Injury to normal vessel or tissue; Ischemia; Mass effect; Myocardial Infarction; Neurological deficits; Occlusion of non-target side branches; Pseudo aneurysm formation; Reactions to anti-platelet/anti-coagulant agents; Reactions due to radiation exposure; Reactions to anesthesia and related procedures; Reactions to contrast agents; Renal failure; Aneurysm rupture; Stenosis of stented segment; Seizure; Stent thrombosis; Stroke or TIA (Transient Ischemic Attack); Thromboembolic event (T/E); Vasospasm; Visual impairment. Potential Risks Associated with X-ray Exposure: The use of the LVIS device requires fluoroscopy, which presents potential risks associated with X-ray exposure. The risks of angiographic and fluoroscopic X-ray radiation doses to the patient include risks such as alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia that increase in probability as procedure time and number of procedures increase. The probability of adverse event occurrence increases as the procedure time and the number of procedures increase. Operators should 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 whenever possible.

For Healthcare Professionals' Intended Use only.

This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures at medical facilities with the appropriate fluoroscopy equipment. The LVIS EVO device should only be used by physicians who have received appropriate training for the device.

Indications for Use: The HEADWAY Microcatheter is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils. The Scepter C/XC Occlusion Balloon Catheters are intended for use in the peripheral and neuro vasculature where temporary occlusion is desired. The balloon catheters provide temporary vascular occlusion which is useful in selectively stopping or controlling blood flow. The balloon catheters also offer balloon assisted embolization of intracranial aneurysms. For use in the peripheral vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents such as embolization materials. For neurovascular use for the infusion of diagnostic agents such as contrast media, and therapeutic agents, such as embolization materials, that have been approved or cleared for use in the neurovasculature and are compatible with the inner diameter of the Scepter C/XC Balloon Catheter.

RX Only: Federal (USA) law restricts this device to sale by or on the order of a physician.