The LVIS® Device Pivotal Study Results

LOW-PROFILE
VISUALIZED
INTRALUMINAL
SUPPORT DEVICE

STUDY DESIGN:

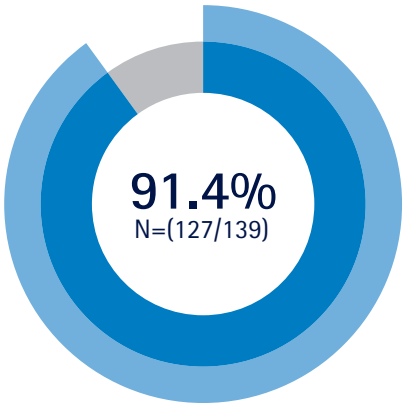
The LVIS® Device Pivotal Study was a multi-center, prospective, single-arm study with follow-up at hospital discharge and 12 months post procedure. 153 patients were enrolled across 22 investigational sites within the United States.

PRIMARY EFFECTIVENESS COMPOSITE SUCCESS[1]: 70.6% (108/153)

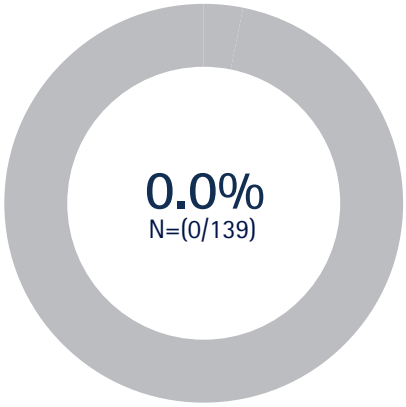
100% aneurysm occlusion without clinically significant in stent stenosis or target aneurysm retreatment.

PRIMARY EFFECTIVENESS ENDPOINT SUBCOMPONENTS[2]:

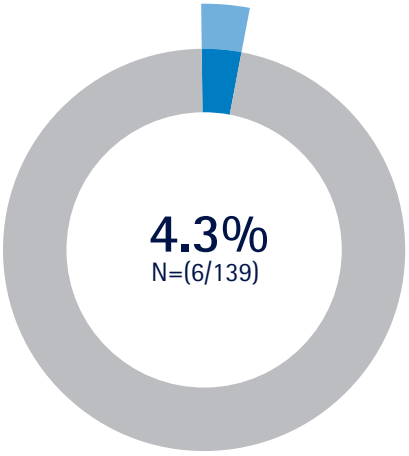
90%–100% Aneurysm Occlusion[3]



Clinically Significant In-Stent Stenosis (≥ 50%) Of Parent Artery



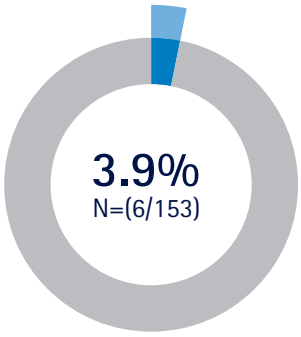
Target Aneurysm Retreatment



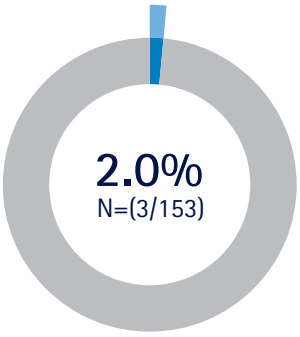
PRIMARY SAFETY COMPOSITE RATE: 5.9% (9/153)

Disabling stroke with mRS ≥ 3 or neurological death within 12 months.

Disabling Stroke With mRS Score ≥ 3[4]



Neurological Death



1. ITT (intended to treat) population N=153. All missing patients were considered failures
2. Evaluable population N=139
3. RR Class 1 (N=111) + RR Class 2 with stable or positive occlusion and no retreatment (N=16). Subjects having negative progression from post-procedure to 12 months or retreatment are considered failures. Missing data imputed as failures
4. mRS score ≥ 3 at any time point between 90 days and last available follow-up. 2 major strokes were caused by pre-existing morbidities and were in vascular territories unrelated to device orprocedure

All data from IFU100003A

MicroVention® TERUMO

Professional use only.

INDICATIONS FOR USE: The LVIS® device is intended for use with embolic coils for the treatment of intracranial neurovascular diseases. **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:** 1) Do not use device for acutely ruptured intracranial aneurysms within a minimum of 30 days from intracranial aneurysm rupture. 2)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. 3) 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. 4) Selection of the LVIS® device size is important for proper product performance and patient safety and must be based on pre-treatment angiograms for correct and accurate vessel measurements from multiple views. 5) 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. 6) 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. 7) Do not attempt to re-position the LVIS® implant after detachment. 8) Do not shape the tip of the delivery wire. 9) Do not torque the delivery wire while advancing or retracting the LVIS® device. A torque device should not be used. **PRECAUTIONS:** 1) 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. 2) 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. 3) See the product label for the device shelf life. Do not use the device beyond the labeled use by date. 4) 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. 5) The safety and effectiveness of the device has not been established in the treatment of large and giant wide-neck intracranial aneurysms. 6) 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. 7) The safety and effectiveness of the device has not been well established in the posterior circulation. 8) Ensure that the specific embolization coil models and sizes used are indicated for the embolization of intracranial aneurysms. **POTENTIAL ADVERSE EVENTS:** The following potential risks and complications associated with general anesthesia, cerebral angiography, intracranial catheterization, intra-cranial stent placement or intra-saccular coil deployment have been identified: 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.

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