LVIS™

LVIS™ Jr.

LVIS™ EVO™

Intraluminal Support Device

INSTRUCTIONS FOR USE

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

IFU100154A
Revised 2022-08

DEVICE DESCRIPTION

The MicroVention Low-Profile Visualized Intraluminal Support (LVIS) device [Figures 1, 2 and 3a] is a self-expanding Nitinol (with Platinum core for LVIS EVO), single wire braid, compliant, closed-cell design that can be deployed and retrieved by a single operator. The LVIS device is sterile and non-pyrogenic and is packaged as a single unit with an introducer sheath and a detachable push wire.

Figure 1.
Device - Components

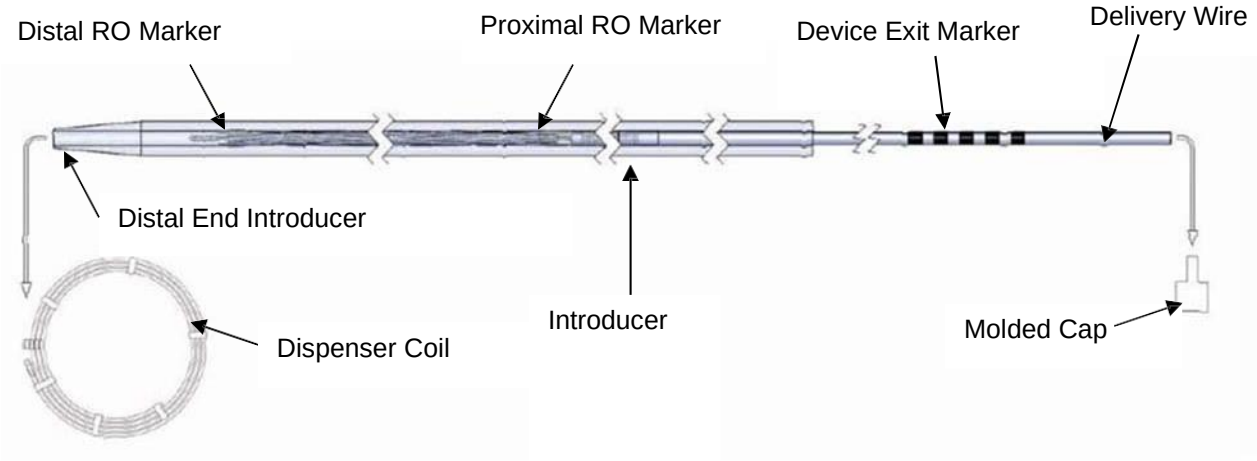
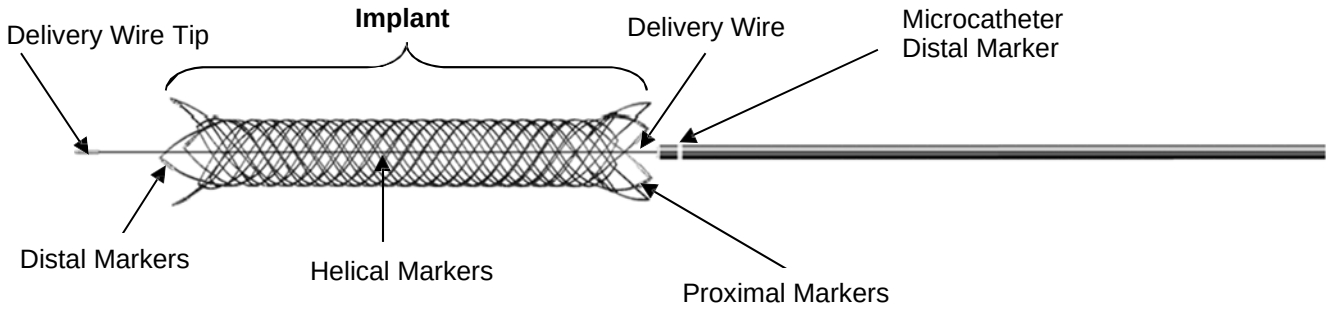


Figure 2.
LVIS Device – Implant Delivery



	Distal Markers	Helical Markers	Proximal Markers
LVIS Device	**4**	**2**	**4**
LVIS Jr. Device	**3**	**3**	**3**
LVIS EVO Device	**4**	**N/A**	**4**

Figure 3a.
LVIS Device Implant Dimensions

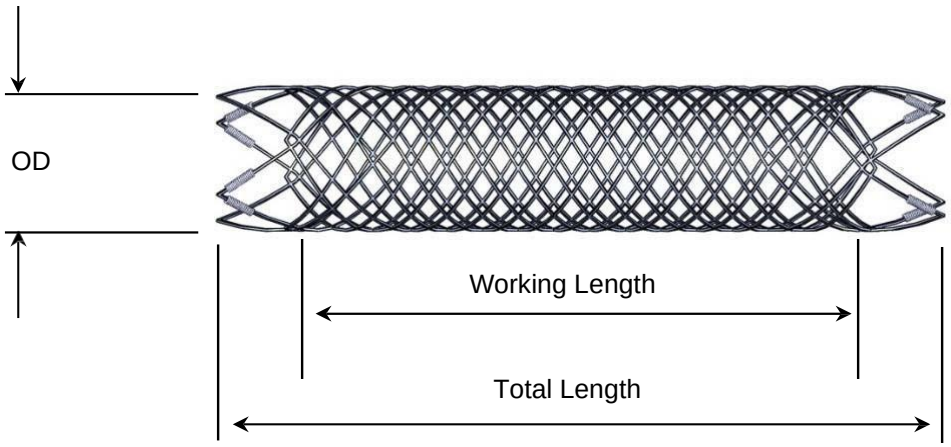


Table 1a: LVIS Device Product Information

LVIS								
Product Code	Undeployed Length † (mm)	Total Length / Working Length* (mm) at device diameter (mm)						
		2.5	3.0	3.5	4.0	4.5	5.0	5.5
212517-LVIS	28	23 / 19	20 / 16	17 / 13				
212525-LVIS	40	32 / 28	27 / 23	22 / 18				
212912-LVIS	18	16 / 12	15 / 11	14 / 10	12 / 8			
212917-LVIS	31	27 / 23	24 / 20	21 / 17	17 / 13			
212922-LVIS	44	37 / 33	34 / 30	29 / 25	22 / 18			
212928-LVIS	57	48 / 44	43 / 39	37 / 33	28 / 24			
212931-LVIS	64	54 / 50	48 / 44	41 / 37	31 / 27			
213015-LVIS	34		28 / 24	26 / 22	22 / 18	18 / 14		
213025-LVIS	49		40 / 36	36 / 32	31 / 27	23 / 19		
213041-LVIS	71		57 / 53	52 / 48	44 / 40	32 / 28		
214035-LVIS	67				51 / 47	45 / 41	39 / 35	30 / 26
214049-LVIS	76				58 / 54	51 / 47	43 / 39	33 / 29
All Sizes Compatible with Headway™ 21 Microcatheter (inner diameter = 0.021" or 0.53 mm)								
* Total Length (which includes flared ends) = Working Length + 4 mm (2 mm each side)								
†Within Headway 21 Microcatheter (inner diameter = 0.021" or 0.53 mm)								

LVIS							
Product Code	Device Diameter (mm)						
	2.5	3.0	3.5	4.0	4.5	5.0	5.5
	Free Area (%)						
212517-LVIS	73	75	74				
212525-LVIS	73	73	71				
212912-LVIS	76	78	80	80			
212917-LVIS	74	77	77	75			
212922-LVIS	74	76	76	73			
212928-LVIS	74	76	76	72			
212931-LVIS	74	76	76	71			
213015-LVIS		78	79	79	77		
213025-LVIS		78	79	78	74		
213041-LVIS		77	78	78	73		
214035-LVIS				82	82	81	78
214049-LVIS				82	82	81	77

Table 1b: LVIS Jr. Device Product Information

LVIS Jr.					
Product Code	Undeployed Length † (mm)	Total Length / Working Length* (mm) at device diameter (mm)			
		2.0	2.5	3.0	3.5
172010-LVISJ	15	14 / 10	13 / 9		
172014-LVISJ	20	18 / 14	17 / 13		
172020-LVISJ	27	24 / 20	23 / 19		
172032-LVISJ	40	36 / 32	34 / 30		
172516-LVISJ	23		20 / 16	19 / 15	18 / 14
172524-LVISJ	31		27 / 23	25 / 21	23 / 19
172530-LVISJ	39		34 / 30	32 / 28	28 / 24
172537-LVISJ	46		40 / 36	37 / 33	33 / 29
All sizes Compatible with Headway 17 Microcatheter (inner diameter = 0.017” or 0.43 mm), Scepter C™ or Scepter XC™ Occlusion Balloons					
* Total Length (which includes flared ends) = Working Length + 4 mm (2 mm each side)					
†Within Headway 17 Microcatheter (inner diameter = 0.017" or 0.43 mm)					

LVIS Jr.				
Product Code	Device Diameter (mm)			
	2.0	2.5	3.0	3.5
	Free Area (%)			
172010-LVISJ	77	81		
172014-LVISJ	77	80		
172020-LVISJ	76	80		
172032-LVISJ	76	79		
172516-LVISJ		82	84	83
172524-LVISJ		83	84	83
172530-LVISJ		83	85	83
172537-LVISJ		83	84	83

Table 1c: LVIS EVO Device Product Information

LVIS EVO						
Product Code	Undeployed Length † (mm)	Total Length / Working Length* (mm) at device diameter (mm)				
		2.0	2.5	3.0	3.5	4.0
LEV2512	20	16 / 15	12 / 11			
LEV2517	29	23 / 22	17 / 16			
LEV2522	38	30 / 29	22 / 21			
LEV2527	47	36 / 35	27 / 26			
LEV3018	34	28 / 27	24 / 23	18 / 17		
LEV3024	44	37 / 36	31 / 30	24 / 23		
LEV3028	54	46 / 45	39 / 38	28 / 27		
LEV3032	60	50 / 49	43 / 42	32 / 31		
LEV3517	32	28 / 27	26 / 25	22 / 21	17 / 16	
LEV3522	44	39 / 38	35 / 34	30 / 29	22 / 21	
LEV3528	56	49 / 48	44 / 43	37 / 36	28 / 27	
LEV3534	67	60 / 59	53 / 52	45 / 44	34 / 33	
LEV4013	22		20 / 19	18 / 17	15 / 14	13 / 12
LEV4018	36		31 / 30	28 / 27	24 / 23	18 / 17
LEV4021	43		36 / 35	33 / 32	28 / 27	21 / 20
LEV4027	56		48 / 47	43 / 42	37 / 36	27 / 26
LEV4031	63		53 / 52	48 / 47	41 / 40	31 / 30
All Sizes Compatible with Headway 17 Microcatheter (inner diameter = 0.017" or 0.43 mm), Scepter C or Scepter XC Occlusion Balloons						
* Total Length (which includes flared ends) = Working Length + 1 mm (0.5 mm each side)						
†Within Headway 17 Microcatheter (inner diameter = 0.017" or 0.43 mm)						

LVIS EVO					
Product Code	Device Diameter (mm)				
	2.0	2.5	3.0	3.5	4.0
	Free Area (%)				
LEV2512	74	74			
LEV2517	74	72			
LEV2522	74	72			
LEV2527	73	72			
LEV3018	76	77	75		
LEV3024	75	77	75		
LEV3028	75	77	74		
LEV3032	76	77	74		
LEV3517	76	78	79	77	
LEV3522	75	78	79	76	
LEV3528	75	78	79	76	
LEV3534	76	78	78	75	
LEV4013		81	83	83	81
LEV4018		79	81	81	79
LEV4021		80	81	81	78
LEV4027		80	81	81	78
LEV4031		81	82	82	79

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.

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 pre-treatment 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.

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 Adverse Events

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), subarchnoid 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.

Summary of Adverse Events in Clinical Study

The CEC reviewed and adjudicated all adverse events in the LVIS study for nature, severity, seriousness, device and procedure relatedness. No unanticipated adverse device effects (UADE) occurred during this trial. A summary of adverse events is shown below. AEs are reported based on CEC adjudication. One hundred forty-five (145) events were reported during the peri-procedural period in 61 subjects. After 30 days (31 days to 12 months), 159 events occurred in 46 subjects. Serious adverse events separated into device or procedure related are also provided.

Overall Adverse Event Summary (independent of relatedness)*

Adverse Event	Peri Procedure		Post Procedure	
	# of Events	% of subjects with event (n/N)	# of Events	% of subjects with event (n/N)
Any Adverse Event	145	39.9% (61/153)	159	30.1% (46/153)
Cardiac	8	4.6% (7/153)	10	5.2% (8/153)
Cardiac arrhythmias	4	2.6% (4/153)	2	1.3% (2/153)
Death	0	0.0% (0/153)	1	0.7% (1/153)
Myocardial Infarction	0	0.0% (0/153)	1	0.7% (1/153)
Other	4	2.6% (4/153)	6	3.9% (6/153)
Gastrointestinal	2	1.3% (2/153)	13	5.9% (9/153)
Bleeding	0	0.0% (0/153)	2	0.7% (1/153)
Hemorrhage	1	0.7% (1/153)	0	0.0% (0/153)
Infection	0	0.0% (0/153)	1	0.7% (1/153)
Ischemia	0	0.0% (0/153)	1	0.7% (1/153)
Other	1	0.7% (1/153)	9	4.6% (7/153)

Adverse Event	Peri Procedure		Post Procedure	
	# of Events	% of subjects with event (n/N)	# of Events	% of subjects with event (n/N)
Infectious / Inflammatory	0	0.0% (0/153)	8	1.3% (2/153)
Infection	0	0.0% (0/153)	8	1.3% (2/153)
Musculoskeletal	9	5.2% (8/153)	17	9.8% (15/153)
Ischemia	0	0.0% (0/153)	1	0.7% (1/153)
Other	9	5.2% (8/153)	16	9.8% (15/153)
Neurological / Neurovascular	74	26.8% (41/153)	50	19.0% (29/153)
Aneurysm rupture	4	2.6% (4/153)	0	0.0% (0/153)
Aphasia	1	0.7% (1/153)	0	0.0% (0/153)
Device Failure	10	6.5% (10/153)	0	0.0% (0/153)
Dissection or perforation of the parent artery	2	1.3% (2/153)	0	0.0% (0/153)
Headache	9	5.2% (8/153)	8	4.6% (7/153)
Hydrocephalus	1	0.7% (1/153)	1	0.7% (1/153)
Intra-Parenchymal Hemorrhage	2	1.3% (2/153)	2	1.3% (2/153)
Neurological deficits	6	3.3% (5/153)	3	1.3% (2/153)
Other	5	3.3% (5/153)	12	7.2% (11/153)
Seizure	4	2.0% (3/153)	1	0.0% (0/153)
Stent Thrombosis	3	2.0% (3/153)	2	1.3% (2/153)
Stroke	6	3.3% (5/153)	6	3.3% (5/153)
Sub-Arachnoid Hemorrhage (SAH)	2	1.3% (2/153)	1	0.7% (1/153)
Sub-Dural Hematoma (SDH)	1	0.7% (1/153)	2	1.3% (2/153)
TIA (Transient Ischemic Attack)	3	2.0% (3/153)	3	2.0% (3/153)
Target aneurysm retreatment	0	0.0% (0/153)	6	3.9% (6/153)
Thromboembolic event	1	0.7% (1/153)	0	0.0% (0/153)
Vasospasm	10	5.9% (9/153)	0	0.0% (0/153)
Visual impairment	4	1.3% (2/153)	3	2.0% (3/153)
Other	22	10.5% (16/153)	35	11.8% (18/153)
Allergic reaction	1	0.7% (1/153)	0	0.0% (0/153)
Bleeding	2	1.3% (2/153)	0	0.0% (0/153)
Death	0	0.0% (0/153)	1	0.7% (1/153)
Headache	0	0.0% (0/153)	1	0.7% (1/153)
Infection	0	0.0% (0/153)	1	0.7% (1/153)
Other	17	8.5% (13/153)	31	9.2% (14/153)
Reactions due to radiation exposure	1	0.7% (1/153)	0	0.0% (0/153)
Reactions to anesthesia and related procedures	1	0.7% (1/153)	0	0.0% (0/153)
Visual impairment	0	0.0% (0/153)	1	0.7% (1/153)
Renal / Genitourinary	5	3.3% (5/153)	8	3.9% (6/153)
Infection	3	2.0% (3/153)	2	0.7% (1/153)
Other	2	1.3% (2/153)	5	3.3% (5/153)
Renal failure	0	0.0% (0/153)	1	0.7% (1/153)
Respiratory / Pulmonary	8	5.2% (8/153)	13	4.6% (7/153)
Death	0	0.0% (0/153)	1	0.7% (1/153)
Emboli	0	0.0% (0/153)	1	0.7% (1/153)
Infection	3	2.0% (3/153)	1	0.7% (1/153)
Other	5	3.3% (5/153)	10	3.9% (6/153)
Vascular	17	11.1% (17/153)	5	3.3% (5/153)
Bleeding	4	2.6% (4/153)	1	0.7% (1/153)
Complications of arterial puncture	9	5.9% (9/153)	0	0.0% (0/153)
Ecchymosis	0	0.0% (0/153)	2	1.3% (2/153)
Hemorrhage	2	1.3% (2/153)	0	0.0% (0/153)
Other	2	1.3% (2/153)	1	0.7% (1/153)
Vascular complication	0	0.0% (0/153)	1	0.7% (1/153)

* Percentages are based on the # of subjects effected and some subjects may have more than one event.

Serious Device Related Adverse Events*

Adverse Event	Peri Procedure		Post Procedure	
	# of Events	% of subjects with event (n/N)		# of Events
Any Serious Device Related Adverse Events	22	11.1% (17/153)	5	3.3% (5/153)
Neurological / Neurovascular	22	11.1% (17/153)	5	3.3% (5/153)
Device Failure	6	3.9% (6/153)	0	0.0% (0/153)
Dissection or perforation of the parent artery	1	0.7% (1/153)	0	0.0% (0/153)
Other	3	2.0% (3/153)	0	0.0% (0/153)
Stent Thrombosis	3	2.0% (3/153)	2	1.3% (2/153)
Stroke	4	2.6% (4/153)	2	1.3% (2/153)
TIA (Transient Ischemic Attack)	1	0.7% (1/153)	1	0.7% (1/153)
Vasospasm	1	0.7% (1/153)	0	0.0% (0/153)
Visual impairment	3	1.3% (2/153)	0	0.0% (0/153)

* Percentages are based on the # of subjects effected and some subjects may have more than one event.

Serious Procedure Related Adverse Events*

Adverse Event	Peri Procedure		Post Procedure	
	# of Events	% of subjects with event (n/N)	# of Events	% of subjects with event (n/N)
Any Serious Procedure Related Adverse Events	61	28.8% (44/153)	8	3.9% (6/153)
Cardiac	1	0.7% (1/153)	0	0.0% (0/153)
Cardiac arrhythmias	1	0.7% (1/153)	0	0.0% (0/153)
Gastrointestinal	1	0.7% (1/153)	1	0.7% (1/153)
Bleeding	0	0.0% (0/153)	1	0.7% (1/153)
Hemorrhage	1	0.7% (1/153)	0	0.0% (0/153)
Neurological / Neurovascular	43	20.9% (32/153)	6	2.6% (4/153)
Aneurysm rupture	4	2.6% (4/153)	0	0.0% (0/153)
Aphasia	1	0.7% (1/153)	0	0.0% (0/153)
Device Failure	9	5.9% (9/153)	0	0.0% (0/153)
Dissection or perforation of the parent artery	1	0.7% (1/153)	0	0.0% (0/153)
Hydrocephalus	1	0.7% (1/153)	0	0.0% (0/153)
Intra-Parenchymal Hemorrhage	2	1.3% (2/153)	0	0.0% (0/153)
Neurological deficits	2	1.3% (2/153)	0	0.0% (0/153)
Other	1	0.7% (1/153)	0	0.0% (0/153)
Seizure	1	0.7% (1/153)	0	0.0% (0/153)
Stent Thrombosis	3	2.0% (3/153)	0	0.0% (0/153)
Stroke	5	3.3% (5/153)	1	0.0% (0/153)
Sub-Arachnoid Hemorrhage (SAH)	2	1.3% (2/153)	0	0.0% (0/153)
TIA (Transient Ischemic Attack)	1	0.7% (1/153)	1	0.7% (1/153)
Target aneurysm retreatment	0	0.0% (0/153)	3	2.0% (3/153)
Thromboembolic event	1	0.7% (1/153)	0	0.0% (0/153)
Vasospasm	7	4.6% (7/153)	0	0.0% (0/153)
Visual impairment	2	1.3% (2/153)	1	0.7% (1/153)
Other	4	2.6% (4/153)	1	0.7% (1/153)
Other	4	2.6% (4/153)	1	0.7% (1/153)
Renal / Genitourinary	2	1.3% (2/153)	0	0.0% (0/153)
Infection	2	1.3% (2/153)	0	0.0% (0/153)
Respiratory / Pulmonary	3	2.0% (3/153)	0	0.0% (0/153)
Infection	1	0.7% (1/153)	0	0.0% (0/153)
Other	2	1.3% (2/153)	0	0.0% (0/153)
Vascular	7	4.6% (7/153)	0	0.0% (0/153)
Bleeding	2	1.3% (2/153)	0	0.0% (0/153)
Complications of arterial puncture	4	2.6% (4/153)	0	0.0% (0/153)
Hemorrhage	1	0.7% (1/153)	0	0.0% (0/153)

* Percentages are based on the # of subjects effected and some subjects may have more than one event.

Summary of Clinical Study

Design:

The study was a multi-center, prospective, single-arm study with follow-up at hospital discharge, 30 days, 6 months and 12 months post procedure. There were twenty-two (22) investigational sites all within the United States.

Inclusion/Exclusion Criteria:

Inclusion Criteria

Subjects were included if they met the following criteria:

- Subject whose age is ≥ 18 and ≤ 75 years;
- Subject with an unruptured or ruptured (> 30 days since occurrence), wide-necked (neck ≥ 4 mm or dome to neck ratio < 2) intracranial, saccular aneurysms (≥ 4 mm and < 20 mm maximum diameter in any plane) arising from a parent vessel with a diameter ≥ 2.0 mm and ≤ 4.5 mm who are candidates for endovascular coil embolization;
- Subject or his/her Legally Authorized Representative understands the nature of the procedure, consents to participation in the study and provides a signed informed consent form;
- Subject (woman of child-bearing potential) with a current negative pregnancy test who has agreed to an appropriate method of contraception throughout the trial;
- Subject lives at a permanent address within commuting range of the investigational site and will be residing at that address during their 12 months of study participation;
- Subject is willing to return to the investigational site for the 30-day, 6-month and 12- month follow-up evaluations.

Exclusion Criteria

Subjects were excluded if any of the following conditions existed:

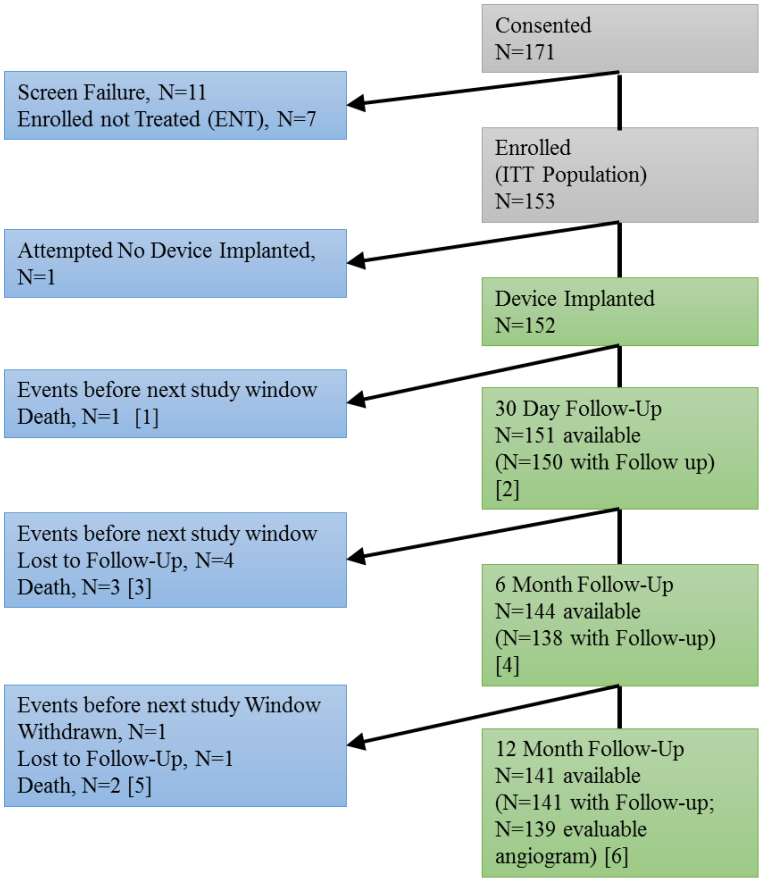
- Subject who presents with ruptured aneurysm, unless rupture occurred 30 days or more prior to screening;
- Subject who presents with an intracranial mass (other than a meningioma) or currently undergoing radiation therapy for carcinoma or sarcoma of the head or neck region;
- Subject with significant extracranial or intracranial stenosis of the parent artery (> 50%) proximal to the target aneurysm;
- Subject with an irreversible bleeding disorder, a platelet count of less than 100,000/ml (< 100x103 cells/mm^3) or known platelet dysfunction or a contraindication to or inability to tolerate anticoagulants and/or antiplatelet agents;
- Subject with serum creatinine level > 3.0 mg/dL at time of enrollment (this will restrict the use of contrast) and not on dialysis;
- Subject with known allergies to nickel-titanium metal; jewelries
- Subject with known allergies or contraindications to required anti-platelet and/or heparin medications required for treatment;
- Subject with a life-threatening allergy to radiographic contrast (unless treatment for allergy is tolerated or can be managed medically);
- Subject with a contraindication to CT (Computed Tomography) and MRI (Magnetic Resonant Imaging);
- Subject who has a known cardiac disorder, likely to be associated with cardioembolic symptoms such as AFIB (atrial fibrillation);
- Subject with any condition which in the opinion of the treating physician would place the Subject at a high risk of embolic stroke;
- Subject who is currently participating in another clinical research study with a conflicting protocol;
- Subject who has had a previous intracranial stenting procedure associated with the target aneurysm;
- Subject who is unable to complete the required follow-up;

- Subject who is pregnant or breastfeeding;
- Subject who has participated in a drug study within the last 30 days.

Angiographic Exclusion Criteria

- Subject has a cerebral diagnostic angiogram that demonstrates an aneurysm that is not appropriate for endovascular treatment;
- Subject has a fusiform or dissecting aneurysm;
- Subject is harboring more than one aneurysm with each aneurysm requiring treatment within 30 days;
- Subject has an arteriovenous malformation (AVM) in the territory of the target aneurysm.

Subject Accountability Flowchart:



[1] Subject 01-04 died on day 2
[2] Subject 22-05 had a missed 30 day visit
[3] Subject 01-05 died on day 63
[4] Subjects 06-25, 09-02, 11-03, 12-04, 12-06, and 19-23 missed the 6 month visit
[5] Subject 03-03 died on day 393; however, this subject completed the 12 month follow-up visit and is included.
[6] Subjects 06-25 and 05-05 had a 12 month visit. 06-25 did not have an angiogram, 05-05 had an angiogram that was not evaluable.

Demographics:

The demographic characteristics of the Intent-to-Treat (ITT) population are shown below. The mean age was 58.3±10.49 years and the majority of subjects (110/153, 71.9%) were women. The demographic characteristics are consistent with typical cohort of subjects undergoing treatment of intracranial, saccular aneurysms.

Demographic Characteristics

Characteristic	Summary Statistic
Age (years)	
Mean ± std (n)	58.3 ± 10.49 (153)
Median (min, max)	59.0 (18, 75)
Gender, % (n/N)	
Male	28.1% (43/153)
Female	71.9% (110/153)
Race, % (n/N)	
American Indian or Alaska Native	0.7 % (1/153)
Asian	1.3 % (2/153)
Black or African American	15.7% (24/153)
Native Hawaiian or other Pacific Islander	0.0 % (0/153)
White	80.4% (123/153)
Other	2.0 % (3/153)
Missing	0.7 % (1/153)

Aneurysm Characteristics:

Location and Sublocation	% of subjects (n/N)
Internal Carotid Artery	28.1% (43/153)
Carotid Cavernous	2.0% (3/153)
Carotid Ophthalmic	5.9% (9/153)
Superior Hypophyseal	6.5% (10/153)
Posterior Communication Artery	5.9% (9/153)
Anterior Choroidal Artery	1.3% (2/153)
Internal Carotid Artery (Supraclinoid)	4.6% (7/153)
Carotid Bifurcation	2.0% (3/153)
Anterior Cerebral Artery	37.3% (57/153)
Anterior Communicating Artery	33.3% (51/153)
Pericallosal	3.9% (6/153)
Middle Cerebral Artery	11.1% (17/153)
Posterior Cerebral Artery	3.9% (6/153)
Basilar Artery	17.6% (27/153)
Basilar Tip	17.0% (26/153)
Anterior Inferior Cerebellar Artery	0.0% (0/153)
Basilar Trunk	0.7% (1/153)
Superior Cerebellar Artery	0.7% (1/153)
Vertebral Artery	1.3% (2/153)
Posterior Inferior Cerebellar Artery (PICA)	0.7% (1/153)
VB Junction	0.7% (1/153)

Characteristic	Mean ± std (n)	Median (min, max)
Dome Height	6.0 ± 2.15(153)	5.8 (2.0,14.0)
Dome Width (perpendicular to height)	5.5 ± 2.33(153)	5.0 (1.4,17.0)
Neck Width	4.2 ± 1.41(153)	4.0 (1.8,10.0)
Dome to Neck Ratio	1.3 ± 0.38(153)	1.3 (0.5,3.3)
Distal Parent Artery Diameter (landing zone)	2.5 ± 0.64(153)	2.2 (1.6,4.8)
Proximal Parent Artery Diameter (landing zone)	2.8 ± 0.70(153)	2.5 (2.0,4.5)
Mean Parent Artery Diameter	2.6 ± 0.64(153)	2.4 (2.0,4.6)

Primary Safety Results:

The pre-specified primary safety endpoint was defined as the composite rate of major stroke or death within 30 days or major ipsilateral stroke or neurologic death with 12 months. Beyond the original primary safety and effectiveness endpoint analysis, additional analyses were conducted based upon a modified primary safety endpoint. The modified primary safety endpoint is defined as the composite rate of neurological death and any disabling stroke within 12 months post-treatment with the LVIS device. A disabling stroke is defined by a modified Rankin Scale (mRS) score ≥ 3 at a minimum of 90 days post-stroke event. Eight subjects (5.2%, 8/153) had at least one primary safety event per the pre-specified primary safety endpoint and nine subjects (5.9%, 9/153) had at least one primary safety event per the modified primary safety endpoint in the ITT population. Thus, the success criterion of the pre-established safety Performance Goal (PG) for the pre-specified and modified primary safety endpoints was achieved.

Primary Safety Endpoint using the modified endpoint analysis (Disabling Stroke or neurological death within 12 months)

Event Type	% of Subjects with Observations (n/N)	Posterior Mean, 95% CI [1]	Posterior Probability [2]
Primary Safety Composite Rate* (Disabling stroke with mRS score ≥ 3 or neurological death within 12 months)	5.9 % (9/153)	6.2% 3.0% - 10.5%	1
Primary Safety Failure Reasons [3]			
Disabling stroke with mRS score ≥ 3 through 12 months*	3.9 % (6/153)	4.2% 1.7% - 7.9%	NA
Neurological death through 12 months	2.0 % (3/153)	2.3% 0.6% - 5.1%	NA

[1] Posterior mean and 95% Credible Interval (CI). The confidence intervals are calculated without multiplicity adjustment. As such, the confidence intervals are provided to show the variability only and should not be used to draw any statistical conclusions.
[2] Posterior probability that the primary safety endpoint event rate is less than the pre-specified PG.
[3] Subjects may have more than one failed safety component. Three (3) subjects with stroke expired from neurological deaths.
[*] mRS score ≥ 3 at any time point between 90 days and last available follow-up.

Primary Effectiveness Results:

The pre-specified primary effectiveness endpoint was defined as successful intracranial aneurysm treatment with the LVIS device as evidenced by complete (100%) aneurysm angiographic occlusion at 12 months without retreatment and no significant (≥ 50%) stenosis of the treated artery at 12 months. The modified primary effectiveness endpoint is defined as the rate of 90-100% aneurysm angiographic occlusion at 12 months (equivalent to Raymond-Roy I and stable Raymond-Roy II occlusion assessed via two imaging scans taken at a minimum of 6 months apart) without retreatment and no significant (≥ 50%) stenosis of the treated artery at 12 months. The modified primary effectiveness analysis most closely aligns with the recommendations provided by the Neurological Devices Panel of the Medical Devices Advisory Committee following the March 1, 2018 meeting convened by FDA to provide scientific and clinical considerations relating to the determination and evaluation of the safety and effectiveness of novel endovascular aneurysm treatment devices for marketing approval in the United States (US).

The effectiveness results show that 70.6% (108/153) of patients in the "*Pivotal Study of the MicroVention, Inc. Neurovascular Self-Expanding Retrievable Stent System LVIS in the Treatment of Wide-Necked Intracranial Artery Aneurysms*" had complete (100%) intracranial aneurysm occlusion without clinically significant in-stent stenosis or retreatment of the target aneurysm, an additional 10.4% (16/153) patients had stable or improved Raymond-Roy II intracranial aneurysm occlusions without clinically significant in-stent stenosis or target aneurysm treatment, for a total composite effectiveness rate of 81.0% (124/153).

For the additional ITT evaluable analysis (patients who were angiographically evaluated at the 12-month follow-up), 77.7% (108/139) of the subjects met the prespecified and 89.2% (124/139) met the modified primary effectiveness success criteria exceeding the prospectively established effectiveness PG. None of the 139 evaluable subjects had clinically significant In-Stent Stenosis at 12-month follow-up. Thus, the success criterion of the pre-established effectiveness Performance Goal (PG) for the pre-specified and modified primary effectiveness endpoints was achieved.

Primary Effectiveness Endpoint using the modified endpoint analysis (90-100% aneurysm occlusion without clinically significant In Stent Stenosis or Target Aneurysm Retreatment)

Endpoint [1]	% of Subjects with Observations (n/N)	Posterior Mean, 95% CI [2]	Posterior Probability [3]
Imputed Analysis per the Prespecified Primary Effectiveness Endpoint			
Primary Effectiveness Composite Success (100% aneurysm occlusion without clinically significant In Stent Stenosis or Target Aneurysm Retreatment)	70.6% (108/153)	70.5% 63.0% – 77.4%	1
Imputed Analysis per the Modified Primary Effectiveness Endpoint			
Modified Primary Effectiveness Composite Success (90% - 99% aneurysm occlusion without clinically significant In Stent Stenosis or Target Aneurysm Retreatment) Σ	10.4% (16/153)		
Modified Primary Effectiveness Composite Success (90% - 100% aneurysm occlusion without clinically significant In Stent Stenosis or Target Aneurysm Retreatment)	81.0% (124/153) [124 = 108 +16]	80.8% 74.3% - 86.6%	1
Primary Effectiveness Endpoint Subcomponents			
90%-100% aneurysm occlusion*	83.7% (128/153)	83.4% 77.2% - 88.9%	NA
Without Clinically Significant In Stent Stenosis (≥ 50%) of Parent Artery	90.8% (139/153)	90.6% 85.5% - 94.7%	NA
No Target Aneurysm Retreatment	96.1% (147/153)	95.8% 92.1% - 98.4%	NA
Evaluable Only Analysis per the Prespecified Primary Effectiveness Endpoint	% of Subjects with Observations (n/N)		
Primary Effectiveness Composite Success (100% aneurysm occlusion without clinically significant In Stent Stenosis or Target Aneurysm Retreatment)	77.7% (108/139)	77.5% 70.3% - 84%	1
Evaluable Only Analysis per the Modified Primary Effectiveness Endpoint			
Modified Primary Effectiveness Composite Success (90% - 99% aneurysm occlusion without clinically significant In Stent Stenosis or Target Aneurysm Retreatment) Σ	11.5% (16/139)		
Modified Primary Effectiveness Composite Success (90% - 100% aneurysm occlusion without clinically significant In Stent Stenosis or Target Aneurysm Retreatment)	89.2% (124/139) [124 = 108 + 16]	82.5% 75.3% - 88.6%	1
Modified Primary Effectiveness Composite Success (90% - 100% aneurysm occlusion without clinically significant In Stent Stenosis or Target Aneurysm Retreatment) using only DSA at 12 months ¥	88.6% (117/132) [124-7 / 139-7]	88.3% 75.3% - 88.6%	1
Primary Effectiveness Endpoint Subcomponents			
90%-100% aneurysm occlusion*	91.4% (127/139)	91.2% 84.4% - 97.4%	NA
Without Clinically Significant In Stent Stenosis (≥ 50%) of Parent Artery	100.0% (139/139)	99.6% 98.2% - 100%	NA
No Target Aneurysm Retreatment	95.7% (133/139)	95.4% 91.3% - 98.2%	NA

Σ Only subjects with stable or positively progressing Raymond-Roy II occlusion between baseline and 12 months are included.
¥ Seven subjects who were assessed using MRA in lieu of DSA are excluded.
[1] Includes primary effectiveness data collected on all ITT subjects at or through 12-month follow-up visit.
[2] Posterior mean and two-sided 95% CI. The confidence intervals are calculated without multiplicity adjustment. As such, the confidence intervals are provided to show the variability only and should not be used to draw any statistical conclusions.
[3] Posterior probability that the primary effectiveness endpoint success rate exceeds the pre-specified PG at 12 months.
*Subjects having negative progression from post-procedure to 12 months are considered failures. Missing data imputed as failures.

Analysis of Subjects with Stroke Events and Worsening mRS Scores:

Subject mRS scores for all strokes in the LVIS study*

#	Subject ID	mRS pre-procedure baseline	mRS at Discharge	mRS at 30 days	mRS at 180 days	mRS at 12 months
Strokes resulting in neurological death						
1	01-04	0	mRS = 6, neurological death	n/a	n/a	n/a
2	01-05	0	0	0	mRS = 6, neurological death	n/a
3	03-03 €	0	0	Not done	0	mRS = 0 at 12 months. Subject expired from a neurological cause 393 days post-procedure
Disabling strokes (mRS ≥ 3 at a minimum of 90 days)						
4	03-02 ¥	0	4	1	3	1
5	09-09 €	0	3	2	2	3
6	12-04	3	3	4	Not done	4
7	14-18	1	1	0	5	5
Disabling strokes caused by pre-existing conditions						
8	03-18 ¥	1	1	0	3	1
9	04-09	3	3	3	3	3
Non-Disabling strokes						
10	03-03 €	0	0	Not done	0	0
11	03-19	1	1	1	1	0
12	06-07	0	0	1	1	0
13	09-05	1	1	1	1	1
14	09-09 €	0	3	2	2	3
15	09-13	0	0	0	0	0
16	16-01	0	0	1	0	0

* 16 strokes occurred in 14 subjects
€ Subjects 03-03 & 09-09 each sustained both a minor stroke peri-operatively and a major stroke post-operatively
¥ Subjects 03-02 & 03-18 sustained strokes that did not result in permanent neurological disability.

At 12 months, 25 subjects (16%, 25/153) had mRS scores which worsened as compared to their baseline scores. Reason for change is described in the table. Fourteen (14) out of the 25 patients (9.2%, 14/153) experienced deterioration in the mRS score at 12 months post-procedure that affected their clinical disability level (mRS ≥ 3). The recorded events that result in clinical deterioration (mRS ≥ 3) included events caused by deficits which occurred following study participation as well as events of non-neurological causes and deficits caused by pre-existing patient conditions (see table).

LVIS Subjects (N=25) with worsening mRS scores at 12 months as compared to baseline

Worsening mRS score by category	Baseline mRS	Discharge mRS	mRS at 30 days	mRS at 6 months	mRS at 12 months	Reason for Change
Neurological Death						
1€	0	6				
2€	0	0	0			
3€	0	0		0	0	
Non-neurological Death						
4€	1	1	1			Cardiac arrest
5€	0	0	0			Drug overdose
6€	2	2	2			Suicide
Neurological decline from new neurological deficits						
7	0	3	2	2	3	Ataxia, Major Stroke
8	1	1	0	5	5	Major stroke
9	0	0	0		4	Subdural Hematoma
10	0	0	0	2	3	New diagnosis of multiple sclerosis
11	2	2	1	0	3	Depression
12	3	4	4	3	4	General Debilitation from visual impairment, anxiety, depression
Neurological decline from pre-existing neurological deficits						
13	1	1	1	3	3	Preexisting neuropathy
14	1	1	1	1	2	General debilitation from right upper intrinsic weakness, right leg weakness, mild motor aphasia
15	3	3	4		4	Preexisting bilateral leg paresthesia & weakness
Other (no new neurological deficit)						
16	0	0	0	1	1	Lightheaded episode
17	0	4	1	3	1	Left foot weakness
18	0	1	0	0	1	Persisting headaches
19	0	0	0	1	1	Left-sided weakness
20	0	0	0	0	1	Headaches & Fatigue
21	0	0	0	1	1	Arthritis
22	0	0	0	1	1	Dizziness
23	0	0	1	1	1	Exacerbation of preexisting low back pain
24	0	0	1	1	1	Headaches & dizziness
25	0	0	0	0	2	Fatigue, CPAP issues

Six subjects footnoted above died throughout the course of the LVIS study:
€ Subject (1) died 2 days post procedure, subject (2) died 63 days post procedure, subject (3) died 393 days post procedure, subject (4) died 310 days post procedure, subject (5) died 92 days post procedure, subject (6) died 202 days post procedure.

Conclusion:

The clinical study results support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use. The overall risk to benefit ratio is favorable for the intended population.

SYMBOLS

	Consult instructions for use
	Caution
	Lot Number
	Catalog Number
	Contents
	Sterilized Using Irradiation
	Do Not Reuse
	Use-by Date
	Date of Manufacture
	Manufacturer
	MR Conditional
	Non-pyrogenic
	Prescription use only
	Do not resterilize
	Do not use if package is damaged

MRI Safety Information

The LVIS (Low-profile Visualized Intraluminal Support) device is MR Conditional. A patient with the LVIS (Low-profile Visualized Intraluminal Support) device may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

MR Conditional

Parameter	***Condition***
Nominal Values of Static Magnetic Field (T)	1.5-T or 3-T, only
Maximum Spatial Field Gradient (T/m and gauss/cm)	40-T/m (4,000-gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., quadrature-driven)
Transmit RF Coil Information	There are no transmit RF coil restrictions. Accordingly, the following may be used: body transmit RF coil and all other RF coil combinations (i.e., body RF coil combined with any receive-only RF coil, transmit/receive head RF coil, transmit/receive knee RF coil, etc.)
Operating Mode of MR System	Normal Operating Mode
Maximum Whole Body Averaged SAR	2-W/kg (Normal Operating Mode)
Maximum Head SAR	3.2-W/kg (Normal Operating Mode)
Limits on Scan Duration	Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back to back sequences/series without breaks)
MR Image Artifact	The presence of this implant produces an imaging artifact. Therefore, carefully select pulse sequence parameters if the implant is located in the area of interest.

CLINICIAN USE INFORMATION

Materials

The following parts are required to use the LVIS device:

- LVIS device should be introduced only by Headway 21 Microcatheter (0.021 inch inner diameter)

The following parts are required to use the LVIS Jr. and LVIS EVO devices:

- LVIS Jr. and LVIS EVO devices should be introduced only Headway 17 Microcatheter (0.017 inch inner diameter) or a Scepter C / Scepter XC Occlusion Balloon (0.0165 inch inner diameter)

Other accessories for performing a procedure and NOT supplied; to be selected based on the physician's experience and preferences:

- Appropriate-sized Guiding catheter for use with selected microcatheter
- Headway 21 microcatheter or Headway 17 microcatheter
- Scepter C / Scepter XC Occlusion Balloon
- Microcatheter-compatible guidewires
- Saline solution/heparin-saline solution continuous flush set
- Contrast solution
- Rotating Hemostatic Valve (RHV)
- Pressurized sterile Infusion solutions – IV stand
- Femoral arterial sheath, compatible with delivery guide catheter
- Femoral artery access device, sterile needle, guidewire

The LVIS device does not contain latex or PVC materials.

PACKAGING AND STORAGE

The LVIS device is placed inside a protective, plastic dispenser coil and packaged in a pouch and unit carton. The LVIS device and dispenser coil will remain sterile unless the package is opened, damaged, or the expiration date has passed. Store at a controlled room temperature in a dry place.

SHELF LIFE

See the product label for the device shelf life. Do not use the device beyond the labeled use by date.

PREPARATION FOR USE

Device and Delivery System Selection

Appropriate selection of the LVIS device is important for patient safety. In order to choose the optimal LVIS device model size for any given lesion, examine pre-treatment angiograms for correct and accurate vessel measurements.

HOW SUPPLIED

Sterile: This device is sterilized with E-Beam irradiation. Non-pyrogenic
Contents: One (1) LVIS device
Storage: Store product in a dry, cool place.

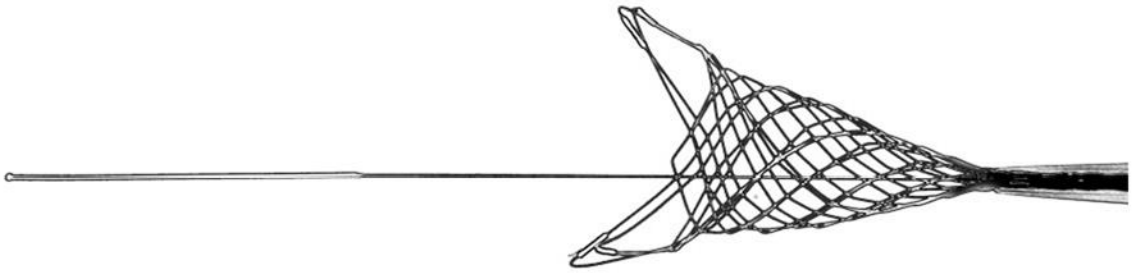
DIRECTIONS FOR USE

1. Gain vascular access according to standard practice.
2. Place guide catheter in the appropriate target vessel.
3. a. Navigate the corresponding microcatheter (.021" MicroVention Headway 21 microcatheter for LVIS device / .017" MicroVention Headway 17 or Scepter C / Scepter XC Occlusion Balloon for LVIS Jr. and LVIS EVO device) over a guidewire at least 15 mm distal to the aneurysm neck or target location.
   b. A second microcatheter can be navigated into the aneurysm sac for future coil deployment steps using the jailing technique (steps 22-24). In this technique, the microcatheter is effectively jailed between the vessel wall and outer surface of the stent and the coils are kept within the aneurysm and outside of the reconstructed vessel lumen.
4. Remove the guidewire.
5. Maintain flush through the microcatheter per standard endovascular practice.
6. Select an appropriately sized LVIS device (Refer to Table 1a/b/c).
7. Carefully inspect the LVIS device package for damage to the sterile barrier.
8. Peel open the pouch using aseptic technique.
9. Carefully place the dispenser coil into the sterile field.
10. a. Unclip the molded cap attached to the delivery wire from the dispenser coil. Pull on the proximal end of the delivery wire until the introducer exits the dispenser coil. Hold the delivery wire and introducer together while continuing to remove the entire device. Do not partially deploy the LVIS device from the introducer.
    b. After removal from the dispenser coil, carefully push on the delivery wire and in a bowl of saline, partially deploy the LVIS implant up to 5 mm or 50% (whichever occurs first, being careful not to detach the implant) from the distal introducer tip (Refer to Table 1a/b/c and Figure 3b). Check for the following:
    - Implant distal marker uniformity
    - Implant distal end shows even displacement with no entanglement
    - Implant tracks smoothly through introducer

    Warning: DO NOT FULLY DEPLOY LVIS device. If the device is deployed, DO NOT attempt to reload the device. Use a new device.
    c. With the LVIS implant and introducer sheath positioned and hydrated within the bowl of saline, gently manipulate the LVIS implant within the saline to hydrate the implant and minimize visible air bubbles. Carefully pull back on the delivery wire to fully retrieve the LVIS implant and the delivery wire tip within the introducer.
    Warning: DO NOT CONTINUE if any defect is observed; return the unit to MicroVention, Inc.
11. Confirm that the tip of the delivery wire is entirely within the introducer.
12. Confirm that the delivery wire is not kinked and that the introducer tip is not damaged. **DO NOT CONTINUE** if either defect is observed; return the unit to MicroVention, Inc.
    Warning: Do not shape the tip of the delivery wire.
13. Partially insert the distal end of the introducer into the RHV connected to the microcatheter. Tighten the RHV locking ring. Flush the y-connector of the RHV with sterile saline and verify that fluid exits the proximal end of the introducer.
    Warning: Purge the LVIS device carefully to avoid the accidental introduction of air into the system. [Figure 4]
14. Untighten the RHV locking ring and advance the introducer until it is **fully engaged** with the microcatheter hub, then tighten the RHV locking ring.
    Warning: Confirm that there are no air bubbles trapped anywhere in the system.
    Caution: Confirm that there is no gap between the introducer and the microcatheter hub to enable LVIS device introduction into the microcatheter. [Figure 5]
15. Advance the delivery wire to transfer the LVIS device from within the introducer into the microcatheter.
    Warning: Do not torque the delivery wire while advancing or retracting the LVIS device. A torque device should not be used.
16. Continue advancing the delivery wire into the microcatheter until the proximal tip of the delivery wire enters the introducer. Loosen the RHV locking ring, remove the introducer, and set it aside.
    Note: Fluoroscopy may be used up to this point at the physician's discretion.
    Warning: 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.
17. Track the LVIS device through the microcatheter to the tip. Carefully advance the LVIS device until the device exit marker on the proximal end of the delivery wire approaches the RHV on the hub of the microcatheter. At this time, fluoroscopic guidance must be initiated.
18. Position the LVIS device for deployment, ensuring a sufficient length of stent will deployed on either side of the aneurysm neck, by aligning the LVIS implant distal radiopaque end markers sufficiently past the aneurysm neck. [Figure 6]

Note: A proper push/pull technique, encompassing sufficient delivery wire push force, in addition to an opposing microcatheter withdrawal force, will facilitate properly deploying the LVIS device to achieve full expansion and good vessel apposition.
Note: Slowly advancing the LVIS device while adjusting the microcatheter position will ensure accurate deployment. Maintain simultaneous control of the LVIS device and microcatheter in order to position and expand the device at the proper location.
Caution: Using a rapid microcatheter withdrawal technique to deploy the LVIS device is not recommended and may result in device elongation.

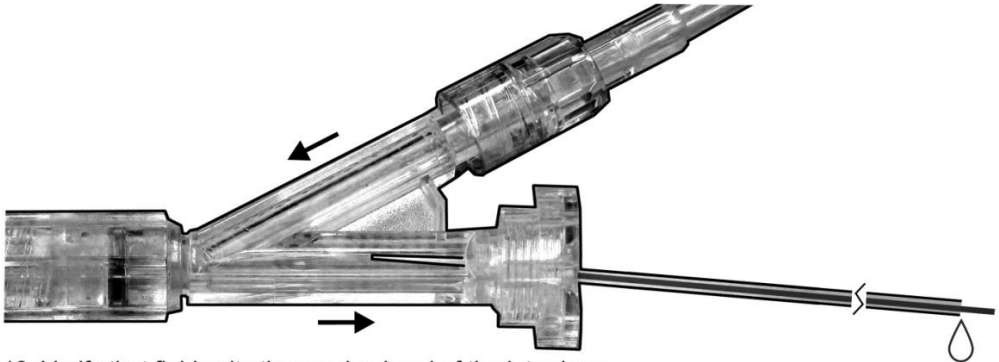
19. If LVIS device positioning is not satisfactory, the LVIS device may be recaptured and repositioned if it is not fully deployed. The LVIS device may be recaptured until the point where the proximal end of the LVIS device markers are aligned 3 mm proximally with the microcatheter distal marker band (approximately 75% deployed). [Figure 7]
Caution: If resistance is felt while recapturing the LVIS device, do not continue to recapture the device. Withdraw the microcatheter slightly to unsheath the LVIS device (without exceeding the recapture limit), and then attempt to recapture the LVIS device.
Caution: The LVIS device must not be re-deployed more than three times.
Note: The LVIS device delivery wire should not be utilized as a guidewire after stent deployment. Do not torque the LVIS device. A torque device should not be used.
20. If LVIS device positioning is satisfactory, carefully retract the microcatheter and advance the delivery wire together, to allow the LVIS device to deploy across the neck of the aneurysm. Ensure the device proximal radiopaque end markers are sufficiently proximal to the aneurysm neck to ensure an adequate landing zone. The LVIS device will expand and total length may foreshorten up to 60% from its undeployed length (refer to Table 1a/b/c) as it exits the microcatheter. Ensure microcatheter is retracted and clear from the proximal flared ends.
Note: Visualize and refer to the implant radiopaque end markers to maintain adequate implant length on each side of the aneurysm neck or target location to ensure appropriate neck coverage. [Figure 8]
Warning: 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.
21. Prior to removing the delivery wire and if necessary, carefully position the microcatheter distal to the LVIS device to maintain access through the LVIS device. Remove and discard the delivery wire.
Warning: 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.
22. a. If applicable, advance a .017" inner diameter (or suitable size) microcatheter over the guidewire.
b. If a second microcatheter has been placed into the aneurysm in step 3b, detachable coils can be delivered into the aneurysm through the second microcatheter (replacing steps 22-24).
Warning: Ensure that the jailed microcatheter does not move while constantly observing LVIS device marker positions during the coiling procedure to ensure that the device does not migrate from its deployed position.
23. Use the guidewire and microcatheter to access the aneurysm through the LVIS device cells.
Warning: Observe LVIS device marker position during placement of the microcatheter into the aneurysm to ensure that the LVIS device does not migrate or dislodge from its deployed position.
Note: Access to the aneurysm may be facilitated by the use of a microcatheter that has been shaped.
24. After the microcatheter is positioned within the aneurysm, detachable coils may be delivered into the aneurysm according to conventional methods.
Warning: Observe LVIS device marker position during the coiling procedure to ensure that the device does not migrate from its deployed position.
25. After placing the last coil, verify that the LVIS device has remained patent and properly positioned. Advance a guidewire, if necessary, to the microcatheter tip and carefully remove the microcatheter.
Note: A microcatheter may be positioned into the aneurysm sac prior to delivery of the LVIS device. The microcatheter will be supported by the LVIS device during delivery of embolic coiling. After completing the coiling, the coiling microcatheter should be carefully removed to avoid dislodging the LVIS device.
26. After completing the procedure, withdraw and discard all applicable accessory devices.
27. **Caution:** Carefully watch the LVIS device distal and proximal markers when passing through the deployed LVIS device with embolic coiling microcatheters to avoid displacing the LVIS device



Check for the following:
- Implant distal marker uniformity
- Implant distal end shows even displacement with no entanglement
- Implant tracks smoothly through introducer

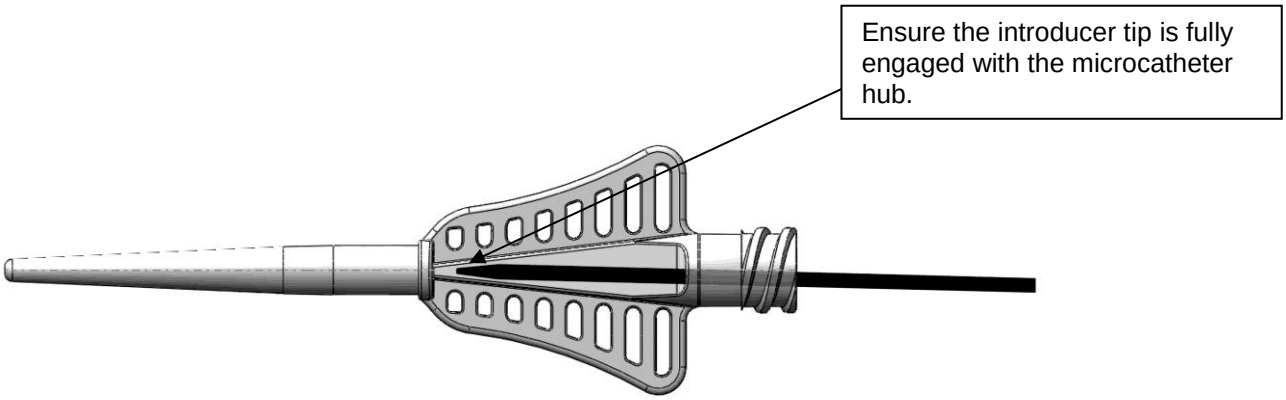
Warning: DO NOT FULLY DEPLOY LVIS device.

[Figure 3b. Step 10b]



13. Verify that fluid exits the proximal end of the introducer

[Figure 4. Step 13]



[Figure 5. Step 14]

18. Position distal markers sufficiently distal to the aneurysm neck

[Figure 6. Step 18]

19. The LVIS device can be recaptured and repositioned if not yet fully deployed

[Figure 7. Step 19]

20. Ensure sufficient proximal landing zone from aneurysm neck.

[Figure 8. Step 20]

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IFU100154A

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