

The logo for LVIS consists of the letters L, V, I, and S in a bold, black, sans-serif font. Each letter is filled with a white, grid-like pattern of intersecting diagonal lines. A small 'TM' trademark symbol is located to the right of the letter S.

Intraluminal Support Device

The logo for LVIS Jr. features the letters L, V, I, and S in a blue, sans-serif font with a white grid-like pattern. To the right of the S is a small 'TM' trademark symbol. Below the letters is the word 'Intraluminal Support Device' in a red, sans-serif font, followed by 'Jr.' in a large, grey, italicized serif font.

INSTRUCTIONS FOR USE

Humanitarian Device:

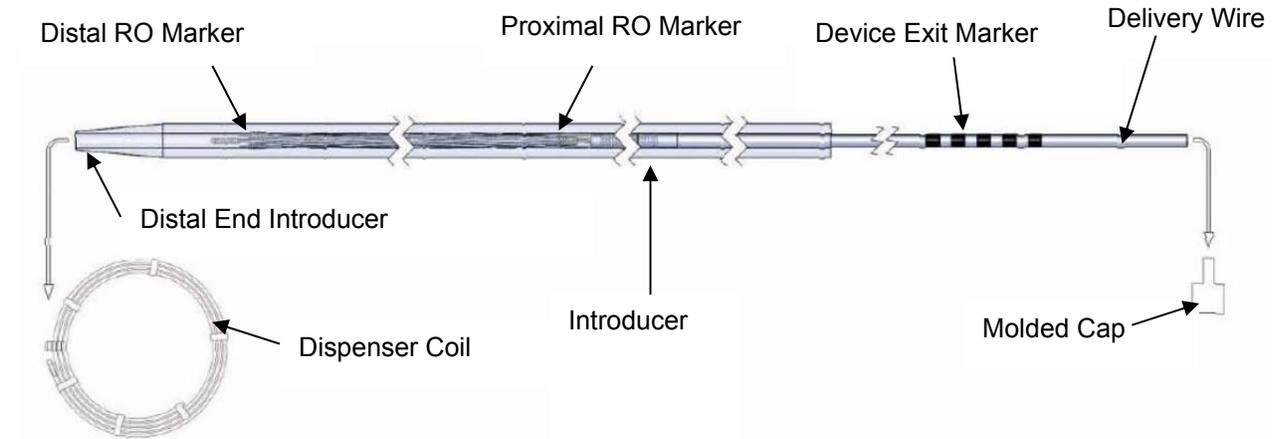
Authorized by Federal Law for use with bare platinum embolic coils for the treatment of unruptured, wide neck (neck \geq 4 mm or dome to neck ratio $<$ 2), intracranial, saccular aneurysms arising from a parent vessel with a diameter \geq 2.5 mm and \leq 4.5 mm. The effectiveness of this device for this use has not been demonstrated.

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

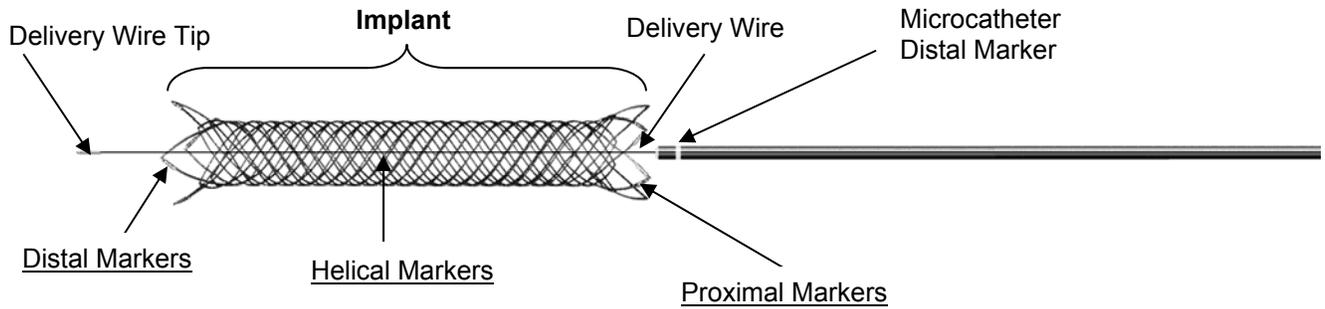
DEVICE DESCRIPTION

The MicroVention Low-profile Visualized Intraluminal Support device [Figures 1, 2 and 3a] is a self-expanding nickel titanium, single wire braid, compliant, closed-cell design that can be deployed and retrieved by a single operator. The LVIS device is packaged sterile as a single unit with an introducer sheath and a detachable push wire.

**Figure 1.
Device - Components**



**Figure 2.
Device - Implant Delivery**



	Distal Markers	Helical Markers	Proximal Markers
LVIS Device	4	2	4
LVIS Jr. Device	3	3	3

Figure 3a.
Device Implant Dimensions

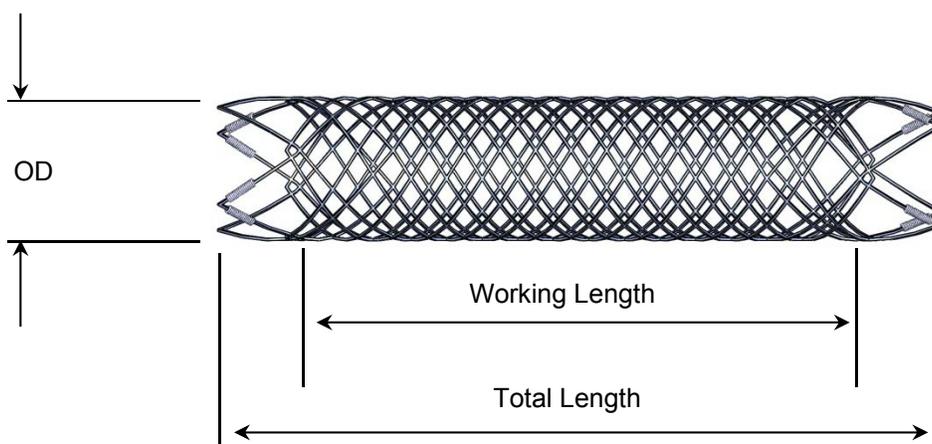


Table 1: LVIS Device Product Specifications and Undeployed Length, Free Area %

LVIS				
Product Code	Total Length/ Working Length** (mm)	Total Length/ Working Length** (mm)	Total Length/ Working Length** (mm)	Total Length/ Working Length** (mm) *
		2.5 mm OD	3.0 mm OD	3.5 mm OD
212517-LVIS		22 / 18	20 / 16	19 / 15
212525-LVIS		30 / 26	27 / 23	24 / 20
	3.0 mm OD	3.5 mm OD	4.0 mm OD	4.5 mm OD
213015-LVIS	20 / 16	19 / 15	18 / 14	16 / 12
213025-LVIS	30 / 26	28 / 24	26 / 22	23 / 19
213041-LVIS	46 / 42	43 / 39	39 / 35	34 / 30
	4.0 mm OD	4.5 mm OD	5.0 mm OD	5.5 mm OD
214035-LVIS	40 / 36	37 / 33	32 / 28	27 / 23
214049-LVIS	54 / 50	49 / 45	43 / 39	34 / 30
Compatible with Headway® 21 Microcatheter (inner diameter = 0.021" or 0.53 mm)				
* Fully expanded diameter				
** Total Length (which includes flared ends) = Working Length + 4 mm (2 mm each side)				

LVIS					
Product Code	Undeployed Length* (mm)	Free Area (%)			
			2.5 mm OD	3.0 mm OD	3.5 mm OD
212517-LVIS	25		79	81	82
212525-LVIS	34		78	80	81
		3.0 mm OD	3.5 mm OD	4.0 mm OD	4.5 mm OD
213015-LVIS	23	82	84	85	85
213025-LVIS	35	82	83	84	84
213041-LVIS	54	81	83	83	83
		4.0 mm OD	4.5 mm OD	5.0 mm OD	5.5 mm OD
214035-LVIS	51	85	85	85	84
214049-LVIS	69	85	85	84	82
* Within Headway® 21 Microcatheter (inner diameter = 0.021" or 0.53 mm)					

Table 1: LVIS Jr. Device Product Specifications and Undeployed Length, Free Area %

LVIS Jr.			
Product Code	Total Length/ Working Length** (mm)	Total Length/ Working Length** (mm)	Total Length/ Working Length** (mm)*
	2.5 mm OD	3.0 mm OD	3.5 mm OD
172516-LVISJ	20 / 16	19 / 15	18/14
172524-LVISJ	27 / 23	25 / 21	23/19
172530-LVISJ	34 / 30	32 / 28	28/24
172537-LVISJ	40 / 36	37 / 33	33/29
Compatible with Headway® 17 Microcatheter (inner diameter = 0.017" or 0.43 mm)			
* Fully expanded diameter			
** Total Length (which includes flared ends) = working Length + 4 mm (2 mm each side)			

LVIS Jr.				
Product Code	Undeployed Length* (mm)	Free Area (%)		
		2.5 mm OD	3.0 mm OD	3.5 mm OD
172516-LVISJ	23	82	84	83
172524-LVISJ	31	83	84	83
172530-LVISJ	39	83	85	83
172537-LVISJ	46	83	84	83
* Within Headway® 17 Microcatheter (inner diameter = 0.021" or 0.53 mm)				

INDICATIONS

The LVIS Device is intended for use with bare platinum embolic coils for the treatment of unruptured, wide neck (neck \geq 4 mm or dome to neck ratio $<$ 2), intracranial, saccular aneurysms arising from a parent vessel with a diameter \geq 2.5 mm and \leq 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

Should unusual resistance be felt at any time during access or removal, the introducer/guide catheter/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 for the treatment of intracranial aneurysms.

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.

In the clinical study, the ages of treated subjects ranged from 38 to 74 years of age.

PRECAUTIONS

This product should only be used by experienced physicians who have completed endovascular training in the use of the LVIS device for angiographic, percutaneous, neurointerventional procedures as prescribed by MicroVention-Terumo.

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.

ADVERSE EVENTS

Possible adverse events include but are not limited to the following:

- Hematoma at the puncture site
- Perforation or dissection of the vessel(s)
- Intravascular spasm
- Hemorrhaging
- Rupture or perforation of aneurysm
- Coil herniation
- Device migration
- Neurologic insufficiencies including stroke and death
- Ischemia
- Vascular occlusion
- Vessel stenosis
- Incomplete aneurysm occlusion
- Pseudoaneurysm formation
- Distal Embolization
- Headache
- Infection
- Reaction to contrast agents including severe allergic reactions and renal failure

Summary of Adverse Events in Clinical Study

Adverse Event (Serious and non-serious)	Number of Occurrences	Number of patients in which it occurred	% (Number of patients/study cohort)
Stroke or TIA	1	1	3.6%
Vasovagal response	1	1	3.6%
Anemia	1	1	3.6%
Respiratory distress	1	1	3.6%
Non-target aneurysm repair	3	2	7.2%
Non-target aneurysm retreatment	1	1	3.6%
Target aneurysm retreatment	1	1	3.6%
Thoracic aneurysm dissection	1	1	3.6%
Back pain	1	1	3.6%
Bottom of stent incompletely opened	1	1	3.6%
Headache	8	8	28.6%

Adverse Event (Serious and non-serious)	Number of Occurrences	Number of patients in which it occurred	% (Number of patients/study cohort)
Hematoma at access site	2	2	7.2%
Hypertension	1	1	3.6%
Hypomagnesemia	1	1	3.6%
Infected tooth	2	1	3.6%
Infection	2	2	7.2%
Low magnesium	2	2	7.2%
Nausea	2	2	7.2%
Non-target aneurysm repair	1	1	3.6%
Non-specific pain	1	1	3.6%
Pain	1	1	3.6%
Positive lyme test	1	1	3.6%
Stroke or TIA (non-serious)	2	2	7.2%
Urinary tract infection	1	1	3.6%
Vasospasm	1	1	3.6%
Vertigo	1	1	3.6%

Summary of Clinical Study

This was a prospective, non-randomized, feasibility study conducted at six institutions in the United States. The goal of the study was to demonstrate the safety and probable benefit of the LVIS Intraluminal Support Device. Subjects were eligible if they presented with an unruptured, wide-necked, intracranial, saccular aneurysms arising from a parent vessel ≥ 2.5 mm and ≤ 4.5 mm. Wide-necked was defined as having a neck > 4 mm or dome to neck ratio < 2 . The age of eligible subjects ranged from ≥ 18 and ≤ 80 years of age.

The primary endpoints of the study were for safety (any major stroke or death within 30 days, or major ipsi-lateral stroke or neurological death within 6 months) and probable benefit (successful aneurysm treatment with the study device as defined by aneurysm angiographic occlusion of $\geq 90\%$ at six months). Secondary endpoints to be assessed were device and procedure related SAEs, successful delivery of the study device, parent artery patency at 6 months, stent migration at 6 months, significant ($> 50\%$) stenosis of the treated artery at 6 months, and unplanned embolization coiling within 6 months.

Safety

The primary safety endpoint was any major stroke or death within 30 days, or major ipsi-lateral stroke or neurological death within 6 months. During the study, no report of this type was received thus the primary safety endpoint was met.

Primary Safety Endpoint

	Results (N=31)	Upper CI Limit
Primary Safety Event	0% (0)	9.2%
Major Stroke w/in 30 days	0% (0)	-
Death w/in 30 days	0% (0)	-
Major ipsi-lateral stroke w/in 6 months	0% (0)	-
Neurological Death w/in 6 months	0% (0)	-

Probable Benefit

Technical success was judged based on angiographic core lab assessment. The primary study endpoint for probably benefit was defined by aneurysm angiographic occlusion of $\geq 90\%$ at 6 months.

Primary Endpoint

Probable Benefit – successful treatment at 6 months	Results (N=29)
Aneurysm Angiographic Occlusion of $\geq 90\%$	89.7% (26) 95% 1-sided limit: 78.4%

The LVIS results in this study yielded a success rate of 90% at six months. Based upon this, the LVIS device met the probable benefit criteria set in the clinical protocol. Secondary endpoints were also evaluated at time points and no significant issues were noted regarding the secondary endpoints.

The clinical feasibility study demonstrated the satisfactory safety profile of the LVIS Intraluminal Support Device to facilitate endovascular coil embolization of unruptured, wide necked, intracranial, saccular aneurysms, and provided the ability to occlude the aneurysm and be maintained through 6 months.

SYMBOLS



Attention, Consult
Accompanying Documents



Lot Number



Catalog Number



Content



Sterilized Using Irradiation



Do Not Reuse



Use-by Date



Date of Manufacture



Manufacturer



MR Conditional



Non-pyrogenic

MR Information



The LVIS device has been determined to be **MR conditional** according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503.

Non-clinical testing demonstrated that the LVIS device is **MR conditional**. A patient can be scanned safely, immediately after placement under the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla only
- Maximum spatial gradient magnetic field of 720 Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the LVIS is expected to produce a maximum temperature rise of 2.6°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the LVIS when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system.

MRI-Related Heating

In non-clinical testing, the device produced the following temperature rises during MRI performed for 15-min of scanning (i.e., per pulse sequence) in 1.5-Tesla/64-MHz (Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MR 2002B DHHS Active-shielded, horizontal field scanner) and 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR systems:

	<u>1.5-Tesla</u>	<u>3-Tesla</u>
MR system reported, whole body averaged SAR	2.9-W/kg	2.9-W/kg
Calorimetry measured values, whole body averaged SAR	2.1-W/kg	2.7-W/kg
Highest temperature change	+2.2°C	+2.6°C

These temperature changes will not pose a hazard to a human subject under the conditions indicated above.

Image Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the implant. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 5-mm relative to the size and shape of this implant.

Pulse Sequence:	T1-SE	T1-SE	GRE	GRE
Signal Void Size:	306-mm ²	25-mm ²	623-mm ²	60-mm ²
Plane Orientation:	Parallel	Perpendicular	Parallel	Perpendicular

MicroVention, Inc. recommends that the patient register the MR conditions disclosed in this IFU with the MedicAlert Foundation or equivalent organization. A device patient implant card is included in the package, which should be completed and provided to the patient.

CLINICIAN USE INFORMATION

Materials

The following parts are required to use the LVIS device:

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

The following parts are required to use the LVIS Jr. device:

- LVIS Jr. device should be introduced only by means of a Headway® 17 Microcatheter (0.017 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
- 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 or one (1) LVIS Jr. device

Storage: Store product in a dry, cool place.

Directions for Use

1. Gain vascular access according to standard practice.
2. Place guidewire in the appropriate target vessel.
3. Navigate the corresponding microcatheter (.021" MicroVention Headway® 21 microcatheter for LVIS device / .017" MicroVention Headway® 17 for LVIS Jr. device) over a guidewire at least 15 mm distal to the aneurysm neck or target location.
4. Remove the guidewire.
5. Maintain flush through the microcatheter per standard endovascular practice.
6. Select an appropriate sized LVIS device (Refer to Table 1).
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 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 1 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.**
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: The introducer must be properly engaged with 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 by aligning the LVIS implant distal radiopaque end markers approximately 7 mm 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 is aligned 3 mm proximally with the microcatheter distal marker band (approximately 80% 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. 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 approximately 7 mm proximal to the aneurysm neck to ensure an adequate landing zone. The LVIS device will expand and total length may foreshorten up to 55% from its undeployed length (refer to Table 1) 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, approximately 7 mm 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. If applicable, remove the .021" microcatheter and advance a .017" inner diameter (or suitable size) microcatheter over the guidewire.
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 to the microcatheter tip and carefully remove the microcatheter through the LVIS device cells.
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 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.

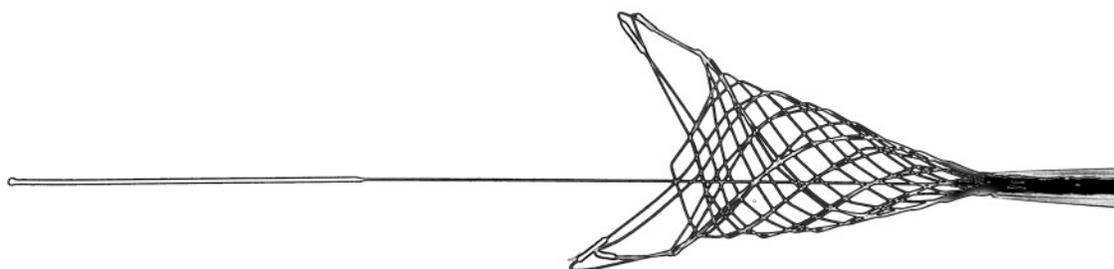
WARRANTY DISCLAIMER

MicroVention warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for particular purpose. Handling, storage, and sterilization of the device as well as factors relating to the patient, diagnosis, treatment, surgical procedure, and other matters beyond MicroVention's control directly affect the device and the results obtained from its use. MicroVention's obligation under this warranty is limited to the repair or replacement of this device through its expiration date. MicroVention shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this device. MicroVention neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. MicroVention assumes no liability with respect to devices reused, reprocessed or resterilized and makes no warranties, expressed or implied, including, but not limited to, merchantability or fitness for intended use, with respect to such device.

Prices, specifications, and model availability are subject to change without notice.

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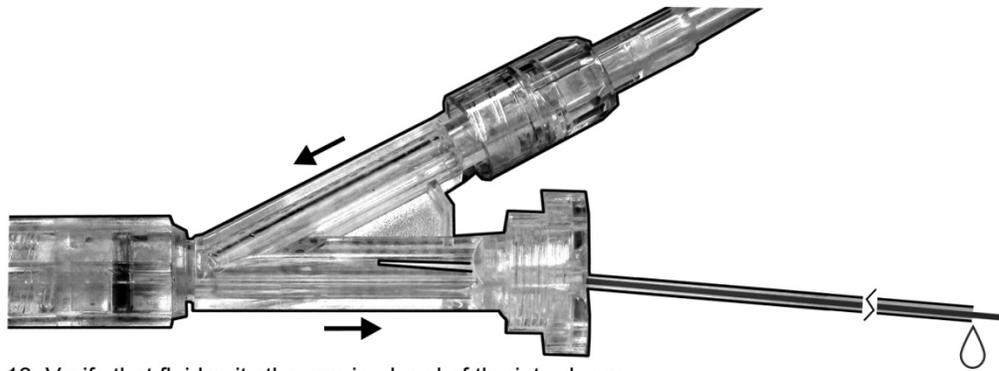


Check for the following:

- Implant distal marker uniformity
- Implant distal end shows even displacement with no entanglement
- Implant tracks smoothly through introducer

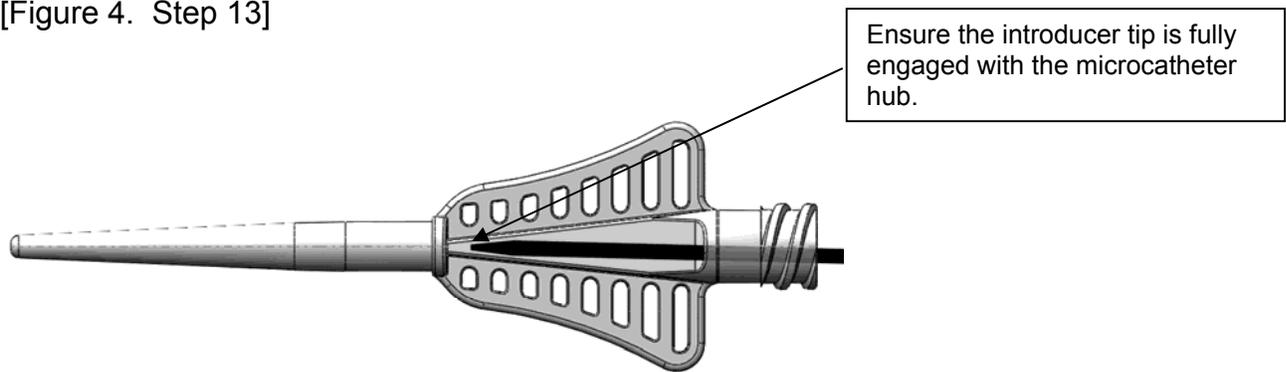
Warning: DO NOT FULLY DEPLOY LVIS device.

[Figure 3b. Step 10b]



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

[Figure 4. Step 13]



14. Seat in microcatheter



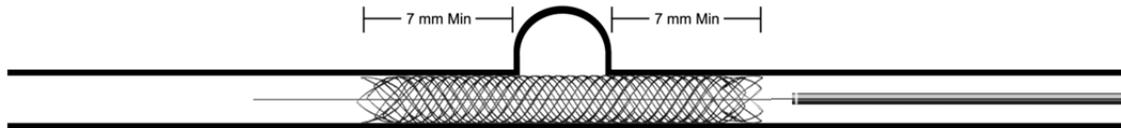
18. Position distal markers 7 mm minimum distal to the aneurysm neck

[Figure 6. Step 18]



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

[Figure 7. Step 19]



20. Ensure proximal markers are 7 mm minimum proximal to aneurysm neck
[Figure 8. Step 20]



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