LVIS®

Intraluminal Support Device

INSTRUCTIONS FOR USE

MicroVention® TERUMO

PD110626D
Revised 2022-03

DEVICE DESCRIPTION

The MicroVention Low-profile Visualized Intraluminal Support (LVIS) 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.
LVIS Device - Components

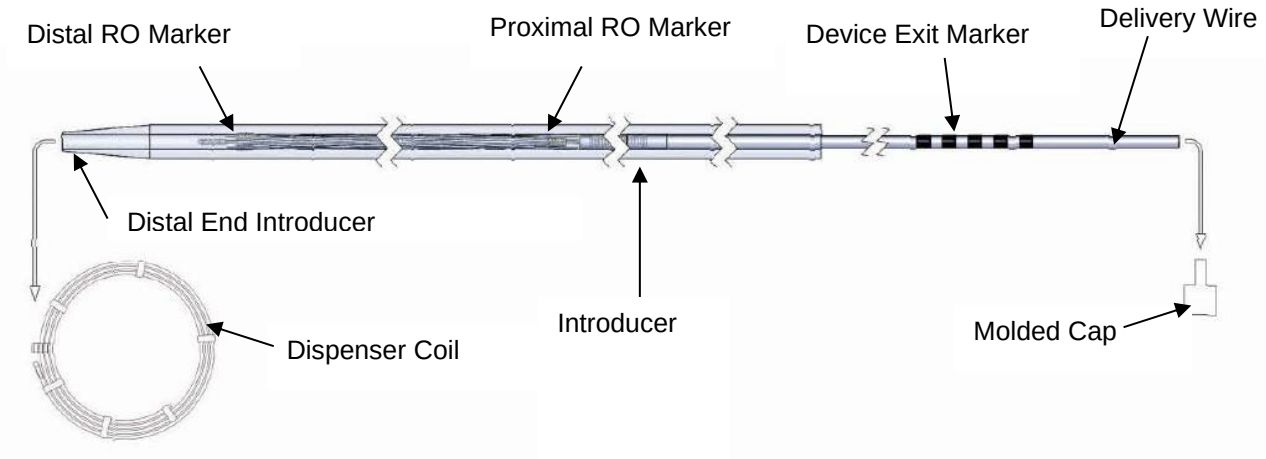


Figure 2.
LVIS Device – Implant Delivery

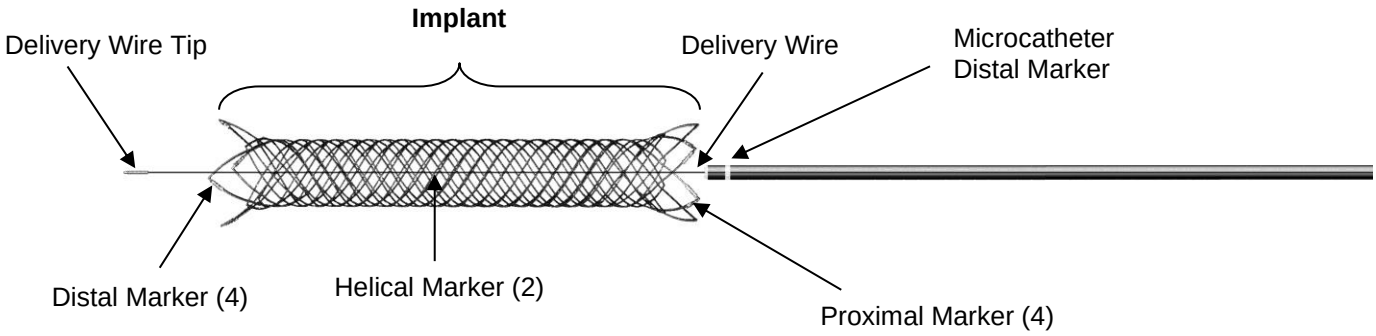


Table 1: LVIS Device – Parent Vessel Sizing Guidelines

Catalog Number					2.5 mm Vessel Diameter				3.0 mm Vessel Diameter				3.5 mm Vessel Diameter**			
					Implant Length (mm)		Length Fore-shortening		Implant Length (mm)		Length Fore-shortening		Implant Length (mm)		Length Fore-shortening	
					Total*	Working	mm	%	Total*	Working	mm	%	Total*	Working	mm	%
212517-CAS					23	19	5	18	20	16	8	29	17	13	11	39
212525-CAS					32	28	8	20	27	23	13	33	22	18	18	45
Catalog Number	**2.5 mm Vessel Diameter**				**3.0 mm Vessel Diameter**				**3.5 mm Vessel Diameter**				**4.0 mm Vessel Diameter****			
	Implant Length (mm)		**Length Fore-shortening**		**Implant Length (mm)**		**Length Fore-shortening**		**Implant Length (mm)**		**Length Fore-shortening**		**Implant Length (mm)**		**Length Fore-shortening**	
	Total*	**Working**	**mm**	**%**	**Total***	**Working**	**mm**	**%**	**Total***	**Working**	**mm**	**%**	**Total***	**Working**	**mm**	**%**
212912-CAS	16	12	2	11	15	11	3	17	14	10	4	22	12	8	6	33
212917-CAS	27	23	4	13	24	20	7	23	21	17	10	32	17	13	14	45
212922-CAS	37	33	7	16	34	30	10	23	29	25	15	34	22	18	22	50
212928-CAS	48	44	9	16	43	39	14	25	37	33	20	35	28	24	29	51
212931-CAS	54	50	10	16	48	44	16	25	41	37	23	36	31	27	33	52
Catalog Number	**3.0 mm Vessel Diameter**				**3.5 mm Vessel Diameter**				**4.0 mm Vessel Diameter**				**4.5 mm Vessel Diameter****			
	Implant Length (mm)		**Length Fore-shortening**		**Implant Length (mm)**		**Length Fore-shortening**		**Implant Length (mm)**		**Length Fore-shortening**		**Implant Length (mm)**		**Length Fore-shortening**	
	Total*	**Working**	**mm**	**%**	**Total***	**Working**	**mm**	**%**	**Total***	**Working**	**mm**	**%**	**Total***	**Working**	**mm**	**%**
213015-CAS	28	24	6	18	26	22	8	24	22	18	12	35	18	14	16	47
213025-CAS	40	36	9	18	36	32	13	27	31	27	18	37	23	19	26	53
213041-CAS	57	53	14	20	52	48	19	27	44	40	27	38	32	28	39	55
Catalog Number	**4.0 mm Vessel Diameter**				**4.5 mm Vessel Diameter**				**5.0 mm Vessel Diameter**				**5.5 mm Vessel Diameter****			
	Implant Length (mm)		**Length Fore-shortening**		**Implant Length (mm)**		**Length Fore-shortening**		**Implant Length (mm)**		**Length Fore-shortening**		**Implant Length (mm)**		**Length Fore-shortening**	
	Total*	**Working**	**mm**	**%**	**Total***	**Working**	**mm**	**%**	**Total***	**Working**	**mm**	**%**	**Total***	**Working**	**mm**	**%**
214035-CAS	51	47	16	24	45	41	22	33	39	35	28	42	30	26	37	55
214049-CAS	58	54	18	24	51	47	25	33	43	39	33	43	33	29	43	57

Compatible with Headway®21 Microcatheter (inner diameter = 0.021"or 0.53 mm)

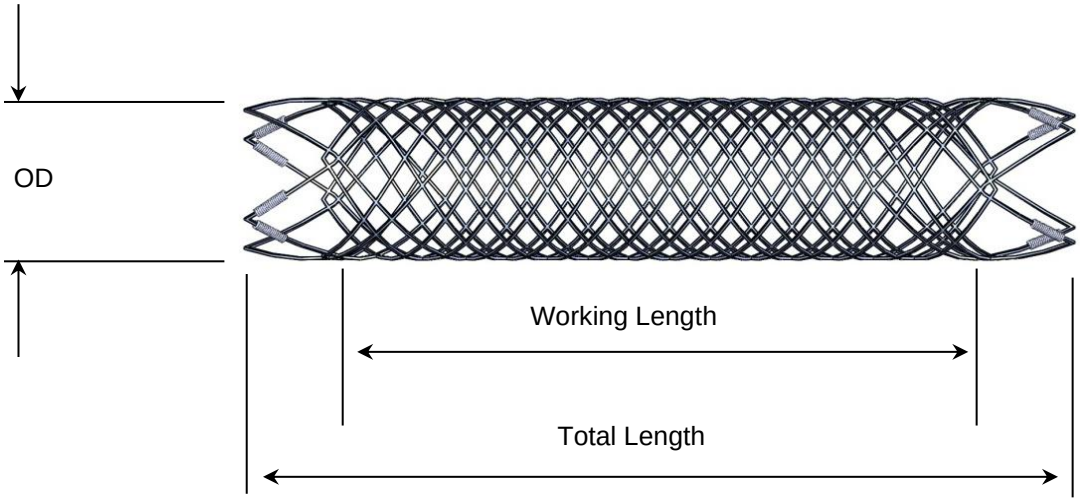
* Total Length (which includes flared ends) = Working Length + 4 mm (2 mm on each side)

** Fully Expanded Diameter

Table 2: LVIS Device Undeployed Length, Free Area %

LVIS					
Product Code	Undeployed Length* (mm)	Free Area (%)			
		2.0 mm OD	2.5 mm OD	3.0 mm OD	3.5 mm OD
212517-CAS	28		73	75	74
212525-CAS	40		73	73	71
		2.5 mm OD	3.0 mm OD	3.5 mm OD	4.0 mm OD
212912-CAS	18	76	78	80	80
212917-CAS	31	74	77	77	75
212922-CAS	44	74	76	76	73
212928-CAS	57	74	76	76	72
212931-CAS	64	74	76	76	71
		3.0 mm OD	3.5 mm OD	4.0 mm OD	4.5 mm OD
213015-CAS	34	78	79	79	77
213025-CAS	49	78	79	78	74
213041-CAS	71	77	78	78	73
		4.0 mm OD	4.5 mm OD	5.0 mm OD	5.5 mm OD
214035-CAS	67	82	82	81	78
214049-CAS	76	82	82	81	77
* Within Headway® 21 Microcatheter (inner diameter = 0.021" or 0.53 mm)					

Figure 3a.
LVIS Device Implant Dimensions



INDICATIONS

The LVIS device is intended for use with embolic coils for the treatment of wide neck (neck ≥ 4mm or dome to neck ratio <2), intracranial, saccular aneurysms arising from a parent vessel with a diameter of ≥ 2mm and ≤ 4.5mm that are not amenable to treatment with surgical clipping.

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 anatomy that does not permit passage or deployment
- Patients with an active bacterial infection;
- Patients with a pre-existing stent in place at the target aneurysm.

POTENTIAL COMPLICATIONS

Possible complications 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

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 or other vascular lesions.

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.

Use extreme caution when using stent-assisted coiling in patients who have suffered subarachnoid hemorrhage (SAH).

This device is not intended for use in the treatment of atheromatous disease.

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 and peripheral vascular procedures as prescribed by a representative from MicroVention-Terumo or a MicroVention-authorized distributor.

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.

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
- Whole body averaged specific absorption rate of 2 W/kg in the normal operating mode for a maximum scan time of 15 minutes

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:

	1.5-Tesla	3-Tesla
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. An LVIS 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)

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
- 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.

Directions for Use

1. Gain vascular access according to standard practice.
2. Place guidecatheter in the appropriate target vessel.
3. Navigate the microcatheter (.021" ID MicroVention Headway® 21 microcatheter) 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 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 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 or adequate length 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 or adequate length 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 Tables 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 or adequate 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. 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.

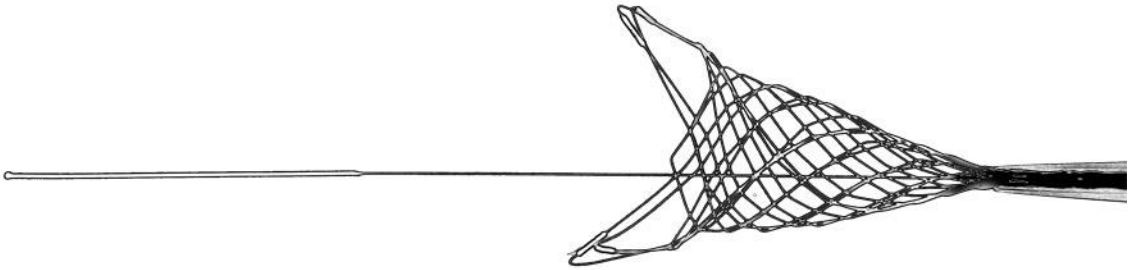
HOW SUPPLIED

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

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, cleaning, 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.

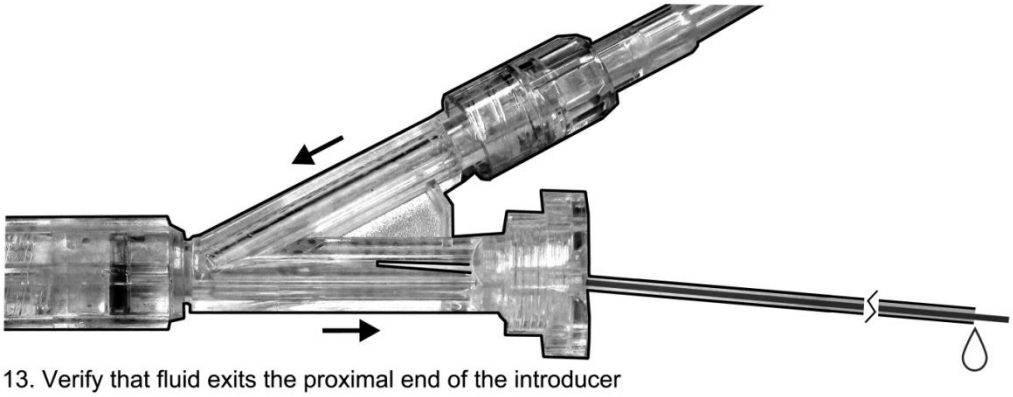
Prices, specifications, and model availability are subject to change without notice.



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

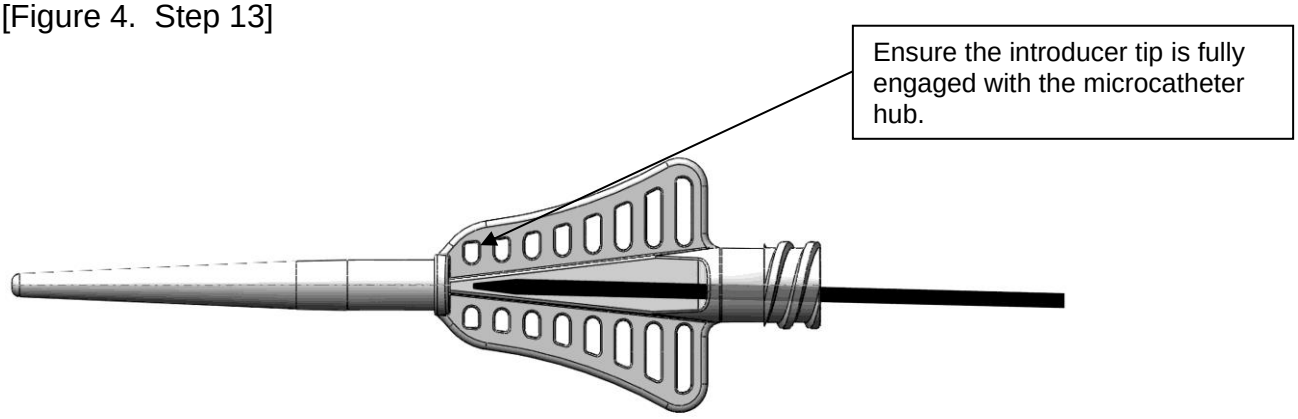
Warning: DO NOT FULLY DEPLOY LVIS device.

[Figure 3b. Step 10b]



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

[Figure 4. Step 13]

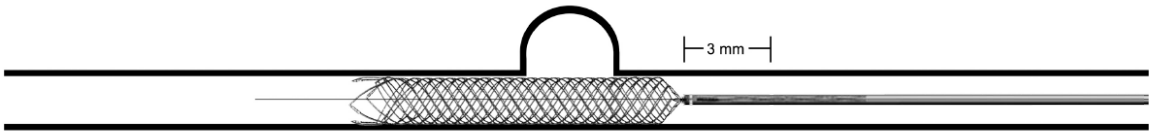


14. Seat in microcatheter

[Figure 5. Step 14]

18. Position distal markers approximately 7 mm or adequate length 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 approximately 7 mm or adequate length to the aneurysm neck

[Figure 8. Step 20]

PD110626D

MicroVention®
TERUMO

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