LVIS®

Intraluminal Support Device

INSTRUCTIONS FOR USE

MicroVention™
TERUMO

IFU100314 Rev. X2
Revised 2023-02

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

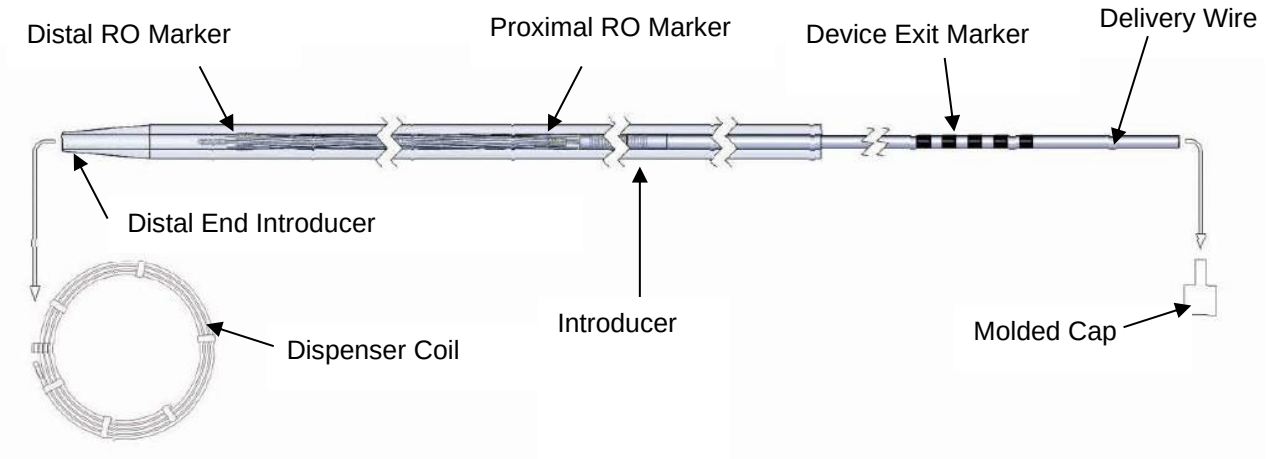


Figure 2.
LVIS Device – Implant Delivery

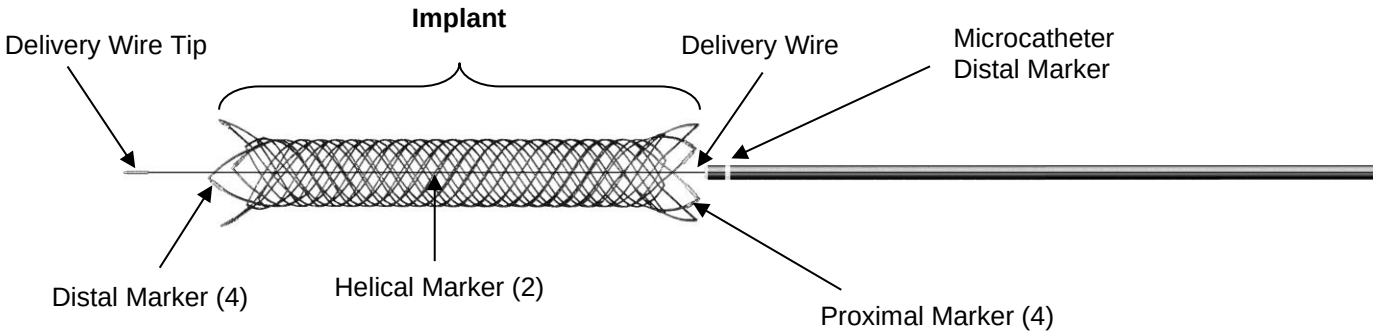


Table 1: LVIS Device Product Specifications and Undeployed Length, Free Area %

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-CAS		23 / 19	20 /16	17 / 13
212525-CAS		32 / 28	27 / 23	22 / 18
	2.5 mm OD	3.0 mm OD	3.5 mm OD	4.0 mm OD
212912-CAS	16 / 12	15 / 11	14 / 10	12 / 8
212917-CAS	27 / 23	24 / 20	21 / 17	17 / 13
212922-CAS	37 / 33	34 / 30	29 / 25	22 / 18
212928-CAS	48 / 44	43 / 39	37 / 33	28 / 24
212931-CAS	54 / 50	48 / 44	41 / 37	31 / 27
	3.0 mm OD	3.5 mm OD	4.0 mm OD	4.5 mm OD
213015-CAS	28 / 24	26 / 22	22 / 18	18 / 14
213025-CAS	40 / 36	36 / 32	31 / 27	23 / 19
213041-CAS	57 / 53	52 / 48	44 / 40	32 / 28
	4.0 mm OD	4.5 mm OD	5.0 mm OD	5.5 mm OD
214035-CAS	51 / 47	45 / 41	39 / 35	30 / 26
214049-CAS	58 / 54	51 / 47	43 / 39	33 / 29
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)				

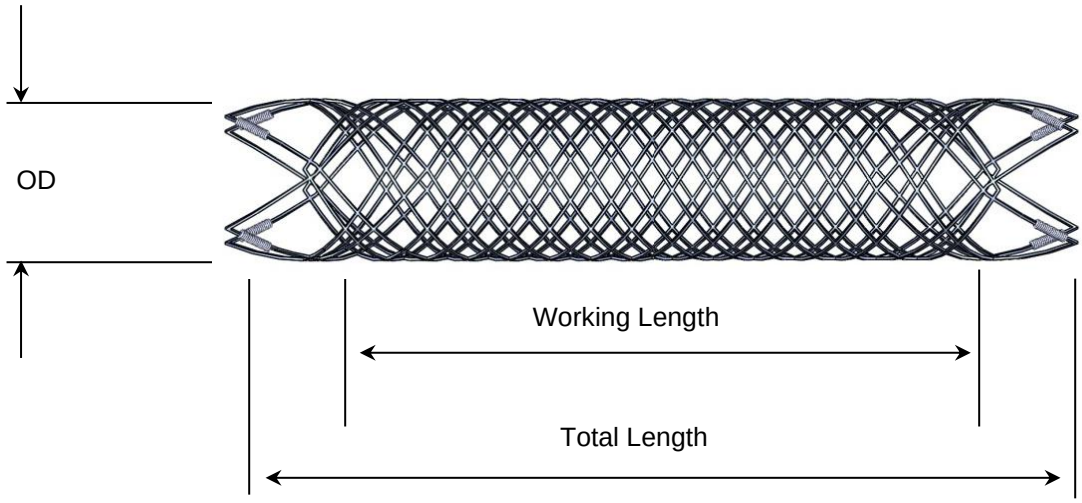
LVIS					
Product Code	Undeployed Length* (mm)	Free Area (%)			
		2.0 mm OD	2.5 mm OD	3.0 mm OD	3.5 mm OD
212517-CAS	28		73	75	74
212525-CAS	40		73	73	71
		2.5 mm OD	3.0 mm OD	3.5 mm OD	4.0 mm OD
212912-CAS	18	76	78	80	80
212917-CAS	31	74	77	77	75
212922-CAS	44	74	76	76	73
212928-CAS	57	74	76	76	72
212931-CAS	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)					

Table 2: Qualitative and Qualitative Implant Material Information

Implant Material		Mass*
Metallic Components	Nitinol, Tantalum	<0.032g
Non-metallic Components	DYMAX	<0.00005g

*Approximate content

Figure 3a.
LVIS Device Implant Dimensions



INTENDED PURPOSE/ INDICATIONS

The LVIS device is intended for use with embolic coils for the treatment of intracranial neurovascular diseases.

CONTRAINDICATIONS

Use of the LVIS device is contraindicated under these circumstances:

- Patients in whom anticoagulant, anti-platelet therapy or thrombolytic drugs are contraindicated;
- Patients with known hypersensitivity to metal, such as nickel-titanium and metal jewelry; Patients with anatomy that does not permit passage or deployment of the LVIS device;
- Patients with an active bacterial infection;
- Patients with a pre-existing stent in place at the target aneurysm.

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.

CLINICAL BENEFIT

The LVIS Devices (implant and delivery device) can be lifesaving and result in benefits such as successful embolization (measured as complete occlusion of aneurysm), improved functional independence, and reduced disability.

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.

ADDITIONAL NOTICE TO USER

- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established
- The Summary of Safety and Clinical Performance (SSCP) for the device will be accessible in the European database on medical devices after the launch of the European Database on Medical Devices (Eudamed) (Eudamed: https://ec.europa.eu/tools/eudamed). The SSCP will be linked to the Basic UDI-DI in the Eudamed public website.
- A patient implant card is included in the package. This card should be completed and provided to the patient.
- Permanent implant. Follow-up required at the discretion of the physician
- The electronic instructions for use (eIFU) is available via MicroVention website: https://microvention.com/products/product-use-and-safety

SYMBOLS

	Attention, Consult Accompanying Documents
	Batch Code
	Catalog Number
	Contents
	Sterilized Using Irradiation

 Do Not Reuse

 Use-by Date

 Date of Manufacture

 Manufacturer

MR Conditional

 CE Mark

 Non-pyrogenic

Medical Device

UDI

 Single sterile barrier system

 Do not resterilize

 Country of Manufacture

 Do not use if package is damaged and consult instruction for use

 Patient information website

MRI Safety Information

Non-clinical testing has demonstrated that the LVIS device is MR Conditional. A patient with this device can be safely scanned in an MR system, meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only

Maximum spatial gradient magnetic field of 2,500 Gauss/cm 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 device is expected to produce a maximum temperature rise of 2.8 ºC at 1.5 T or 3.6 ºC at 3 T for 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 4 mm from the LVIS device when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system.

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. Dispose of device in accordance with hospital policy and local regulations for biohazardous waste.

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 guide catheter 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 60% 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.

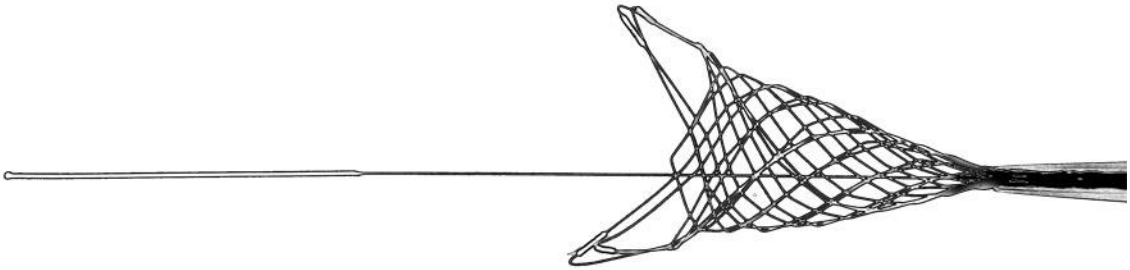
HOW SUPPLIED

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.

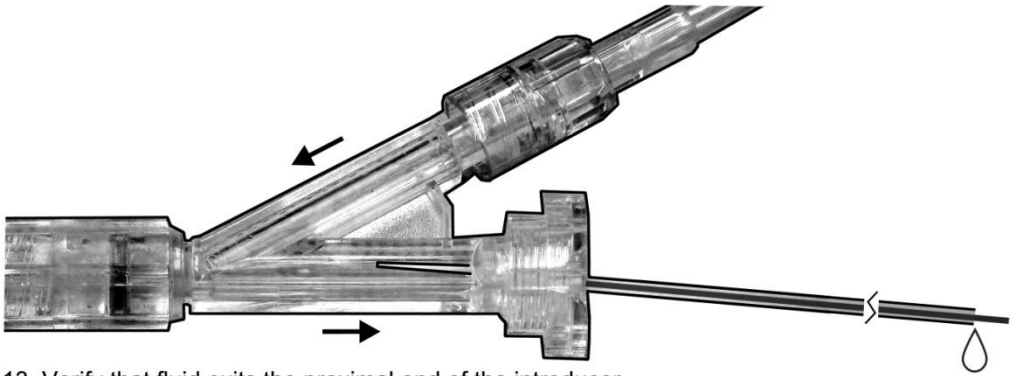
Prices, specifications, and model availability are subject to change without notice.



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

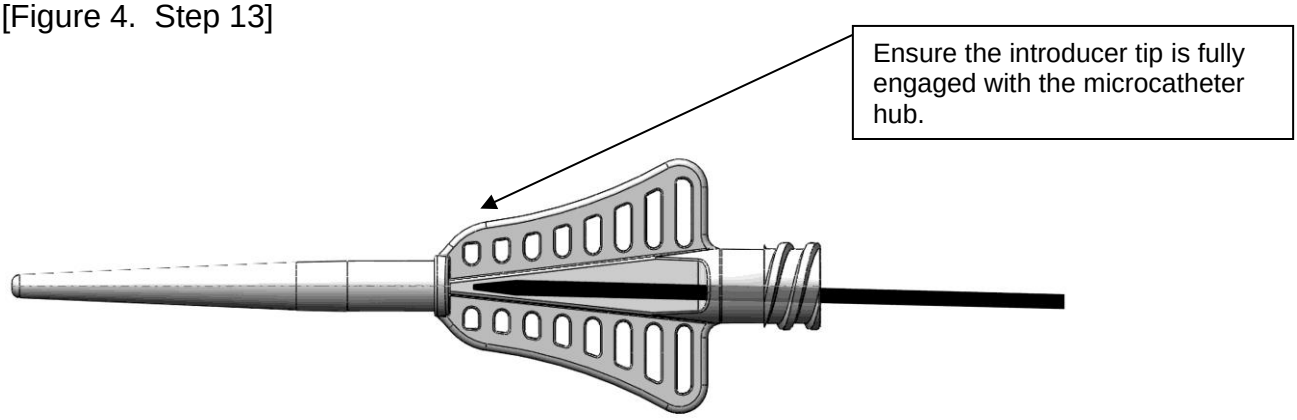
Warning: DO NOT FULLY DEPLOY LVIS device.

[Figure 3b. Step 10b]



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

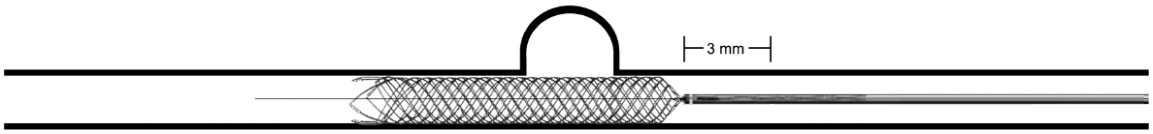
[Figure 4. Step 13]



[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]

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