LVIS® Intraluminal Support Device Jr.

INSTRUCTIONS FOR USE

MicroVention™ TERUMO

IFU100313 Rev. X2
Revised 2023-02

DEVICE DESCRIPTION

The MicroVention Low-profile Visualized Intraluminal Support Junior (LVIS Jr.) 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 Jr. device is packaged sterile as a single unit with an introducer sheath and a detachable delivery wire.

Figure 1.
LVIS Jr. Device - Components

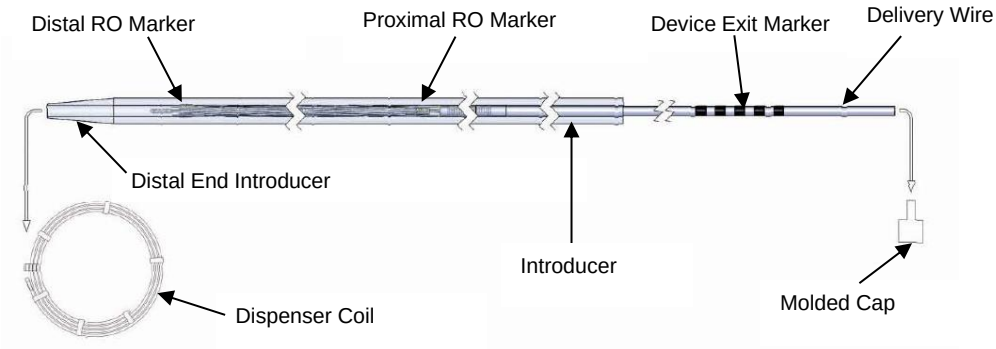


Figure 2.
LVIS Jr. Device – Implant Delivery

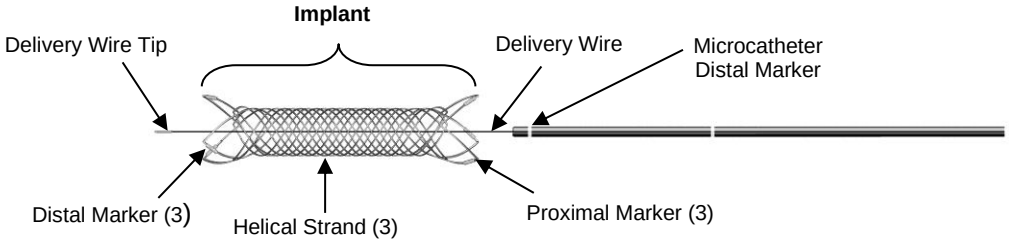


Figure 3a.
LVIS Jr. Device Implant Dimensions

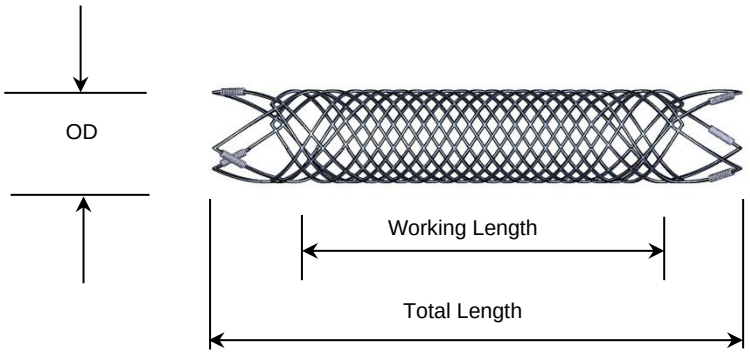


Table 1. LVIS Jr. Device - Product Specifications & Parent Vessel Sizing Guidelines

LVIS Jr.			
Product Code	Total Length/ Working Length** (mm)	Total Length/ Working Length** (mm)	Total Length/ Working Length** (mm)*
		2.0 mm OD	2.5 mm OD
172010-CASJ		14 / 10	13 / 9
172014-CASJ		18 / 14	17 / 13
172020-CASJ		24 / 20	23 / 19
172032-CASJ		36 / 32	34 / 30
	2.5 mm OD	3.0 mm OD	3.5 mm OD
172516-CASJ	20 / 16	19 /15	18 / 14
172524-CASJ	27 / 23	25 / 21	23 / 19
172530-CASJ	34 / 30	32 / 28	28 / 24
172537-CASJ	40 / 36	37 / 33	33 / 29
Compatible with Headway™ 17 Microcatheter or Scepter C™/Scepter XC™ Occlusion Balloon			
* Fully Expanded diameter			
** Total Length (which includes flared ends) = Working Length + 4 mm (2 mm each side)			

Table 2. LVIS Jr. Device – Undeployed Length, Free Area %

LVIS Jr.				
Product Code	Undeployed Length* (mm)	Free Area (%)		
			2.0 mm OD	2.5 mm OD
172010-CASJ	15.0		77	81
172014-CASJ	20.0		77	80
172020-CASJ	26.5		76	80
172032-CASJ	39.5		76	79
		2.5 mm OD	3.0 mm OD	3.5 mm OD
172516-CASJ	23	82	84	83
172524-CASJ	31	83	84	83
172530-CASJ	39	83	85	83
172537-CASJ	46	83	84	83
* Within Headway 17 Microcatheter (inner diameter = 0.017" or 0.43 mm)				

Table 3: Quantitative and Qualitative Implant Material Information

Implant Material		Mass*
Metallic Components	Nitinol, Tantalum	<0.016g
Non-metallic Components	DYMAX	<0.00004g

*Approximate content

The LVIS Jr. delivery wire contains a hazardous substance. Cobalt (CAS No. 7440-48-4) is classified as a carcinogenic, mutagenic, or toxic for reproduction (CMR) substance of Category 1A or 1B, or as an endocrine disruptor (ED), and is present at a concentration >0.1% weight/weight.

INTENDED PURPOSE/ INDICATIONS

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

CONTRAINDICATIONS

Use of the LVIS Jr. 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 Jr. device;
- Patients with an active bacterial infection

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 Jr. device should be removed as a single unit. Applying excessive force during delivery or retrieval of the LVIS Jr. device can potentially result in loss or damage to the device and delivery components.

The LVIS Jr. 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 Jr. device with compatible microcatheters. If repeated friction is encountered during LVIS Jr. 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 Jr. device in the parent vessel without fully retrieving the device. The LVIS Jr. 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 Jr. implant after detachment.

Do not shape the tip of the delivery wire.

Do not torque the delivery wire while advancing or retracting the LVIS Jr. device. A torque device should not be used.

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 Jr. device for angiographic, percutaneous neurointerventional and peripheral vascular procedures as prescribed by a representative from MicroVention-Terumo or a MicroVention-authorized distributor.

The LVIS Jr. 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 Jr. 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 Jr. 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
	Content
	Sterilized Using Irradiation
	Do Not Reuse
	Use-by Date
	Date of Manufacture
	Manufacturer
	CE Mark
	MR Conditional
	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
	Contains hazardous substance
	Patient information website

MR Information 

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

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

Static Magnetic Field

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

MicroVention, Inc. recommends that the patient register the MR conditions disclosed in this IFU with the MedicAlert Foundation or equivalent organization. An LVIS Jr. 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 Jr. device:

- LVIS Jr. device should be introduced only by means of a Headway 17 Microcatheter (0.017 inch (0.43 mm) 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 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 Jr. device does not contain latex or PVC materials.

PACKAGING AND STORAGE

The LVIS Jr. device is placed inside a protective, plastic dispenser coil and packaged in a pouch and unit carton. The LVIS Jr. 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 Jr. device is important for patient safety. In order to choose the optimal LVIS Jr. 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 (.017" MicroVention Headway 17 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 Jr. device (Refer to Tables 1 and 2).
7. Carefully inspect the LVIS Jr. 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 Jr. 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 Jr. implant up to 5 mm or 50% (whichever comes first, being careful not to detach the implant) from the 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 Jr. device.

c. With the LVIS Jr. implant and introducer sheath positioned and hydrated within the bowl of saline, gently manipulate the LVIS Jr. 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 Jr. 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 Jr. 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 Jr. device introduction into the microcatheter. [Figure 5]
15. Advance the delivery wire to transfer the LVIS Jr. device from within the introducer into the microcatheter.
    Warning: Do not torque the delivery wire while advancing or retracting the LVIS Jr. 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 Jr. device delivery or manipulation, withdraw the unit and select a new LVIS Jr. device.
17. Track the LVIS Jr. device through the microcatheter to the tip. Carefully advance the LVIS Jr. 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 Jr. device for deployment by aligning the LVIS Jr. implant distal 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 Jr. device to achieve full expansion and good vessel apposition.
    Note: Slowly advancing the LVIS Jr. device while adjusting the microcatheter position will ensure accurate deployment. Maintain simultaneous control of the LVIS Jr. 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 Jr. device is not recommended and may result in device elongation.
19. If LVIS Jr. device positioning is not satisfactory, the LVIS Jr. device may be recaptured and repositioned if it is not fully deployed. The LVIS Jr. device may be recaptured until the point where the proximal end of the LVIS Jr. device markers is aligned 3 mm proximally with the microcatheter distal marker band (approximately 75% deployed). [Figure 7]
    Caution: If resistance is felt while recapturing the LVIS Jr. device, do not continue to recapture the device. Withdraw the microcatheter slightly to unsheath the LVIS Jr. device (without exceeding the recapture limit), and then attempt to recapture the LVIS Jr. device.
    Caution: The LVIS Jr. device must not be re-deployed more than three times.
    Note: The LVIS Jr. device delivery wire should not be utilized as a guidewire. Do not torque the LVIS Jr. device. A torque device should not be used.
20. If LVIS Jr. device positioning is satisfactory, carefully retract the microcatheter and advance the delivery wire together, to allow the LVIS Jr. 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 Jr. device will

expand and total length may foreshorten up to 35% from its undeployed length (refer to Tables 1 and 2) 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 Jr. 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 Jr. device to maintain access through the LVIS Jr. device. Remove and discard the delivery wire.
    Warning: The LVIS Jr. delivery wire should not be used as a guidewire. Do not torque the LVIS Jr. device. A torque device should not be used.
22. Advance an exchange-length guidewire through the .017" inner diameter microcatheter.
23. If required or desired, remove the .017" inner diameter microcatheter and advance a .017" (0.43 mm) inner diameter (or suitable size) microcatheter over the exchange guidewire.
    Note: The original Headway 17 microcatheter used in step 3, to deploy LVIS Jr. device may also be positioned through the LVIS Jr. device cell mesh and used for coil embolization.
24. Use the guidewire and microcatheter to access the aneurysm through the LVIS Jr. device cells.
    Warning: Observe LVIS Jr. device marker position during placement of the microcatheter into the aneurysm to ensure that the LVIS Jr. 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.
25. After the microcatheter is positioned within the aneurysm, detachable coils may be delivered into the aneurysm according to conventional methods.
    Warning: Observe LVIS Jr. device marker position during the coiling procedure to ensure that the device does not migrate from its deployed position.
26. After placing the last coil, verify that the LVIS Jr. device has remained patent and properly positioned. Advance a guidewire to the microcatheter tip and carefully remove the microcatheter through the LVIS Jr. device cells.
    Note: A microcatheter may be positioned into the aneurysm sac prior to delivery of the LVIS Jr. device. The microcatheter will be supported by the LVIS Jr. device during delivery of embolic coiling. After completing the coiling, the microcatheter should be carefully removed to avoid dislodging the LVIS Jr. device.
27. After completing the procedure, withdraw and discard all applicable accessory devices.
28. **Caution:** Carefully watch the LVIS Jr. device distal and proximal markers when passing through the deployed LVIS Jr. device with embolic coiling microcatheters to avoid displacing the LVIS Jr. device.

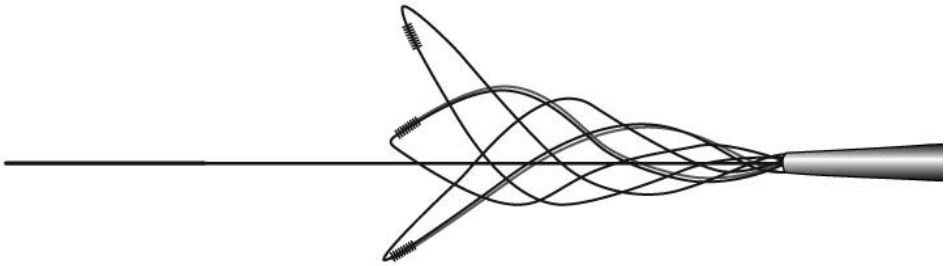
HOW SUPPLIED

Sterile: This device is sterilized with E-Beam irradiation. Non-pyrogenic
Contents: One (1) LVIS Jr. 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 sole 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, indirect, special 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.

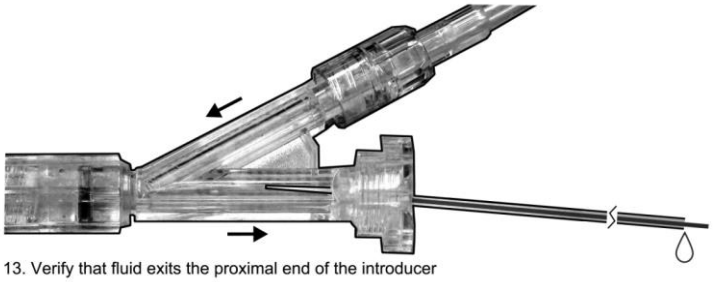
Prices, specifications, and model availability are subject to change without notice.



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

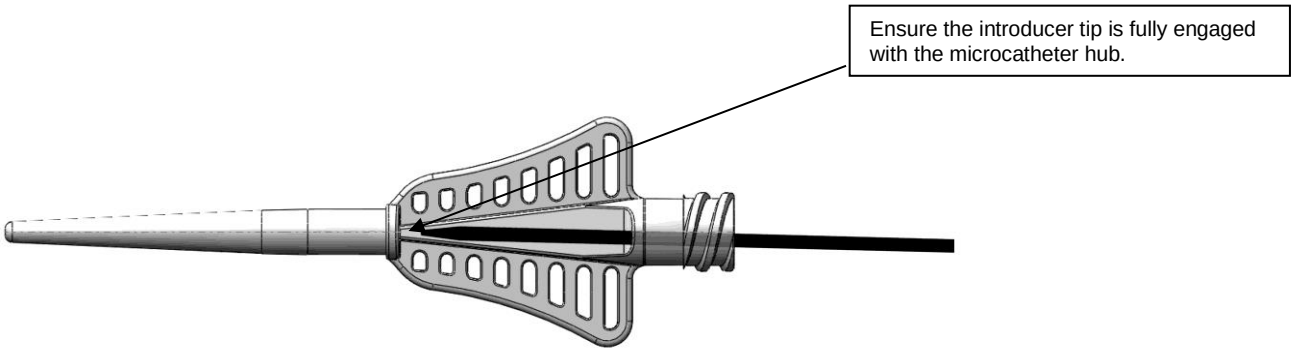
Warning: DO NOT FULLY DEPLOY LVIS Jr. device.

[Figure 3b. Step 10b]



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

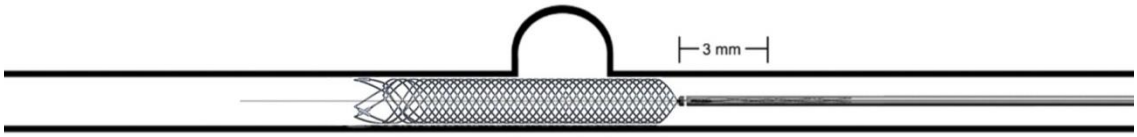
[Figure 4. Step 13]



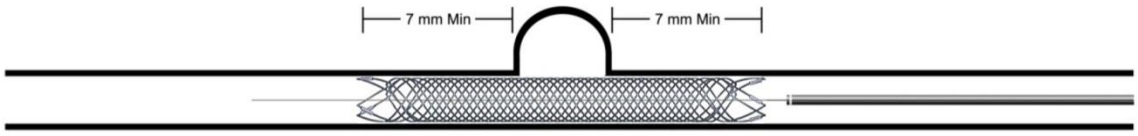
14. Seat in microcatheter

[Figure 5. Step 14]

18. Position distal markers 7 mm minimum distal to the aneurysm neck
[Figure 6. Step 18]



19. The LVIS Jr. 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]

IFU100313X2

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