

LVIS™ EVO™

Intraluminal Support Device

Instructions for Use



DEVICE DESCRIPTION

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

Figure 1.
LVIS EVO Device – Components Inside Package

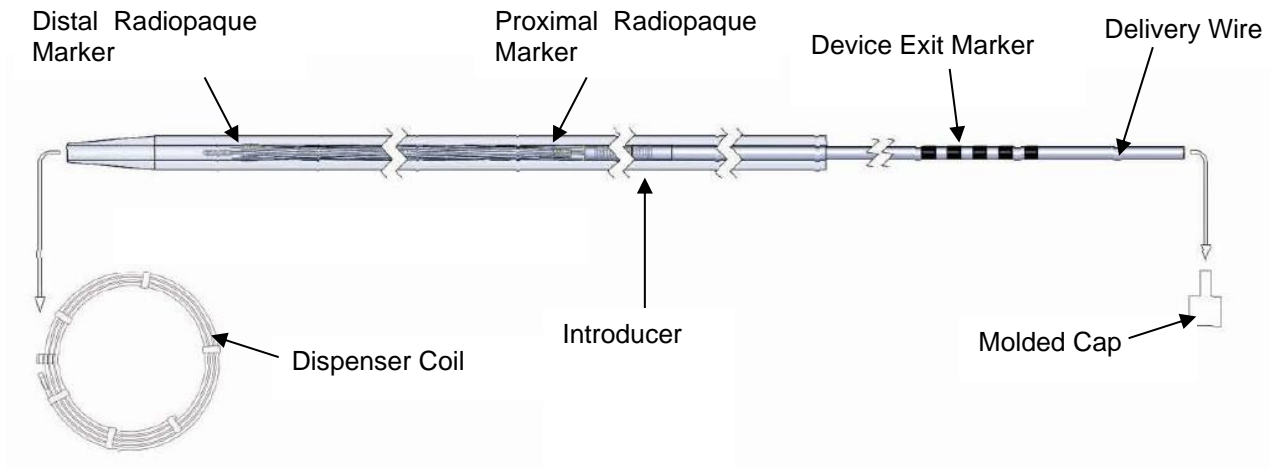


Figure 2.
LVIS EVO Device – Implant Delivery System

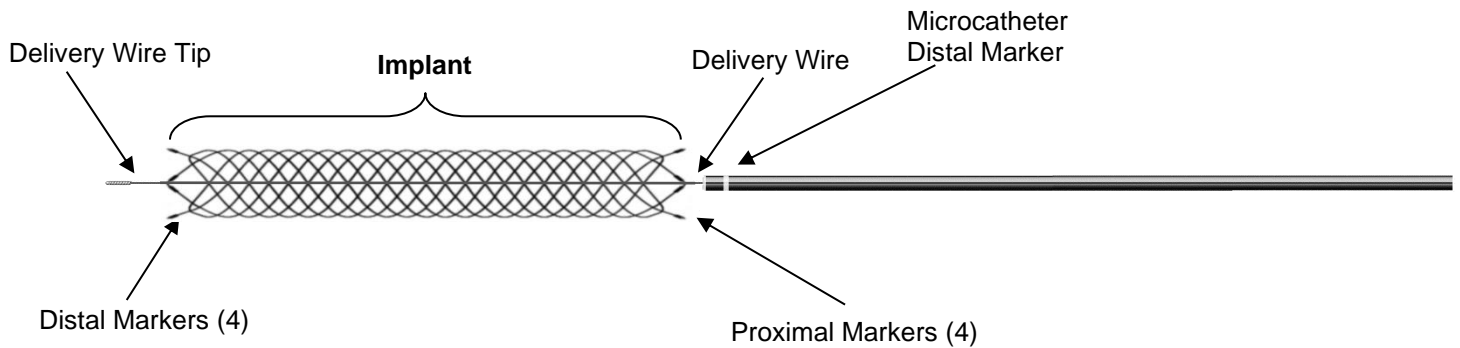


Table 1: LVIS EVO Device Product Specifications and Undeployed Length, Metal Surface Area %

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

LVIS EVO					
Product Code	Metal Surface Area (%)				
	2.0 mm	2.5 mm	3.0 mm	3.5 mm	4.0 mm
LEV2512	26	26			
LEV2517	26	28			
LEV2522	26	28			
LEV2527	27	28			
LEV3018	24	23	25		
LEV3024	25	23	25		
LEV3028	25	23	26		
LEV3032	24	23	26		
LEV3517	24	22	21	23	
LEV3522	25	22	21	24	
LEV3528	25	22	21	24	
LEV3534	24	22	22	25	
LEV4013		19	17	17	19
LEV4018		21	19	19	21
LEV4021		20	19	19	22
LEV4027		20	19	19	22
LEV4031		19	18	18	21

All Sizes Compatible with Headway 17 Microcatheter (inner diameter = 0.017" or 0.43 mm) & Scepter C / Scepter XC Occlusion Balloon Catheter

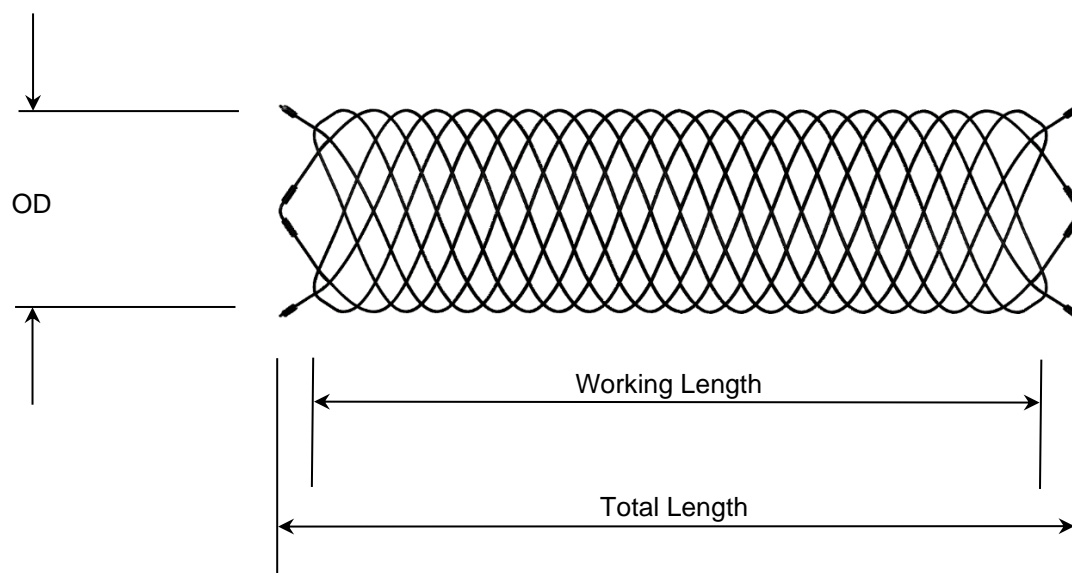
Table 2: Quantitative and Qualitative Implant Material Info

Implant Material		Mass*
Metallic Components	Nitinol, Platinum, Tantalum	<0.023g
Non-metallic Components	DYMAX	<0.00003g

*Approximate content

The LVIS EVO 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.

Figure 3.
LVIS EVO Device Implant Dimensions



INTENDED PURPOSE / INDICATIONS

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

CONTRAINDICATIONS

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

The LVIS EVO 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 EVO device with compatible microcatheters. If repeated friction is encountered during LVIS EVO 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 EVO device in the parent vessel without fully retrieving the device. The LVIS EVO 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 EVO 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 EVO device for angiographic, percutaneous neurointerventional and peripheral vascular procedures as prescribed by an authorized representative of MicroVention.

The LVIS EVO 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 EVO 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 EVO 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

	Caution
	Batch Code
	Catalog Number
	Contents
	Sterilized Using Irradiation
	Do Not Reuse
	Use-by Date
	Date of Manufacture
	Manufacturer
	MR Conditional
	CE Mark
	Non-pyrogenic
	Consult instructions for use
	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 Safety Information

Non-clinical testing demonstrated that the LVIS EVO device is MR Conditional. A patient with an implant from this family can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, an implant from the LVIS EVO Stent is expected to produce a maximum temperature rise of 3.8°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by an implant from the LVIS EVO Stent extends approximately 4 mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system. The lumen of the LVIS EVO Stent could not be visualized on gradient echo or T1-weighted, spin echo pulse sequences.

CLINICIAN USE INFORMATION

Materials

The following parts are required to use the LVIS EVO device:

- LVIS EVO device should be introduced only by means of a Headway 17 Microcatheter (0.017 inch inner diameter) or Scepter C / Scepter XC Occlusion Balloon.

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 or Scepter C / Scepter XC Occlusion Balloon
- 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 EVO device does not contain latex or PVC materials.

PACKAGING AND STORAGE

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Revised 2023-02

The LVIS EVO device is placed inside a protective, plastic dispenser coil and packaged in a pouch and unit carton. The LVIS EVO 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 EVO device is important for patient safety. In order to choose the optimal LVIS EVO 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.
 - a. Navigate the microcatheter (.017" ID MicroVention Headway 17 microcatheter or Scepter C / Scepter XC Occlusion Balloon) over a guidewire at least 15 mm distal to the aneurysm neck or target location.
 - b. A second microcatheter can be navigated into the aneurysm sac for future coil deployment steps using the jailing technique (steps 22 - 24). In this technique, the microcatheter is effectively jailed between the vessel wall and outer surface of the stent and the coils are kept within the aneurysm and outside of the reconstructed vessel lumen.
4. Remove the guidewire.
5. Maintain flush through the microcatheter per standard endovascular practice.
6. Select an appropriately sized LVIS EVO device (Refer to Table 1).
7. Carefully inspect the LVIS EVO 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 EVO 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 EVO 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 3). Check for the following:
 - Implant distal marker uniformity
 - Implant distal end shows even displacement with no entanglement
 - Implant tracks smoothly through introducer
 - c. With the LVIS EVO implant and introducer sheath positioned and hydrated within the bowl of saline, gently manipulate the LVIS EVO 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 EVO 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 EVO device carefully to avoid the accidental introduction of air into the system.
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 EVO device introduction into the microcatheter.
15. Advance the delivery wire to transfer the LVIS EVO device from within the introducer into the microcatheter.
Warning: Do not torque the delivery wire while advancing or retracting the LVIS EVO 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 EVO device delivery or manipulation, withdraw the unit and select a new LVIS EVO device.
 17. Track the LVIS EVO device through the microcatheter to the tip. Carefully advance the LVIS EVO 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 EVO device for deployment by aligning the LVIS EVO implant distal radiopaque end markers approximately 7 mm or adequate length past the aneurysm neck.
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 EVO device to achieve full expansion and good vessel apposition.
Note: Slowly advancing the LVIS EVO device while adjusting the microcatheter position will ensure accurate deployment. Maintain simultaneous control of the LVIS EVO 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 EVO device is not recommended and may result in device elongation.
 19. If LVIS EVO device positioning is not satisfactory, the LVIS EVO device may be recaptured and repositioned if it is not fully deployed. The LVIS EVO device may be recaptured until the point where the proximal end of the LVIS EVO device markers is aligned 3 mm proximally with the microcatheter distal marker band.
Caution: If resistance is felt while recapturing the LVIS EVO device, do not continue to recapture the device. Withdraw the microcatheter slightly to unsheath the LVIS EVO device (without exceeding the recapture limit), and then attempt to recapture the LVIS EVO device.
Caution: The LVIS EVO device must not be re-deployed more than three times.
Note: The LVIS EVO device delivery wire should not be utilized as a guidewire. Do not torque the LVIS EVO device. A torque device should not be used.
 20. If LVIS EVO device positioning is satisfactory, carefully retract the microcatheter and advance the delivery wire together, to allow the LVIS EVO 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 EVO device will expand and total length may foreshorten up to 60% 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 or adequate length on each side of the aneurysm neck or target location to ensure appropriate neck coverage.
Warning: Do not detach the LVIS EVO 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 EVO device to maintain access through the LVIS EVO device. Remove and discard the delivery wire.
Warning: The LVIS EVO device delivery wire should not be utilized as a guidewire. Do not torque the LVIS EVO device. A torque device should not be used.
 22. a. If applicable, advance a .017" inner diameter (or suitable size) microcatheter over the guidewire.
b. If a second microcatheter has been placed into the aneurysm in step 3b, detachable coils can be delivered into the aneurysm through the second microcatheter (replacing steps 22-24).
Warning: Ensure that the jailed microcatheter does not move while constantly observing LVIS EVO device marker positions during the coiling procedure to ensure that the device does not migrate from its deployed position.
 23. Use the guidewire and microcatheter to access the aneurysm through the LVIS EVO device cells.
Warning: Observe LVIS EVO device marker position during placement of the microcatheter into the aneurysm to ensure that the LVIS EVO 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.

25. **Warning:** Observe LVIS EVO device marker position during the coiling procedure to ensure that the device does not migrate from its deployed position. After placing the last coil, verify that the LVIS EVO device has remained patent and properly positioned. Advance a guidewire, if necessary, to the microcatheter tip and carefully remove the microcatheter.
Note: A microcatheter may be positioned into the aneurysm sac prior to delivery of the LVIS EVO device. The microcatheter will be supported by the LVIS EVO device during delivery of embolic coiling. After completing the coiling, the coiling microcatheter should be carefully removed to avoid dislodging the LVIS EVO device.
26. After completing the procedure, withdraw and discard all applicable accessory devices.
27. **Caution:** Carefully watch the LVIS EVO device distal and proximal markers when passing through the deployed LVIS EVO device with embolic coiling microcatheters to avoid displacing the LVIS EVO device.

HOW SUPPLIED

Sterile: This device is sterilized with E-Beam irradiation. Non-pyrogenic

Contents: One (1) LVIS EVO 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.

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