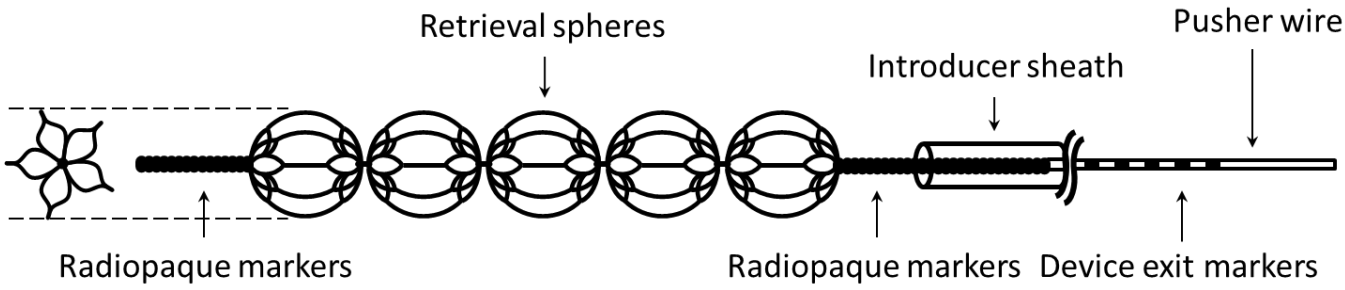
ERIC™ Retrieval Device

Instructions for Use

Carefully read all instructions prior to use.

DEVICE DESCRIPTION

The ERIC Retrieval Device is a resheathable mechanical thrombectomy device for restoring blood flow by removing clots from occlusive vasculature. The ERIC Retrieval Device consists of retrieval spheres that are located on a pusher wire delivery system which requires a Microcatheter. Radiopaque markers provide visualization under fluoroscopic guidance for navigation. The device exit markers on the proximal end of the pusher wire indicate the initiation of fluoroscopic guidance.



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One Retrieval Device
One Introducer Sheath

INDICATIONS FOR USE

The ERIC Retrieval Device is indicated to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

CONTRAINDICATIONS

Patients with known hypersensitivity to nickel-titanium.
Patients with stenosis and/or pre-existing stent proximal to the thrombus site that may prevent safe recovery of the ERIC Retrieval Device.
Patients with angiographic evidence of carotid dissection.

CAUTION

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

Do not use if pouch is opened or damaged.

This device is intended 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.

After use, dispose in accordance with hospital, administrative and/or local government policy.

Do not use the ERIC Retrieval Device after the expiration date printed on the product label.

WARNINGS

The ERIC Retrieval Device should only be used by physicians who have received appropriate training in interventional techniques.

The ERIC Retrieval Device is provided sterile and non-pyrogenic. Do not use if the packaging is breached or damaged.

Appropriate anti-coagulation and anti-platelet therapy should be administered per standard medical practice.

Administer IV thrombolytic therapy as soon as possible for all patients who are indicated to receive the drug. Do not cause delays in this therapy. Refer to the IV thrombolytic therapy manufacturer labeling for indications, contraindications, warnings, precautions, potential complications, and instructions for use.

Verify the size of the vessel under fluoroscopy. Ensure that the ERIC Retrieval Device is appropriate for the size of the vessel. Do not oversize device.

Do not advance or withdraw the ERIC Retrieval Device when excessive resistance is observed. Assess the source of resistance using fluoroscopic means. If needed, resheath the ERIC Retrieval Device into the Microcatheter and remove the entire system under aspiration. If resistance is encountered during resheathing, stop resheathing and remove the entire system under aspiration.

Position the distal tip marker of Microcatheter just proximal to the retrieval spheres after deployment of the ERIC Retrieval Device and maintain the distal tip marker in the same position during withdrawal to reduce risk of device fracture.

Do not perform more than three (3) retrieval attempts in the same vessel using the ERIC Retrieval Device.

Do not apply excessive force to the distal tip of the ERIC Retrieval Device when cleaning the device for additional retrieval attempts.

Do not torque the ERIC Retrieval Device.

Ensure during cleaning of the ERIC Retrieval Device that all foreign components (e.g., clot, fibers) are fully removed before reinsertion.

PRECAUTIONS

Initiate mechanical neurothrombectomy as soon as possible.

Exercise care in handling the ERIC Retrieval Device to reduce the chance of accidental damage.
Use of other organic solvents may damage the ERIC Retrieval Device.

Carefully inspect the sterile package and the ERIC Retrieval Device prior to use to verify that neither has been damaged during shipment. Do not use kinked or damaged components.

Verify that the inner lumen of the Microcatheter is compatible with the ERIC Retrieval Device prior to use.

Verify ERIC Retrieval Device compatibility when using other ancillary devices commonly used in intravascular procedures. Physician must be familiar with percutaneous, intravascular techniques and possible complications associated with the procedure.

Use caution when manipulating the ERIC Retrieval Device in tortuous vasculature to avoid damage to the vasculature or the device. Avoid advancing or withdrawal against resistance until the cause of resistance is determined.

Presence of calcifications, irregularities, or other devices may damage the ERIC Retrieval Device and potentially affect its insertion or removal.

Maintain saline perfusion between the ERIC Retrieval Device and Microcatheter and Guiding Catheter and Microcatheter to prevent thrombus formation.

Exposure to angiographic and fluoroscopic X-radiation presents potential risks of alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia that increase in probability as procedure time and number of procedures increase.

Exercise necessary precautions to limit X-radiation doses to patients and operators by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors where possible.

POTENTIAL COMPLICATIONS

Potential complications include, but are not limited to: adverse reaction to platelet/anticoagulation agents or contrast media, air embolism, allergic reactions, angina, arrthymia, arteriovenous fistula, brain edema, coagulopathy, distal embolization including to a previously uninvolved territory, necrosis, nerve damage, pain, vascular occlusion, vision symptoms, vessel or aneurysm perforation, vasospasm, hematoma at the site of entry, embolism, ischemia, intracerebral/intracranial hemorrhage, pseudo aneurysm, seizure, stroke, infection, vessel dissection, thrombus formation, and death.

Please notify your MicroVention representative immediately if a device malfunction, patient complication or injury, or death is experienced or suspected. Please make every attempt to retain any suspect device, its associated components and their packaging for return to MicroVention.

COMPATIBILITY

ERIC Retrieval Device with a 3 mm diameter is compatible with a Microcatheter with an inner diameter of 0.017 inch (0.43 mm) or larger and a Guide Catheter with an inner diameter of 0.070 inch (1.78 mm) or larger. Compatibility testing was performed with the Headway™ 17 Advanced Microcatheter.

ERIC Retrieval Device with 4 mm and 6 mm diameter is compatible with a Microcatheter with an inner diameter of 0.021 inch (0.53 mm) or larger and a Guide Catheter with an inner diameter of 0.070 inch (1.78 mm) or larger. Compatibility testing was performed with the Headway 21 Microcatheter.

Refer to the labeling supplied with all interventional devices, materials, and products to be used in conjunction with the ERIC Retrieval Device for their indicated uses, contraindications, warnings, precautions, potential complications, and instructions for use.

Table 1: Product Specifications and Recommended Microcatheter and Guide Catheter Sizes

ERIC Retrieval Device Diameter	Working Length	Minimum Microcatheter Inner Diameter	Recommended Microcatheter[1]	Minimum Guide Catheter Inner Diameter	Radiopaque Markers		Push Wire Length	Maximum Length from Distal Tip to Fluorosafe Marker
3 mm (0.12 in.)	20 mm (0.79 in.)	0.017 in. (0.43 mm)	Headway 17 Advanced	0.070 in. (1.78 mm)	1 Distal	1 Proximal	203 cm (80 in.)	145 cm (57 in.)
4 mm (0.16 in.)	30 mm (1.18 in.)	0.021 in. (0.53 mm)	Headway 21					
6 mm (0.24 in.)	44 mm (1.73 in.)	0.021 in. (0.53 mm)	Headway 21					

[1]Compatibility testing has been performed with the recommended microcatheters.

The recommended patient vessel diameters for each ERIC Retrieval Device size are listed in Table 2.

Table 2: Recommended Device and Patient Vessel Diameters

ERIC Retrieval Device Diameter	Recommended Vessel Diameter	
	Minimum (mm)	Maximum (mm)
3mm	1.5	3.0
4mm	2.0	4.0
6mm	2.0	5.5

PREPARATION FOR USE

1. Administer anti-coagulation and anti-platelet medications per standard medical practice.
2. By performing angiography, determine the location and size of the target anatomy to be revascularized.
3. Select suitable Guiding Catheter for thrombus removal and navigate it to an appropriate place. Attach the rotating hemostatic valve (RHV) to proximal end of the Guiding Catheter and connect saline perfusion line to the side port of the RHV. Keep maintaining saline perfusion for the rest of procedure.
4. Choose the suitable ERIC Retrieval Device and remove the device by pulling it from the dispenser tube. Select appropriate Microcatheter.
5. Connect the RHV to proximal end of the Microcatheter. Attach saline perfusion line to the side port of the RHV. Keep maintaining saline perfusion for the rest of procedure.
6. Navigate the Microcatheter using a suitable Guidewire. Under Fluoroscopic guidance, advance the Microcatheter through the thrombus and tighten the RHV to fix the Microcatheter to the Guiding Catheter.

DELIVERY OF THE ERIC RETRIEVAL DEVICE

7. Insert the distal end of the Introducer Sheath into the RHV attached to the Microcatheter. Tighten the RHV around the Introducer Sheath and verify saline flushes back from the proximal end of the Introducer Sheath.

8. Loosen the RHV and advance the distal end of the Introducer Sheath until the distal end reaches the end of the hub of the Microcatheter. Tighten the RHV around the Introducer Sheath and make sure there is no bubble observed within the entire system.

9. Gently push the pusher wire of the ERIC Retrieval Device into the Microcatheter until the distal end of the pusher wire approaches to the proximal end of the Introducer Sheath. Loosen the RHV and remove the Introducer Sheath from the pusher wire and tighten the RHV around the pusher wire.

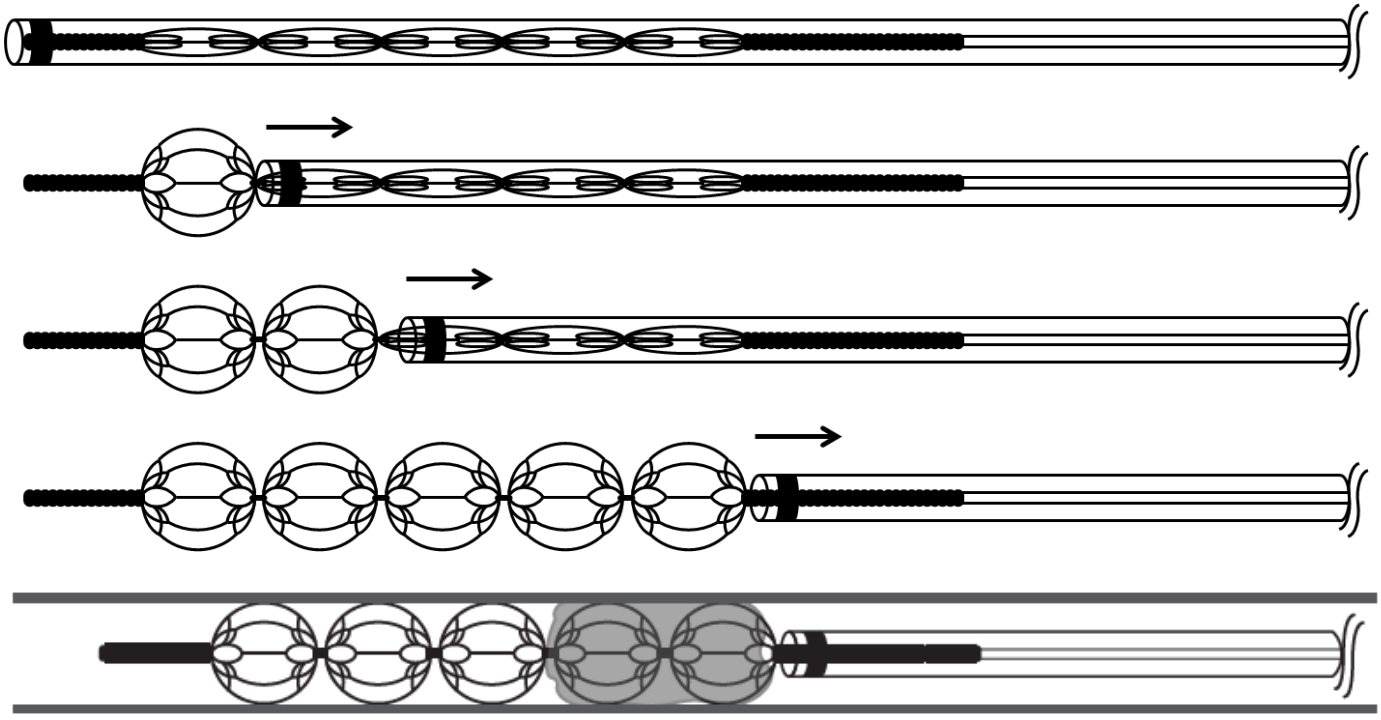
10. Keep pushing the pusher wire until the device exit marker approaches to the RHV. Fluoroscopic guidance must be initiated at this moment.

11. Carefully advance the ERIC Retrieval Device until the distal marker of the Microcatheter and the distal radiopaque tip of the ERIC Retrieval Device are aligned.
    Note: The distal radiopaque tip of the ERIC Retrieval Device is 5mm.
    WARNING: Do not advance the ERIC Retrieval Device when excessive resistance is observed. Assess the source of resistance using fluoroscopic means. The devices may be damaged and cause injury if the ERIC Retrieval Device is advanced.

DEPLOYMENT OF THE ERIC RETRIEVAL DEVICE

12. Position the proximal marker to align with the proximal interface of the thrombus to allow for the device to extend beyond the clot. Loosen the RHV around the Microcatheter. Withdraw the Microcatheter to deploy the ERIC Retrieval Device while maintaining the retrieval spheres in the same location. Refer to Figure below for device deployment.
    Note: Length of the distal tip is 5mm.

13. Once the ERIC Retrieval Device is fully deployed, place the distal tip of the Microcatheter close to the proximal end of the retrieval sphere. Tighten the RHV around the Microcatheter to fix the system.



RETRACTION OF THE ERIC RETRIEVAL DEVICE

14. Make sure that the distal tip of the Microcatheter is positioned just proximal to the retrieval spheres.
    WARNING: Maintain the distal tip marker in the same position during withdrawal to reduce risk of device fracture.

15. Loosen the RHV around the Microcatheter just enough to allow retraction of the Microcatheter while maintaining seal for aspiration.

16. Replace saline perfusion line with 60 cc syringe to the side port of the RHV at the proximal end of the Guiding Catheter. Make sure that the RHV maintains seal within the Guiding Catheter by applying aspiration using the 60 cc syringe. Adjust the RHV if necessary.

17. Start aspiration to the Guiding Catheter using the 60 cc syringe and slowly retract the ERIC Retrieval Device together with the Microcatheter to retrieve thrombus. While maintaining aspiration to the Guiding Catheter, continue retracting the ERIC Retrieval Device and the Microcatheter until the retrieval spheres arrive in the proximal end of the Guiding Catheter.
    WARNING: Do not withdraw the ERIC Retrieval Device when excessive resistance is observed. Assess the source of resistance using fluoroscopic means. If needed resheath the ERIC Retrieval Device with Microcatheter and remove the entire system under aspiration. If resistance is encountered during resheathing, stop resheathing and remove the entire system under aspiration.
    WARNING: Do not perform more than three (3) retrieval attempts in the same vessel using the ERIC Retrieval Device.

18. Open the RHV and remove the ERIC Retrieval Device and the Microcatheter from the Guiding Catheter.

19. Aspirate the Guiding Catheter to make sure inner lumen of the Guiding Catheter is clear from any thrombus.

20. Replace the 60 cc syringe with saline perfusion line to the side port of the RHV at the proximal end of the Guiding Catheter.

21. If additional retrieval attempts are desired with the same device, inspect the ERIC Retrieval Device for any damage. Do not use the same device if any damage is observed and use a new device. Clean the ERIC Retrieval Device using saline. Ensure during cleaning of the ERIC Retrieval Device that all foreign components (e.g., clot, fibers) are fully removed before reinsertion. Use extra caution when cleaning the distal tip of the ERIC Retrieval Device. Use a Microcatheter to navigate the ERIC Retrieval Device for subsequent retrieval attempts following the same steps from 1 through 20 above.
    WARNING: Do not perform more than three (3) retrieval attempts in the same vessel using the ERIC Retrieval Device.
    WARNING: Do not apply excessive force to the distal tip of the ERIC Retrieval Device when cleaning the device for additional retrieval attempts.

Clinical Studies

ETIS Study
ETIS is a prospective, multi-center, observational, Good Clinical Practice (GCP) compliant study conducted in France assessing the angiographic and clinical outcomes associated with the use of CE-marked thrombectomy devices [including the ERIC device, Trevo and Solitaire FR Revascularization Device (Solitaire)] that are intended to restore blood flow in patients experiencing acute ischemic stroke due to large intracranial vessel occlusion. This ongoing ETIS study was initiated in 2011 and has enrolled more than 14,000 subjects as of January 2022. The data presented in here represents an analysis population that is a subset of the ETIS study and includes all consecutive subjects treated by the ERIC device, Solitaire and Trevo at all 7 active sites from the beginning of the study to September 2018. The data analysis included the clinical, angiographic, and functional outcomes of two hundred six (N=206) patients treated with the ERIC device in comparison to N=1058 patients treated with Trevo or Solitaire. The angiographic and clinical outcomes demonstrate that the ERIC device performs similarly to the Trevo and Solitaire in terms of successful reperfusion rate and good clinical outcome (mRS 0-2) at 90 days based on available follow-up data in the two analysis groups. The ERIC device also exhibits a comparable safety profile, including similar rates of procedural complications, sICH, and 90-day all-cause mortality based on available follow-up data in the two analysis groups. One of the limitations of the ETIS study due to its design is the number of subjects with missing data; therefore, the conclusions made from the ETIS study in support of this 510(k) are based on subjects with available follow-up data in both analysis groups.

All patients were selected for endovascular thrombectomy based on evaluation by a multi-disciplinary team of physicians including neuroradiologists and neurologists. Selection included patients with acute ischemic stroke (AIS), in relation to an occlusion of a large caliber intracranial artery of the anterior circulation, visible in imaging within a period of 6 hours after the onset of symptoms, either initially in combination with intravenous thrombolysis (IVT), or as recourse technique: after failure of treatment with IVT, or alone in case of contraindication to IVT. Both arms of the study included the use of thrombolytics. The ETIS study was conducted in accordance with the GCP guidelines and applicable regulatory requirements (FR, ICH E3-E6, ISO14155).

Inclusion Criteria

1. Age 18 and older (i.e., candidates must have had their 18th birthday)
2. Neuroimaging demonstrates acute ischemic stroke in a large vessel indicated for use with neurothrombectomy devices intended to restore blood flow
3. No upper or lower limits of the neurological severity at baseline (NIHSS)
4. With or without intravenous thrombolysis
5. Oral informed consent (patient and/or trustworthy person)

Exclusion Criteria

1. Pregnant or breast-feeding women
2. Patient benefiting from a legal protection
3. Non-membership of a national insurance scheme

Study Results

The study assessed the efficacy and safety of the ERIC Retrieval Device using marketed devices used in usual clinical practice in comparison to the predicate device, Trevo XP ProVue, and reference device, Solitaire. The study results are shown in tables below.

Table 3: ETIS Study Outcomes: ERIC vs Trevo/Solitaire Cohort

ETIS Study Results	ERIC Device Cohort (N=206)		Trevo/Solitaire Cohort (N=1058)	
	n/N	Value [Rate (CI)]	n/N	Value [Rate (CI)]
Primary Effectiveness Outcome				
Successful reperfusion at end of procedure (mTICI 2b-3)	166/202	82.2% (76.9-87.5%)	842/1044	80.7% (78.2-83.1%)
Primary Safety Outcome				
Occurrence of sICH within 24h-48h*	7/169	4.1% (1.1-7.2%)	81/965	8.4% (6.6-10.2%)

*59 ERIC-treated patients and 37 Trevo/Solitaire patients without follow-up CT scan/MRI due to absence of symptoms (per site hospital usual care) were treated as absence of symptomatic intracerebral hemorrhage. The number of missing patients without follow-up CT/MRI in the ERIC-treated group is proportionally higher than the number of missing patients without follow-up CT/MRI in the Trevo/Solitaire-treated group. Therefore, the occurrence of sICH within 24-48 hours with the ERIC-treated patients could be higher than the confidence intervals presented in this table.

The primary effectiveness outcome results generated by treating the subjects with rescue mechanical thrombectomy device after failure of the primary intended device to achieve mTICI 2b or greater and missing subjects as failures are shown below.

Table 4: Primary Effectiveness Endpoint (mTICI 2b-3) – ERIC Device vs Trevo/Solitaire: Use of Rescue Mechanical Thrombectomy Device Considered Treatment Failure

Primary Effectiveness Endpoint	ERIC (N=206)		Trevo/Solitaire (N=1058)	
	n/N	Value	n/N	Value
Successful reperfusion at end of procedure (mTICI 2b-3)*	130/206	63.1%	639/1058	60.4%

*The effectiveness outcomes were considered as failures for missing subjects as well as those subjects with use of rescue mechanical thrombectomy device.

The secondary outcome for good clinical outcome (90-day mRS 0-2) is shown in the table below. The results of this analysis demonstrate that the 90-day mRS of the ERIC arm and the control arm are substantially equivalent based on available follow-up data.

Table 5: Secondary Outcome (90-day mRS) - ERIC vs Trevo/Solitaire

Secondary Outcome	ERIC (N=206)		Trevo/Solitaire (N=1058)	
	n/N	Value	n/N	Value
Good Clinical Outcome (90-day mRS 0-2)	67/136	49.3% (40-57.7%)	413/919	44.9% (41.7-48.2%)

Comparison of the primary safety and effectiveness outcomes and secondary outcome for the ERIC cohort versus the Trevo/Solitaire cohort from the ETIS study demonstrated that the ERIC device is substantially equivalent to the predicate device.

The procedural complications observed in the study are shown in Table 6 based on subjects in the ERIC device cohort and the Solitaire/Trevo cohort with available safety data within 24-48 hours post-procedure.

Table 6: Procedural Complications

ETIS Study Results	ERIC Device Cohort (N=206)		Solitaire/Trevo Cohort (N=1058)	
	n/N	Rate	n/N	Rate
Emboli in new territory	13/203	6.4%	62/999	6.2%
Dissection	1/203	0.05%	21/999	2.1%
Perforation	5/203	2.5%	19/999	1.9%
Vasospasm	4/203	2.0%	49/999	4.9%
Puncture site hematoma	2/203	1.0%	3/999	0.3%
Gas emboli (probable)	1/203	0.05%	0/999	0%
Additional hemorrhagic complication potentially due to SAH of traction	0/203	0%	1/999	0.1%
Cardiogenic shock with inhalation	0/203	0%	1/999	0.1%
Femoral access failure	0/203	0%	1/999	0.1%
Emesis	0/203	0%	1/999	0.1%
Hemodynamic instability	0/203	0%	1/999	0.1%
Iatrogenic clot	0/203	0%	1/999	0.1%

STORAGE

Avoid exposure to water, sunlight, extreme temperatures and high humidity during storage. Store the ERIC Retrieval Device under controlled room temperature. See the product label for the device shelf life. Do not use the device beyond the labeled shelf life.

MATERIALS

The ERIC Retrieval Device is not manufactured with natural rubber latex, synthetic latex, or polyvinylchloride (PVC).

SYMBOLS

REF	Catalog Number	Rx ONLY	For Prescription Use Only
CONTENTS	Contents	LOT	Lot Number
UDI	UDI		Manufacturer
	Caution	MD	Medical Device
	Consult instructions for use		Non-Pyrogenic
	Date of Manufacture		Single Sterile barrier system with protective packaging outside
	Do Not Reuse	STERILE R	Sterilized Using Irradiation
	Do not use if packaging is damaged and consult instructions for use		Use-by Date

WARRANTY

MicroVention, Inc. 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. 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 and MicroVention shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this device, through its expiration date. 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.

IFU100054B

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IFU100054 Rev. B
Revised 2023-01