NeuroVasc TECHNOLOGIES

eNVi™-SR

Retriever for Mechanical Thrombectomy

Articulating Segmented Design

Unique articulating segmented design resists Retriever collapse when retrieving in tortuosity, leading to better clot retention vs non segmented designs during in vitro testing[1]

- Segmented clot retriever, designed to remain open under tension when retracting thereby improving clot retention[1,2]
- Tapered softness
- Designed for navigating and delivering through tight siphons and cervical loops in the ICA and MCA tortuosity
- 3mm eNVi™-SR compatible with .0165 inch microcatheters
- Based on the segmented design of the versi retriever for mechanical thrombectomy

- Articulating segments expand under tension
- Retriever working length and body markers for precision placement
- Full range of sizes available from 3mm x 10mm to 5mm x 55mm

3mm x 20mm

4mm x 25mm

5mm x 55mm

Unique Articulating Segmental clot retriever designed to remain open under tension when retracting thereby improving clot retention[2,3]

3mm Retriever Microcatheter Compatibility [2,4]

Compatible with microcatheters with an inner diameter of .0165 inch (0.42mm) or larger.

Non-clinical compatibility testing performed with:

- Stryker Excelsior® SL-10®
- Medtronic (ev3) Echelon™ 10/14 150cm
- NeuroVasc Technologies **ENVOKE™** 017

4mm & 5mm Retriever Microcatheter Compatibility [2,4]

Compatible with microcatheters with an inner diameter of .021 inch (0.53mm) or larger

Non-clinical compatibility testing performed with:

- Medtronic (ev3) Rebar™ 18 153cm
- NeuroVasc Technologies **ENVOKE™** 021

- Articulating Segments Expand under tension
- Marker to Identify Working Length[1]
- All sizes provided with Extension Wire for microcatheter removal[2]
- Full range of sizes available

Sizes available:
3mm x 10mm to
5mm x 55mm

[1] *TR18-003*
[2] *TR18-001*
[3] *Kaneko N, Komuro Y, Yokota H, et al. J NeuroIntervent Surg. 2019;11:119–122. Testing per Kaneko et. al. refers to the Versi Retriever. Articulating segmental design is substantially similar between the Versi Retriever and ENVI-SR Retriever.*
[4] *TR20-003*

Pending FDA Clearance, Not Available for Sale in the United States.
Instructions for use can be found in the product labeling supplied with each device.

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EC REP
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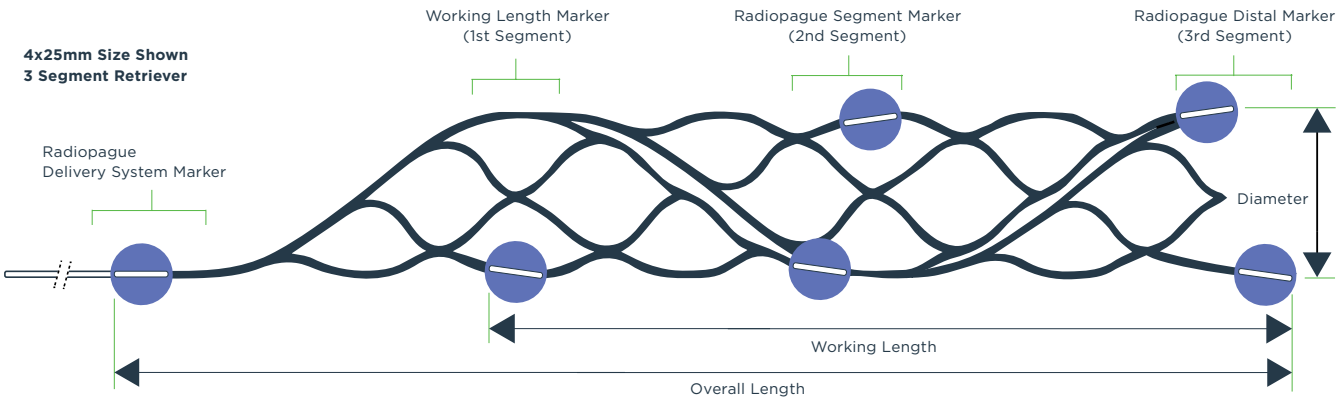
CE 0297

eNVi™-SR RETRIEVER FOR MECHANICAL THROMBECTOMY



System Specifications

eNVi™-SR Diameter x Length (mm)	Ordering Reference	Retriever Information				Recommended Vessel Diameter (mm)		Min Microcatheter ID
		Retriever Segments	Expanded Device Diameter (mm)	Working Length (mm)	Overall Length (mm)	Min.	Max.	
3mm x 10mm	**FG-004-001**	1	3.5mm	10mm	15mm	1.5mm	3.0mm	0.0165 inch
3mm x 15mm	**FG-004-002**	2	3.5mm	15mm	25mm			
3mm x 20mm	**FG-004-003**	3	3.5mm	20mm	30mm			
4mm x 25mm	**FG-004-014**	3	5.0mm	25mm	40mm	2.0mm	4.0mm	0.021 inch
4mm x 35mm	**FG-004-016**	4	5.0mm	35mm	50mm			
4mm x 45mm	**FG-004-018**	5	5.0mm	45mm	60mm			
5mm x 30mm	**FG-004-035**	3	6.0mm	30mm	45mm	2.5mm	5.0mm	
5mmx 40mm	**FG-004-037**	4	6.0mm	40mm	55mm			
5mm x 55mm	**FG-004-039**	5	6.0mm	55mm	70mm			

INTENDED USE

The eNVi™-SR is intended for use 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 IV tPA or who fail IV tPA therapy are candidates for treatment.

DEVICE DESCRIPTION

The eNVi™-SR is a self-expanding, nitinol stent-like mechanical thrombectomy device that is designed to be delivered to the neurovasculature through a microcatheter to retrieve thrombus. The eNVi™-SR is intended to restore blood flow in patients experiencing acute ischemic stroke.

COMPATIBILITY

The eNVi™-SR 3mm Retrievers are compatible with microcatheters with an inner diameter of 0.0165 inch (0.42mm) or larger.

The eNVi™-SR 4mm and 5mm Retrievers are compatible with microcatheters with an inner diameter of 0.021 inch (0.53mm) or larger.

POTENTIAL COMPLICATIONS

Possible complications of the use of the eNVi™-SR include, but are not limited to: adverse reaction to antiplatelet/anticoagulation agents or contrast media, air embolism, arteriovenous fistula, change in mental status, death, device deformation, collapse, fracture, or malfunction, distal embolization including to a previously uninvolved territory, hematoma and hemorrhage at puncture site, infection, intracranial hemorrhage, ischemia, neurological deficits, neurological deterioration including stroke and death, perforation or dissection of vessel, post procedural bleeding, pseudo aneurysm formation, thrombosis, vascular occlusion, and vessel spasm.

WARNINGS

- Do not use if damage to the device is observed.
- Do not use if the product sterile barrier system or its packaging is compromised.
- Do not resterilize and/or re-use in multiple patients. Structural integrity, sterility and/or function may be impaired by resterilization or re-use.
- To reduce risk of device damage, vessel damage, and/or patient injury:
  - Select the appropriate eNVi™-SR based on the vessel size to be revascularized
  - Do not perform more than 3 revascularization attempts in the same vessel.
  - Do not deliver and retrieve the eNVi™-SR more than 3 times.
  - Do not torque the eNVi™-SR.
  - Monitor eNVi™-SR positioning in vessel during exchange to prevent movement.
  - Do not pull the eNVi™-SR through a pre-existing stent or entanglement and vessel damage may occur.

PRECAUTIONS

- Carefully read these directions before using this product. Observe warning and safety precautions.
- For each new Retriever, use a new microcatheter.
- The appropriate anti-platelet and anti-coagulation therapy should be administered in accordance with standard medical practice.
- The eNVi™-SR should only be used by physicians experienced in angiographic and percutaneous neurointerventional procedures.
- Use device prior to Use-by date printed on label.
- Prevent exposure to temperatures in excess of 60°C. Exposure to temperatures above this temperature may damage device and accessories. Do not autoclave.
- To prevent thrombus formation and contrast media crystal formation, maintain a constant infusion of appropriate flush solution between guide catheter and microcatheter and between the microcatheter and the Retriever or guidewire.
- Caution: Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician.

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