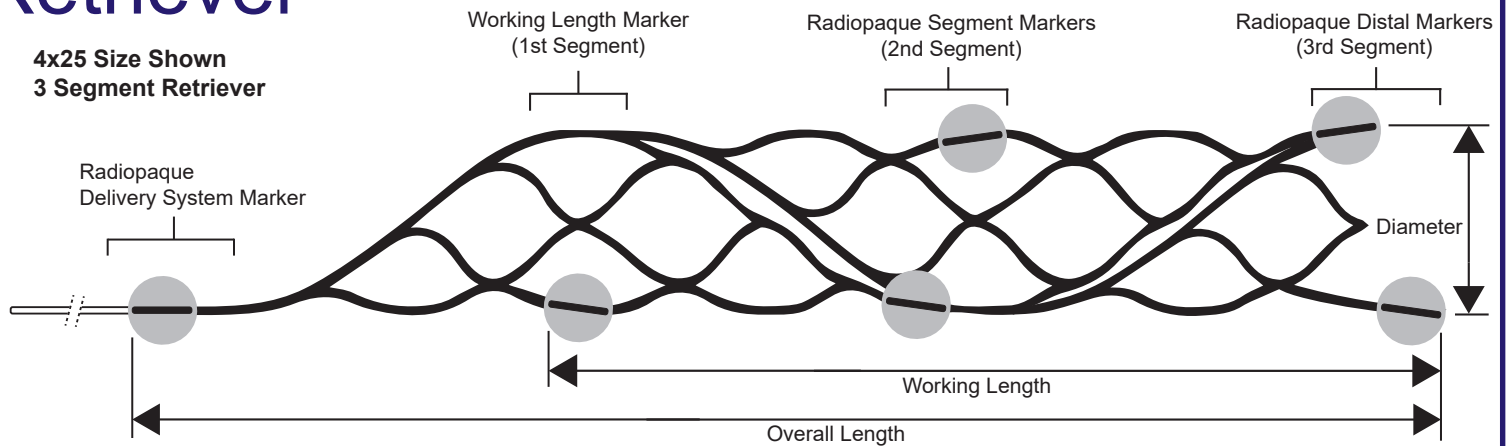


TECHNICAL BROCHURE

Envi™-SR Retriever for Mechanical Thrombectomy

Retriever

**4x25 Size Shown
3 Segment Retriever**



System Specifications

Envi™-SR Labeled Sizing Diameter x Length (mm)	REF	Retriever Information				Recommended Vessel Diameter (mm)	
		Retriever Segments	Expanded Device Diameter (mm)	Working Length (mm)	Overall Length (mm)	Min.	Max.
3x10	FG-004-001	1	3.5	10	15	1.5	3.0
3x15	FG-004-002	2	3.5	15	25		
3x20	FG-004-003	3	3.5	20	30		
4x25	FG-004-014	3	5.0	25	40	2.0	4.0
4x35	FG-004-016	4	5.0	35	50		
4x45	FG-004-018	5	5.0	45	60		
5x30	FG-004-035	3	6.0	30	45	2.5	5.0
5x40	FG-004-037	4	6.0	40	55		
5x55	FG-004-039	5	6.0	55	70		

Envi™-SR Retriever for Mechanical Thrombectomy

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.

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.

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.

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.

Ordering Information

Labeled Size (mm)	REF	Description
3x20	FG-004-003	Envi™-SR 3x20
4x25	FG-004-014	Envi™-SR 4x25
4x35	FG-004-016	Envi™-SR 4x35
4x45	FG-004-018	Envi™-SR 4x45
5x40	FG-004-037	Envi™-SR 5x40

Specialty Sizes (Available by special request)

Labeled Size (mm)	REF	Description
3x10	FG-004-001	Envi™-SR 3x10
3x15	FG-004-002	Envi™-SR 3x15
5x30	FG-004-035	Envi™-SR 5x30
5x55	FG-004-039	Envi™-SR 5x55



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