Overview of Newer Stent Devices for Aneurysm Treatment

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Disclosure

- Outcome adjudication for THERAPY, Penumbra

FDA Pathways

- Premarket Notification (510[K]): may allow device to go to market if “substantially equivalent” to previously marketed devices
- Pre-market Approval (PMA): Efficacy trial required
  - Investigational Device Exemption (IDE): allows use in clinical trials
- Humanitarian Device Exemption (HDE): Only for rare diseases (<4,000 cases per year). Only requires demonstration of safety. Local IRB approval and monitoring required.

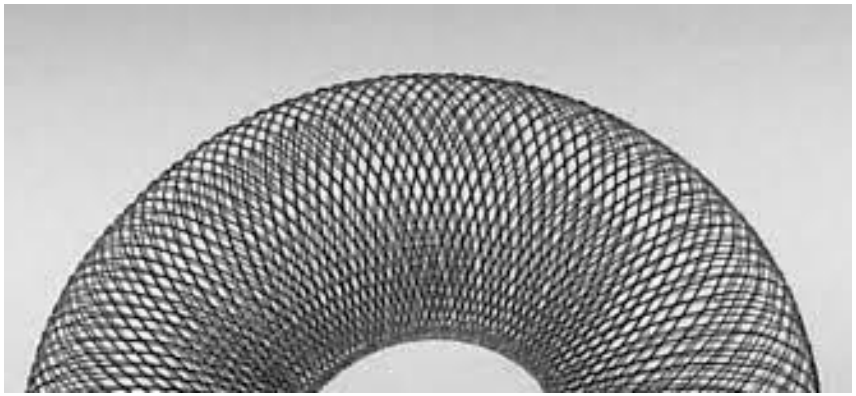
WARNING

- Most devises presented are investigational.
- Seeking HDE or PMA approval.
- Some slides/images graciously provided by industry

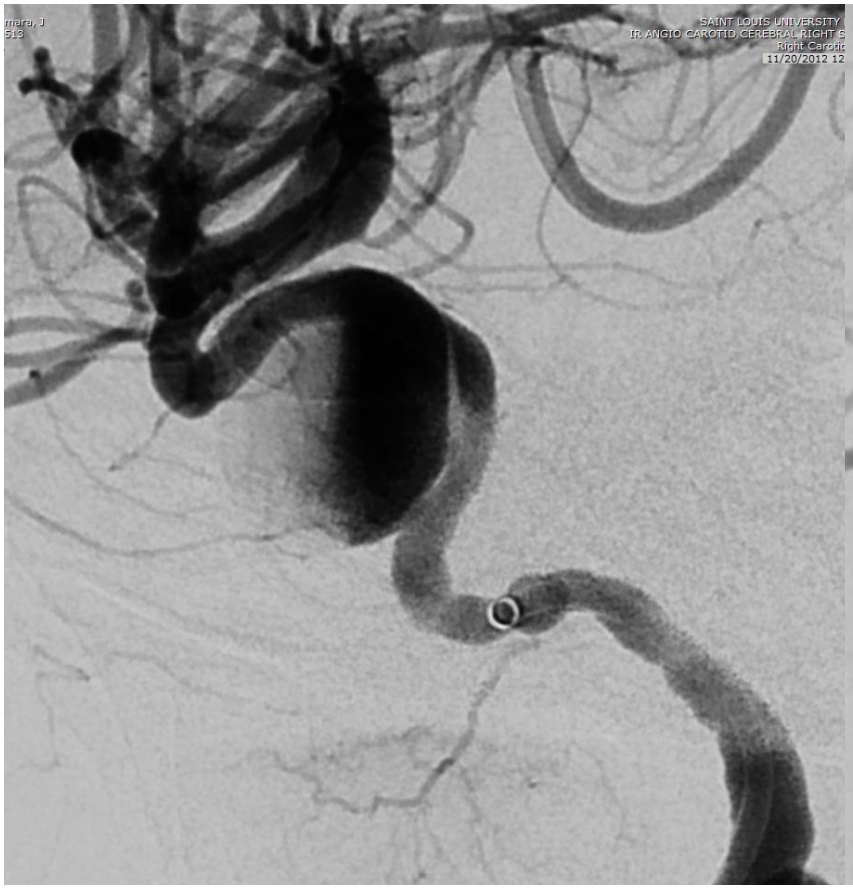
Flow Diverting Stents

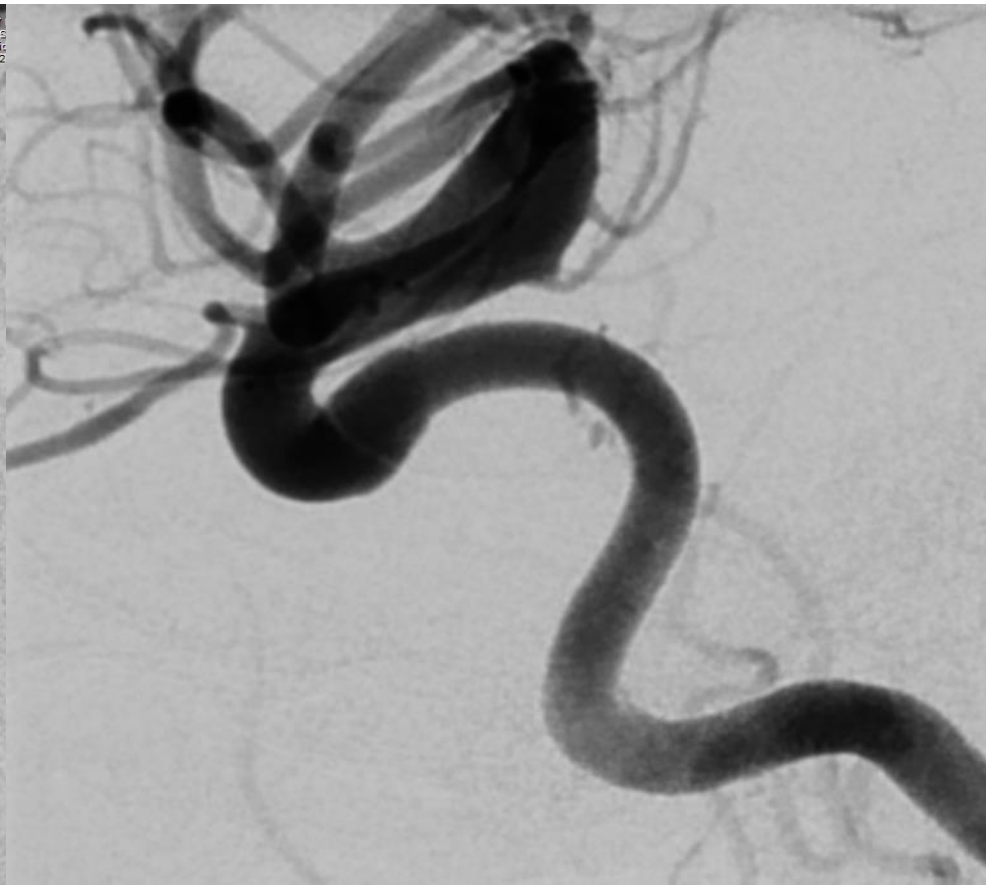
Pipeline™ Embolization Device(Covidien)

- 30-35% surface coverage at nominal diameter
- 48-strand braided mesh
- 75% cobalt chromium/25% platinum tungsten
- Scaffolding for endothelial repavement
- Branch vessels preserved



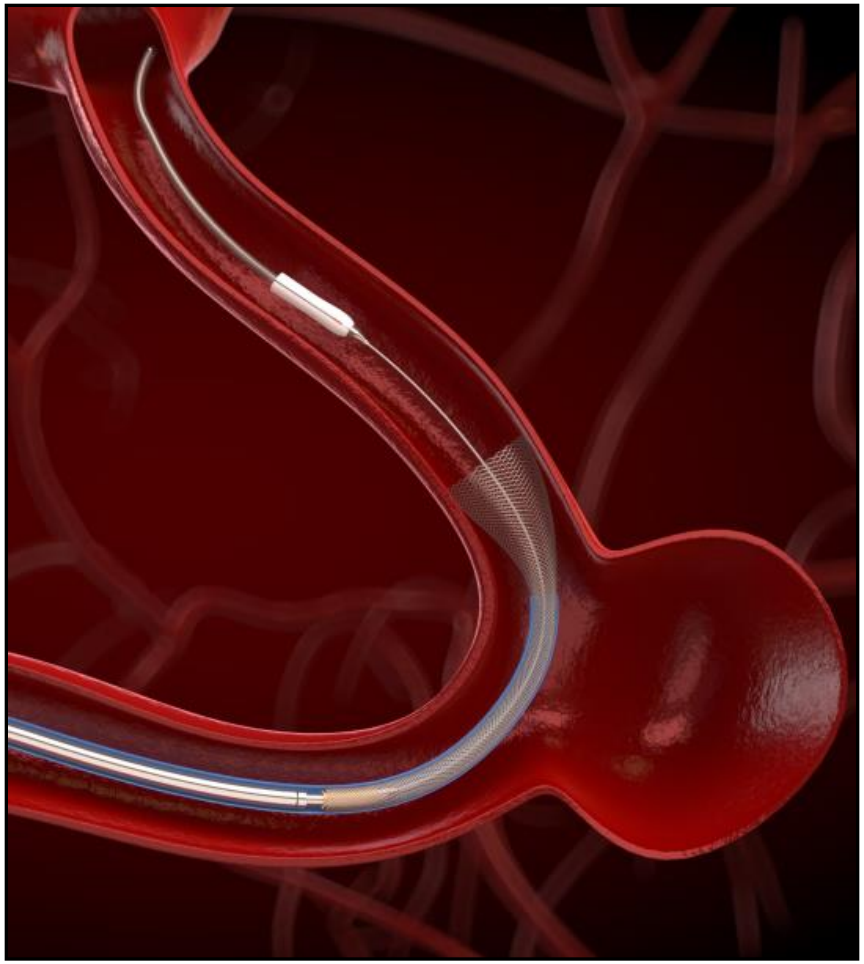
Pipeline™ Embolization Device(Covidien)





Pipeline™ Flex Embolization Device(Covidien)

Investigational

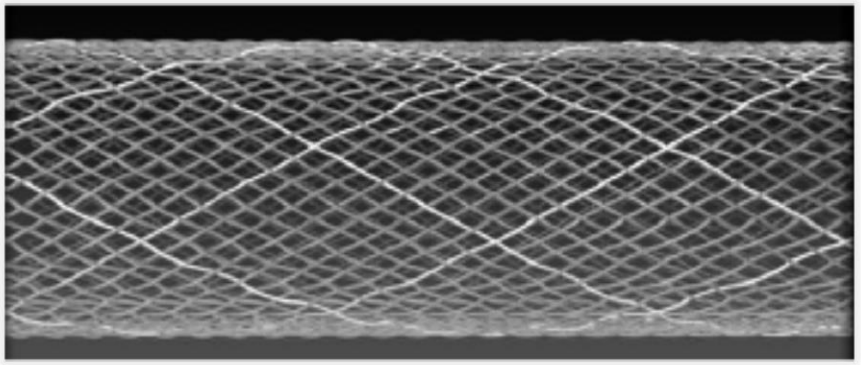


- Improved delivery systemt
- New distal wire
- Resheathable
- No protective coil

Surpass™ Flow Diverter (Stryker)

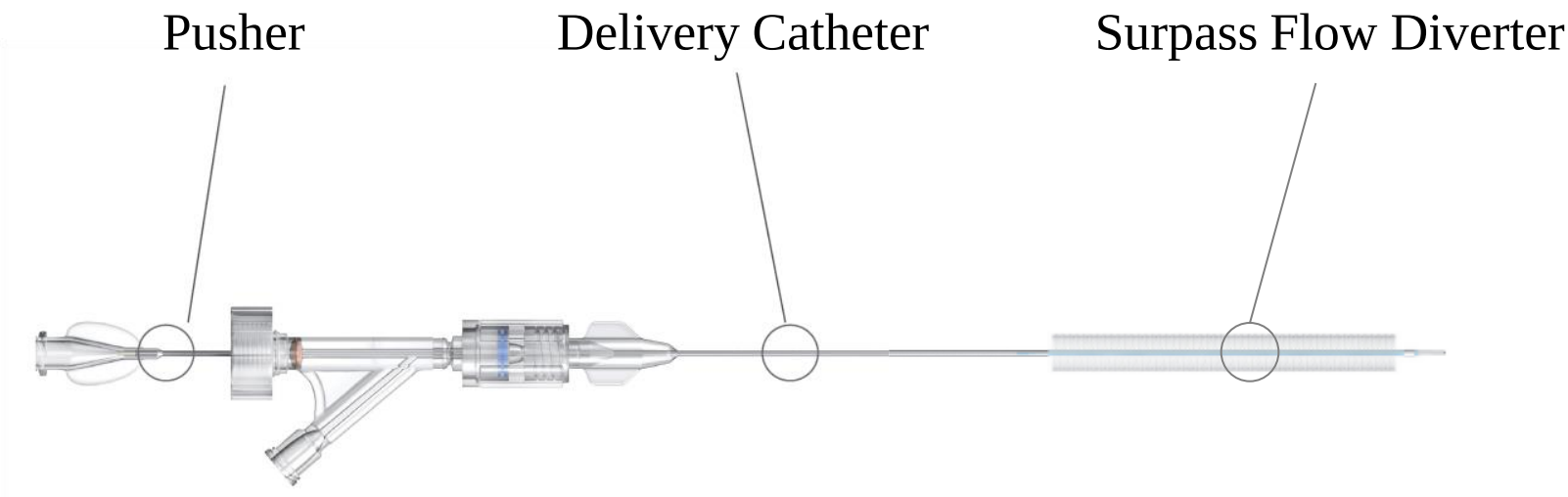
Investigational

- High pore density (72-wire & 96-wire braids)
- Long lengths (15mm to 50mm)
- 3mm, 4mm, 5mm diameters



Investigational

Surpass™ Flow Diverter (Stryker)

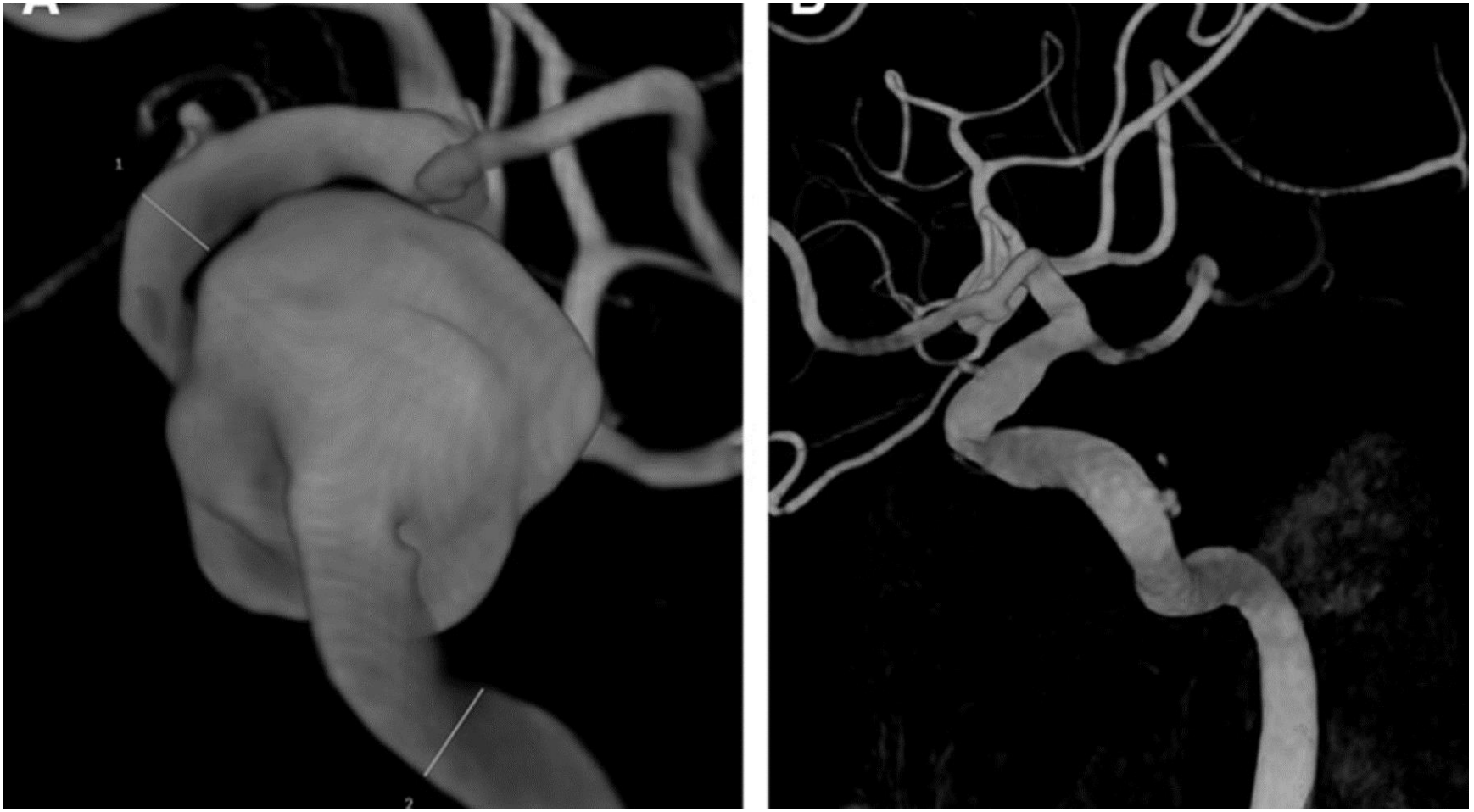


Description	Statistics
Number of Pts/Aneurysms Successfully Treated	**161/186**
Average Number of Devices/Aneurysm	1.05
Aneurysm Location	Anterior (ICA) = 63.4% (118/186)
	Anterior (Distal to Willis) = 22.0% (41/186)
	Posterior Circulation = 14.5% (27/186)
Number of Pts Available for Safety/Clinical Follow-up (at 6Mo)	**150 (Anterior = 123; Posterior = 27)**
Primary Endpoint (any stroke and neurologic death)	12.0% (18/150)
Anterior Circulation	5.7% (7/123)
Posterior Circulation	14.8% (4/27)
Permanent Morbidity	6.0% (9/150)
Procedure-Related Mortality	2.7% (4/150)
Anterior Circulation	1.6% (2/123)
Posterior Circulation	7.4% (2/27)
Patients with Perforator Occlusion	0.7% (1/150)
Aneurysms Available for DSA Follow-up (at 6Mo)	**84.9% (158/186)**
Compete Occlusion	74.7% (118/158)
Anterior Circulation (ICA); Anterior Circulation (Distal to Willis)	78.6% (77/98); 65.8% (25/38)
Posterior Circulation	72.7% (16/22)
Near Complete Occlusion (>95%) or Complete Occlusion	80.4% (127/158)

Surpass Flow Diverter in the Treatment of Intracranial Aneurysms: A Prospective Multicenter Study.
A.K. Wakhloo, et al. for the Surpass Study Group (AJNR Am. J. Neuroradiol. 2014 : ajnr.A4078v1-0.)

Surpass™ Flow Diverter (Stryker)

Investigational



De Vries J et al. Stroke. 2013;44:1567-1577

SCENT Trial

The Surpass IntraCranial Aneurysm EmbolizatioN System Pivotal Trial to Treat Large or Giant Wide Neck Aneurysms

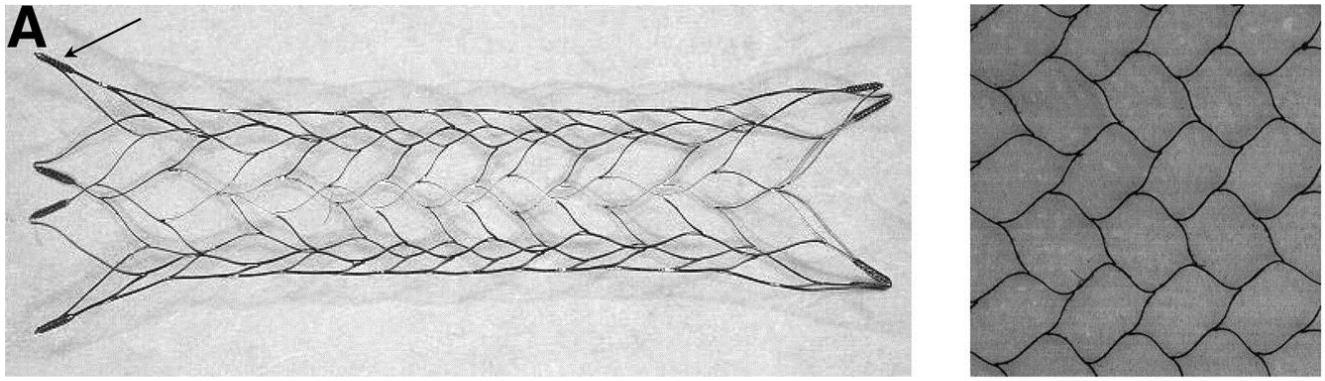
- Multi-center (23 US sites)
- Single-arm
- Prospective
- Non-randomized
- PMA trial

For patients that have a single targeted intracranial aneurysm that:

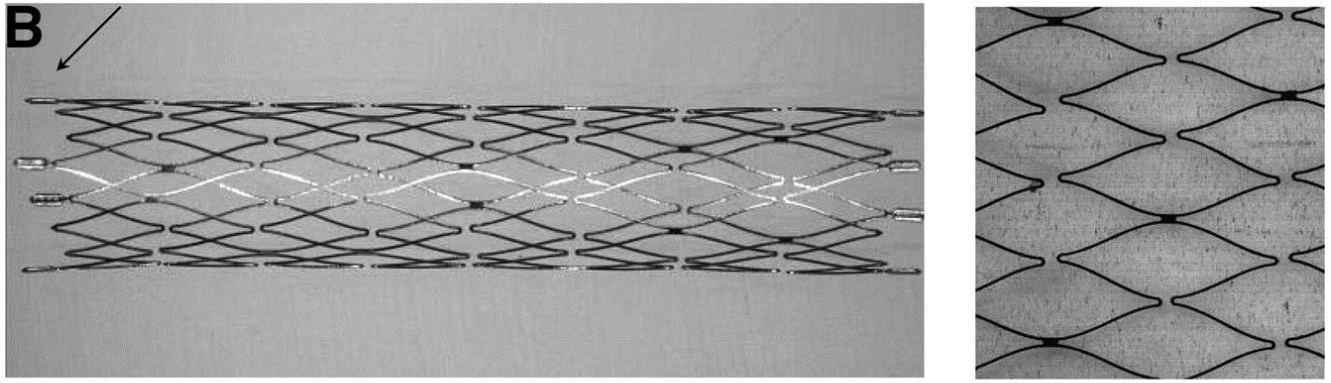
- Is located in the internal carotid artery (ICA) distribution **up to the terminus**
- Has a neck >4 mm or no discernible neck and an aneurysm size >10 mm (including saccular, fusiform and dissecting configuration)

Aneurysm Scaffold Devices

Current Aneurysm Stents Embody 12 Year Old HDE Technology



Enterprise - Closed Cell Design

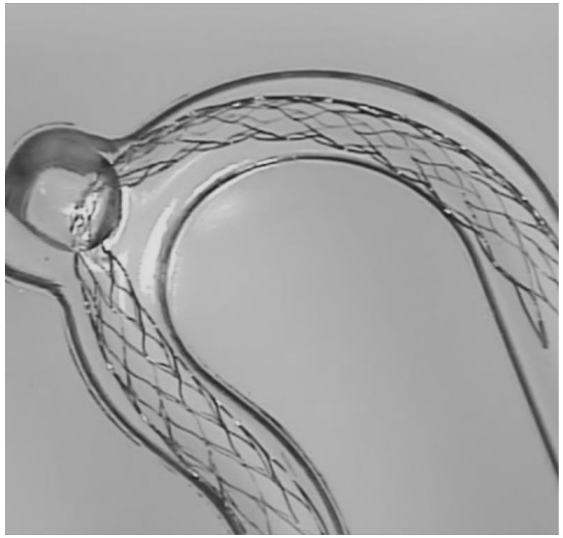


Neuroform - Semi-open Cell Design

Stroke. 2009; 40: e305-e312

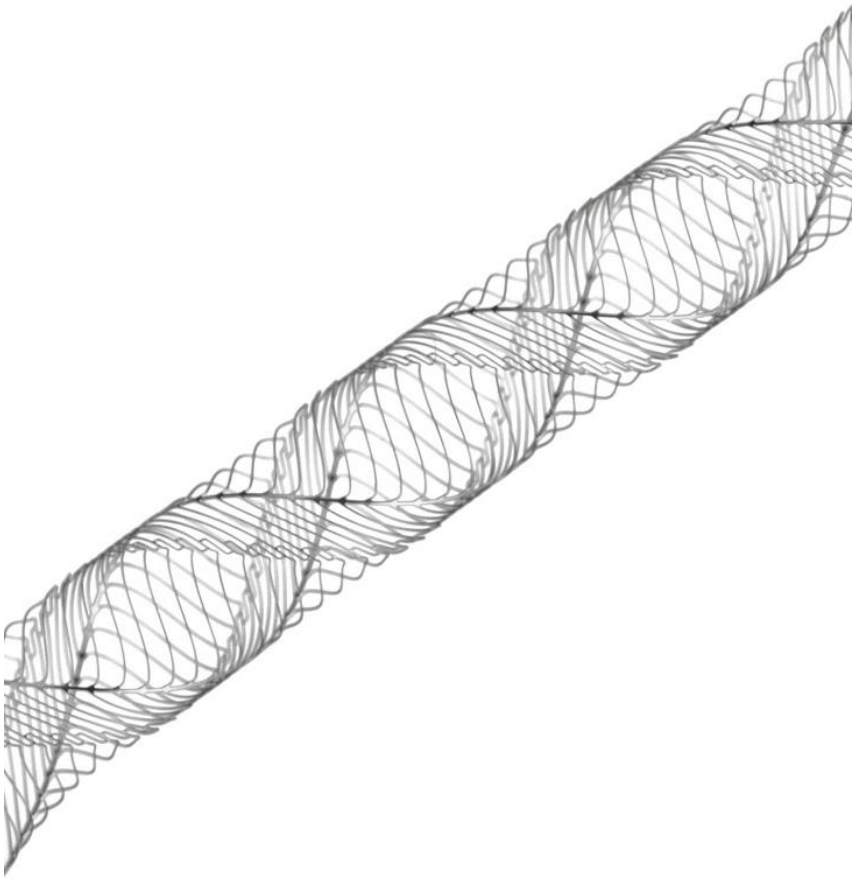
Common Goals

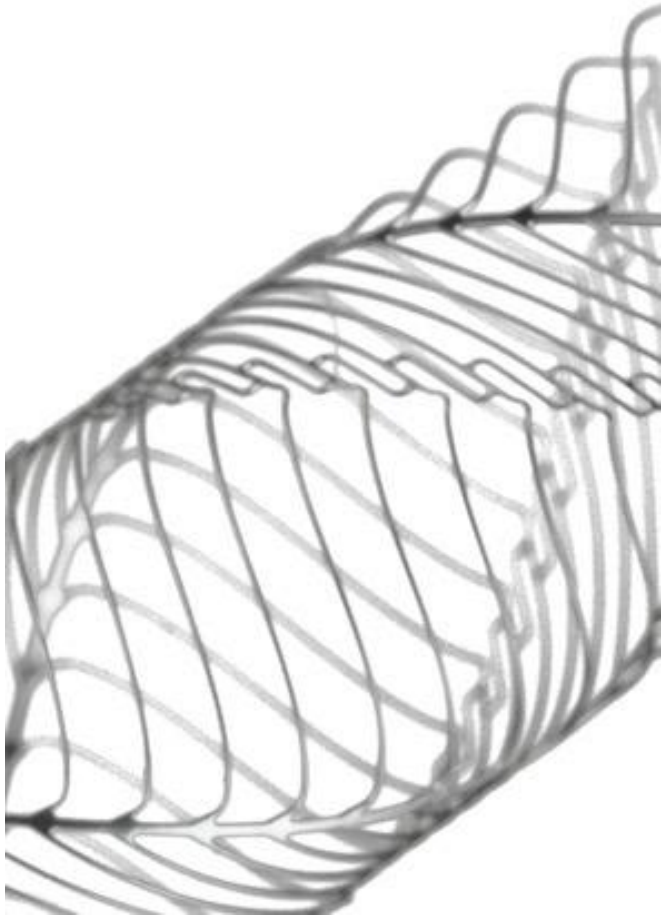
- Improved wall apposition
- Increased surface area coverage
- Resheathable
- Deliverable through standard coiling catheters
- PMA not HDE approval pathway



Liberty™ Stent System (Penumbra)

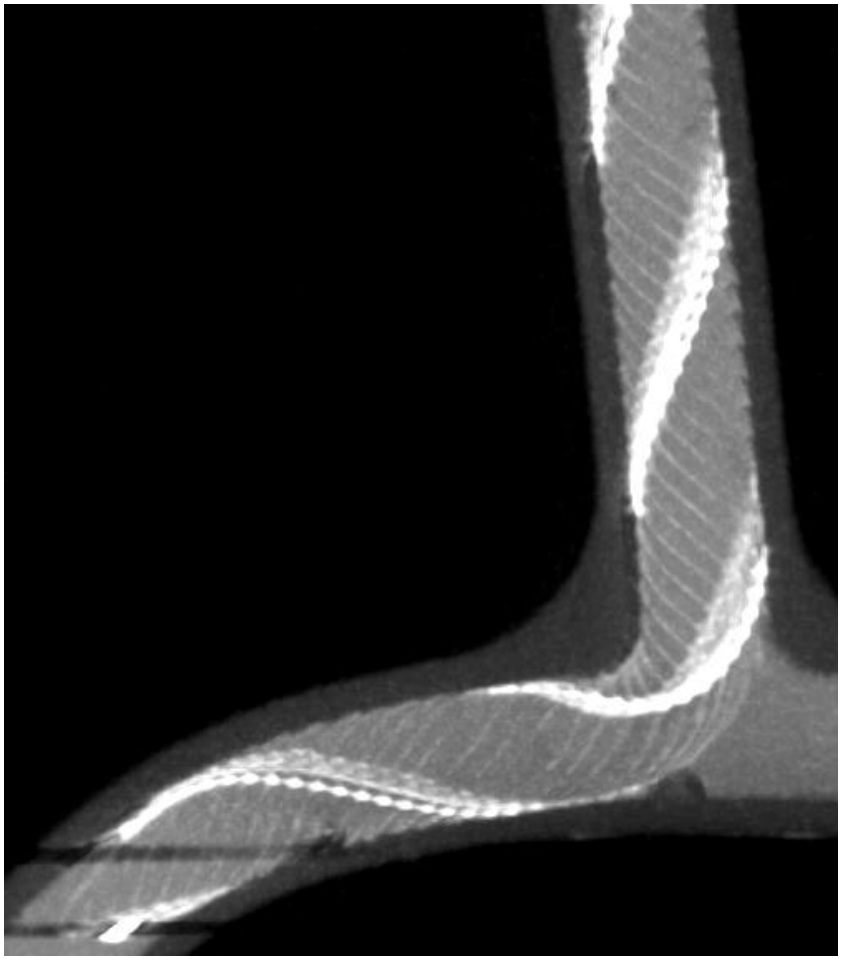
Investigational





Investigational

Liberty™ Stent System (Penumbra)



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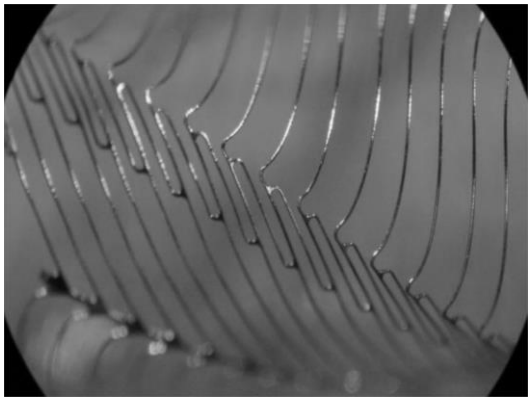
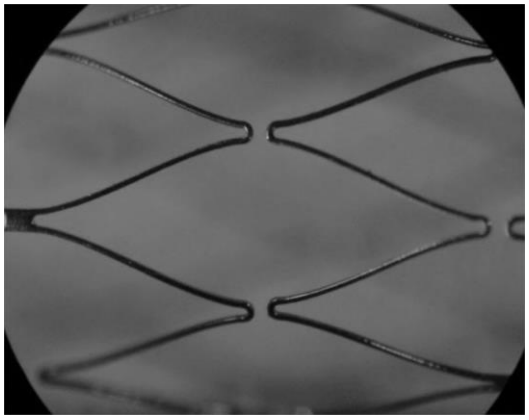
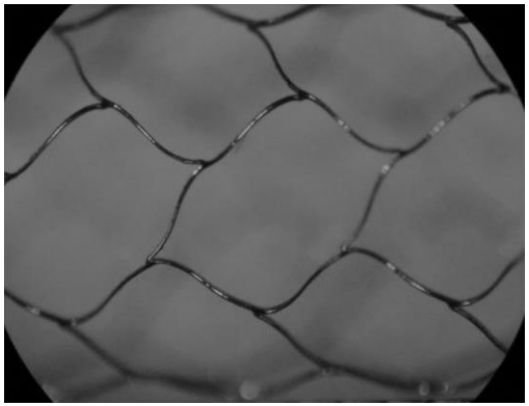






Stent	Approximate Coverage
Neuroform, Enterprise	6%
Liberty	15%
Pipeline, Silk	30%

Investigational

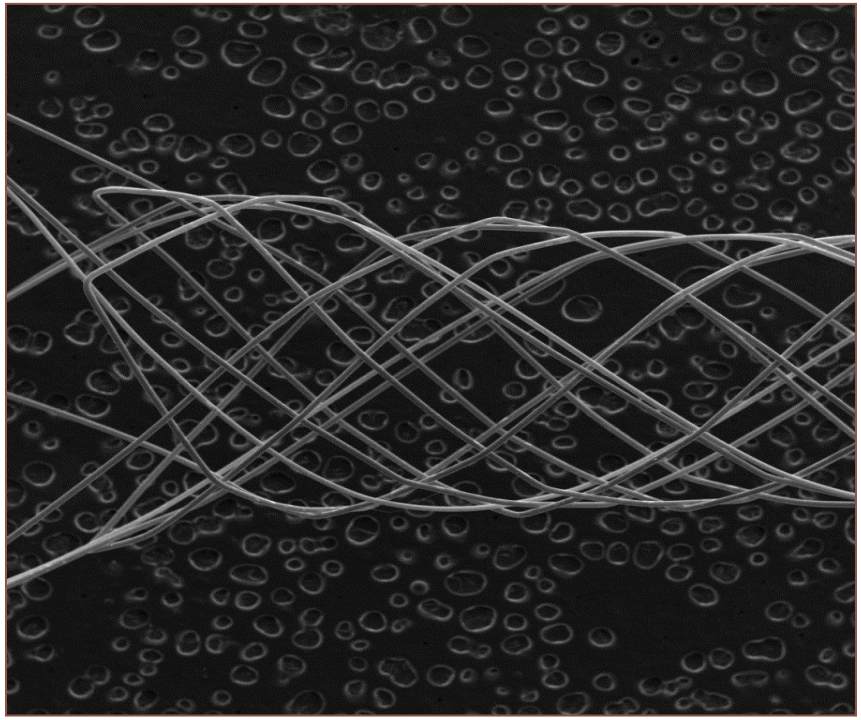
Liberty Clinical Trial Pathway

- Premarket Approval Pathway
- Single Arm Trial, 120 patients
- ICA Aneurysms only (per FDA guidance)
- Primary Endpoint: Complete occlusion (Raymond Scale 1) at 6 months without rupture, retreatment or parent artery compromise.

LVIS® Device Key Features (Microvention)

Investigational

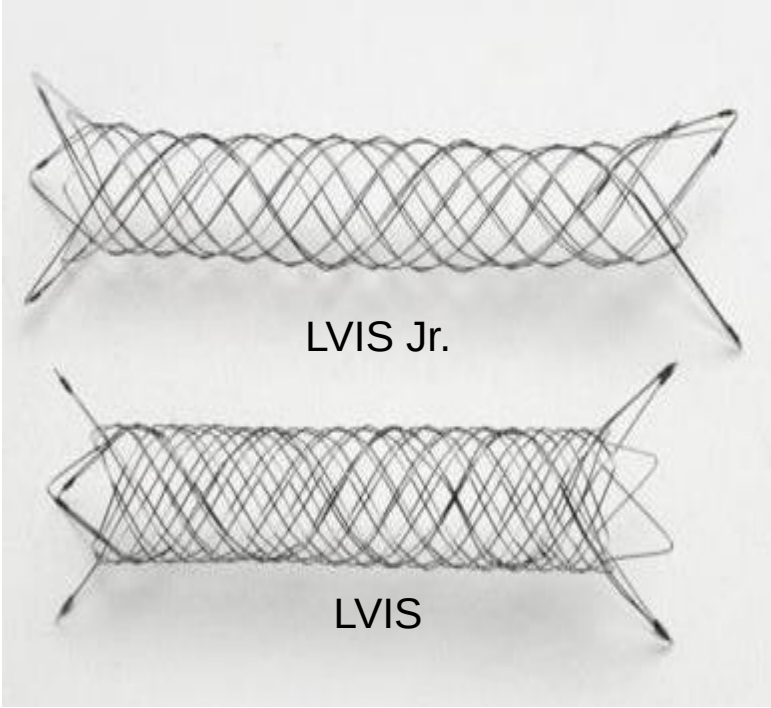
- Braided design
- Increased visibility
- Deliverable through Scepter Balloon
- LVIS®
- LVIS Jr. ®
- PMA trial ongoing



LVIS vs. LVIS Jr. Device Comparison

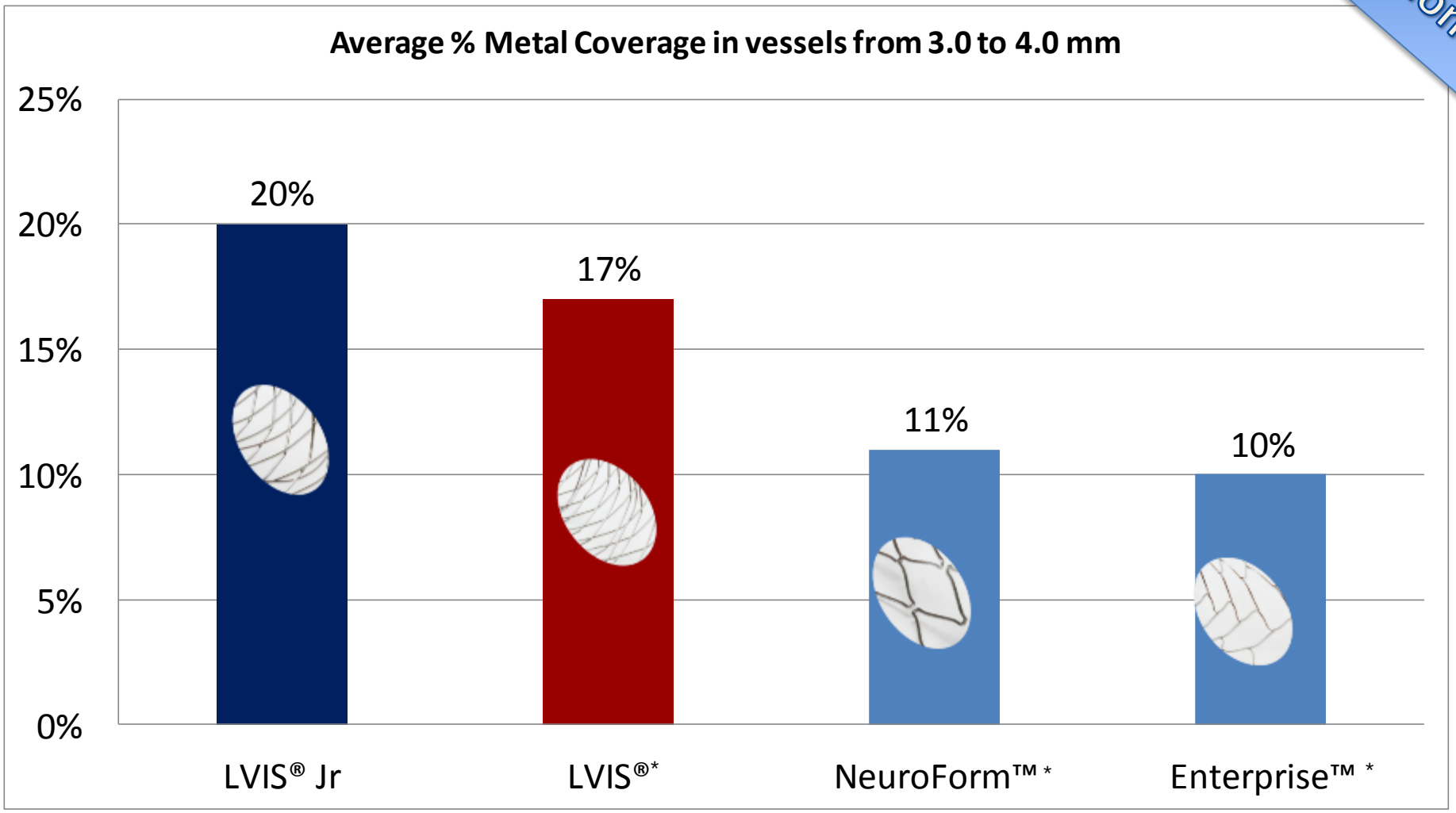
Investigational

Attribute	LVIS	LVIS Jr.
No. of wires	16	12
Implant Material	Nitinol	Nitinol
RO Material	Tantalum	Tantalum
Headway MC Compatibility	21	17
No. of Flared Ends	4	3
No. of Helical RO Wires	2	3
Implant Wire OD	.0023-.0025“ (58 – 64 um)	0.0023 -.0025” (58 – 64 um)
Retrievability up to	~80%	~75%
Foreshortening	30% max	22% max
Metal Surface Area (%)	22% max	18% max
Cell Size (mm)	~1.0mm	~1.5mm
Pusher Material	Nitinol	Stainless Steel



Competitive Neck Coverage Analysis

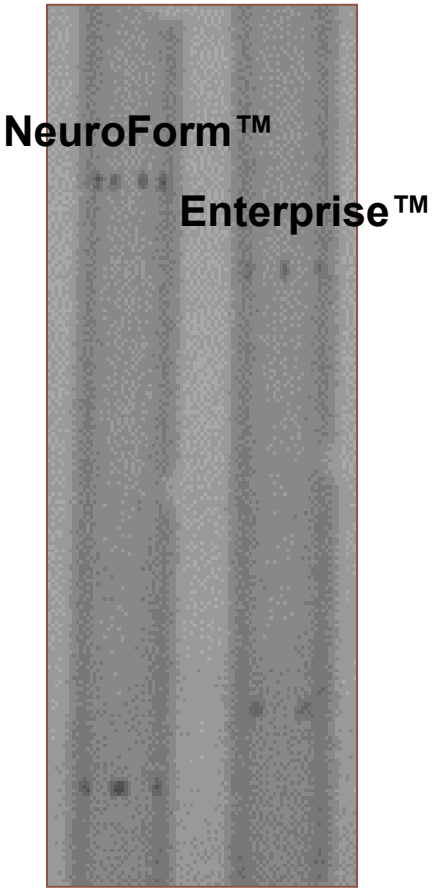
Investigational



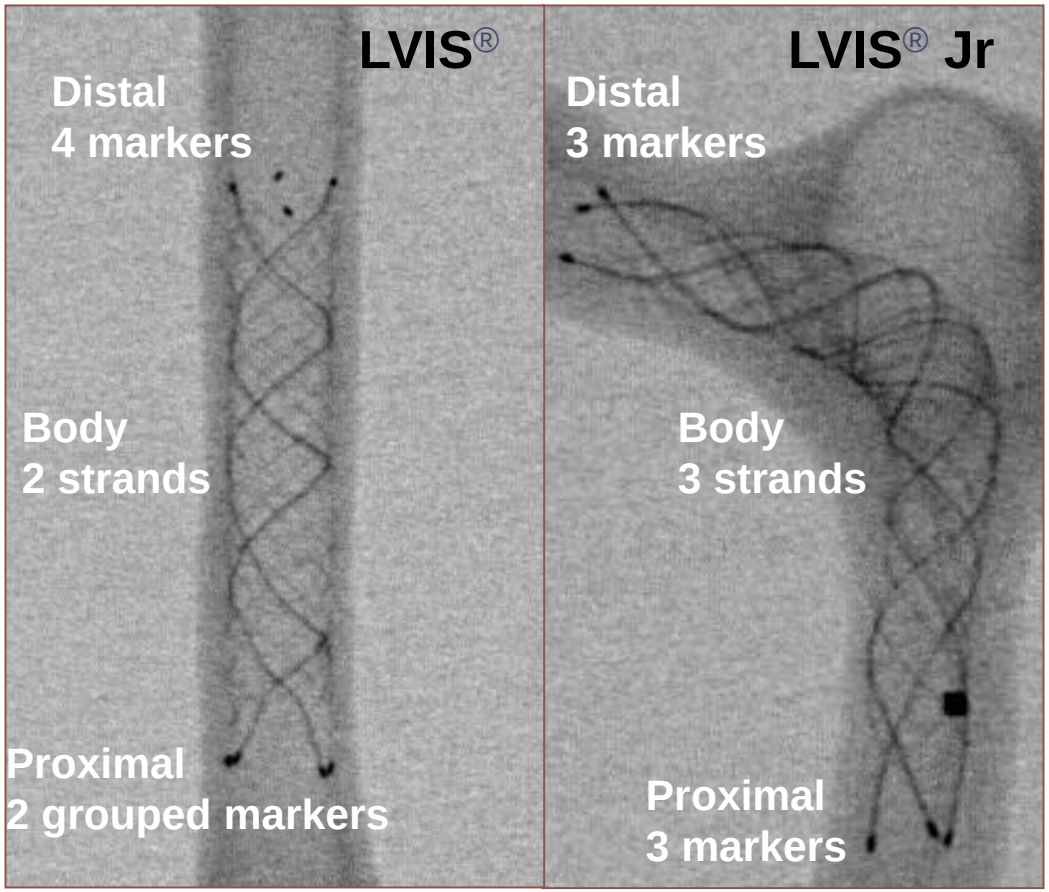
Investigational

Visibility Comparison

Laser-Cut Stents:
Visible only at ends

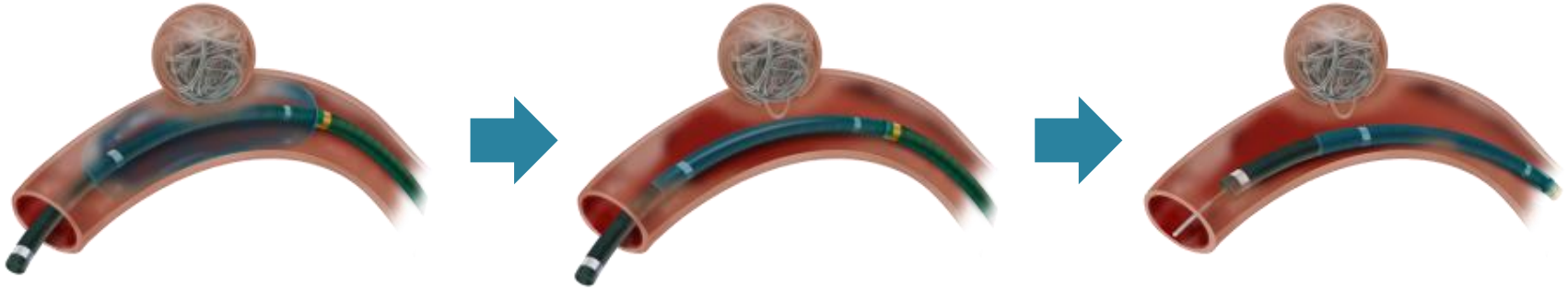


The LVIS® & LVIS® Jr. Devices:
Visible throughout the entire body, not just the ends



Investigational

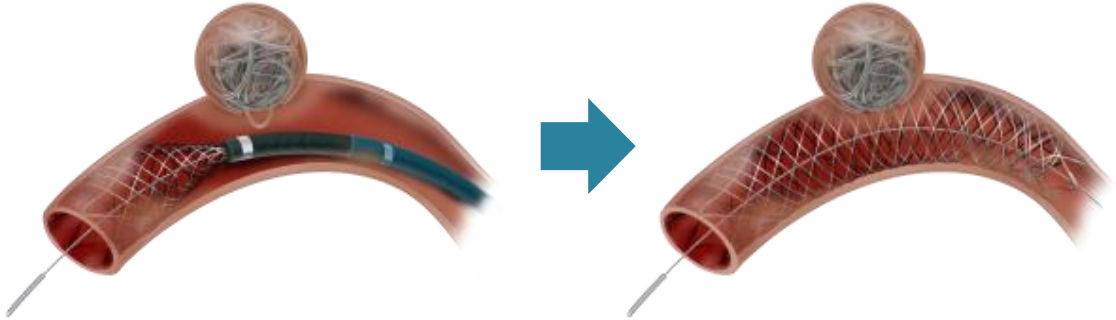
LVIS® Jr. Delivery Through Scepter Balloons



1 - Balloon assisted embolization

2 - After balloon deflation, if a coil prolapses into the parent vessel

3 – Deliver LVIS® Jr. device through the Scepter C® or Scepter XC® Balloon

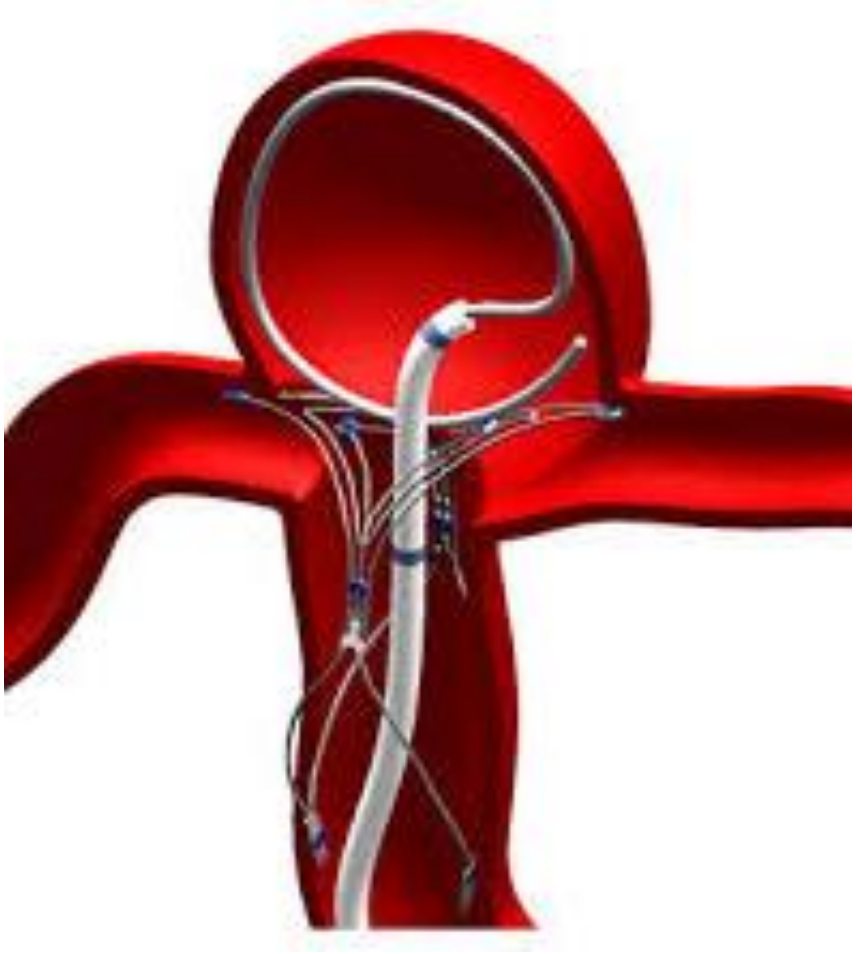


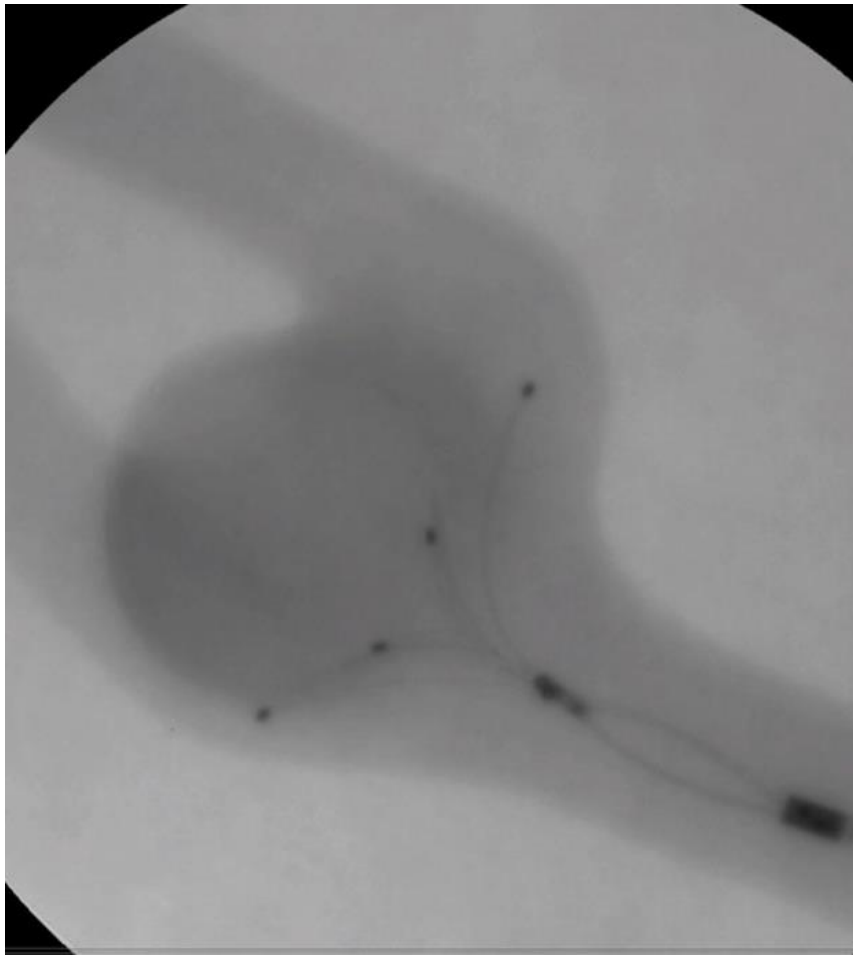
4 – Deploy the stent

5 – The stent is placed in the parent vessel, trapping the coil in the aneurysm

PulseRider
(Pulsar Vascular/Codman Neuro)

Investigational





PulseRider
(Pulsar Vascular/Codman Neuro)

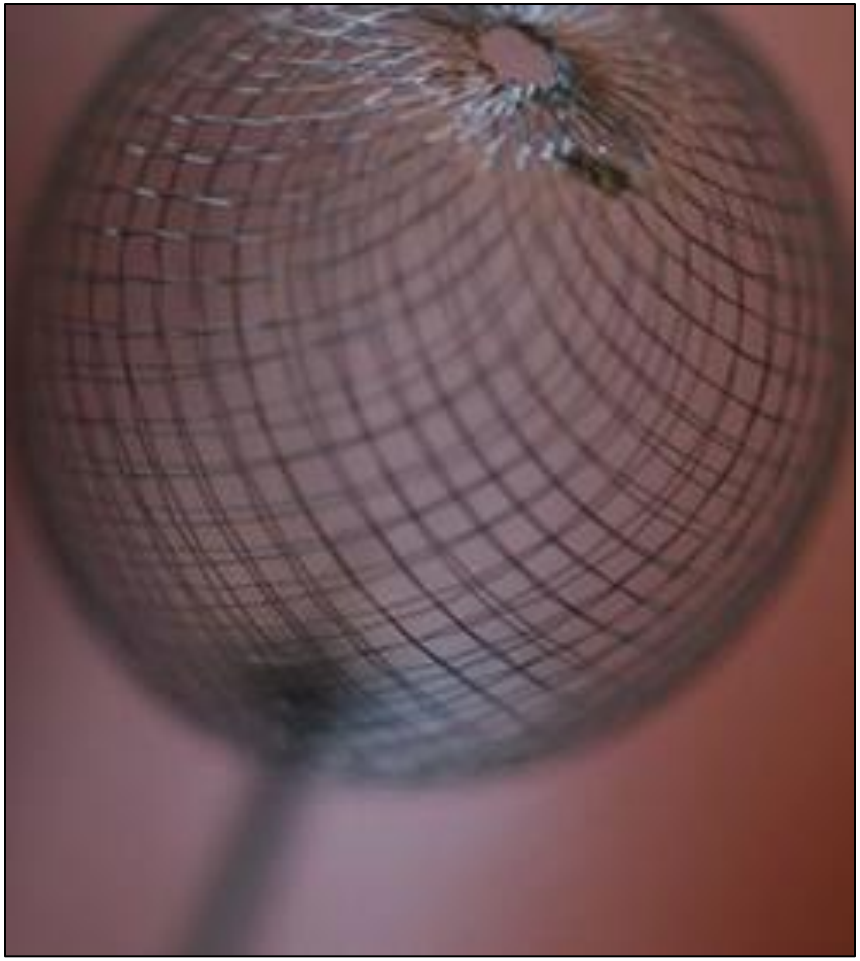
Investigational

- In conjunction with detachable coils
- Self-expanding, Nitinol, neck scaffold
- Fully retrievable
- IDE approval, study ongoing
- Seeking HDE approval for treatment of basilar tip aneurysms

Intra-aneurysmal Flow Diversion

Anatomy of Luna™ AES Implant (Covidien)

Investigational



- Double layer, Nitinol Wire 0.001”
- Mesh basket
- Proximal & distal radiopaque markers (Platinum)
- 9 Sizes: 4.5 – 8.5 mm

Woven Endobridge (WEB) (Sequent Medical)

Investigational

- Retrievable
- Nitinol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