


Neuroguard 3-In-1 Carotid Stent System (Contego Medical) With Integrated Balloon, Stent And Distal Filter: Trial Results And Advantages Including Preventing Particulate Emboli Released During Presumed Flow Reversal Protected CAS From Reaching The Brain (Or Distal Filter)

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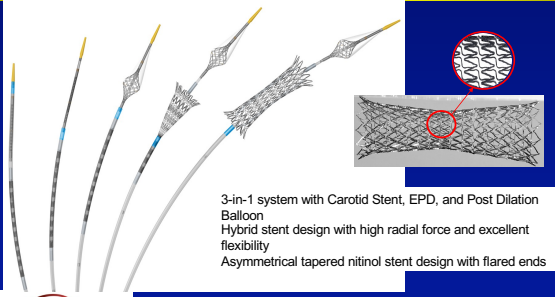



Disclosures



- Consultant: BD, Boston Scientific, Contego Medical, Cordis, Endologix, Inspire MD, Medtronic, Rapid Medical, Shockwave, Penumbra, Vivasure, Nectero, Reflow
- Stock options: Inspire MD and Centerline Biomedical, Reflow
- VIVA Physicians, Board Member
- Research Studies: Abbott, Endologix, Surmodics, W.L. Gore, Terumo Aortic, NIH, Boston Scientific, Merit, Contego Medical, Inspire MD, Reva Medical, Penumbra, Medalliance, Nectero




Neuroguard IEP Carotid Stent



3-in-1 system with Carotid Stent, EPD, and Post Dilatation Balloon
Hybrid stent design with high radial force and excellent flexibility
Asymmetrical tapered nitinol stent design with flared ends



Performance II Trial 30 Day and 1 Year Outcomes

N=305	Intention-to-Treat	Per-Protocol ¹
All stroke	1.31% (4)	0.98% (3)
Minor stroke	1.31% (4)	0.98% (3)
Major stroke	0.0% (0)	0.0% (0)
All Stroke - Asymptomatic Patients	0.81% (2)	0.81% (2)
All Stroke - Contralateral	0.0% (0)	0.0% (0)

n=270	Intention-to-Treat	Per-Protocol
30 Day Death/Stroke/MI + Ipsilateral Stroke between Day 31 to 12 Months	2.67% (8)	2.33% (7)
Ipsilateral Stroke, day 31 to 12 months	0.37% (1)	0.37% (1)
Minor stroke	0.37% (1)	0.37% (1)
Major stroke	0.0% (0)	0.0% (0)
30 Day All Stroke + Ipsilateral Stroke Day 31 to 12 months	1.68% (5)	1.34% (4)
Neurological Death	0.0% (0)	0.0% (0)
CD-TLR	0.0% (0)	0.0% (0)
Target Lesion Revascularization	1.47% (4)	1.47% (4)



¹CD-TLR: Any revascularization procedure of the original treatment site associated with revascularization of 50% as determined by the angiographic core lab within 12 months of the intervention.

One Minor Stroke Between Day 31 and 12 Months
No Major Strokes at One Year
No Neurological Deaths at One Year

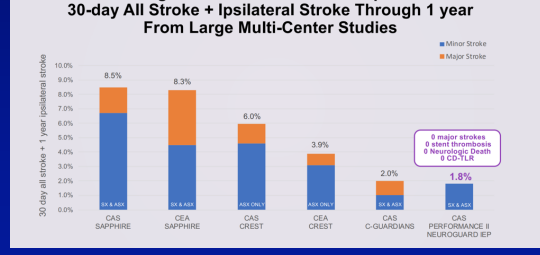
Performance II Trial 2 Year Outcomes

	Intention-to-Treat	Per-Protocol ¹
Neurological Death	0.0% (0)	0.0% (0)
Stent Thrombosis	0.0% (0)	0.0% (0)
Clinically-driven Target Lesion Revascularization (CD-TLR) ²	0.4% (1/260)	0.4% (1/259)
Target Lesion Revascularization (TLR) ³	2.7% (7/260)	2.7% (7/259)
In-Stent Restenosis (ISR) ⁴	3.9% (10/260)	3.9% (10/259)

New Data in Context



30-day All Stroke + Ipsilateral Stroke Through 1 year From Large Multi-Center Studies



Study	30-day All Stroke + Ipsilateral Stroke Through 1 year
CAS SAPHIRE	8.5%
CEA SAPHIRE	8.3%
CAS CREST	6.0%
CEA CREST	3.9%
CAS C-GUARDIANS	2.0%
CAS PERFORMANCE II NEUROGUARD IEP	1.8%

Legend: ■ Minor Stroke, ■ Major Stroke

Legend: ■ major strokes, ■ stent thrombosis, ■ Neurological Death, ■ CD-TLR

PERFORMANCE III IDE Study Neuroguard IEP® Direct Access

Objective To evaluate the safety and effectiveness of direct carotid access using the Neuroguard IEP® Direct Access System in subjects at elevated risk for adverse events following carotid endarterectomy (CEA).

Study Design A prospective, multi-center, single-arm study at up to 30 sites

Patient Population Symptomatic and asymptomatic patients requiring carotid revascularization who are at high risk for complications from carotid endarterectomy (CEA)

Sample Size Approximately 229 subjects; up to 80 lead in subjects and 149 pivotal subjects

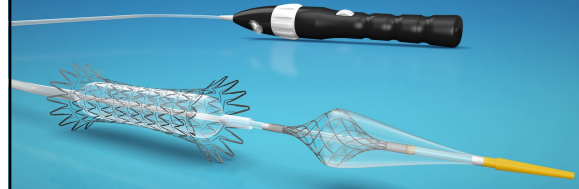
Primary Endpoint Composite 30-day rate of Major Adverse Events (MAE), defined as the cumulative incidence of all stroke, myocardial infarction (MI) or death within 30 days of the index procedure

Principal Investigators Sean Lyden, MD, D. Christopher Metzger, MD.



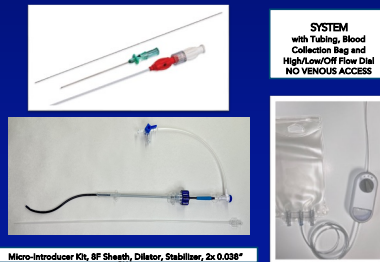
Neuroguard Direct Carotid Stent System Same as the TF Carotid Stent System, but Shorter Catheter

70 Cm Working Catheter Length



Neuroguard Direct Access Kit

- ACCESS KIT**
1. 8F Arterial Sheath and Stiffening Dilator
 2. Sheath Stabilizer with locking feature
 3. Flow Redirection System
 4. 0.038" Guidewire (2)
 5. 0.014" Guidewire and wire insertion tool
 6. Micro-Introducer Kit and Hemostatic Valve Adaptor



Micro-introducer Kit, 8F Sheath, Dilator, Stabilizer, 2x 0.038"

SYSTEM
with Tubing, Blood Collection Bag and High/Low/Off Flow Dial
NO VENOUS ACCESS



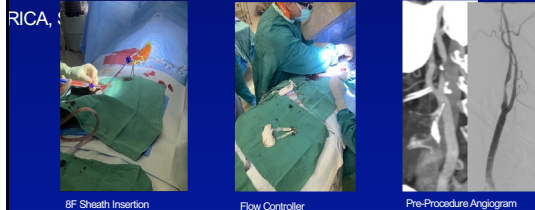
Neuroguard IEP Direct System

Advantages of Neuroguard IEP Direct System

- ✓ Integrated filter = double protection (40-micron filter and flow reversal)
- ✓ Integrated angioplasty balloon for stent post-dilation = fewer procedural steps
- ✓ Closed cell stent with optimized flexibility and radial strength
- ✓ No venous access
- ✓ Flexible sheath with pre-formed curve, 8F ID and 9.5 F OD



Symptomatic RICA treatment in PERFORMANCE III



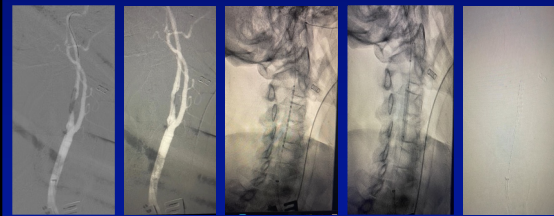
8F Sheath Insertion

Flow Controller

Pre-Procedure Angiogram



Direct Carotid Placement of 8-6-7 x 40 mm Neuroguard stent



Pre-Dilation 4mm x 20mm

Neuroguard Insertion

Neuroguard Deployment 8-6-7 x 40mm

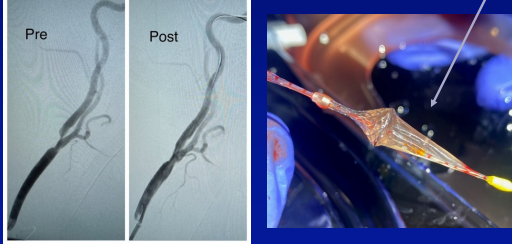
Post Dilatation

Final Result



Neuroguard IEP Direct - Debris in Filter - P3 Case

Debris in Filter



The slide displays two angiograms labeled 'Pre' and 'Post' on the left, showing the cerebral vasculature before and after the procedure. On the right is a close-up photograph of a Neuroguard IEP filter, with a white arrow pointing to a small, dark, irregular object caught within the filter's mesh, labeled 'Debris in Filter'. The slide includes the VEITH logo and Cleveland Clinic branding at the bottom.

Conclusions

- Neuroguard IEP lowest stroke rate
 - 30 Day Stroke per protocol
 - 0% major
 - 0.98% minor
 - Day 31 to 1 year
 - 0% major
 - 0.37% minor
 - 2 year CD-TLR 0.4%, ISR 3.4%
- Performance 3 Eval Direct Access underway

The slide features the VEITH logo and Cleveland Clinic branding at the bottom.

