

Dilation of Carotid Artery with Integrated Embolic Protection

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Committee Meeting

Carotid Artery Disease Overview

Carotid artery disease (CAD) is a major risk factor for ischemic stroke, characterized by the narrowing or blockage of carotid arteries due to atherosclerosis.

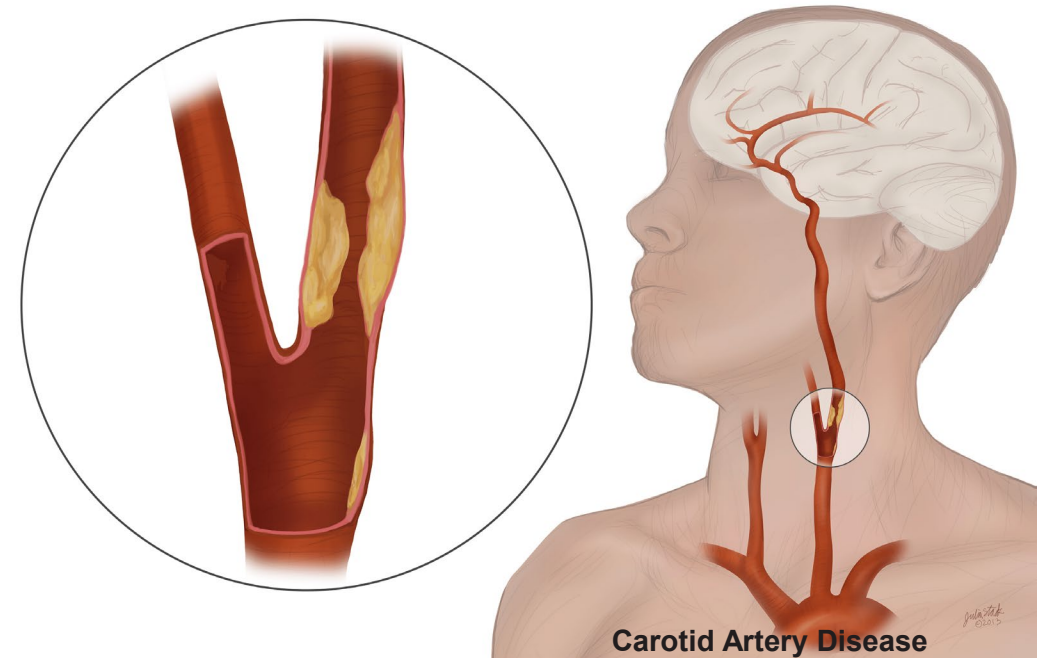
If untreated, CAD can lead to transient ischemic attacks (TIAs) or ischemic strokes, causing permanent neurological damage, disability, or death.

446,000 US patients: annual incidence with CAD

30-40% of these patients undergo procedural interventions

~**120k** surgical carotid endarterectomy

~ **50k** carotid artery stenting (TFCAS and TCAR)

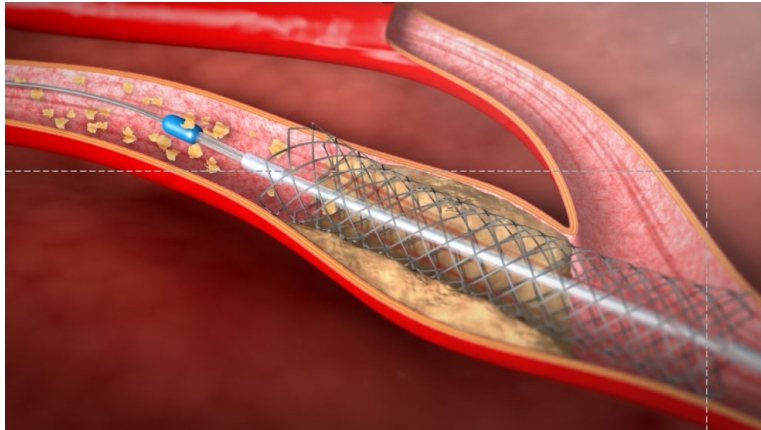


Source: hopkinsmedicine.org

The Achilles Heel of CAS - Higher Stroke: CAS vs CEA

Carotid artery stenting (CAS) offers an alternative to carotid endarterectomy (CEA) but has a **higher stroke risk due to procedural embolization**.

Release of Embolic Material



Poststent ballooning is associated with increased periprocedural stroke and death rate in carotid artery stenting

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J. Vasc Surg 2015;62:616-23

Cerebral embolic protection device with embolized plaque



- Conventional cerebral protection filters are separate devices.
- Since they are open throughout the procedure, they have large pores to prevent thrombosis.
- However, large pores do not capture small particles which may cause stroke.

Existing filters do not capture particles < 100 Microns ➡ MINOR STROKE

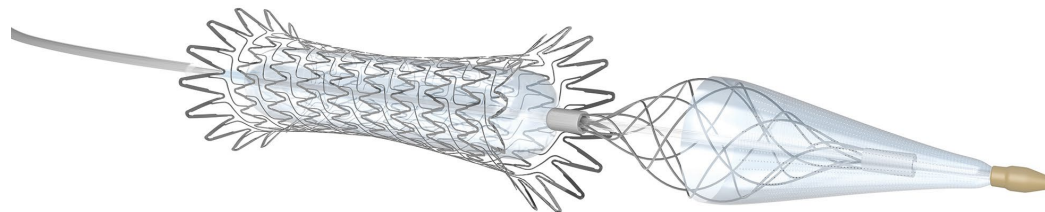
The Neuroguard IEP® 3-in-1 Carotid Stent, Post-Dilation Balloon System with Integrated Embolic Protection (Neuroguard IEP® System)

- A novel, 3-in-1 device that integrates a nitinol self-expanding stent, a post-dilation balloon, and a 40 µm embolic protection filter, **all in a single catheter system**.
- Dynamic filter adjustment ensures a complete seal against the artery wall, minimizing embolic escape.
- Filter captures microemboli (40 µm), **smaller than traditional devices** (100-150 µm).
- Enhances procedural efficiency and embolic protection.
- **Greater protection** during riskiest carotid stenting phases: stent deployment & post-dilation.

The Neuroguard IEP® System utilizes an integrated embolic protection system which provides additional protection during the riskiest parts of the procedure.

The Neuroguard IEP® System.

A 3-in-1 System: Carotid Stent + Dilation Balloon + Integrated Embolic Protection

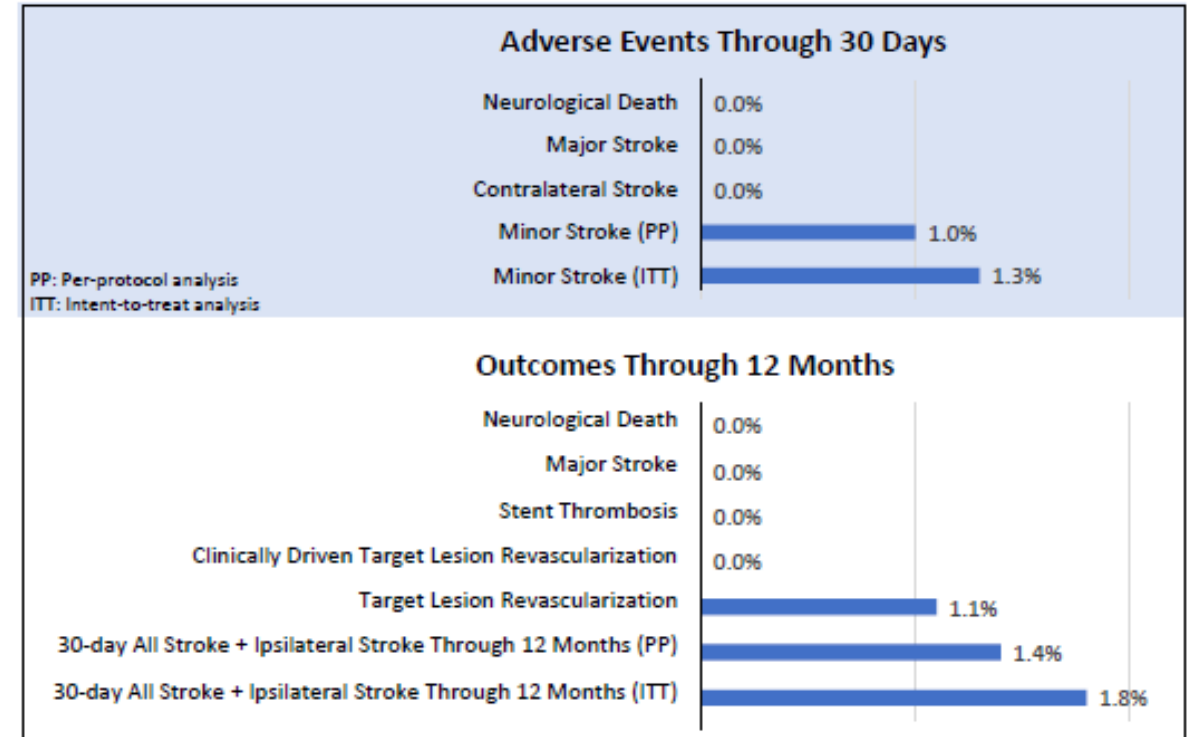


Clinical Results

The Neuroguard IEP® System has been studied in 2 clinical trials: **PERFORMANCE I** and **PERFORMANCE II**

- PERFORMANCE I feasibility study with 67 patients:
 - No strokes or deaths at 30 days.
 - No strokes, neurological deaths, target lesion revascularizations, or instances of in-stent restenosis at 12 month follow up.
- PERFORMANCE II pivotal trial with 305 patients:
 - No major strokes or deaths at 30 days.
 - 4 minor strokes (1.3%)
 - No major strokes, neurological deaths, target lesion revascularizations, or instances of in-stent restenosis at 12 months.
 - Major adverse event rate was 2.8% at 12 months.
 - Importantly, no device-related complications such as dissections, perforations, or distal embolizations were reported in either study.

PERFORMANCE II CLINICAL RESULTS



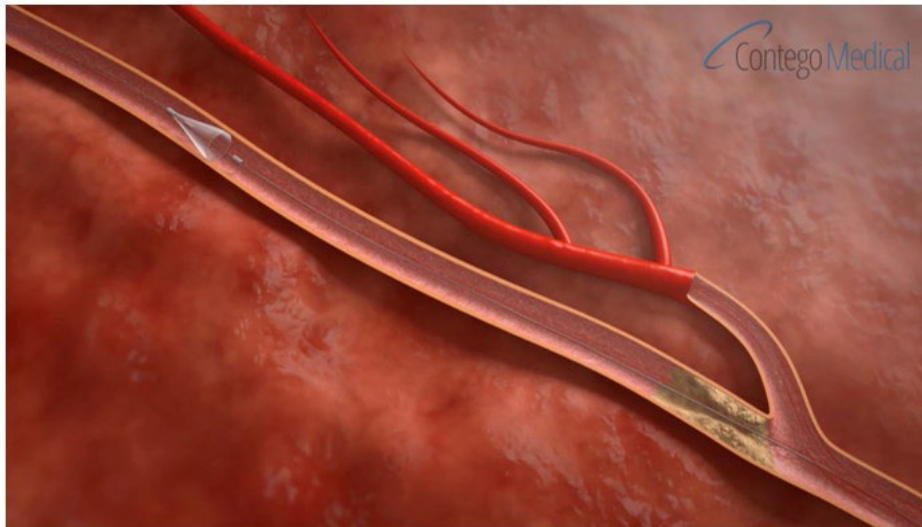
Clinical Results Comparison

These recent clinical studies demonstrate that the Neuroguard IEP® System provides a substantial clinical improvement in reducing stroke risk during CAS procedures at 30 days and at one-year follow-up as compared to historical outcomes

Neuroguard IEP® System			Conventional Systems					
Study Name	PI Study	PII Study	SECURITY	SAPPHIRE	ARCHER	BEACH	CREST	SCAFFOLD
Author / Year	Langhoff et al./ 2022/	Gray et al./ 2024	Xact Stent SSED 2004	Yadav et al./ 2004	Gray et al./ 2006	Iyer et al./ 2008	Brott et al./ 2010	Gray./ 2017
N	67	305	305	334	581	480	2,502	312
30-day stroke rate	0%	ITT: 1.3%, no major strokes	6.89%	ITT: 4.8% (CAS) vs 9.8% (CEA) (P=0.09)	6.9%	4.5%	4.1% (CAS) vs. 2.3% (CEA), (P = 0.01)	2.9 %
12-month stroke rate	0%	1.8%, no major strokes	7.9% ipsilateral stroke	ITT: 6.2%(CAS) and 7.9% (CEA) (P=0.08)	1.3% (major ipsilateral stroke)	2.7%(late neurological event)	NA	NA

Procedural Steps (1)

1. Conventional, stand-alone primary embolic protection is placed



2. The Neuroguard IEP® System is deployed via minimally invasive access of the carotid artery
3. The system is advanced over a guidewire to the site of carotid stenosis



Procedural Steps (2)

4. Additional integrated embolic protection filter is deployed distal to the lesion to capture any potential debris



5. The self-expanding stent (permanent) is then deployed to restore vessel patency, and the integrated post-dilation balloon is inflated to optimize stent apposition



6. Finally, the filter, potentially containing captured debris, is retrieved along with the delivery system

Typically, one Neuroguard IEP System is used per procedure although multiple devices may be used per procedure for certain anatomical situations that necessitate multiple stents.

Documentation and Terminology

- Use of the Neuroguard IEP® System will be documented in the procedure report.
- The technology may be documented as:
 - The Neuroguard IEP® System
 - Neuroguard®
 - Carotid stent with integrated distal embolic protection filter

Questions

References

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