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Micromesh Technology in Carotid Stents: Soft vs. Hard Landing

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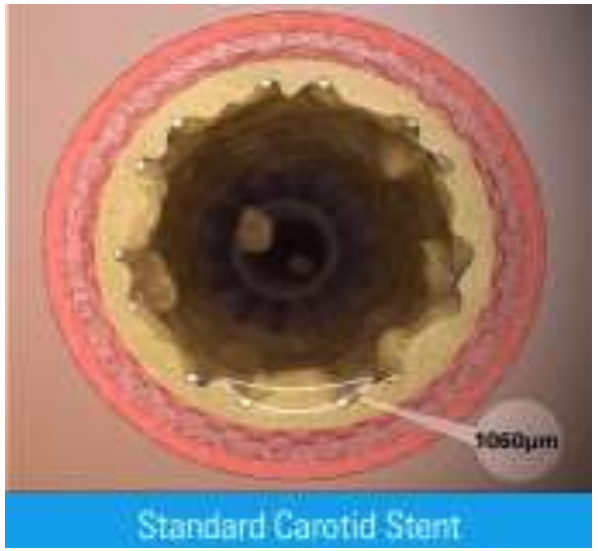
Disclosures

Physician name	Company	Relationship
Horst Sievert	4tech Cardio, Abbott, Ablative Solutions, Ancora Heart, Bavaria Medizin Technologie GmbH, Bioventrix, Boston Scientific, Carag, Cardiac Dimensions, Celonova, Cibiem, CGuard, Comed B.V., Contego, CVRx, Edwards, Endologix, Hemoteq, InspireMD, Lifetech, Maquet Getinge Group, Medtronic, Mitralign, Nuomao Medtech, Occlutech, pfm Medical, Recor, Renal Guard, Rox Medical, Terumo, Vascular Dynamics, Vivasure Medical, Venus, Veryan	Consulting fees, Travel expenses, Study honoraria

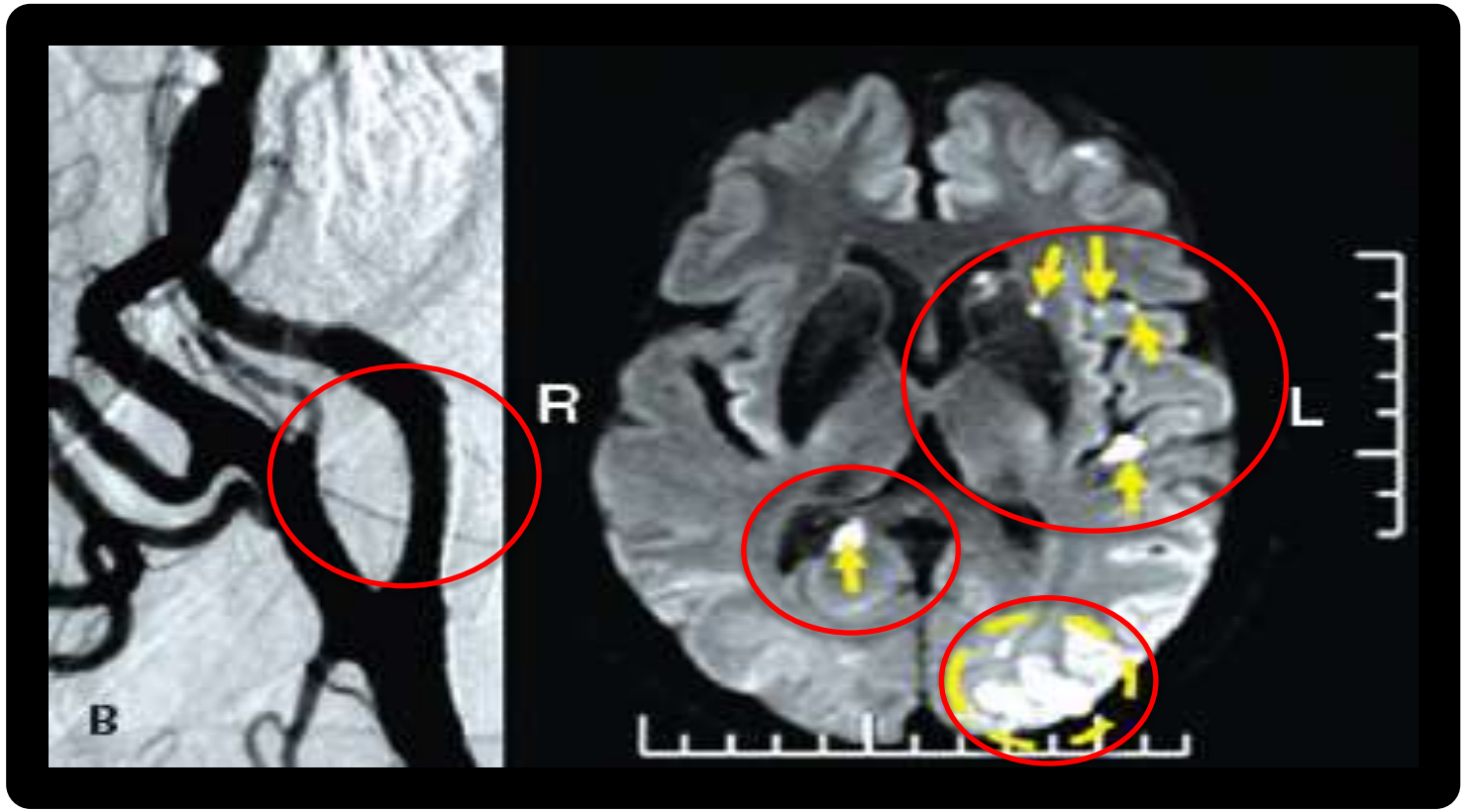
Stroke/TIA Following Carotid Stenting

- Up to two-thirds of carotid stenting-associated strokes/TIAs occurred after the procedure[1]
- Plaque prolapse through the stent struts occurs in 23% to 65% of cases[2]
- The degree of prolapse depends on the free stent cell area[2]
- This explains why embolic protection devices have limited effectiveness in abolishing carotid stenting-associated strokes[3]
- Prevention of plaque protrusion through the struts may result in reduced embolization[4,5,6]



1. Annals of SurgeryVolume 246, Issue 4, October 2007, Pages 551-556
2. De Donato et al. Eur J Vasc Endovasc Surg. 2013;45: 579-87.
3. J Am Coll Cardiol 2012 Apr 10. 59:1383-9. 10.1016/j.jacc.2011.11.035
4. N Engl J Med 2004;351:1493–501.
5. Ann Surg 2007;246:551–6.
6. J Vasc Surg 2010;52:1367–75.

Post procedural embolization following carotid stenting is frequent



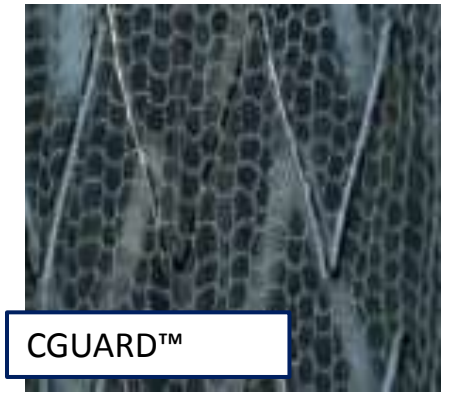
Post-Procedure

Post-intervention showing successful opening of the occluded carotid artery with conventional stenting and an MRI showing multiple micro-infarcts (obstructions) post-procedure due to liberation of embolic particles.

Cano et al. Rev Bras Cardiol Invasiva 2013; 21(2): 159-64.

Mesh Stents are Designed to Prevent Distal Embolization

- Ultrathin mesh inside or outside of the stent struts
- This “safety net” offers a greater vessel area coverage
- It prevents large plaque protrusion through the scaffold into the vessel lumen
- Mesh-Stents have identical deliverability as other stents
- They provide equivalent revascularization to conventional devices
- Designed to trap and seal thrombus and plaque against the vessel wall, preventing embolization


CGUARD™


TERUMO


GORE

Best of both worlds

- Open cell stent design with large cell area
  - for better flexibility
- Smaller pore size
  - for better plaque coverage

Pore Size

CGUARD™

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*165µ

375µ

500µ

1050µ

Closed cell stent

1900µ

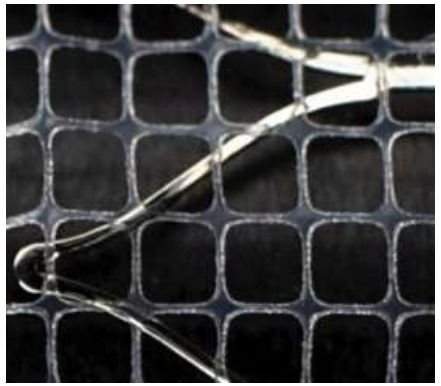
Open cell stent

* Average in lesion at expanded state

			
Name	**RoadSaver *aka* Casper**	**Gore® Carotid Stent**	**CGuard™ Embolic Prevention Stent**
Stent frame	closed-cell Nitinol	open-cell Nitinol	open-cell Nitinol
Mesh position in relation to frame	inside	outside	outside
Mesh material	Nitinol	PTFE	PET
Mesh structure	braided	inter-woven	single-fiber knitted
Pore size	375 µm	500 µm	150 - 180 µm

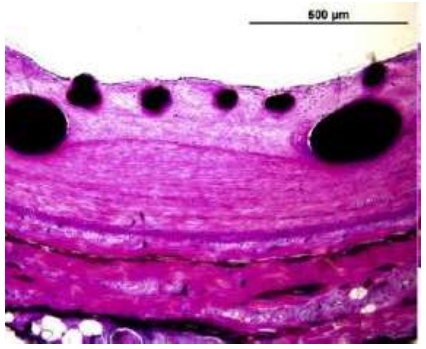
Dual-layer stent comparison

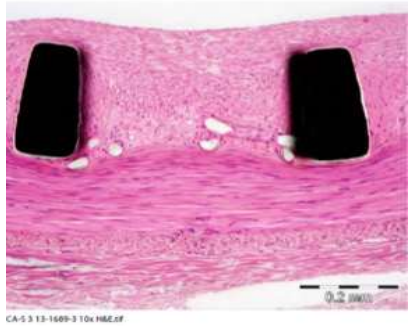
RoadSaver ®
Casper



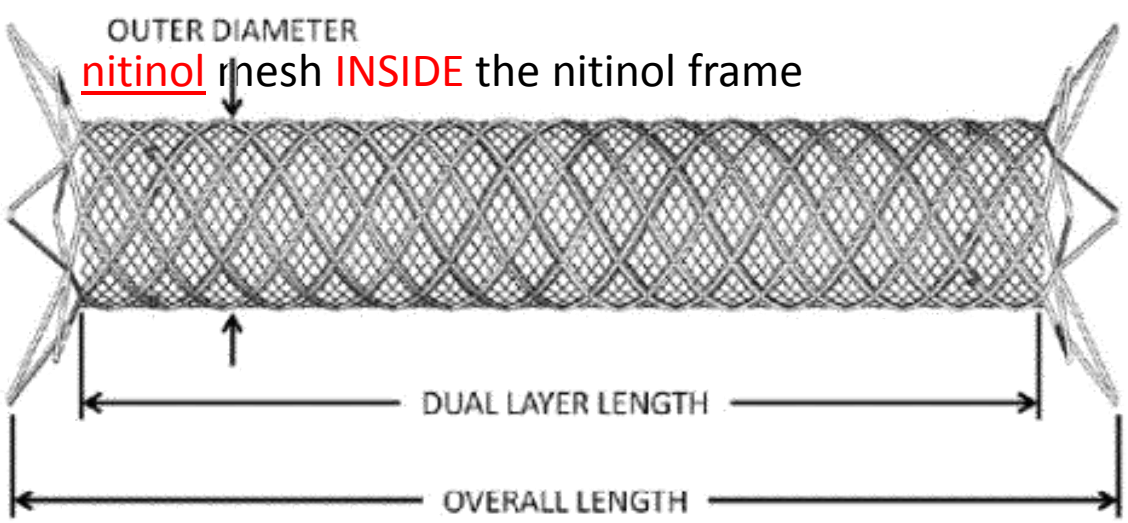
Gore®
Carotid Stent

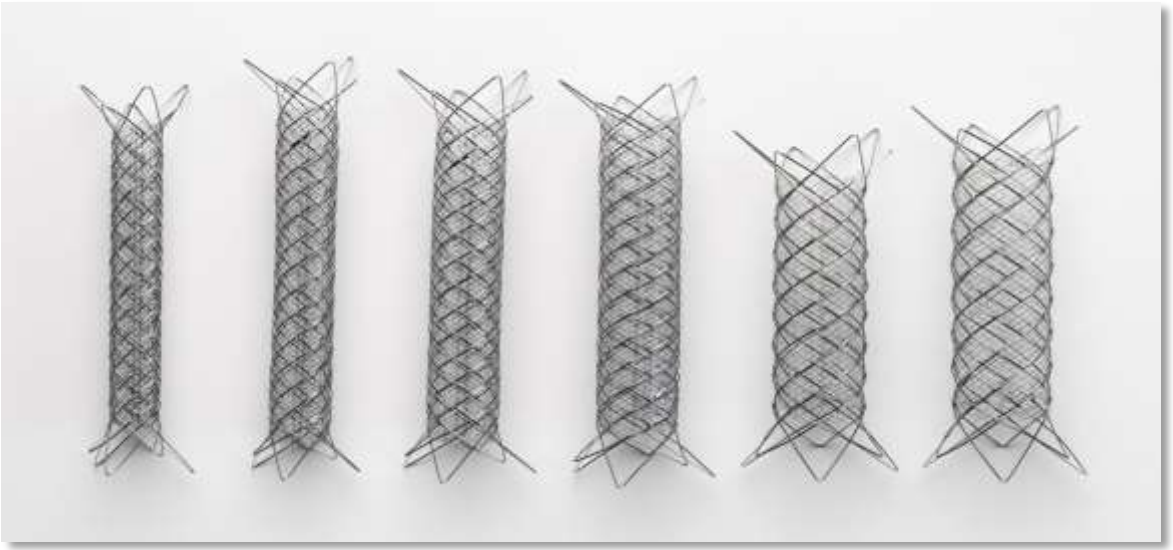
CGuard™ Embolic
Prevention System

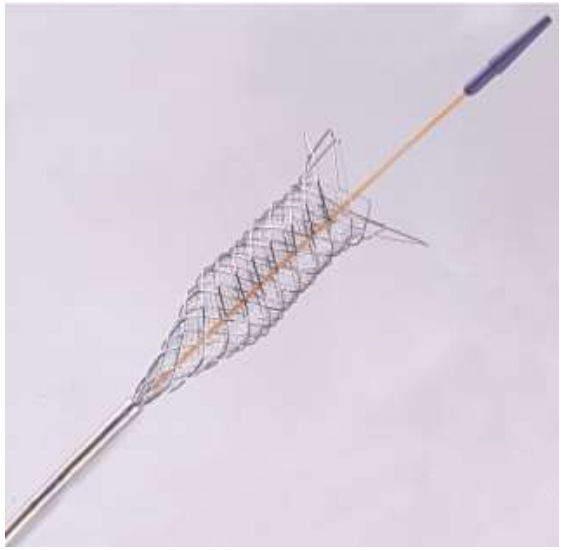




RoadSaver (Terumo) = Casper (MicroVena)

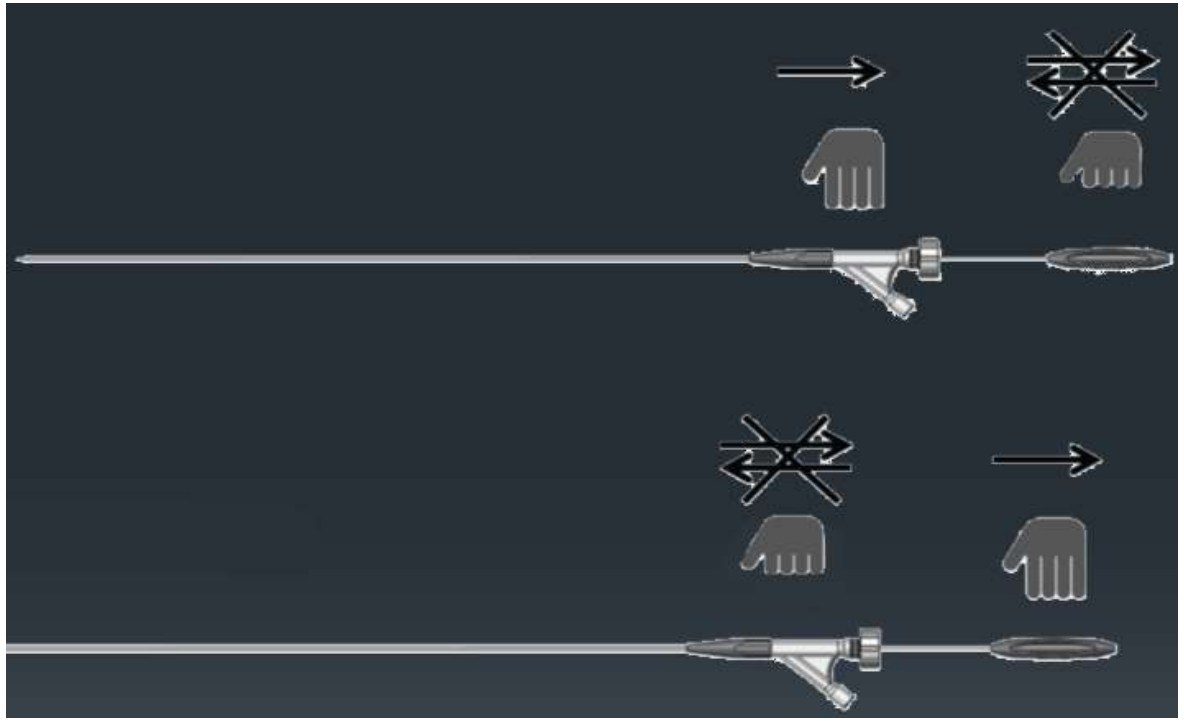


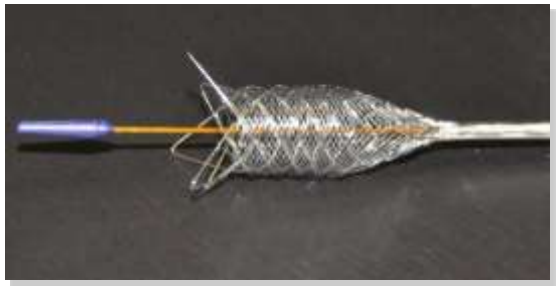




Images by Terumo / used with permission

RoadSaver: Push-Pull Stent Delivery System



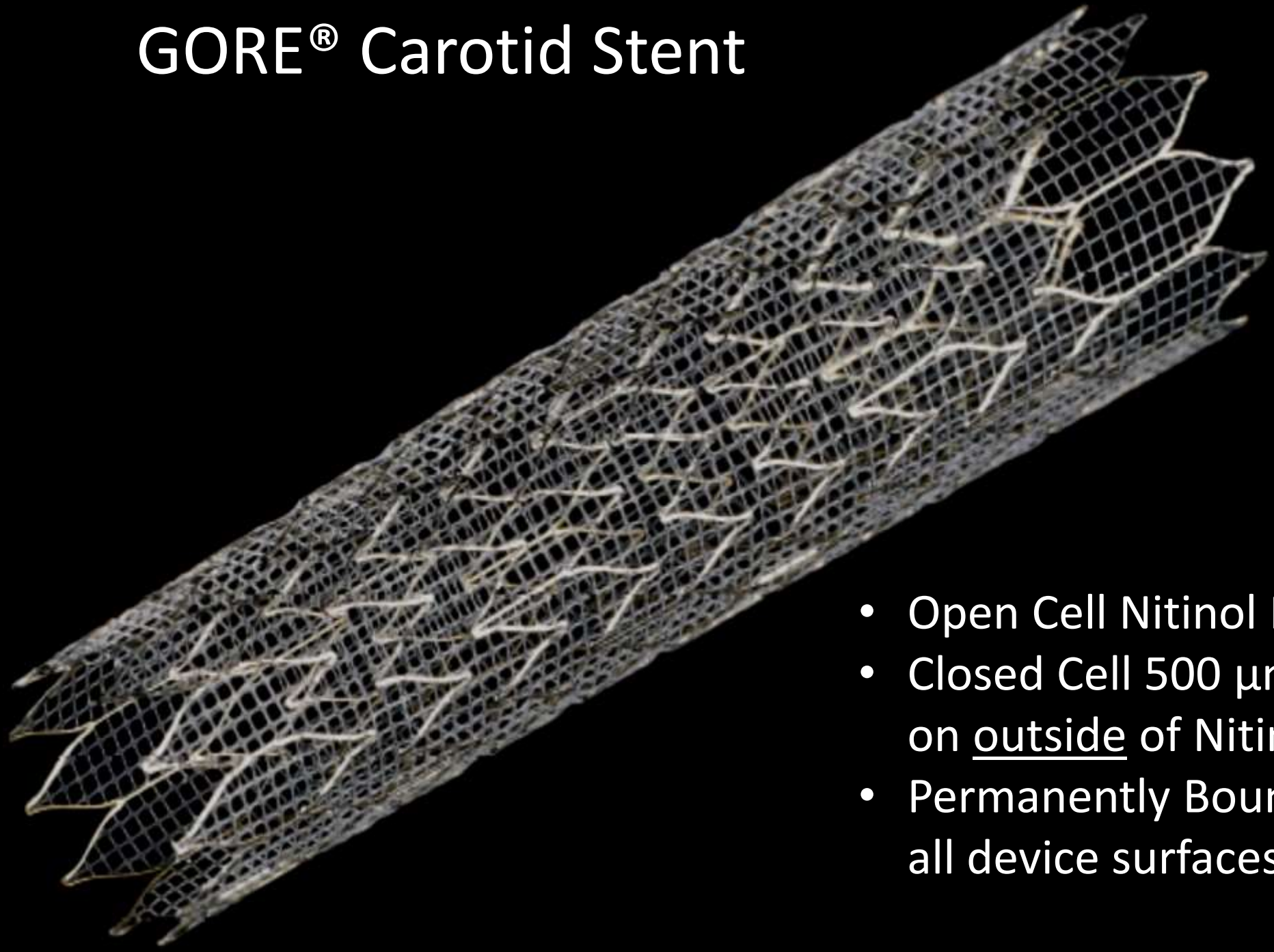


re-sheathable up to 50% stent length release

CE Mark – January 2014

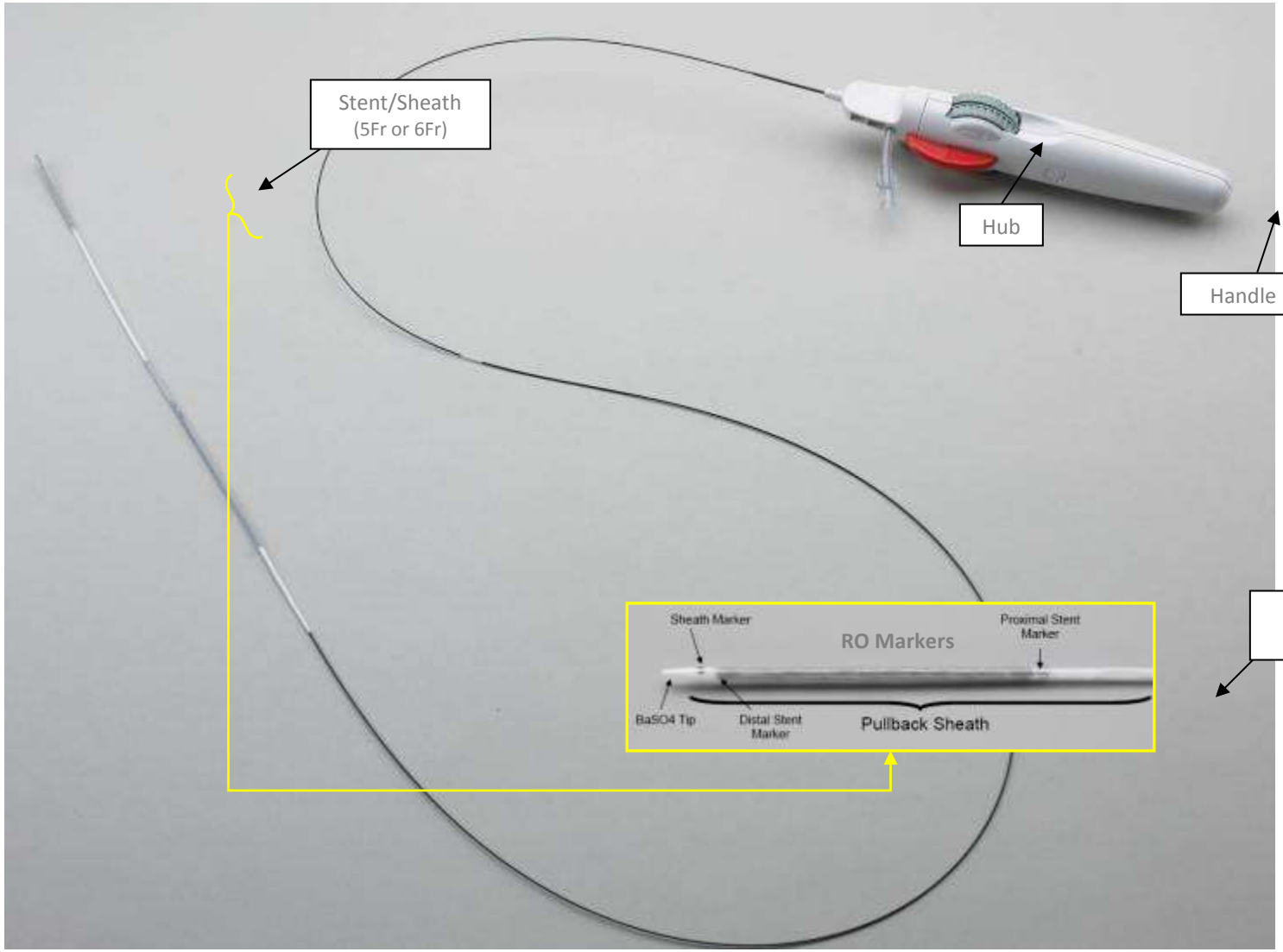
Images courtesy P. Pieniazek / Krakow and Terumo

GORE® Carotid Stent



- Open Cell Nitinol Frame
- Closed Cell 500 µm PTFE lattice on outside of Nitinol Frame
- Permanently Bound Heparin on all device surfaces

The Gore Stent Delivery System



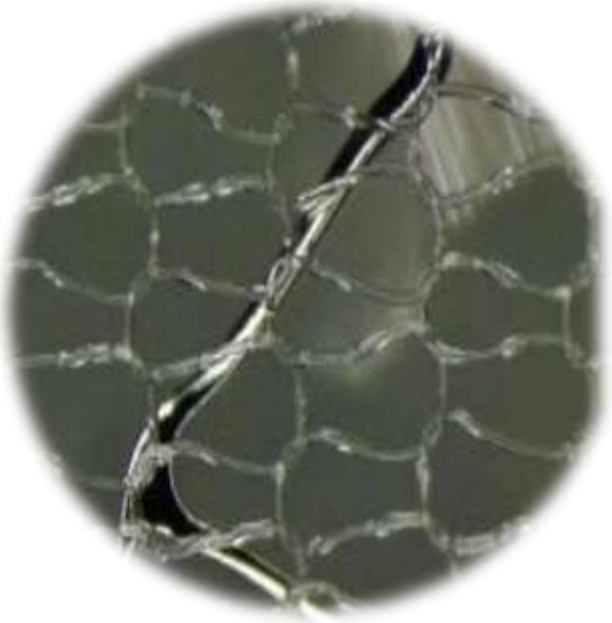
Attributes

- Single handed delivery
- 5Fr or 6F
- Hypotube Design
  - Allows for complete closure of hemostatic valve
- 135 cm Working Length
- 30 cm Rx

CGUARD MicroNet™ Technology

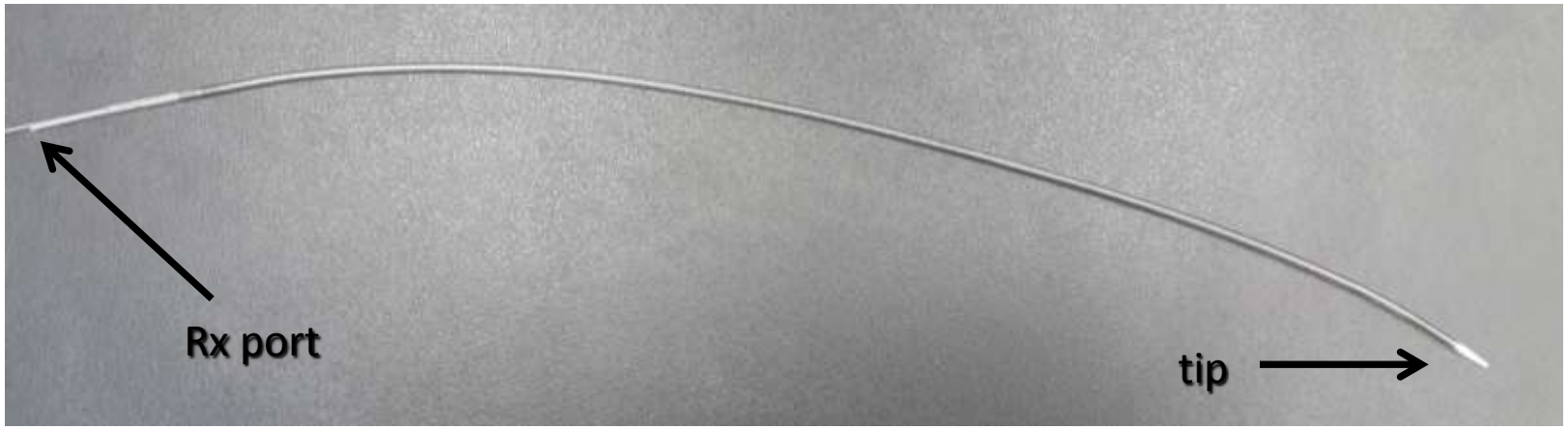
The MicroNet™

- **Woven mesh of one single 20µm strand of Polyethylene Terephthalate (PET)**
- **Is sutured to both distal and proximal crowns of the stent platform**



MicroNet™ technology supported by 6+ years of MGuard™ coronary data

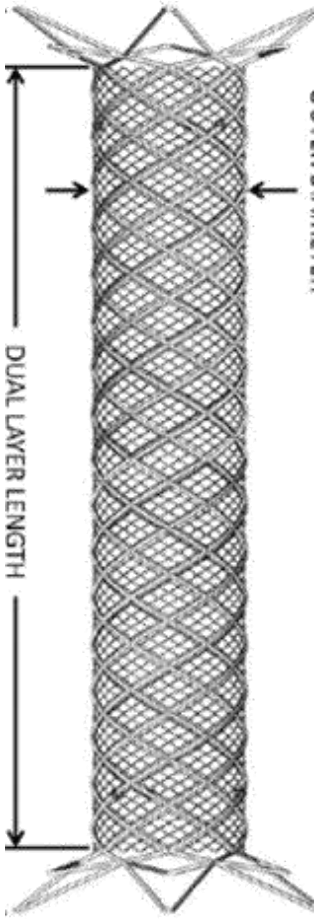
CGuard™ Embolic Prevention Stent System



Trial results

Roadsaver – CLEAR-ROAD Study

- N = 100
- 8 EU centers
- Primary endpoint:
  - 30 day MAE (death, stroke, MI)
- Secondary endpoints
  - Technical success
  - MAE by subgroup symptomatic/asymptomatic
  - Late ipsilateral stroke (day 31-365)
  - TLR



Bosiers et al

Roadsaver – 30 day results

Per Protocol	MAE's
All Death, Stroke, or MI	2.00%
Death	1.00%
Any Stroke	1.00%
- Major Stroke	0.00%
- Minor Stroke	1.00%
MI	0.00%

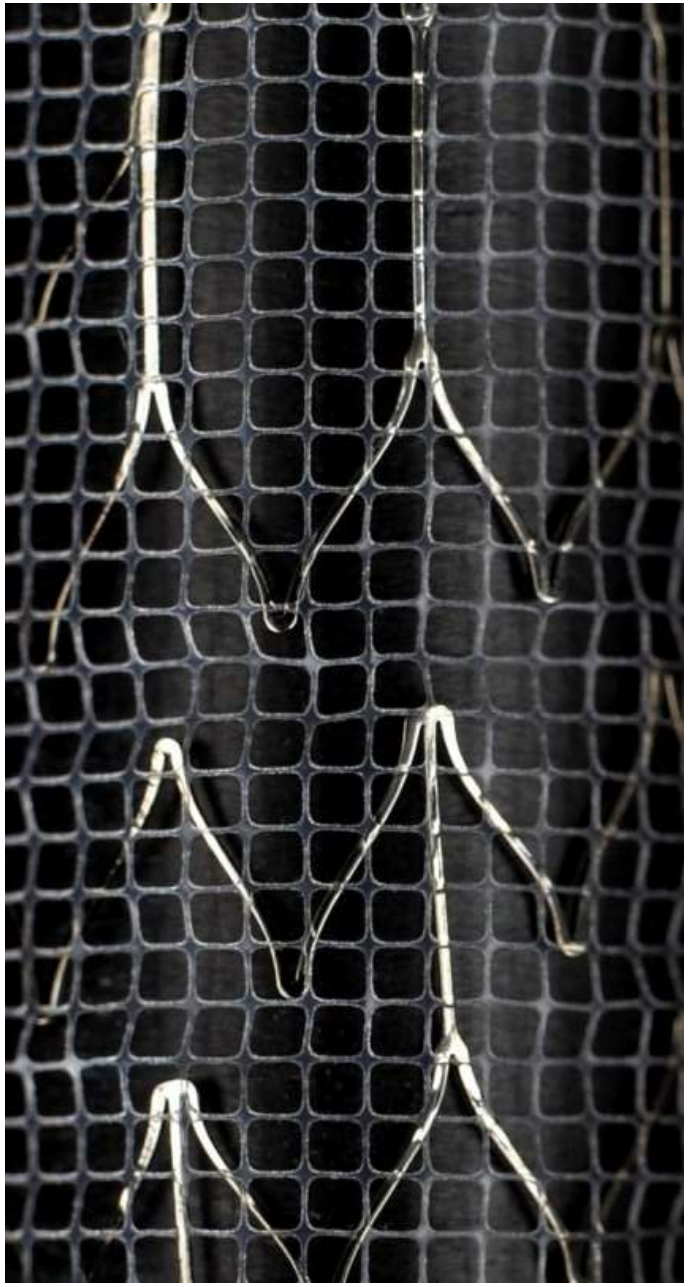
- One MI, patient died on day 4
- One ipsilateral stroke on day 12 (Afib?)

Bosiers et al

Gore Scaffold Trial

- 312 patients
- 30 US sites

- PI William Gray, Peter Schneider



SCAFFOLD Procedural Data: Technical Success

Number of subjects	312
Gore carotid stent successfully implanted	100% (312/312)
Gore embolic filter successfully deployed	94.6% (295/312)
Additional EPD used	4.5% (14/312)

William A. Gray, LINC 2018

SCAFFOLD Primary Endpoints

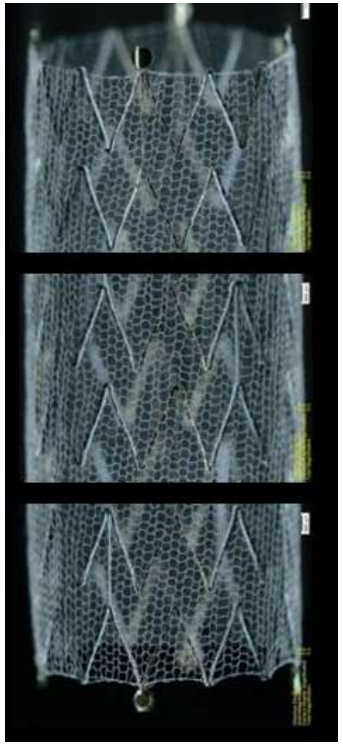
	Intention to treat (n=311)	Per protocol (n=264)
30 day endpoints		
MAE	4.8 %	3 %
Death	0.6 %	0.4 %
Myocardial infarction	1.3 %	1.5 %
Stroke	2.9 %	1.1 %
1 year endpoint		
ipsilateral stroke day 31-365	1.7 %	1.2 %

William A. Gray, LINC 2018

Clinically-driven 1-year Target Lesion Revascularization (TLR): ITT

William A. Gray, LINC 2018

CGUARD CARENET



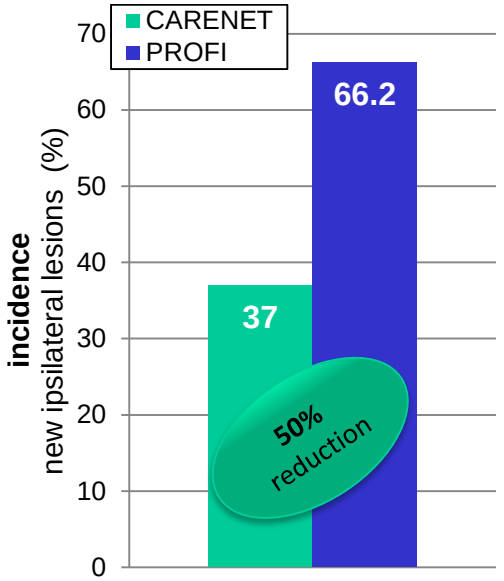
- N = 30
- 4 centers in Germany and Poland
- Primary endpoints
  - Technical success
  - New ipsilateral lesions on MRI at 48 hours and 30 days
- Secondary endpoint: 30-day major adverse cardiac or cerebrovascular events (death, stroke, or myocardial infarction)

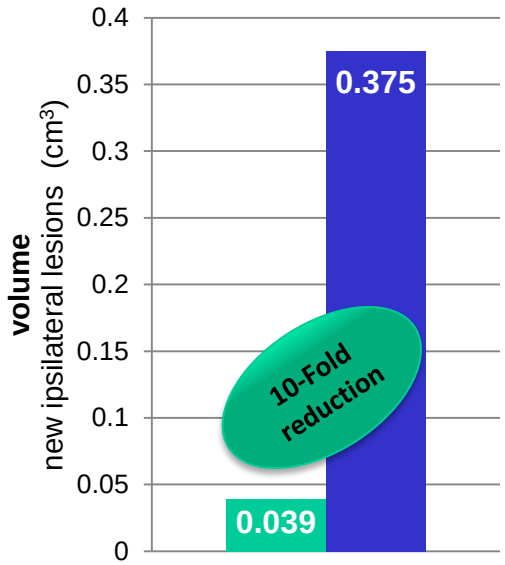
CGUARD CARENET

- Procedural success: 100%
- Procedural complications: 0
- 30-day MACE: 0
- New ipsilateral ischemic lesions at 48 h: 37%
  - Complete resolution of all but 1 periprocedural lesion and only 1 new minor (0.116 cm(3)) lesion in relation to the 48-h scan

CGUARD CARENET *DW-MRI Analysis*

DW-MRI analysis @ 48 hours, n=27*





Incidence of new ipsilateral lesions at 48 hours was reduced by almost half compared to published data, and volume was reduced almost 10-fold.

All but one lesion had resolved completely by 30 days.

DW-MRI analysis @ 30 days, n=25**

Incidence of new ipsilateral lesions	4.0%
Average lesion volume (cm^3)	0.08 ± 0.00
Permanent lesions at 30 days	1

Schoferet *et al*. JACC 2015;8:1229–1234

Bijuklic et al. *JACC*, 2012;59

CGUARD - PARADIGM

- 101 patients
  - 51-86 years
  - 55 symptomatic, evolving stroke in nine
- 106 CAS
- Embolic protection device mandatory
- Results
  - Technical success 106 (100%)
  - Periprocedural death/major stroke/MI rate: 0
  - Minor stroke (no sequlae): 1 (0.9%)
  - New events by 30 days: 0

et al

Summary and Conclusions

- Mesh Carotid stents are open cell stents with an additional layer with very small pores
- They are designed to prevent periprocedural embolic events
- Prospective clinical trials have shown promising results
  - Very low periprocedural stroke rate
  - No increased risk of re-stenosis
- Imagine we could have used these stents in CREST and other trials

Thank you!