

# Latest techniques for carotid revascularisation



## **Micronet-covered stent in stroke prevention and treatment: New evidence**

MicroNET-covered Embolic Prevention Stent

**Piotr Musialek**

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John Paul II Hospital, Kraków, Poland



# Disclosure

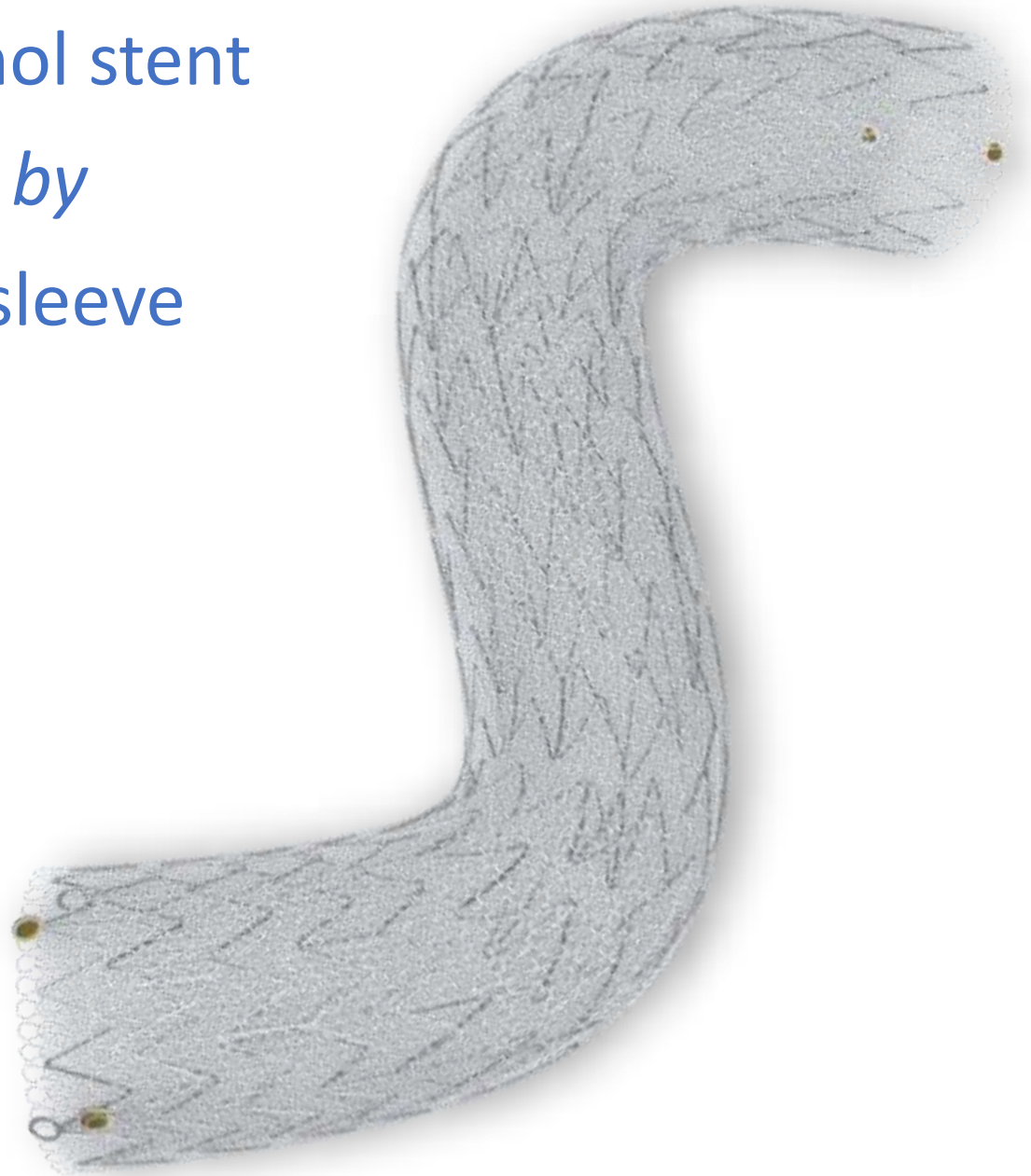
Speaker name:

Piotr Musialek

I have the following potential conflicts of interest to report:

- ☒ Consulting: Abbott, InspireMD, Medtronic
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☒ Other(s): Research support: Abbott, InspireMD, SilkRoad  
Proctoring: InspireMD, Medtronic  
CGUARDIANS FDA-IDE - CoPI
- ☐ I do not have any potential conflict of interest

Open-cell Nitinol stent  
*wrapped by*  
a MicroNET sleeve



**CGuard MicroNET – covered  
2nd generation carotid stent**

The **MOST 'open'** amongst open-cell stents (metallic FRAME)  
& the **MOST 'close'** amongst close-cell stents (MicroNET mesh)

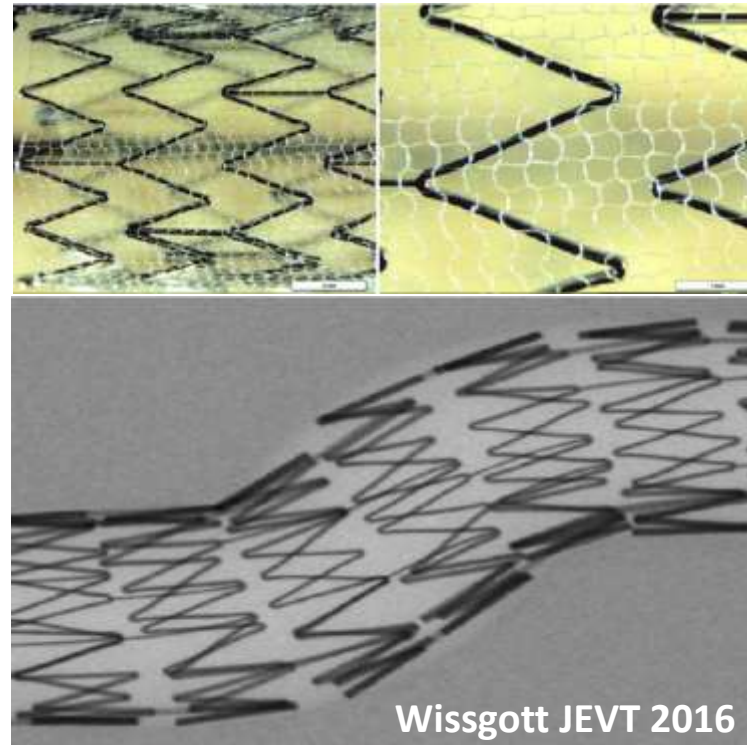


CGuard MicroNET – covered  
2nd generation carotid stent

UNIQUE  
mechanical  
properties

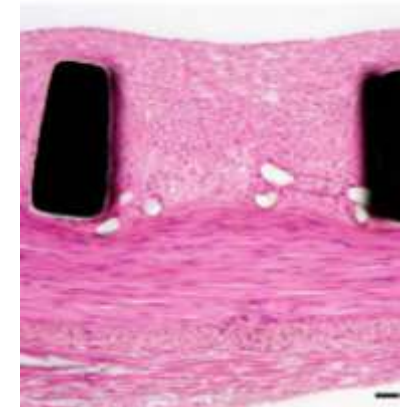
RESPECT  
of anatomy

FULL  
apposition



Wissgott JEVT 2016

**NORMAL**  
healing



90 days



Nitinol scaffold open-cell size : 11.48 mm<sup>2</sup>  
MicroNET pore diameter/area: 165  $\mu$ m / 0.023–0.032 mm<sup>2</sup>



# Respecting Anatomy



# Respecting Anatomy



MicroNet Embolic Prevention

# PARADIGM-500



## Study Population:

500 Consecutive, Unselected, Patients with

- SYMPTOMATIC

*or*

- Increased-Stroke-Risk ASYMPTOMATIC

atherosclerotic carotid stenosis

# PARADIGM-500



Hypotheses:

**#1** 30-d Death/Stroke **<1%**

**#2** 12-mo procedure\*/device-related events **<1%**

\*inclusive of any failure to prevent ipsilateral carotid-related stroke



# PARADIGM-500



## Methods:

- **Primarily-intended TF\* CAS**
- **"Tailored" use of distal / proximal EPD**
- **Routine coronary-like stent optimization**

**100% Study data external monitoring (CRO)**

\*other access routes Protocol-accepted if/when TF unfeasible or failed

# PARADIGM-500



Primary endpoint:

**Composite of death, stroke (major/minor) and MI**

in the periprocedural period (defined as the period from CAS admission to 48 hours after CAS or to CAS-related discharge, whichever was longer) and at 30 days

# PARADIGM-500



## Key secondary endpoints:

- **Death/stroke by 30 days**
- **Ipsilateral stroke by 12-months and 5-years**
- **Device success**

**Acute study device success:** the ability to treat the index carotid lesion using the study device (CGuard-EPS) successfully delivered and deployed at the lesion site, obtaining residual diameter stenosis <30% by quantitative angiography.

**Long-term device success:** freedom from ISR/TLR by 12-mo/5-years

- **Procedure success**

- **Acute procedural success**, defined as device success in the absence of any periprocedural stroke, MI, or vascular complication that would require interventional management.
- 12-mo procedural success, defined as **freedom from ipsilateral stroke and ISR**
- 5-year procedural success, defined as **freedom from ipsilateral stroke and ISR**

# PARADIGM-500



## Demographic characteristics of subjects

Variable	Measure/Level	Value
Age	n	500
	Mean( $\pm$ SD)	69.96 ( $\pm$ 8.14)
Gender:	n	500
	Female	137 (27.4%)
	Male	363 (72.6%)
Symptomatic status	n	500
	no	201 (40.2%)
	yes	299 (59.8%)

## Medical history

	PARADIGM 500 (n=500)
Prior CABG	56 (11%)
Prior PCI	137 (27%)
Prior myocardial infarction	152 (30%)
Atrial fibrillation	68 (13%)
Previous neck or chest radiotherapy	35 (7%)

# PARADIGM-500



**# Arteries/Procedures – 533**

**TF – 514 96.4%**

**TR/TCR – 19 3.6%**

**Prox EPD – 259 48.6%**

**Dist EPD – 274 51.4%**

**Study device use – 533 CAS 100%**

**(NO CAS outside the study; ZERO any other stent use)**

**100% Study data external monitoring (CRO)**



# PARADIGM-500



## Adverse Clinical Events in PARADIGM 500

PARADIGM 500 (n=500)	Periprocedural	48 to 30 days	Up to 30 days (cumulative)	30d to 12 months	Up to 12 months (cumulative)
MACCE (MI, any stroke, death)	3	2	5	19	24
MI	1	0	1	2	3
<b>major stroke – ipsilateral</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
major stroke – contralateral	0	0	0	1	1
<b>minor stroke – ipsilateral</b>	<b>2</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>2</b>
minor stroke – contralateral	0	0	0	0	0
retinal stroke	0	0	0	1	1
death	0	2	2	16	18

Deaths:

sepsis/urosepsis - 2, MI -1, PE -1 , CHF -1, SCD -2, brain stem stroke -1, cancer -4, bleeding -1, multiple organ failure -1, sepsis -1, COVID-19 -3

**ISR: 2**

1 asympt. occlusion – larynx cancer relapse with RadioTx 2 months after CAS, 1 asymptomatic restenosis @12 – treated with DEB-PTA (no relapse)

# PARADIGM-500

## OUTCOMES



Device success	533/533	100 %
Procedure success	529/533	99.2%
30-d Death/Stroke	4/533	0.75%
30-d Death/Stroke/MI	5/533	0.94%
12-mo freedom from ipsi stroke	480/482	99.6%
12-mo freedom from ISR/TLR	480/482	99.6%
12-mo freedom from procedure*		
/device-related events	478/482	99.2%

\*inclusive of any failure to prevent ipsilateral carotid-related stroke (4 events: 2 perip. minor strokes, 1 bleeding-related death, 1 TLR)





# Long-term outcomes from the micronet-covered stent system routine use for carotid revascularization in primary and secondary stroke prevention: 5-year evidence from the PARADIGM-Extend prospective academic study

A. Mazurek<sup>1</sup>, A. Boratyńska<sup>2</sup>, T. Tomaszewski<sup>2</sup>, A. Lesniak-Sobelga<sup>1</sup>, P. Wilkolek<sup>1</sup>, M. Brozda<sup>1</sup>, E. Sobieraj<sup>1</sup>, M. Sikorska<sup>1</sup>, L. Czyz<sup>1</sup>, M. Urbanczyk<sup>3</sup>, M. Trystula<sup>4</sup>, T. Drabik<sup>1</sup>, P. Musialek<sup>1</sup>

<sup>1</sup>Jagiellonian University Department of Cardiac & Vascular Diseases and Cathlab, John Paul II Hospital, Krakow, Poland; <sup>2</sup>Outpatient Neurology Clinic, Krakow, Poland; <sup>3</sup>John Paul II Hospital Dept. of Vascular Surgery, Krakow, Poland; <sup>4</sup>Neurology and Vascular Surgery, Krakow, Poland



PARADIGM-Extend = Prospective evaluation of All-comer perCutaneous carotid revascularization in symptomatic and increased-stroke-risk asymptomatic carotid artery stenosis using CGuard™ MicroNet-covered embolic prevention stent system – clinical study extension

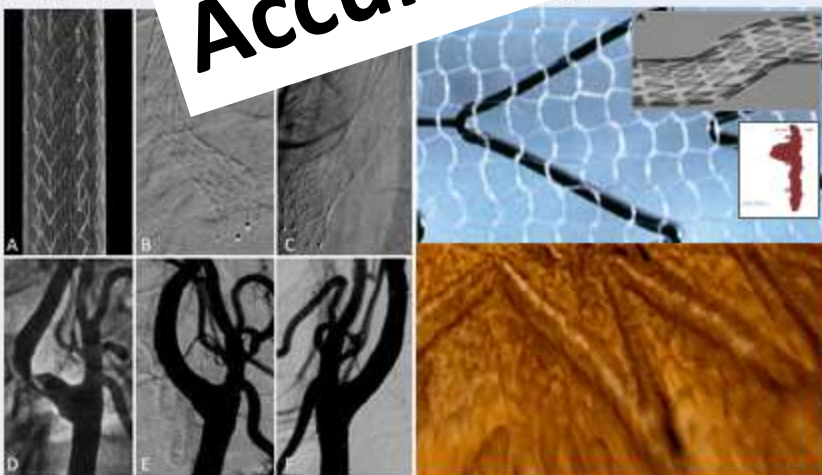
## Background

The CGuard™ EPS system is a dual layer (hybrid) stent which consists of nitinol, open-cell frame wrapped with ultra-closed-cell polyethylene terephthalate (PET) MicroNet

Principal stent features:

- large open cell area of the nitinol frame (21.66 mm<sup>2</sup>)
- high flexibility and high conformability consistent with the open cell stent design
- ultra-low cell area of MicroNet (0.023-0.032 mm<sup>2</sup>) with the MicroNet fibre thickness of 0.001 mm – “cheese grater effect”
- optimal radial force - 0.055 N/mm (comparable to the PreScribe stent)
- placement predictability/ precision and lack of foreshortening

Diffusion-weighted magnetic resonance imaging (DWI-MRI) showed no periprocedural cerebral embolism in carotid arteries treated with the CGuard™ MicroNet-covered embolic prevention stent system effectively minimizing periprocedural cerebral embolism in carotid arteries.



## Purpose

To evaluate long-term clinical/neurologic and duplex ultrasound (DUS) outcomes of the MicroNET-covered stent system routine use in unselected, consecutive patients with a confirmed indication for carotid revascularization for primary or secondary stroke prevention.

## Methods

PARADIGM-EXTEND is an all-comer, all-referrals-tracked study with no exclusion criteria other than lack of NeuroVascular Team-determined indication. Clinically asymptomatic patients receive revascularization only in case of increased-stroke-risk characteristics. Adverse events are independently adjudicated.

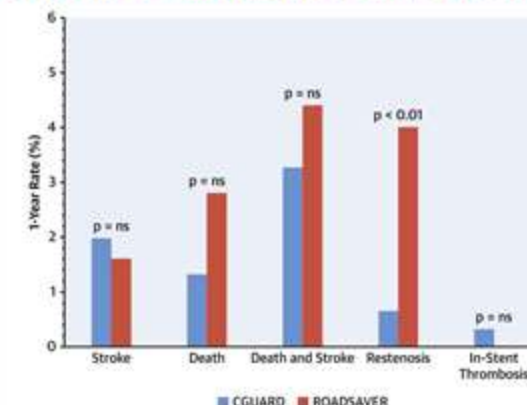
- Accumulating Long-Term Outcomes**
- 480 patients (39-87 yo, 59.8% symptomatic, 142 women), 514 arteries - crossed 30 day follow up period
  - 100% MicroNet-covered embolic prevention stent system use (ie, not a single other stent type has been used throughout study duration).
  - Proximal/distal intra-procedural neuroprotection use was 39.2%/60.8%.
  - Large balloon/high-pressure stent optimization was routinely performed, leading to a single-digit (6.7%) mean post-procedural residual angiographic stenosis.
  - Adequate heparinization, with ACT control (2250 s)
  - Independent neurologist and duplex evaluation are performed before and after (48h and 30 days, then yearly) carotid revascularization.
- Peri-procedural safety and clinical outcomes:**
- peri-procedural death or major ischemic stroke (IS) rate was 0%.
  - two events were adjudicated as minor IS (0.42%) – extension of prior infarct scar in a patient with prolonged hypotension; diplopia, that recovered after 24h with new lesions on brain imaging
  - myocardial infarction (MI) (type 2; 0.21%) - two-vessel non-revascularizable CTO.
- 30-day follow-ups:**
- total death/stroke rate at 30 days - 0.83%, and total death/stroke/MI rate at 30 days was 1.04%
  - one IS haemorrhagic transformation leading to death (0.21%)
  - one bleeding-related death (0.21%)
  - no major IS by 30 days (0.0%)
- Long-term follow-up**

	12 mo	24 mo	36 mo	48 mo	60 mo
Ipsilateral stroke	n = 354 1* (device correlated)	n = 248 0	n = 173 0	n = 106 0	n = 46 1* (device correlated)
Any stroke	1	2 (1 contralateral)	1 (stroke stroke)	1 (stroke stroke)	1
Stroke related death	0	0	0	0	1
MI or other non - cerebral VA	1	3	2	2	0
Restenosis	1 (after 11%)	1	0	0	0
Any death	13 (2HF - 4, 1Ca - 3, PE - 1, arrhythmia - 1, MI - 3, CTO - 2, sepsis - 2)	10 (2HF - 3, 1Ca - 2, MI - 2, intracranial bleed - 1, sepsis - 2)	7 (1Ca - 2, 2HF - 3, MI - 1, sepsis - 1)	6 (2HF - 2, MI - 1, 1Ca - 1)	1 (stroke)

## Duplex ultrasound (DUS) in-stent/lesion velocities (m/s)

	PSV ± SD	EDV ± SD
Baseline	3.76 ± 1.34	0.64 ± 0.71
Post-procedural	0.69 ± 0.28	0.18 ± 0.09
12 mo	0.78 ± 0.40	0.21 ± 0.11
24 mo	0.76 ± 0.36	0.20 ± 0.09
36 mo	0.75 ± 0.34	0.20 ± 0.09
48 mo	0.75 ± 0.41	0.20 ± 0.08
60 mo	0.78 ± 0.50	0.20 ± 0.10

## Use of Dual-Layered Stents for Carotid Artery Angioplasty: 1-Year Results of a Patient-Based Meta-Analysis; (RoadSaver-250; CGuard-306)



Stabile et al. JACC Cardiovasc Interv. 2020;13(14):1709-1715. doi:10.1016/j.jcin.2020.03.048

## Conclusions

PARADIGM-Extend long-term clinical and duplex ultrasound evidence is consistent with normal healing and sustained safety and stroke prevention efficacy of the micronet-covered embolic prevention stent system used routinely, on top of optimized medical therapy, for stroke prevention in symptomatic and increased-stroke-risk asymptomatic subjects with carotid stenosis with the NeuroVascular Team-established recommendation for carotid artery revascularization.

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“TCAR is more  
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TFCAS,\* but appears  
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\* a “CAS” ≠ a “CAS”

HISTORICAL “CAS” is of HISTORICAL value :)





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1° I am an admirer of Dr. Peter Schneider!  
2° I am a TCAR believer (and user! :)



“TCAR is more invasive than TFCAS\*, but appears to be dramatically safer from a neurologic standpoint.”

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”[CAS] Using second-generation stents such as the MicroNet-covered stent is very different from CAS a decade ago.”

”Competent-operator CAS (including transfemoral/transradial CAS), using embolic prevention stents combined with tailored use of intra-procedural proximal cerebral protection, may prove superior to surgery!”

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## SYSTEMATIC REVIEW

## TCAR

**Editor's Choice –** Early and Late Outcomes after Transcarotid Revascularisation for Internal Carotid Artery Stenosis: A Systematic Review and Meta-Analysis

George C. Galyfos <sup>✉</sup>, Ioannis Tsoutsas <sup>✉</sup>, Theofanis Konstantopoulos <sup>✉</sup>, Georgios Galanopoulos <sup>✉</sup>, Frangiska Sigala <sup>✉</sup>, Konstantinos Filis <sup>✉</sup>, Vassilios Papavassiliou <sup>✉</sup>

**“Symptomatic patients had a higher risk of early stroke/TIA than asymptomatic patients (2.5% vs. 1.2%; odds ratio 1.99; 95% CI 1.01 -3.92)!” \***

**\* TCAR using a single-layer (1st gen) Carotid Stent**



**“We need to remember that a patient’s preference will always be with less invasive, but safe and effective, and long-term durable, treatments.”**



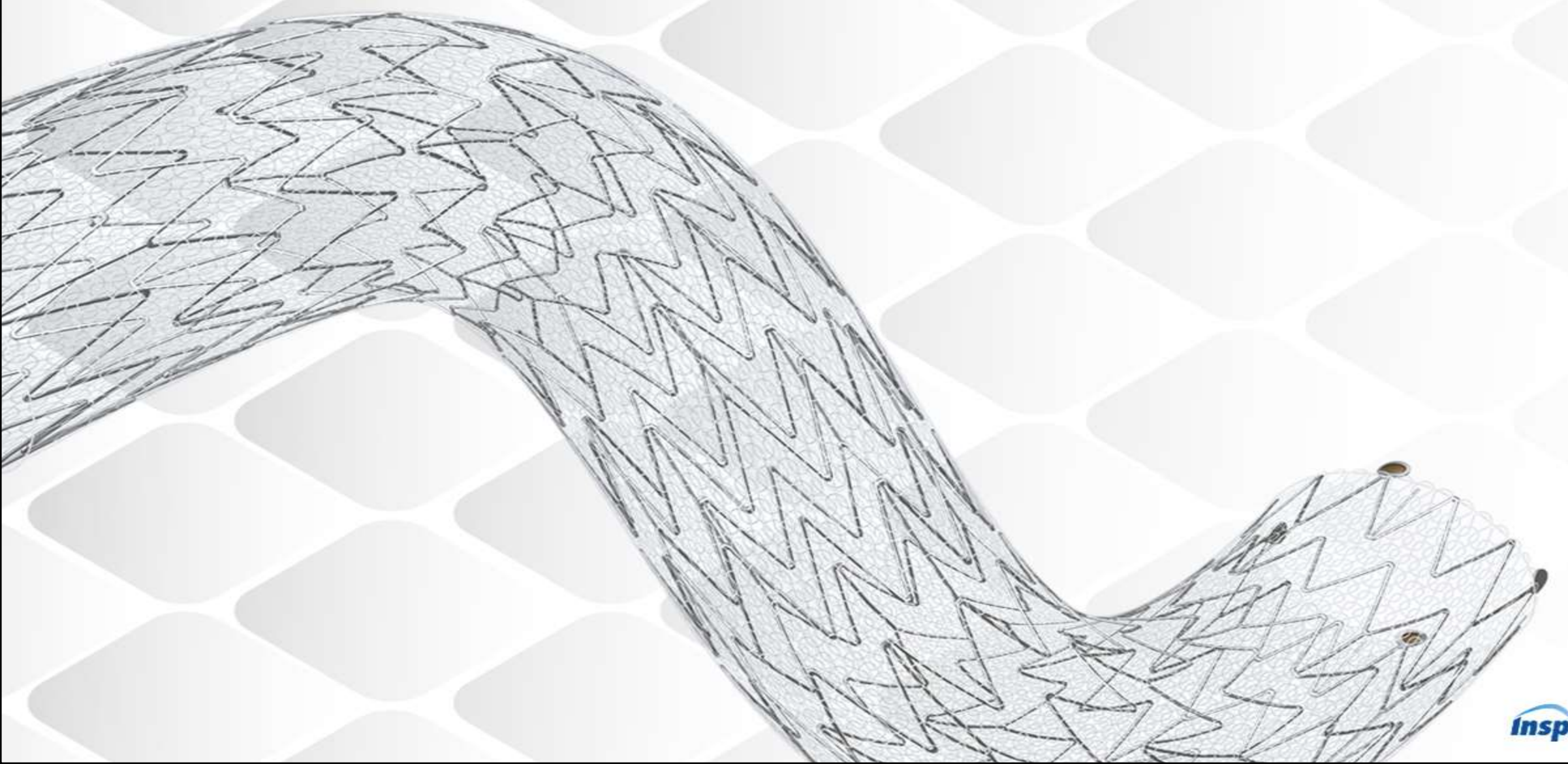
**“Patients should have a say in treatment decision-making”**



# FDA-IDE Clinical Trial:

**CGUARDIANS**

NCT 04900844



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NCT 04900844

**Co-PIs**    **D. Christopher Metzger (US)**  
                  **P. Musialek (Europe)**

**DSMB**    G. Ansel – Chair, N. Hopkins, B. Gersh  
**CEC**      M. Burket – Chair, R. Sakhulja, P. Faries

**Standard FDA Inclusion/Exclusion criteria for Clinically Symptomatic or Asymptomatic CS**  
(anatomic or clinical high-risk for CEA)

## **Primary Outcome Measure**

Composite of **D+S+MI  $\leq$  30 days** or **ipsilateral stroke 31–365 days** post-index procedure

**Recruitment goal = 315 patients**

**Study Centers = 18 US + 6 Europe** (up to 40 total)

**Multi Specialty:** Interv. Cardiology, Vascular Surgery, Vascular Medicine/Angiology, Neurology, Neurosurgery



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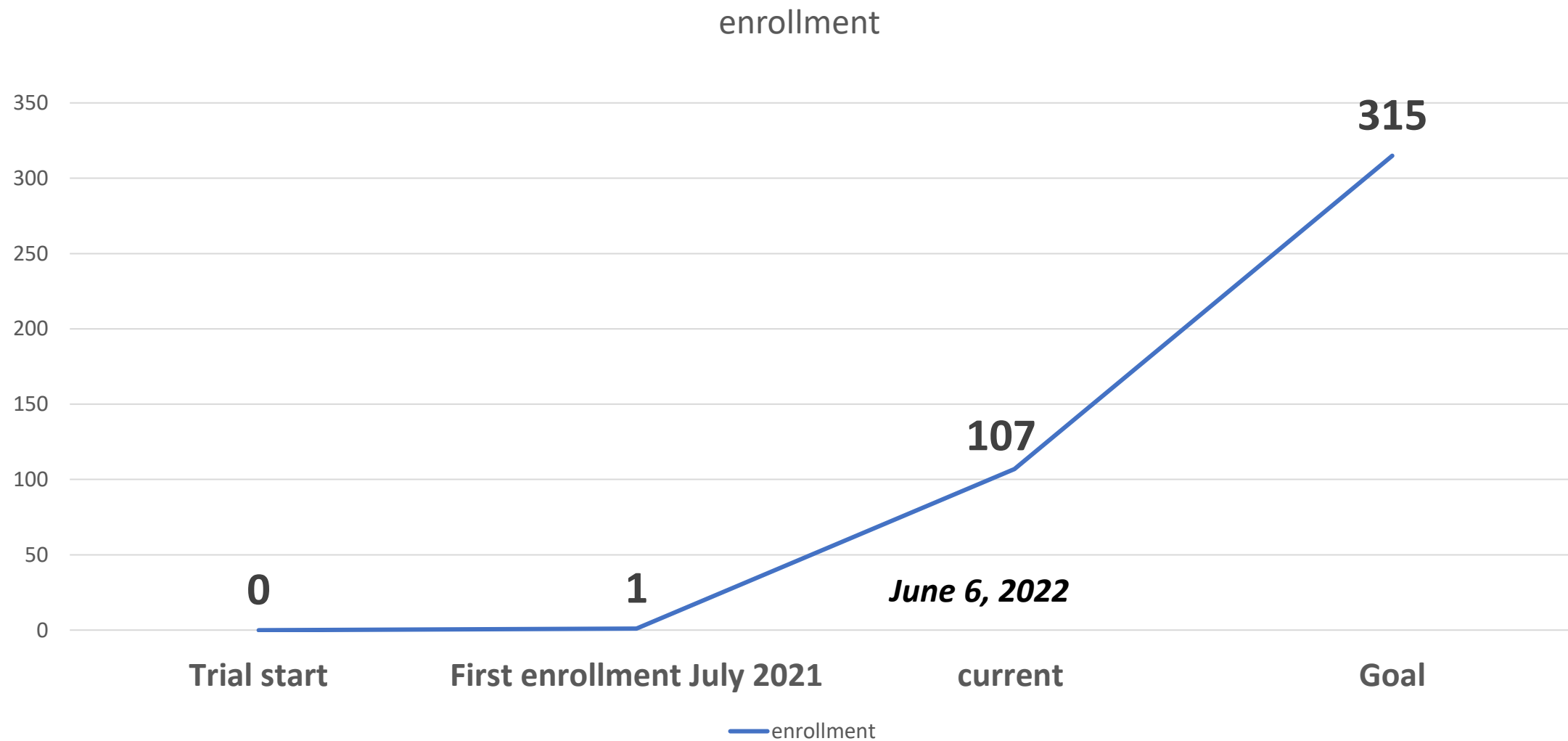
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**CGUARDIANS**

NCT 04900844





P. Pieniazek

P. Paluszek

L. Tekieli

E. Weglarz

A. Mazurek



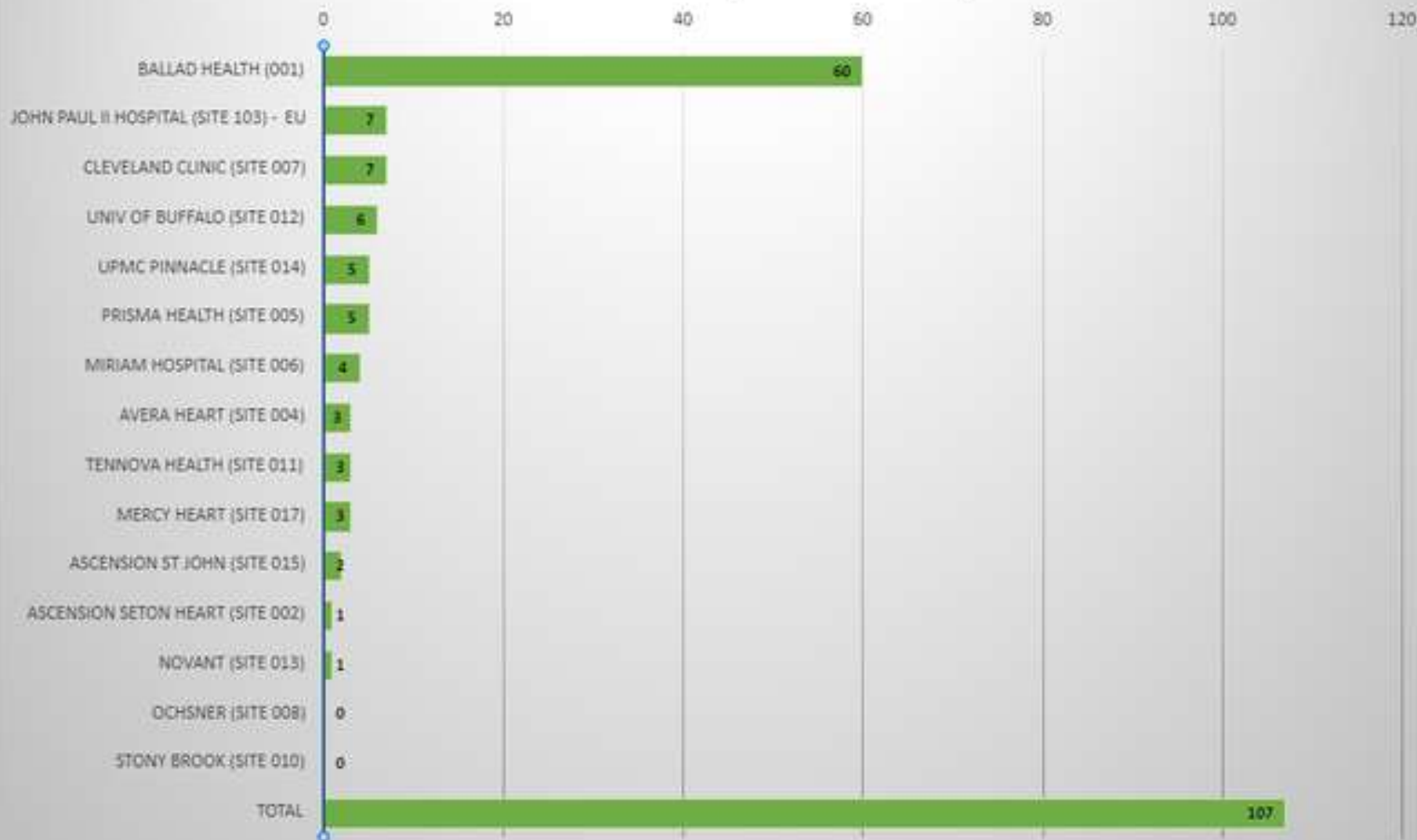
# FDA-IDE Clinical Trial:

CGUARDIANS

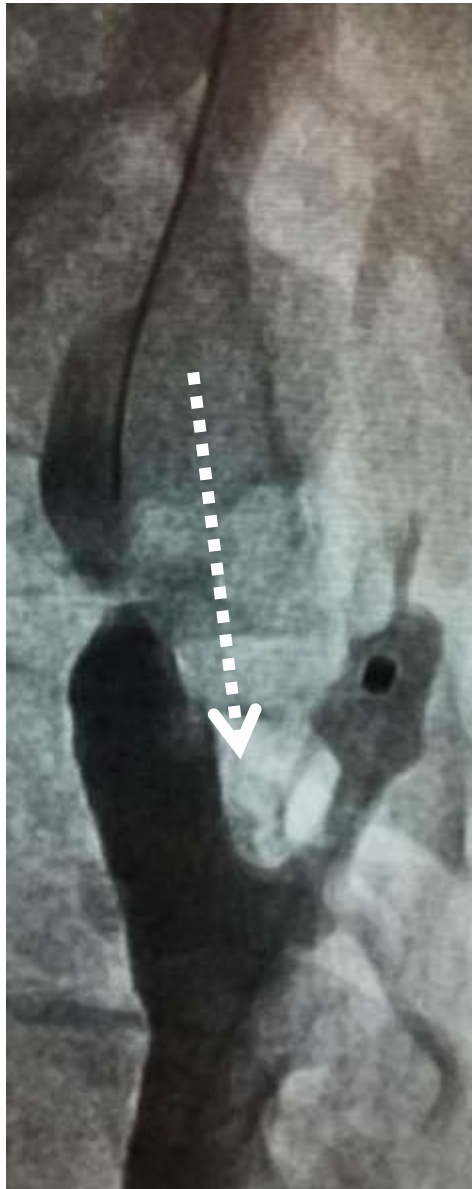
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June 6, 2022

## Total Enrollment (activated sites)









# Randomized Controlled Trial of Conventional Versus MicroNet-Covered Stent in Carotid Artery Revascularization

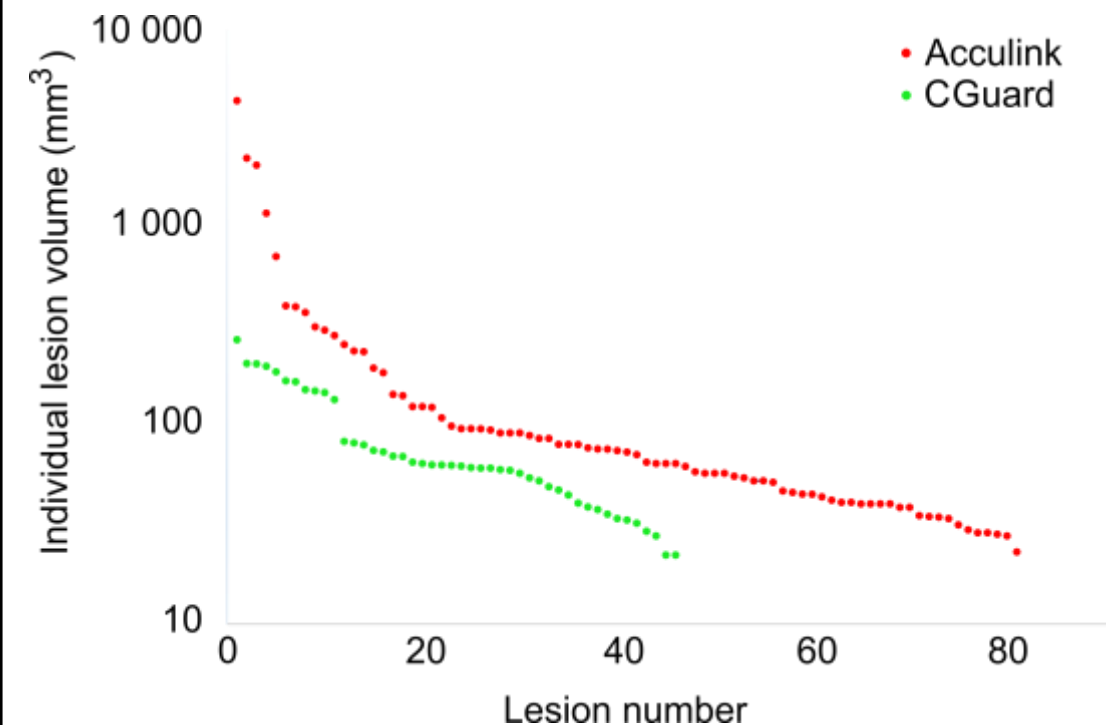
Andrey Karpenko, MD, PhD,<sup>a</sup> Savr Bugurov, MD,<sup>a</sup> Pavel Ignatenko, MD, PhD,<sup>a</sup> Vladimir Starodubtsev, MD, PhD,<sup>a</sup>  
Irina Popova, MD, PhD,<sup>a</sup> Krzysztof Malinowski, MSc,<sup>b</sup> Piotr Musialek, MD, DPM.<sup>c</sup>

## Embololic Load to the Brain

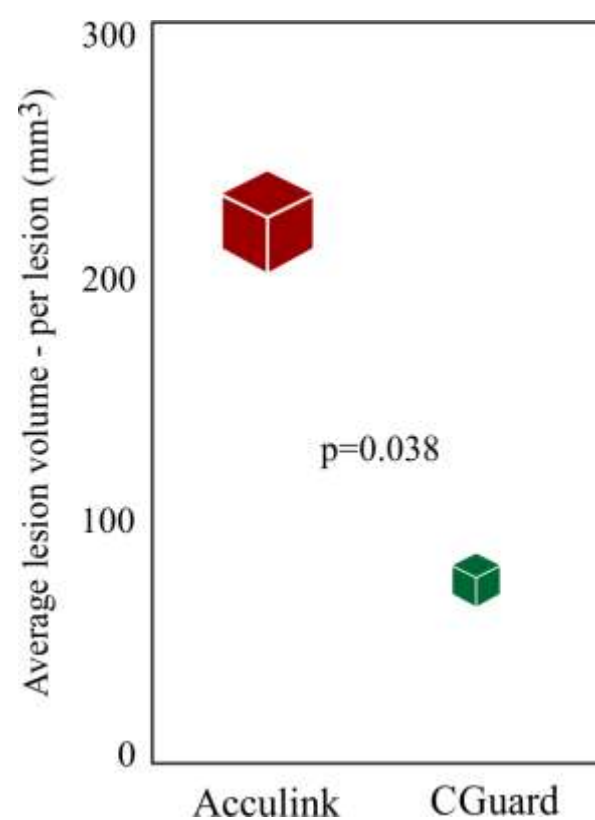
**Acculink** (CREST study device)

**MicroNet-Covered Stent - CGuard**

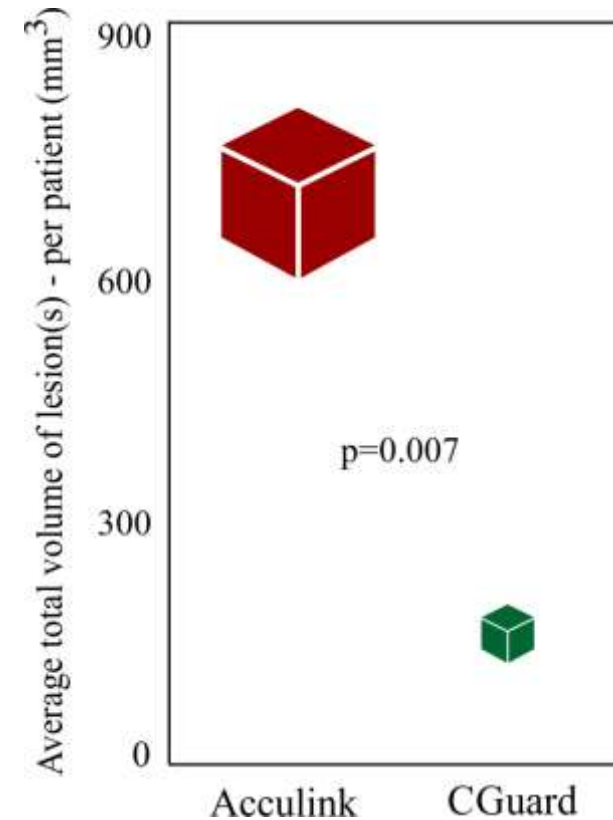
*DW-MRI Embolism*  
raw data



*Per Lesion*



*Per Ipsil Haemisphere*



Emboshield NAV in ALL CAS

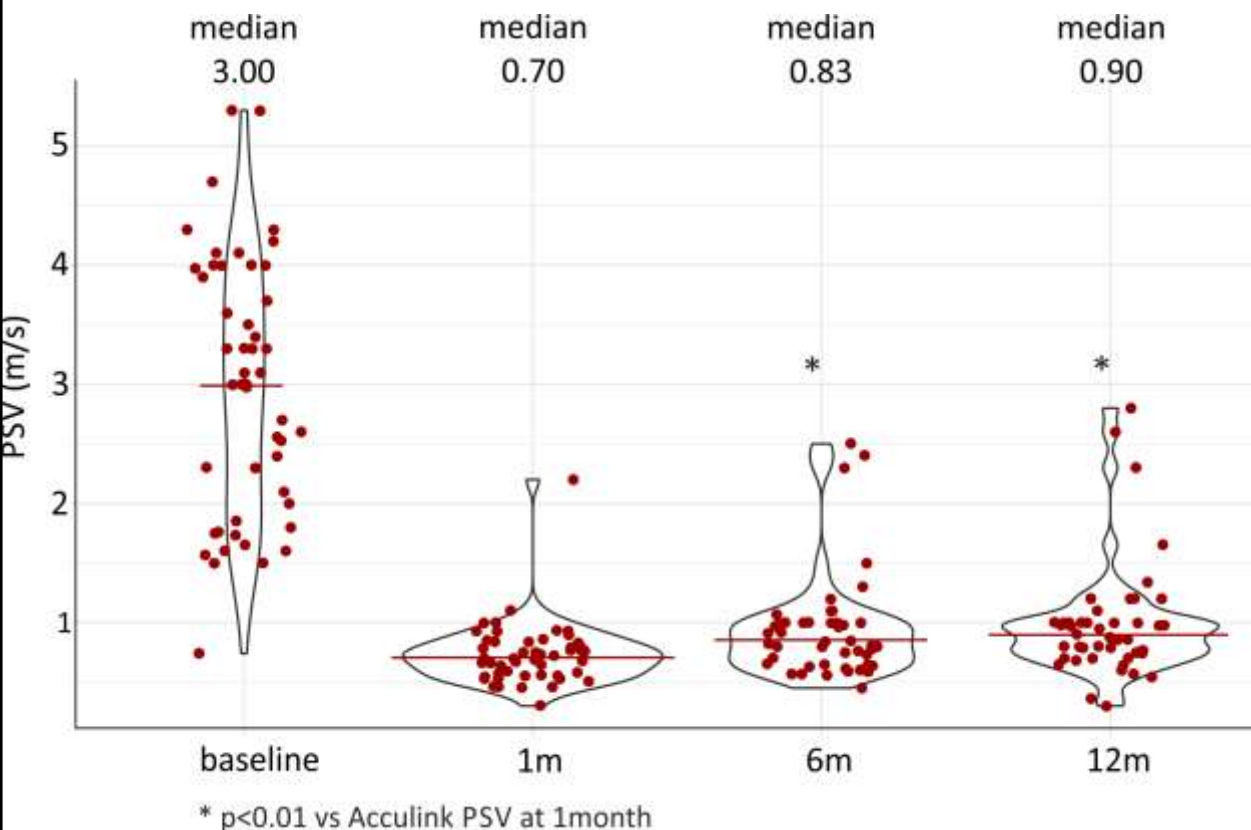
Blinded CoreLab independent analysis

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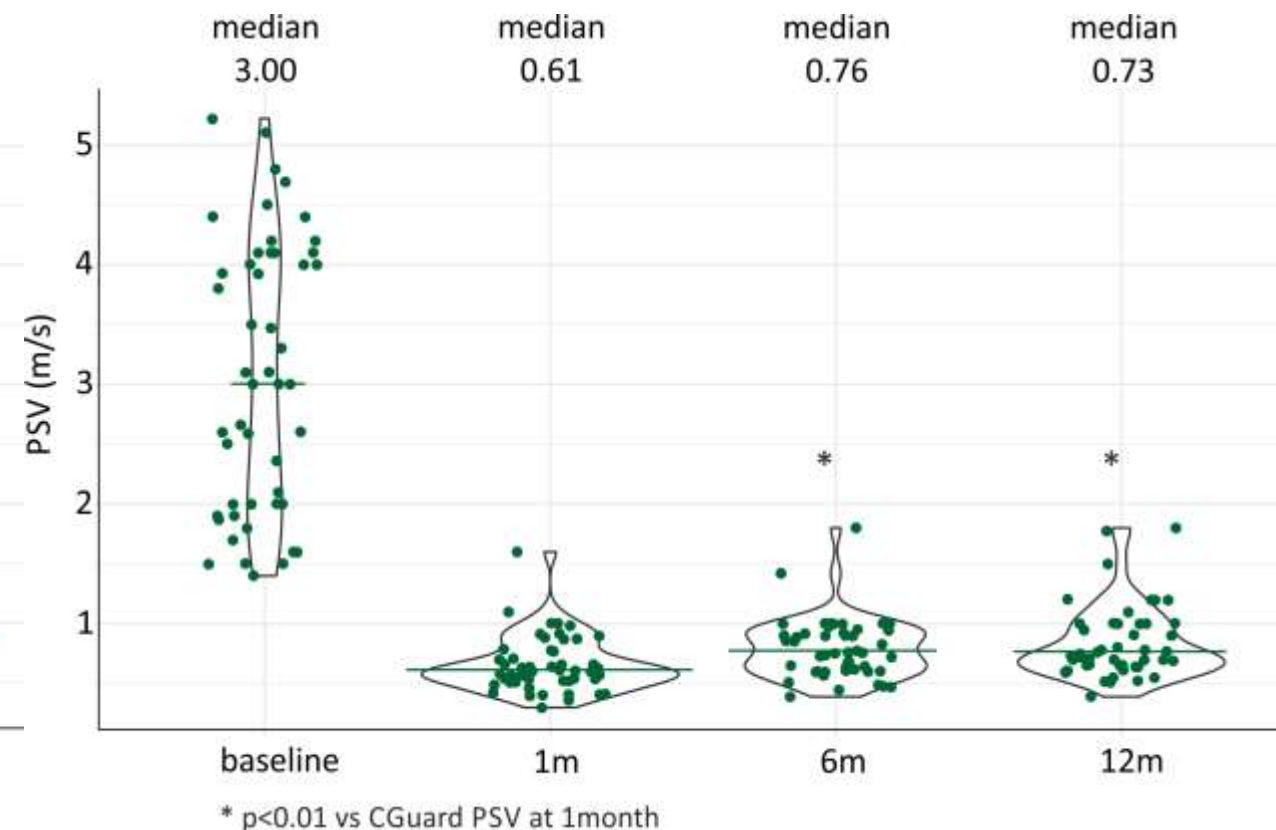
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## 12-mo Follow-up: *Similar Healing Profile*

**Acculink** (CREST study device)



**MicroNet-Covered Stent - CGuard**

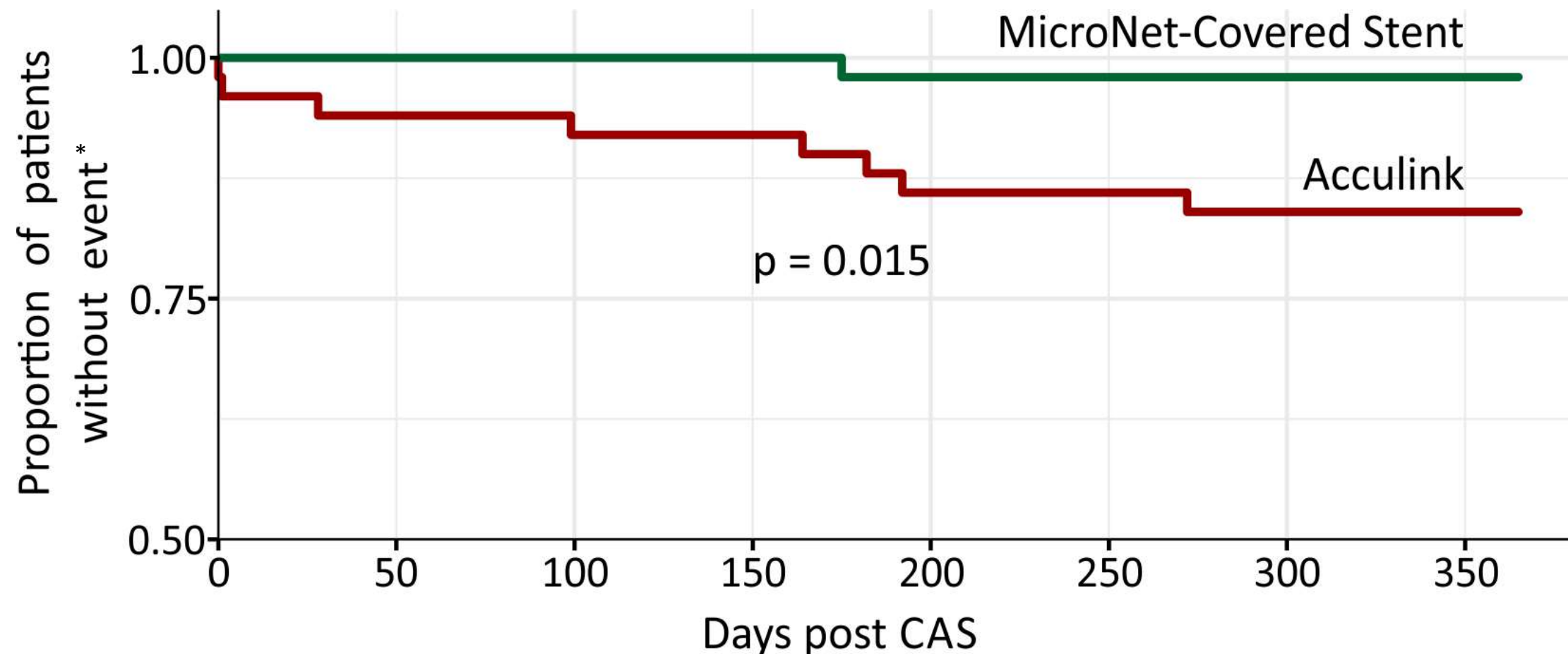


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## 12-mo Follow-up: *Similar Healing Profile...*

**BUT**



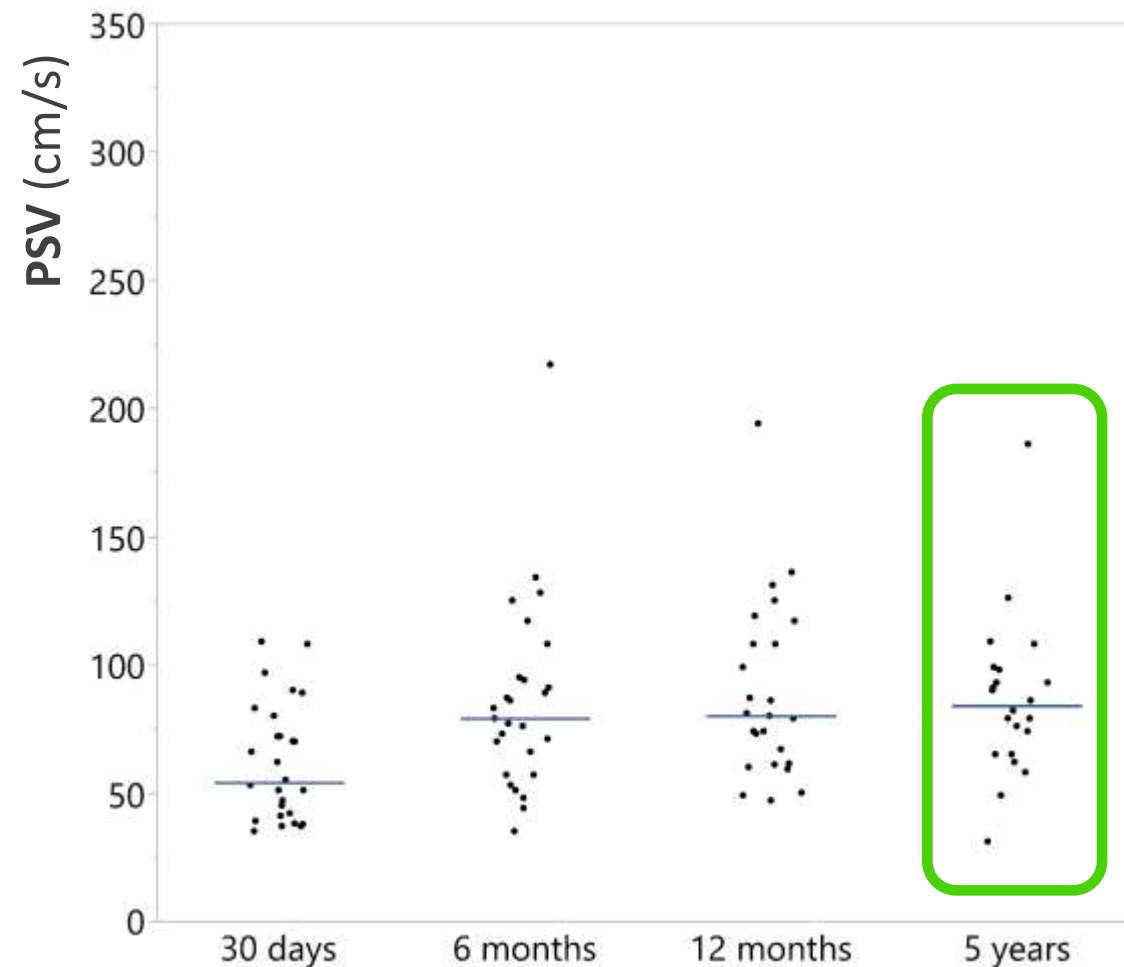
\* Patient-related outcomes: death/stroke/MI/ISR

# A Prospective, Multicenter Study of CARENET Trial

## a Novel Mesh-Covered Carotid Stent

The CGuard CARENET Trial  
(Carotid Embolic Protection Using MicroNet)

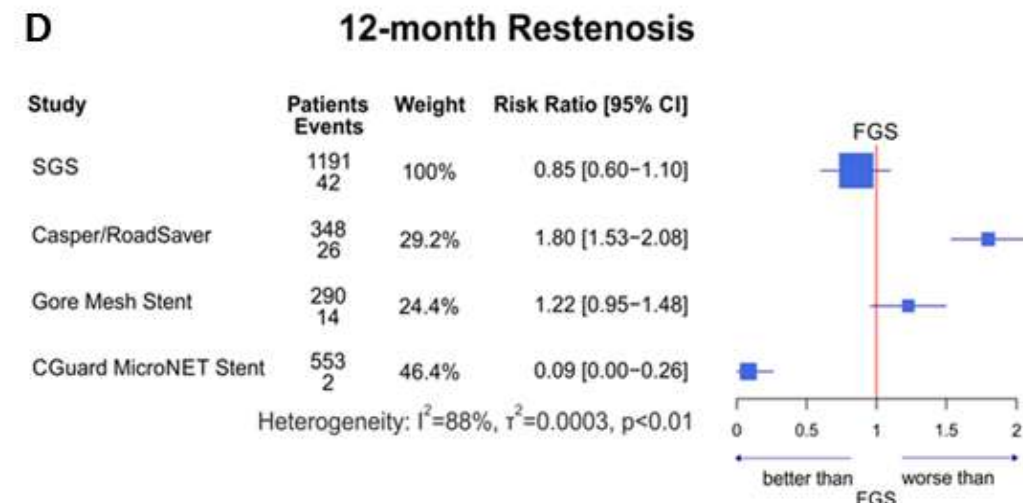
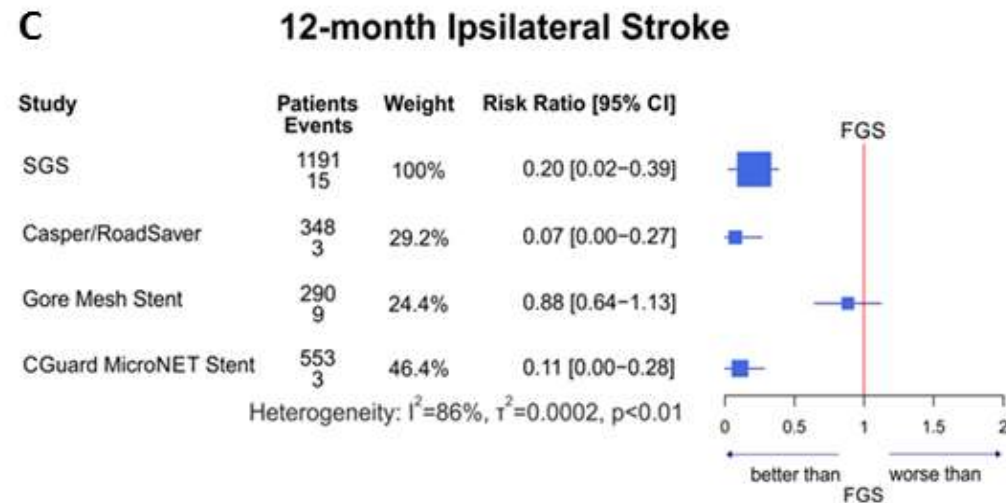
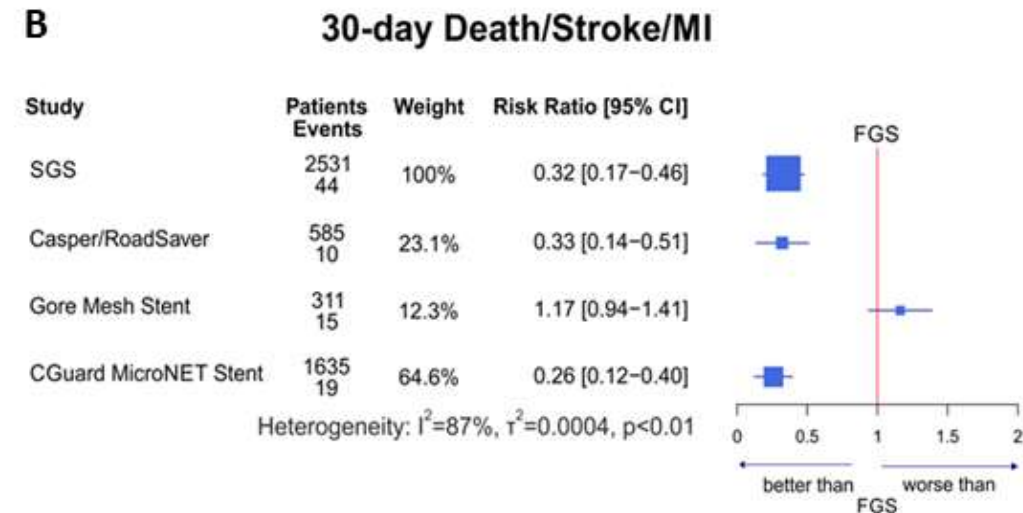
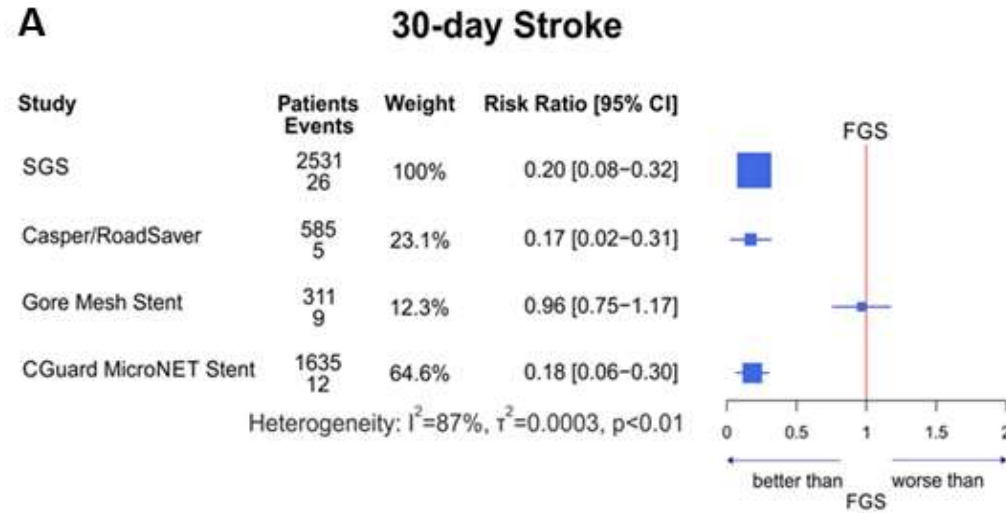
## 5-year follow-up



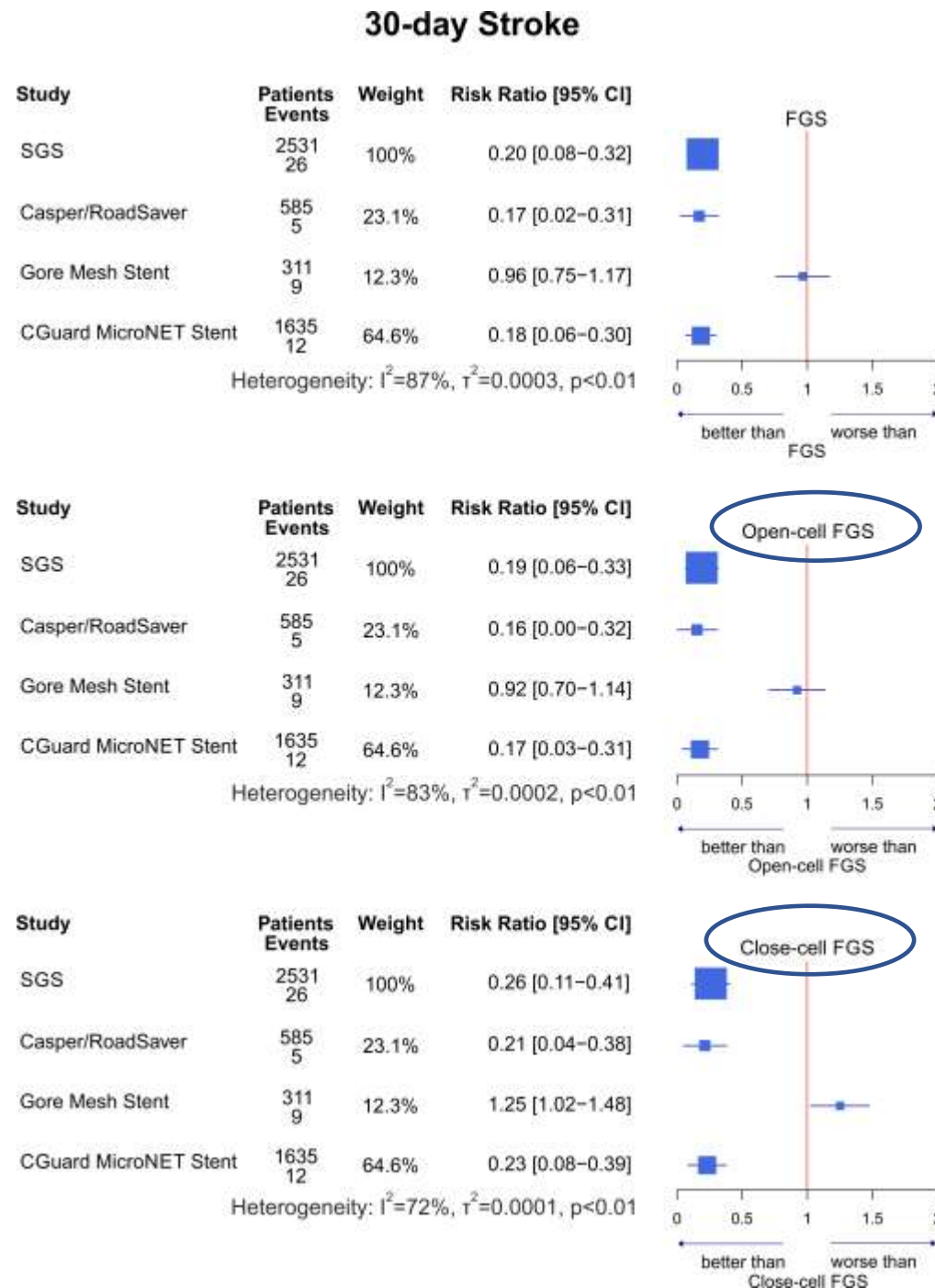


"CAS" ≠ "CAS"

Mesh-covered (second-generation) vs single-layer (first-generation) carotid stents  
(n= 68,043 patients) / 112 studies



# Clinical Outcomes of Second- versus First-generation Carotid Stents: A Systematic Review and Meta-analysis



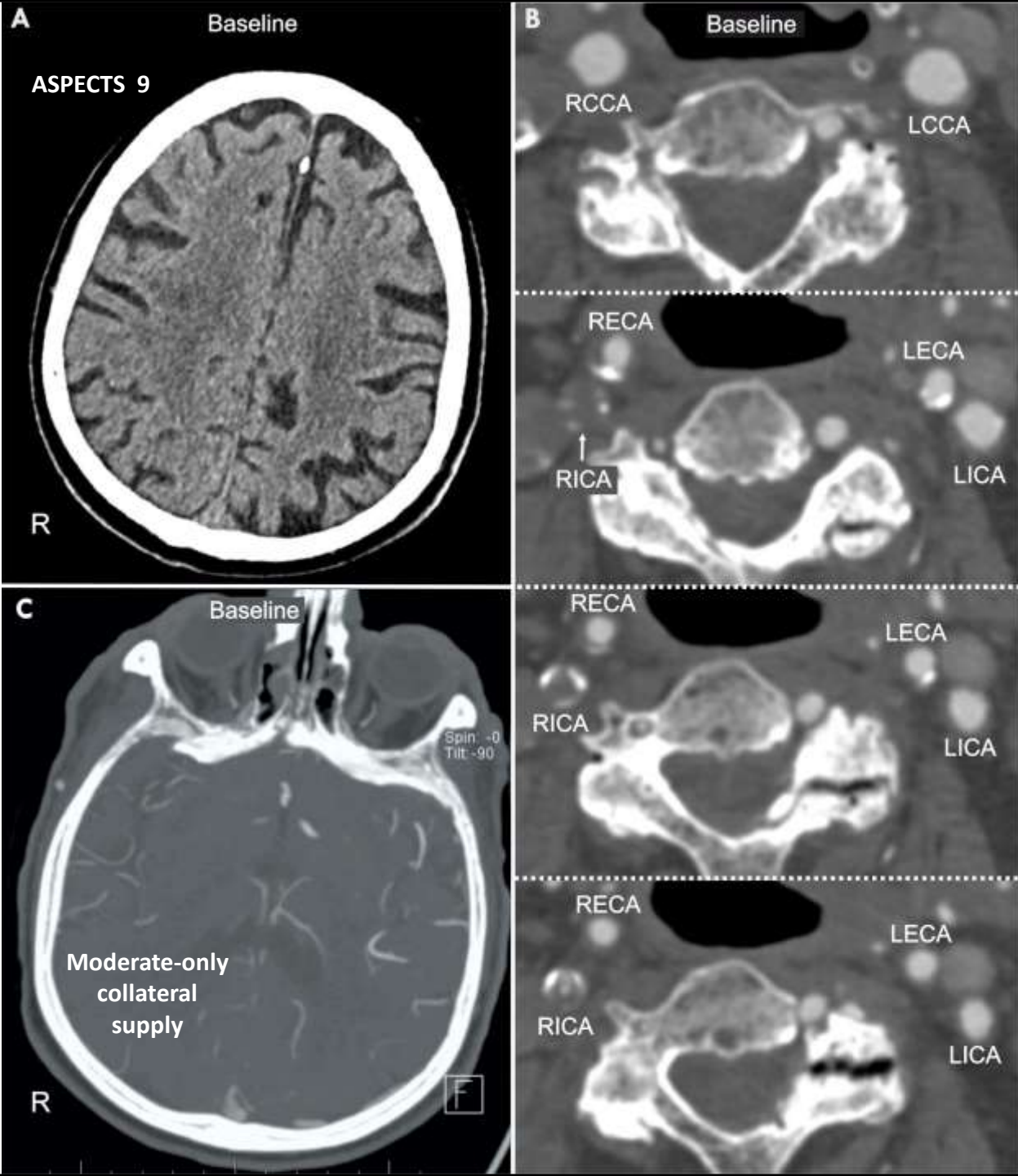


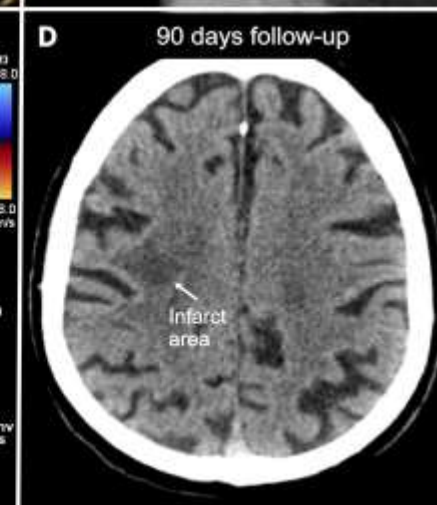
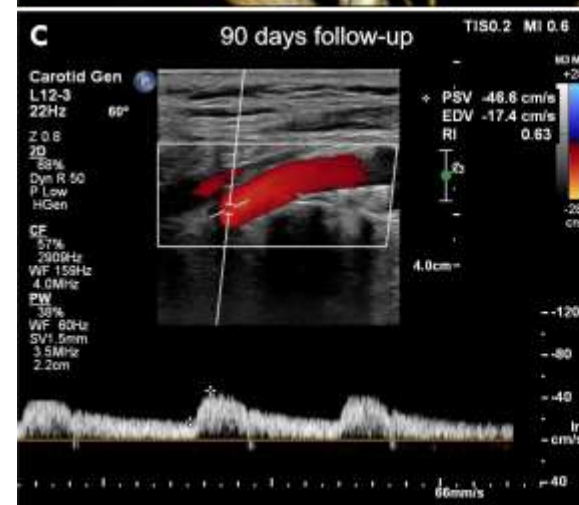
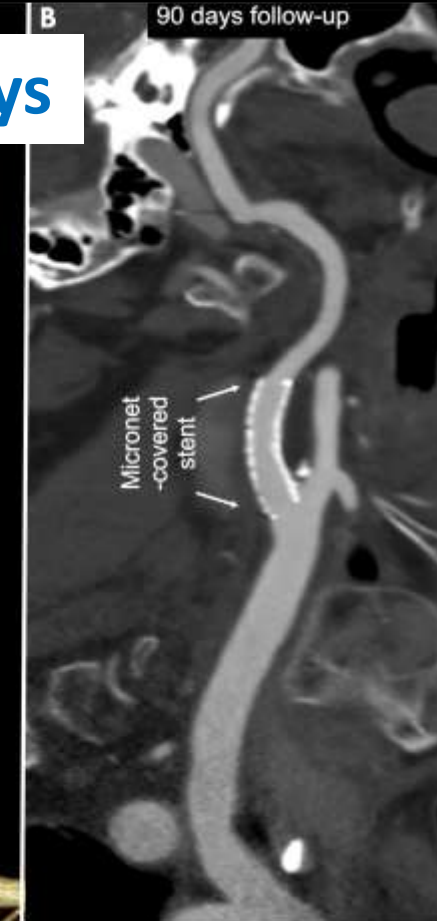
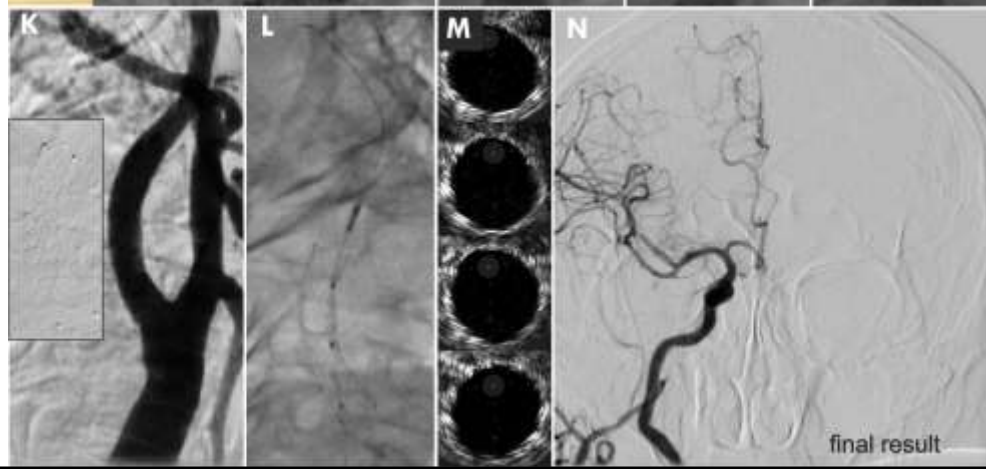
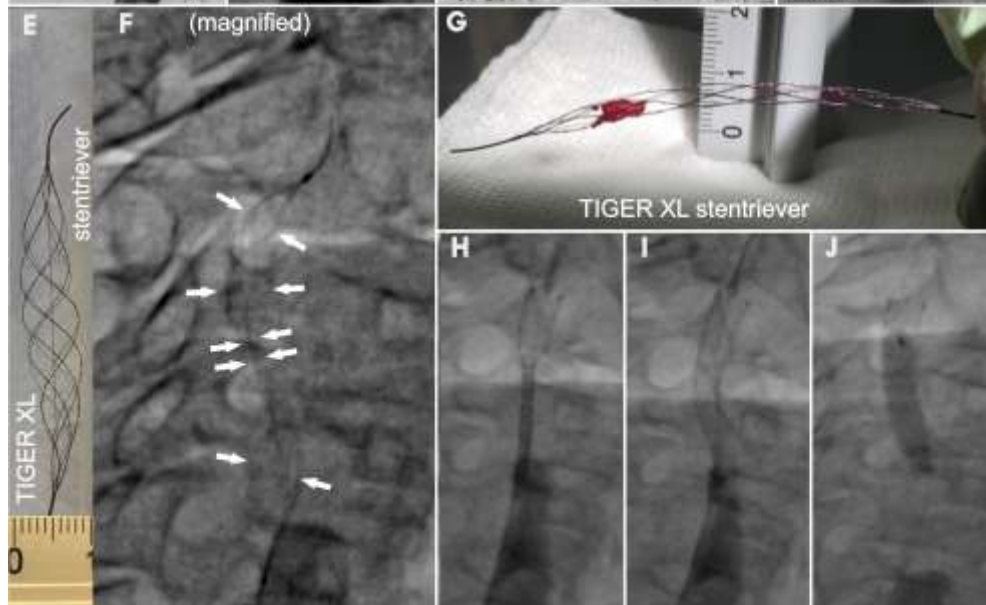
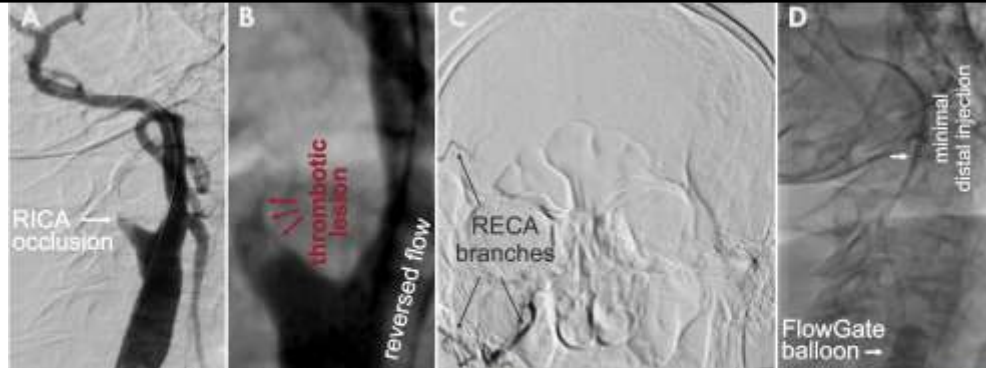
# Novel Large-Diameter Controlled-Expansion Stentriever, Embolic-Prevention Stent and Flow Reversal in Large-Thrombus-Burden ICA Proximal Occlusion Stroke

Lukasz Tekieli, MD, PhD,<sup>a,b,c</sup> Krzysztof Banaszkiewicz, MD, PhD,<sup>c,d</sup> Zbigniew Moczulski, MD,<sup>c,e</sup> Małgorzata Urbańczyk-Zawadzka, MD,<sup>c,e</sup> Piotr Musialek, MD, DPhil,<sup>b,c</sup>

SAFE-GUARD STROKE

ClinicalTrials.gov Identifier: NCT05195658





CLINICALLY  
and  
ANATOMICALLY

**EFFECTIVE**

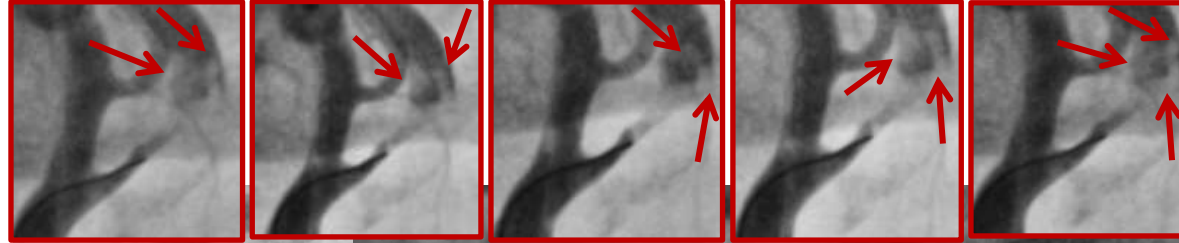
ENDOVASCULAR  
RECONSTRUCTION



# CGuard MicroNET Stent to treat acute ischaemic stroke

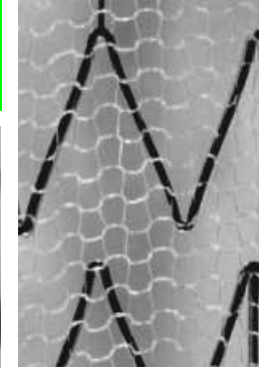
Krakowski Szpital Specjalistyczny Jana Pawła II  
STANISLAW  
-04-10 M 634708  
2021-01-14 14:29:40.703000

## Haemodynamically critical, floating-thrombus lesion



**IMMEDIATE  
Regression  
of symptoms**

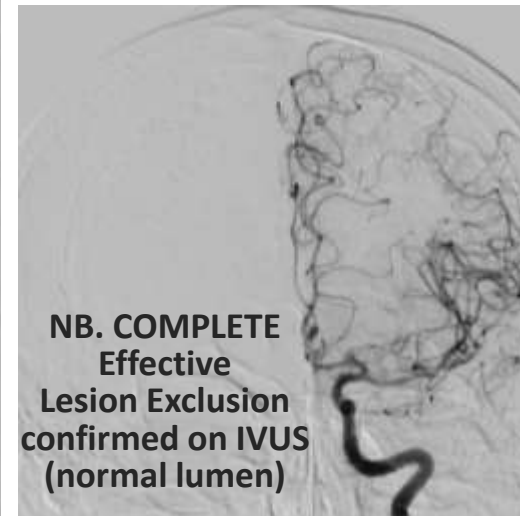
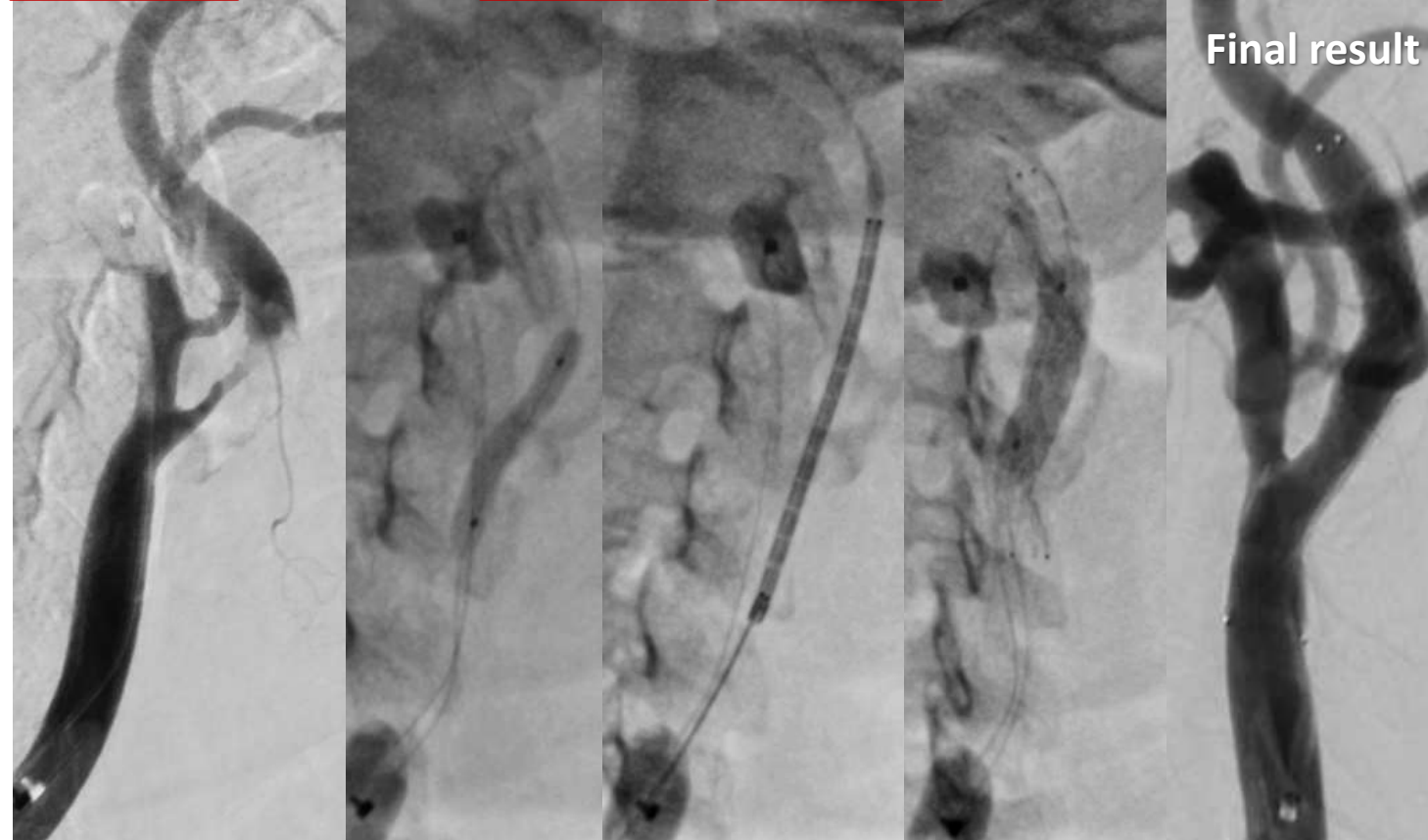
**CGuard**



**MicroNET**

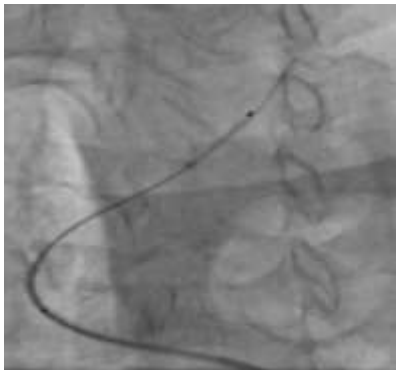


**Final result**



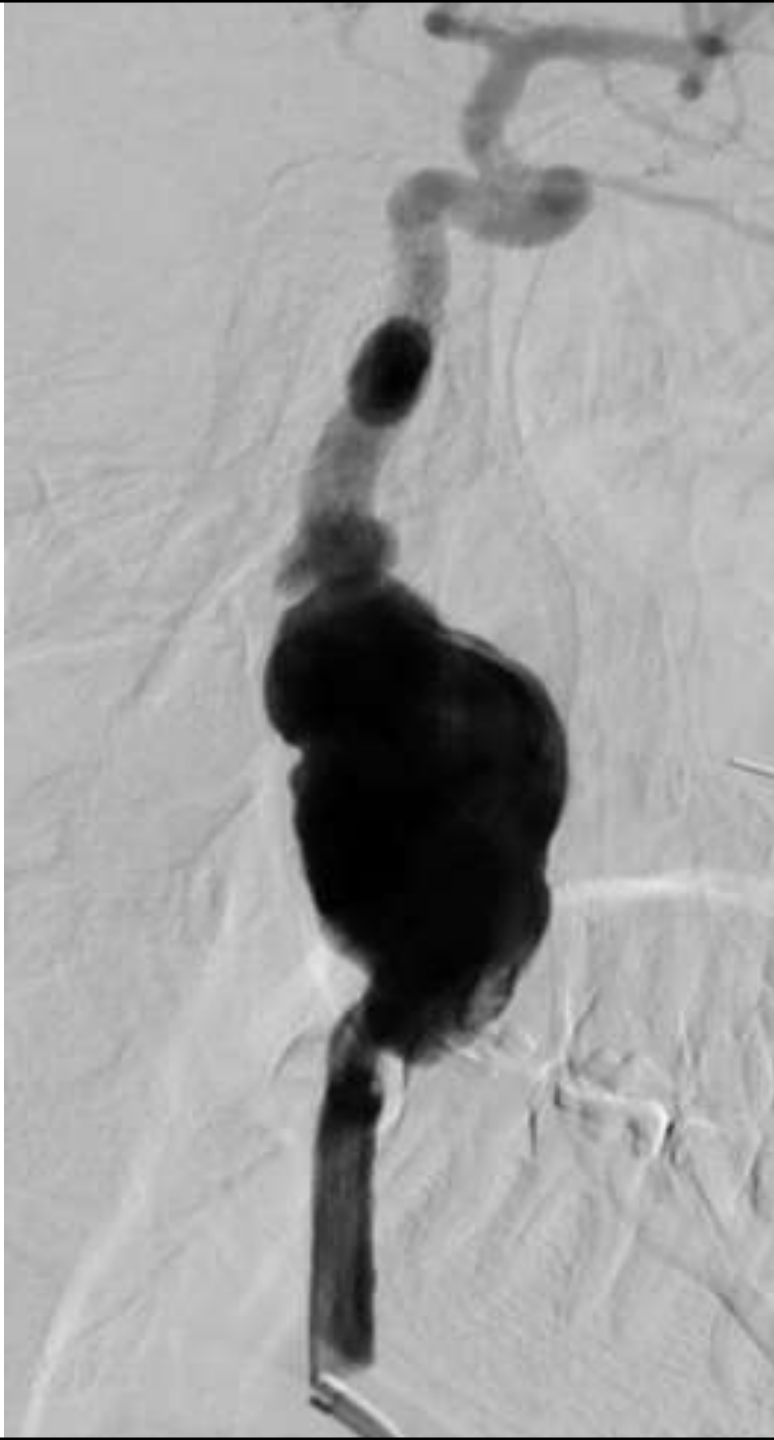
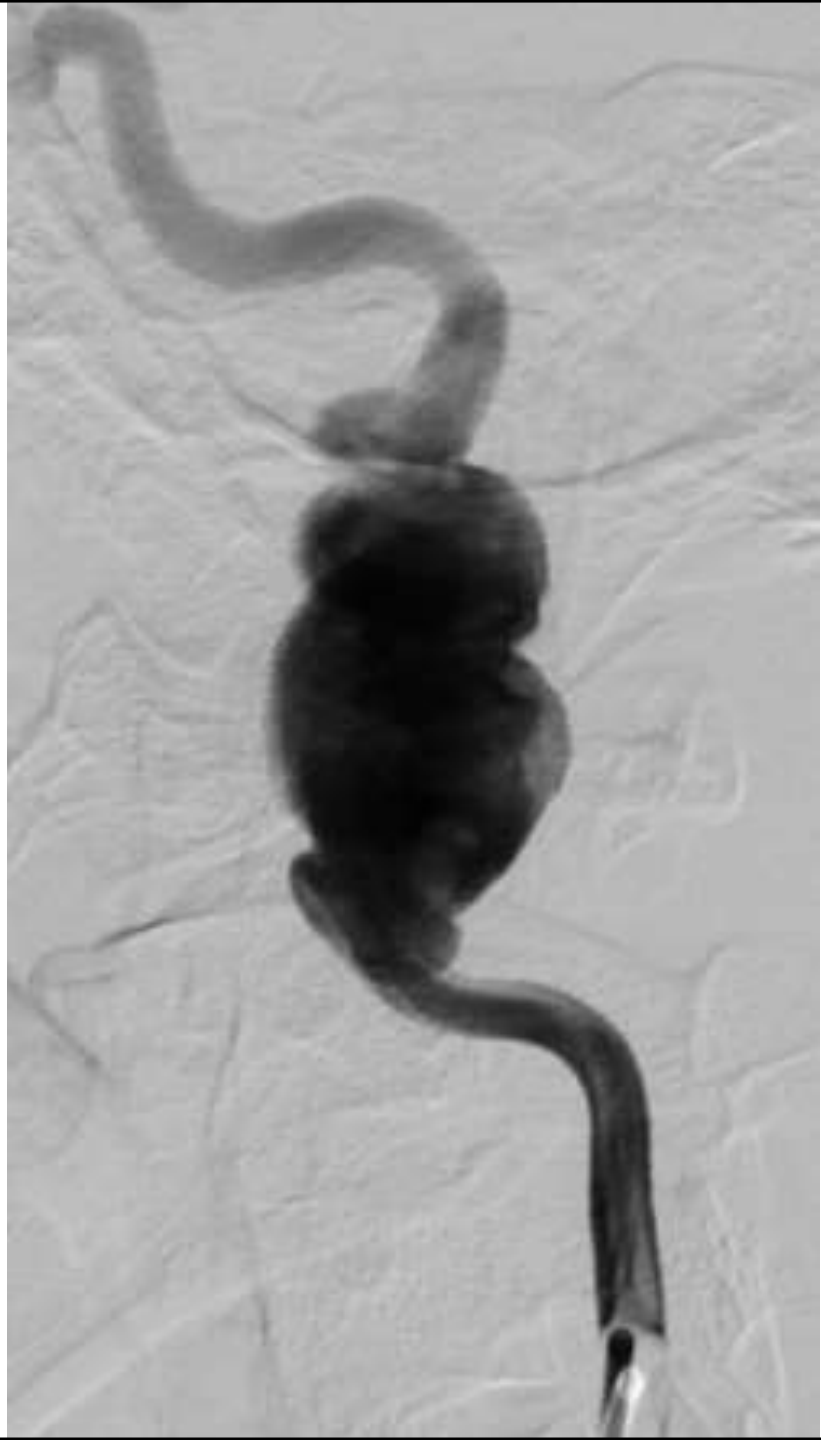
**NB. COMPLETE  
Effective  
Lesion Exclusion  
confirmed on IVUS  
(normal lumen)**

- R-limbs heamiparesis
- TOTAL motoric aphasia
- Severe sensoric aphasia



IFU-heparinization (ACT 261s)

**SAFE & uncomplicated, with optimal angiographic and clinical outcome**

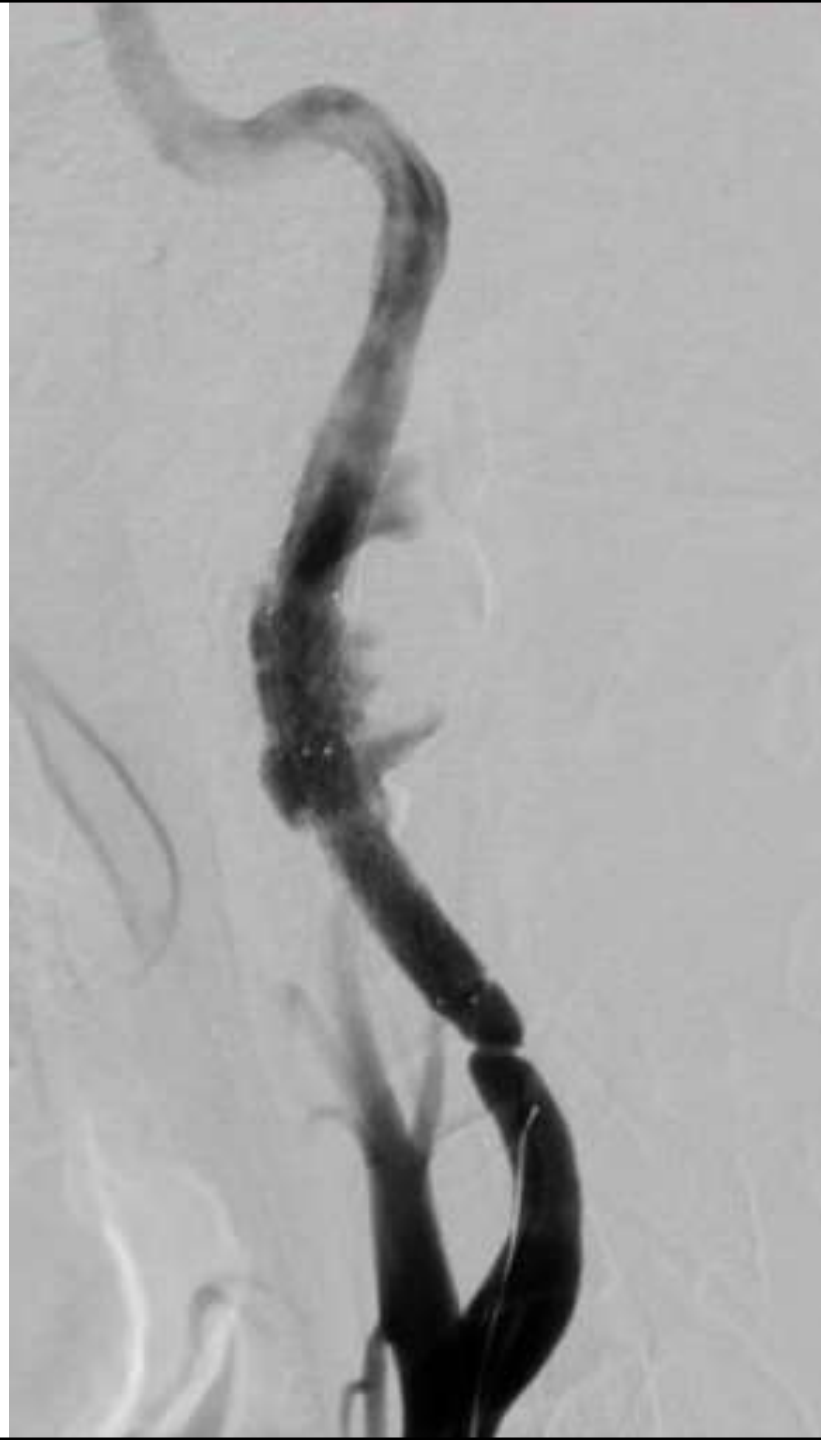
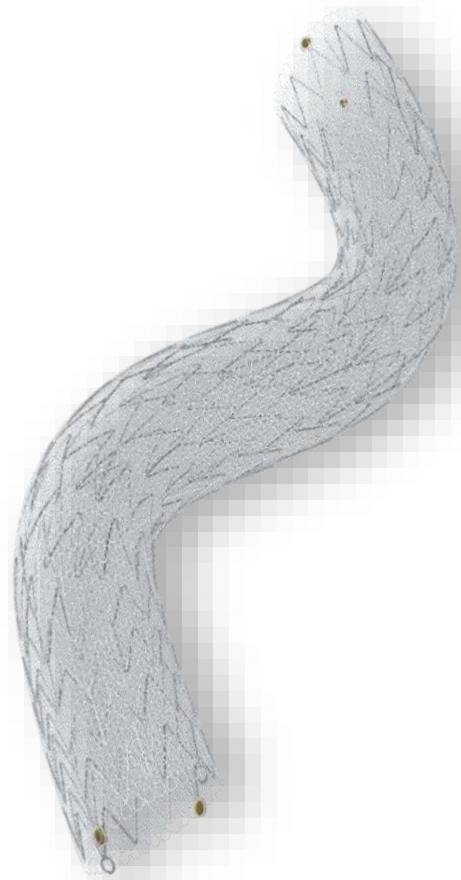




# C-HEAL STUDY



NCT04434456



Immediate  
result

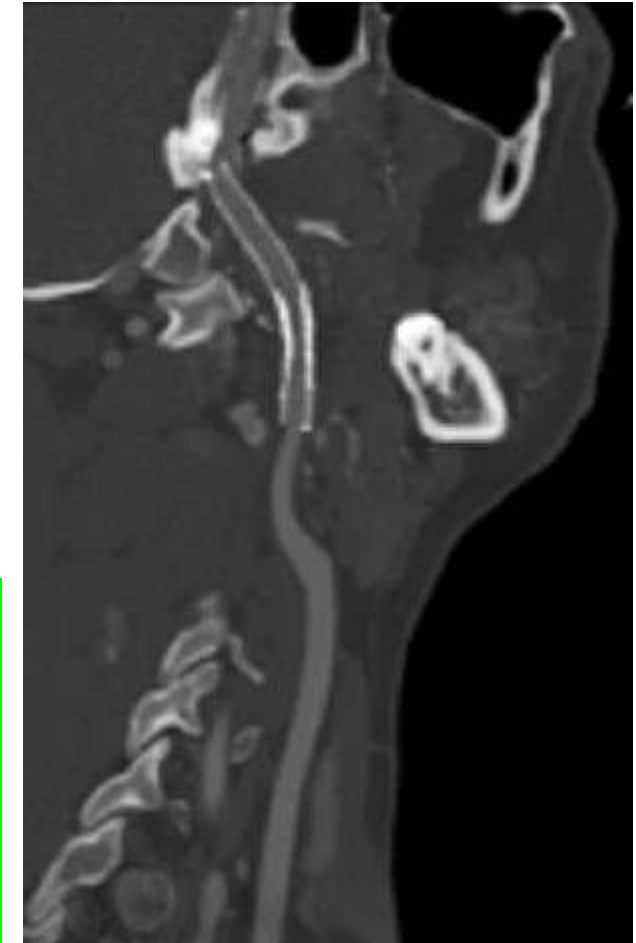
# C-HEAL STUDY



**ANEURYSM**  
Total Exclusion  
@ 72h

SPONTANEOUS HEALING

Reconstruction of  
**NORMAL**  
ANATOMY



6-mo Follow-up

NCT04434456

Patient **CURED**

**Competent CAS,**

with a tailored use of the access route (TF, TR, TC),  
tailored use of proximal/distal EPD,  
and 100% Embolic Prevention Stent use  
shows

**unprecedented safety and efficacy**

in Asymptomatic and Increased-stroke-risk Asx pts



**Competent CAS,**

with a tailored use of the access route (TF, TR, TC),  
tailored use of proximal/distal EPD,  
and 100% Embolic Prevention Stent use  
shows

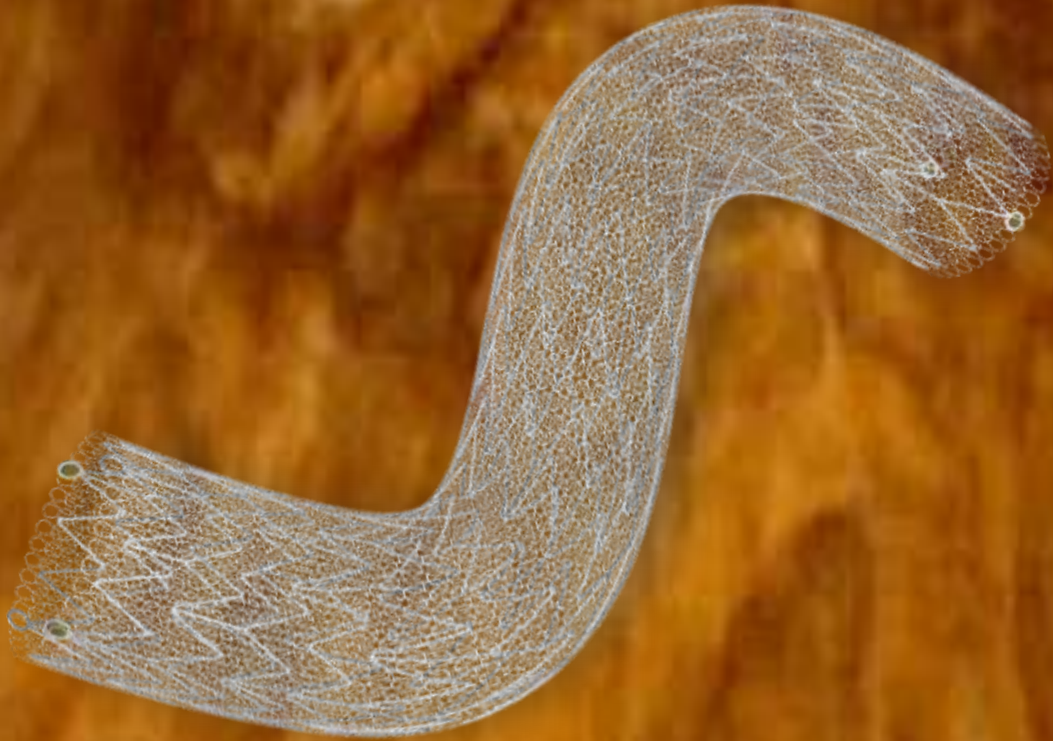
**unprecedented safety and efficacy**

in Asymptomatic and Increased-stroke-risk Asx pts

**New-generation endovascular management in primary and secondary prevention of carotid-related strokes is doing VERY well – and it is here to stay!**

# MicroNet-covered Carotid Stent

A NEW  
STANDARD  
OF CARE



Symptomatic carotid lesion – FULLY INSULATED with CGuard MicroNET-covered stent system (OCT)

# Latest techniques for carotid revascularisation



## **Micronet-covered stent in stroke prevention and treatment: New evidence**

MicroNET-covered Embolic Prevention Stent

**Piotr Musialek**

Jagiellonian University Dept. of Cardiac & Vascular Diseases  
John Paul II Hospital, Kraków, Poland

