CGuard EPS Carotid Stent Platform for Sustained Embolic Protection

INSPIRE MD

Nasdaq: NSPR

Disclaimers

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Investment Highlights : Transformational Market Drivers

CGuard EPS Stent Platform utilizing Proprietary MicroNet™ Technology

Highly differentiated platform for treatment of carotid artery disease and stroke prevention

Expanding Commercial Footprint

Double-digit market share in **30** served countries (34% in Italy)

Over **48,000** stents sold to date

Unmatched Clinical Outcomes Data (both Short- and Long-Term) (published and peer reviewed)

CGuard™ EPS – (**9**) clinical trials completed >**1,850** patients

CMS Approved Standard Risk Reimbursement

Decision, October 2023

- **Opens entirety of Carotid Revascularization segment to stenting**
- **Enables Trans Femoral stenting to broader patient cohort (155,000)**

US IDE Trial Advancing toward US approval

FDA decision on approval of CGuard EPS anticipated in **H1 2025**

*milestones and study design noted in U.S. Market / Regulatory Pathway

Market Potential

Current treated market: **$1.3 billion** (Dx & Treated with CEA + CAS)

Total untreated market: **$8 billion** (Dx with HGCS not treated)

Deep Pipeline and Strategic Roadmap

MicroNet™ technology pipeline: SwitchGuard for TCAR; Acute Stroke with tandem lesions

Transformational May 2023 financing up to $113.6 million provides runway through potential US approval of CGuard Prime EPS and other value-creating milestones

CMS Final National Coverage Determination, October 11, 2023

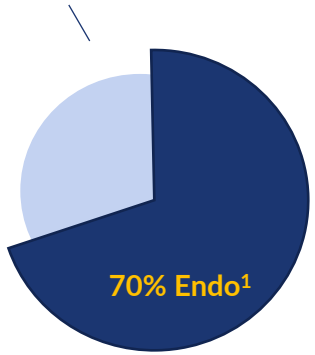
In summary, this final decision memorandum, which affects NCD 20.7 sections B4 and D, revises Medicare coverage for Percutaneous Transluminal Angioplasty (PTA) of the carotid arteries concurrent with stenting by:

1. **Expanding coverage** to individuals previously only eligible for coverage in clinical trials;
2. Expanding coverage to **standard surgical risk** individuals by removing the limitation of coverage to only high surgical risk individuals;
3. Adding **formal shared decision-making** with the individual prior to furnishing CAS; and
4. Allowing **MAC discretion** for all other coverage of PTA of the carotid artery concurrent with stenting not otherwise addressed in NCD 20.7.

Endovascular Procedures: Landscape and InspireMD Potential

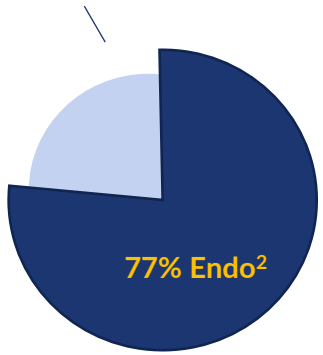
CEREBRAL ANEURYSMS

30% Surgical[1]



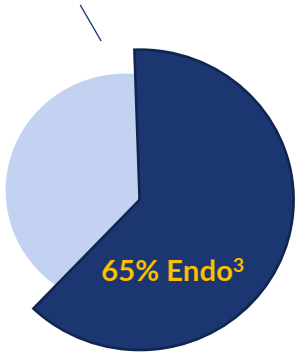
CORONARY ARTERY DISEASE

23% Surgical[2]



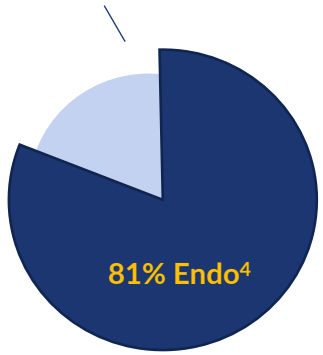
THORACIC/ABDOMINAL AORTIC ANEURYSMS

35% Surgical[3]



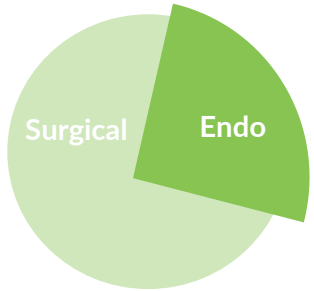
PERIPHERAL ARTERIAL DISEASE

19% Surgical[4]



CAROTID ARTERY DISEASE[5]

AWAITING CONVERSION TO ENDO



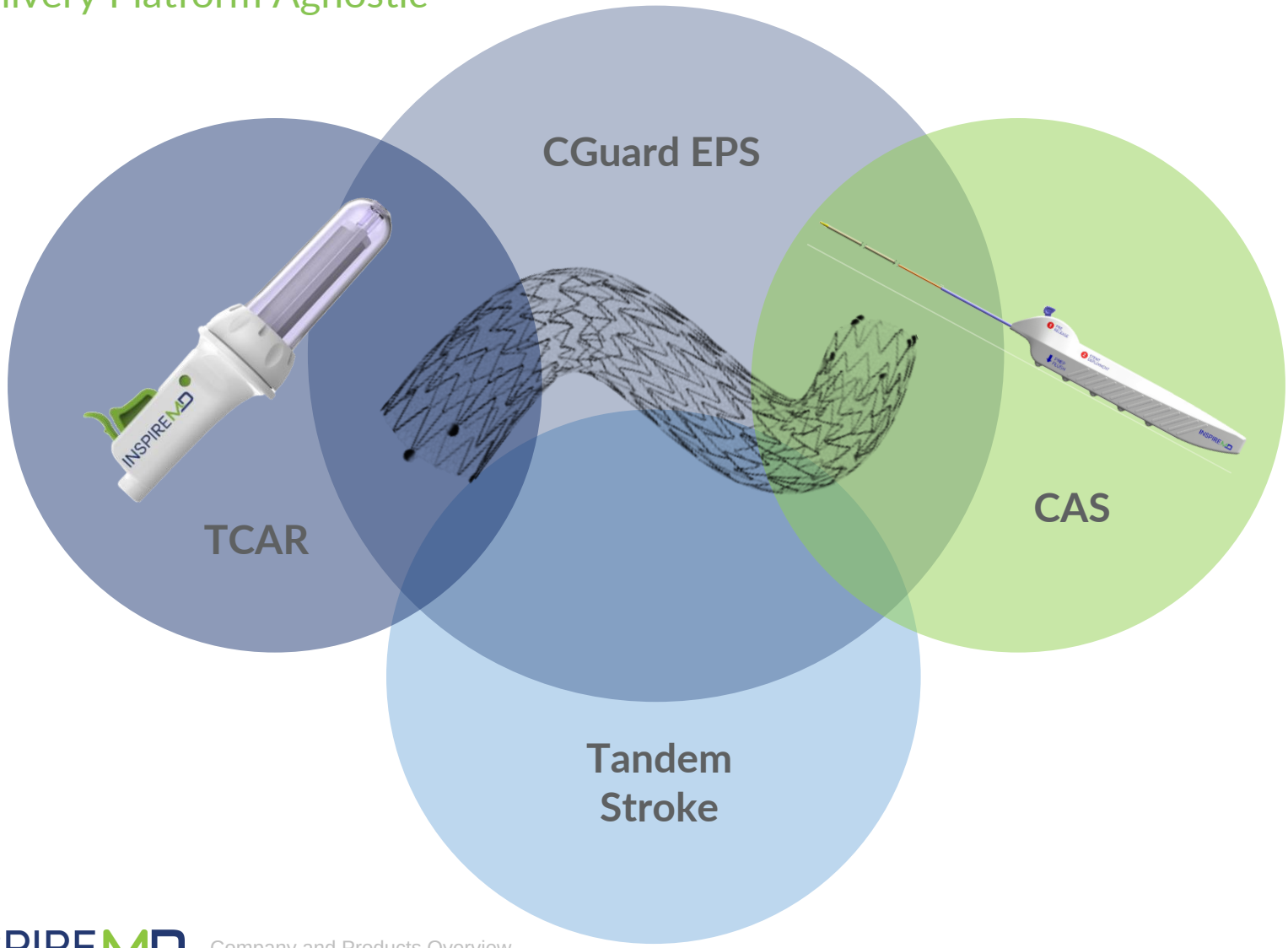
CAD market potential open to endo conversion Globally:

Already have been converted to endovascular procedures

[1] Bekelis K, Gottlieb DJ, Su Y, et al. Comparison of clipping and coiling in elderly patients with unruptured cerebral aneurysms. J Neurosurg. 2017;126(3):811–818
[2] Culler SD, Kugelmass AD, Brown PP, , et al. Trends in Coronary Revascularization Procedures Among Medicare Beneficiaries Between 2008 and 2012. Circulation. 2015;131(4):362-70
[3] Beck AW, Sedrakyan A, Mao J, et al. Variations in Abdominal Aortic Aneurysm Care: A Report From the International Consortium of Vascular Registries. Circulation. 2016;134(24):1948-1958
[4] Guez, D., Hansberry, D. R., Gonsalves, C. F., Eschelman, D. J., Parker, L., Rao, V. M., & Levin, D. C. Recent Trends in Endovascular and Surgical Treatment of Peripheral Arterial Disease in the Medicare Population. AJR Am J Roentgenol. 2020 May;214(5):962-966.
[5] Procedures For Selected Nations, 2017 – 2025 presented to InspireMD, Inc. by Health Research International Personal Medical Systems, Inc. Sept. 13, 2021

Long-Term Stent Performance is the Cornerstone of Our Focus

Delivery Platform Agnostic

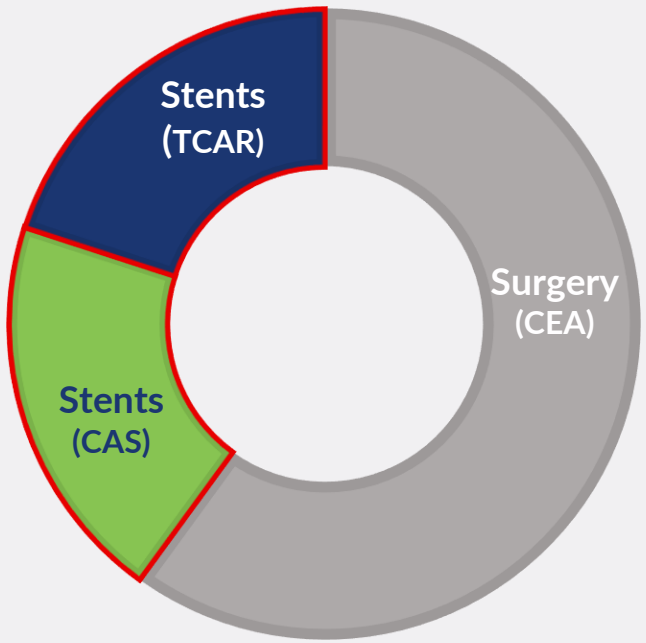


- ✓ Well positioned to capitalize on the ongoing **paradigm shift toward a "stent first" approach** and away from surgery
- ✓ **Agnostic to stent delivery platform** (TCAR vs. CAS)

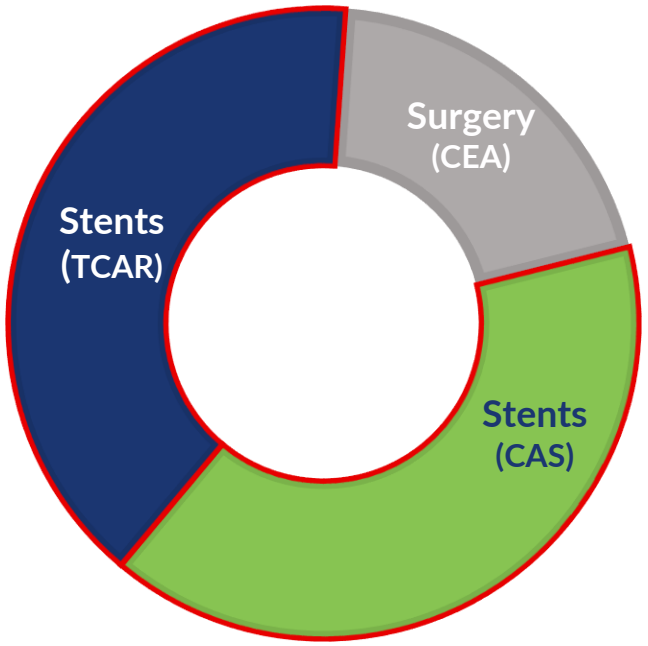
Potential Multi Billion Dollar Market Opportunity

MicroNet™ covered CGuard™ stent platform could become the new gold standard

WW carotid procedures today are primarily surgical



Carotid procedures tomorrow could be mostly minimally invasive with CGuard™



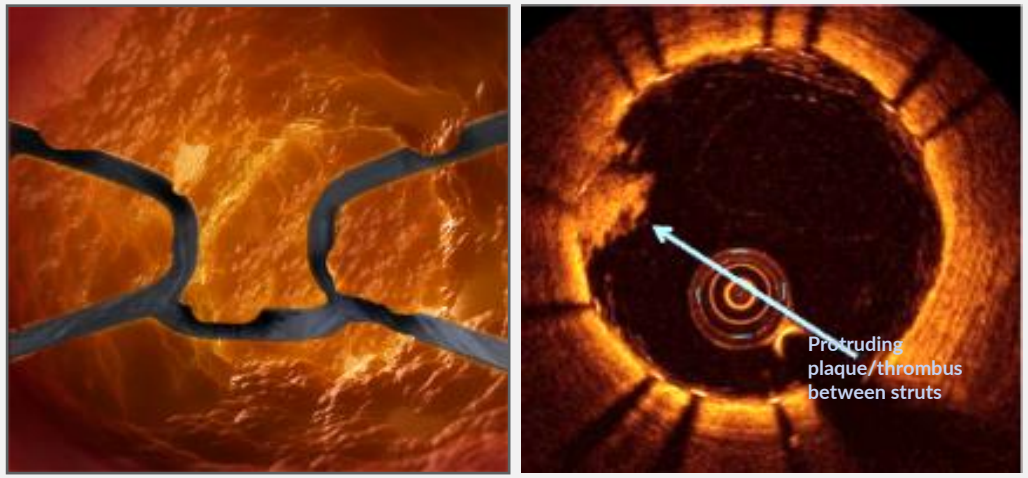
- **Current Treated Global Market**: [1]
  → **$1.3 billion**
  407K Global procedures (CEA/CAS/TCAR) to treat HGCS
- **Current Treated U.S. Market**:
  → **$809 million**
  155K procedures to treat HGCS (High Grade Carotid Stenosis)
- **Current Untreated Global Market**:
  → **$8 billion**
  ~2.8 million people diagnosed with HGCS (Untreated)
- **Standard Risk Reimbursement (US) increases CAS potential**

= InspireMD focus areas

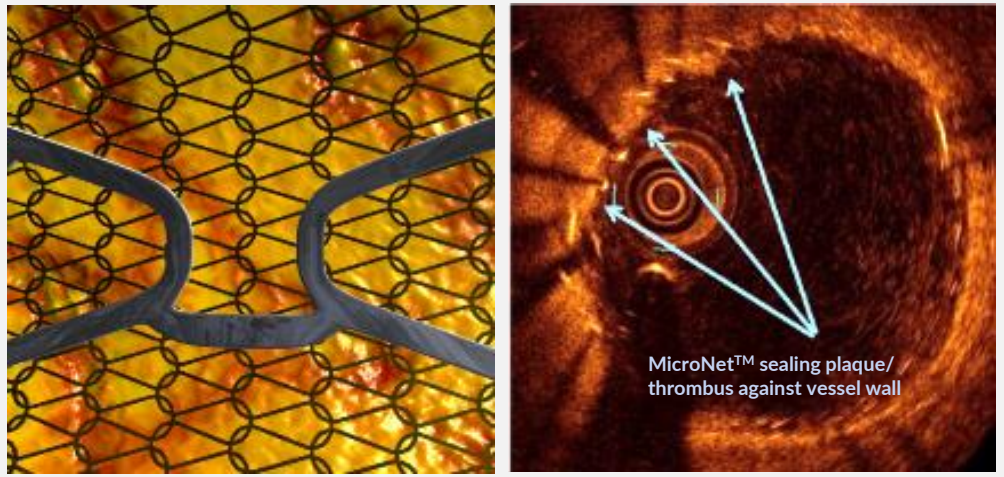
1. 2021 Health Research International Market Report; internal estimates

OUR SOLUTION: Proprietary MicroNet™ Technology[1]

New mesh covered stent offers superior plaque coverage when compared to conventional stent approaches



VS.



Conventional Open Cell Stent (1St GEN):

Bare or dual layer approach, with plaque protrusion risk

CGuard Stent System (2nd GEN):

Stents are covered in MicroNet

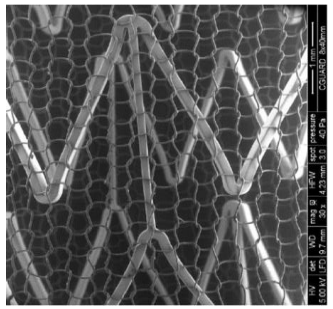
An Embolic Prevention System (EPS) for Ultimate Thrombus Protection

MicroNet captures and locks thrombus & plaque materials against the arterial wall, deterring debris from entering the bloodstream while also acting as a mechanical barrier to prevent plaque protrusion

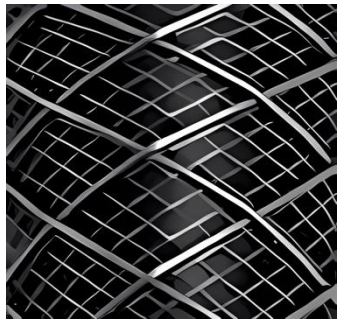
[1] Tomoyuki Umemoto, MD. Optical coherence tomography assessment of new generation mesh-covered stents after carotid stenting. Eurointerventional 2017;1348-1355 (published online)

Image: Prof. Valdés Chávarri

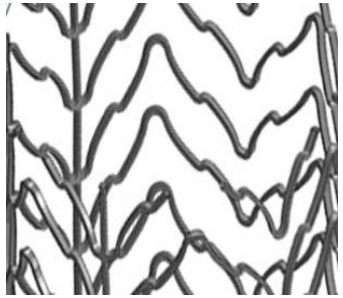
Pore Sizes



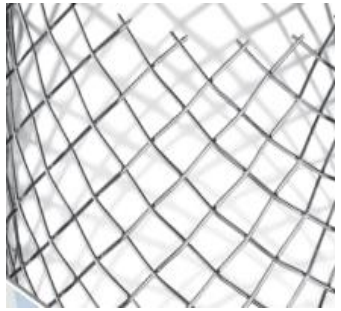
CGUARD™



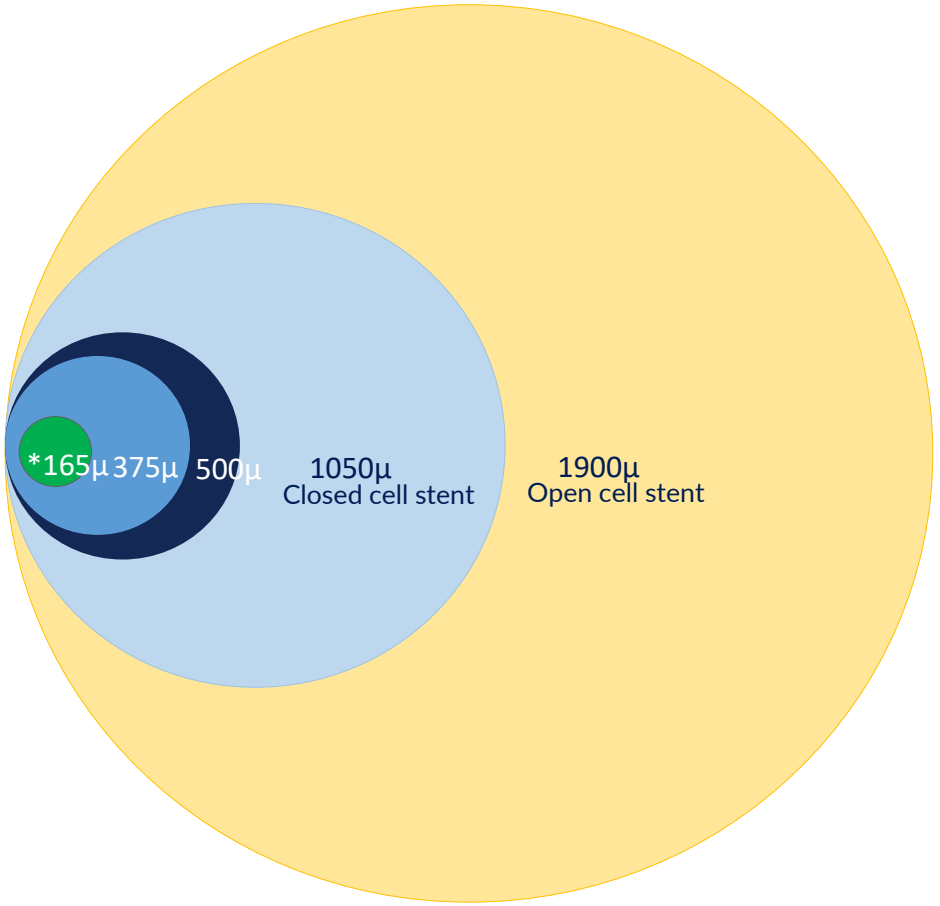
CASPER®

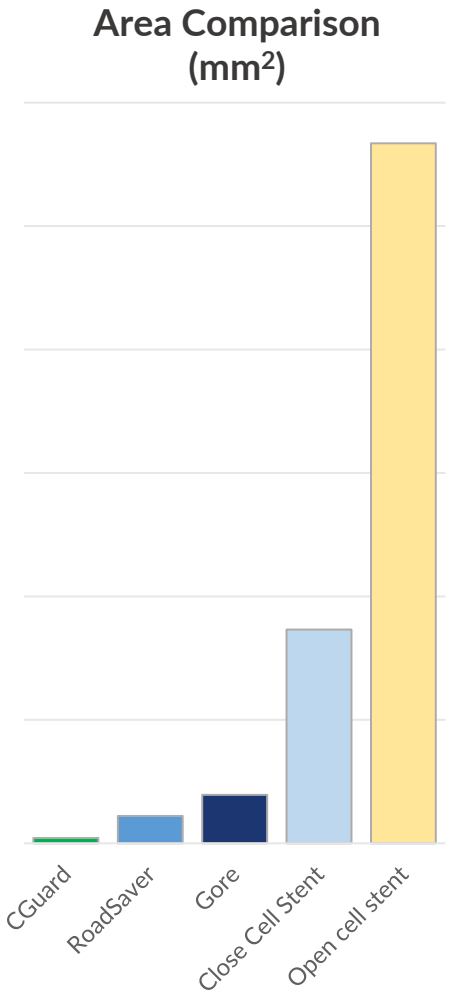


ACCULINK™



WallStent™





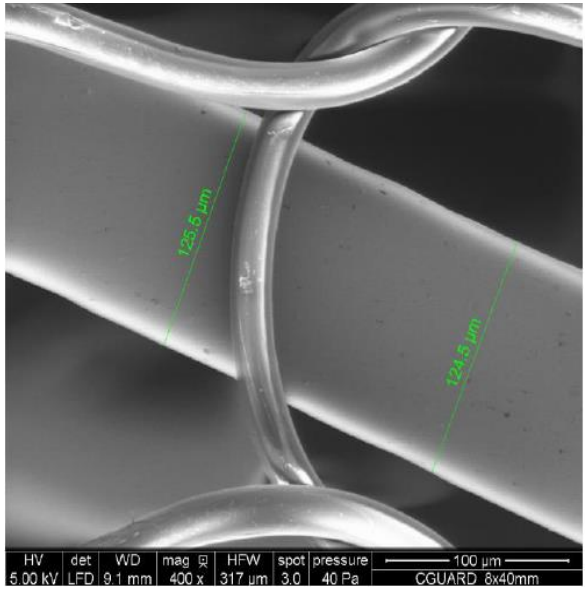
* Bench test results may not necessarily be indicative of clinical performance.
Stent images approximately at scale but not exact

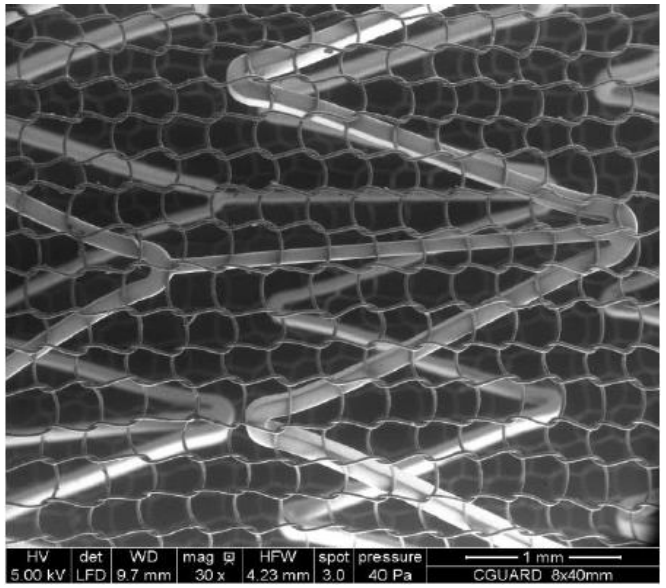
** Average in lesion at expanded state*

PROBLEM: Approximately 2/3 of neurovascular events (stroke, TIA) occur after the carotid surgery procedure takes place[2]. How to preserve the flexibility of an open-celled stent while building in embolic protection?

OUR SOLUTION: The CGuard EPS

The only stent platform available with our patented MicroNet mesh technology

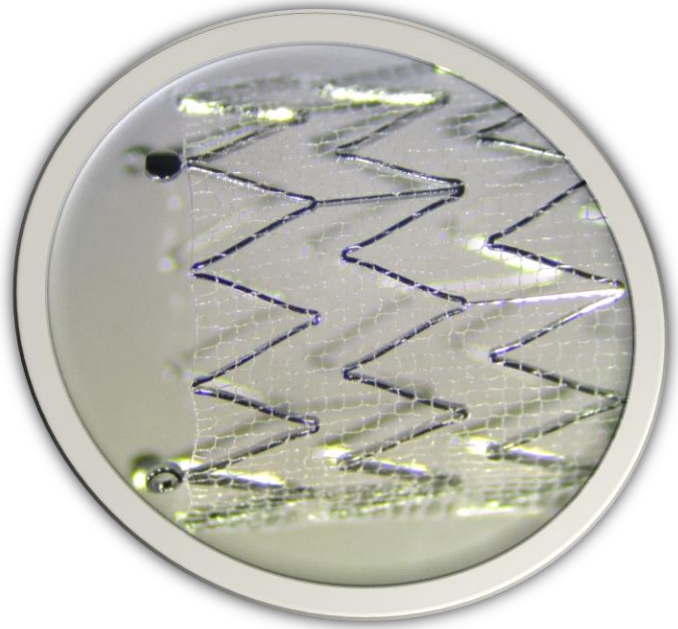




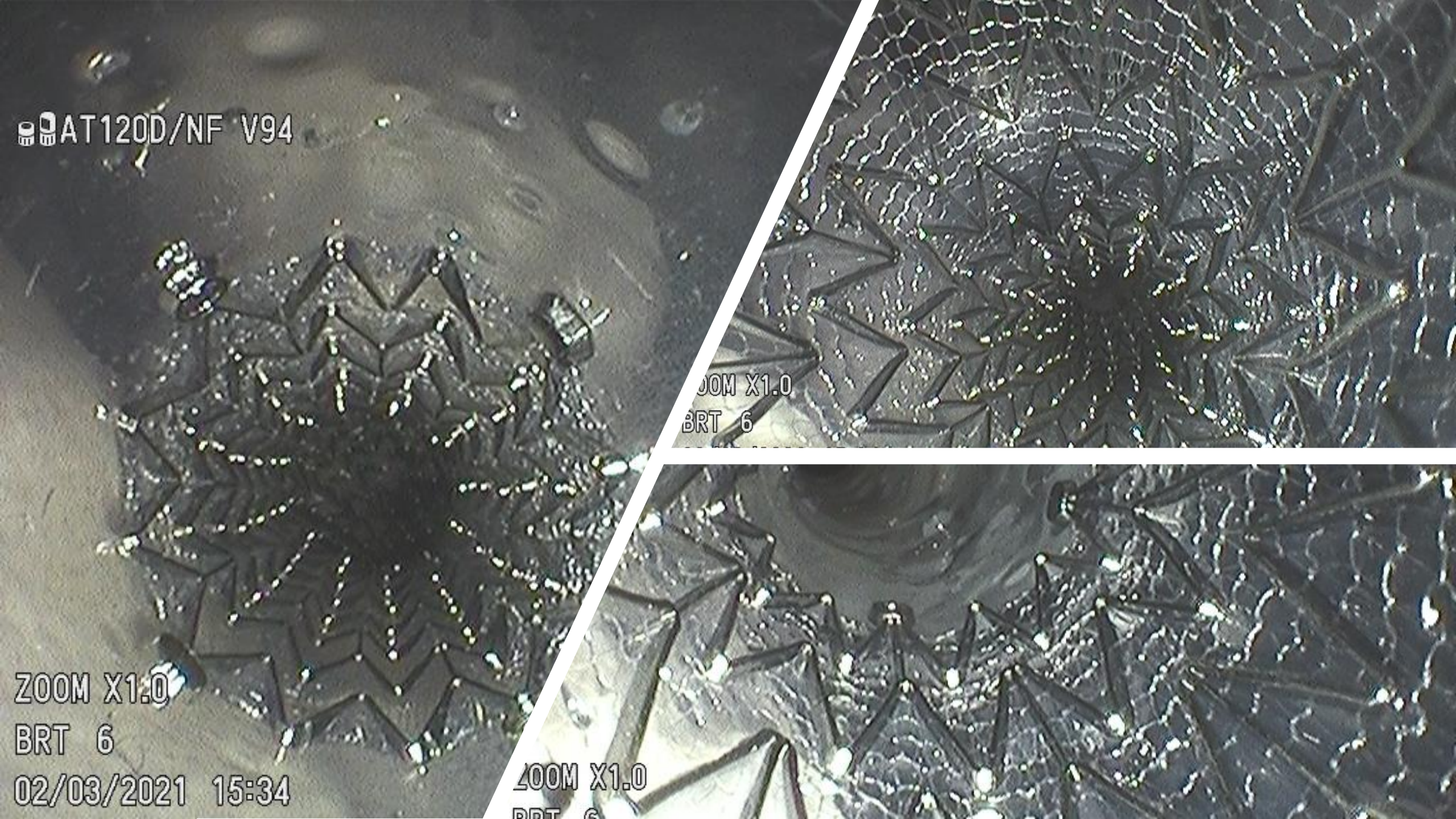
Interior Component:
Open-Cell Nitinol stent
(92 µm and 125 µm)

Exterior Component :
Closed-cell PET
(Polyethylene terephthalate)
25 µm

Cell size: **165 µm**



1. Cano et al. Rev Bras Cardiol Invasiva 2013; 21(2): 159-64. 2. Bosiers et al. Eur J Vasc Endovasc Surg Vol 33, Feb 2007.,


AT120D/NF V94
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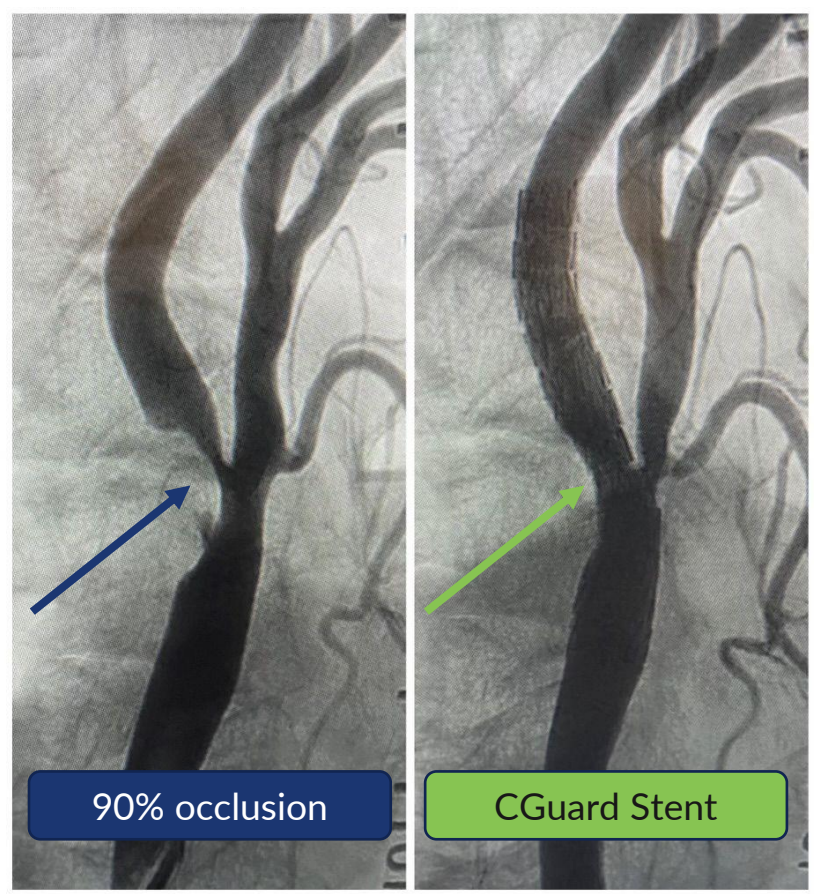
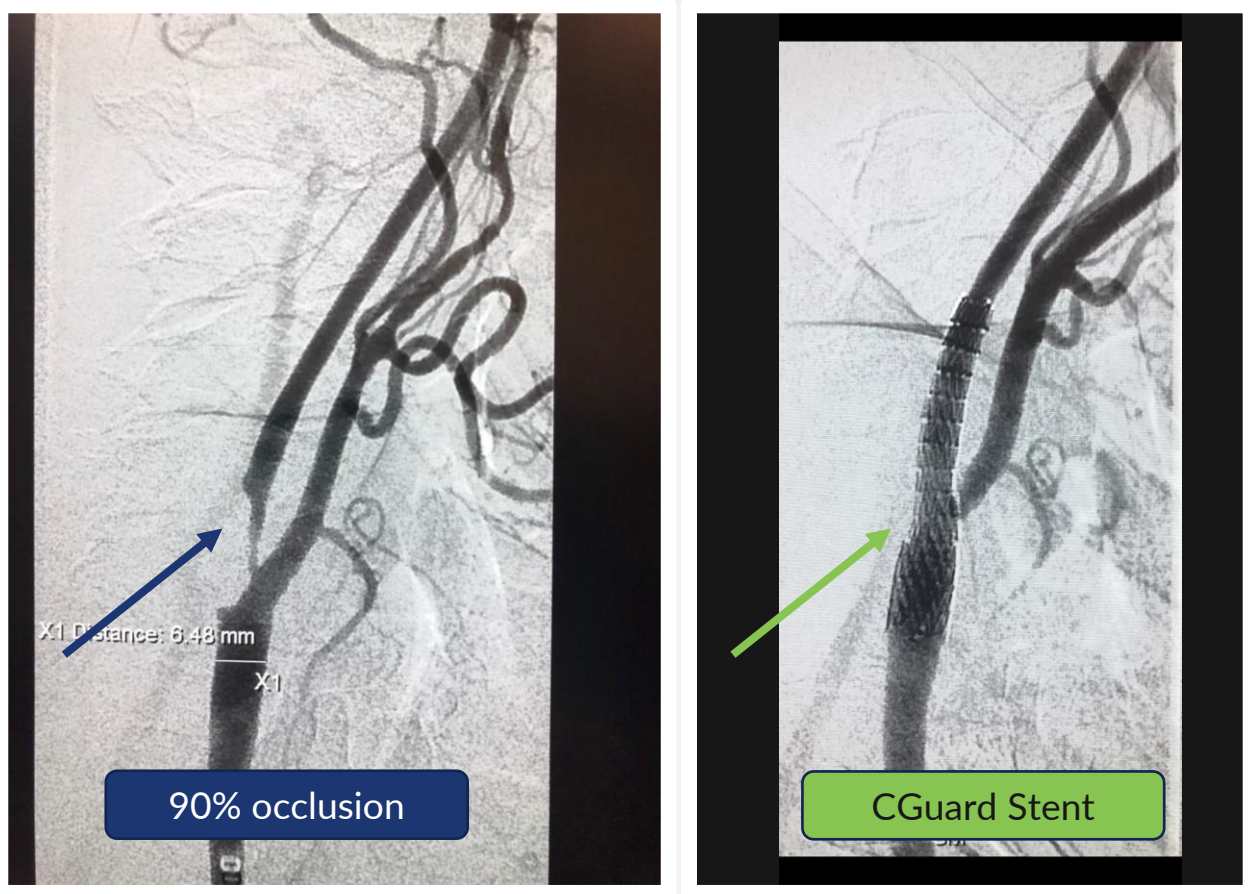
02/03/2021 15:34
OOM X1.0
BRT 6
OOM X1.0

A picture is worth a thousand words …

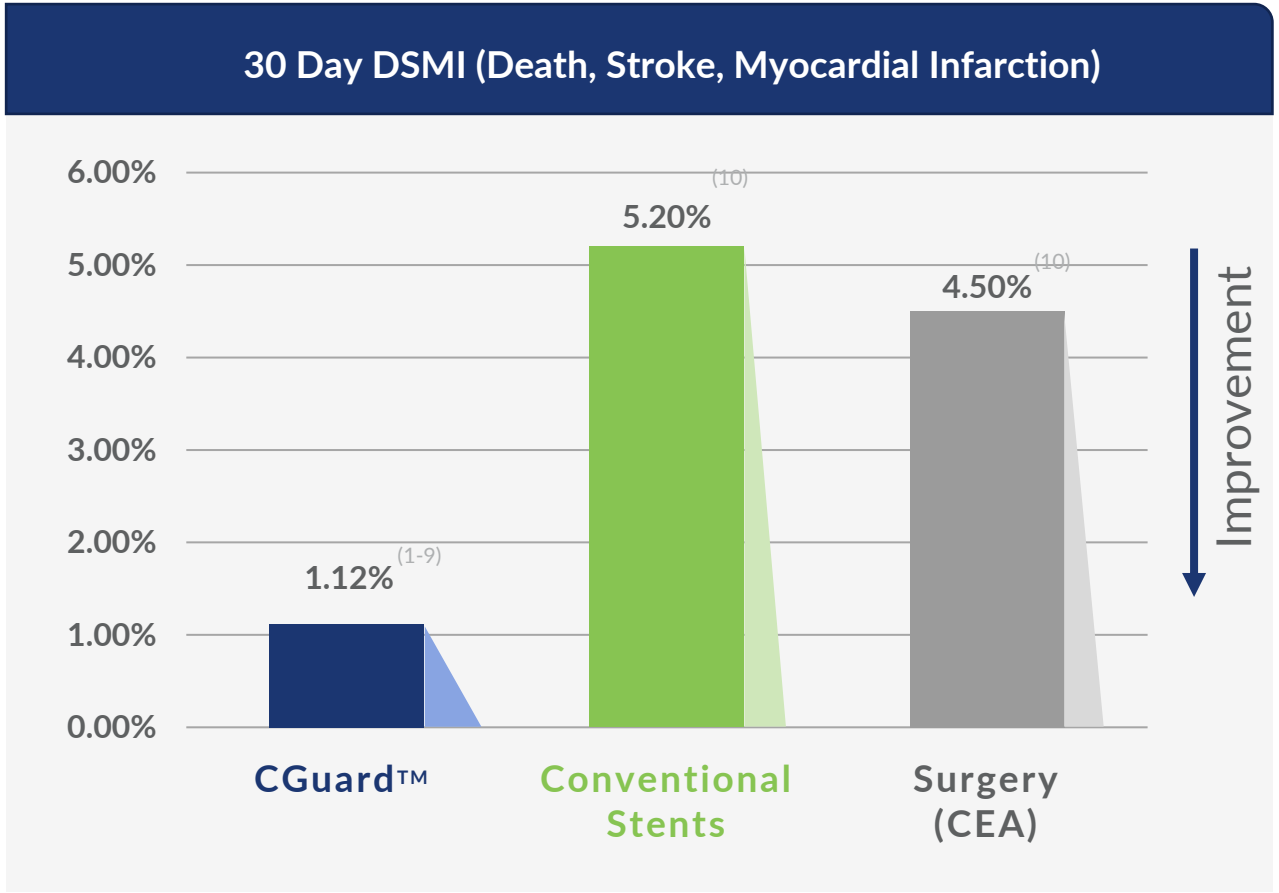




Unmatched Superior Foundational Data

CGuard™ EPS Yields Superior Clinical Outcomes

When compared with Conventional Stents and Surgery (CEA), CGuard trends Superior



- No stent related major stroke and 11 minor strokes to date with CGuard in 1,873 patients in 9 studies (0.6%)
- CGuard is a next-generation stent supported by a strong clinical data

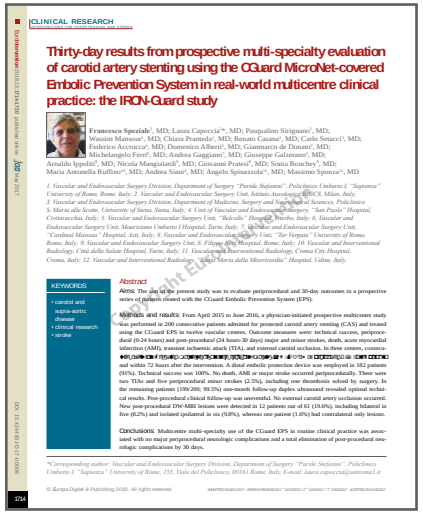
1. IRONGUARD I EuroIntervention 2018 Nov 20. 14:1150-1152. 2. IRONGUARD II, LINC 2020 3. CASANA Eur J Vasc Endovasc Surg 2017 Dec. 54:681-687. 4. WISSGOTT I J Endovasc Ther 2019 08. 26:578-582. 5. WISSGOTT II J Endovasc Ther 2017 02. 24:130-137. 6. PARADIGM Extend, EuroIntervention 2016 Aug 05. 12:e658-70. Updated LINC 2020. 7. CARENET JACC Cardiovasc Interv 2015 Aug 17. 8:1229-1234. 8. Randomize Clinical Trial EuroPCR e-Course, June 25, 2020. 9. Tigkiropoulos J Endovasc Therapy Volume 28 Issue 4, Aug 2021 10. CREST N Engl J of Med 2010 July 1. 11-23. * Calculated on Event Count

Carotid Solution: Our Well Studied Mesh-Covered Technology

More than

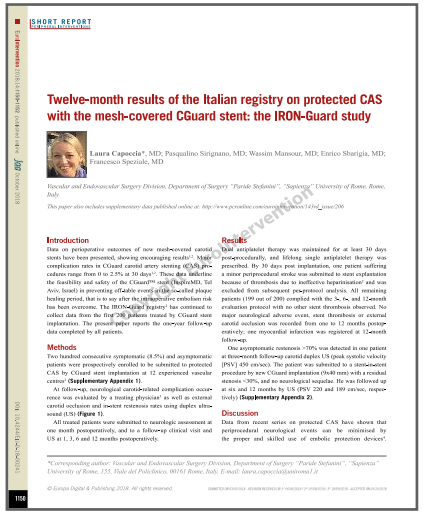
1,850

patients in Clinical Publications & Studies



CLINICAL RESEARCH

Thirty-day results from prospective multi-specialty evaluation of carotid artery stenting using the CGuard MicroNet-covered Embolic Prevention System in real-world multicentre clinical practice: the IRON-Guard study

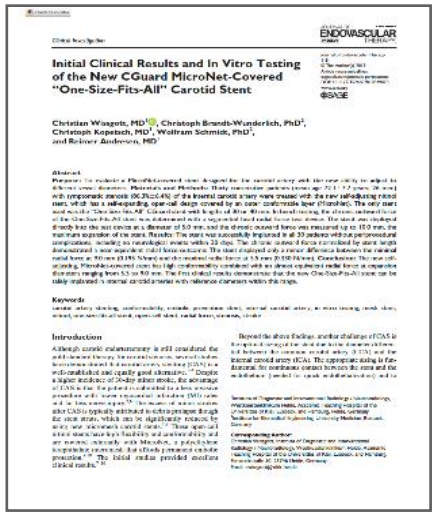


SHORT REPORT

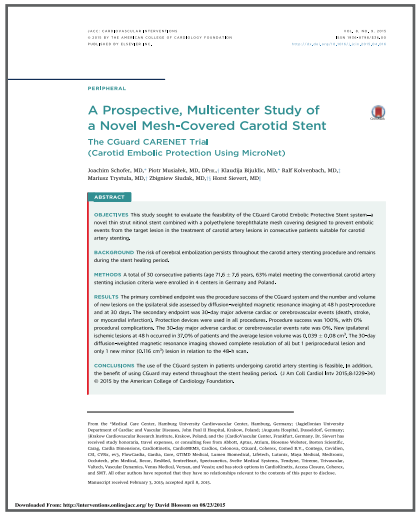
Twelve-month results of the Italian registry on protected CAS with the mesh-covered CGuard stent: the IRON-Guard study

euro PCR 2016 LATE BREAKING TRIALS

Novel PARADIGM in carotid revascularisation: Prospective evaluation of All-comer peRcutaneous cArotiD revascularisation in symptomatic and Increased-risk asymptomatic carotid artery stenosis using CGuard™ MicroNet-covered embolic prevention stent system



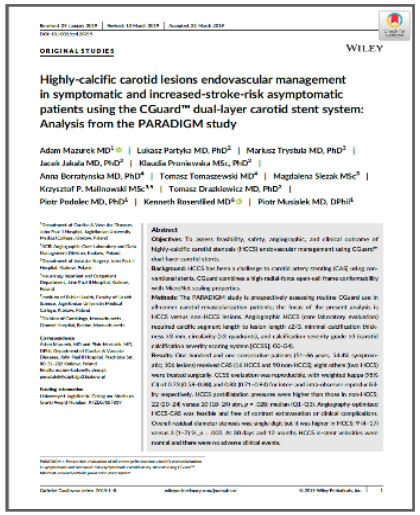
Initial Clinical Results and In Vitro Testing of the New CGuard MicroNet-Covered "One-Size-Fits-All" Carotid Stent



PERIPHERAL

A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent

The CGuard CARENET Trial (Carotid Embolic Protection Using MicroNet)

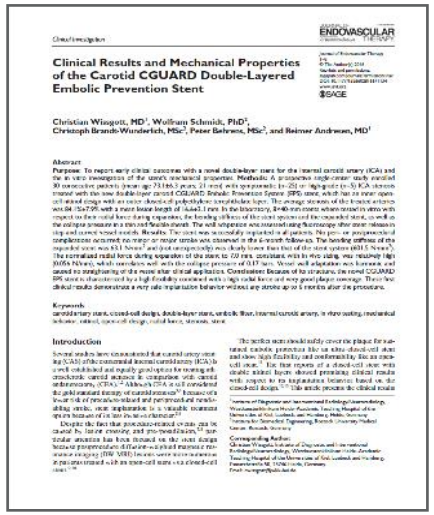


ORIGINAL STUDIES

Highly-calcific carotid lesions endovascular management in symptomatic and increased-stroke-risk asymptomatic patients using the CGuard™ dual-layer carotid stent system: Analysis from the PARADIGM study

ARTICLE IN PRESS

Safety and Efficacy of the New Micromesh-Covered Stent CGuard in Patients Undergoing Carotid Artery Stenting: Early Experience From a Single Centre



Clinical Results and Mechanical Properties of the Carotid CGUARD Double-Layered Embolic Prevention Stent

Clinical Results and Mechanical Properties of the Carotid CGUARD Double-Layered Embolic Prevention Stent

Clinical Support Highlights

2015-2022

CARENET Trial

First in Man Study- Demonstrated Safety, Efficacy, & Neuroprotection over other stents data

Reduction of embolization

(50% fewer lesions / 80% less volume with 0 events @ 30 days)

PARADIGM + Extend

Opened CARENET study inclusion criteria all comers.

Concluded the safety and clinical outcomes were applicable to all.

500 patients followed 5 years. Defines standard for measured sustained protection and long-term outcomes

Randomized Control Trial

CGuard vs. Conventional Stent (Abbott Acculink)

CGuard superiority in Randomized study format

Confirms CARENET results with statistical significance

CARMEN Meta-Analysis (112 Studies, 68K Patients)

- Improvements from second-generation stents (SGS) relative to first-generation stents (FGS), but important differences exist amongst the SGS:

- **CGuard's MicroNet drives improvement both in event reduction (due to improved scaffolding) and restenosis reduction (due to less metal burden)**

Table 2A. 30-day and 12-month event rates by stent type (random-effect model).

	FGS	SGS	Competitor #1	Competitor #2	CGuard
30-day Stroke [%] (95% CI)	**3.01** (2.63-3.38)	**0.60** (0.28-0.92)	**0.50** (0-1.15)	**2.89** (1.03-4.76)	0.54 (0.17-0.92)
30-day Death/Stroke/MI [%] (95% CI)	**4.11** (3.65-4.56)	**1.30** (0.64-1.96)	**1.33** (0-2.66)	**4.82** (2.44-7.2)	1.08 (0.55-1.60)
12-mo Ipsilateral Stroke [%] (95% CI)	**3.51** (2.52-4.50)	**0.7** (0-1.47)	**0.26** (0-1.27)	**3.1** (1.11-5.1)	0.38 (0-0.9)
12-mo Restenosis [%] (95% CI)	**3.97** (0.28-5.14)	**3.38** (1.39-5.37)	**7.16** (4.45-9.86)	**4.83** (2.36-7.29)	0.34 (0-0.82)
12-mo Ipsilateral Stroke/Restenosis [%] (95% CI)	**8.15** (6.34-9.96)	**5.12** (2.14-8.10)	**7.86** (5.04-10.68)	**7.93** (4.82-11.04)	0.73 (0-1.44)

1. Clinical Outcomes of Second- versus First-Generation Carotid Stents: A Systematic Review and Meta-Analysis, J. Clin. Med. 2022, 11

US Regulatory Pathway

PMA Trial Design (CGuardians I)

FDA Trial Performance Goal – 11.6% vs European Clinical Trials' Mean Performance 1.32% (w/ 1 Yr)

- **Pivotal study objective** evaluate the safety and efficacy of the CGuard™ Carotid Stent System in the treatment of carotid artery stenosis
  - **Intent to Treat Protocol**
  - **Primary Endpoint:** Symptomatic and asymptomatic patients undergoing carotid artery stenting (CAS) to a performance goal of <**11.6%** developed from published CAS literature. (Composite of DSMI through 30 days or ipsilateral stroke 31 - 365 days post-index procedure). Calculation will be the composite of the following: incidence of the following major adverse events: death (all-cause mortality), all stroke, and myocardial infarction (DSMI) through 30-days post-index procedure, based on the clinical events or ipsilateral stroke from 31-365-day follow-up, based on CEC adjudication.
  - In European clinical studies, CGuard data of **1,485 patients** followed for one year - **1.32%*****
- **Chris Metzger, M.D.** (Ballad Health) : Principal Investigator
- **316 Patients – Enrollment completed (23 months)**
- **25 Centers** (20 in the United States and 5 in Europe)
- **HCC (Hart Clinical Consultants)** CRO specializing in Carotid trial execution
- **Christina Brennan, M.D.** and **Gary Roubin, M.D.,PhD. :** Supporting advisory experts

*** 1. IRONGUARD I EuroIntervention 2018 Nov 20. 14:1150-1152 2. IRONGUARD II 1-Year Results From a Prospective Experience on CAS Using the CGuard Stent System JACC: Cardiovascular Interventions Vol. 14, No. 17, 2021. 3. Academic Data Registry PARADIGN-EXTENDED Monitored 30 days and 12 Months Outcomes Report, Oct 24, 2022 (Prospective evaluation of All-comer percutaneous carotid revascularisation in symptomatic and increased risk asymptomatic carotid artery stenosis using CGuard MicroNet –covered embolic prevention stent system) 4. 5 Year Clinical Ultrasound Outcomes in CARENET Prospective Multicenter Trial of CGuard MicroNET Covered Stent JACC: Cardiovascular Interventions Vol. 15, No. 18, 2022 September 26, 2022:1183-1891

* 2021 Health Research International Market Report; internal estimates

CGuardians I: 30-day Major Adverse Events

Results presented at VIVA23

Event rate in % (n)	ITT (N=316)	Per Protocol^
Death, Stroke or MI*	0.95% (3)	0.63% (2)
Death#	0.32% (1)	0.% (0)
Any stroke#	0.95% (3)	0.63% (2)
Major Stroke#	0.63% (2)	0.32% (1)
Minor Stroke#	0.32% (1)	0.32% (1)
MI#	0.0% (0)	0.0% (0)
Death or any stroke*	0.95% (3)	0.63% (2)
Death or major stroke*	0.63% (2)	0.32% (1)

* Hierarchical: patient count (each patient first occurrence of the most serious event).

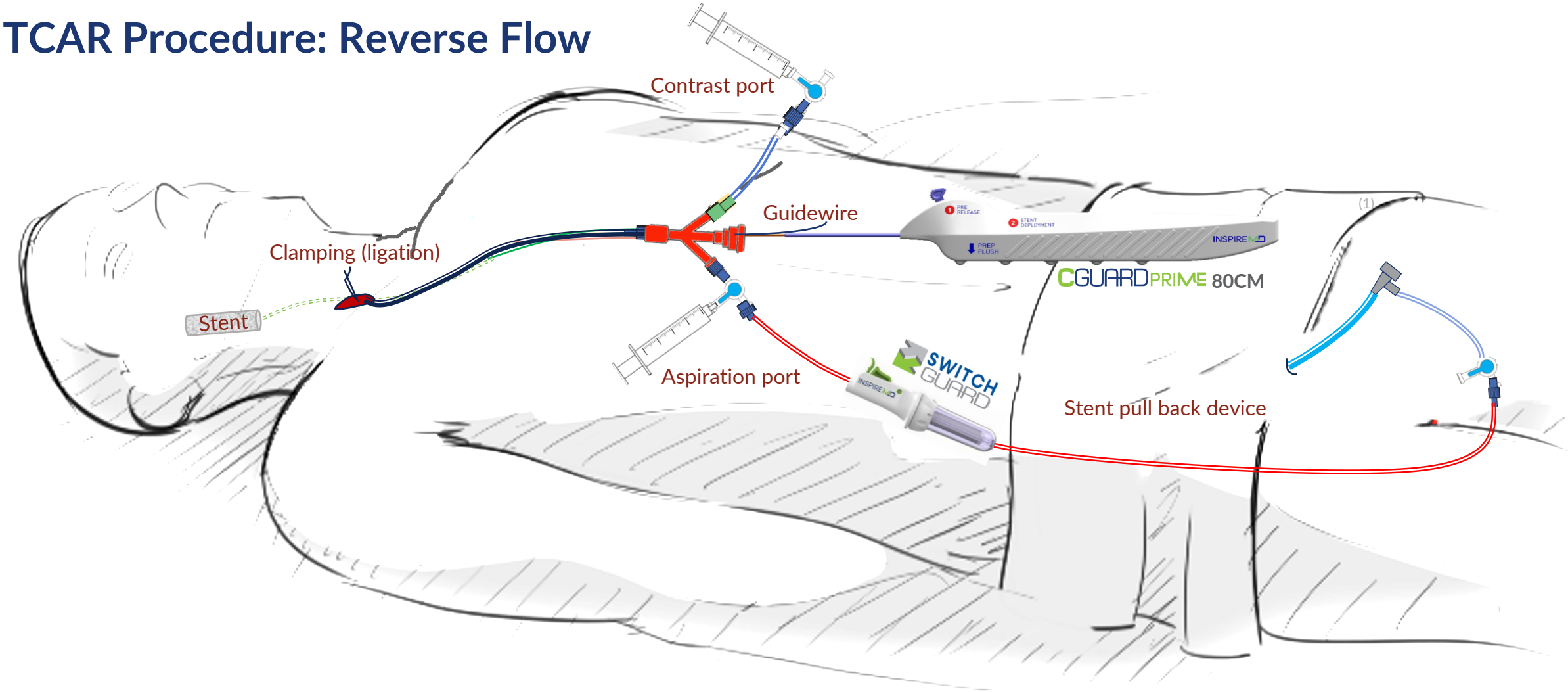
Non-hierarchical: event count (multiple events in each patient are counted individually).

^ Per Protocol Analysis excludes 1 patient (did not take dual antiplatelet therapy; had a major stroke and died).

CGuard Stent system is investigational only and not for sale in the USA.

TCAR

TCAR Procedure: Reverse Flow

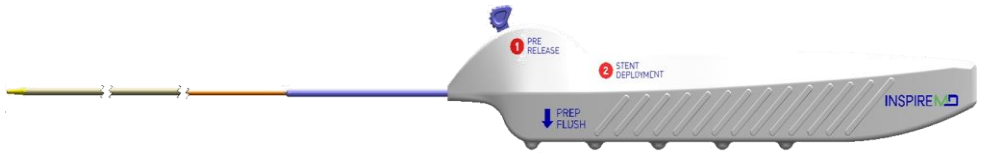


(1)

SwitchGuard NPS serves Trans carotid (TCAR) Opportunity with Best-in-Class CGuard Implant

1. Transient flow reversal combined with sustained embolic prevention in transcervical revascularization of symptomatic and highly-emboligenic carotid stenoses for optimized endovascular lumen reconstruction and improved peri- and post-procedural outcomes, Advances in Interventional Cardiology 2020;16, 4 (62):495-506

SwitchGuard NPS (TCAR)



80CM

CGUARD PRIME

SWITCH GUARD

TCAR Market Opportunity

>2,600 TCAR-trained physicians in the U.S.[1]

>24,000 TCAR procedures ($170M) projected in the U.S. in 2023, strong double-digit growth projected[1,2]

InspireMD's C-GUARDIANS II TCAR trial anticipated to commence mid-2024; Potential clearance in H2 2025

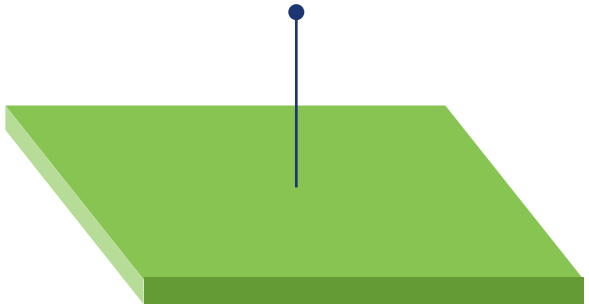
[1] SILK reporting
[2] Piper-Sandler model, 11/8/23

Roadmap + Milestones

Our Advancement Roadmap / Milestones

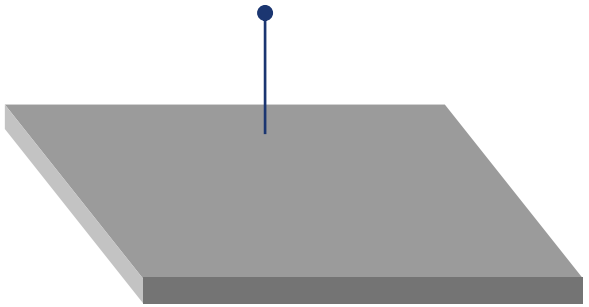
Our Expected Key Value Drivers and Strategic Pathways

- ✓ **USA Trial** Enrollment Complete
  - Inclusion of CGuard Prime
- ✓ **SwitchGuard** 510K Clinical Pre Sub Submission
- ✓ **Acute Stroke (NGuard)** EFS (Early Feasibility Study)
- ✓ **U.S. Standard Risk Reimbursement**
- ✓ **FDA PMA** Submission (Module I)



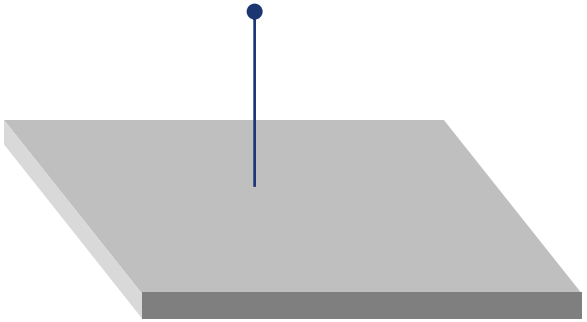
2023

- **FDA PMA** Submission (Modules II, III and IV)
- Initiation of **C-GUARDIANS II (TCAR)** study
- **Tandem Lesion EFS** for **Acute Stroke**
- **China** Regulatory Submission
- **CGuard Prime** Commercial Launch (EU)



2024

- **FDA PMA Approval** of **CGuard Prime**
- **FDA 510K Clearance** of **SwitchGuard NPS Kit**
- **U.S.** Commercial Launch



2025

CGUARDPRIME 80

Corporate

Our Board of Directors

Marvin L. Slosman President and CEO	Mr. Slosman has over 30 years of experience in the medical device industry with focused leadership in commercialization and international market development in both public and privately held companies. He has had senior management roles in a variety of public and privately held companies.
Paul Stuka Chairman	Mr. Stuka was named to the Board of Directors in August of 2011 and serves as Chairman of the Board of Directors. Mr. Stuka is a Managing Member of Osiris Partners and a 30-year investment industry veteran.
Michael Berman Director	Mr. Berman is a successful entrepreneur within the medical device industry. He joined Scimed in 1986, leading its marketing activities until its merger with Boston Scientific in 1995. From 1995-2000, he served as President of Boston Scientific/Scimed. Venture partner in RiverVest Ventures
Thomas Kester Director	Mr. Kester is CFO of Kester Search Group, Inc., a private executive search firm specializing in sales force placement for medical, dental and diagnostic device companies. He spent 28 years at KPMG LLP.
Gary Roubin, M.D.,Ph.D. Director	Dr. Roubin was named to the board of Directors in October 2020. Dr. Roubin has co-authored more than 280 clinical publications and has contributed to 20 textbooks in the fields of Interventional Cardiology and Vascular Surgery. He was a key contributor in the CREST trial which has validated the use of carotid stents for the treatment of carotid artery stenosis.
Katie Arnold Director	Ms. Arnold was named to the Board of Directors in May 2021. Ms. Arnold founded and leads SPRIG Consulting, providing the entire spectrum of strategic marketing services to medical companies. Ms. Arnold is currently an adjunct professor at Northwestern University's Kellogg School of Business, where she teaches medical product commercialization and financing.
David Bonita, MD Board Observer	Dr. Bonita is a General Partner of OrbiMed. Prior to joining OrbiMed, he worked in the healthcare investment banking groups of Morgan Stanley and UBS. Dr. Bonita received his A.B. magna cum laude in Biological Sciences from Harvard University and his joint M.D./M.B.A. from Columbia University where he was elected to the Alpha Omega Alpha Medical Honor Society and Beta Gamma Sigma Business Honor Society.

Scientific Advisory Board (Multidisciplinary KOLs)

Kenneth Rosenfield, M.D.

Interventional

Cardiologist

Mass General Brigham

Adnan H. Siddiqui, M.D. Ph.D

Professor, Vice Chairman of the

Department of Neurosurgery

UBNS Neurosurgery
UNIVERSITY AT BUFFALO

Chris Metzger , M.D.

Medical Director

Cardiologist

OhioHealth

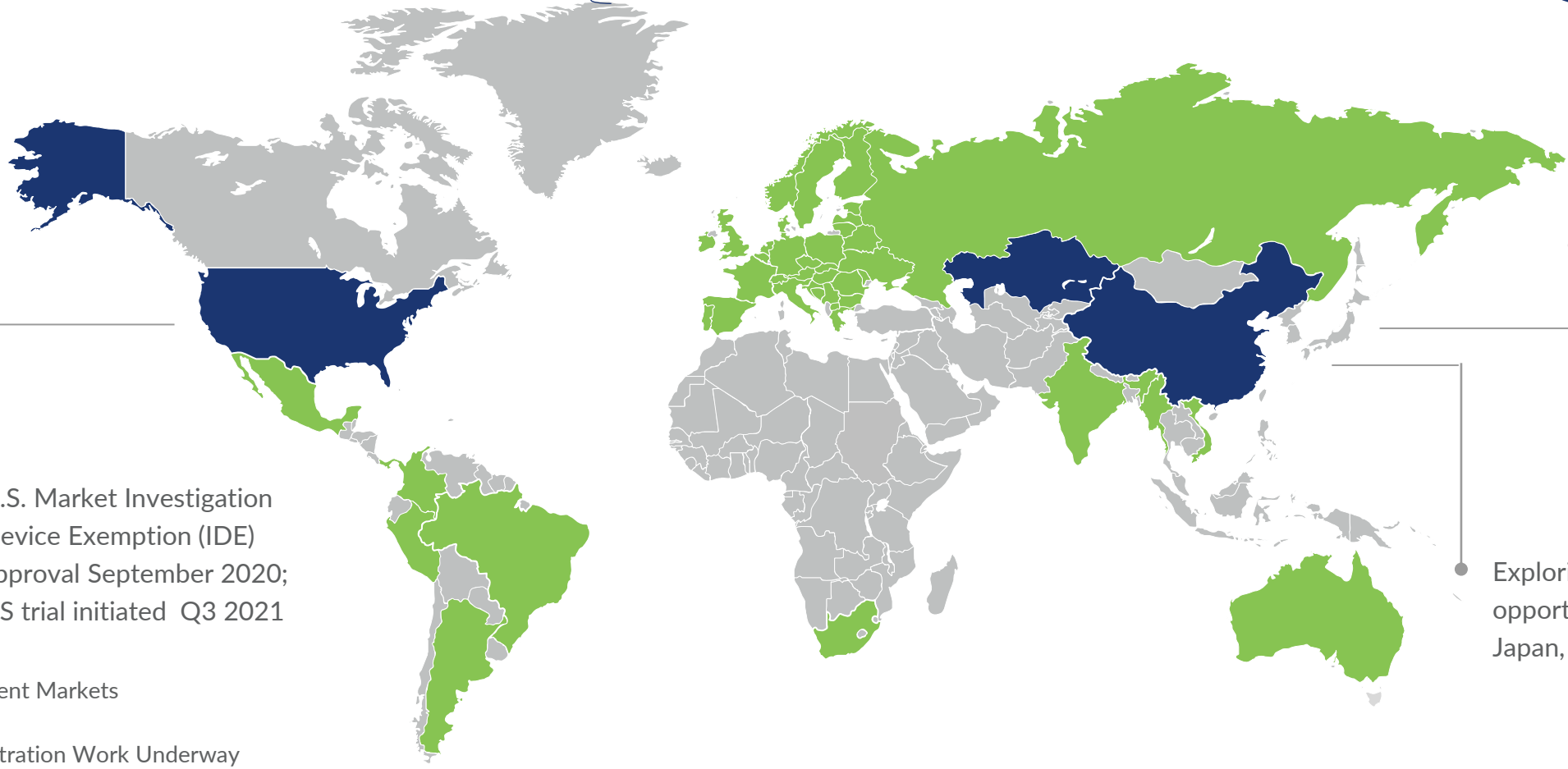
Sean Lyden, M.D.

Vascular Surgeon

Cleveland Clinic

Commercial Footprint

- Active selling in more than 30 countries
- Over 45,000 systems sold
- Average CAS Market share of 25%



U.S. Market Investigation Device Exemption (IDE) approval September 2020; US trial initiated Q3 2021

Signed agreement with Chinese distributor. Working toward distribution

Exploring expansion opportunities Taiwan, Japan, and Korea

Current Markets

Registration Work Underway

Our Robust Intellectual Property Portfolio

Proprietary platform technology supported by IP

Patent Rights	Issued	Pending
USA	19	6
Rest of World	40	17

InspireMD will continue to strengthen and broaden its patent protection globally to enable future pipeline products

IP Counsel: Kligler and Associates, P.A.

Transformational May 2023 Financing Up To $113.6 Million

To advance the company towards potential US approval and launch of CGuard EPS and other value-creating milestones

- **$42.2 million** upfront funding
- **$71.4 million** tied to the achievement of four milestones (**$17.9 million** each) each expiring upon the earlier of 5 years or 20 trading days following the achievement of the following milestones:
  1. Release of primary and secondary end points related to one year follow up study results from the C-Guardians pivotal trial;
  2. Receipt of Premarket Approval (PMA) from the FDA for the CGuard Prime Carotid Stent System (135 cm);
  3. Receipt of FDA approval for the SwitchGuard trans carotid system and CGuard Prime 80 cm; and
  4. Completion of four quarters of commercial sales of the CGuard in the United States.

- **Strong validation** from leading fundamental healthcare investors, with additional participation by select NSPR Board members.

ROSALIND

MARSHALL WACE

SOLEUS CAPITAL

OrbiMed Healthcare Fund Management

NANTAHALA CAPITAL MANAGEMENT, LLC

VELAN CAPITAL

Summary Financials

February 9, 2024

NASDAQ Capital Markets	NSPR
Stock Price	$2.75
Average 3 Month Volume	36.8K
Shares Outstanding	23.5M
Shares Outstanding with Prefunded Warrants	38.7M
Market Capitalization with Prefunded Warrants	$106.4M
Cash Balance - Sept. 30, 2023	$43.0M
Debt	$0M

INSPIREMD

Nasdaq: NSPR