



# CGuard EPS Carotid Stent Platform for Sustained Embolic Protection

**INSPIRE** 

Nasdaq: NSPR

# Disclaimers

## Forward Looking Statement

This presentation contains "forward-looking statements." Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. For example, the Company is using forward-looking statements when it discusses the potential commercialization and market opportunities for its products and product candidates, its cash runway, and its anticipated future milestone Company events. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company's control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with (i) market acceptance of our existing and new products, (ii) negative clinical trial results or lengthy product delays in key markets, (iii) an inability to secure regulatory approvals for the sale of our products, (iv) intense competition in the medical device industry from much larger, multinational companies, (v) product liability claims, (vi) product malfunctions, (vii) our limited manufacturing capabilities and reliance on subcontractors for assistance, (viii) insufficient or inadequate reimbursement by governmental and other third party payors for our products, (ix) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (x) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (xi) our reliance on single suppliers for certain product components, (xii) the fact that we will need to raise additional capital to meet our business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain and (xiii) the fact that we conduct business in multiple foreign jurisdictions, exposing us to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction. More detailed information about the Company and the risk factors that may affect the realization of forward- looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's web site at <http://www.sec.gov>. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

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# Investment Highlights : Poised to Transform the Carotid Intervention Market



## CGuard EPS Stent Platform Utilizing Proprietary MicroNet™ Technology

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



## Unmatched Clinical Outcomes (both Short- and Long-Term)

CGuard™ EPS – nine clinical trials completed with >1,850 patients- published and peer reviewed



## Deep Pipeline and Strategic Roadmap

MicroNet™ technology pipeline; SwitchGuard NPS for TCAR; acute stroke with tandem lesions



## CMS Coverage Expanded to Include Standard Risk and Asymptomatic Reimbursement

Enables stent-first approach to carotid revascularization

## Regulatory Efforts Advancing Toward US Approval

FDA approval of CGuard Prime EPS anticipated in H1 2025



## Significant Market Potential

Current treated market: **\$1.3 Billion** (patients treated with CEA + CAS globally), with significant growth potential from demographic trends and increased screening and diagnosis

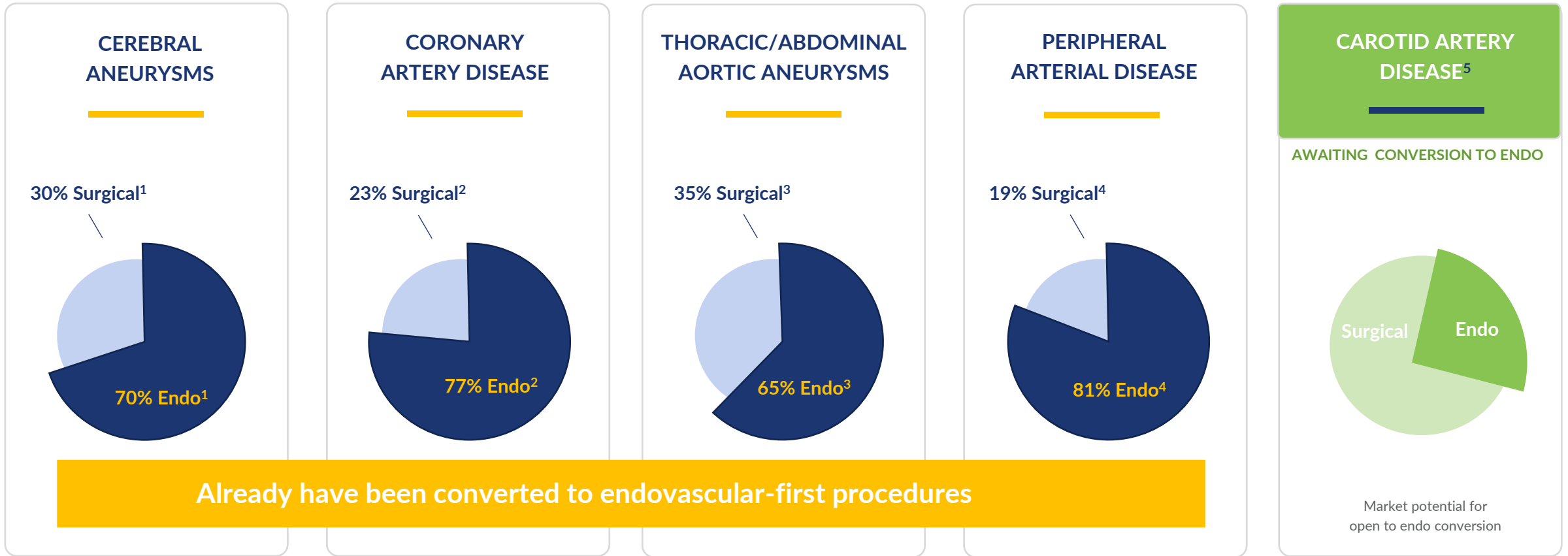


## Expanding Commercial Footprint

Double-digit market share in >30 served countries (>30% in Italy)  
Over 50,000 stents sold to date

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

# Cardiovascular Procedures: The Endovascular Revolution is Nearly Complete



<sup>1</sup> 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

<sup>2</sup> 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





<sup>3</sup> 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

<sup>4</sup> 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.

<sup>5</sup> Procedures For Selected Nations, 2017 - 2025 presented to InspireMD, Inc. by Health Research International Personal Medical Systems, Inc. Sept. 13, 2021

# CMS Final National Coverage Determination, October 11, 2023

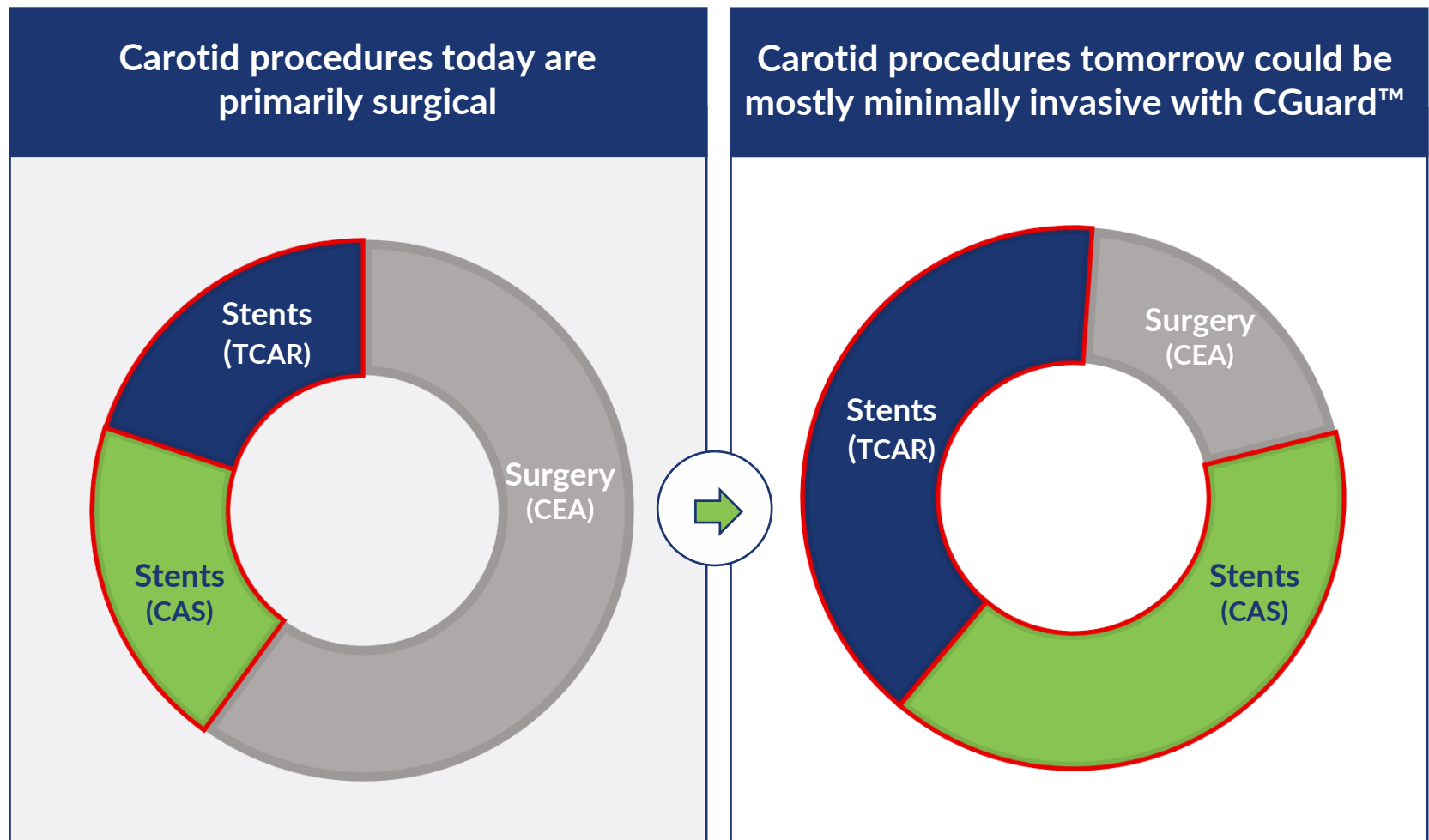
This final decision memorandum, which affects NCD 20.7 sections B4 and D, revises Medicare coverage for Percutaneous Transluminal Angioplasty (PTA) of the carotid arteries concurrent with stenting by:

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



# Potential Multi-Billion Dollar Market Opportunity

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



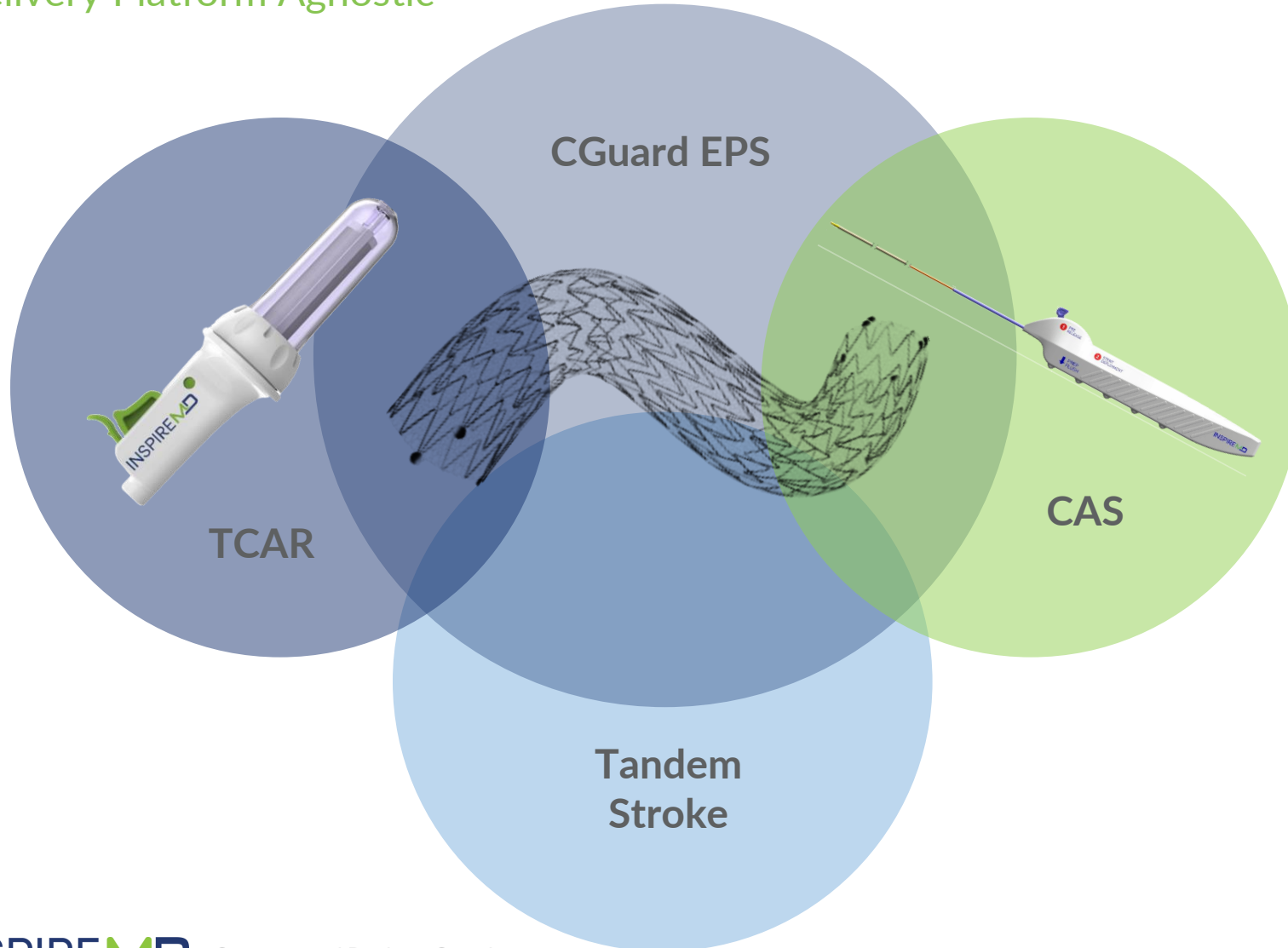
- ◆ **Current Treated Global Market:**  
→ **\$1.3 billion** <sup>(1)</sup>  
407K Global procedures (CEA/CAS/TCAR) to treat HGCS (High Grade Carotid Stenosis)
- ◆ **Current Treated U.S. Market:**  
→ **\$809 million**  
155K procedures to treat HGCS
- ◆ **Current Untreated Global Market:**  
→ **\$8 billion**  
~2.8 million people diagnosed with HGCS (Untreated)
- ◆ **Standard Risk and Asymptomatic reimbursement (US) increases CAS potential, expected to increase screening and diagnosis**

1. 2021 Health Research International Market Report; internal estimates

 = InspireMD focus areas

# Long-Term Stent Performance is the Cornerstone of Our Focus

Delivery Platform Agnostic

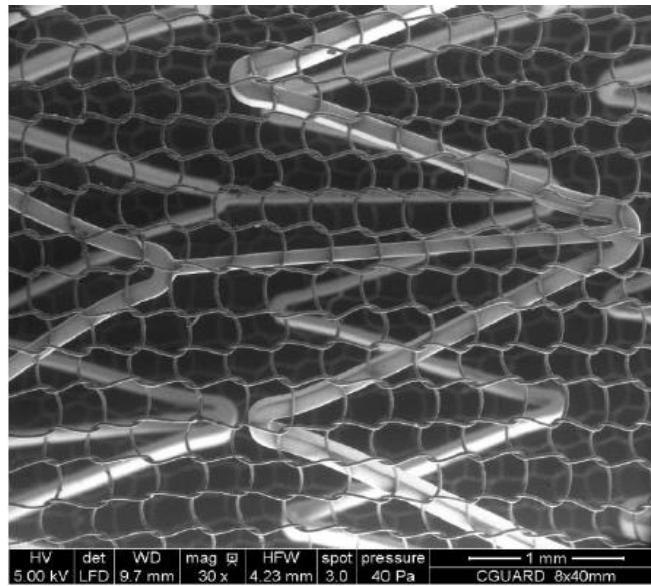
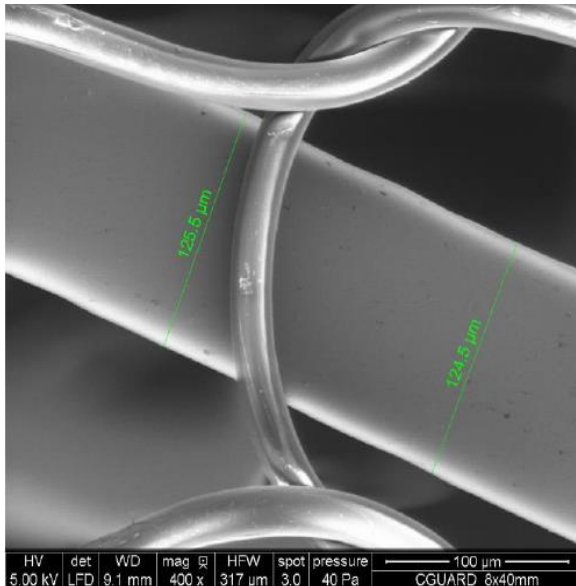


- ✓ Well-positioned to capitalize on the ongoing paradigm shift toward a “stent first” approach and away from surgery
- ✓ Agnostic to stent delivery approach (TCAR vs. CAS)

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

## OUR SOLUTION: The CGuard EPS

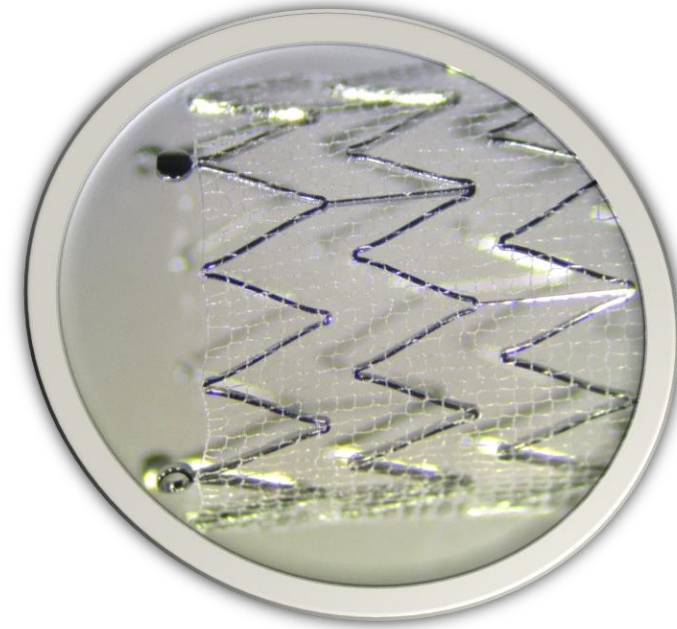
The only stent platform available with our patented MicroNet mesh technology



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

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

Cell size: 165 μm

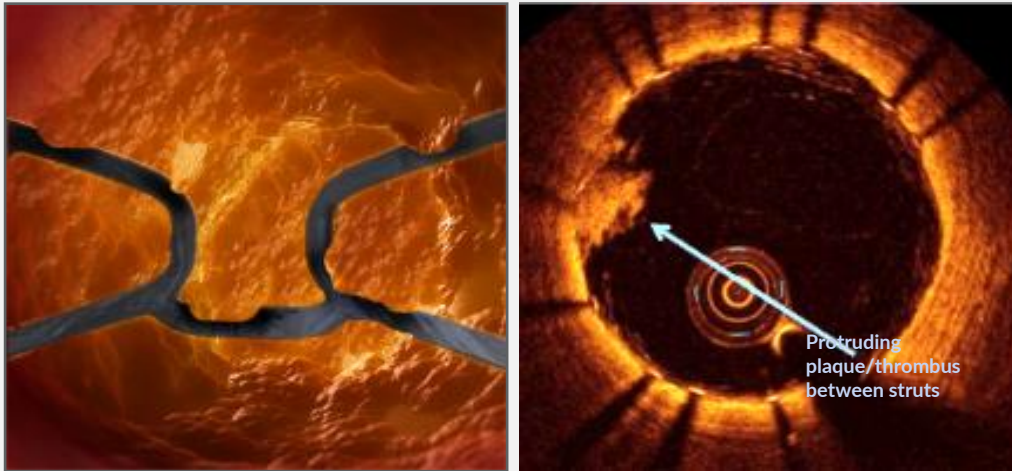


1. Cano et al. Rev Bras Cardiol Invasiva 2013; 21(2): 159-64. 2. Bosiers et al. Eur J Vasc Endovasc Surg Vol 33, Feb 2007.,



# OUR SOLUTION: CGuard™ Stent with Proprietary MicroNet™ Technology<sup>1</sup>

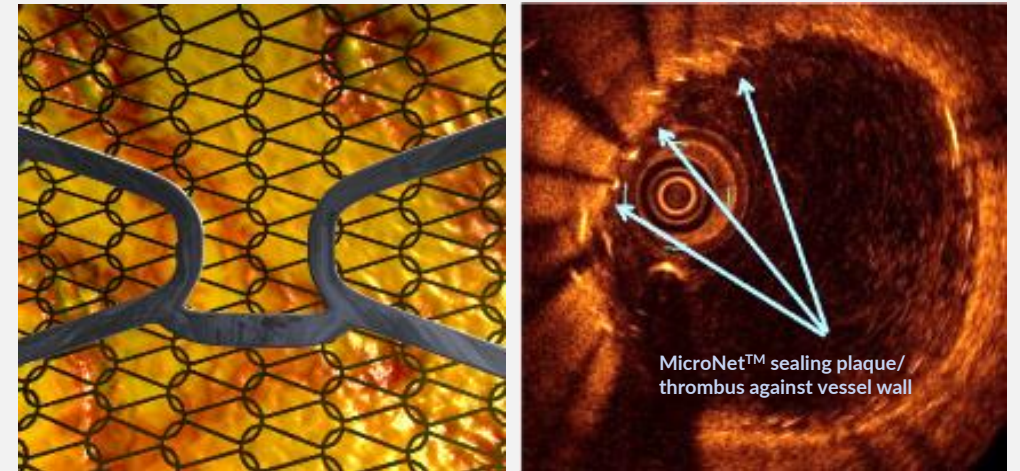
Mesh-covered stent offers superior plaque coverage when compared to conventional stents



## Conventional Open Cell Stent (1<sup>st</sup> GEN):

Larger cell sizes allow increased plaque protrusion risk

VS.



## CGuard Stent System (2<sup>nd</sup> GEN):

Stents are covered in MicroNet to minimize plaque prolapse

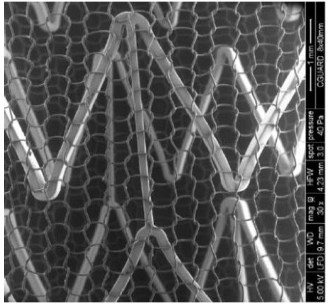
## An Embolic Prevention System (EPS) for Ultimate Thrombus Protection

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

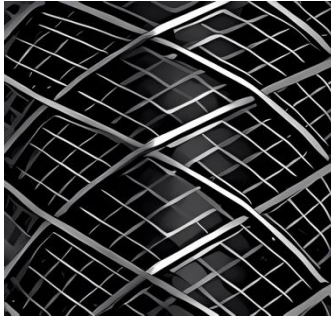
<sup>1</sup>Tomoyuki Umemoto, MD. Optical coherence tomography assessment of new generation mesh-covered stents after carotid stenting. Eurointerventional 2017;1348-1355 (published online)

Image: Prof. Valdés Chávarri

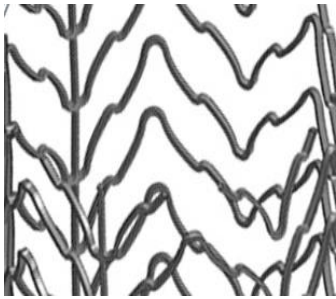
# Stent Cell Sizes



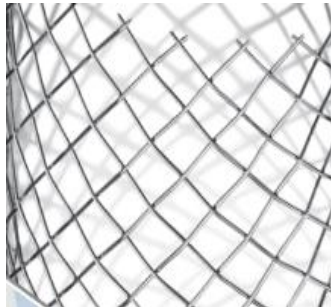
CGUARD™



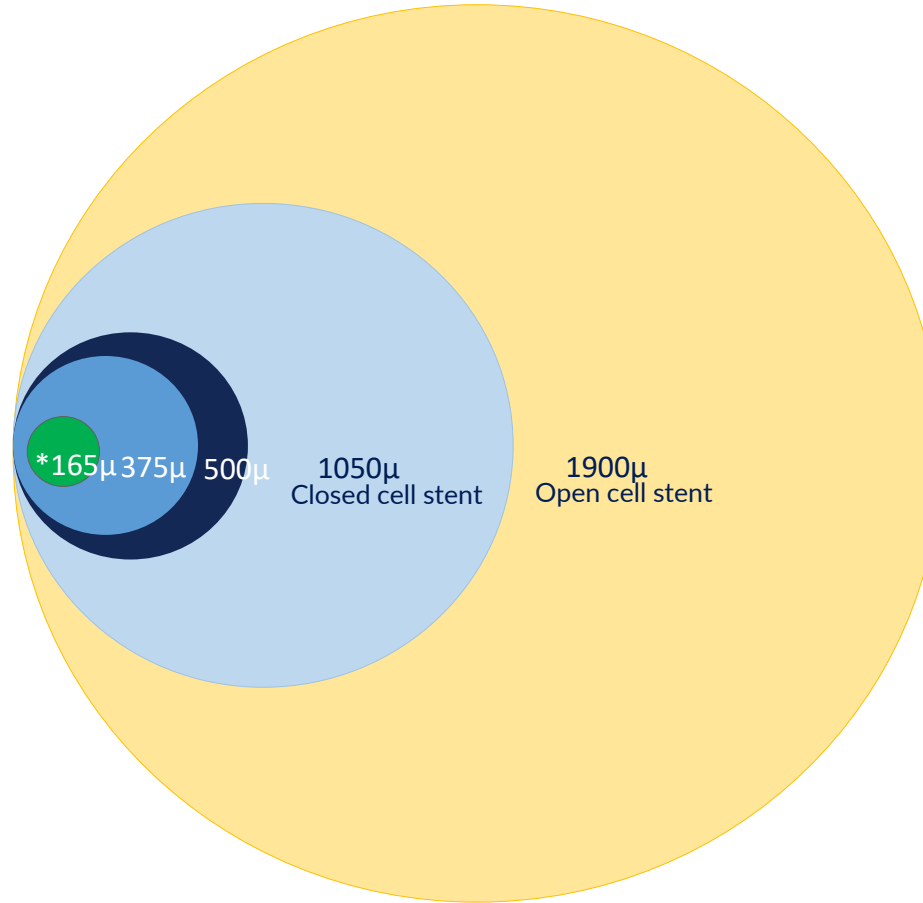
CASPER®



ACCULINK™

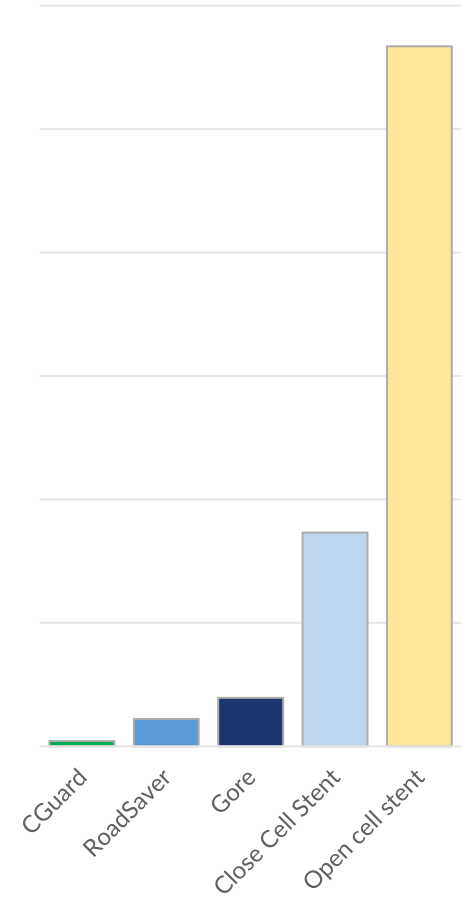


WallStent™



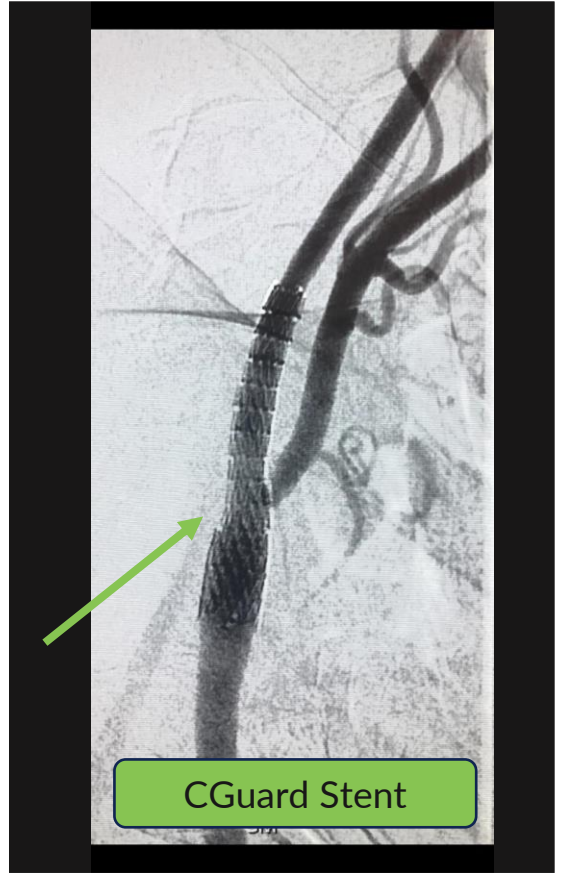
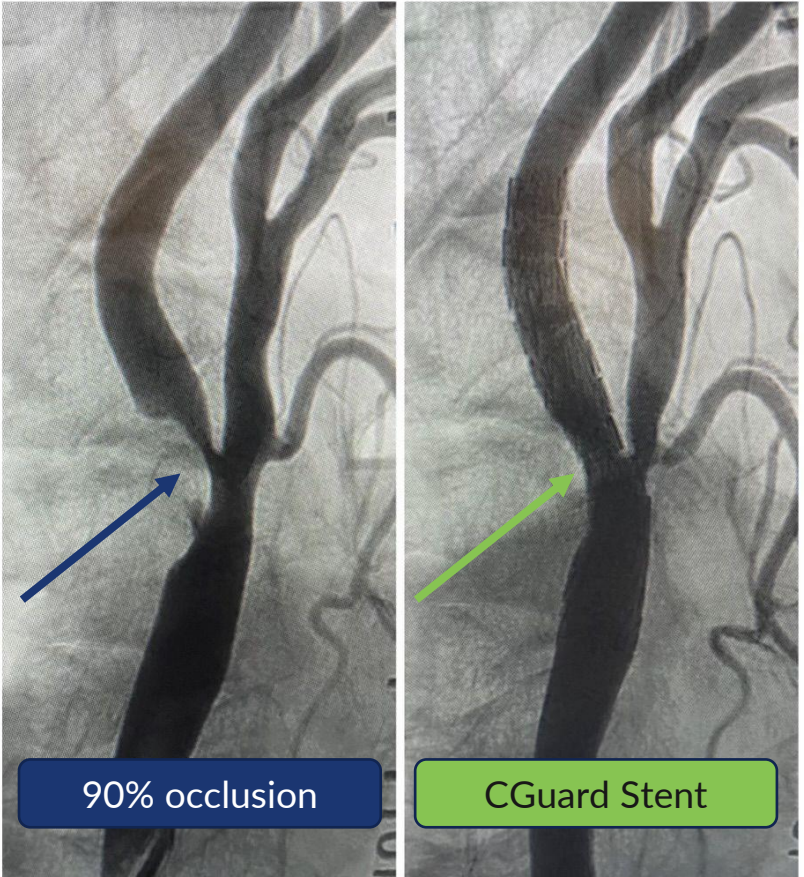
\* Average in lesion at expanded state

Area Comparison (mm<sup>2</sup>)



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

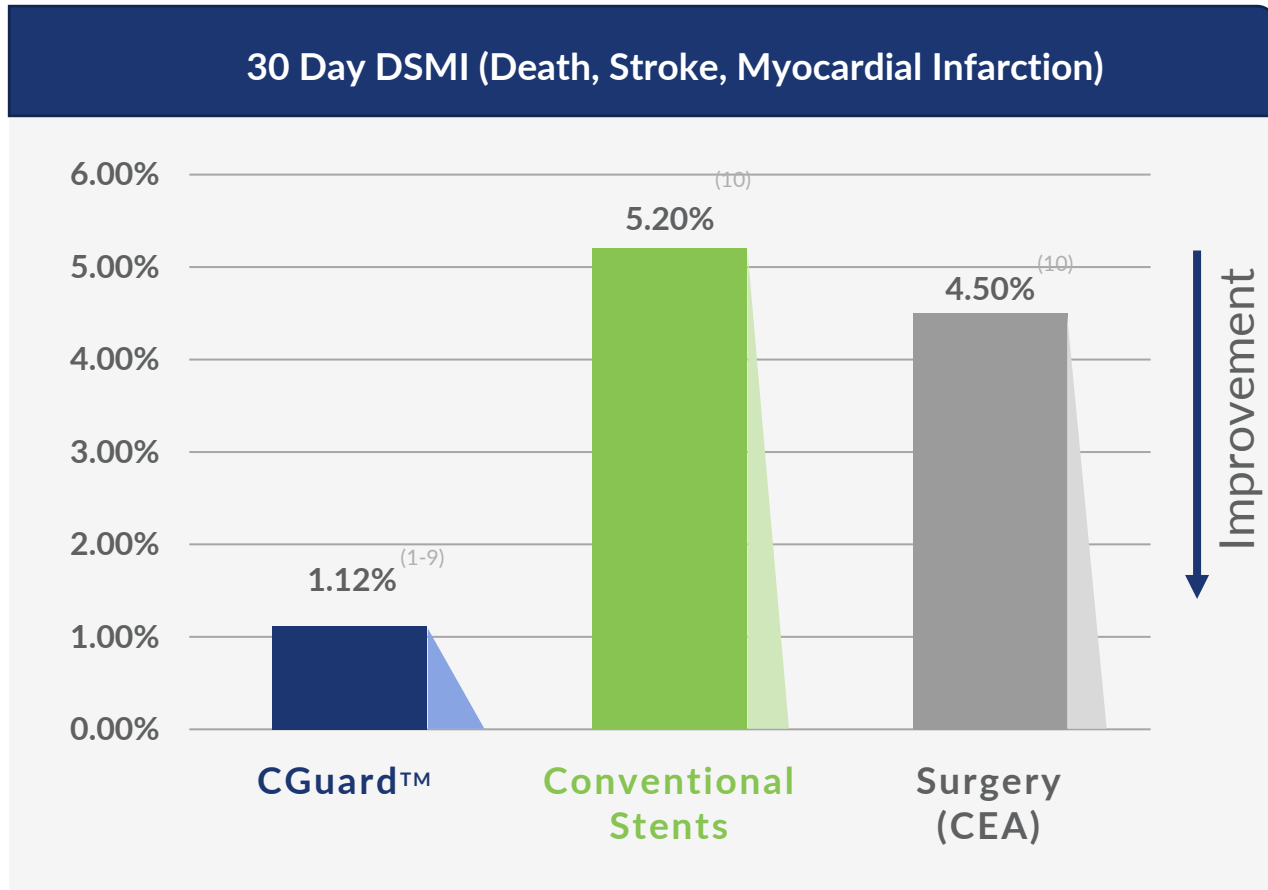
# A Picture is Worth a Thousand Words...



# Unmatched 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



# Clinical Evidence 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

# Comparative Clinical Evidence: CARMEN Meta-Analysis

- Meta-analysis of 112 studies, 68K+ CAS patients (all devices)
- Improvements from second-generation stents (SGS) relative to first-generation stents (FGS), but important differences exist amongst the SGS
- CGuard's MicroNet drives improvement in both
  - Acute results/event reduction (due to improved scaffolding)
  - Long-term outcomes/restenosis reduction (likely 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
<b>30-day Stroke [%]</b> (95% CI)	<b>3.01</b> (2.63-3.38)	<b>0.60</b> (0.28-0.92)	<b>0.50</b> (0-1.15)	<b>2.89</b> (1.03-4.76)	<b>0.54</b> (0.17-0.92)
<b>30-day Death/Stroke/MI [%]</b> (95% CI)	<b>4.11</b> (3.65-4.56)	<b>1.30</b> (0.64-1.96)	<b>1.33</b> (0-2.66)	<b>4.82</b> (2.44-7.2)	<b>1.08</b> (0.55-1.60)
<b>12-mo Ipsilateral Stroke [%]</b> (95% CI)	<b>3.51</b> (2.52-4.50)	<b>0.7</b> (0-1.47)	<b>0.26</b> (0-1.27)	<b>3.1</b> (1.11-5.1)	<b>0.38</b> (0-0.9)
<b>12-mo Restenosis [%]</b> (95% CI)	<b>3.97</b> (0.28-5.14)	<b>3.38</b> (1.39-5.37)	<b>7.16</b> (4.45-9.86)	<b>4.83</b> (2.36-7.29)	<b>0.34</b> (0-0.82)
<b>12-mo Ipsilateral Stroke/Restenosis [%]</b> (95% CI)	<b>8.15</b> (6.34-9.96)	<b>5.12</b> (2.14-8.10)	<b>7.86</b> (5.04-10.68)	<b>7.93</b> (4.82-11.04)	<b>0.73</b> (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 (C-GUARDIANS)

FDA Trial Performance Goal – 11.6% (vs European Clinical Trials' Mean Performance 1.32% @ 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)**
- **24 Centers** (19 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

# C-GUARDIANS: 30-Day Major Adverse Events

Results presented at VEITH - 2023

Event rate in % (n)	ITT (N=316)	Per Protocol <sup>^</sup>
Death, Stroke or MI <sup>*</sup>	0.95% (3)	0.63% (2)
Death <sup>#</sup>	0.32% (1)	0.00% (0)
Any stroke <sup>#</sup>	0.95% (3)	0.63% (2)
Major Stroke <sup>#</sup>	0.32% (1)	0.00% (0)
Minor Stroke <sup>#</sup>	0.63% (2)	0.63% (2)
MI <sup>#</sup>	0.00% (0)	0.00% (0)
Death or any stroke <sup>*</sup>	0.95% (3)	0.63% (2)
Death or major stroke <sup>*</sup>	0.32% (1)	0.00% (0)

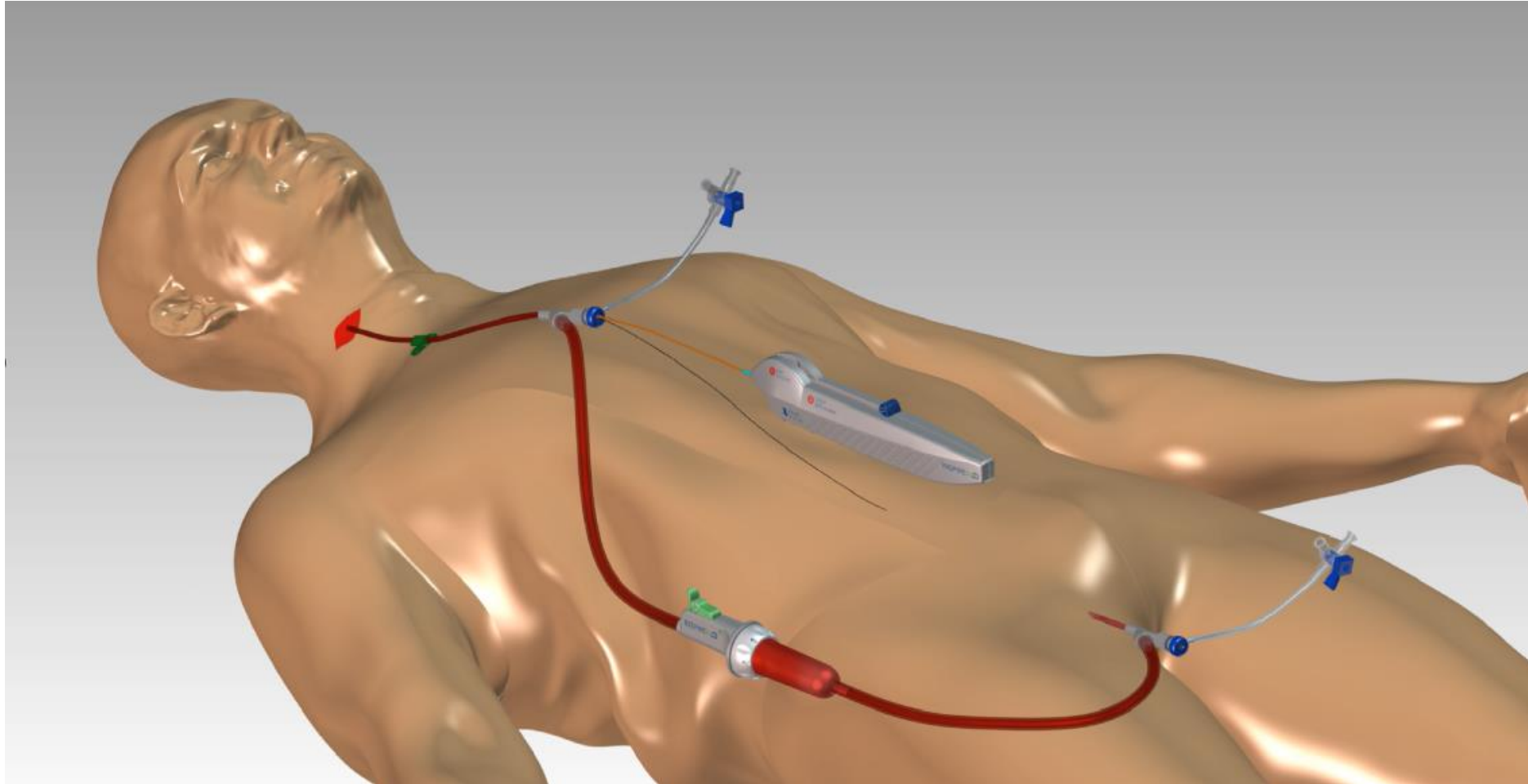
\* Hierarchical: patient count (each patient first occurrence of the most serious event).

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

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

TCAR

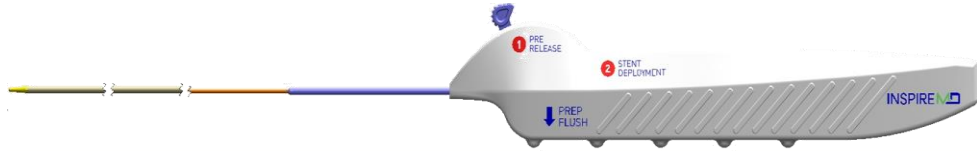
# Transcarotid Arterial Revascularization (TCAR): Direct Carotid Access with Reverse Flow



InspireMD combines SwitchGuard NPS 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  
**C**GUARD**PRIME**



**SWITCH**  
GUARD

## TCAR Market Opportunity

>2,800 TCAR-trained physicians in the U.S.<sup>1</sup>

>25,000 TCAR procedures (\$177M) performed in the U.S. in 2023, double-digit growth projected<sup>1,2</sup>

InspireMD's C-GUARDIANS II TCAR trial anticipated to commence H2 2024; Potential clearance in H1 2026

<sup>1</sup> SILK reporting

<sup>2</sup> Piper-Sandler model, 11/8/23

# Corporate



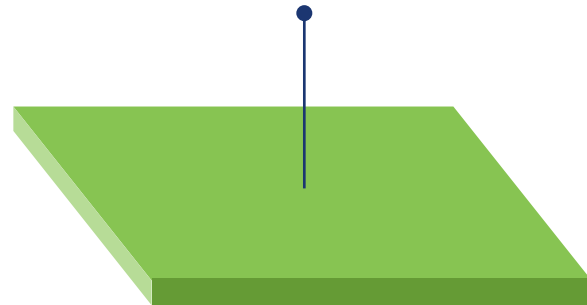
# Roadmap / Milestones

## Key Value Drivers

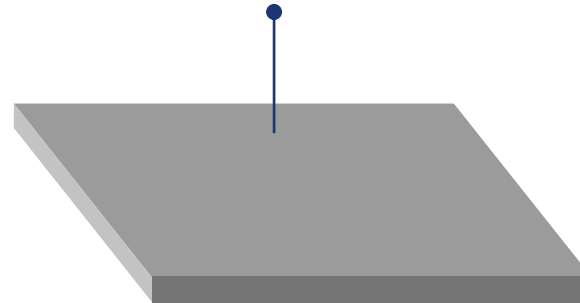
- FDA PMA Submission (Module II, III and IV)
- Initiation of CGUARDIANS II (TCAR) study
- Acute Stroke EFS- Tandem Lesions
- China Regulatory Submission
- CGuard Prime CE Mark

- CGuard Prime PMA Approval for CAS and TCAR
- U.S. Commercial Launch
- Build out of U.S. HQ and Production

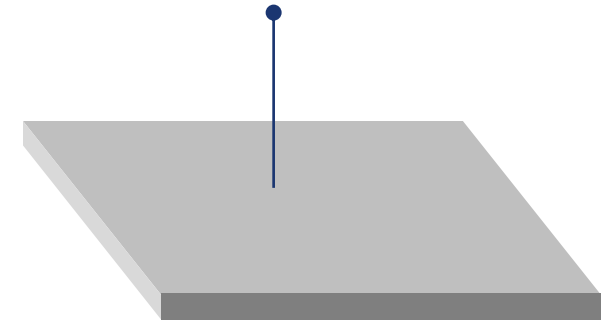
- SwitchGuard NPS Approval + Launch
- Scale US Operations
- Approval China



2024



2025



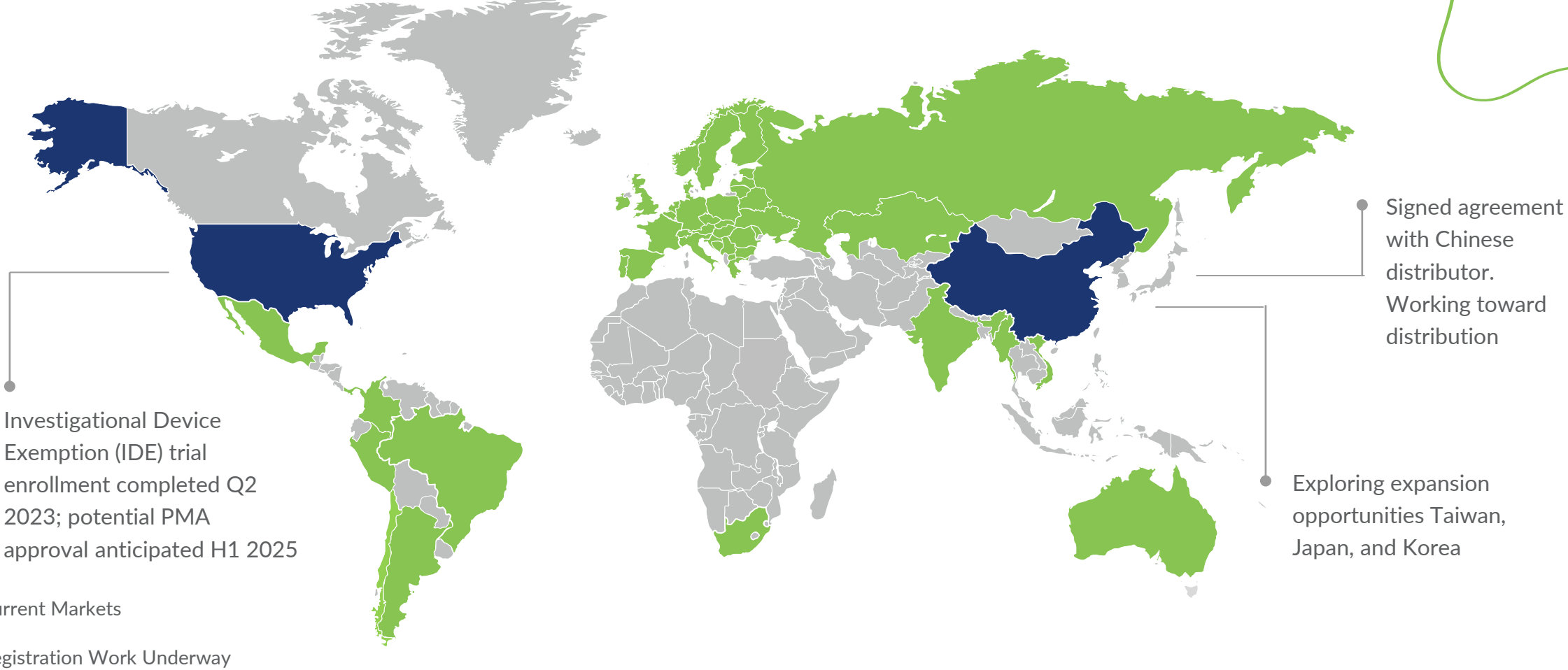
2026





# Commercial Footprint

- Active selling in more than 30 countries
- Over 50,000 systems sold
- Average CAS Market share of 25%



# Scientific Advisory Board (Multidisciplinary KOLs)



**Kenneth Rosenfield, M.D.**  
Interventional  
Cardiologist



**Adnan H. Siddiqui, M.D. Ph.D**  
Professor, Vice Chairman of the  
Department of Neurosurgery



**Chris Metzger, M.D.**  
Medical Director  
Cardiologist



**Sean Lyden, M.D.**  
Vascular Surgeon



# 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.

# 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.



# 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



# Summary Financials

March 19, 2024

## NASDAQ Capital Markets

NSPR

Stock Price	\$2.31
Average 3 Month Volume	29.0K
Shares Outstanding	23.4M
Shares Outstanding with Prefunded Warrants	38.7M
Market Capitalization with Prefunded Warrants	\$89.3M
Cash Balance - Dec. 31, 2023	\$39.0M
Debt	\$0M

INSPIREMD



Nasdaq: NSPR