



# Sustained Embolic Protection

Investor Presentation I March 2023

INSPIREMD

# 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.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

# Our Leadership



**Marvin L. Slosman**

President and CEO



**Craig Shore**

Chief Financial Officer



**Andrea Tommasoli**

Chief Operating Officer



**Shane Gleason**

GM US Business



**Juan Rigla, M.D., Ph.D.**

Medical Director



**Tamar Nativ**

VP QA & RA



# Scientific Advisory Board (Multidisciplinary KOL's)



**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





# Summary Financials

January 17, 2023

NASDAQ Capital Market	NSPR
Stock Price	\$1.15
Average 3 Month Volume	29.3K
Shares Outstanding	8.3M
Market Capitalization	\$9.6M
Cash Balance – September 30, 2022	\$21.0
Debt	\$0M

# Investment Highlights



## CGuard EPS Stent Platform utilizing Proprietary MicroNet™ Technology

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



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

CGuard™ EPS – (9) clinical trials completed >1,850 patients  
CGuard results **1.12%** vs. Conventional Stents **5.2%** and Surgery **4.5%** (30 Day Death, Stroke, Myocardial Infarction)



## Market Potential

Current treated market: **\$1.3 billion** (Dx & Treated with CEA + CAS)  
Total untreated market: **\$8 billion** (Dx with HGCS not treated)  
Standard risk reimbursement (US) increases CAS potential



## Expanding Commercial Footprint \*

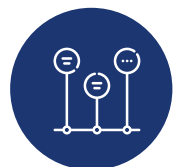
Double-digit market share in **30** served countries (34% in Italy)  
**35,406** stents sold through September 30, 2022



## US IDE Trial Advancing toward US approval

Anticipated approval of CGuard EPS in **2024**

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



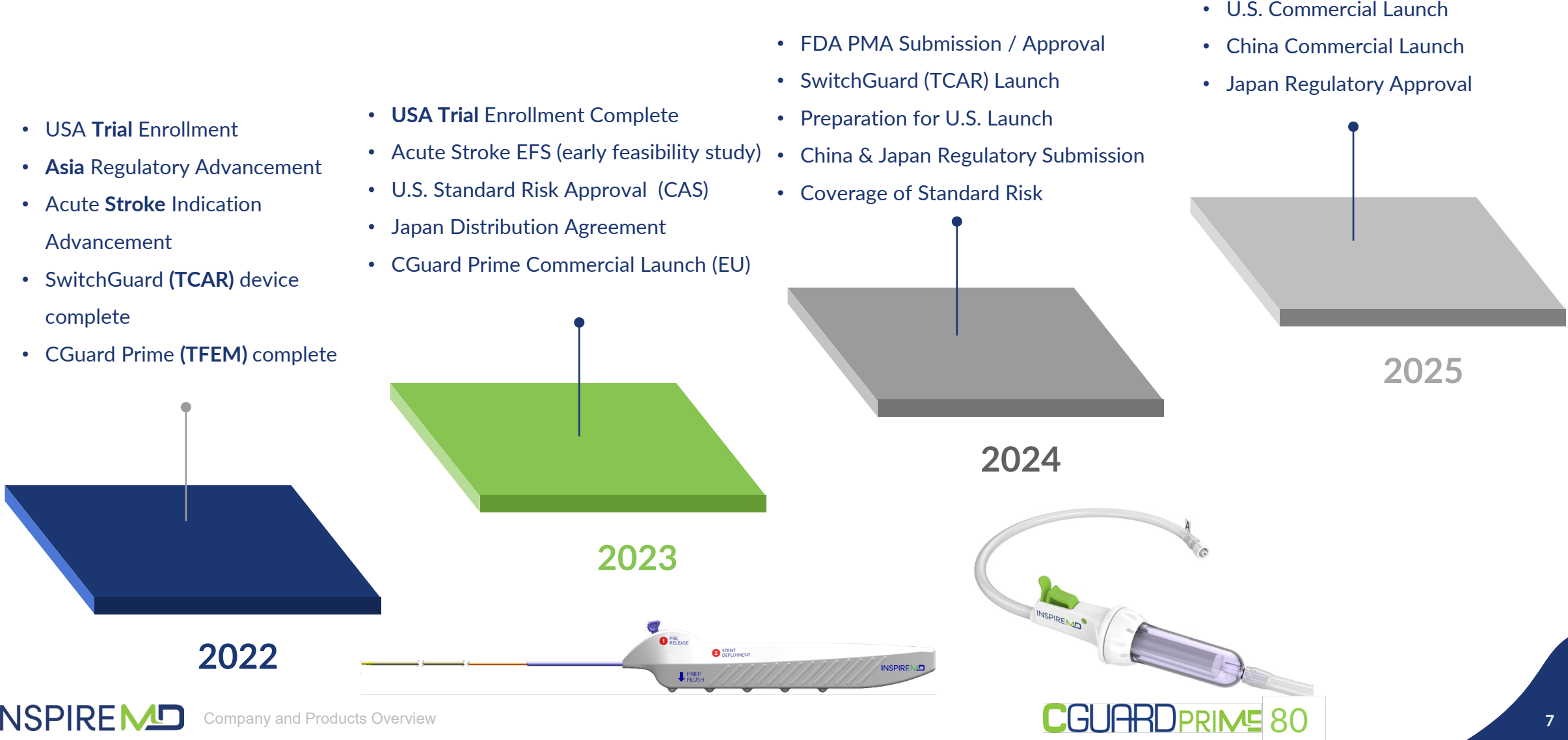
## Deep Pipeline and Strategic Roadmap

**MicroNet™** technology pipeline advancing into multi generational development plans including: SwitchGuard for TCAR; Acute Stroke with tandem lesions

Experienced management team and directors with extensive healthcare expertise

# Our Advancement Roadmap / Milestones

## Our Expected Key Value Drivers and Strategic Pathways

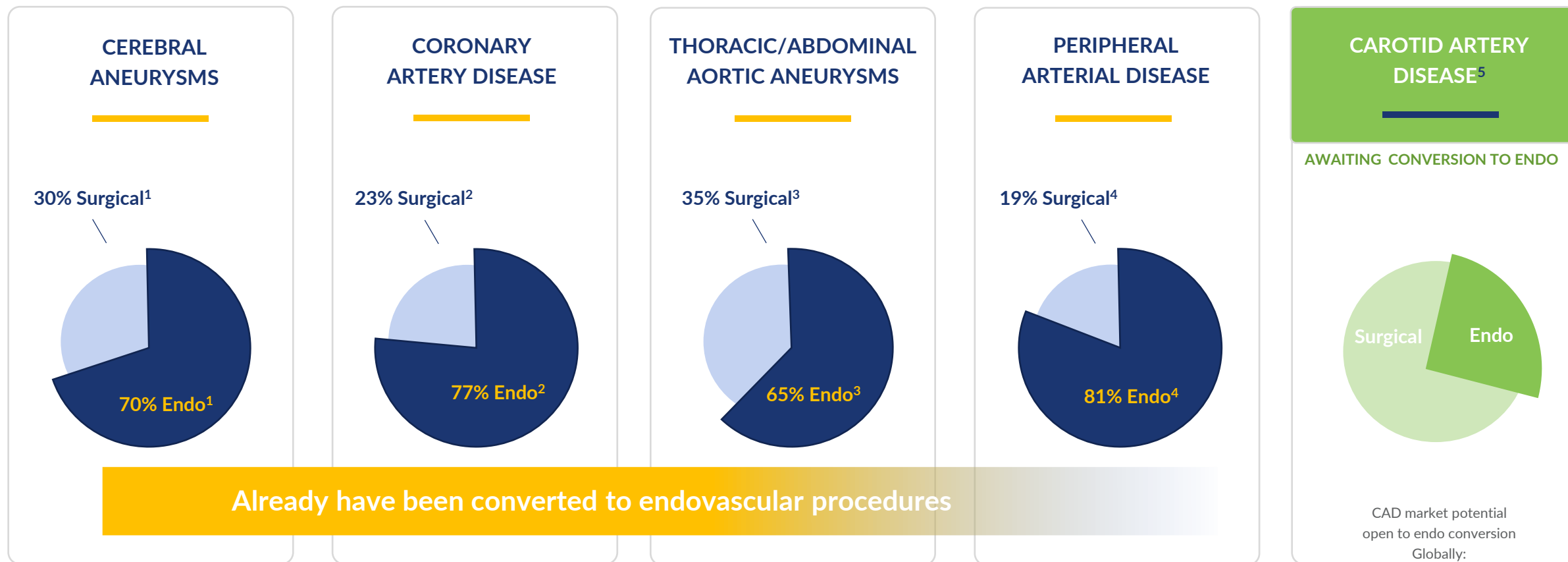


# InspireMD Pipeline





# Endovascular Procedures: Landscape and InspireMD Potential



<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

# Unmet Clinical Need

# THE PROBLEM: Risks with Existing Approaches to CAD

Conventional approaches come with risks

## Carotid Endarterectomy (CEA)

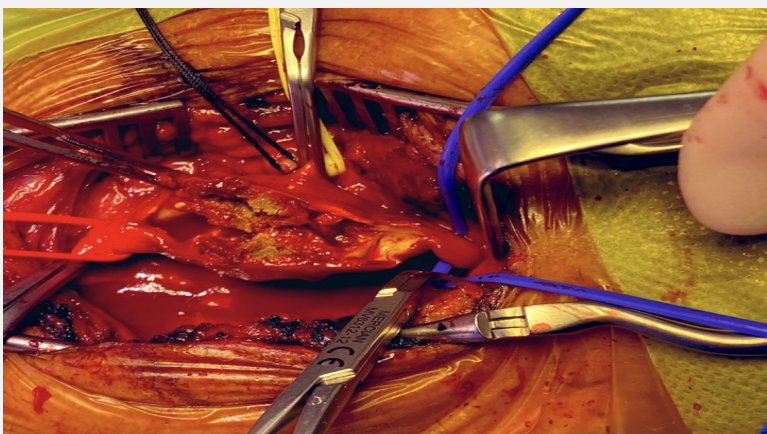
Surgical Approach

### Risk of complications:

Myocardial infarction risk<sup>1</sup> (heart attack)

Cranial nerve injury risk<sup>1</sup> (vertigo, hearing loss, paralysis, etc)

Esthetic concern

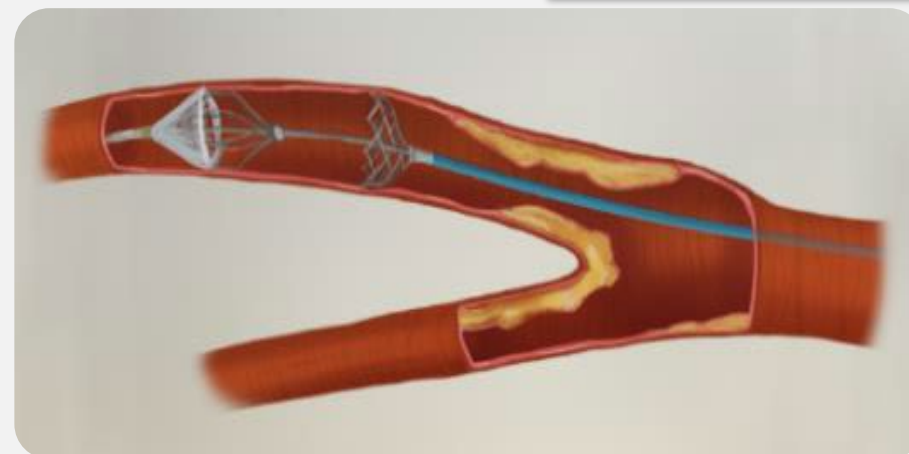


## Carotid Artery Stenting (CAS)

Conventional Approach (Bare Stent)

### Risk of complications:

Procedural and post-procedural increase minor stroke risk<sup>1</sup>

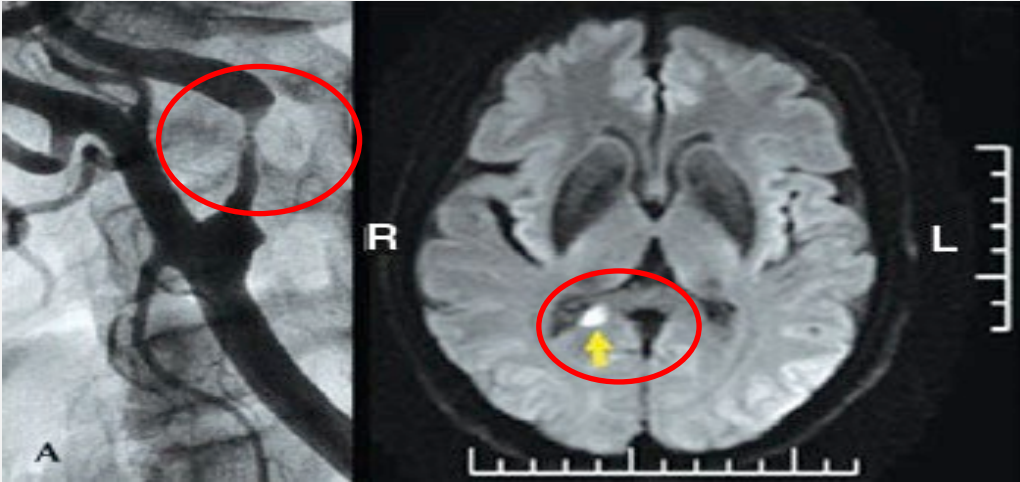


<sup>1</sup> Based on the CREST clinical trial data, in which only conventional carotid stents were used vs. surgery, CREST Trial: N Engl J Med 2010;363:11-23

# THE PROBLEM: Risk of Embolism Following Conventional Carotid Stenting

MRI reveals post-procedural cerebral embolization

## Pre-Procedure

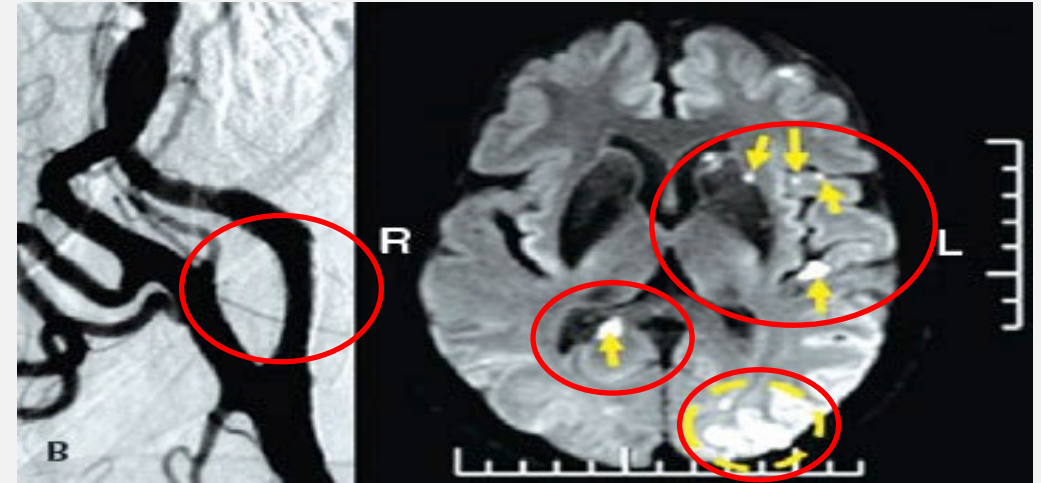


90% occlusion of the carotid artery

MRI of a pre-existing white matter infarction (obstruction)

## Post-Procedure

with Conventional Stent



Successful opening of the carotid artery

MRI reveals new multiple micro-infarcts (obstructions) due to liberation of embolic particles

Approximately 2/3 of neurovascular events (stroke, TIA) occur after the procedure takes place.<sup>2</sup>

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.,



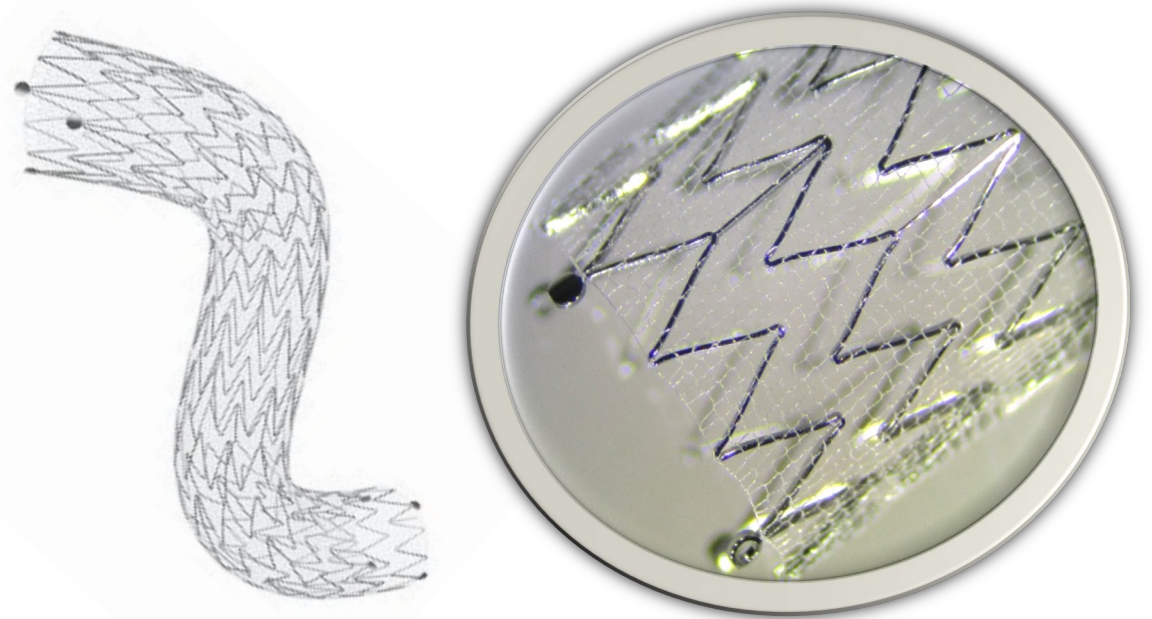
# Our Solution

# OUR SOLUTION: The CGuard EPS

The only stent platform available with our patented MicroNet mesh technology

## Stent- Nitinol (NiTi):

- The CGuard framework is manufactured from a 3mm Nitinol tube
- This tubing is used for all CGuard stent designs (Ø 6-10 mm, L=20,30,40,60mm)
- The tubing is laser cut into a helical open cell design formed by circumferential strut rings that are connected to each other by peak to valley long connection.
- The connecting links are aligned in one direction

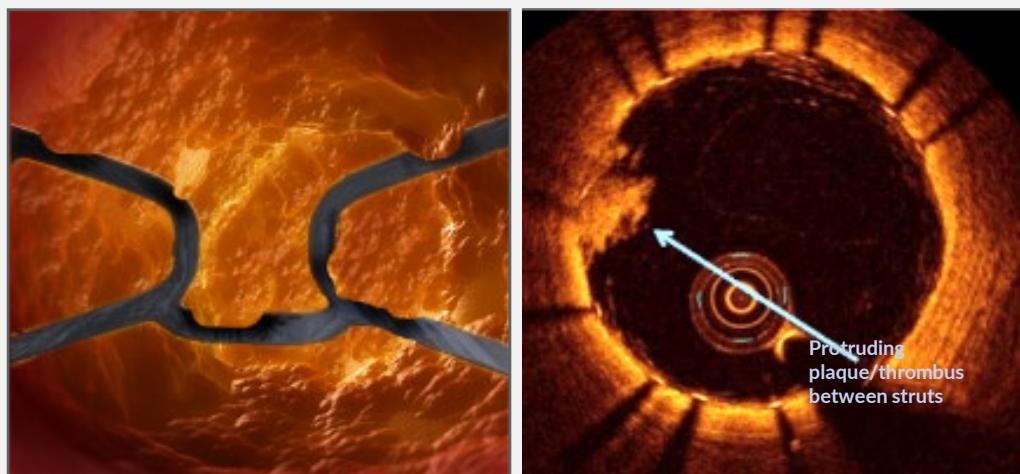


Approximately 2/3 of neurovascular events (stroke, TIA) occur after the procedure takes place.<sup>2</sup>

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: Proprietary MicroNet™ Technology<sup>1</sup>

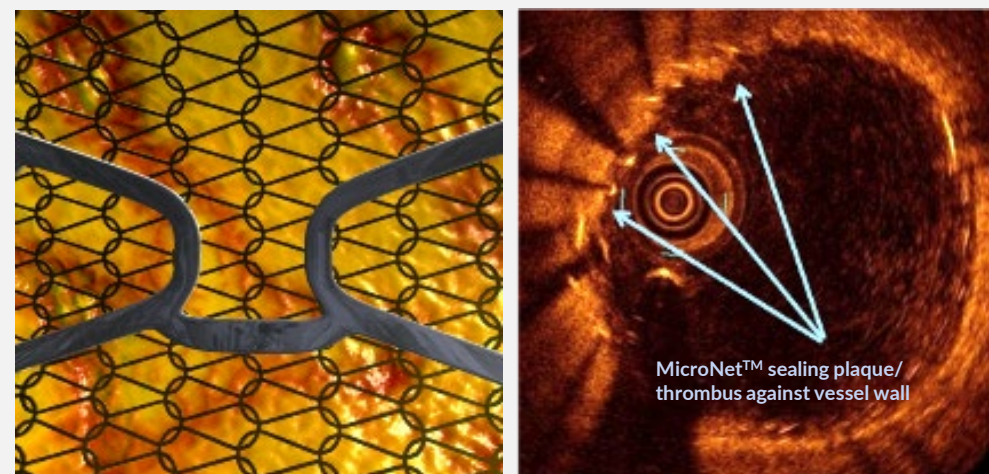
New mesh covered stent offers superior plaque coverage when compared to conventional stent approaches



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

Bare or dual layer approach, with plaque protrusion risk

VS.



## CGuard Stent System (3<sup>rd</sup> GEN):

Stents are covered in MicroNet

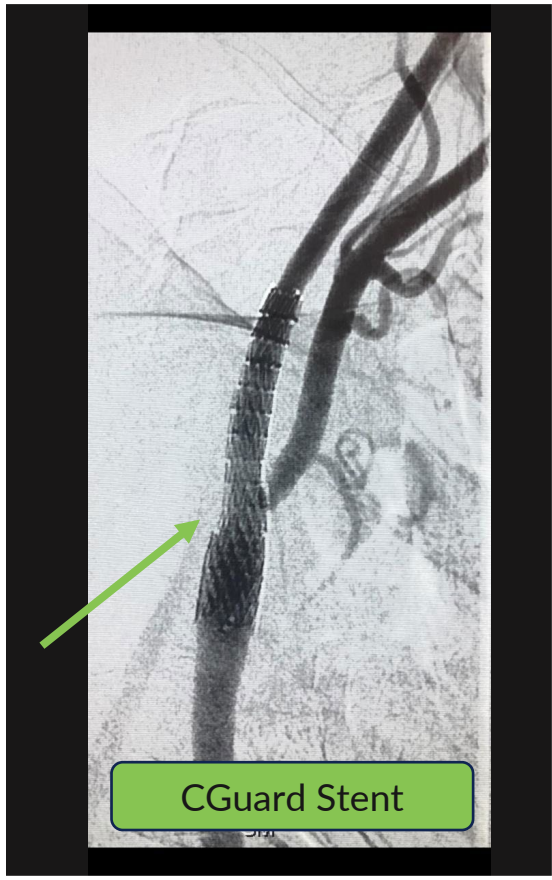
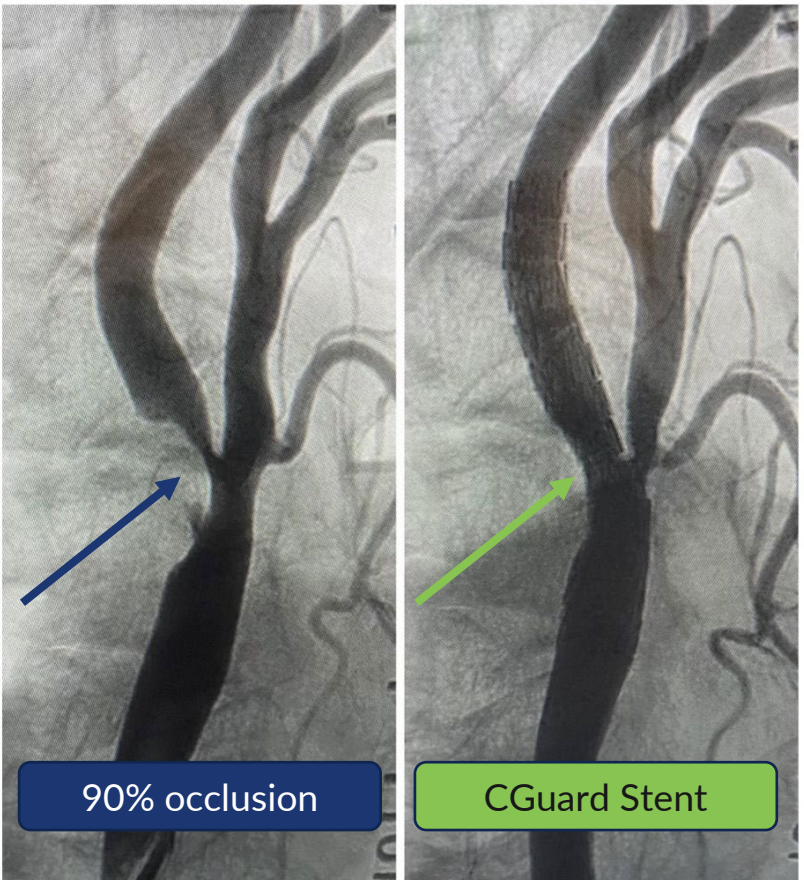
## An Embolic Prevention System (EPS) for Ultimate Thrombus Protection

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

<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



# A picture is worth a thousand words ...



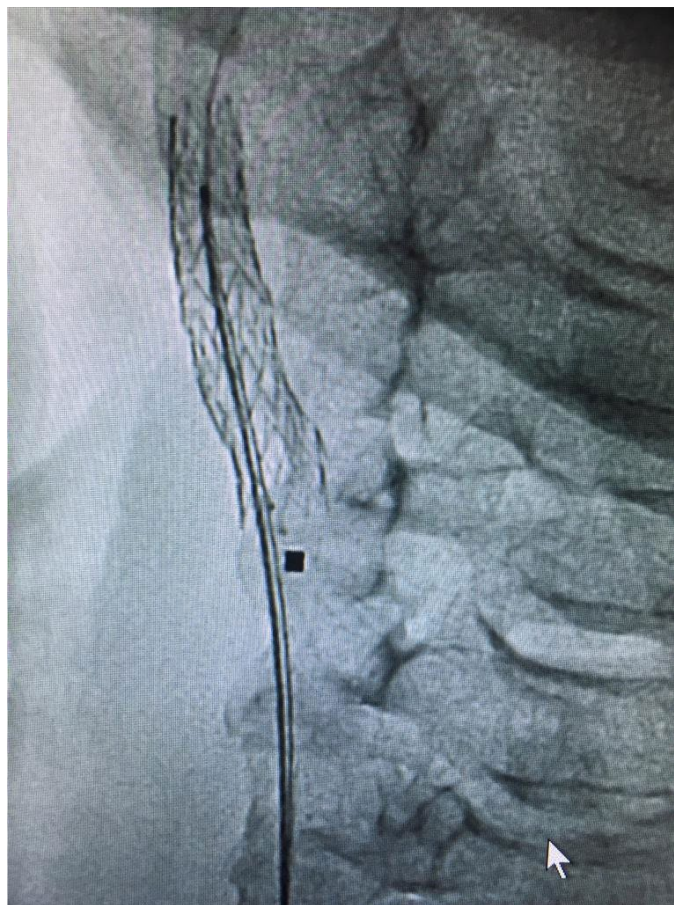


# A picture is worth a thousand words ...

Thrombus Burden Stroke



CGuard Stent Angio



Post Stented Vessel





## INSPIREMD Company and Products Overview

INSPIREMD Company and Products Overview

\*Corresponding author: *Francesca and Erika Maria Saggari* (Department of Biology "Pavlo Stofanin", Politecnico di Torino), "Sapienza" University of Rome, I-55 Politecnico 00137 Rome, Italy. E-mail: francesca.saggari@polito.it

*\*Corresponding author: Jyoti Chaturvedi, University Department of Centre for Macroeconomic Studies, P.O. Box 10, Prashasti NO 23-262 Durgam, Pune-411 004; E-mail: jyoti@centrescm.ac.in*

procedures.<sup>1,10</sup> The initial studies provided mediocre clinical results.<sup>11-13</sup>

Get the full book online at [www.mhhe.com/9780071220693](http://www.mhhe.com/9780071220693) © 2011 McGraw-Hill Education, Inc.

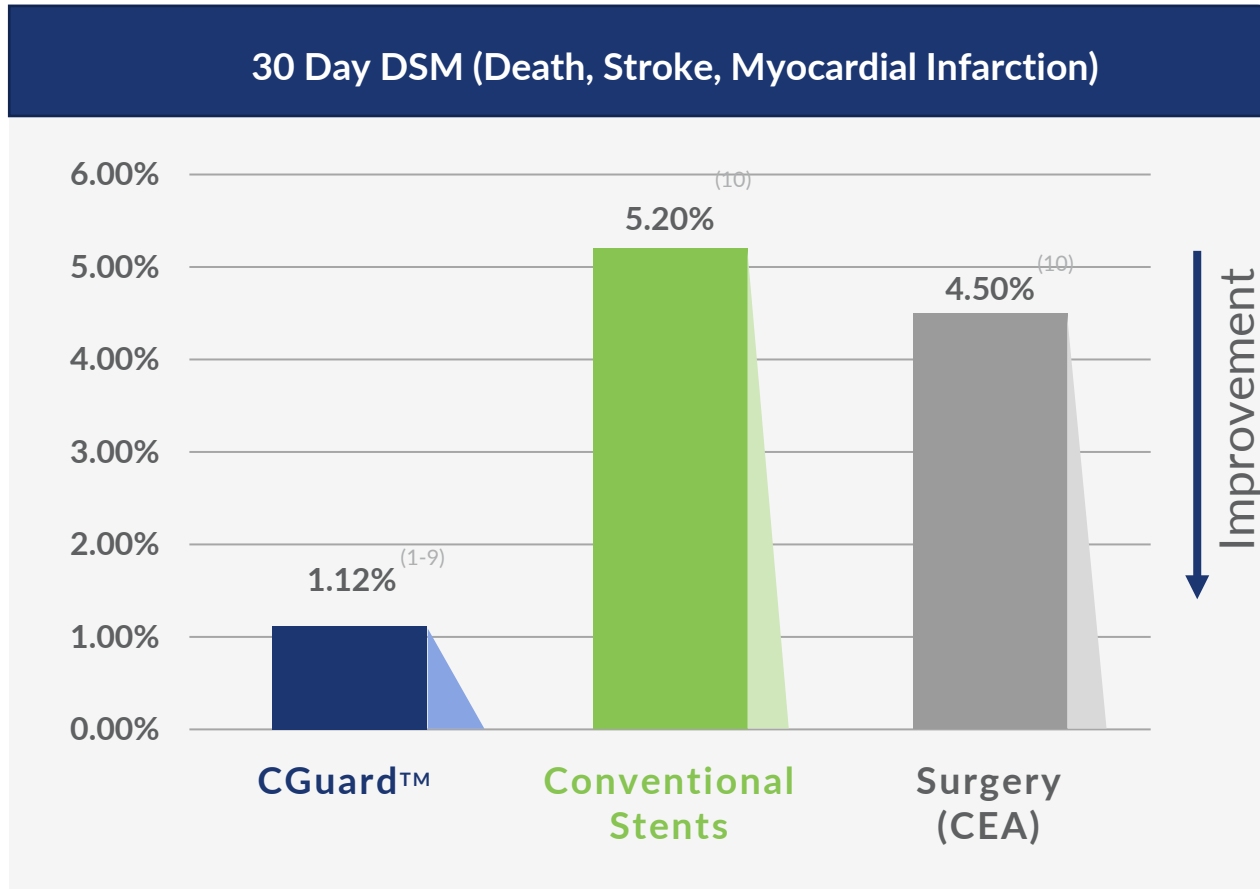
Received 16 July 2010; accepted 12 October 2010; published online 12 November 2010

Frederick Hospital of the University of Göttingen and the University of Göttingen, Germany.  
E-mail: frederick@publi.uni-goettingen.de

in patients treated with an open-cell stent vs a closed-cell stent.<sup>9,10</sup>

# 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 has a superior profile vs. historical data on both conventional carotid stents and surgery
- 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. Tigkopoulos J Endovasc Therapy Volume 28 Issue 4, Aug 2021 10. CREST N Engl J of Med 2010 July 1. 11-23.

# Clinical Data Foundation: Evolution to Standard of Care

YEAR	STUDY	PUBLICATION HIGHLIGHTS	CGUARD'S STANDING (known & anticipated)	Journal
2015	CARENET	Safety, Efficacy & Neuroprotection over other stents data	<b>CGuard evaluated as new approach 'to CAS</b>	JACC
2016	PARADIGM	All comers population; Excellent clinical results		Eurointervention, LINC
2017	CASANA	Large surgical center, Clinical results over conventional stents historical data		Eur J Endovasc Surg
2017	WISSGOTT	Clinical & mechanical assessment; Mechanical advantages vs competitive stents	<b>CGuard demonstrates best performance in field</b>	J Endovasc Ther
2017	IRON-GUARD 1	Real world multicentric 30d results; Excellent clinical results in multicentric		Eurointervention
2018	WISSGOTT 10MM	"One-Size-Fit-All" (OSFA); 10 mm CGuard OSFA demonstrates safety and efficacy		J Endovasc Ther
2019	IRON-GUARD 1	Real world multicentric 1y results; Excellent long-term results in multicentric		Eurointervention
2020	IRON-GUARD 2	Large real world multicentric; Large Multicentric Best-In-Class clinical results	<b>CGuard demonstrates superiority to other stents</b>	Cardiovasc Interv
2021	CGuard-TCAS	CGuard Trans-Cervical excellent results		Adv Interv Cardiol
2021	IRON-GUARD 2	12-month 733 pts clinical results		JACC
2021	Randomized Control Trial	Randomized Trial; CGuard demonstrates Neuroprotection vs Conventional stents		JACC, LINC
2021	ONE SIZE-FIT-ALL	CGuard 150 pts 12m-FU		CIRSE
2021	Greek Registry	CGuard in Real live at 30d		J Endovasc Ther
2021	Meta-Analysis	CGuard superior to Other Stents at 1y-FU		J Clin Med
2021-24	PARADIGM Extend	CGuard in all-comers 550 pts 30d / 5y FU		LINC, DEKRA PMCF
2021	Meta-Analysis	CGuard superior to CEA at 1y-FU	<b>CGuard demonstrates superiority to surgery</b>	Writing
2021	OCTOPVS	OCT comparison CGuard vs CEA; CGuard superior post-intervention OCT than CEA		Writing
2022	OPTIMA	IVUS assessment after CGuard: Anticipated Plaque exclusion detnonstrated		Writing
2022	FLOW-GUARD	Use of CGuard as flow diverter in very high-risk patients beyond carotids; Potential new CGuard indications		Writing



# Clinical Support Highlights / Call out

2015-2022



## CARENET Trial

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

### **Reduction of embolization**

*(50% less 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.**

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



## Randomized Control Trial

Randomized Trial; CGuard  
vs. Conventional Stent  
(Acculink);

**CGuard superiority in  
Randomized study format**

Confirms CARNET results with  
statistical significance

CGuard™ EPS (9) clinical trials completed with >1,850 patients followed

# U.S. Market and Regulatory Pathway

## FDA Trial Performance Goal – 11.6% v Real World Performance 1.32% (w/ 1 Yr)

\$809M\*

### U.S. Market Opportunity\*

Size: 155K High Grade Carotid Artery Stenosis (HGCS) interventions estimated in 2023

Opportunity: The addressable market is estimated to be approximately **\$809 million**

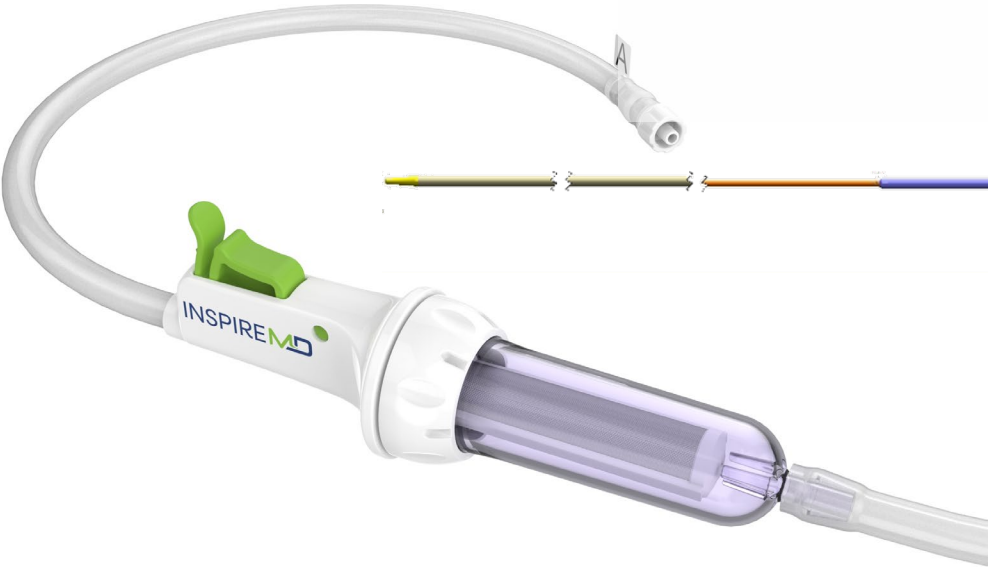
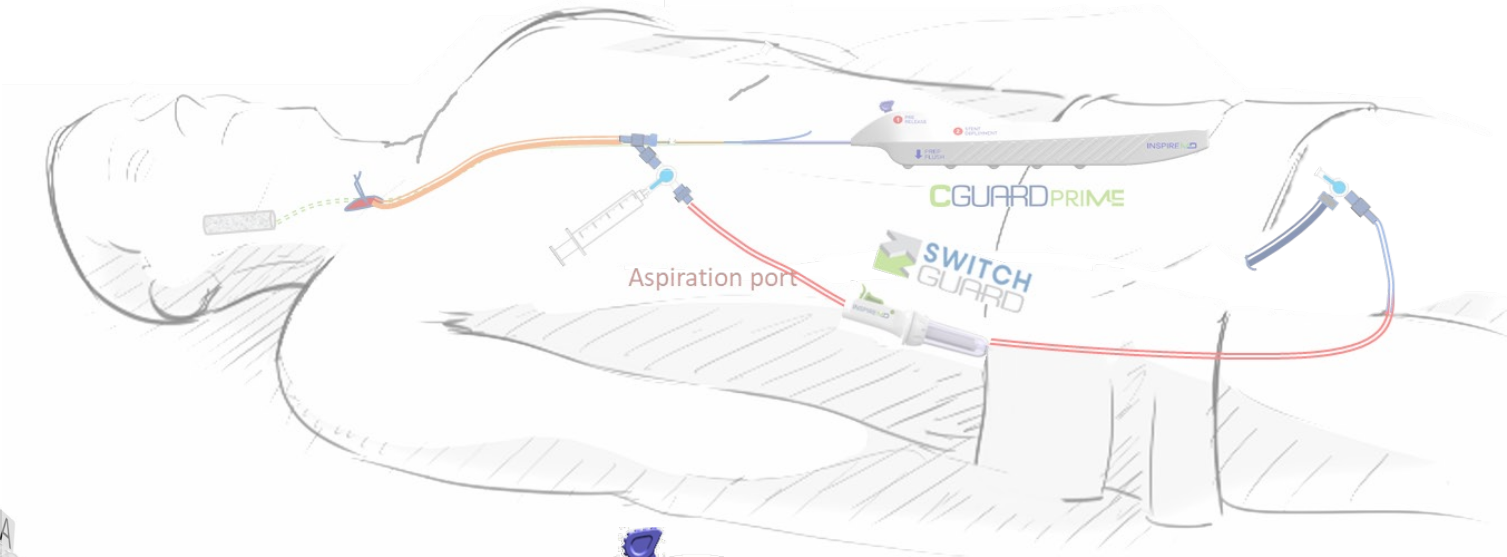
- **Pivotal study objective** evaluate the safety and efficacy of the CGuard™ Carotid Stent System in the treatment of carotid artery stenosis.
  - **Primary Endpoint: Symptomatic and asymptomatic** patients undergoing carotid artery stenting (CAS) . The performance goal will be considered met if the upper bound of the two-sided 95% confidence interval calculated from the observed primary endpoint rate is < 11.6% and the p-value is less than 0.025. The **11.6% performance goal** is developed from published CAS literature\*\*. The primary end point consists of 30 Day DSMI + 31-365 days Ipsilateral Stroke.
  - **Intent to Treat Protocol**
  - Real World CGuard data of **1,485 patients** followed for one year - **1.32%\*\*\***
- **Chris Metzger, M.D.** (Ballad Health) named as Primary Investigator
- **315 Patients – Enrollment anticipated end of Q1 '23**
- **25 Centers** (20 in the United States and 5 in Europe)
- **HCC (Health Care Consultants)** CRO specializing in Carotid trial execution
- **Christina Brennan, M.D.** and **Gary Roubin, M.D.** : Supporting advisory experts

\*\* The primary endpoint of the study 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 committee (CEC) adjudication or ipsilateral stroke from 31-365day follow-up, based on Clinical Events Committee (CEC) adjudication.

\*\*\* 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

# SwitchGuard and CGuard Prime

TCAR Delivery System will Facilitate Accelerating Conversion from Surgery to Stenting



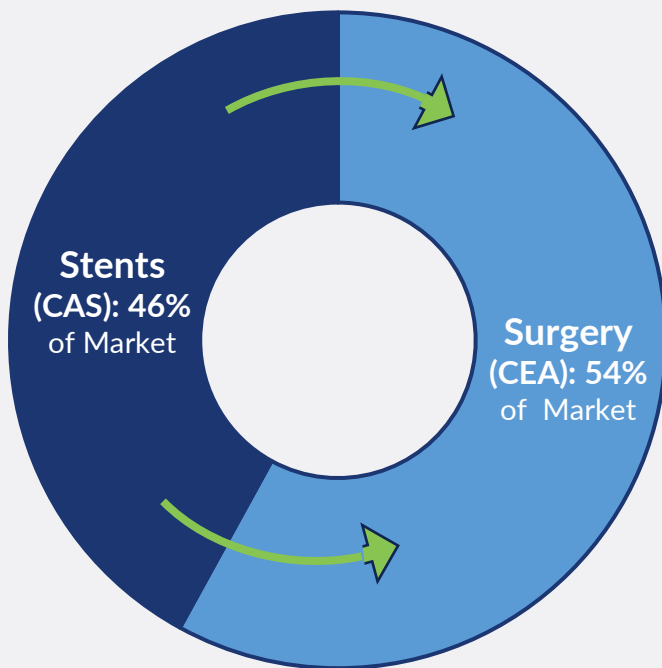
CGUARDPRIME 80

# Market Opportunity

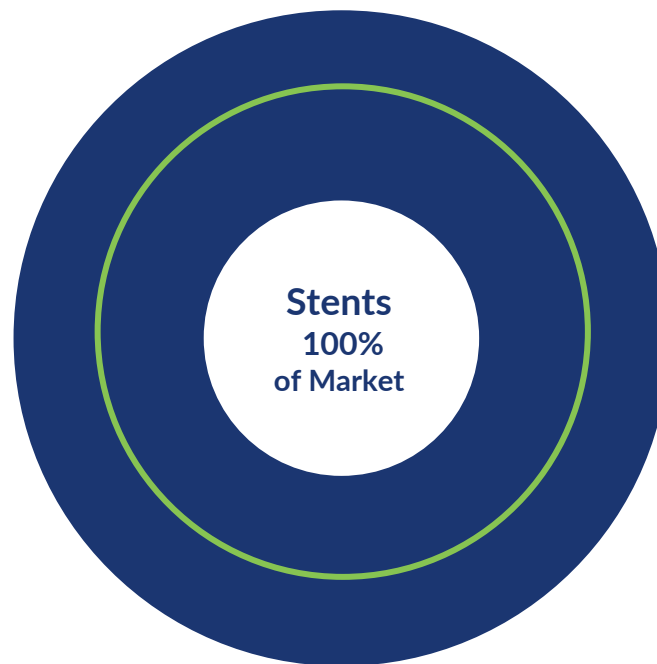
# Potential Multi Billion Dollar Market Opportunity

Our MicroNet™ covered stents like CGuard™ could become the new gold standard

WW carotid procedures today are primarily surgical



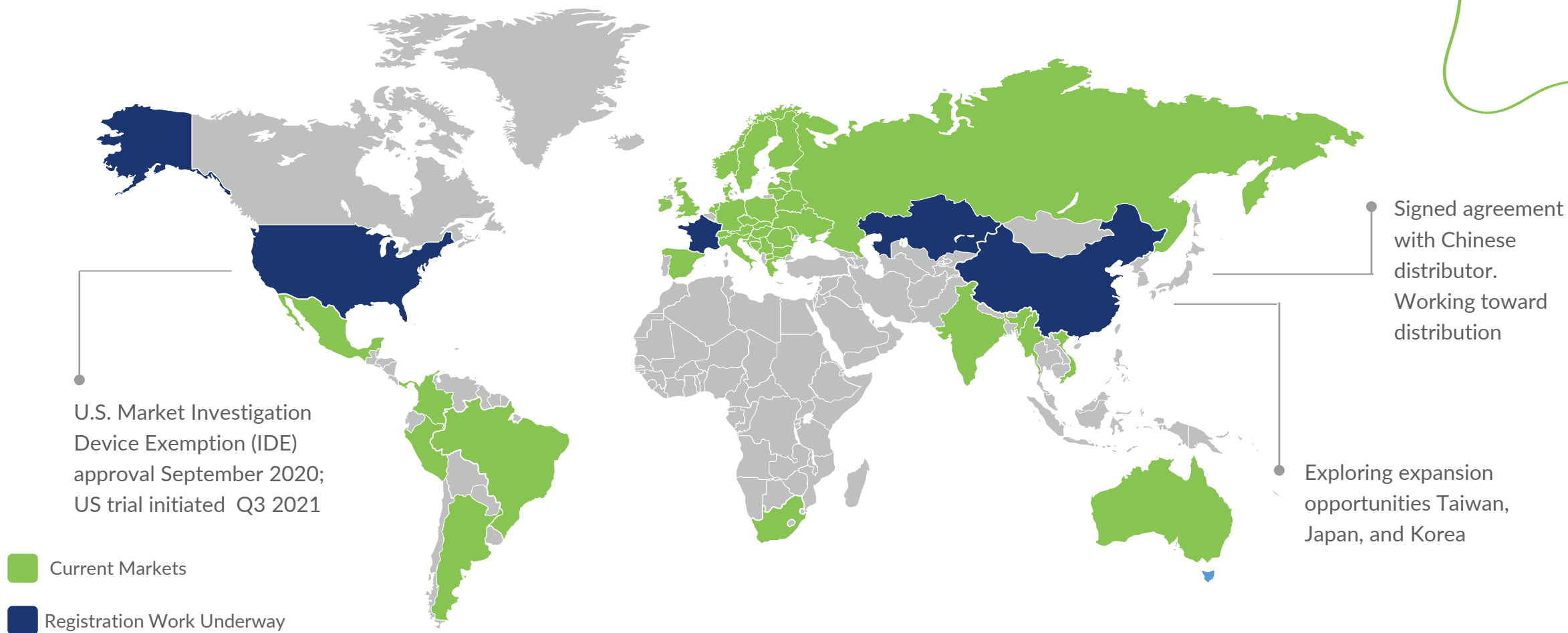
Carotid procedures tomorrow could be mostly minimally invasive with CGuard™



- ◆ **Current Treated Global Market:**  
→ **\$1.3 billion** <sup>(1)</sup>  
407K Global procedures treated for HGCS (High Grade Carotid Stenosis – Dx and Treated with CEA/CAS)
- ◆ **Current Treated U.S. Market:**  
→ **\$809 million**  
155K procedures treated for HGCS (High Grade Carotid Stenosis – Dx and Treated with CEA/CAS)
- ◆ **Current Untreated Global Market:**  
→ **\$8 billion**  
~2.8 million people diagnosed with HGCS (Untreated)
- ◆ **Standard Risk Reimbursement (US) increases CAS potential:**

1. 2021 Health Research International Market Report; internal estimates

# Commercial Footprint



- Active selling in more than 30 countries
- Over 90% of sales are through channel partners/distributors with move to direct



# Corporate

# Our Robust Intellectual Property Portfolio

Proprietary platform technology supported by IP

Patent Rights	Issued	Pending
USA	16	6
Rest of World	42	11

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

IP Counsel: Kligler and Associates, P.A.

# 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.





NASDAQ = NSPR