



# Sustained Embolic Protection



INSPIREMD

# Disclaimers

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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.

# 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



## 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)  
Over **40,000** stents sold to date



## CMS Consideration of Standard Risk Reimbursement

Decision, Expected 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 **Q1 2025**

\*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

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

# Transformational May 2023 Financing Up To \$113.6 Million

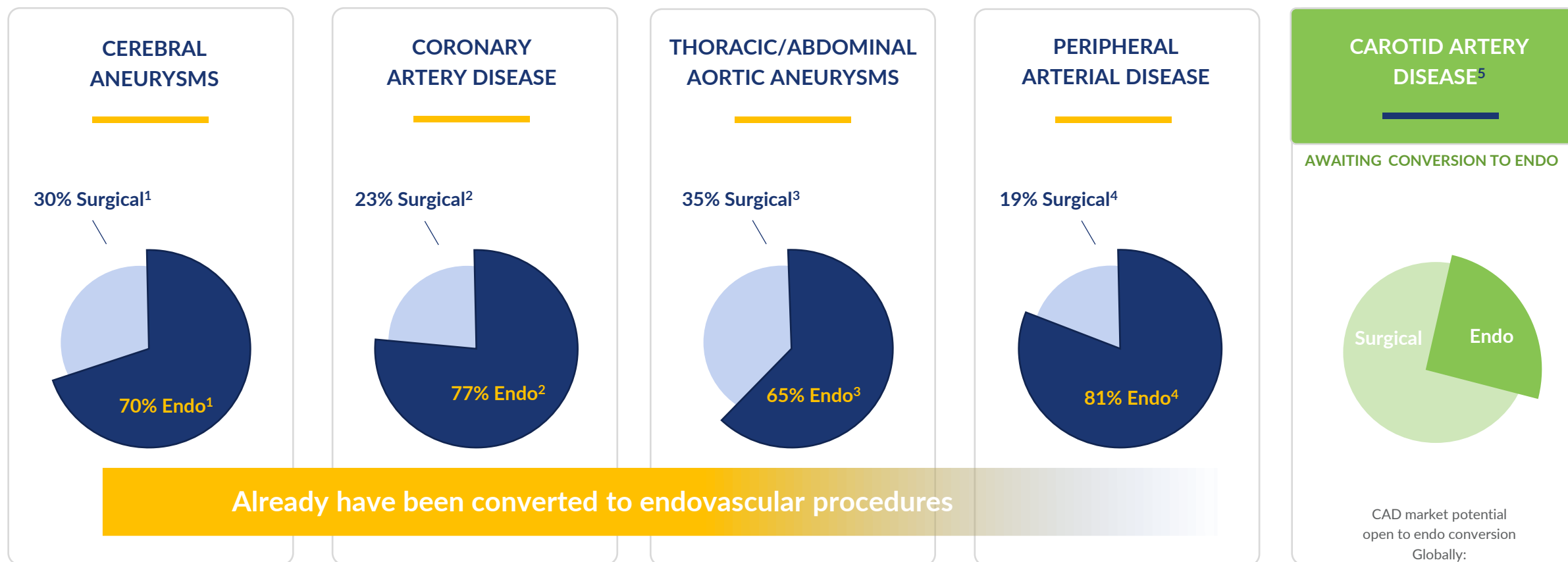
To advance the company towards potential US approval and launch of CGuard EPS and other value-creating milestones

- \$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



# 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



# Approaches to Treating Carotid Artery Disease

155,000 Procedures Annually

## Surgical Approach

Carotid Endarterectomy (CEA) (70%)

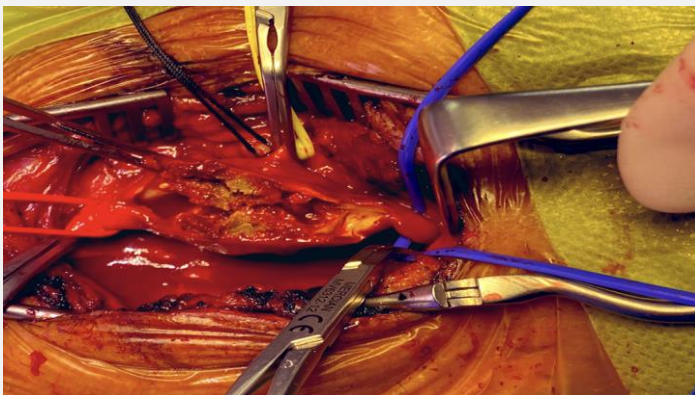
TCAR (10%)

### Risk of complications:

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

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

Aesthetic concern



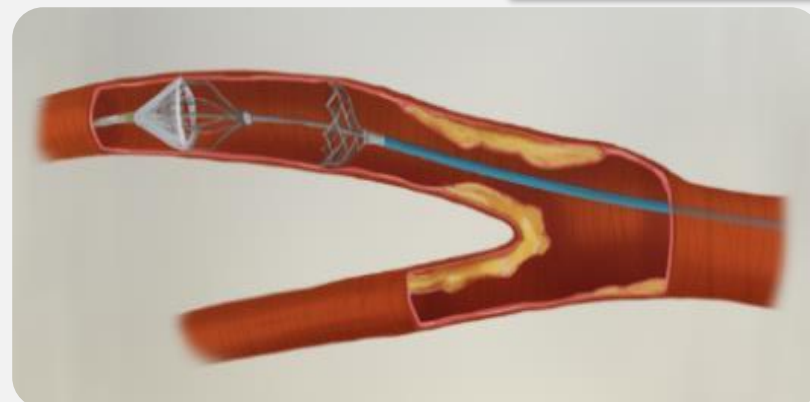
## Carotid Artery Stenting (CAS)

(20%)

Conventional Approach (Bare Stent)

### Risk of complications:

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

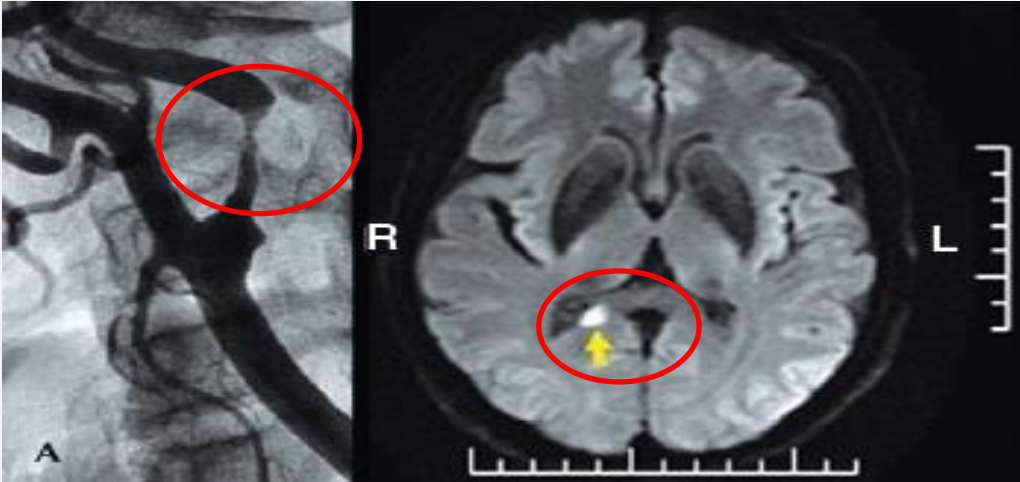


<sup>1</sup> Based on the CREST clinical trial data, in which only conventional carotid stents were used vs. surgery, CREST Trial: N Engl J Med 2010;363:11-23

# THE PROBLEM: Risk of Embolism Following Conventional Carotid Stenting (1<sup>st</sup> Generation Stents)

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

## Pre-Procedure

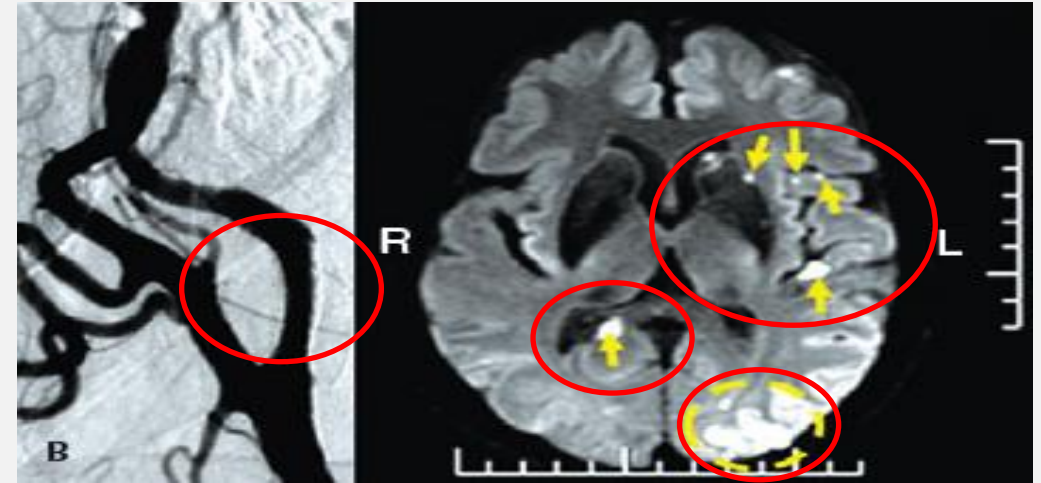


90% occlusion of the carotid artery

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

## Post-Procedure

with Conventional Stent



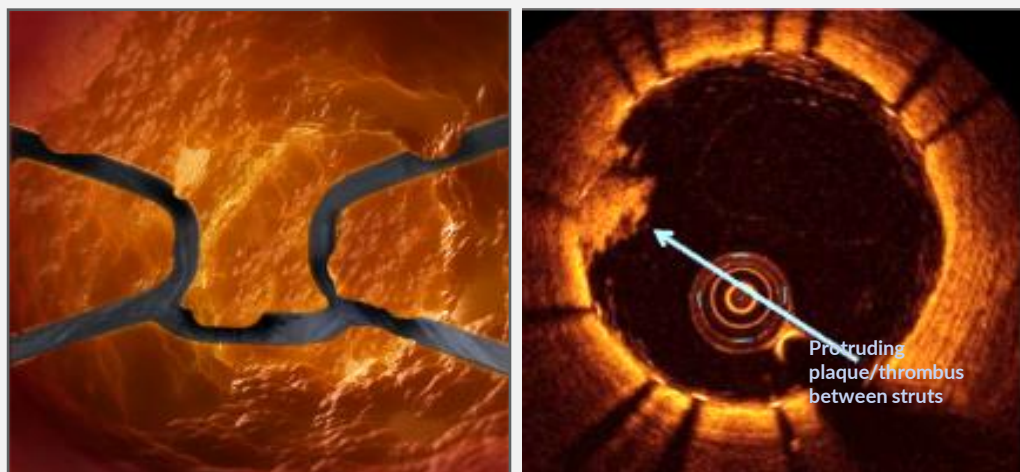
Successful opening of the carotid artery

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

MRI reveals post-procedural cerebral embolization

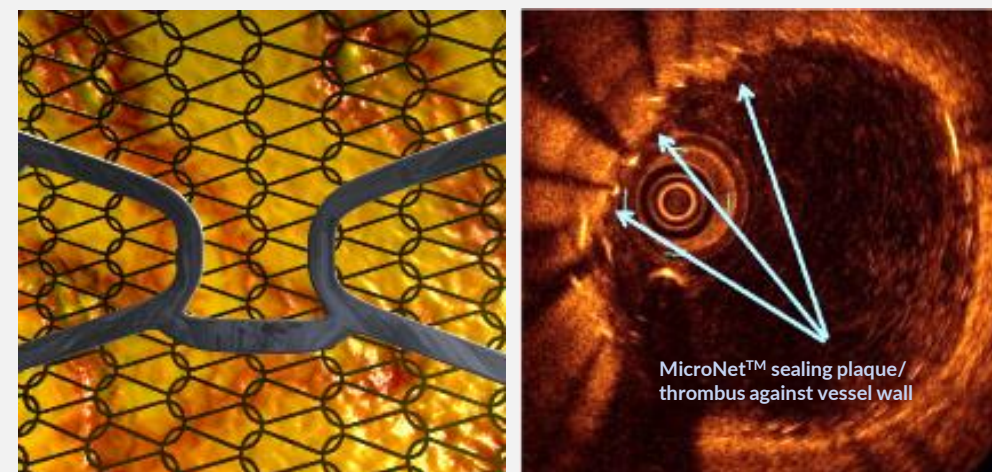
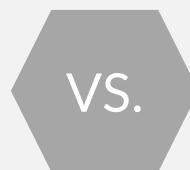
# OUR SOLUTION: Proprietary MicroNet™ Technology<sup>1</sup>

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



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

Stents are covered in MicroNet

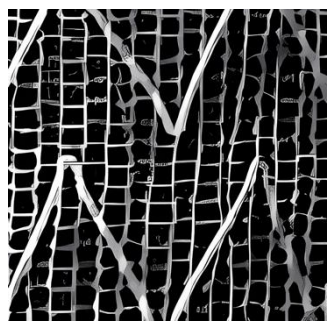
## An Embolic Prevention System (EPS) for Ultimate Thrombus Protection

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

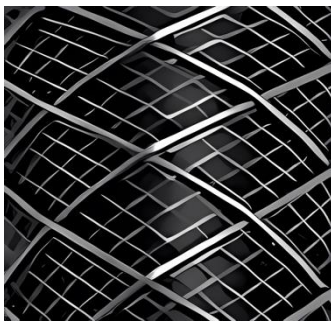
<sup>1</sup>Tomoyuki Umemoto, MD. Optical coherence tomography assessment of new generation mesh-covered stents after carotid stenting. Eurointerventional 2017;1348-1355 (published online)  
Image: Prof. Valdés Chávarri



# Pore Sizes Diameters



CGUARD™



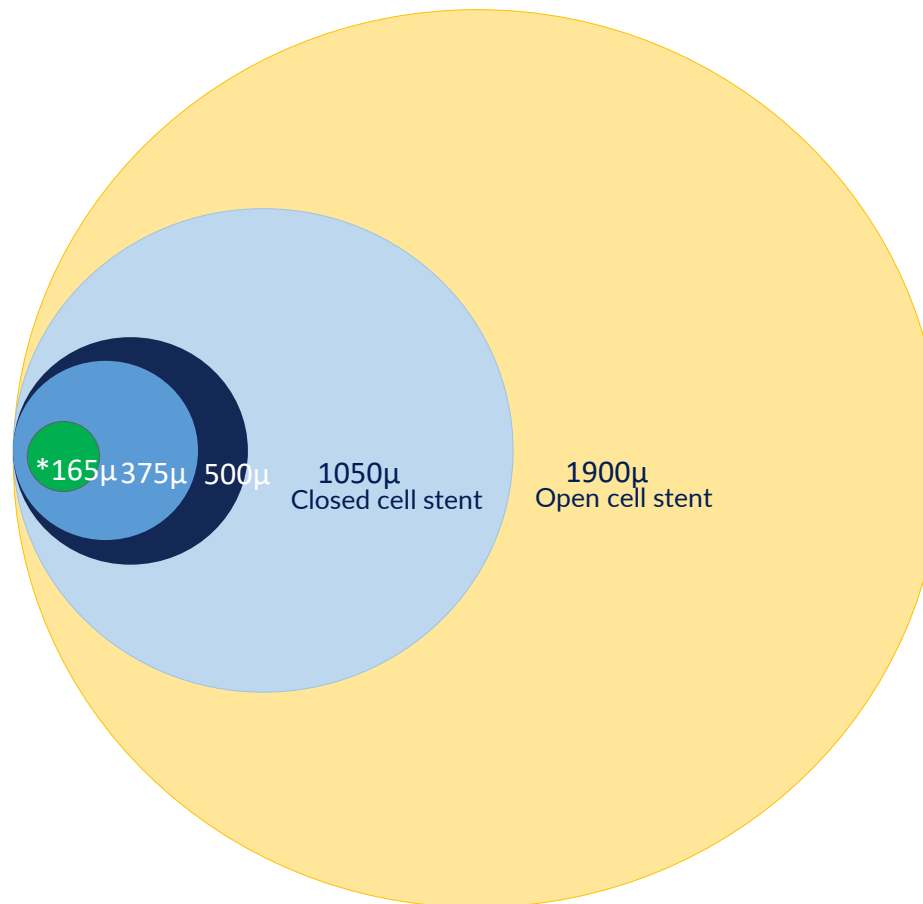
CASPER®



ACCULINK™

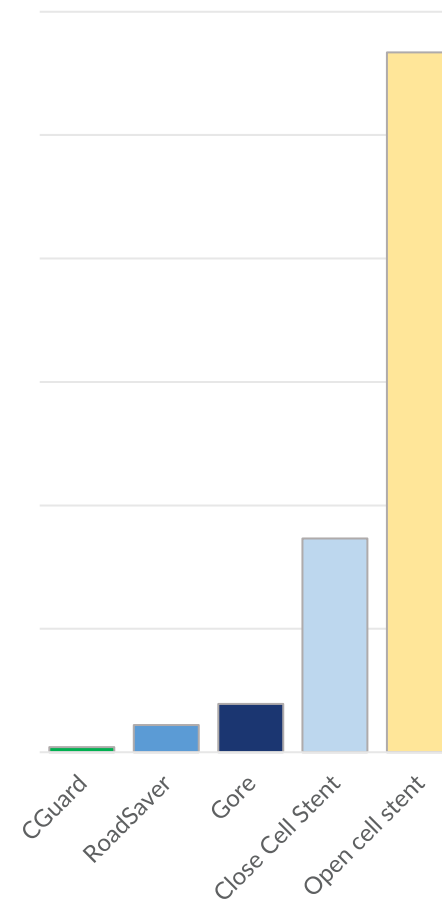


WallStent™



\* Average in lesion at expanded state

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

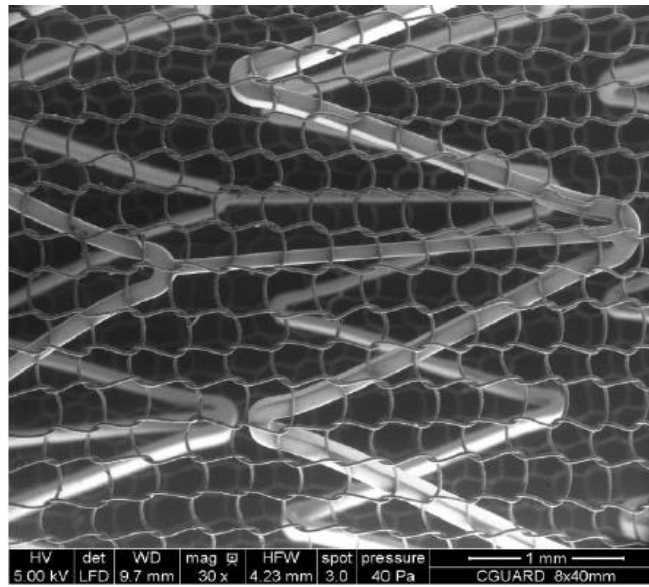
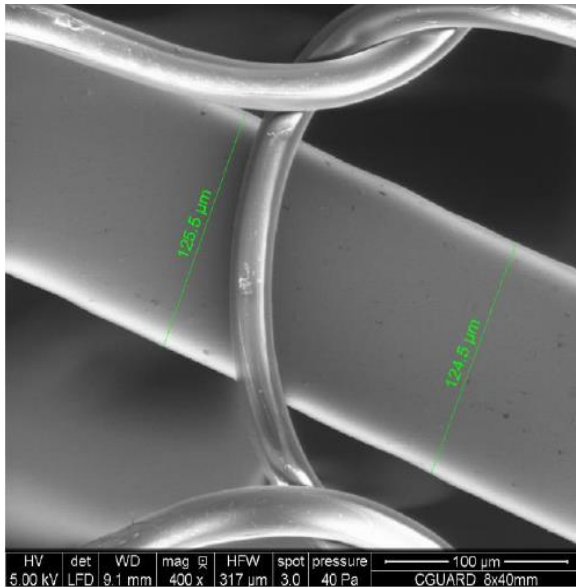


\* Bench test results may not necessarily be indicative of clinical performance.  
Stent images approximately at scale but not exact

**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

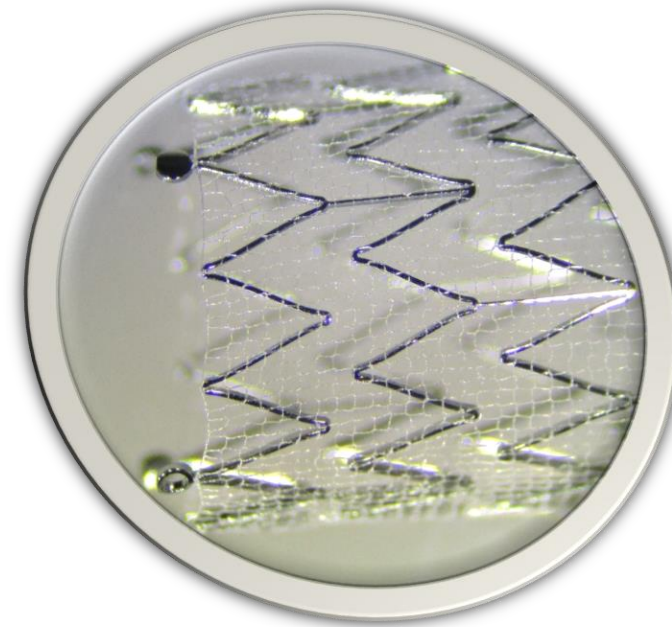
The only stent platform available with our patented MicroNet mesh technology



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.,



AT120D/NF V94

ZOOM X1.0

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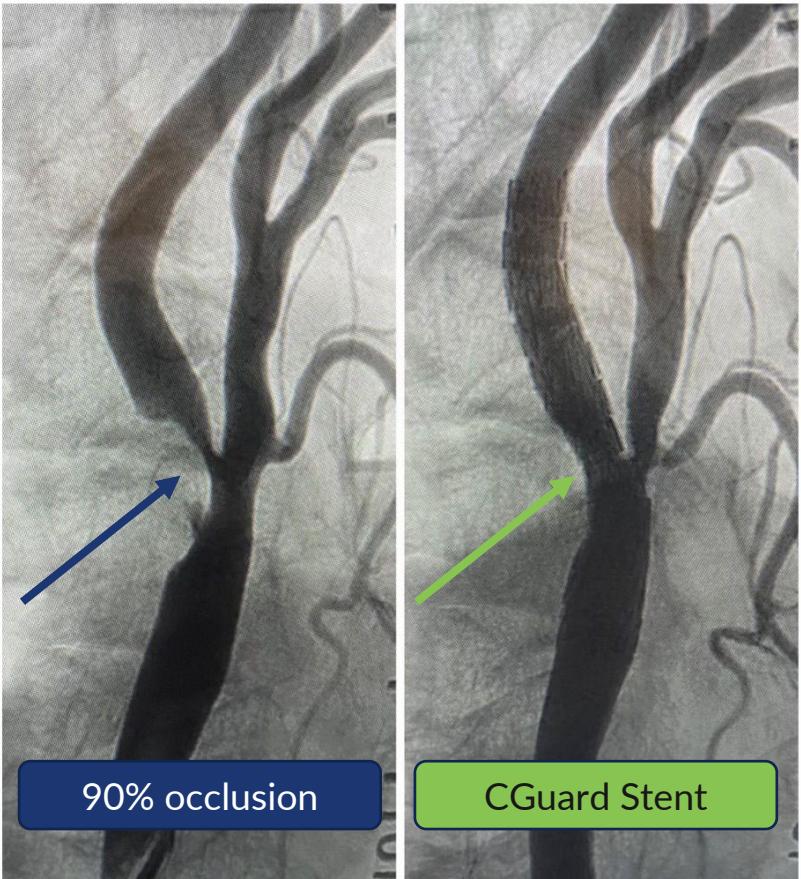
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ZOOM X1.0  
BRT 6

ZOOM X1.0  
BRT 6



# A picture is worth a thousand words ...

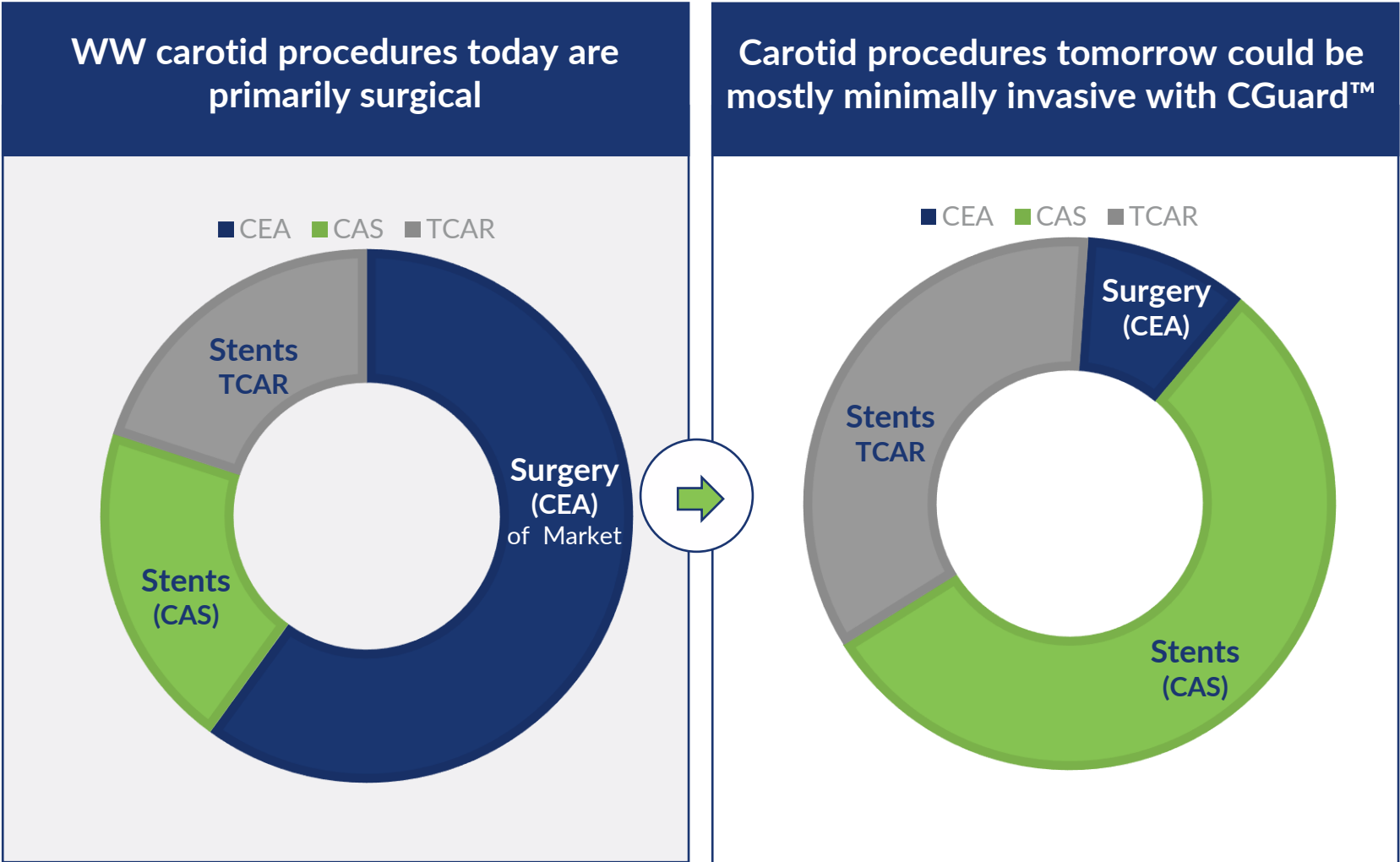






# Potential Multi Billion Dollar Market Opportunity

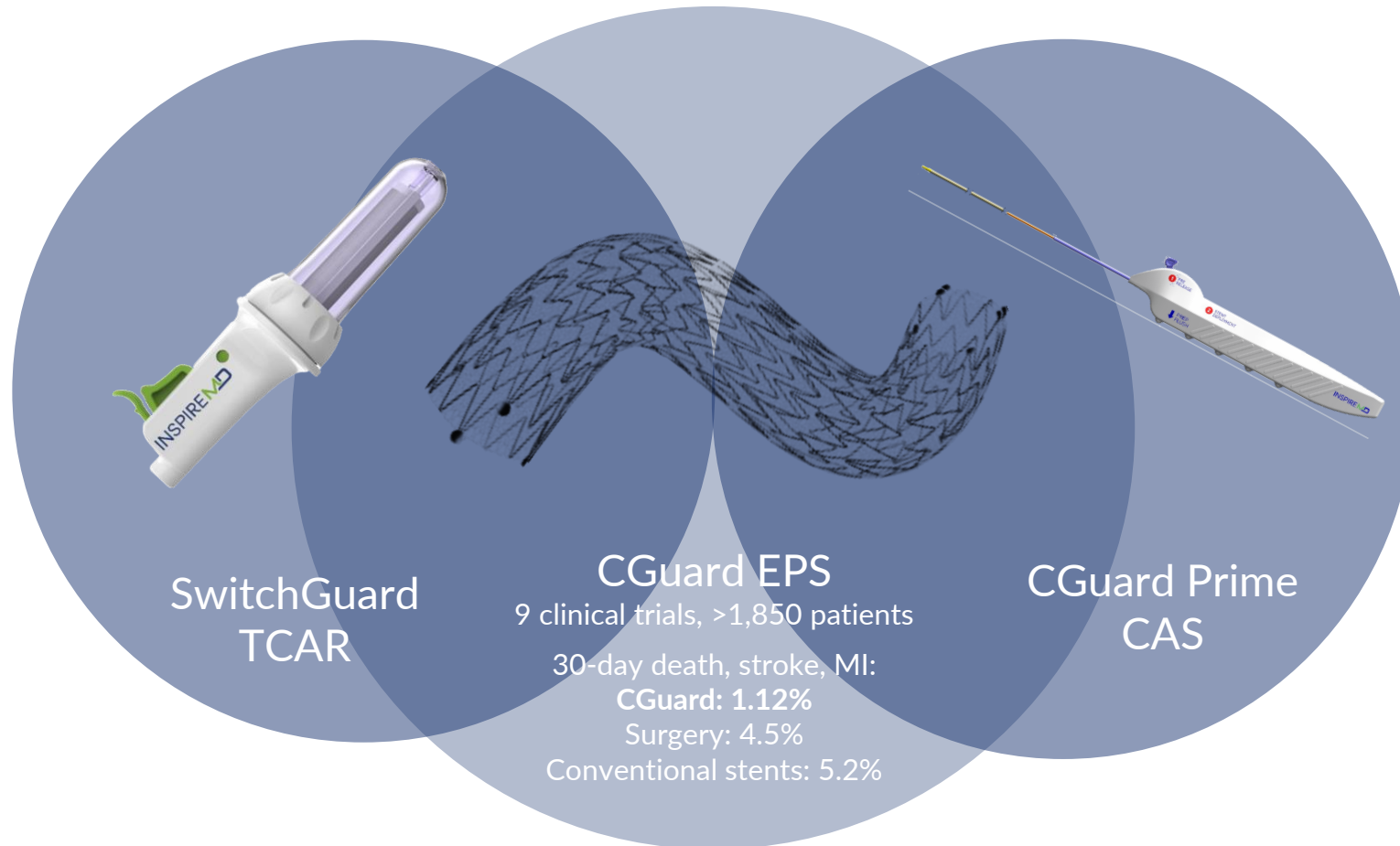
MicroNet™ covered CGuard™ stent platform could become the new gold standard



- ◆ **Current Treated Global Market:**  
→ **\$1.3 billion** <sup>(1)</sup>  
407K Global procedures (CEA/CAS/TCAR) to treat HGCS
- ◆ **Current Treated U.S. Market:**  
→ **\$809 million** <sup>(1)</sup>  
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**

## Long-Term Stent Performance is the Cornerstone of Our Focus, Regardless of Delivery Platform

CGuard EPS with its novel MicroNet mesh covering is a best-in-class implant that has demonstrated superior patient outcomes compared to both surgery and first-generation stents

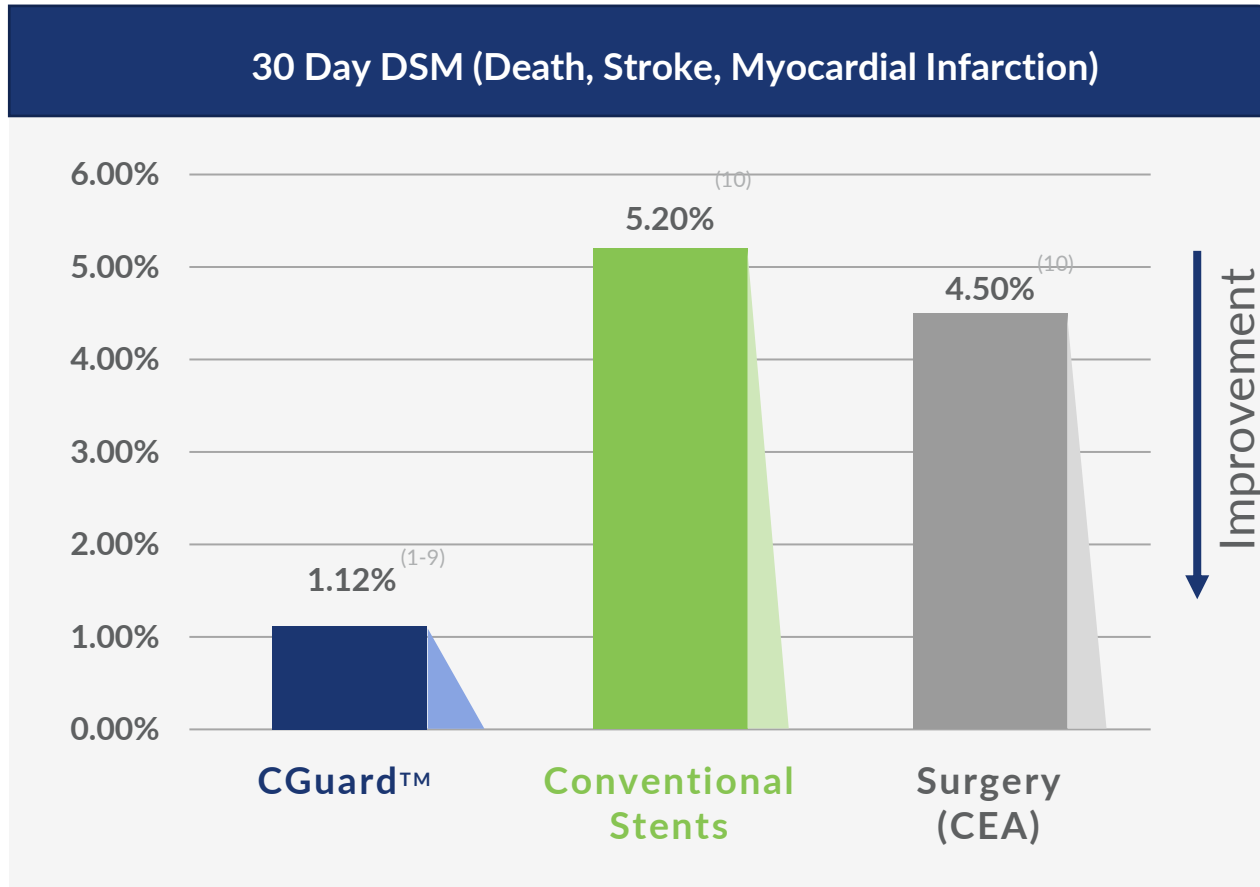


- ✓ Well position to capitalized on the ongoing **paradigm shift** toward a “**stent first**” approach and away from surgery
- ✓ **Agnostic to stent delivery platform** (TCAR vs. CAS)
- ✓ 155k procedures to treat high-grade carotid stenosis = **>\$800 million U.S. market** today
- ✓ Potential standard risk reimbursement **increases CAS potential**

# 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. Tigkopoulos J Endovasc Therapy Volume 28 Issue 4, Aug 2021 10. CREST N Engl J of Med 2010 July 1. 11-23.



Carotid Solution: Our Well Studied Mesh-Covered Technology

More than 1,850 patients in Clinical Publications & Studies

A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent The CGuard CARENet Trial (Carotid Embolic Protection Using MicroNet)

CLINICAL RESEARCH Thirty-day results from prospective multi-center evaluation of carotid artery stenting using the CGuard MicroNet-covered Embolic Protection System in real-world multicenter 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

CLINICAL RESEARCH Novel PARADIGM in carotid revascularisation: Prospective evaluation of All-corer perCutaneous aroTid revascularisation in symptomatic and Increased-risk asymptomatic carotid artery stenosis using CGuard™ MicroNet-covered embolic prevention stent system

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





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 Guard in Patients Undergoing Carotid Artery Stenting: Early Experience From a Single Center

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

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

# 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% 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

CGuard™ EPS: Nine clinical trials completed with >1,850 patients followed

# CARMEN Meta-Analysis (112 Studies, 68K Patients)<sup>(1)</sup>

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

- 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)

	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

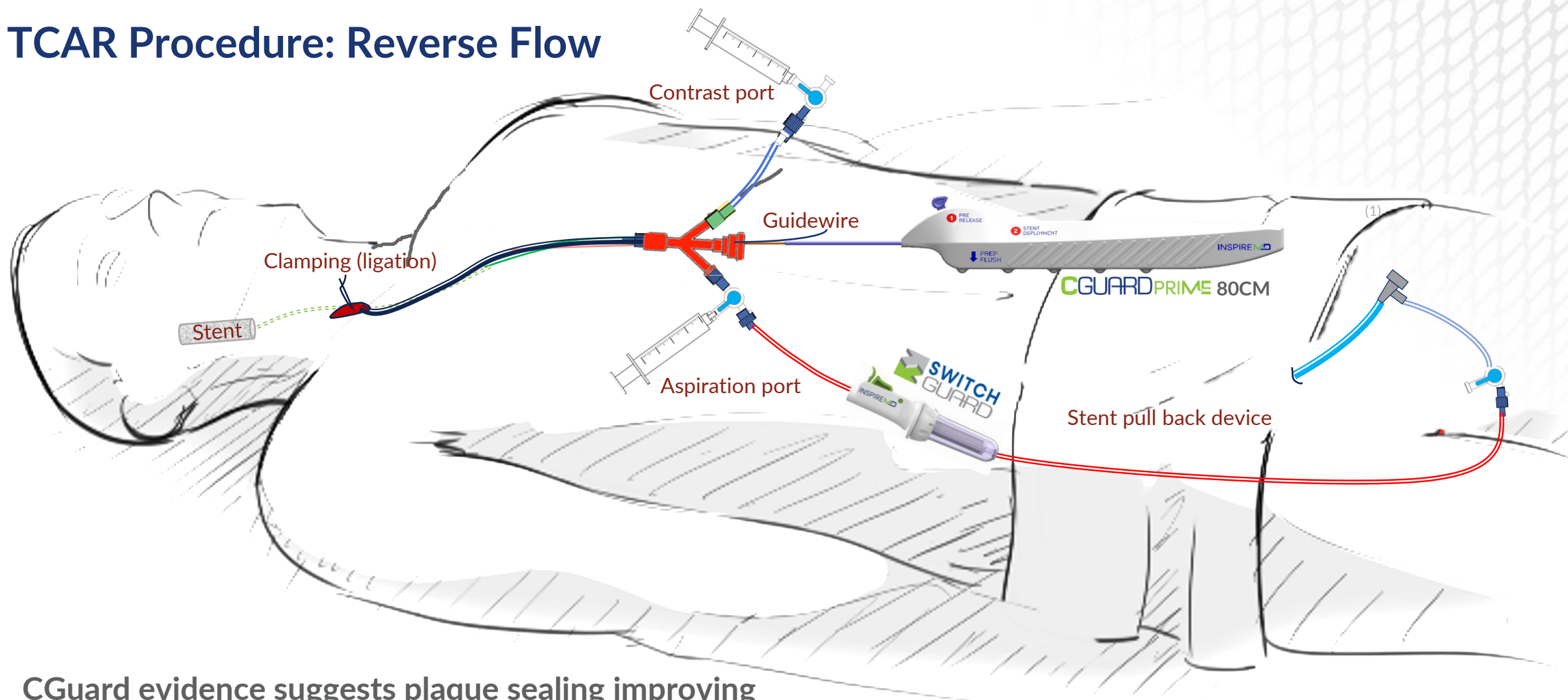
## FDA Trial Performance Goal – 11.6% vs European Clinical Trials' Mean Performance 1.32% (w/ 1 Yr)

- **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) : Primary Investigator
- **315 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

TCAR

## TCAR Procedure: Reverse Flow



- CGuard evidence suggests plaque sealing improving TCAR outcomes in symptomatic patients <sup>(1)</sup>

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



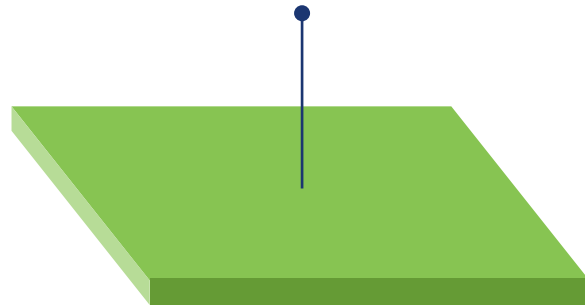
# Roadmap + Milestones



# Our Advancement Roadmap / Milestones

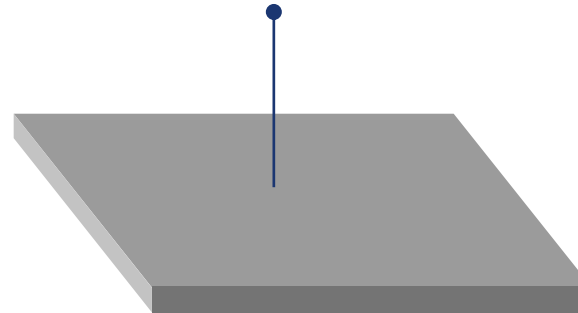
## Our Expected Key Value Drivers and Strategic Pathways

- ✓ **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**
- **CGuard Prime Commercial Launch (EU)**



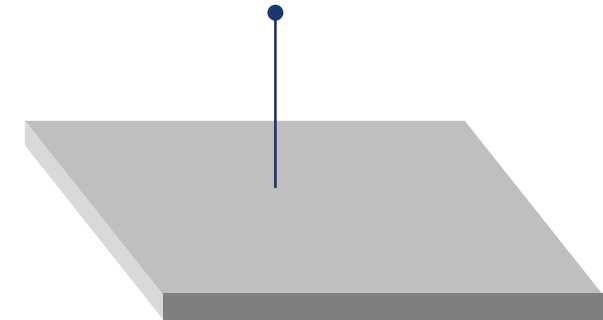
2023

- **FDA PMA Submission**
- **Acute Stroke (NGuard)** Pivotal
- **China Regulatory Submission**
- **NCD Reimbursement Decision**
- **SwitchGuard Clinical Submission**

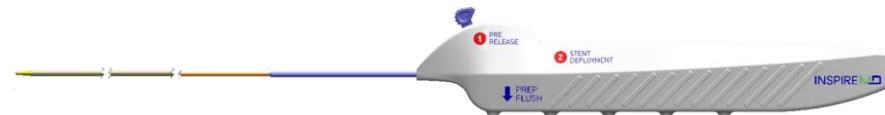


2024

- **FDA PMA Approval**
- **SwitchGuard (TCAR)** Launch (U.S. + EU)
- **U.S. Commercial Launch**
- **China 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.



# 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

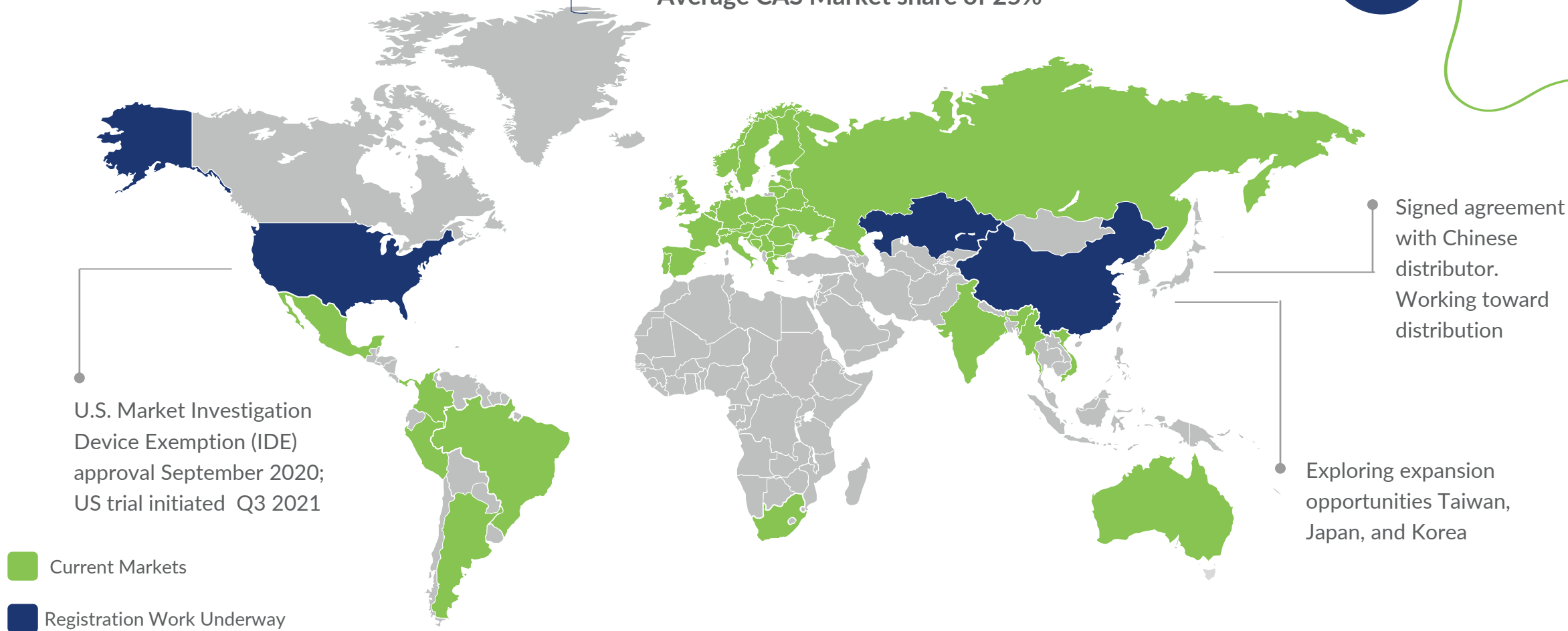


**Sean Lyden, M.D.**  
Vascular Surgeon



# Commercial Footprint

- Active selling in more than 30 countries
- Over 40,000 systems sold
- Average CAS Market share of 25%





# 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.

# Summary Financials

August 7, 2023

## NASDAQ Capital Markets

NSPR

Stock Price	\$3.10
Average 3 Month Volume	136.3K
Shares Outstanding	21.1M
Shares Outstanding with Prefunded Warrants	36.8M
Market Capitalization with Prefunded Warrants	\$113.9M
Cash Balance - June 30, 2023*	\$47.0M
Debt	\$0M

\* Includes ~\$37.5 million, net, of upfront proceeds from May 2023 private placement



NASDAQ = NSPR