UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT PURSUANT
TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): **June 23, 2025**

InspireMD, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-35731	**26-2123838**
(Commission File Number)	(IRS Employer Identification No.)
4 Menorat Hamaor St. Tel Aviv, Israel	**6744832**
(Address of Principal Executive Offices)	(Zip Code)

(888) 776-6804
(Registrant's Telephone Number, Including Area Code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	NSPR	The Nasdaq Capital Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On June 24, 2025, InspireMD, Inc. (the "Company") issued a press release titled "InspireMD Announces FDA PMA Approval for CGuard Prime Carotid Stent System for the Prevention of Stroke". A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference in this Item 7.01. Additionally, on June 24, 2025, the Company made available an updated investor presentation. A copy of the presentation is attached hereto as Exhibit 99.2 and incorporated by reference in this Item 7.01. A copy of the presentation is also available on the Company's website https://www.inspiremd.com/en/investors/investor-relations/.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K that is furnished pursuant to this Item 7.01, including Exhibit 99.1 and Exhibit 99.2, shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

As previously disclosed on September 16, 2024, the Company submitted a premarket approval ("PMA") application for its the CGuard Prime carotid stent system to the U.S. Food and Drug Administration (the "FDA"). On June 23, 2025, the Company received PMA approval of the CGuard Prime Carotid Stent System in the United States from the FDA.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release, dated June 24, 2025
99.2	Investor Presentation June 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INSPIREMD, INC.

Date: June 24, 2025

By: */s/ Marvin Slosman*
Name: Marvin Slosman
Title: Chief Executive Officer

Exhibit 99.1

InspireMD Announces FDA Approval for CGuard® Prime Carotid Stent System for the Prevention of Stroke

Miami, Florida — June 24, 2025 (GLOBE NEWSWIRE) – InspireMD, Inc. (the "Company") (Nasdaq: NSPR), developer of the CGuard Prime Carotid Stent System for the prevention of stroke, today announced that the U.S. Food and Drug Administration (FDA) has granted premarket application (PMA) approval of the CGuard Prime Carotid Stent System in the United States.

The PMA approval is backed by best-in-class evidence from the Company's C-GUARDIANS pivotal trial, first presented at the Leipzig Interventional Course (LINC) in May 2024. The study, which enrolled 316 patients across 24 sites in the United States and Europe, evaluated the safety and efficacy of CGuard Prime for treating carotid artery stenosis. CGuard Prime demonstrated the lowest 30-day (0.95%) and 1-year (1.93%) primary endpoint major adverse event rates of any pivotal study of carotid intervention.

"The C-GUARDIANS clinical trial provides strong scientific evidence to support the neuro-protective benefits of the next generation MicroNet™ mesh technology of the CGuard Prime Carotid Stent System and results are consistent with the large body of evidence from outside of the United States with this device", said Dr. D. Chris Metzger, System Vascular Chief at OhioHealth. "As U.S. Primary Investigator for this pivotal IDE trial, I am proud of the scientific rigor and integrity of the data, which demonstrates the lowest event rates (stroke, death and MI to 30 days and ipsilateral stroke at 1 year) ever reported in any trial of carotid revascularization. These excellent results were in patients who were at high risk for carotid endarterectomy, a quarter of whom were symptomatic. CGuard Prime now offers an important frontline, proven technology for treatment of United States patients with obstructive carotid artery disease, and continued benefits to patients worldwide."

"I am proud to announce the PMA approval of CGuard Prime, our best-in-class carotid stent system. This is a pivotal milestone for the Company after many years of commitment to bringing this innovative stent platform to patients in the United States," said Marvin Slosman, Chief Executive Officer of InspireMD. "The significance of CGuard Prime to the shift toward less invasive carotid artery revascularization is tremendous. Our approval marks a true breakthrough in the treatment of carotid disease. Our innovation is built around the protective MicroNet mesh barrier providing durable protection and preventing post procedural events, a unique and next generation advancement in the carotid field. With over 65,000 implants sold to date and studies in over 2,000 patients, CGuard Prime offers an established and tested advancement to patient care. We are grateful to the many who have contributed to this approval, including all of our trial investigators and investors. We look forward to making this technology available to all who can benefit with an immediate and aggressive U.S. launch."

The Company's announcement of FDA approval of the CGuard Prime Carotid Stent System triggers the second of four milestone-driven warrant tranches pursuant to the private placement financing of up to $113.6 million announced in May 2023. Gross proceeds from this warrant tranche are expected to be $17.9M if exercised in full. Proceeds, if any, will be used to support the imminent commercial launch of the CGuard Prime Carotid Stent System in the United States, initiating new regulatory pathways for advanced applications of our CGuard stent platform, and developing new products, while at the same time continuing to develop our business outside of the United States. Warrant holders include Marshall Wace, OrbiMed, Rosalind, Nantahala, Soleus, Velan, and certain InspireMD Board members.

About CGuard Prime

The CGuard Prime Carotid Stent System is a novel mesh-covered carotid stent designed to improve patient safety through sustained embolic protection. CGuard Prime combines the largest open-cell frame of available carotid stents with the smallest mesh pore size, preventing plaque protrusion through the stent, for lasting embolic protection demonstrated beyond five years.

About C-GUARDIANS

The C-GUARDIANS clinical trial evaluated the safety and efficacy of the CGuard Carotid Stent System for the treatment of carotid artery stenosis. The study enrolled 316 patients across 24 trial sites in the United States and Europe.

The trial included both symptomatic and asymptomatic patients undergoing carotid artery stenting (CAS). The primary endpoint includes the composite of the following: incidence of the following major adverse events: death (all- cause mortality), all stroke, or myocardial infarction (DSMI) through 30-days post-index procedure, based on the Clinical Events Committee (CEC) adjudication or ipsilateral stroke from 31-365-day follow-up, based on CEC adjudication. The performance goal was considered to have been 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 <0.025.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MicroNet mesh technology to make its products the industry standard for carotid stenting by providing outstanding acute results and durable, stroke-free long-term outcomes. InspireMD's common stock is quoted on Nasdaq under the ticker symbol NSPR. We routinely post information that may be important to investors on our website. For more information, please visit www.inspiremd.com.

Forward Looking Statements

This press release contains "forward-looking statements." Forward-looking statements include, but are not limited to, statements regarding InspireMD or its management team's expectations, hopes, beliefs, intentions or strategies regarding future events, future financial performance, strategies, expectations, competitive environment and regulation, including potential U.S. commercial launch and expectations regarding the exercise of any warrants. Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential", "scheduled" or similar words. 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 our history of recurring losses and negative cash flows from operating activities; substantial doubt about our ability to continue as a going concern; significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives; our need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute out stockholders' ownership interests; market acceptance of our products; an inability to secure and maintain regulatory approvals for the sale of our products; negative clinical trial results or lengthy product delays in key markets; our ability to maintain compliance with the Nasdaq listing standards; our ability to generate revenues from our products and obtain and maintain regulatory approvals for our products; our ability to adequately protect our intellectual property; our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and to increase production as necessary; the risk that the data collected from our current and planned clinical trials may not be sufficient to demonstrate that our technology is an attractive alternative to other procedures and products; intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do; entry of new competitors and products and potential technological obsolescence of our products; inability to carry out research, development and commercialization plans; loss of a key customer or supplier; technical problems with our research and products and potential product liability claims; product malfunctions; price increases for supplies and components; insufficient or inadequate reimbursement by governmental and other third-party payers for our products; our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful; adverse federal, state and local government regulation, in the United States, Europe or Israel and other foreign jurisdictions; 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; the escalation of hostilities in Israel, which could impair our ability to manufacture our products; and current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk. 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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Exhibit 99.2

INSPIREMD

Nasdaq: NSPR

Disclaimers

Forward Looking Statement

This presentation contains "forward-looking statements." Such statements may be preceded by the words "intends," "may," "will," "pl "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. For example, the Company is using forwar discusses the potential commercialization and market opportunities for its products and product candidates, its cash runway, and its Company events. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are unknown risks and uncertainties, many of which are beyond the Company's control, and cannot be predicted or quantified and conse materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitatio associated with (i) market acceptance of our existing and new products, (ii) negative clinical trial results or lengthy product delays in secure regulatory approvals for the sale of our products, (iv) intense competition in the medical device industry from much larger, mu liability claims, (vi) product malfunctions, (vii) our limited manufacturing capabilities and reliance on subcontractors for assistance, (vi reimbursement by governmental and other third party payors for our products, (ix) our efforts to successfully obtain and maintain inte covering our products, which may not be successful, (x) legislative or regulatory reform of the healthcare system in both the U.S. and reliance on single suppliers for certain product components, (xii) the fact that we will need to raise additional capital to meet our busi and that such capital raising may be costly, dilutive or difficult to obtain and (xiii) the fact that we conduct business in multiple foreign foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign instability in each jurisdiction. More detailed information about the Company and the risk factors that may affect the realization of forw forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 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.se 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 securitie in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such sta

Executive Leadership Team

Deep industry experience and subject matter expertise

Marvin Slosman
Chief Executive Officer

- 30+ years medical device experience, NSPR since 2019
- Previous CEO/President of ITAMAR Medical, Ovalum Vascular, Phormax Medical
- Prior experience at JNJ, GE Healthcare and Baxter
- BS from University of Alabama, MBA from University of Chicago

Shane Gleason
Chief Commercial Officer

- 20+ years cardiovascular medical device experience, NSPR since 2023
- Previous CCO of Nuvaira; VP Sales of TriVascular, Cordis and Surmodics
- Prior experience at Abbott and Edwards Lifesciences
- BS in Engineering Science and Mechanics from Virginia Tech, MBA from University of Maryland

Craig Shore
Chief Financial Officer

- 25+ years of international financial management, NSPR since 2010
- Previous CFO of RIT Technologies
- Prior experience at GE, Dunn and Bradstreet, Pfizer Pharmaceuticals and Bristol Meyer Squibb
- BS in Finance from Penn State, MBA from George Washington University

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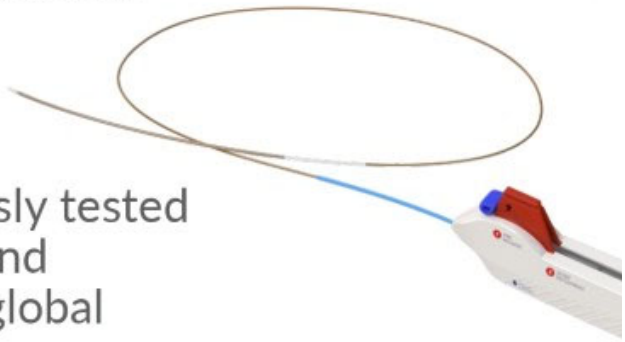
Now Approved in the U.S. CGuard® Prime Carotid Stent System

Imminent U.S. Commercial Launch, With a Trained and Seasoned Salesforce at the Ready

A New Level of Stroke Prevention is Here

- With 60,000+ patients treated worldwide, we're ready to elevate embolic prevention for U.S. physicians and their patients



Tested. Trusted. Ready.

- Our U.S. entry brings a rigorously tested solution to stroke prevention and positions us to become a true global carotid technology leader

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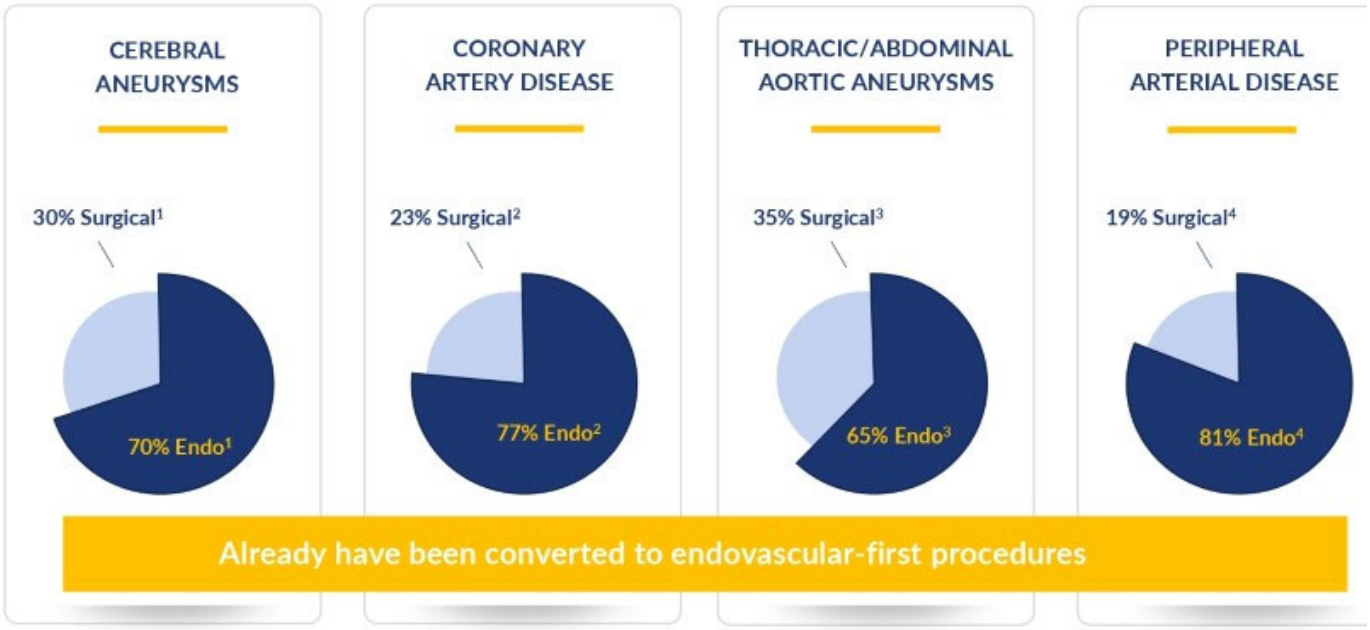
Endovascular Revolution Has Arrived

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



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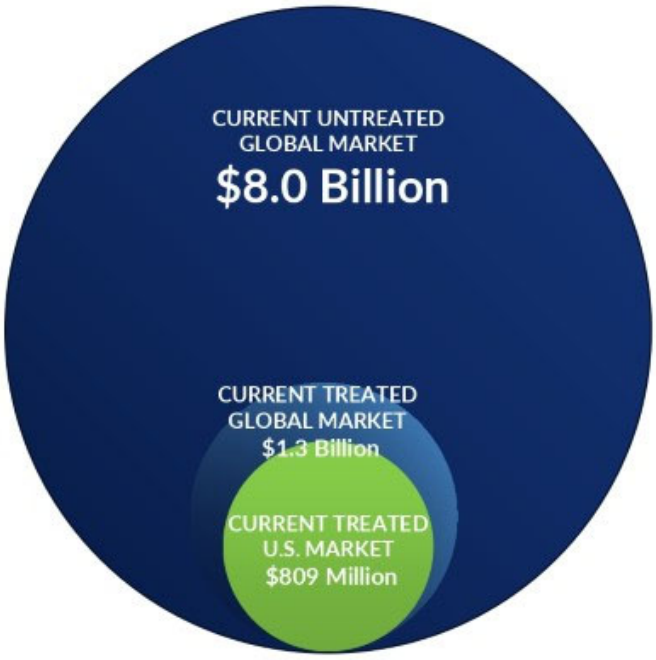
[1] Bekelis K, Gottlieb DJ, Su Y, et al. Comparison of clipping and coiling in elderly patients with unruptured cerebral aneurysms. J Neurosurg. 2017;126(3):811-818
[2] Culler SD, Kugelmass AD, Brown PP, , et al. Trends in Coronary Revascularization Procedures Among Medicare Beneficiaries Between 2008 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
[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 i
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

$8B Global Market Potential



~2.8 million
People diagnosed with
Stenosis (HGCS)

~400,000
Global procedures (CE
to treat HGCS

~155,000
US Procedures (CEA/C
annually

Market Growth Driver
Reimbursement for the
asymptomatic and stan
patients increases CAS
to increase screening a

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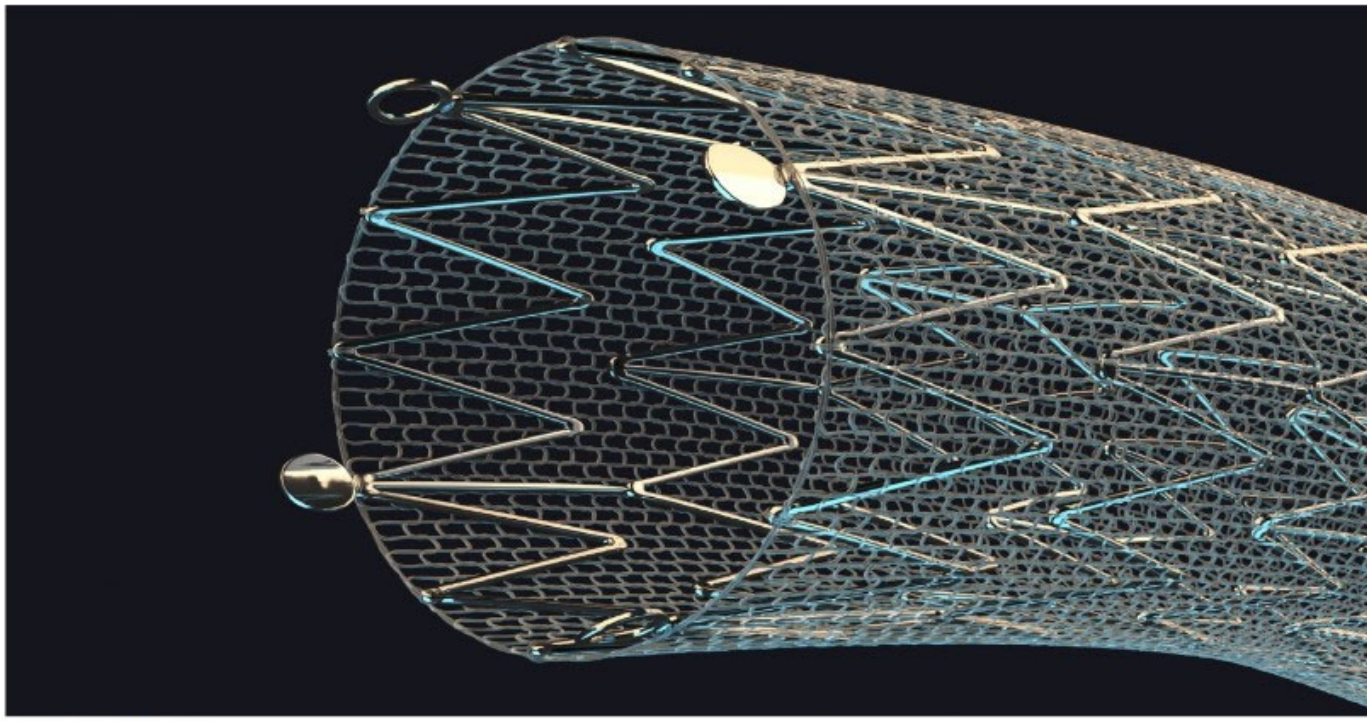
1. 2021 Health Research International Market Report; internal estimates

Developer of CGuard® Prime Carotid Stent Platform

Dedicated to advancing the prevention of stroke and treatment of carotid artery disease



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Transforming the Carotid Intervention Market

CGuard®Carotid Stent Platform
Proprietary MicroNet™ Technology
Highly differentiated platform for treatment of carotid artery disease and stroke prevention

CMS Coverage Expanded
Standard Risk and Asymptomatic
Enables stent-first approach to car revascularization

Unmatched Clinical Outcomes
Short and Long-Term Results
Ten clinical trials completed with >2,000 patients presented or published including US IDE trial

Significant Market Potential
Current Treated Market: $1.3 Billi
(Patients treated with CEA + CAS
significant growth potential

Deep Pipeline and Strategic Roadmap
MicroNet™ technology pipeline; SwitchGuard NPS for TCAR; acute stroke with tandem lesions

Expanding Commercial Footp
Double-digit market share in >30
(>30% in Italy)
Over 64,000 stents sold to date

CGuard Prime Received FDA Approval in June 2025

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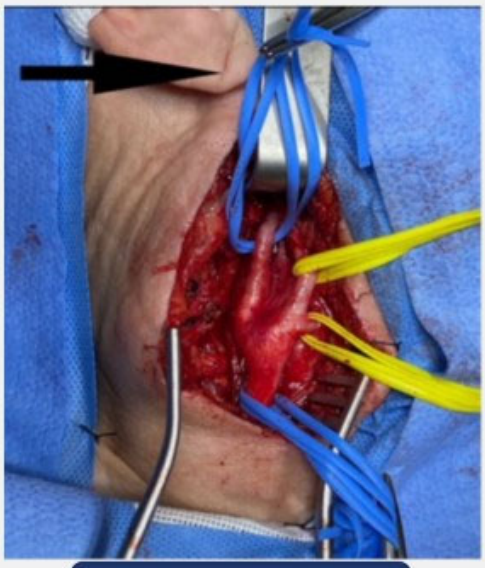
A Picture is Worth a Thousand Words...



Surgical Endarterectomy

VS

Stenting

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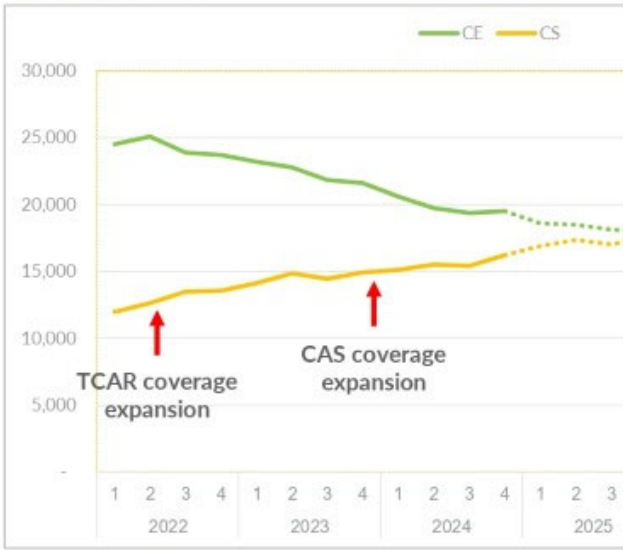
Carotid Stenting (CAS + TCAR) is on the Rise

- DRG/CPT data by Facility and HCP
- Trailing 12 Quarters through Q4 2024 (one quarter in arrears)
- ~147K annual carotid intervention claims
  - Represents ~90% of procedures (does not include Kaiser, Gov't/DoD)
  - **10.6% stent (CAS + TCAR) CAGR over prior three years** (TCAR reimbursement expansion 2022, CAS 2023)



Diagnosis

- Carotid Endarterectomy DRG
  3 DRG Codes
- Carotid Artery Stent DRG
  3 DRG Codes

INSPIREMD Data provided by acuity MD

Market Shift

The market has already begun the shift from surgery to stents (procedures and revenue c

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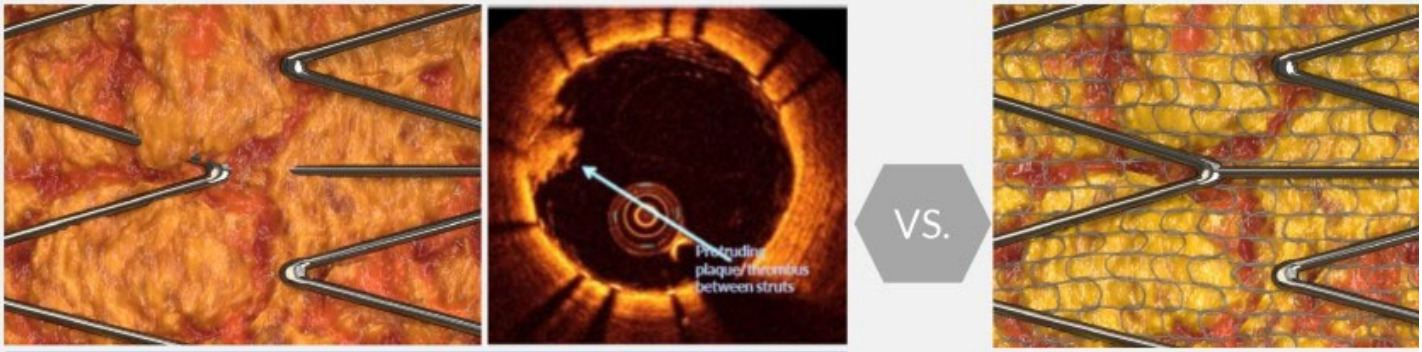
The CGuard® Difference: The Impact of MicroNet™ Technology[1]

Approximately 2/3 of neurovascular events (stroke, TIA) occur after carotid interventions take place
the protection from the stent implanted



Conventional Open Cell Stent (1St GEN):

Larger cell sizes allow increased plaque protrusion risk

CGuard Stent Sy

Stents are covered in MicroNe

MicroNet™ : Advanced Protection Technology

MicroNet captures and locks thrombus & plaque materials against the arterial wall, deterring
the bloodstream by acting as a mechanical barrier to prevent plaque prolap

Image: Prof. Valdés Chávarri

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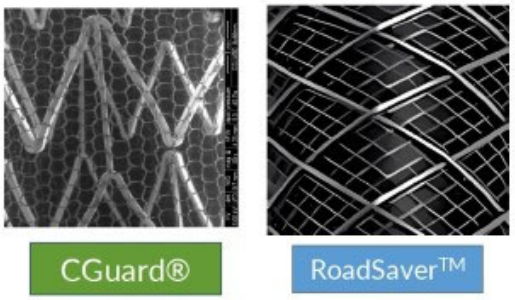
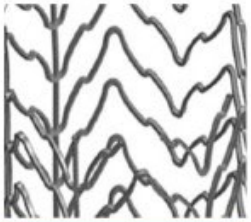
[1,2] Tomoyuki Umemoto, MD. Optical coherence tomography assessment of new generation mesh-covered stents after carotid stenting. Eurointerventional 2017;1

Stent Cell Sizes (Mechanism of Action)

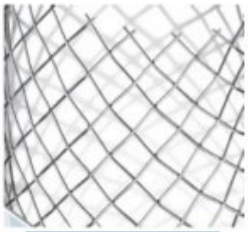


CGuard®

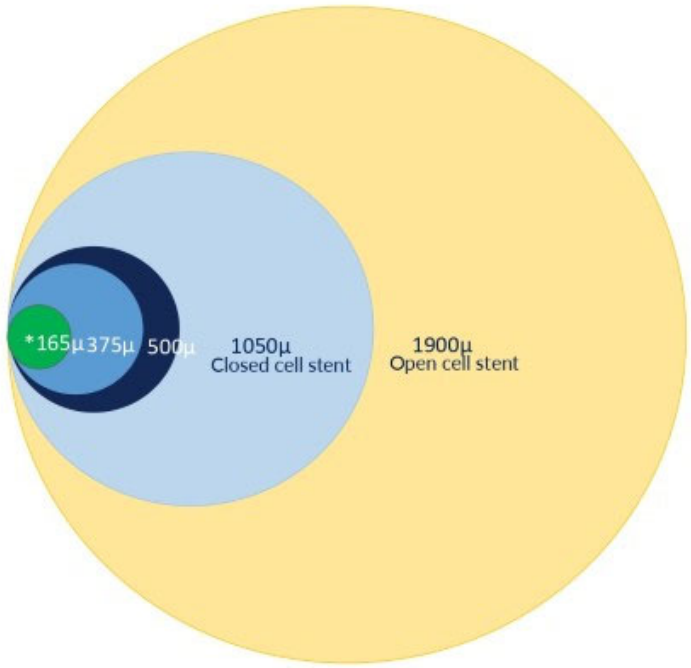
RoadSaver™



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*

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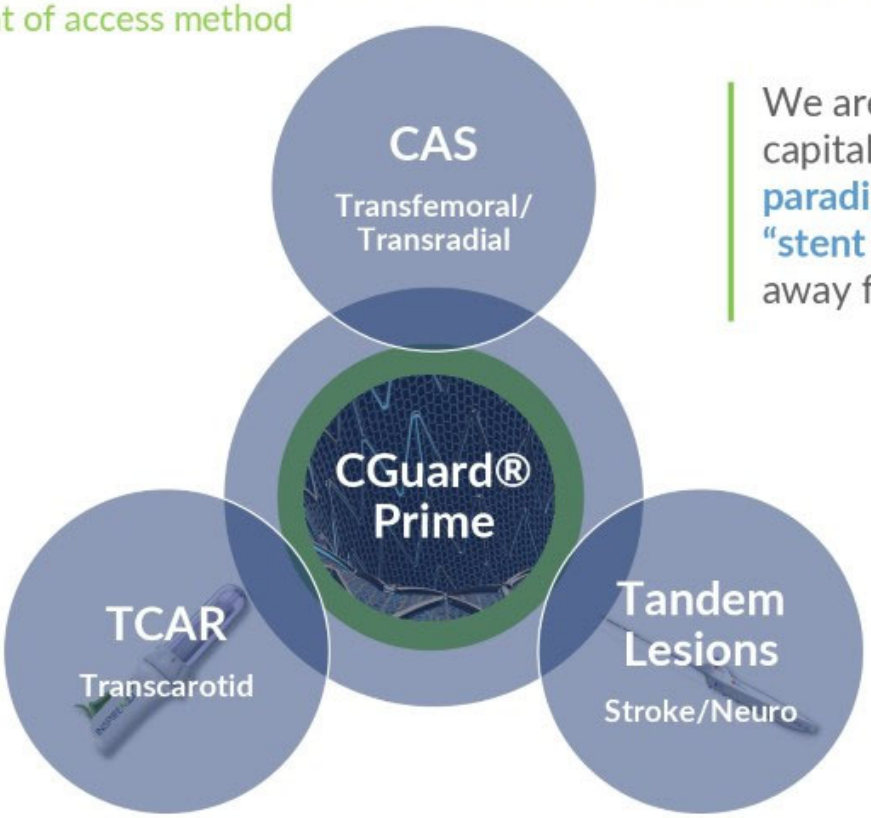
Long-Term Stent Performance is the Cornerstone of Our Business

Benefits are independent of access method



We are positi
capitalize on
paradigm shi
"stent first" a
away from su

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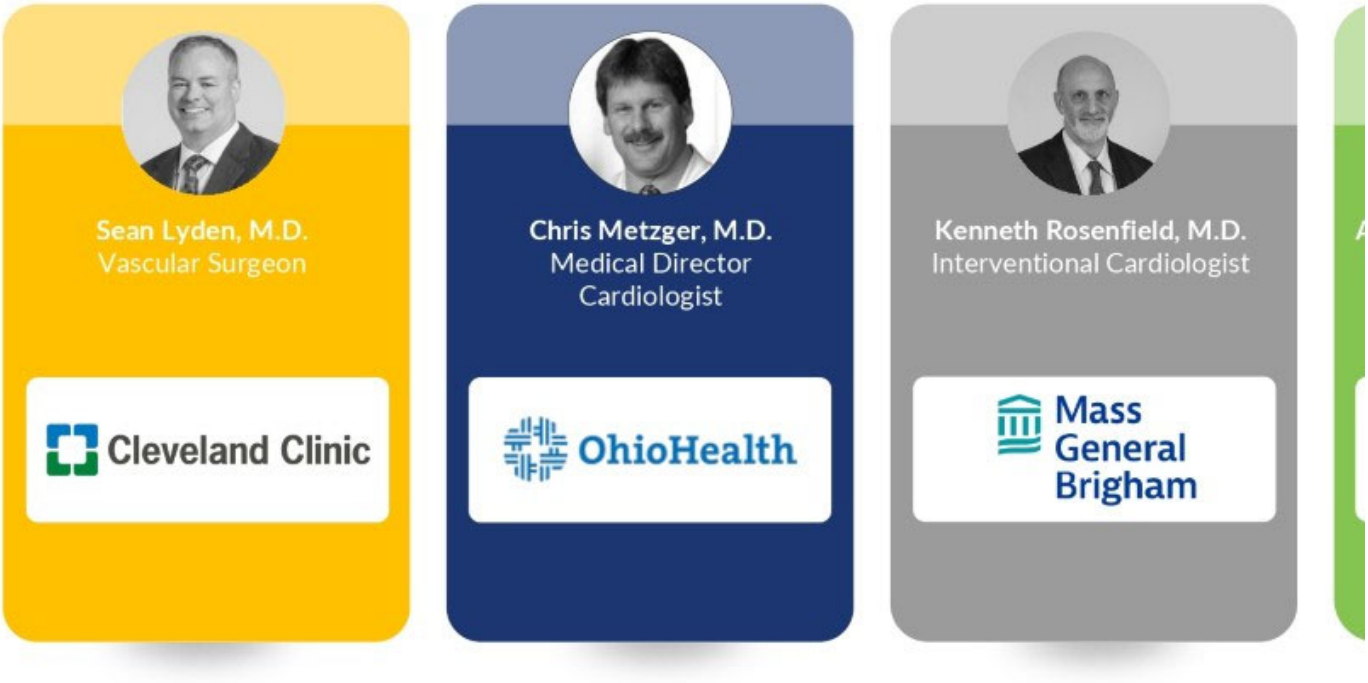
Scientific Advisory Board (Multidisciplinary KOLs)



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Unmatched Foundational Data and Evidence

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PMA Trial Design (C-GUARDIANS)

Prospective, multicenter international single-arm clinical trial

Pivotal Study Objective

Evaluate the safety and efficacy of the CGuard® Carotid Stent System in the treatment of carotid artery stenosis

Study Metrics

316 Patients – Enrollment completed (23 months)

24 Centers (19 in the United States and 5 in Europe)

Principal Investigators

Chris Metzger, M.D. (Ballad Health, Kingsport, TN)

Piotr Musialek, M.D. (John Paul II Hospital, Krakow, Poland)

Primary Endpoints

Composite of DSMI through 30 days or 365 days post-index procedure

Calculation will be the composite of the the following major adverse events: dea all stroke, and myocardial infarction (DS post-index procedure, based on the clir stroke from 31-365-day follow-up, bas The rate will be compared to a perform developed from published CAS literatur

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* Schofer, J. et al. JACC Cardiovasc. Interv. 2015; Speziale, F. et al. EuroIntervention. 2018; Sirignano, P et al. Cardiovascular Interv. 2020; Musialek et al. EuroIntervention. 2020; Karpenko, A. et al. JACC Cardiovasc. Interv. 2021.

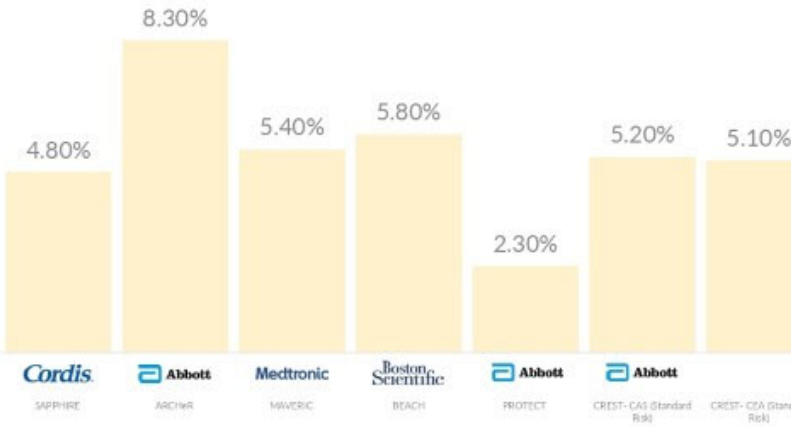
C-GUARDIANS: 30-Day Safety Outcomes

30-Day Death/Stroke/MI (DSMI) rates, compared to other carotid trials

CGUARDIANS 30-day outcomes

	Intention to Treat	Per Protocol[1,2]
30-day DSMI	0.95% (3)	0.63% (2)
Death	0.32% (1)	0.0% (0)
Stroke	0.95% (3)	0.63% (2)
MI	0.00% (0)	0.0% (0)

30-day DSMI (multiple FDA trials)



- Demonstrates the lowest 30-day DSMI rates of any FDA approval/clearance trial for carotid intervention (CAS or TCAR)
- Trial includes independent event adjudication
- 0.95% event rate consistent with 1.03% 30-day event rate from >1350 patients in peer-reviewed, published studies of real-wo Stent as a front-line therapeutic option for carotid revascularization

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1. Kaplan-Meier estimate for all 1-year endpoints
2. Per Protocol Analysis excludes 15 patients with Major Protocol Deviations

Yadav JS, et al, N Engl J Med 2004;351:1493-501. Gray WA, et al, J Vasc Surg. 2006 Aug;44(2):25 Feb;41(2):e102-9. White CJ, et al, CCI 2006 Apr;67(4):503-12. Iyer SS, et al, J Am Coll Cardiol. 200 et al, J Vasc Surg. 2012 Apr;55(4):968-976.e5. SSED Premarket Approval Application (PMA) Numbe Vasc Surg. 2015 Nov;62(5):1227-34. W. Gray VIVA 2023

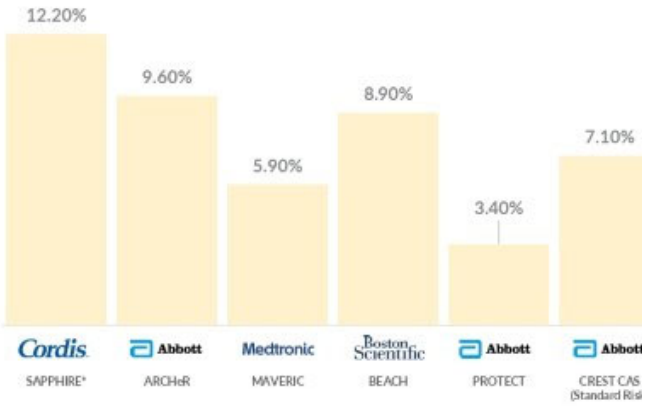
C-GUARDIANS: 1 Year Outcomes

365-Day Death/Stroke/MI (DSMI) rates, compared to other carotid trials

CGUARDIANS 365-day

	Intention to Treat	Per Protocol[1,2]
Primary Endpoint: 30-day Death, Stroke, or MI + Ipsilateral Stroke between 31 and 365 days	1.93% (6)	1.70% (5)
Target Lesion Revascularization (TLR) through 365 days.	0.98% (3)	1.01% (3)

365-day (multiple FDA tria



- Demonstrates the lowest primary endpoint event rates of any FDA approval/clearance trial for CAS
- Trial includes independent event adjudication
- 1.93% event rate consistent with 1.99% 1-year event rate from >1100 patients in peer-reviewed, published studies of real-wor Stent as a front-line therapeutic option for carotid revascularization

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1. Kaplan-Meier estimate for all 1-year endpoints
2. Per Protocol Analysis excludes 15 patients with Major Protocol Deviations
3. SAPPHIRE one-year primary endpoint also included Death/MI from 31-365 days

Yadav JS, et al, N Engl J Med 2004;351:1493-501. Gray WA, et al, J Vasc Surg. al, Stroke. 2010 Feb;41(2):e102-9. White CJ, et al, CCI 2006 Apr;67(4):503-12. 29;51(4):427-34. Matsumura JS, et al, J Vasc Surg. 2012 Apr;55(4):968-976.e5. (PMA) Number: P040012/S034. Kwolek CJ, et al, J Vasc Surg. 2015 Nov;62(5):

OUS Clinical Data Supporting CGuard® Periprocedural Safety

CGuard commercially available in Europe since 2015 (CE Mark)

Study	Year	N	DS 30-Day % (n)	D
CARENET	2015	30	0.0%(0)	0.
PARADIGM	2016	101	0.0%(0)	0.
CASANA	2017	82	1.22%(1)	1.
WISSGOTT I	2017	30	0.0%(0)	0.
IRONGUARD I	2018	200	2.50%(5)	2.
WISSGOTT II	2019	30	0.0%(0)	0.
IRONGUARD 2	2020	733	0.5%(4)	1.
GREEK Study	2021	103	0.0%(0)	0.
SIBERIA	2021	50	0.0%(0)	0.
Total		**1,359**	**0.80%(11)**	**1.**

INSPIREMD

1. Schofer, J. et al. JACC Cardiovasc. Interv. 2015; 2) Casana, R. et al. Eur. J. Vasc. Endovasc. 2017; 3) Musialek, P. et al. Interv. Cardiol. 2016
4. Wissgott, C. et al. Int. Soc. Endovasc. Spec. 2017; 5) Speziale, F. et al. EuroIntervention 2018; 6) Wissgott, C. et al. J Endovasc Ther. 2019
7. Sirignano, P et al. Cardiovascular Interventions 2020;8) Tigkiropoulos, K. et al. Journal of EndoTherapy 2021; 9) Karpenko, A. et al JACC Cardiovasc. Interv. 20

CARMEN Meta-Analysis (112 Studies, 68K Patients)[1]

- 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)

30-day and 12-month event rates by stent type (ra

Event	FGS	SGS	Terumo RoadSav Caspe
30-day Stroke [%] (95% CI)	3.01 (2.63-3.38)	0.60 (0.28-0.92)	0.50 (0.0-1.1
30-day Death / Stroke / MI [%] (95% CI)	4.11 (3.65-4.56)	1.30 (0.64-1.96)	1.33 (0.0-2.6
12-month Ipsilateral Stroke [%] (95% CI)	3.51 (2.52-4.50)	0.7 (0.0-1.47)	0.26 (0.0-1.2
12-month Restenosis [%] (95% CI)	3.97 (0.28-5.14)	3.38 (1.39-5.37)	7.16 (4.45-9.8
12-month Ipsilateral Stroke / Restenosis [%] (95% CI)	8.15 (6.34-9.93)	5.12 (2.14-8.10)	7.86 (5.04-10.6

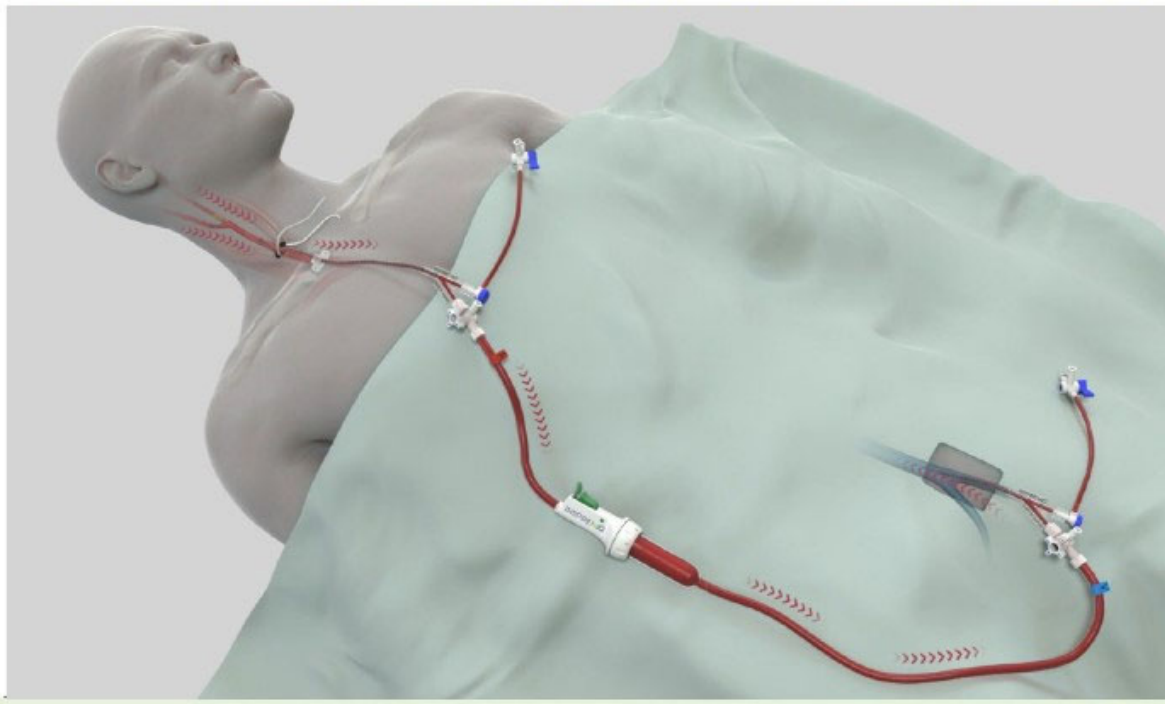
INSPIREMD

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

TCAR

INSPIREMD

Transcarotid Arterial Revascularization (TCAR): Direct Carotid Access w



InspireMD Combines SwitchGuard NPS with Best-in-Class CGuard® Impl

INSPIREMD

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

Developing Comprehensive TCAR Solution

80cm

CGUARD® PRIME

SWITCH GUARD

TCAR Market Opportunity

~3,000 TCAR-trained physicians in the U.S.[1]

~30,000 TCAR procedures (~$210M) performed in the U.S. in 2024, double-digit growth projected

INSPIREMD

1 Piper-Sandler model, 05/01/24
2 Piper-Sandler model, 05/01/24

Commercial and Corporate

INSPIREMD

Roadmap / Milestones

Key Value Drivers

2025

CGuard® Prime CAS Approval
Launch for CAS

U.S Operational Expansion
Build out of U.S. HQ, Operational and Commercial

Acute Stroke EFS- Tandem Lesions

CGuard Prime CE Mark

2026

CGuard Prime CAS Market Expansion

CGuard Prime TCAR Approval
CGuard Prime indicated stent for TCAR

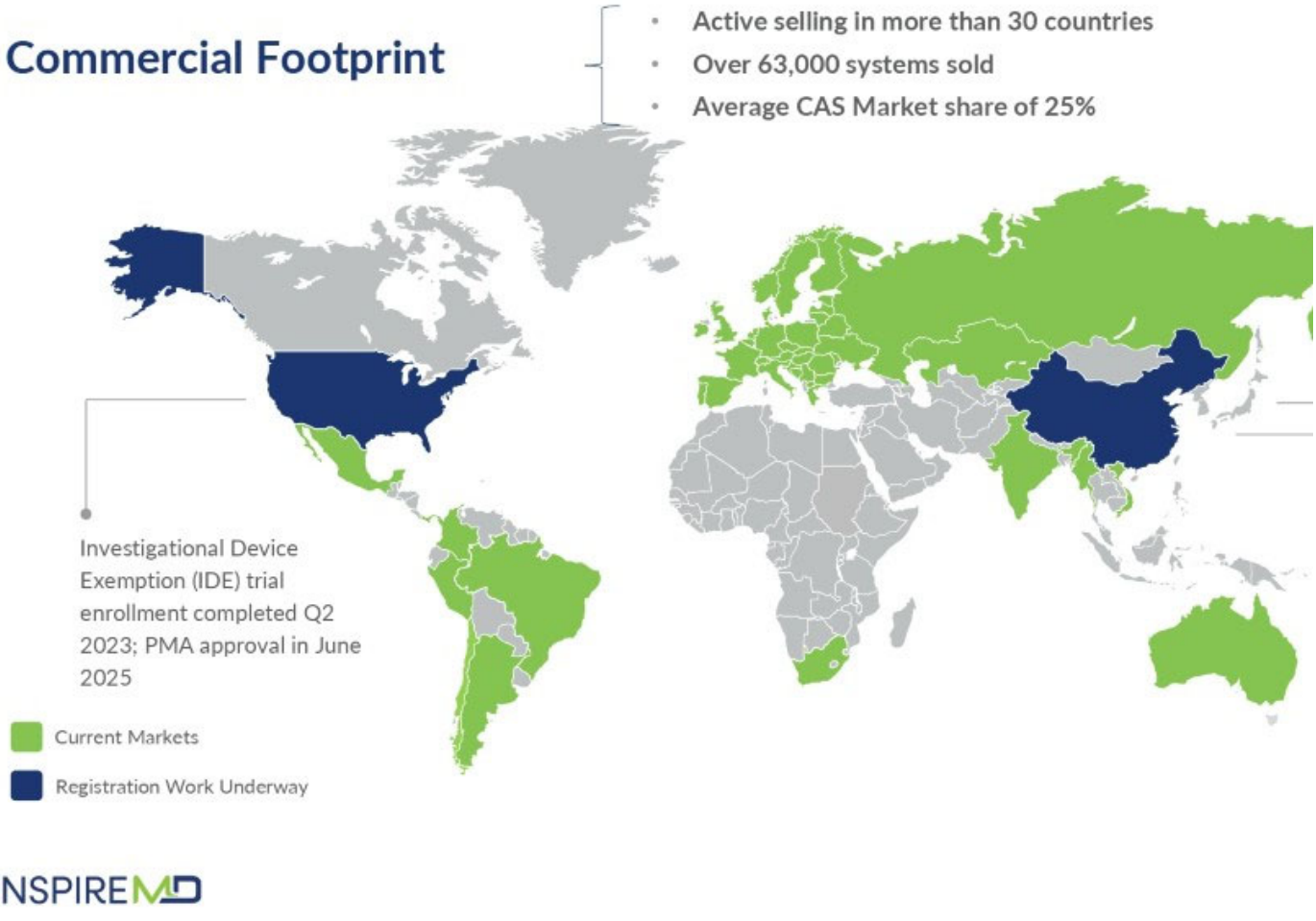
SwitchGuard NPS Clearance / Launch (Full TCAR Tool Kit)
CGuard Prime indicated stent with SwitchGaurd Neuro Protection for TCAR

Further Cor

Potential Gl

Potential Po

INSPIREMD


Commercial Footprint
Active selling in more than 30 countries
Over 63,000 systems sold
Average CAS Market share of 25%
Investigational Device Exemption (IDE) trial enrollment completed Q2 2023; PMA approval in June 2025
Current Markets
Registration Work Underway
INSPIREMD

Robust Intellectual Property Portfolio

Proprietary platform technology supported by IP

Patent Rights	Issued	Pendi
USA	20	7
Rest of World	54	21

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

IP Counsel: Klgler and Associates, P.A.

INSPIREMD

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

$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. **Complete** : 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 fr
fundamental health
additional participa
Board members.

ROSALIND

NANTAHALA
CAPITAL MANAGEMENT, LLC

MARSHALL WACE

INSPIREMD

Summary Financials

June 23, 2025

NASDAQ Capital Markets

Stock Price
Average 3 Month Volume
Shares Outstanding
Shares Outstanding with Prefunded Warrants
Market Capitalization with Prefunded Warrants
Cash Balance - March 31, 2025
Debt

INSPIREMD


INSPIREMD