U.S. Studies and the Status of the CGuard and CGuard Prime Micromesh Stents: Can They Be Used in TCAR and Are They Making a Difference

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Conflicts

• InspireMD	*Research Funding (Co-PI)*
• MedAlliance/Cordis	*Advisory Board, Equity*
• Aveera	*Advisory Board, Equity*
• Protexa	*Advisory Board, Equity*
• Pulse Therapeutics	*Advisory Board, Equity*

C-Guardians II and III Trials

- C-Guard Prime micromesh stent / Switchguard flow reversal
- C-Guardians I trial demonstrated superb TF-CAS results through one year
- Abluminal micromesh traps plaque particulates against the artery wall
- Facilitates appropriate post-dilation after stent deployment

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C-Guard Prime Stent with MicroNet Mesh

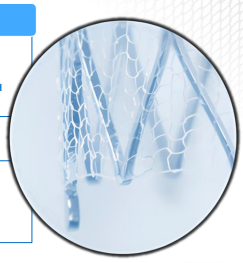
- Fine meshwork prevents plaque prolapse
- Minimal pore size (165µ) for maximal plaque prolapse prevention

CGUARD PRIME

CGuard ™ Prime Stent: MicroNet™ Technology

The Micronet™

- Bio-stable mesh woven
- 20µm single strand
- Polyethylene Terephthalate (PET)
- The MicroNet™ covers the stent and is sutured to both the distal and proximal crowns of the stent platform

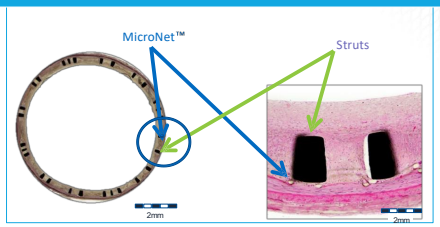


The MicroNet™ is designed to:

- Trap and seal thrombus and plaque against the vessel wall, preventing embolization
- Optimal pore size (average 165µ) to avoid embolization

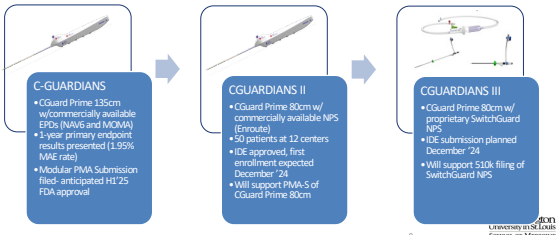
Pre-Clinical: Histopathology in Carotid Artery

Micronet™ doesn't compromise endothelization



Images taken at 90 days; photograph by InspireMD

CGuard Prime/SwitchGuard Regulatory Strategy



C-GUARDIANS
- CGuard Prime 135cm w/commercially available EPDs (NAV6 and MOMA)
- 1-year primary endpoint results presented (1.95% MAE rate)
- Modular PMA Submission filed- anticipated H1'25 FDA approval

CGUARDIANS II
- CGuard Prime 80cm w/ commercially available NPS (Enroute)
- 50 patients at 12 centers
- IDE approved, first enrollment expected December '24
- Will support PMA-S of CGuard Prime 80cm

CGUARDIANS III
- CGuard Prime 80cm w/ proprietary SwitchGuard NPS
- IDE submission planned December '24
- Will support 510k filing of SwitchGuard NPS

The Promise of TCAR with CGuard

DW MRI study of recently symptomatic patients- Professor Nacho Leal at LINC 2024

- *"Transcarotid Flow Reversal and MicroNET Covered Stent for Carotid Revascularization in Recently Symptomatic Patients: A DW MRI-Based Prospective Evaluation"*
  - *[illegible] recently-symptomatic (< 14 days) patients were treated with CGuard using flow-reversal (TCAR)*
  - *[illegible] remained patent with no major adverse events through 30 days. 0% TLR, MAE*
  - *Post-procedural DW MRI lesion found in only one patient (6.7%); complete resolution in follow-up imaging at 30 days*
- *Conclusions:*
  - *(TCAR) combined with a MicroNET stent performed within 14 days of symptom onset could carry a remarkably low incidence of new ischemic brain infarcts detected by DW MRI studies.*
  - *may improve the safety of CAS, and has the potential to produce results at least comparable to that of carotid endarterectomy*

INSPIREMD

C-Guardians II Trial

- Single arm study, 12 sites
- Patrick Muck, MD and Patrick Geraghty, MD
- 50 patients at high risk for CEA
- Lesion length < 36 mm
- Artery diameter 4.8- 9.0 mm

C-Guardians II Trial

- **High Risk Comorbid Conditions**
- Age 70-80, unstable angina, NYHA class III-IV heart failure, recent MI, LVEF < 35%, severe COPD, planned CABG or AAA repair, contralateral cranial nerve injury, restenosis after prior CEA

C-Guardians II Trial

- **High Risk Anatomic Conditions**
- Contralateral carotid occlusion, prior radiation therapy or radical neck dissection or laryngectomy, lesion above C2, severe tandem lesions, inability to extend neck

C-Guardians II Trial- Endpoints

- Acute device success (introduction, deployment, removal)
- Technical success (less than 30% residual after post-dilation)

- 30 day hierarchical death/stroke/myocardial infarction
- 30 day hierarchical death/stroke
- Major/minor stroke
- Stroke through one year

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C-Guardians II Trial

- Protocol approved
- DSMB, CEC, screening committee
- Angiographic and duplex ultrasound core labs

- Site initiation visits are underway

- Anticipate first enrollment in December

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Stay Tuned… C-Guardians III Trial

- **TCAR using C-Guard Prime Stent + SwitchGuard NPS**

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