

A Single-arm, Pivotal Study to Evaluate Acute Device and Technical Success of the CGuard Prime Carotid Stent System When Used in Conjunction to the ENROUTE Transcarotid Neuroprotection System in Patients Undergoing Carotid Artery Stenting Via the Transcarotid Artery Revascularization Approach

NCT06653387

Status	RECRUITING
Phase	Not Applicable
Sponsor	InspireMD
Enrollment	50 participants

Key Eligibility Criteria

Inclusion (35)

- Patient is e 18 years and \< 80 years of age.
 - Patient is willing and able to provide appropriate study-specific informed consent, follow protocol procedures, and comply with follow-up visit requirements.
 - Patient is diagnosed with carotid artery disease treatable with a Carotid Artery Stent via a Transcarotid Artery Revascularization approach and is either symptomatic or asymptomatic, defined as:
 - Symptomatic carotid stenosis e 50%. Symptomatic is defined as amaurosis fugax, transient ischemia attack (TIA) or stroke within the last 6 months ipsilateral to the side of the stenosis Or
 - Asymptomatic carotid stenosis e 80%
- ... and 30 more (see full listing online)

Exclusion (34)

- Patient had or will have an interventional procedure or surgery of the carotid, coronary or peripheral arteries within 30 days before or after the index carotid procedure.
 - Patient had or will have open heart surgery or valvular intervention (percutaneous or surgical), or any major operation, within 30 days before or after the index carotid procedure.
 - Vascular anatomy that would preclude safe sheath insertion or deliverability of stent
 - Patient had a previously placed stent in the ipsilateral ICA or CCA.
 - Total occlusion or presence of a "string sign" of the ipsilateral ICA or CCA.
- ... and 29 more (see full listing online)

Locations (8 total)

UC Davis Health, Sacramento, California, United States
Indiana University School of Medicine, Indianapolis, Indiana, United States
Allina, Minneapolis, Minnesota, United States
... and 5 more locations

<https://clinicaltrials.gov/study/NCT06653387>

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