



Prairie

EDUCATION & RESEARCH COOPERATIVE

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EPIC US - PIVOTAL

- Trial Sponsor:** Lumen Biomedical
- Principal Investigator:** Krishna Rocha-Singh, MD
- Trial Name:** Evaluating the Use of the FiberNet Embolic Protection System in Carotid Artery Stenting: The EPIC US Pivotal Study.
- Purpose:** Multicenter, prospective, pivotal study designed to demonstrate the safety and efficacy of the Lumen Biomedical, Inc. FiberNet® Embolic Protection System as an adjunctive device during carotid artery percutaneous intervention in high surgical risk patients.

Eligibility

Ages Eligible for Study: 18 years and above

Genders Eligible for Study: Both

Inclusion Criteria:

- One or more of the high surgical risk criteria.
- Symptomatic with atherosclerotic stenosis $\geq 50\%$ or asymptomatic with atherosclerotic stenosis $\geq 70\%$ of the carotid artery by NASCET Criteria.

Exclusion Criteria:

- Prior stenting of ipsilateral carotid.
- Planned treatment of contralateral carotid within 30 days.
- Experienced a myocardial infarction within the last 14 days.
- Undergone an angioplasty or PTCA/PTA procedure within the past 48 hours.
- Undergone cardiac surgery within the past 60 days.
- Suffered a stroke within the past 14 days.
- Suffered a transient ischemic neurological attack (TIA) or amaurosis fugax within the past 48 hours.
- Abnormal baseline blood counts; platelets $< 50,000$ or $> 700,000/\text{mm}^3$ or WBC count $< 3 \times 10^3/\text{uL}$.
- Intracranial stenosis that exceeded the severity of an extracranial stenosis.
- Total occlusion of the target vessel.
- Lesion within 2cm of the ostium of the common carotid artery.
- A stenosis that is known to be unsuitable for stenting because of one or more of:
 1. Tortuous or calcified anatomy proximal or distal to the stenosis
 2. Presence of visual thrombus
 3. Pseudo occlusion ('string sign')
- Serial lesions that requires more than one stent to cover entire lesion