



# Prairie

## EDUCATION & RESEARCH COOPERATIVE

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### ACT 1

**Trial Sponsor:** Abbott Vascular

**Principal Investigator:** Gregory J. Mishkel, MD

**Trial Name:** Carotid Angioplasty and Stenting Versus Endarterectomy in Asymptomatic Subjects Who Are at Standard Risk for Carotid Endarterectomy With Significant Extracranial Carotid Stenotic Disease (ACT I)

**Purpose:** The study is being conducted to demonstrate the non-inferiority of carotid artery stenting (CAS) using the Emboshield® Embolic Protection System and Emboshield® Pro Embolic Protection System with the Xact® Carotid Stent System to carotid endarterectomy (CEA) for the treatment of asymptomatic extracranial carotid atherosclerotic disease.

**Details:** Patients will be randomized to either an interventional treatment using a carotid artery stent and filter or the surgical procedure of carotid endarterectomy, on a 3:1 basis. This means that three interventional procedures will be conducted to each surgical (CEA) one, on average, for every four patients.

### Eligibility

**Ages Eligible for Study:** 18 - 79 Years

**Genders Eligible for Study:** Both

**Inclusion Criteria:**

- Severe carotid artery disease
- Patients who have not had symptoms related to their carotid artery disease in the last 180 days
- Patients who are able to undergo either an interventional stenting or surgical procedure

**Exclusion Criteria:**

- Patients who have had symptoms in the last 180 days
- Patients who are high risk for surgery
- Patients who have certain conditions that might confound the results of the study