

## CLINICAL STUDIES

The EPIC Trial pivotal phase was a prospective, multi-center, single-arm trial. The objective of the study was to evaluate the safety and efficacy of the system used with commercially available carotid stents in the treatment of internal and/or common carotid artery stenoses in patients at high-risk for carotid endarterectomy. A total of 237 patients were enrolled at 26 clinical sites in the U.S. and Germany.

## ELIGIBILITY CRITERIA

Patients who presented for percutaneous treatment of an internal and/or common carotid artery were considered. Patients were required to be at least 18 years old and at high risk for CEA based on one or more criteria listed in Table 2. A target lesion stenosis  $\geq 70\%$  was required for asymptomatic patients,  $\geq 50\%$  for symptomatic patients (patients with a stroke or TIA  $\leq 6$  months prior to enrollment). Major baseline characteristics are summarized in Table 3.

<b>Clinical Criteria</b>	<b>Anatomical Criteria</b>
1. Age > 75	1. Contralateral occlusion
2. CCS angina class 3-4 or unstable angina	2. CEA restenosis
3. CHF NYHA Class 3-4	3. Low infraclavicular lesion
4. LVEF < 35%	4. Tandem lesion $\geq 70\%$
5. MI within past 2-6 weeks	5. Hostile neck
6. CAD with $\geq 2$ vessel disease in major vessel	6. Cervical immobility
7. Severe pulmonary disease	7. High cervical lesion (above the angle of the jaw)
8. Dialysis dependent renal failure	
9. Requires CAB, cardiac valve, PV surgery, or abdominal aneurysm repair $\leq 60$ days	

<b>Variable</b>	
Age, mean $\pm$ sd	74 $\pm$ 8 (237)
Age $\geq 80$ years	21% (50/237)
Male	62% (148/237)
Symptomatic	20% (48/237)
Diabetes	40% (94/237)
Hyperlipidemia	93% (220/237)
Hypertension	93% (220/237)
Renal insufficiency	22% (51/237)
History of myocardial infarction	31% (74/237)
History of congestive heart failure	18% (42/237)
History of pulmonary Disease	25% (59/237)
Lesion length, mean $\pm$ sd	14 $\pm$ 7 (235)
Lesion stenosis, mean $\pm$ sd	72 $\pm$ 10 (235)

## CLINICAL RESULTS SUMMARY

The EPIC pivotal trial primary endpoint was a composite endpoint of all death, MI or stroke at 30 days post-procedure. Endpoint results are summarized in Table 4.

<b>Primary Endpoint</b>	
30-Day Death, Stroke, MI	3.0% (7/237)
Death	0.4% (1/237)
Stroke	2.1% (5/237)
Myocardial infarction (MI)	0.8% (2/237)
<b>Secondary Endpoints</b>	
Technical success rate	98% (231/237)
Device success rate	94% (223/237)
Non-stroke neurological event	1.7% (4/237)

Statistical analysis of the pivotal phase was designed to demonstrate that the primary endpoint event rate was less than a performance goal of 12.55%. Statistical analysis confirmed the FiberNet EPS rate was less than the performance goal.

No differences were noted among the stents used (AccuLink, Precise, Protégé, NexStent, Xact).