EPIC Trial

Evaluating the Use of the FiberNet® Embolic Protection System In Carotid Artery Stenting

Subbarao Myla, MD FACC

Principal Investigator & Medical Director CV Research and Vascular Intervention
Hoag Memorial Hospital

on behalf of

Co-Principal Investigator J. Michael Bacharach, MD FACC

and the EPIC investigators

EPIC Study Design

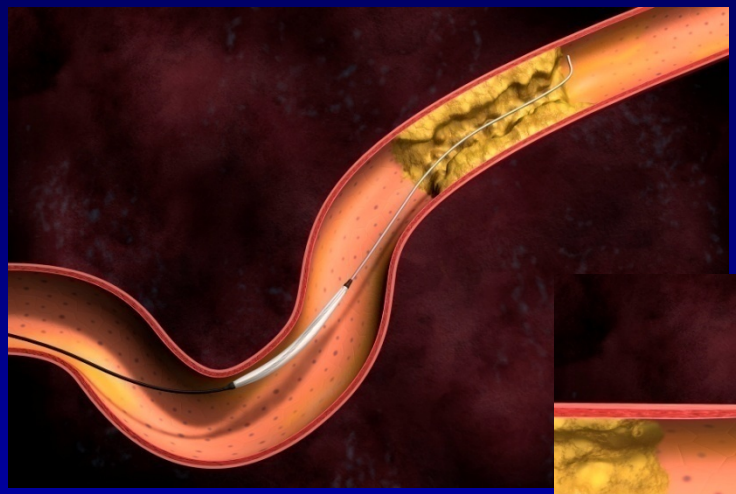
Patients at High-Risk for CEA
Prospective, Multi-center, Non Randomized Trial
Evaluating the FiberNet® Embolic Protection System for
Use During Carotid Artery Stenting Procedures
(26 Sites)

N = 237

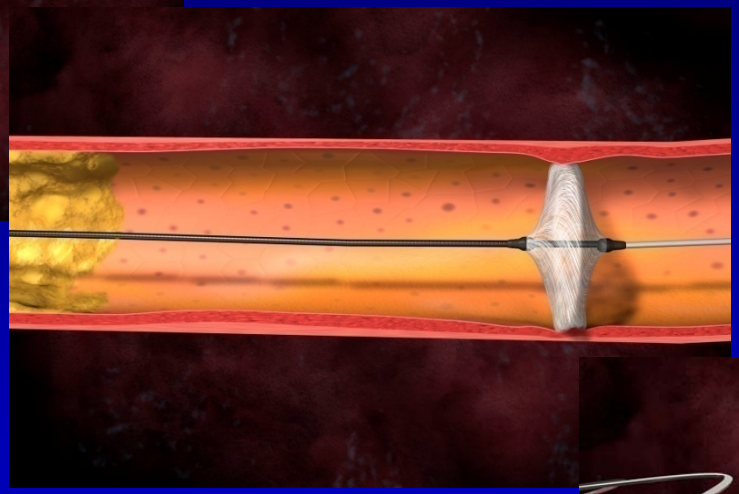
Follow Up - 30 Days

Primary Endpoints Adjudicated by
Independent Clinical Events Committee

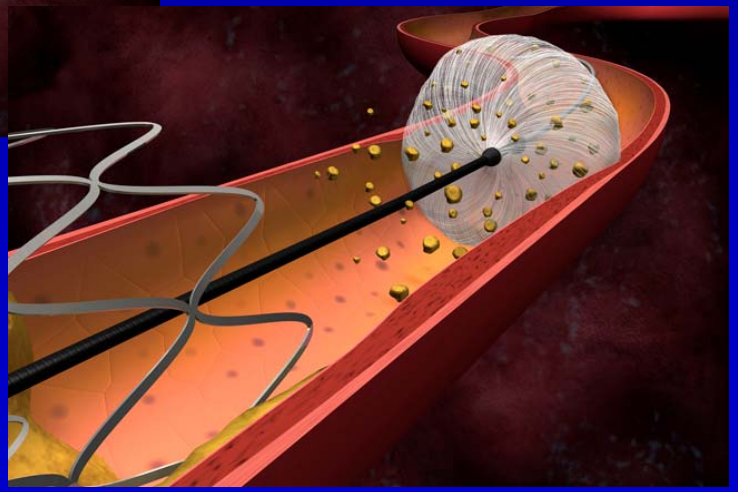
EPIC FiberNet® EPS



No delivery system required with a crossing profile
1.7 to 2.9 F



Fiber-based filter conforms to asymmetrical vessels



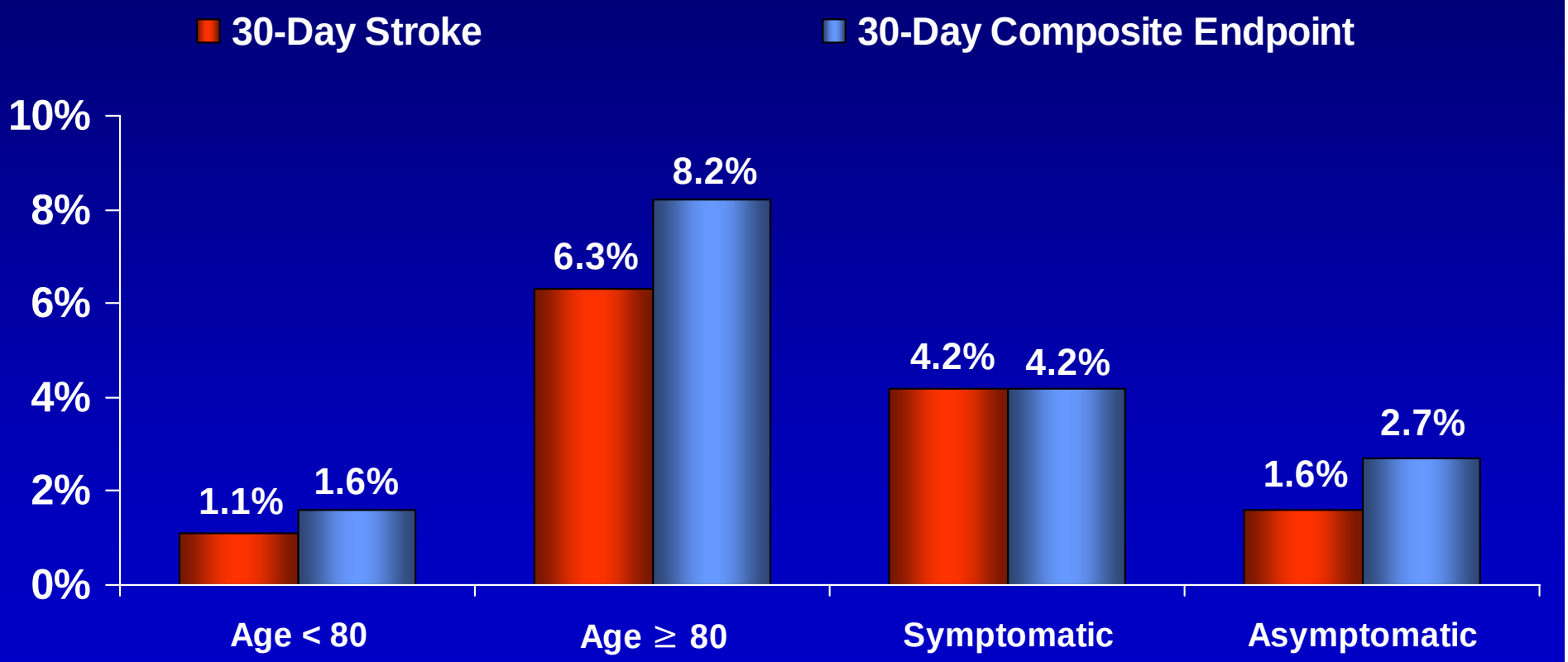
Particle entrapment as small as 40 µm

EPIC Study
Key Endpoints

- Primary Endpoint
  - Composite rate of death, stroke and MI at 30 Days
- Secondary Endpoints
  - Death, stroke, and MI rates
  - Non-stroke neurological events
  - Device success, technical success and procedural success rate

EPIC Study 30 Day Event Rates

Primary Endpoint by Age and Symptom Status



EPIC Study Conclusions

- The EPIC study reveals very low stroke, MI & death rates using a novel embolic protection system during Carotid stenting with commercial stents.

- The unique Filter design with low porosity and ease of use features combined with aspiration prior to retrieval led to low event rates.

- The FDA OPC are clearly met for the FiberNet Embolic protection system in a prospective multi-center single arm study.