

**ID:** O-001

**Session Title:** Best of the Best Oral Abstracts

**Session Time:** Thursday, May 6, 10:30 am- 10:42 am (Pacific Time)

**Session Location:** Aqua 308 (3rd Floor)

## **Use of the INVATEC MO.MA<sup>®</sup> proximal cerebral protection device during carotid stenting (The ARMOUR Trial)**

**Category:** Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)

**Presenter:** Robert Bersin, MD, FSCAI, Swedish Medical Center, Seattle, WA

**Background:** The ARMOUR trial is a pivotal, prospective, multi-center, non-randomized trial to evaluate the safety and effectiveness of cerebral protection with the MO.MA device in high surgical risk subjects undergoing carotid artery stenting (CAS).

**Methods:** All subjects who provided informed consent and met inclusion/exclusion criteria, underwent percutaneous revascularization of the carotid artery using the MO.MA device and a stent approved by the FDA for carotid artery stenting. Follow-up took place at pre-discharge and at 30 days post-procedure.

A total of 262 subjects (225 ITT, 37 Roll-In) were enrolled at 25 investigational sites in the United States (20) and the European Union (5) between September 2007 and February 2009. For the ITT population, mean age was 74.7 years and 66.7% were male. Symptomatic subjects comprised 15.1% of the population and 28.9% of the subjects were octogenarians.

The primary endpoint for this trial was major adverse cardiac and cerebrovascular events (MACCE) within 30 days of stent implantation. MACCE was defined as any myocardial infarction (MI), stroke, or death through 30 days post-procedure as adjudicated by the Clinical Events Committee (CEC). Results were compared to a performance goal of 13% for the 30-day MACCE composite rate, which was derived from previous carotid stenting trials.

Secondary endpoints included device, technical, and procedural success

**Results:** The 30-day MACCE rate was 2.7%, well beneath the performance goal of 13%. The major stroke rate through 30 days was less than 1%. The device success for the MO.MA device was 98.2%. Technical success was 94.6% and procedural success was 93.2%. The access site complication rate was 3.1%.

**Conclusions:** The MO.MA<sup>®</sup> Proximal Cerebral Protection Device used in combination with FDA approved carotid stents in high surgical risk subjects, resulted in excellent safety and

effectiveness outcomes as compared to a performance goal derived from previous carotid stenting trials.

**Author Disclosures:** Robert Bersin: 5 Cordis Endovascular, 5 WL Gore, 5 Abbott, 5 Palmaz Scientific, 5 ev3, 5 ReVascular Therapeutics, 5 Cook, 5 Vascular Solutions, 5 Boston Scientific, 5 Cardiovascular Systems, 8 Abbott, 8 Boston Scientific, 8 Cordis Endovascular, 9 Medtronic Vascular/Proctor