

**A New Modular Embolic Protection Device First In Man Experience**

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**Aims:** The use of Embolic Protection Devices (EPD) in Carotid Artery Stenting (CAS) procedures has shown to lower the periprocedural rate of major adverse cardiac and cerebrovascular events (MACCE). Current EPDs are complex and difficult to use.

We present a First In Man study in patients undergoing CAS to evaluate a new distal filter EPD delivered in a stent-like delivery system

**Methods and Results:** The GARDEX EPD (Gardia Medical Ltd.) is a new rapid-exchange pre-crimped distal filter EPD delivered in standard stent-like delivery system. The GARDEX EPD can be used over any 0.014" guide wire (according to physician preference), after the guidewire was positioned across the lesion in a standard fashion. Its modular stand-alone filter unit can be locked anywhere along the guide wire to optimize filter location.

Twenty (n=20) consecutive patients with a mean age of 69 yrs were enrolled. Four patients were symptomatic and 16 were asymptomatic. The lesions treated (n=20) had average stenosis of 83.8% and residual stenosis post CAS of 6.0%. After guide wire was positioned across the lesion the Gardia EPDs were passed across the lesion and positioned in a pre determined location, regardless of lesion severity or vessel tortuosity.

Device and Angiographic Success were achieved in all cases (100%). One patient had transient neurological deficiencies which resolved within 12hrs. No other Major Adverse Events were recorded up to 30 days follow up.

**Conclusions:** The use of the GARDEX EPD in CAS is encouraging. The GARDEX system is very simple to use and require very limited learning curve. The system is has excellent deliverability and can be locked on any commercially available guide wires, to optimize position distal to the treated lesion. Early clinical experience suggests that the device functions well in a variety of challenging lesions and vessel's anatomies. Clinical outcomes are favorable. The full role of the GARDEX EPD needs to be further confirmed in a larger patient population study and other clinical applications (e.g. SVGs, STEMI).