Ancillary Devices for TAVI Procedures

Stroke Protection - Claret Device -
Disclosure Statement of Financial Interest

Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Physician Name</th>
<th>Company/Relationship</th>
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<tbody>
<tr>
<td>Eberhard Grube, MD</td>
<td>Medtronic, CoreValve: C, SB, AB,</td>
</tr>
<tr>
<td>OF</td>
<td>Sadra Medical: E, C, SB, AB</td>
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<td>Direct Flow: C, SB, AB</td>
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<td>Mitralign: AB, SB, E</td>
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<td>Boston Scientific: C, SB, AB</td>
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<td>Biosensors: E, SB, C, AB</td>
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<td>Cordis: AB</td>
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<td>Abbott Vascular: AB</td>
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<td>Capella: SB, C, AB</td>
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<td>Devax: SB, AB,</td>
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<td>Embrella: SB</td>
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<td>Claret: SB</td>
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Key
- **G** – Grant and or Research Support
- **E** – Equity Interests
- **S** – Salary, **AB** – Advisory Board
- **C** – Consulting fees, Honoraria
- **R** – Royalty Income
- **I** – Intellectual Property Rights
- **SB** – Speaker’s Bureau
- **O** – Ownership
- **OF** – Other Financial Benefits’
Perioperative Stroke by Type

Figure 1. Mechanisms of Perioperative Stroke.
Data are from Likosky et al.12
Silent and Apparent Cerebral Ischemia after Percutaneous Transfemoral Aortic Valve Implantation

A Diffusion-Weighted Magnetic Resonance Imaging Study

Philipp Kahlert, MD; Stephan C. Knipp, MD; Marc Schlamann, MD; Matthias Thielmann, MD; Fadi Al-Rashid, MD; Marcel Weber, MD; Uwe Johansson, MD; Daniel Wendt, MD; Heinz G. Jakob, MD; Michael Forsting, MD; Stefan Sack, MD, FESC; Raimund Erbel, MD, FESC; Holger Eggebrecht, MD, FESC

From the Departments of Cardiology and Thoracic and Cardiovascular Surgery, West German Heart Center Essen; and Institute of Diagnostic and Interventional Radiology and Neuroradiology and Department of Neurology, University Hospital Essen, University Duisburg-Essen, Essen, Germany.

Background— The risk of stroke after transfemoral aortic valve implantation (TAVI) due to dislodgement and subsequent embolization of debris from aortic arch atheroma or from the calcified

Conclusions— Clinically silent new foci of restricted diffusion on cerebral magnetic resonance imaging were detected in almost all patients (84%) undergoing TAVI. Although typically multiple, these foci were not associated with apparent neurological events or measurable deterioration of neurocognitive function during 3-month follow-up. Further work needs to be directed to determine the clinical significance of these findings in a larger patient population.
Example of an 82-year-old patient two days after successful TAVI
Group 1: 89 new DWI lesion in 19 of 22 patients (86%)
Group 2: 26 new DWI lesions in 8 of 10 patients (80%)
Group 3: 33 new DWI lesions in 10 of 21 patients (48%)

Lesion size was significantly smaller in TAVI patients.
268 of 3404 CABG patients (8%) had atheroma (≥ 5 mm, or mobile) defined by epi-aortic ultrasound\(^1\)

15.3\% of group had intra-operative stroke\(^1\)

Claret
Claret – Dual Filter Protection
Claret – Dual Filter Protection

Clinical Experience
Essen Germany – Dr. Christoph Naber
Claret with Edwards Delivery

Patient #1 88 year old female with Aortic stenosis
TAVI w/Medtronic CoreValve

Patient: 82 year old female with Aortic stenosis
TAVI w/Edwards - Sapien
Claret Dual Filter Device

Handle

Filters Sheathed

Filters Deployed
CT Rendering – Normal Anatomy
CT Rendering – Normal Anatomy
CT Rendering – Complex Anatomy
Claret - Complex Anatomy

CT Aortic Arch

Fluoro Aortic Arch
Embolic Material
Embolic Material
Embolic Material
Embolic Material
Embolic Material
<table>
<thead>
<tr>
<th>Clinical Data (latest)</th>
<th>DIRECT (no guidewire)</th>
<th>OTW</th>
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<tbody>
<tr>
<td>Number of Patients Treated</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Age Range</td>
<td>75-87</td>
<td>N/A</td>
</tr>
<tr>
<td>Female / Male</td>
<td>4 (80%) / 1 (20%)</td>
<td>0 (0%) / 3 (100%)</td>
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<tr>
<td>Logistic EuroSCORE</td>
<td>15-35</td>
<td>10-29</td>
</tr>
<tr>
<td>Valve Type</td>
<td>3 – Medtronic/CoreValve (100%)</td>
<td>3 – Medtronic/CoreValve (100%)</td>
</tr>
<tr>
<td></td>
<td>2 – Edwards Sapien</td>
<td>0 – Edwards Sapien (0%)</td>
</tr>
<tr>
<td>Average Delivery and Deployment Time</td>
<td>19 minutes</td>
<td>9 minutes</td>
</tr>
<tr>
<td>Brachiocephalic Filter Placement Success</td>
<td>5/5 (100%)</td>
<td>3/3 (100%)</td>
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<tr>
<td>Left Carotid Filter Placement Success</td>
<td>3/5 (60%)</td>
<td>3/3 (100%)</td>
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Claret Dual Filter System

- Carotid Filtration (embolic material captured and removed)
- Right Radial/Brachial Access, OTW (0.014")
- 6F Sheath
- 140 Micron Pore Size
- (8) TAVI Clinical cases (Germany)
- CE Mark in process (Approval target Q4 2010)
Clinical Use: What we learned

- System can be safely delivered via radial or brachial entry
- Standard 6F introducer, over a 0.014 guidewire
- Embolic material was found in nearly all filters deployed
- Claret catheter did NOT interfere with any valve delivery or retrieval
Stroke Devices for TAVI Procedures
Thank you!