

TCT 2010

**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.

Physician Name

Company/Relationship

Eberhard Grube, MD
OF

Medtronic, CoreValve: C, SB, AB,

Sadra Medical: E, C, SB, AB

Direct Flow: C, SB, AB

Mitralign: AB, SB, E

Boston Scientific: C, SB, AB

Biosensors: E, SB, C, AB

Cordis: AB

Abbott Vascular: AB

Capella: SB, C, AB

Devax: SB, AB,

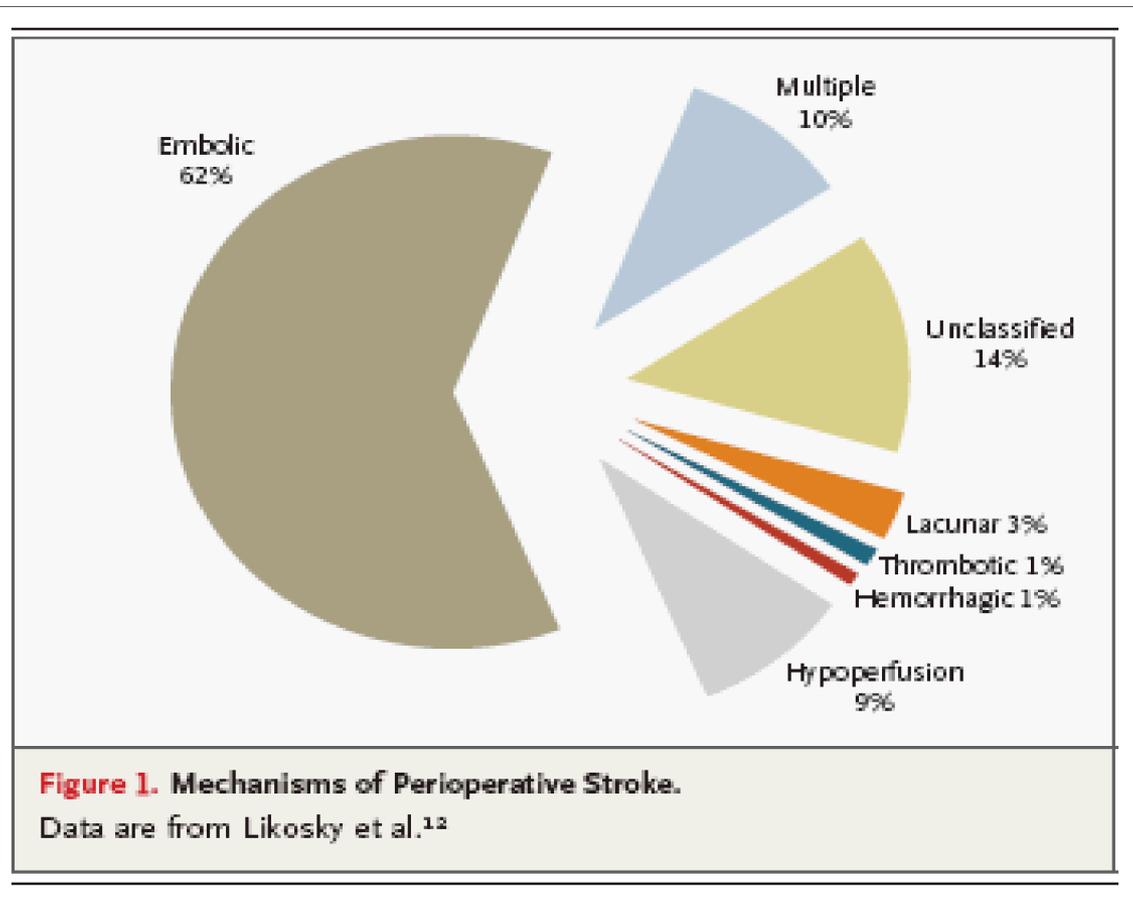
Embrella: SB

Claret: SB

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



84% SILENT STROKE following TAVI

Circulation. 2010;121:870-878
doi: 10.1161/CIRCULATIONAHA.109.855866

Stroke

Silent and Apparent Cerebral Ischemia after Percutaneous Transfemoral Aortic Valve Implantation

A Diffusion-Weighted Magnetic Resonance Imaging Study

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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.

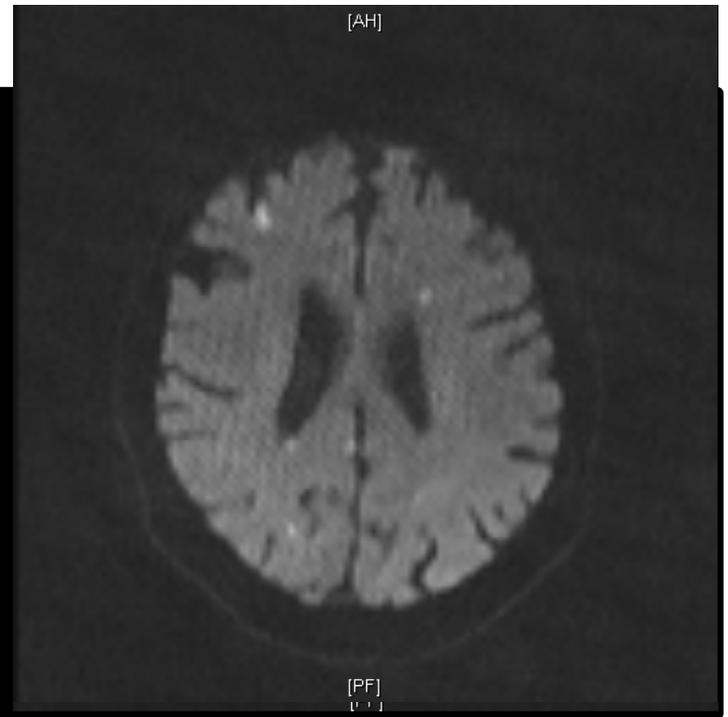
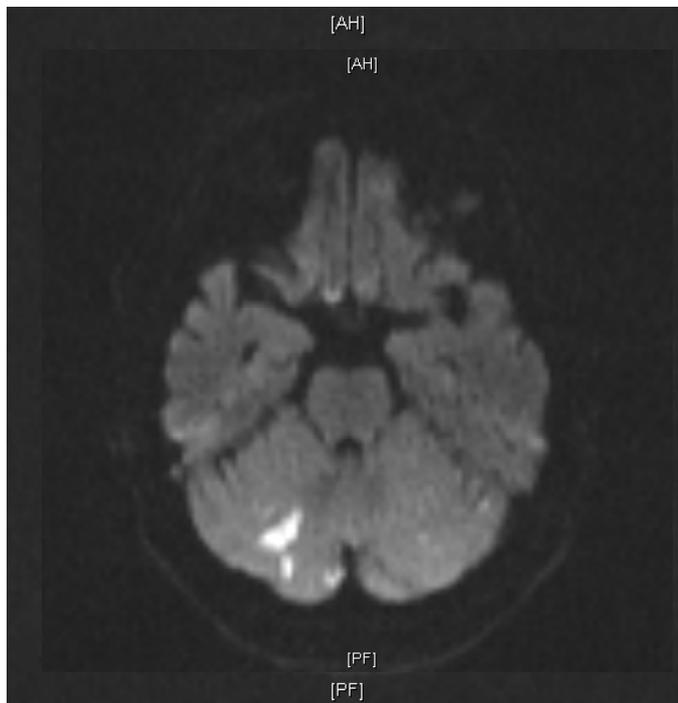
Background— The risk of stroke after transfemoral aortic valve implantation (TAVI) due to dislodgement and subsequent embolization of debris from aortic arch atheroma or from the calcified

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.

Circulation

Diffusion-Weighted MRI Study

Example of an 82-year-old patient two days after successful TAVI



Diffusion-Weighted MRI Study

Group 1 → 

Group 2 CoreValve(n=10)

Group 3 Surgical aortic valve
replacement *

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.

Aortic Atheroma: High Risk



- **High Risk for:**

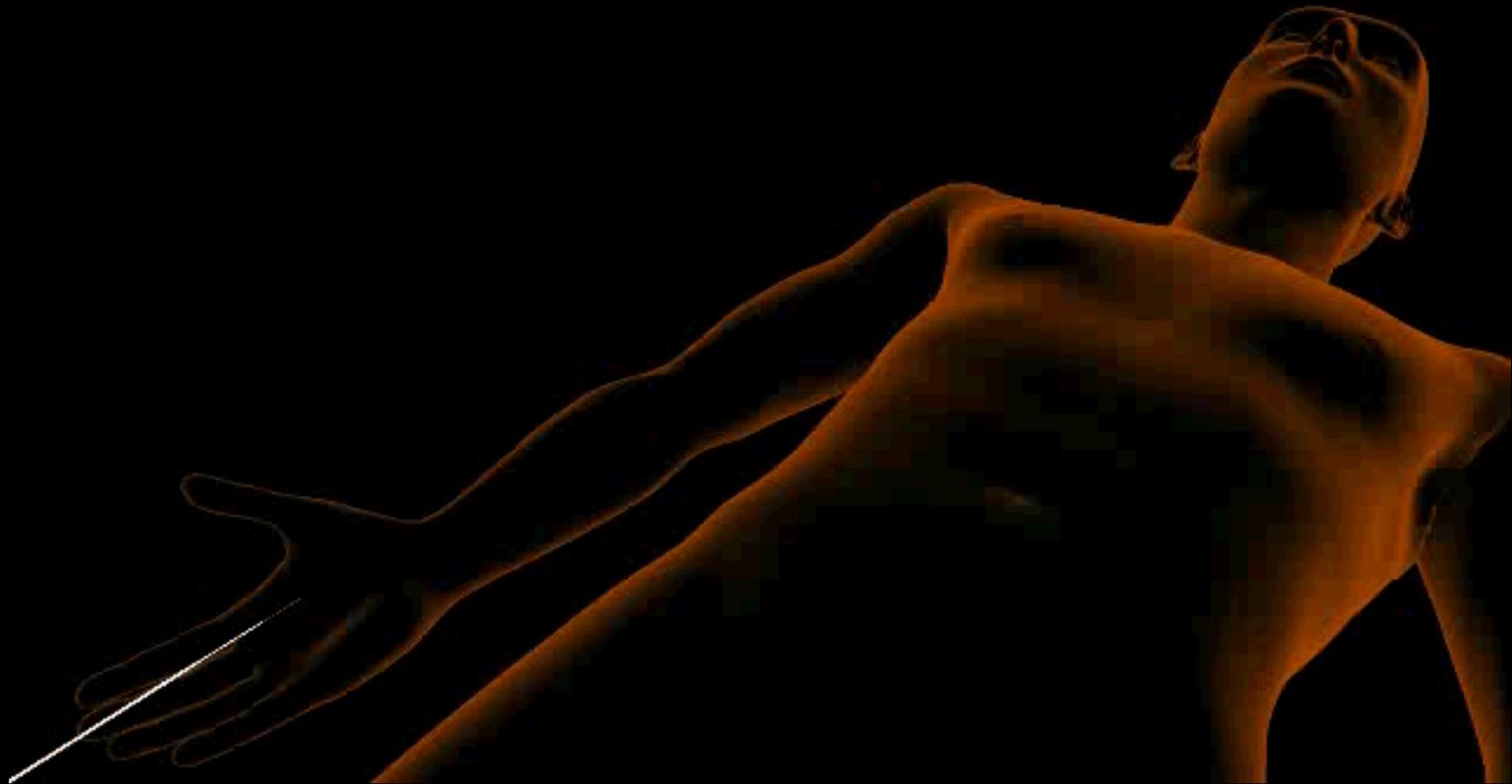
- Intra-operative stroke
- Multiple morbidity
- Prolonged hospital stay,
- Death resulting from heart surgery.¹

268 of 3404 CABG patients (8%) had atheroma (≥ 5 mm, or mobile) defined by epi-aortic ultrasound¹

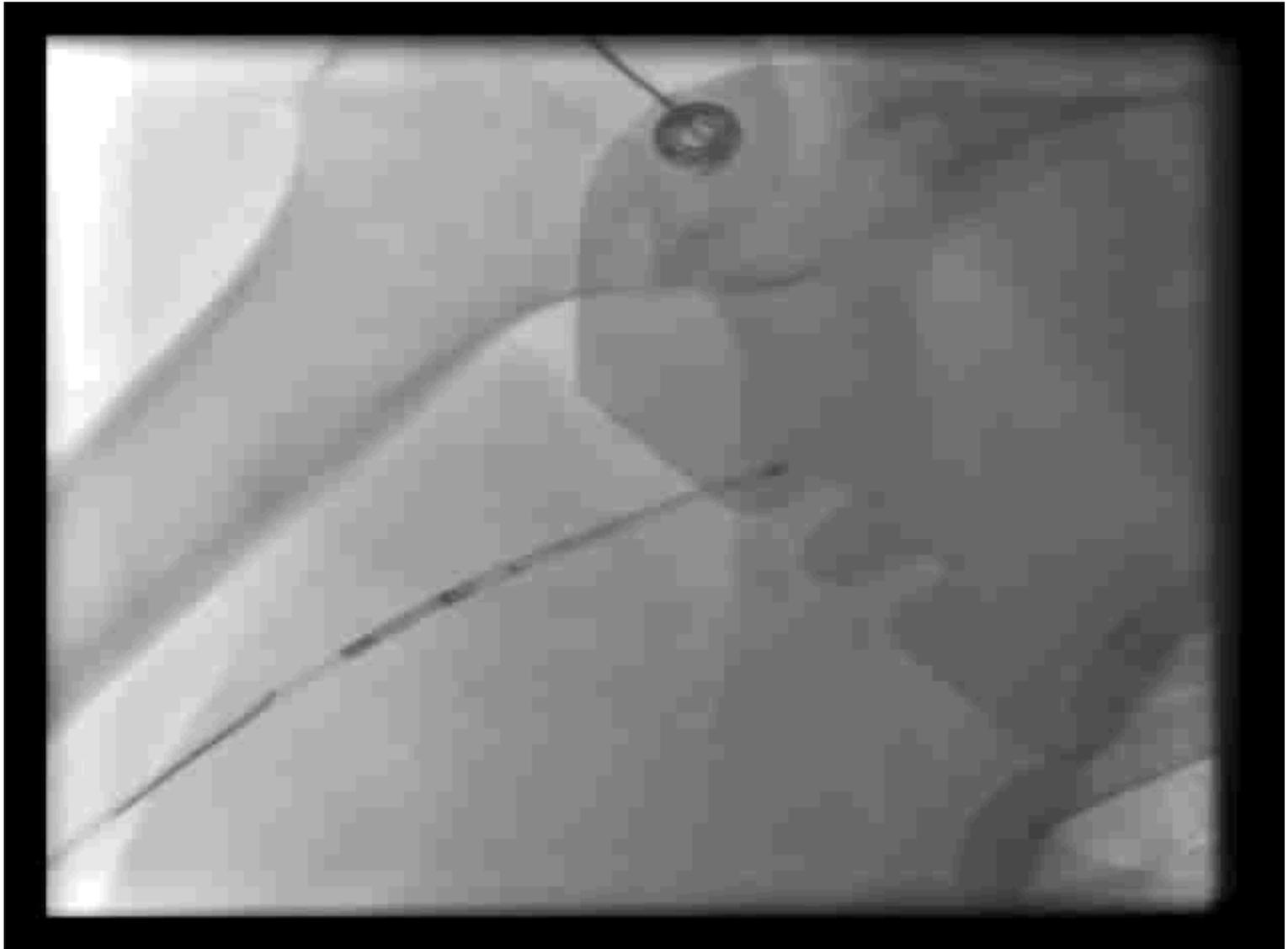
15.3% of group had intra-operative stroke¹

¹Protruding aortic arch atheromas: risk of stroke during heart surgery with and without aortic arch endarterectomy. Stern et al. American Heart Journal Oct. 1999.

Claret



Claret – Dual Filter Protection

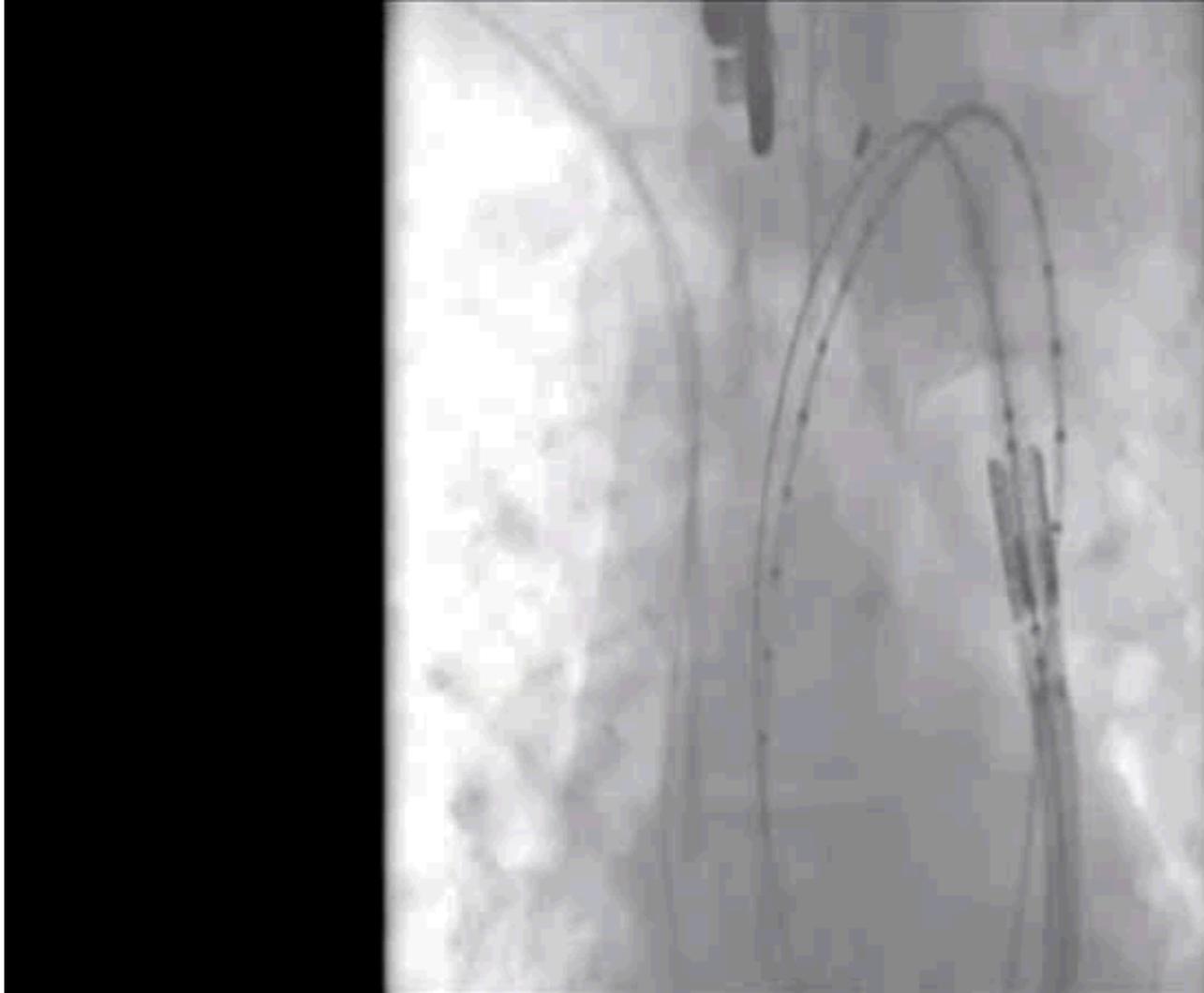


Claret – Dual Filter Protection



Clinical Experience
Essen Germany – Dr. Christoph Naber

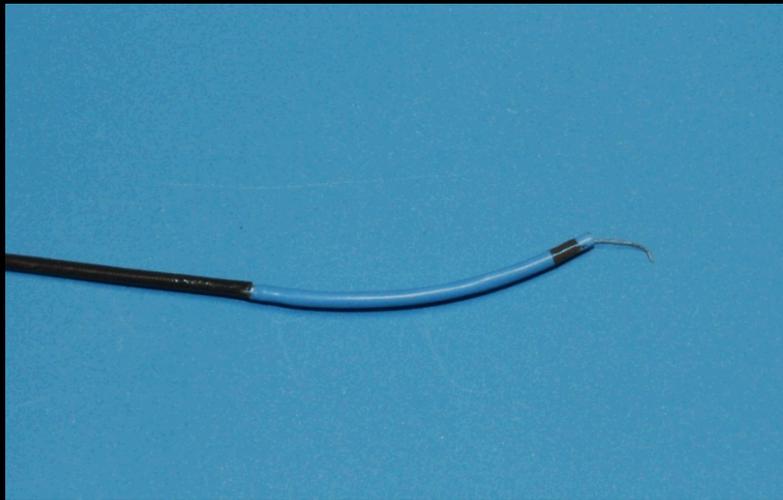
Claret with Edwards Delivery



Claret Dual Filter Device



Handle

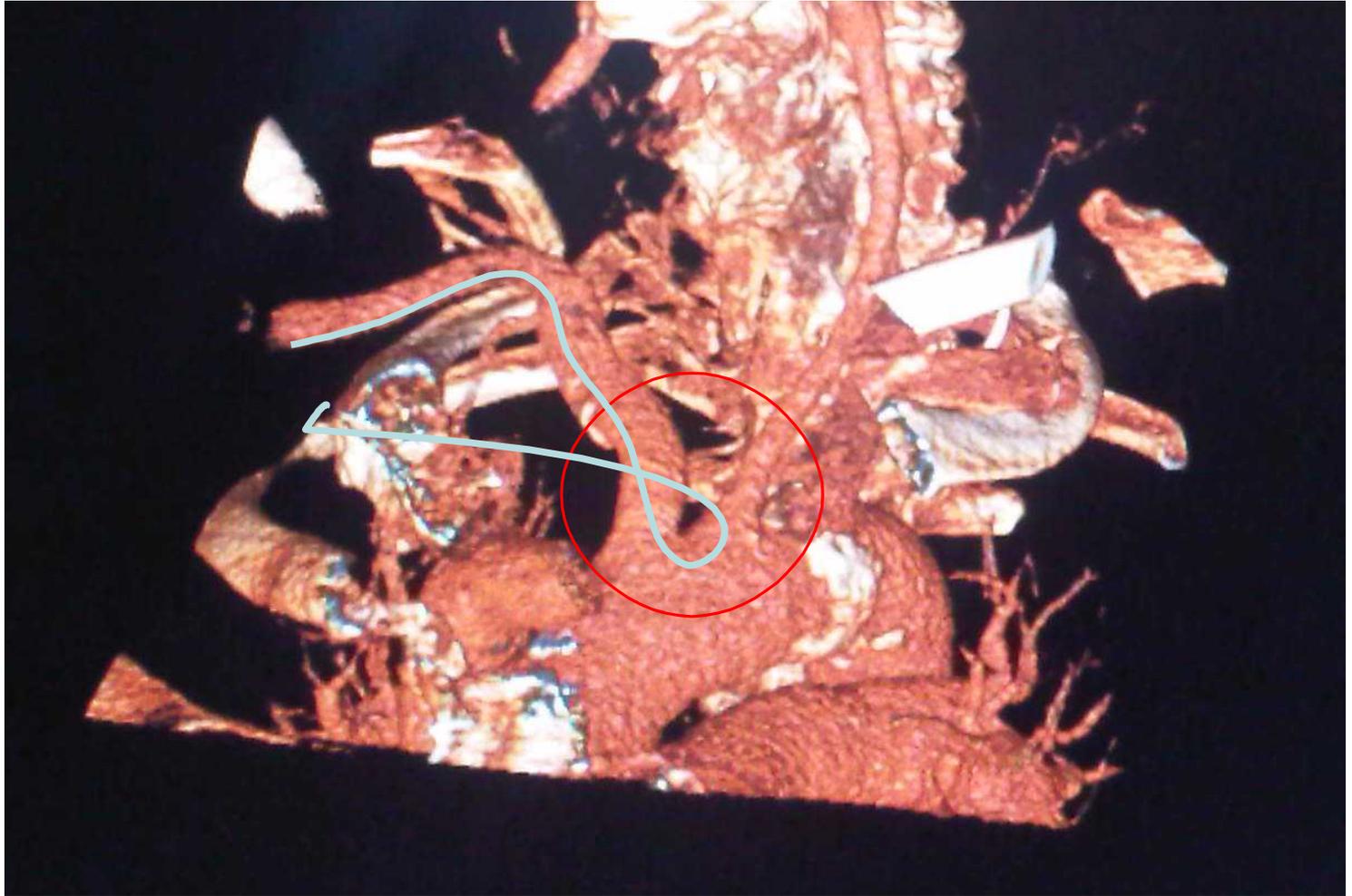


Filters Sheathed

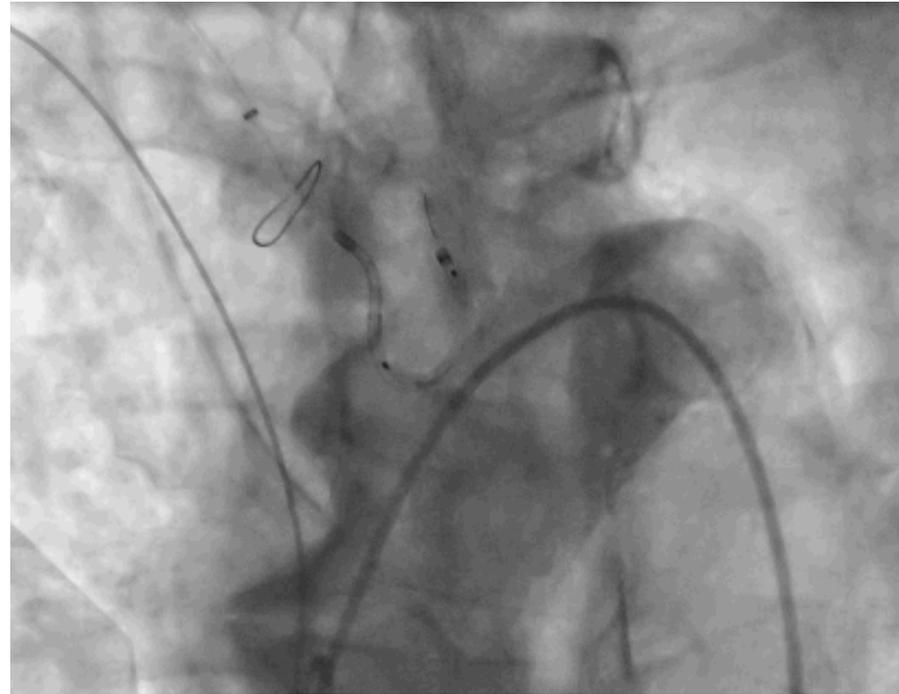
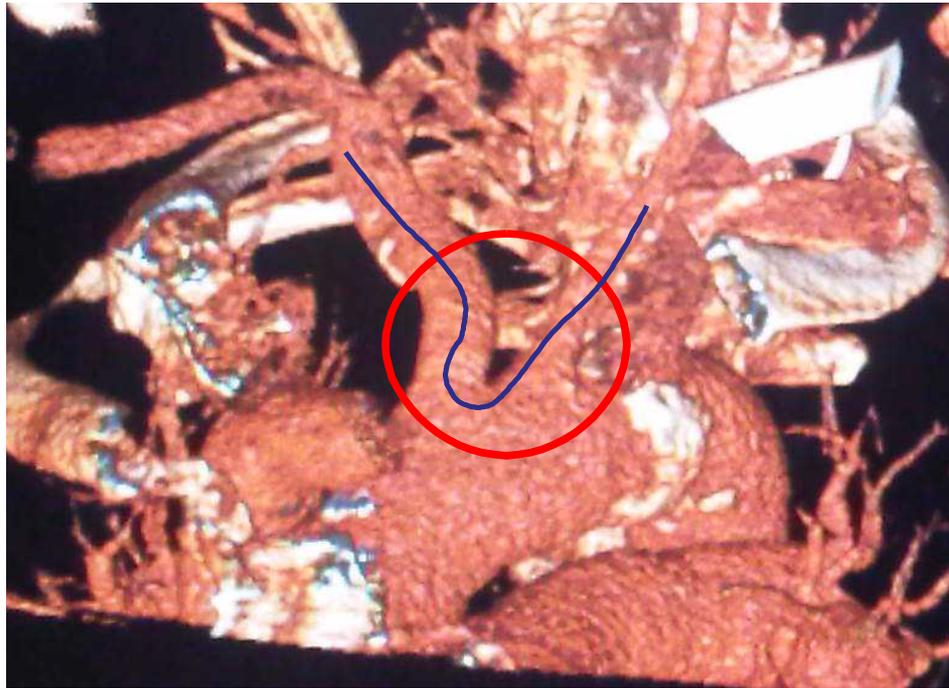


Filters Deployed

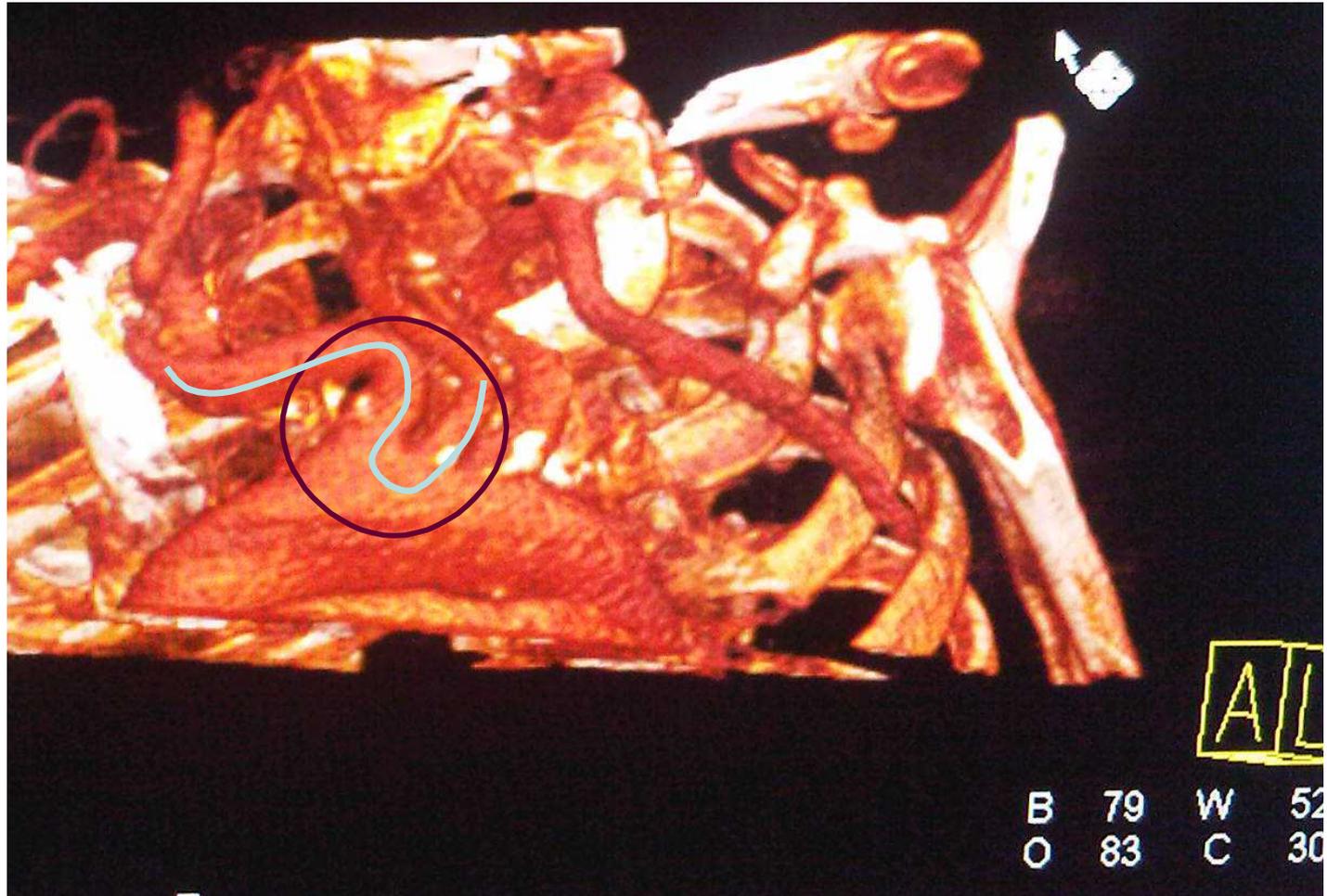
CT Rendering – Normal Anatomy



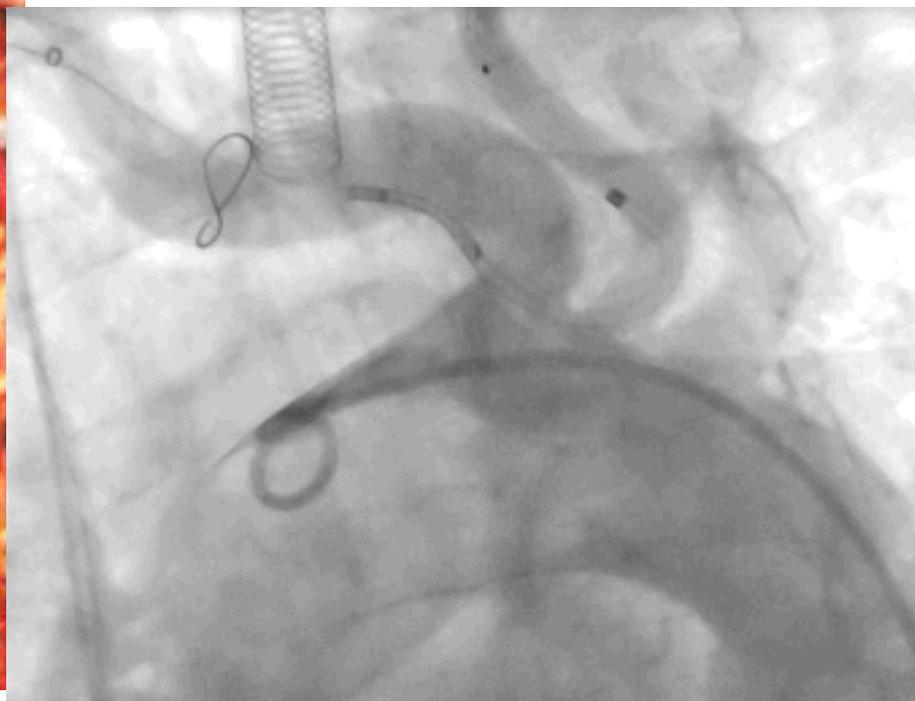
CT Rendering – Normal Anatomy



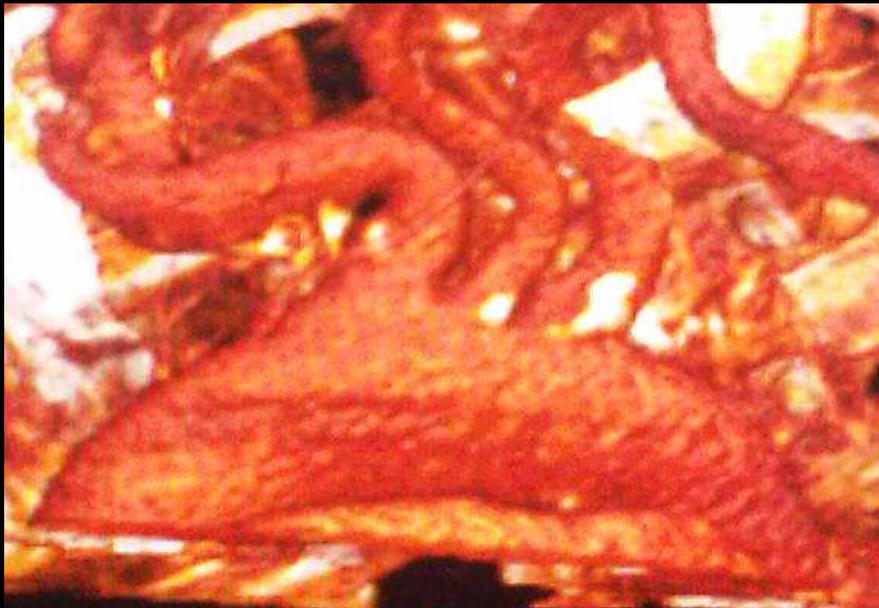
CT Rendering – Complex Anatomy



CT Rendering – Complex Anatomy



Claret - Complex Anatomy

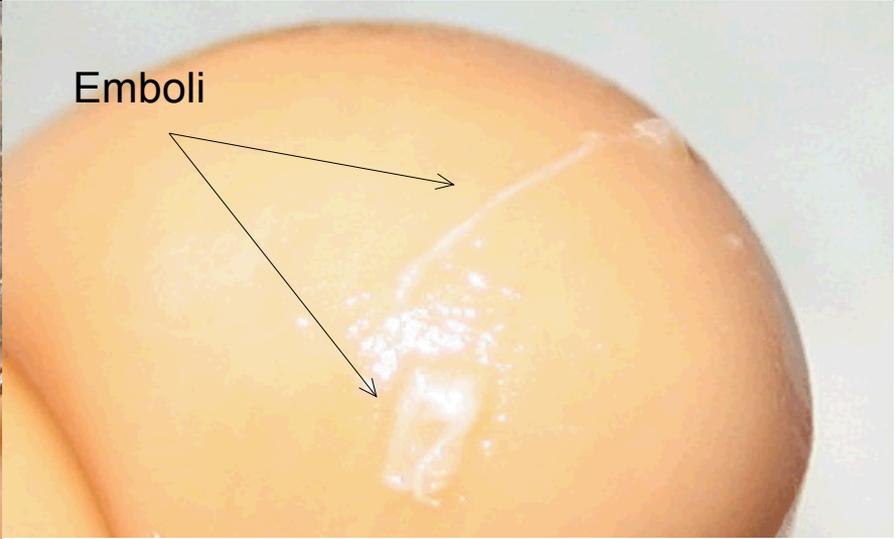
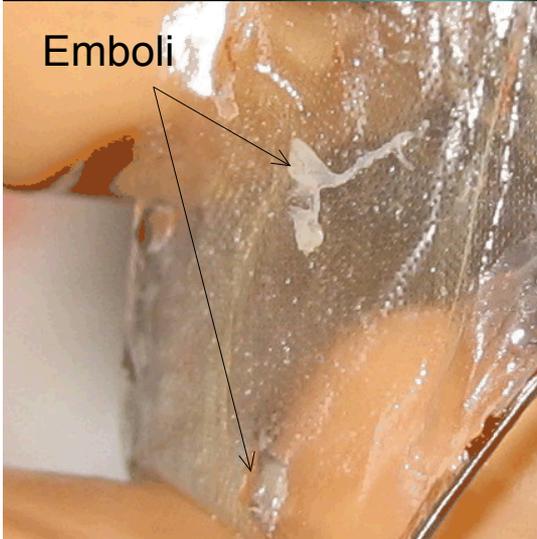
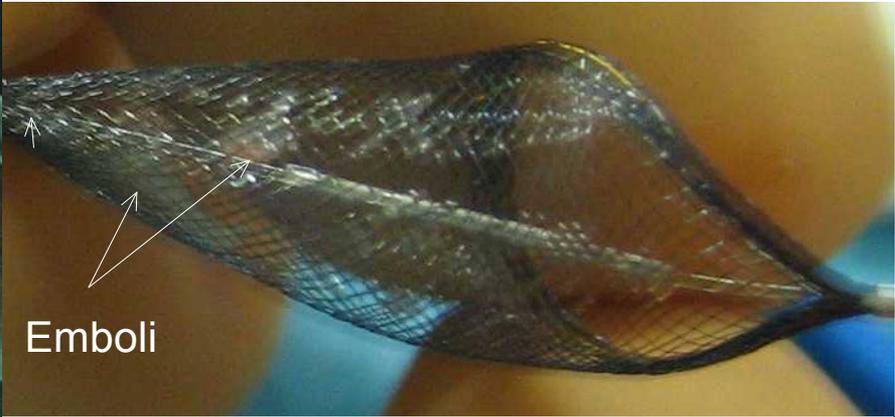
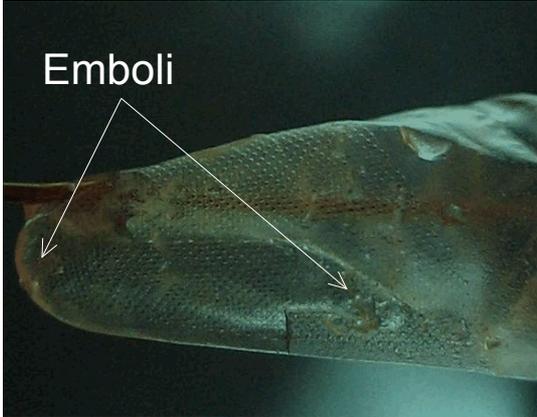


CT Aortic Arch

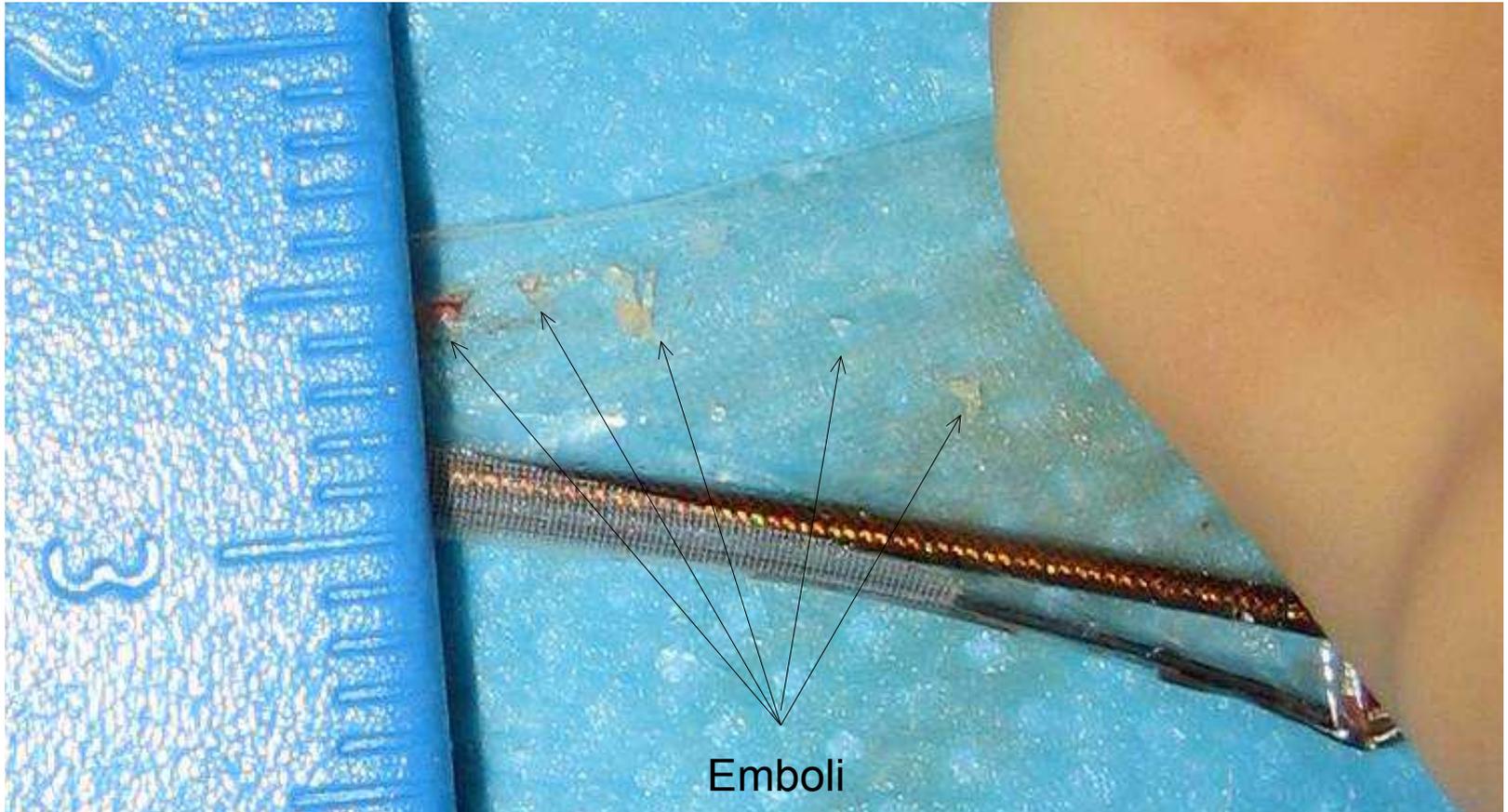


Fluoro Aortic Arch

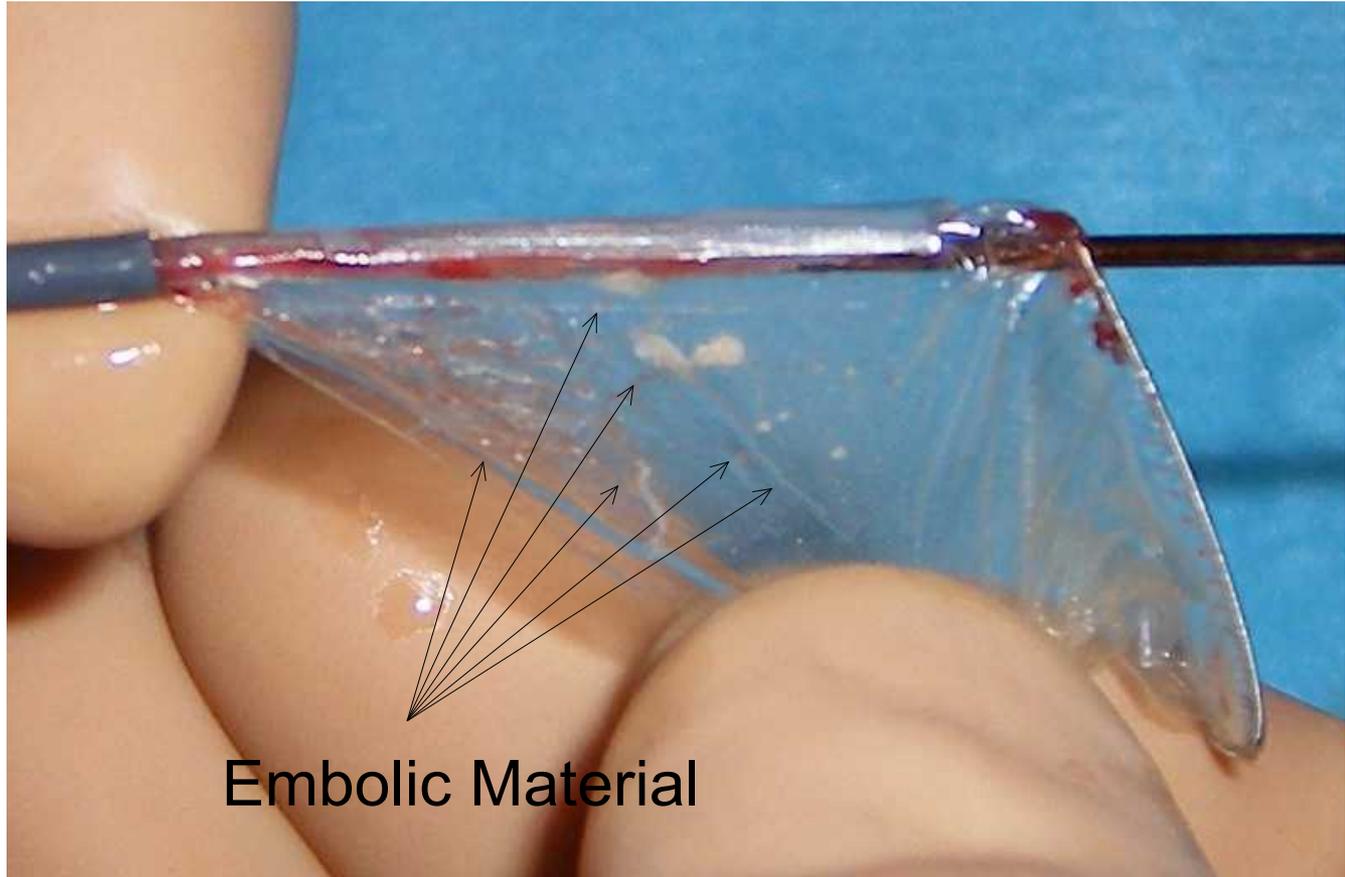
Embolitic Material



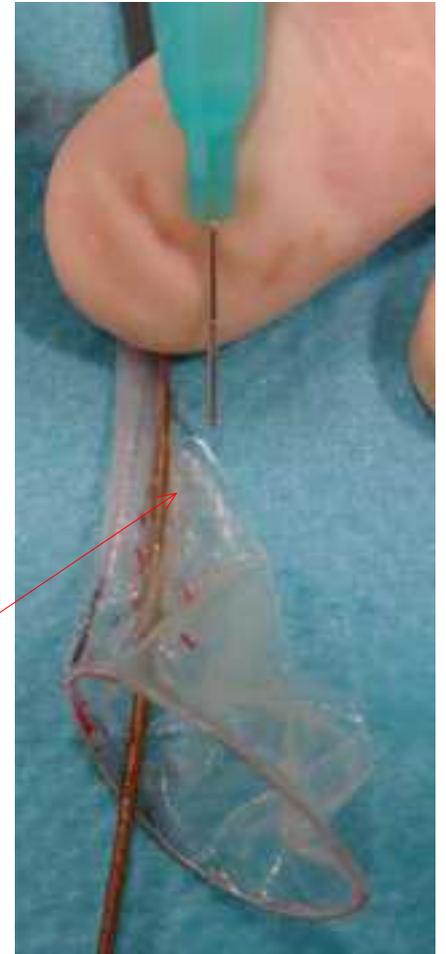
Embolic Material



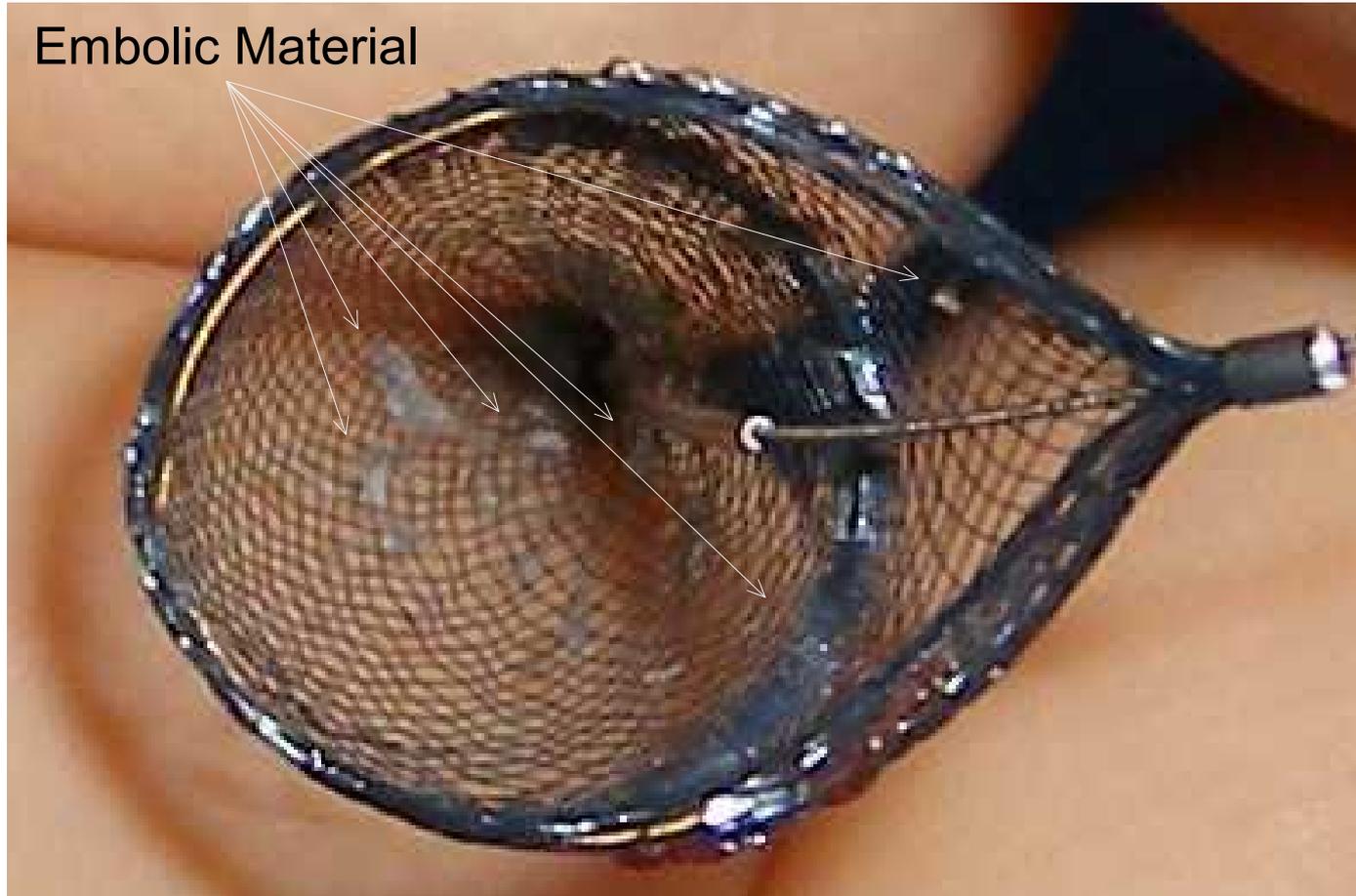
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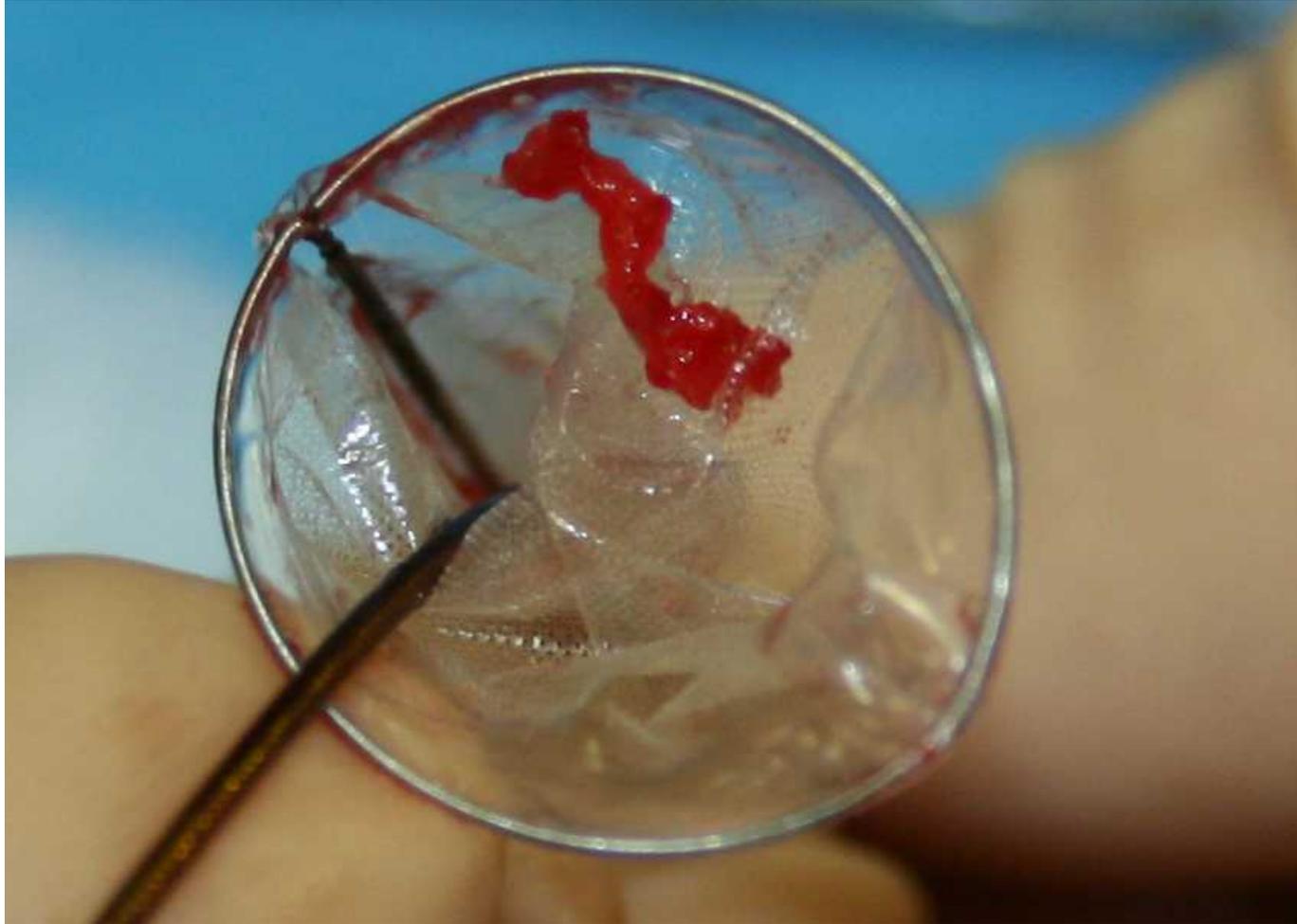
Embololic Material



Embolic Material



Embolitic Material



Clinical Data (latest)

	<u>DIRECT (no guidewire)</u>	<u>OTW</u>
Number of Patients Treated	5	3
Age Range	75-87	N/A
Female / Male	4 (80%) / 1 (20%)	0 (0%) / 3 (100%)
Logistic EuroSCORE	15-35	10-29
Valve Type	3 – Medtronic/CoreValve 2 – Edwards Sapien	3 – Medtronic/CoreValve (100%) 0 – Edwards Sapien (0%)
Average Delivery and Deployment Time	19 minutes	9 minutes
Brachiocephalic Filter Placement Success	5/5 (100%)	3/3 (100%)
Left Carotid Filter Placement Success	3/5 (60%)	3/3 (100%)

Claret Dual Filter System

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Clinical Use: What we learned

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Stroke Devices for TAVI Procedures

Thank you!