

Stroke during TAVI

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Disclosure Statement of Financial Interest

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

Financial Relationship

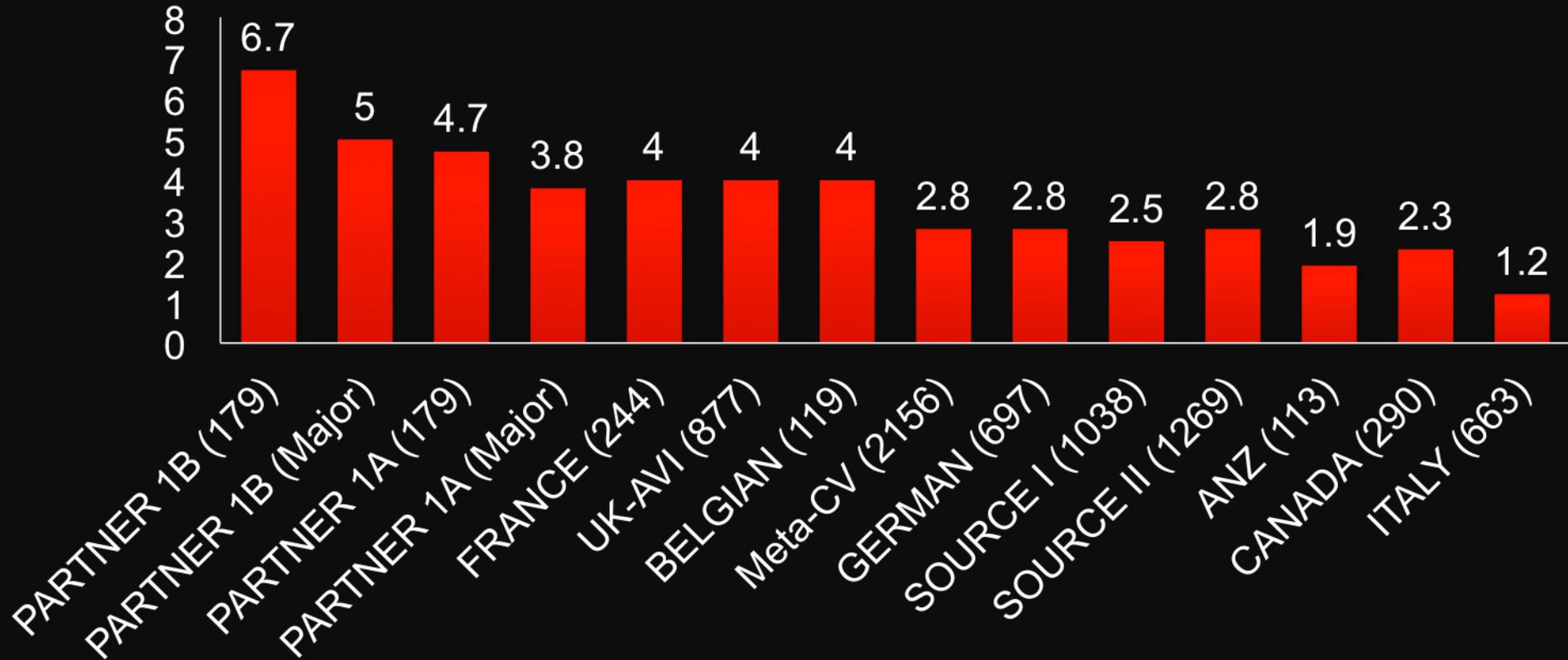
- Grant/Research Support

Company

- Edwards Lifesciences
- Siemens
- Phillips
- Paieon Medical
- Valtech Cardio
- Guided Delivery Systems
- Cardiapex
- Entourage Medical
- St Jude Medical
- Endoluminal Solutions



Stroke Rates at 30 days



Patient factors

- **Age**
- **History of cerebrovascular disease/stroke**
- **LV dysfunction**
- **Atrial fibrillation**
- **Bulky aortic atheroma**
- **Complex access issues**



Mechanical factors

- **Catheter/wire passage**
 - Arch, Cerebral vessel, Valve
- **Valve Delivery system**
 - Arch, Cerebral vessel, Valve
- **Balloon valvuloplasty**
- **Valve deployment**
- **Valve redilation**



Thrombus

- **Clot on devices / wires**
 - Dwell time, anticoagulation
- **Injected clot**
 - Flushing, anticoagulation
 - Pigtails, apical sheaths
- **LV thrombus**
 - Screening echo, apical access



Hypoperfusion

- **Bleeding**
- **Low output state / hypotension**
- **Air emboli**



Athero-calcific embolism

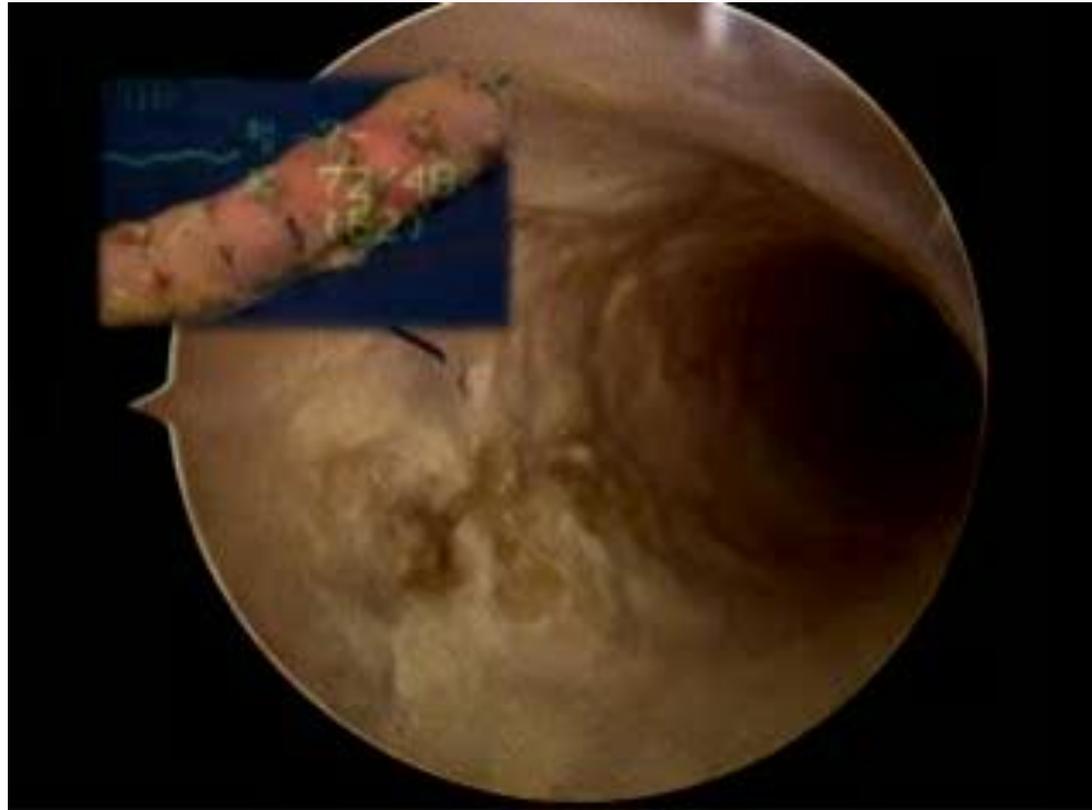
Aorta



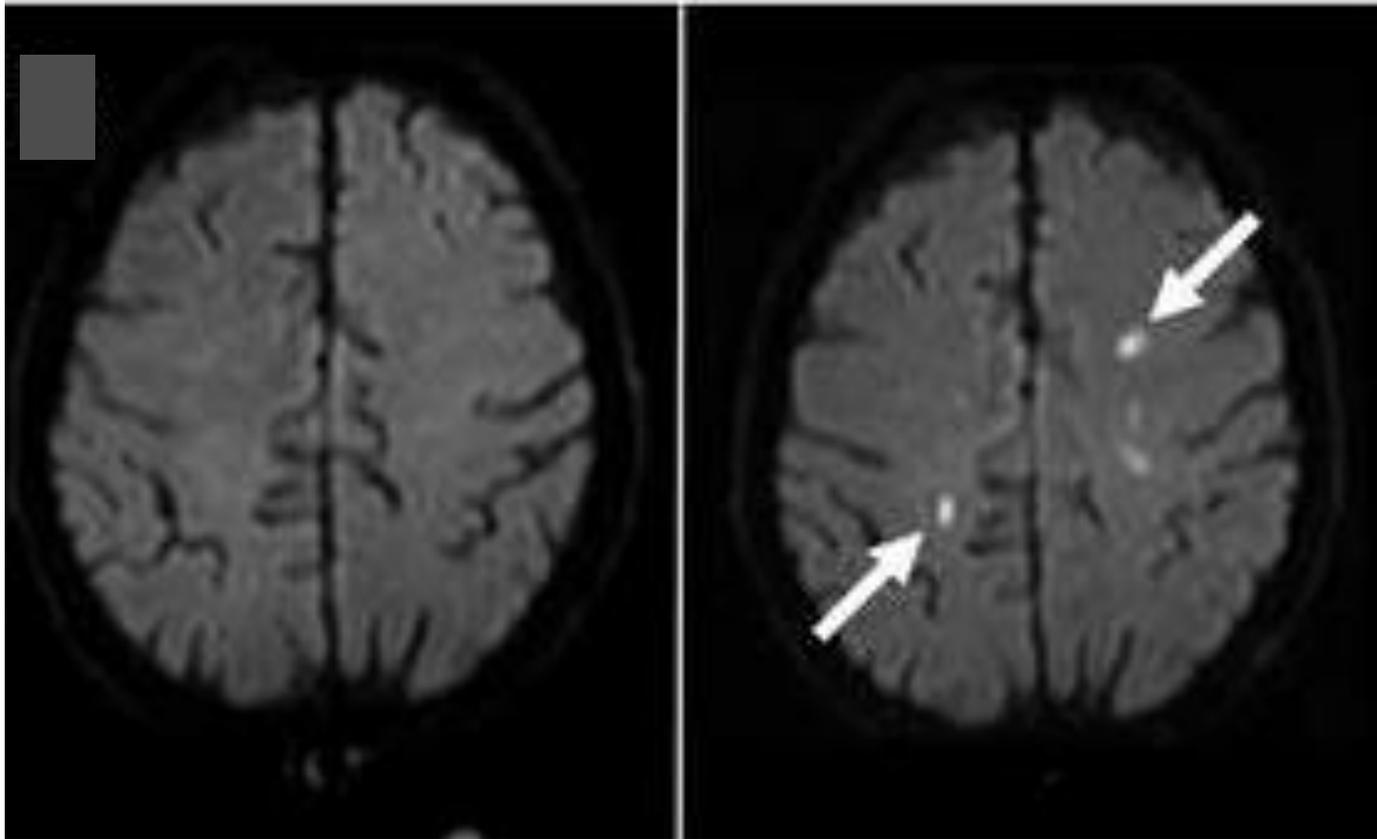
Valve



In vitro model of athero-embolism



New DW-MRI lesions post TAVI are common



DW-MRI after TAVI

Ghanem	CoreValve	22	73%	10%
Knipp	SAPIEN	27	58%	4%
Kahlert	Both	32	84%	0%
Astarci	Both	35	91%	0%
Rodes, Webb	SAPIEN	60	68%	3.3%



Embrella Embolic Deflector

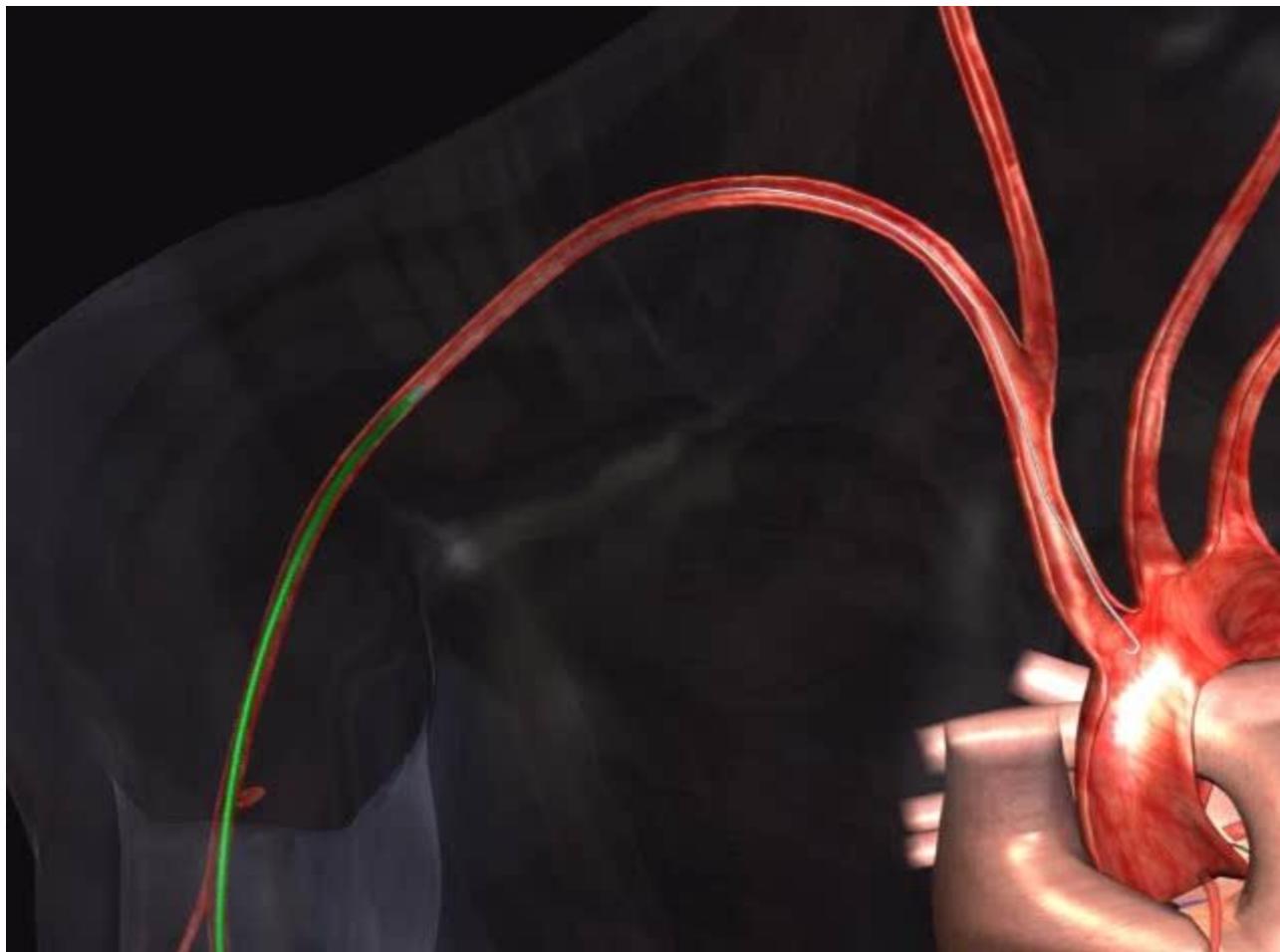
Edwards Lifesciences



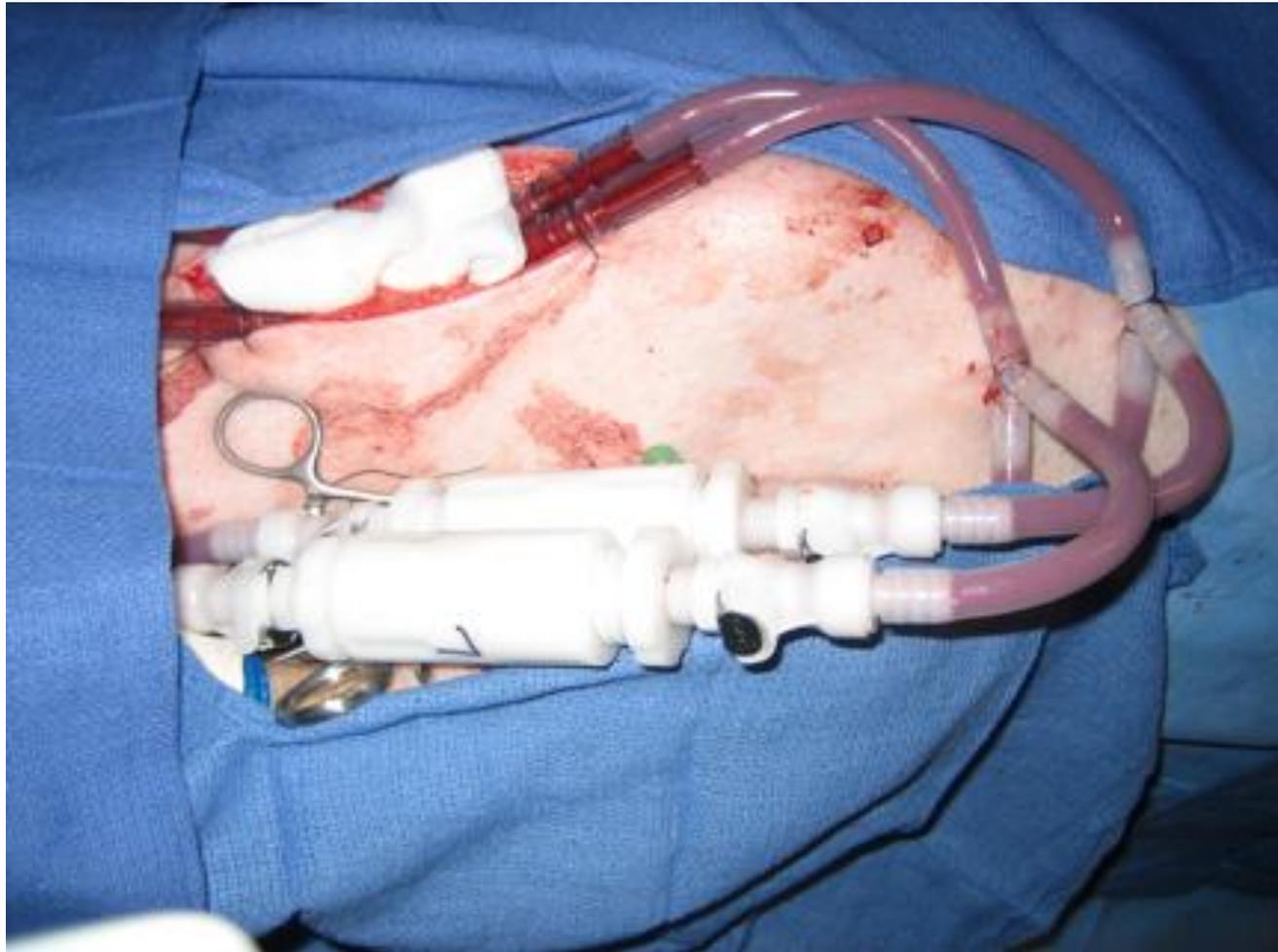
- Porous membrane designed to deflect embolic debris
- Nitinol® Frame & Shaft
- Polyurethane Porous Membrane
- Hydrophillic coating with anti-thrombogenic properties
- 3 Radiopaque Markers



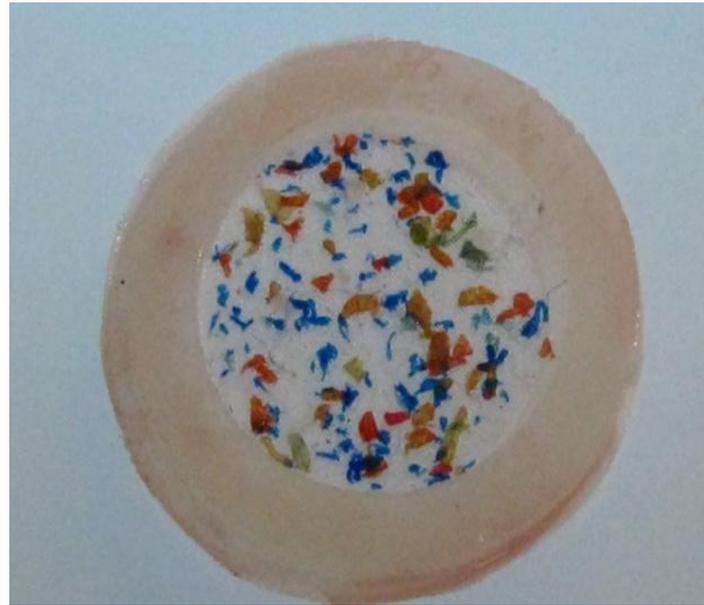
Embololic deflection



Porcine carotid embolization model



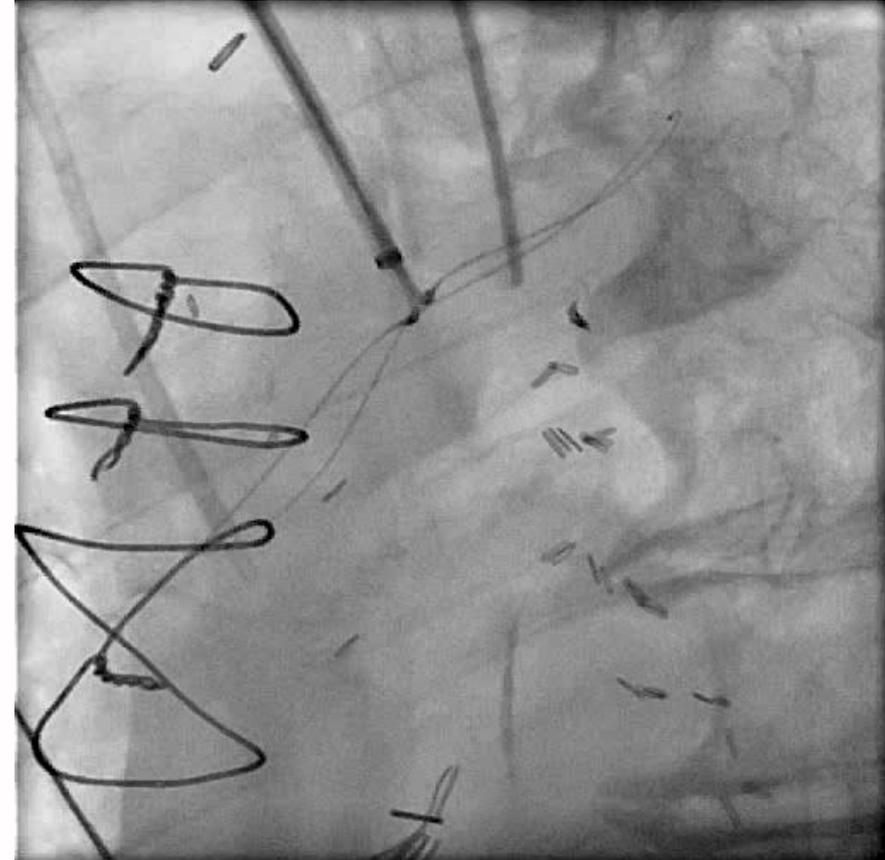
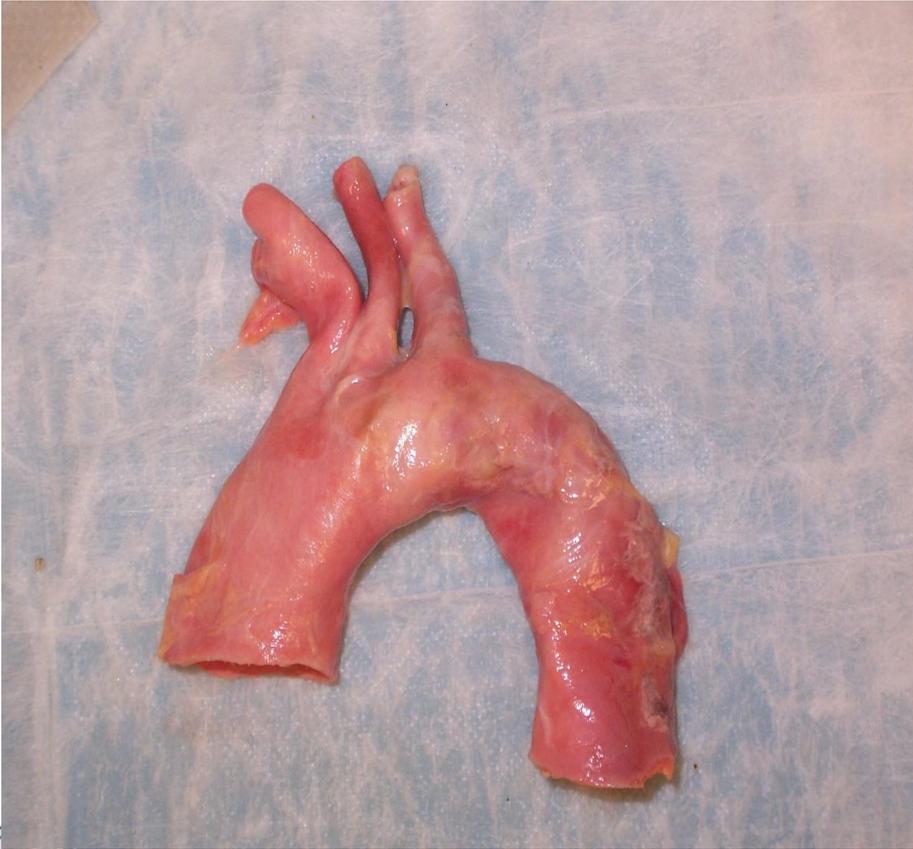
No Deflector



Deflector



Cerebral vessel coverage



Total Clinical Experience

Clinical Sites	
St. Paul's Hospital Vancouver, BC	16
HELIOS Heart Center, Siegburg, DE	14
Hamburg University Cardiovascular Center Hamburg, DE	8
Städtisches Klinikum und Herzklinik Karlsruhe, DE	2
TOTAL	40

TAVI = 38

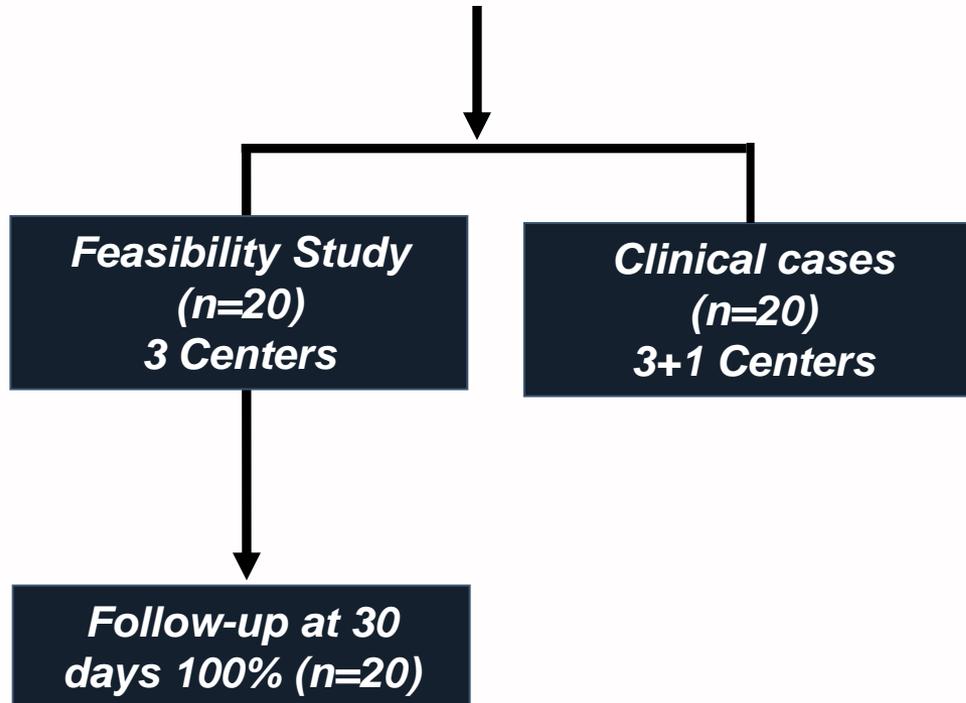
TF=35, TA=1

Edwards=24, CoreValve 14)

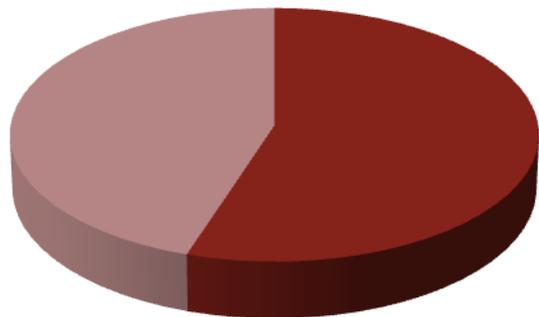
Valvuloplasty = 2



**40 Patient Experience Dec 2009 - Sep 2011
4 sites in Germany and Canada**



Index Procedure (n=20)



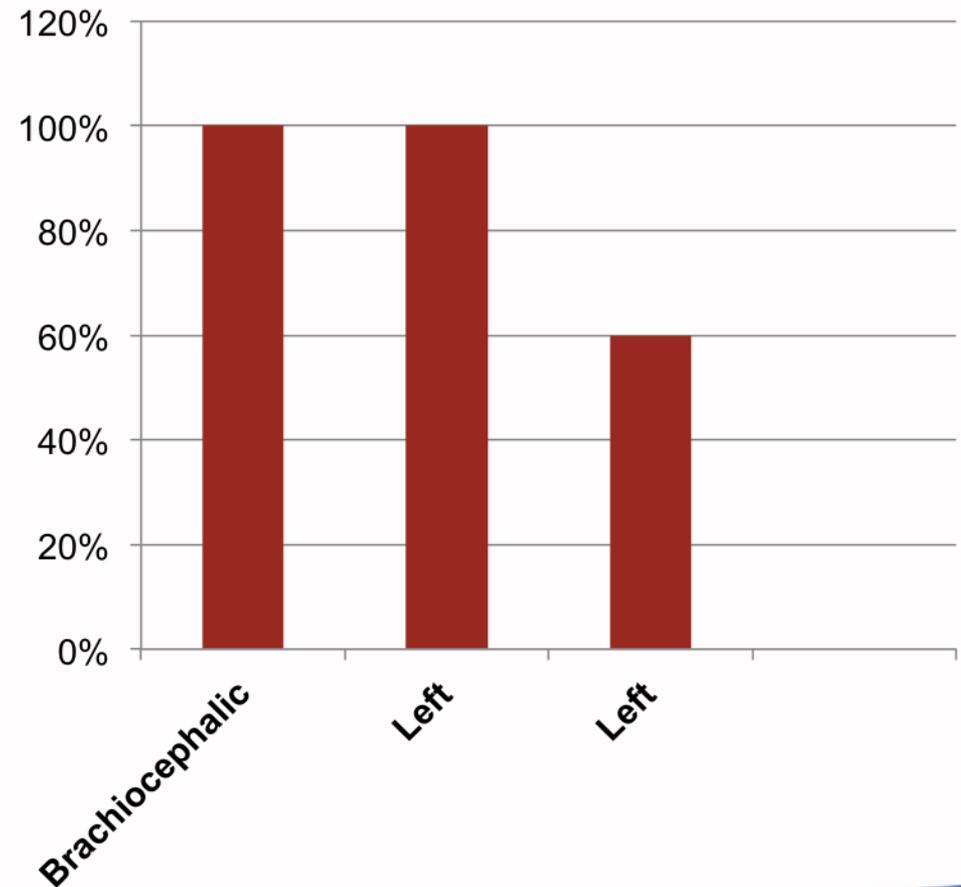
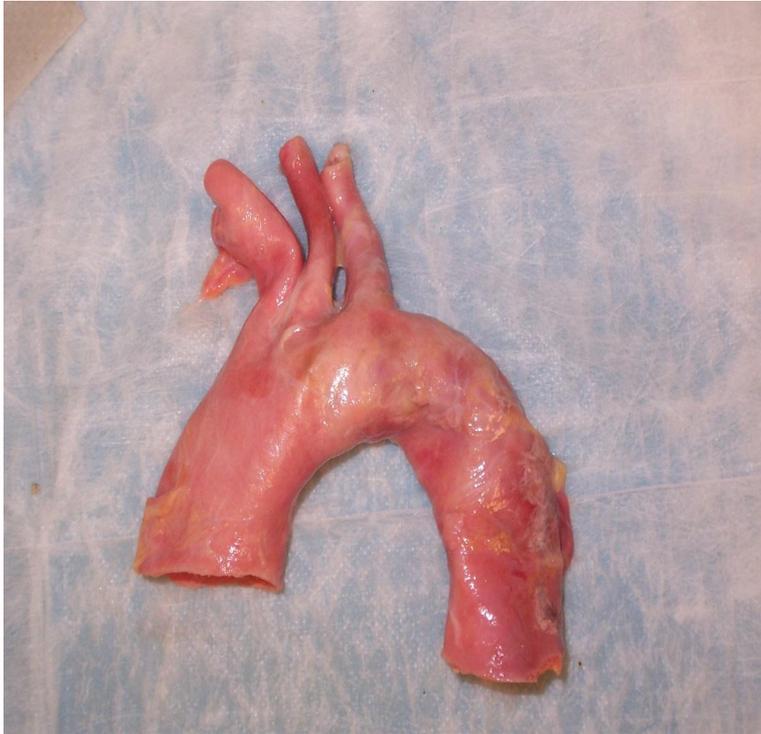
■ Radial
55%
■ Brachial
45%

Access Site (n=20)

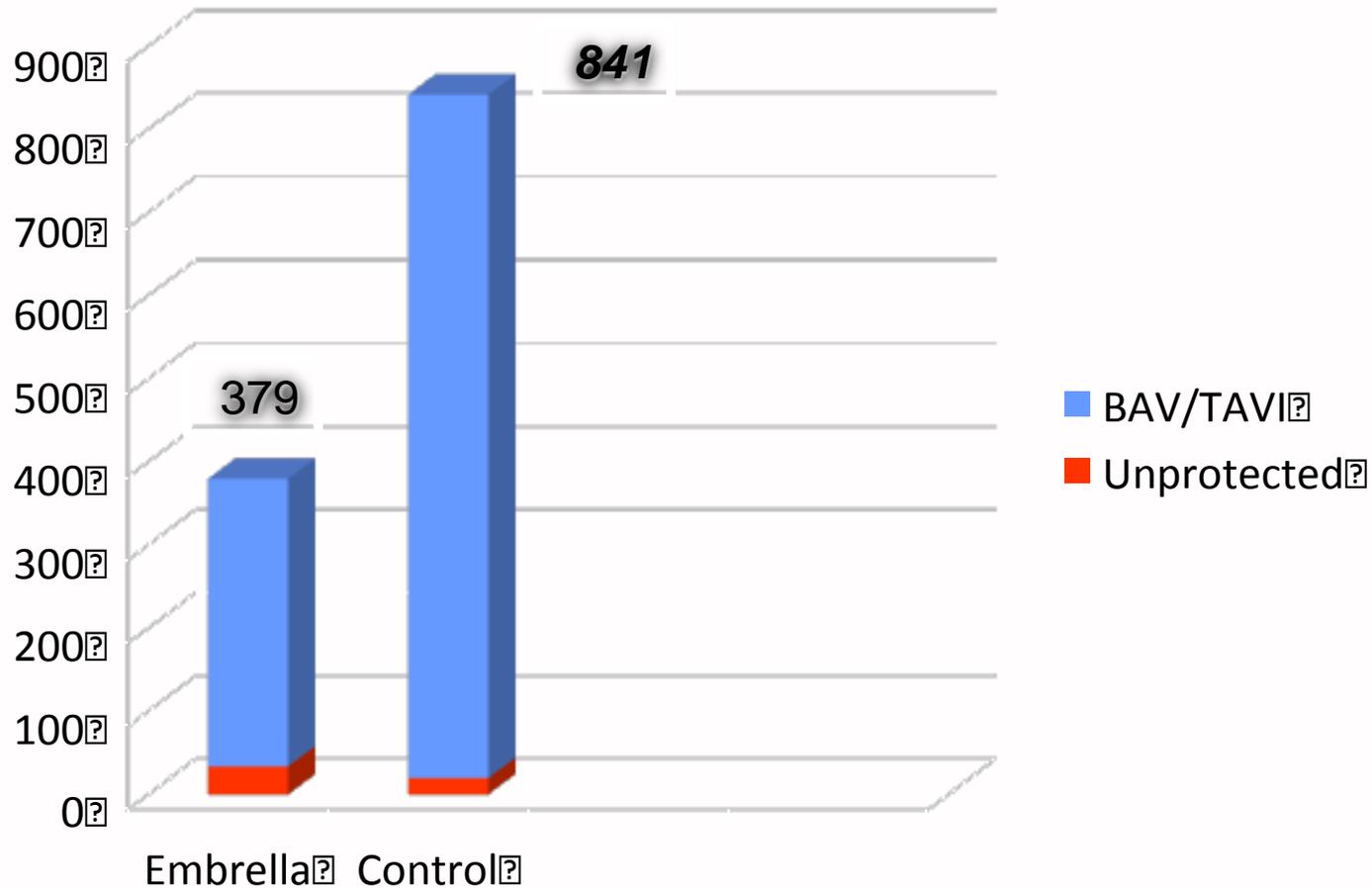


■ Radial 55%
■ Brachial 45%

Arch Arteries Coverage



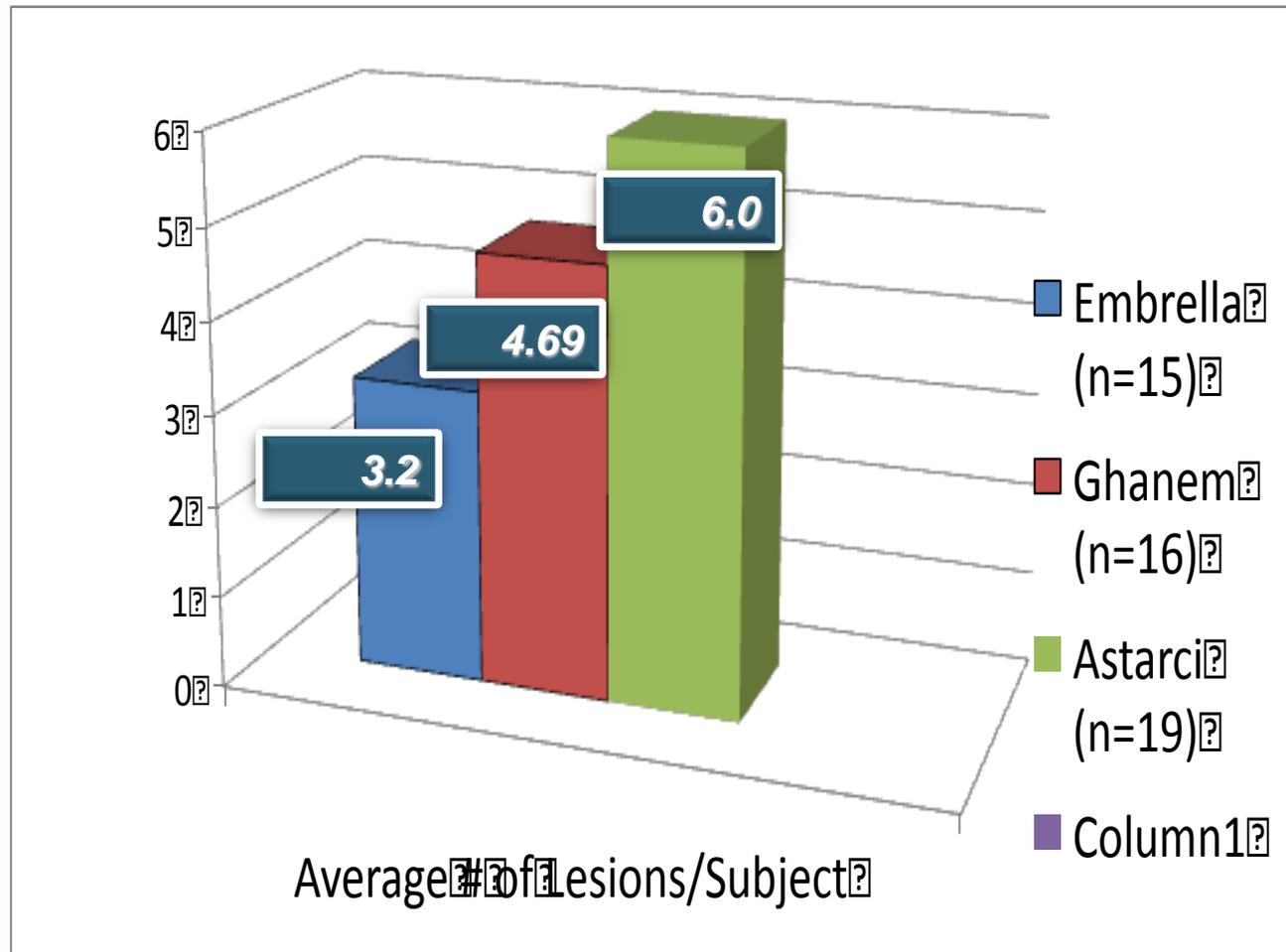
Average # of TCD HITS/Subject



Technical Feasibility

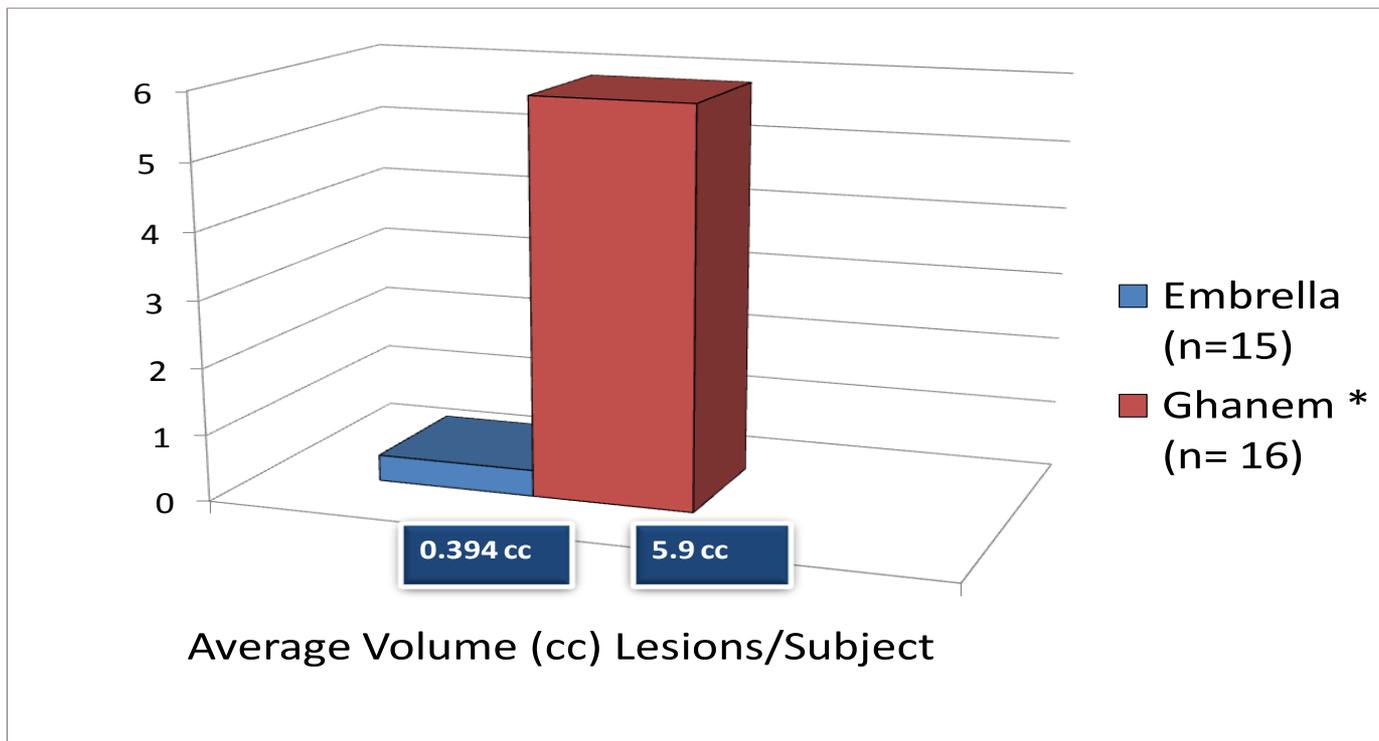
Measure	Number Successful	Technical Success
Device Deployment	18/18	100%
Device Seated Against Aortic Arch	18/18	100%
Covered Ostia of Brachiocephalic and LCC Arteries	18/18	100%
Device Removal	18/18	100%

Average Number of Lesions/Subject



Ghanem et al, J Am Coll Cardiol 2010;55:1427–32
Astarci et al, Abstract presentation EACTS 2010

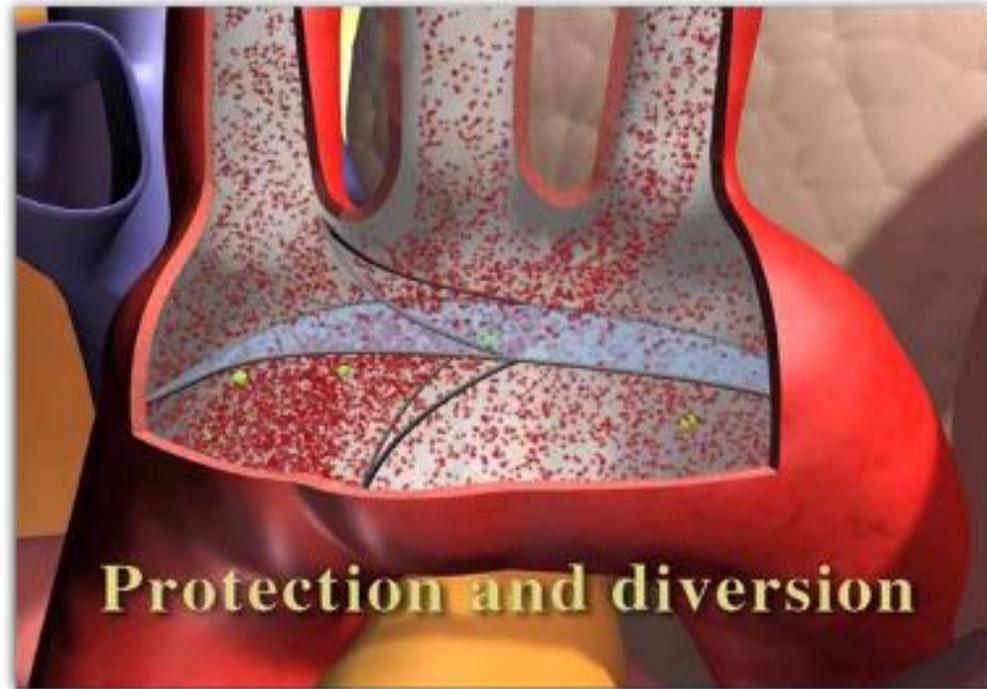
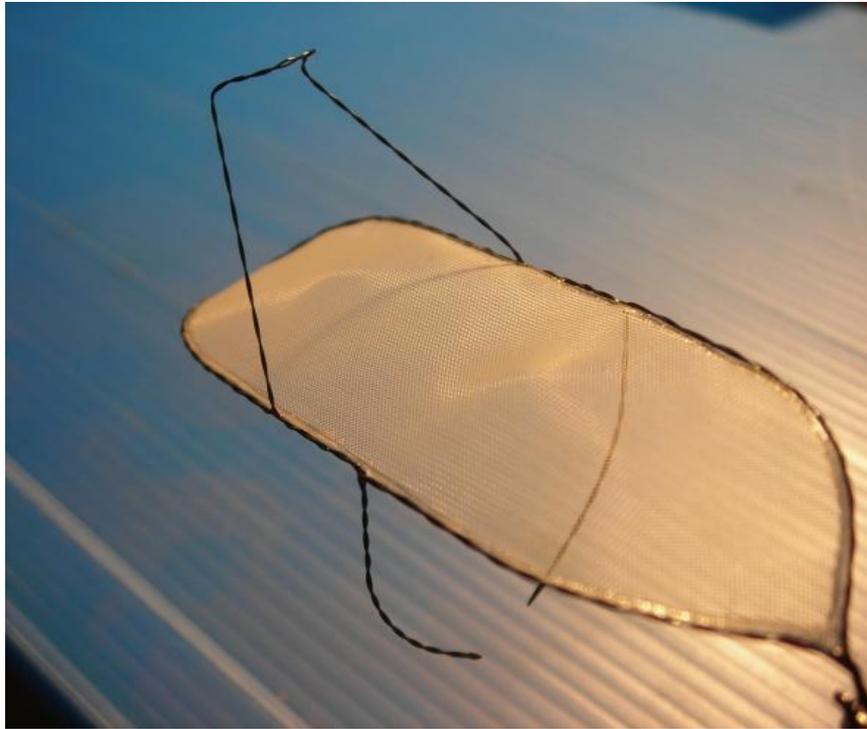
Average Volume (cc) of Lesions/Subject



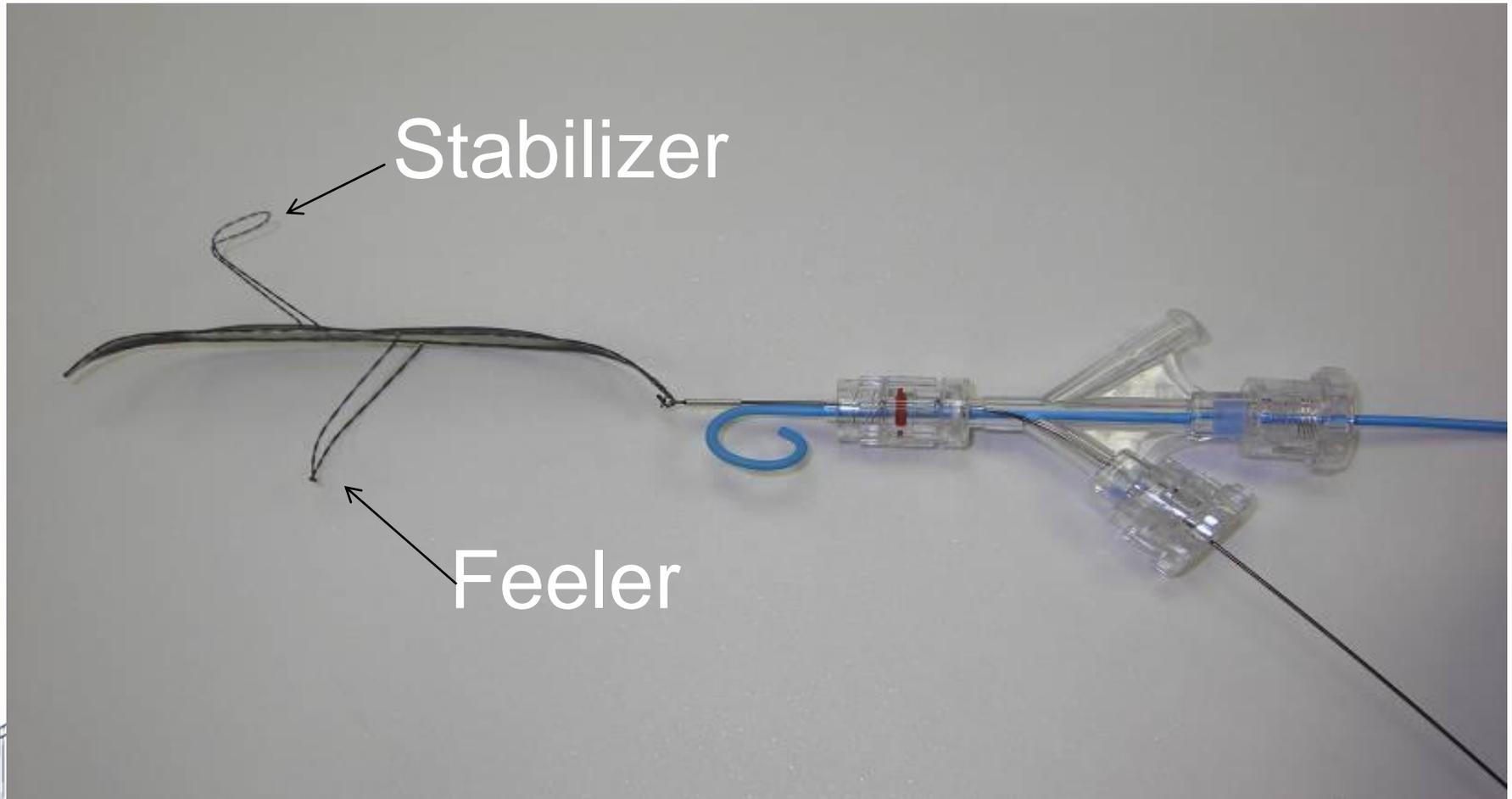
•Ghanem et al, J Am Coll Cardiol 2010;55:1427-32

Escort Device

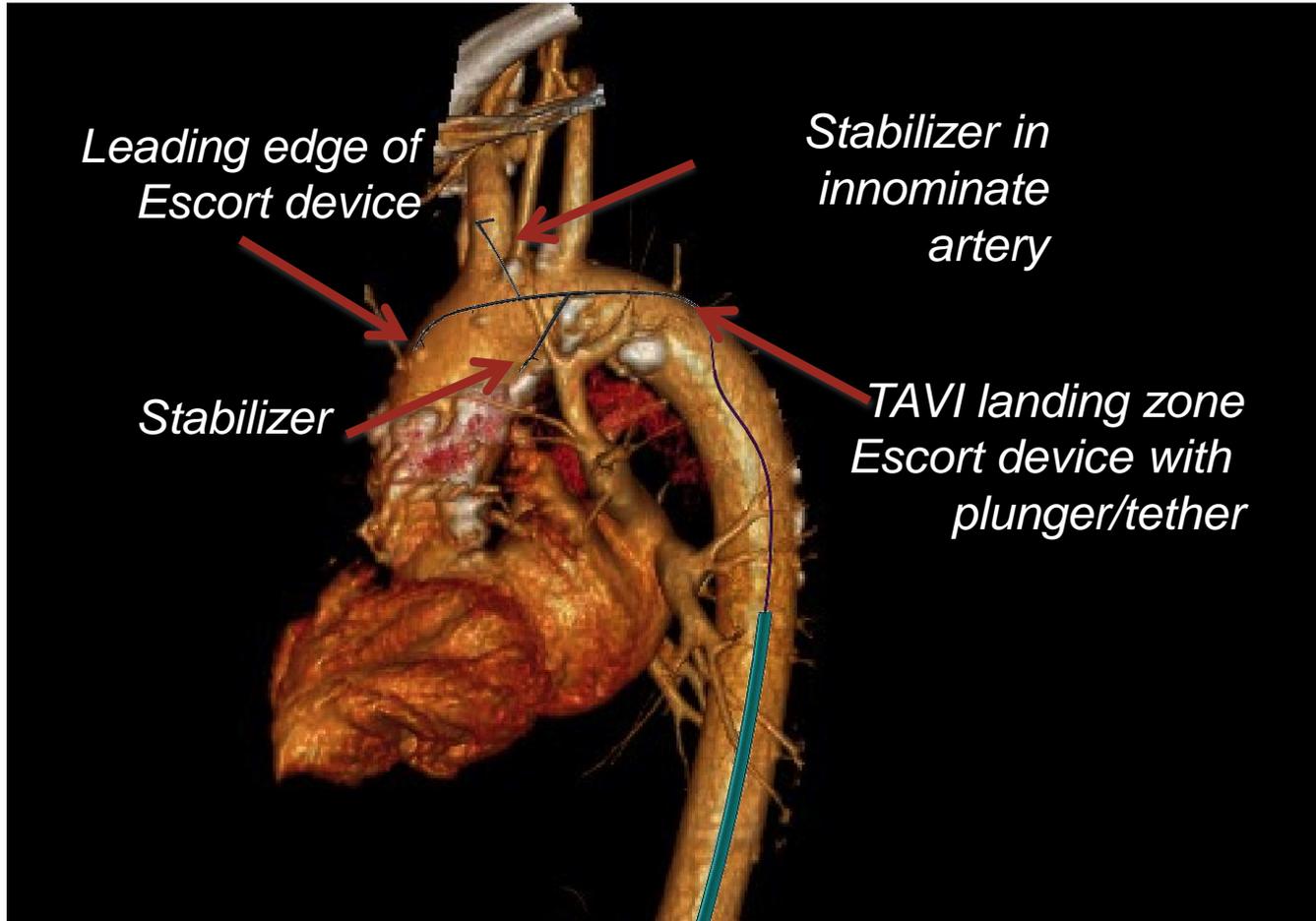
SMT Medical



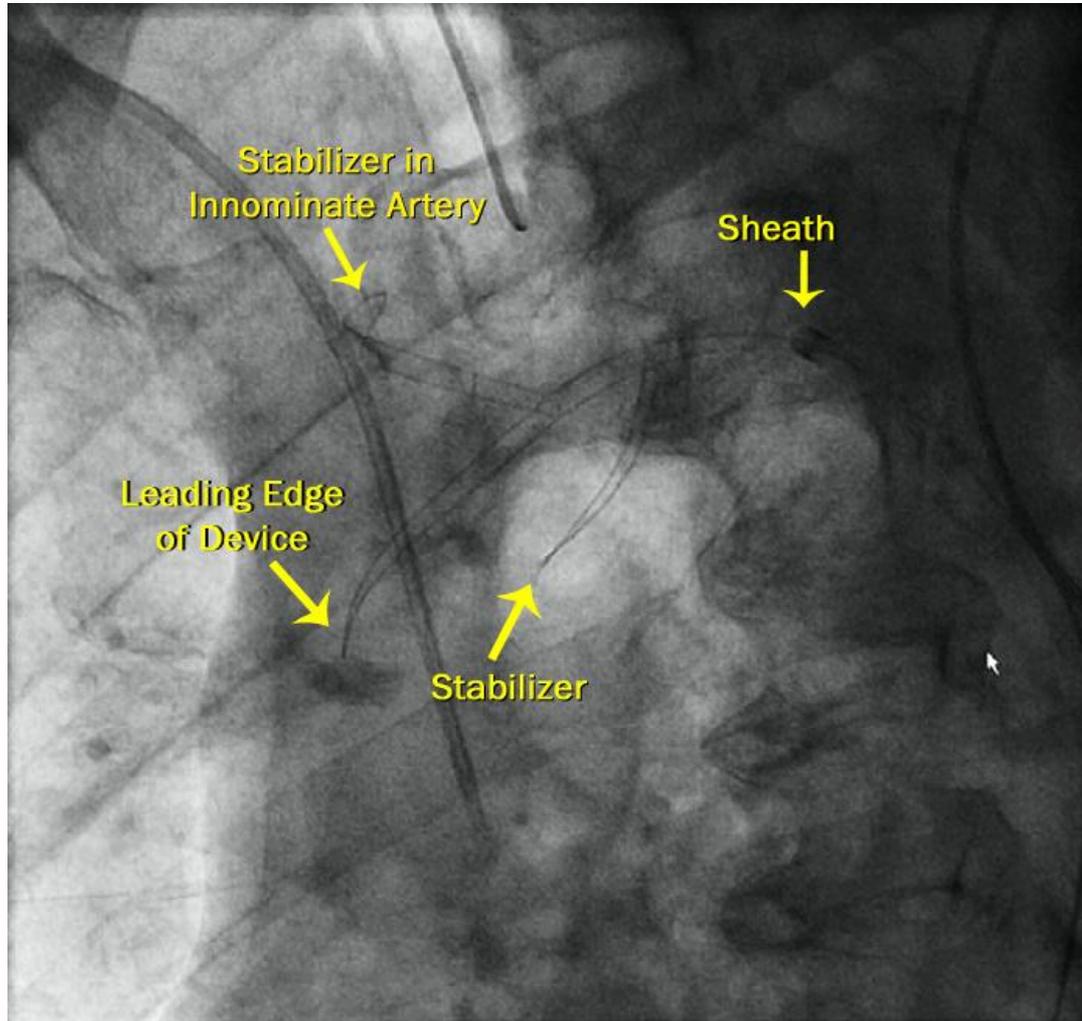
Escort device



Escort Device



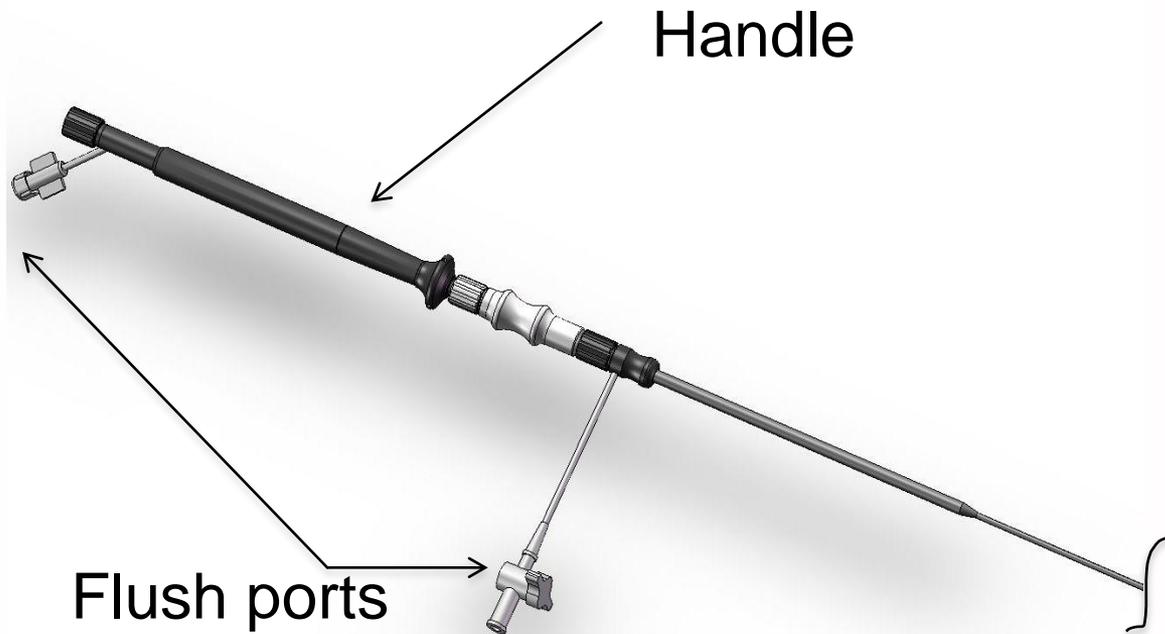
Escort device



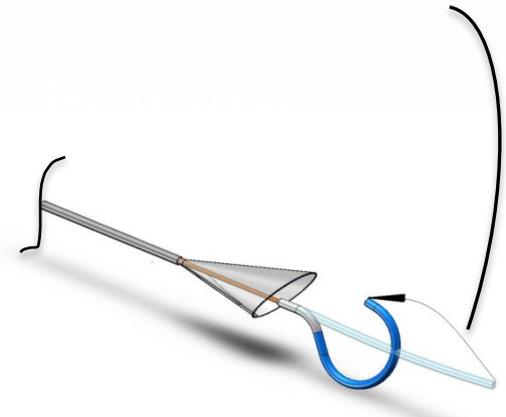
Claret Medical

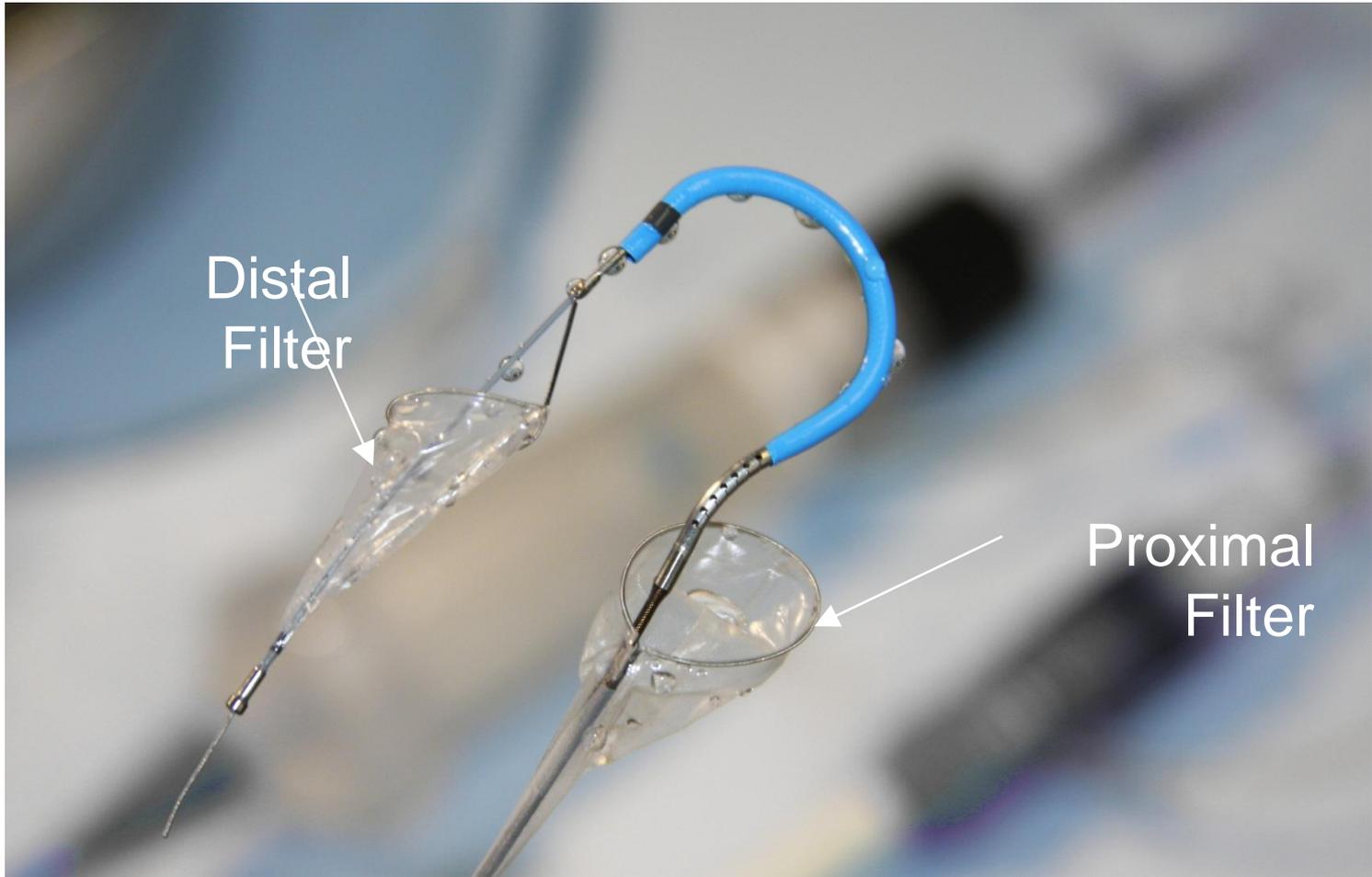


Radial/Brachial 6 Fr Delivery System



Adjustable Tip
& 0.014" wire

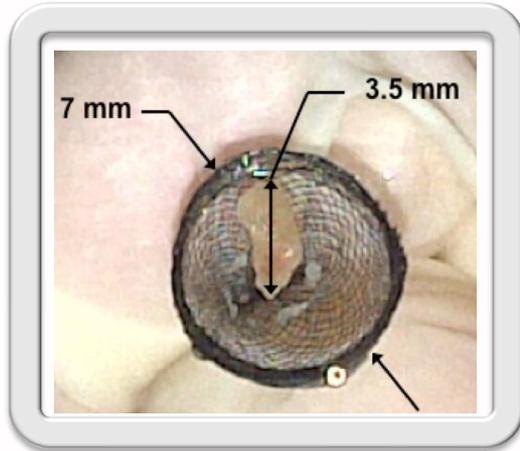
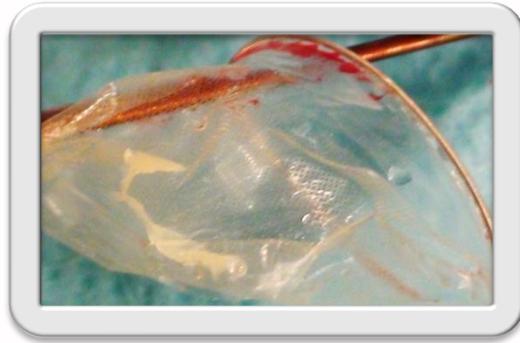




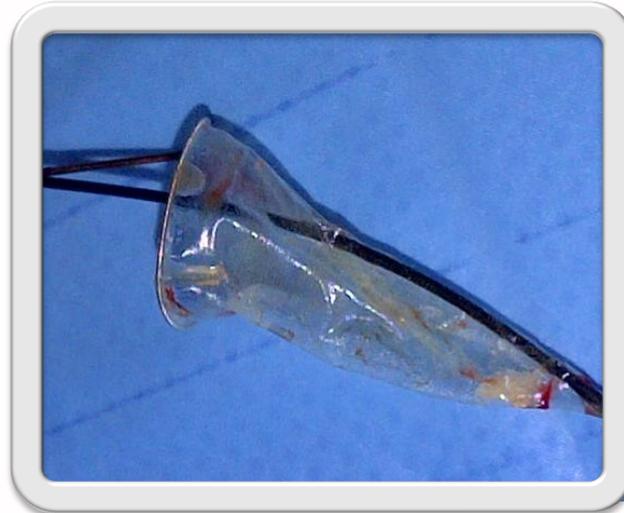
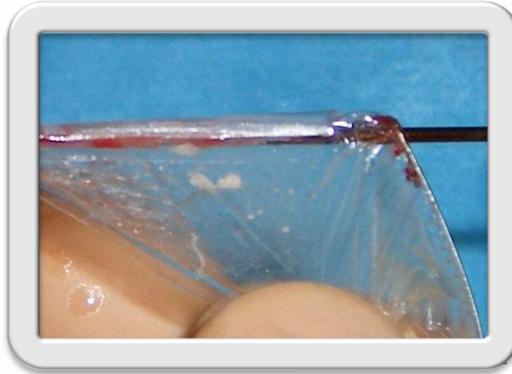
Filter Location



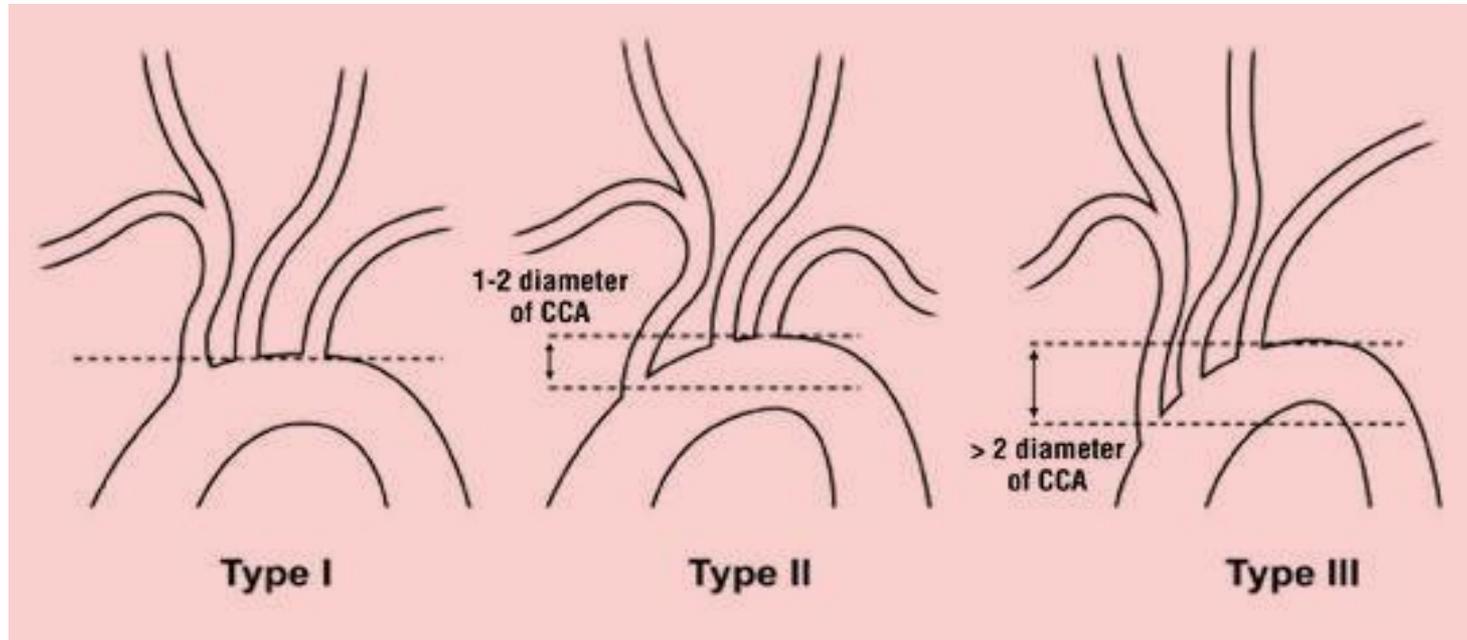
Variety of Captured & Removed Emboli



Variety of Captured & Removed Emboli



Can accommodate variable arch anatomy



Claret



Thank you