

# Cerebral Embolic Protection during TAVI

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**HEART CENTRE**  
AT ST. PAUL'S HOSPITAL

# **Disclosure Statement of financial Interest**

**Consulting fees/honoraria**

**Edwards Lifesciences**

# TAVR and Stroke : Recent registries

Registry	n	Strokes (30 days)
Belgian	328	4.4
UK-TAVI	870	4.1
FRANCE	244	3.6
German	697	2.8
SOURCE	1038	2.6
PARTNER-EU	130	2.3
Canadian	339	2.3
European Reg	646	1.9
Australia NZ	118	1.7
Italian	663	1.2

## Risk of stroke after transcatheter aortic valve implantation (TAVI): a meta-analysis of 10,037 published patients

Holger Eggebrecht<sup>1</sup>, MD, FESC; Axel Schmermund<sup>1</sup>, MD, FESC; Thomas Voigtländer<sup>1</sup>, MD, FESC; Philipp Kahlert<sup>2</sup>, MD; Raimund Erbel<sup>2</sup>, MD, FESC, FACC, FAHA; Rajendra H. Mehta<sup>3</sup>, MD, MS

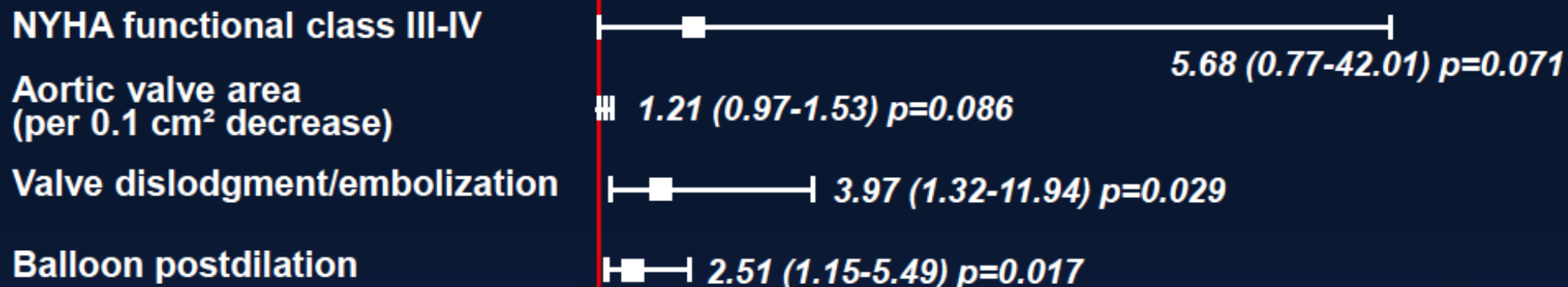
n			Log. EuroScore	Stroke / TIA 30-days
3236	TF	MCV	22 %	3.1 ±2.2 %
1733	TF	ES	26 %	4.2 ±2.2 %
2482	TA	ES	29 %	2.7 ±1.4 %



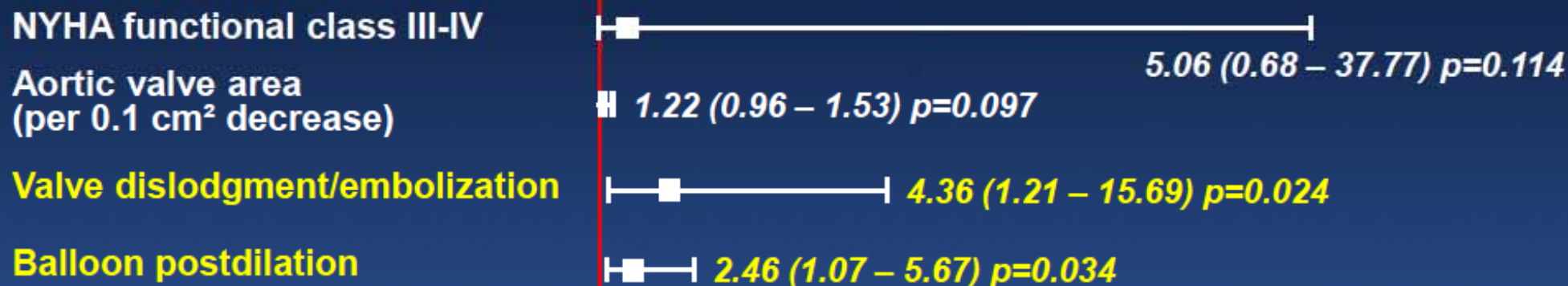
*Eurointervention* 2012;8:129-38

# Predictors of Acute Cerebrovascular Events (≤24hrs)

## UNIVARIATE



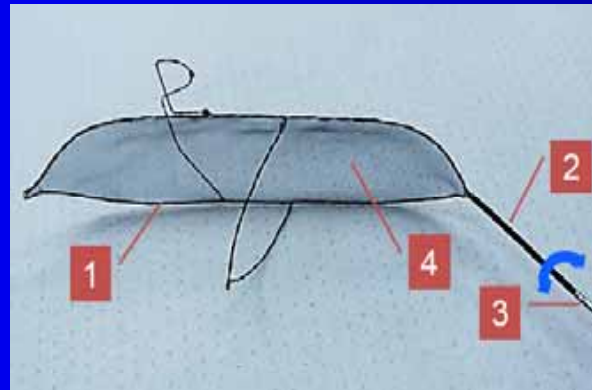
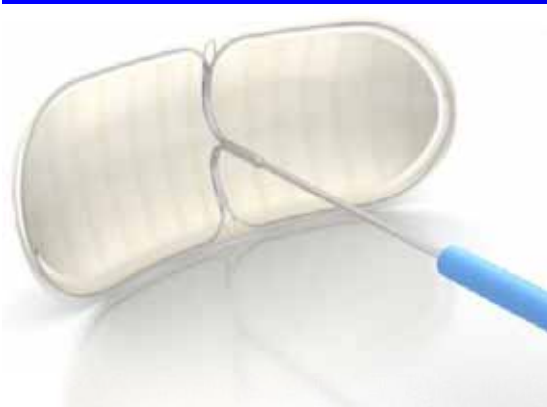
## MULTIVARIATE



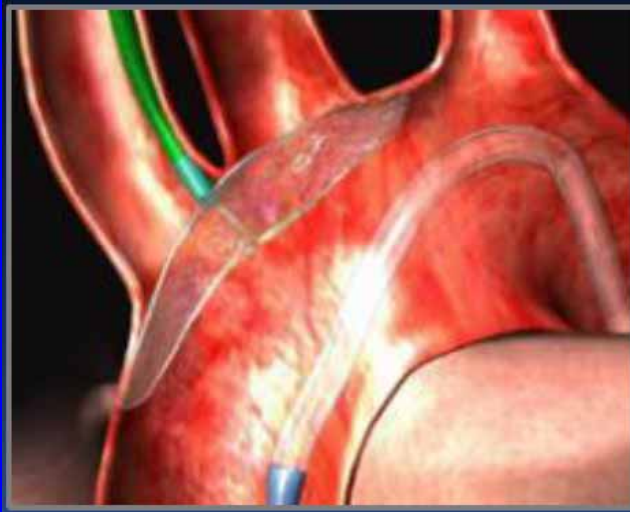
Odds ratio (95% Confidence Interval)

# Cerebral Embolic Protection Devices

Embrella™ Deflector	TriGuard™ Cerebral Deflector	Claret Montage 2™ Filter	EMBO-X Intra- aortic Filter
Deflection	Deflection	Capture	Capture
100 micron	130 micron	140 micron	100 micron
2-3 arch vessel coverage	3 arch vessel coverage	2 arch vessel coverage	Aortic arch coverage
Radial/brachial artery	Radial/brachial artery	Femoral artery	Ascending aorta
6Fr sheath	9Fr sheath	6Fr sheath	14Fr sheath



# Cerebral Embolic Protection Devices



**Embrella™ Deflector**



**TriGuard™ Cerebral Deflector**



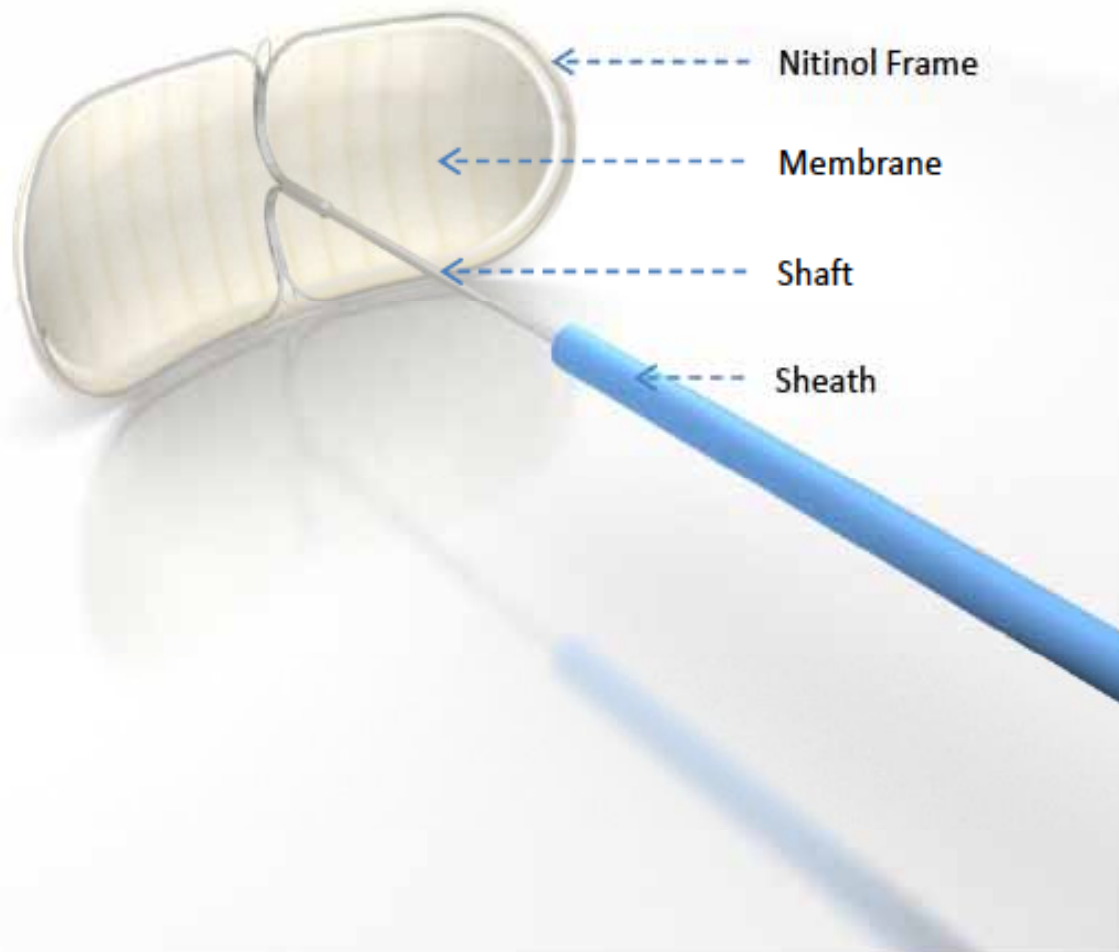
**Claret Montage 2™ Filter**



**EMBOL-X Intra-aortic Filter**

# Embrella™ Deflector

## Edwards Lifesciences



### Access

- Radial or brachial

### Frame

- Oval Nitinol frame

### Porous membrane

- Polyurethane
- Hydrophilic with heparin coating
- 100 micron pore size

### Shaft

- Nitinol
- 0.035" diameter



# Embrella TA Case



# The PROTAVI-C Trial

**PR**ospective **O**utcome Study in Patients undergoing **TAVI** to Examine Cerebral Ischemia and Bleeding Complications

## Pilot trial

- 50 patients
- Europe and Canada
- TCD & DW-MRI



Completed

## Randomized trial

- 500 patients
- 1<sup>o</sup> endpoint DW-MRI

# Clinical Outcomes at 7 Days

<b>Adverse Events</b>	<b>TAVI+Embrella (N=41)</b>
All-cause Mortality	1 (2.4%)
Stroke*	1 (2.4%)
TIA	0 (0.0%)
Life-threatening bleeding	2 (4.9%)
Renal insufficiency	1 (2.4%)

*\* Post-procedural Day 2, CEC adjudicated as minor; not device related*

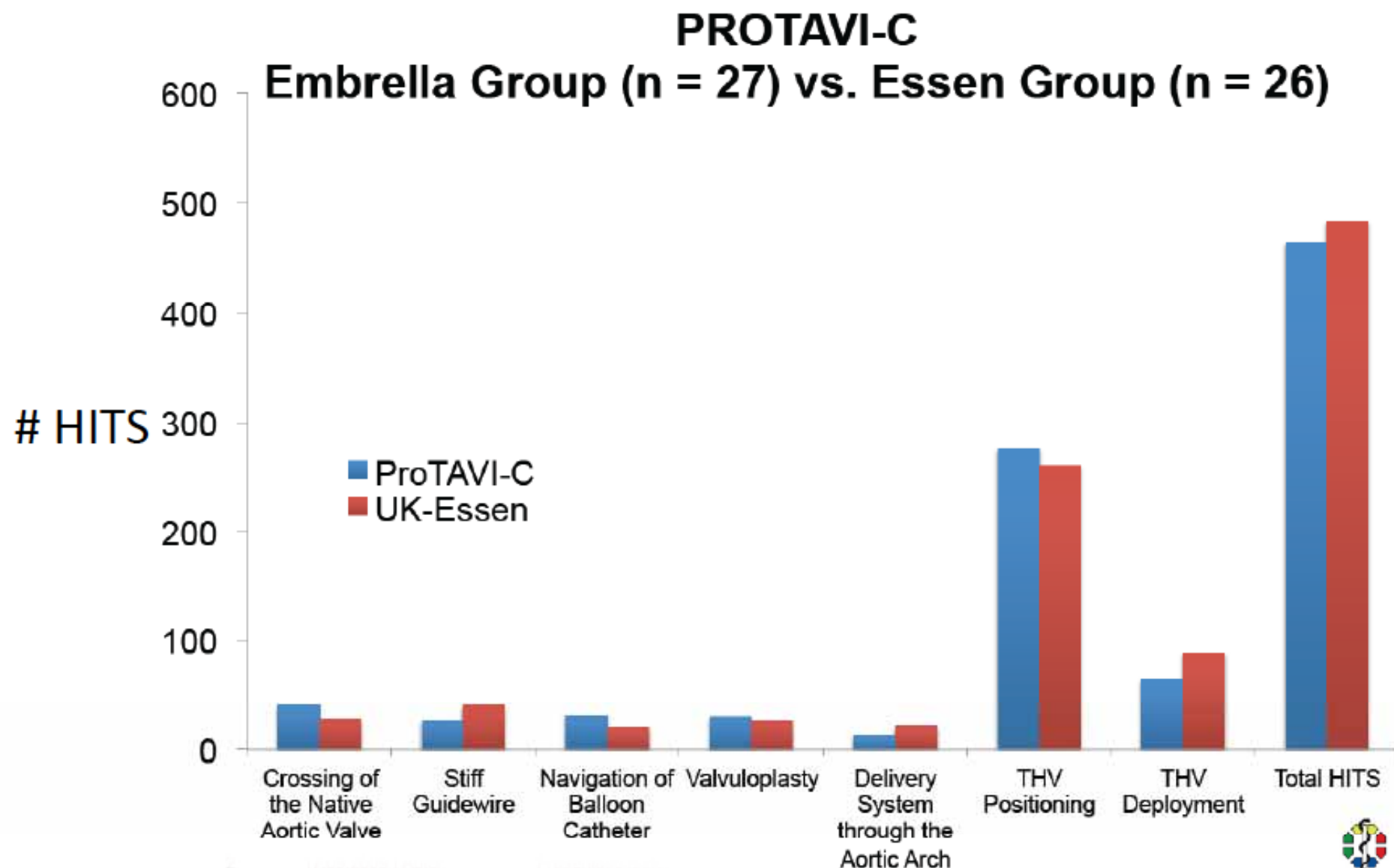
# DW-MRI Data

	<b>Treatment TAVI + Embrella (N=33)</b>
<b>Time from TAVI procedure, days, median (min, max)</b>	3 (1-7)
<b>Patients with new Lesions</b>	33 (100%)
<b>Total No. of lesions, patients</b>	
<b>Anterior cerebral artery</b>	7 (21%)
<b>Medial cerebral artery</b>	29 (88%)
<b>Posterior cerebral artery</b>	22 (67%)
<b>Cerebellum</b>	23 (70%)
<b>Border zone</b>	2 (6%)
<b>Patients with single lesions</b>	4 (12%)
<b>Patients with multiple lesions</b>	29 (88%)
<b>Lesions per patient, median (min, max)</b>	8 (1, 70)
<b>Lesion volume (mm<sup>3</sup>), median (IQR)</b>	42.3 (27.5, 85.0)



Adapted from John Webb, TVT 2013

# Historical comparison with Essen experience



\*Adapted from Kahlert et al, AHA 2010



# Neurological and Cognitive Test Results

## TAVI+Embrella

Variables	Baseline evaluation	Post-procedure evaluation	P value
NIHSS (median, min-max)	0.0 (0.0,3.0)	0.0 (0.0,2.0)	0.793
MRS (median, min-max)	0.0 (0.0,3.0)	0.0 (0.0,5.0)	0.979
Barthel Index (median, min-max)	100.0 (65.0,100.0)	97.5 (5.0,100.0)	0.375
MoCa (median, min-max)	24.0 (14.0,29.0)	25.0 (11.0,30.0)	0.162
MMSE (median, min-max)	28.0 (19.0,30.0)	28.5 (15.0,30.0)	0.623



# PROTAVI-C Pilot Trial Conclusions

- The Embrella Embolic Deflector System during TAVI is feasible and safe
- There were no procedural strokes; one minor stroke occurred 2 days after the procedure. No impairment of neurocognitive function was observed.
- TCD suggested cerebral microembolization(HITs) in all patients.
- Most HITs occur during THV positioning/implantation and Embrella device insertion.
- All patients had new cerebral ischemic MRI lesions.
- MRI lesions were clinically silent.
- There may be a decrease in cerebral lesion volume.
- This preliminary experience does not suggest a decrease in the occurrence and number of new ischemic defects as evaluated by compared to historical data.

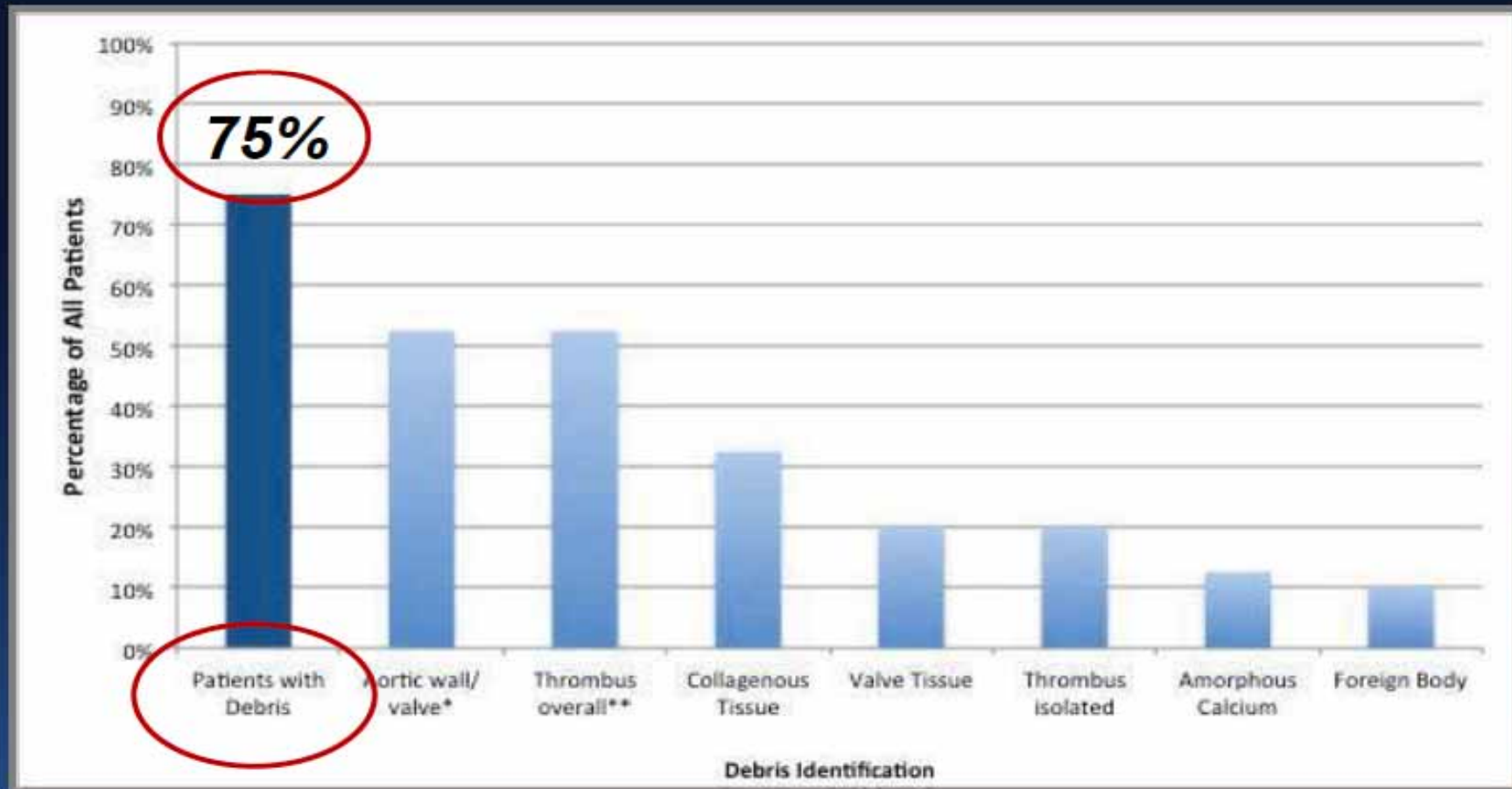
# Claret Montage 2™ Filter



Adapted from Eberhard Grube, TVT 2013

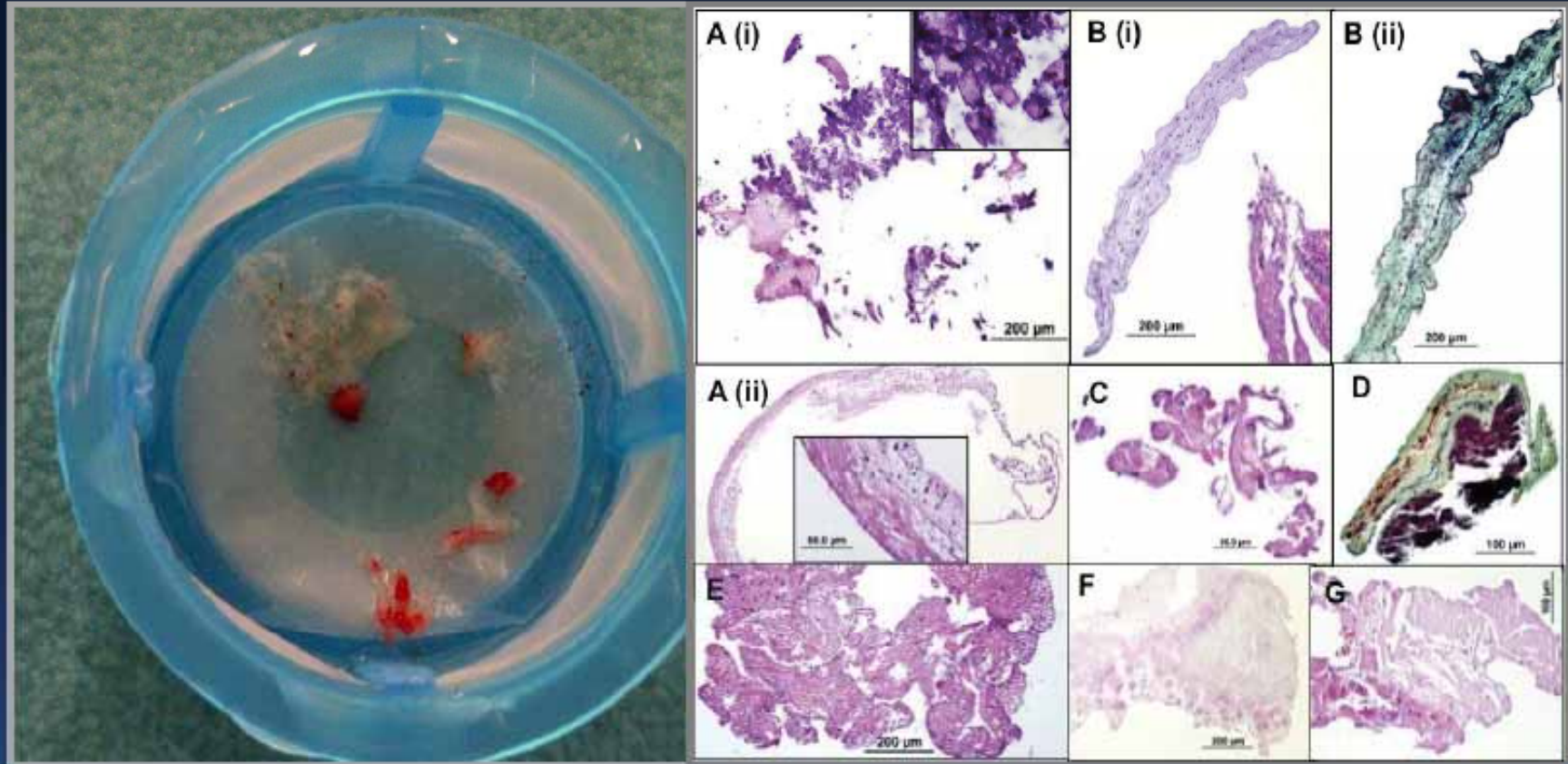


# Embololic Debris Evidence



Van Mieghem, Circulation May 2013 ISSN 1524-4539

Adapted from Eberhard Grube, TVT 2013



**Materials Captured:** Aortic Valve Leaflet, Collagenous, Calcium,  
Isolated Thrombus, Foreign Body

**Adapted from Eberhard Grube, TVT 2013**

# TriGuard™ Cerebral Deflector



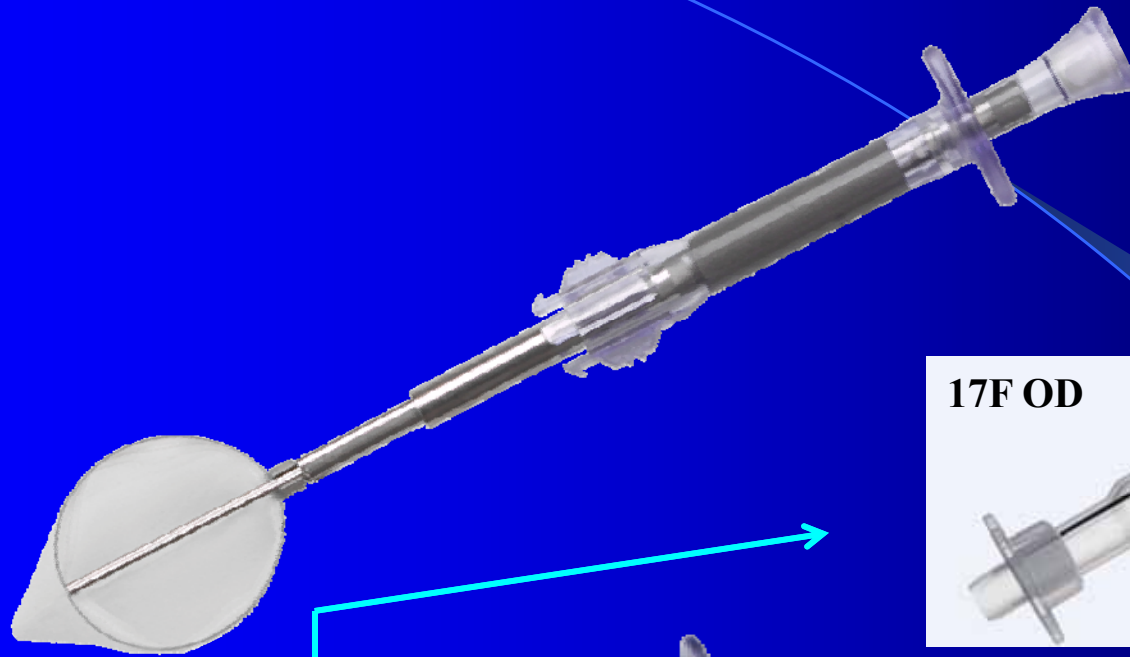
# DW-MRI Results (DEFLECT 1)

## *Lesion Volume Reduction vs. Historic Controls*

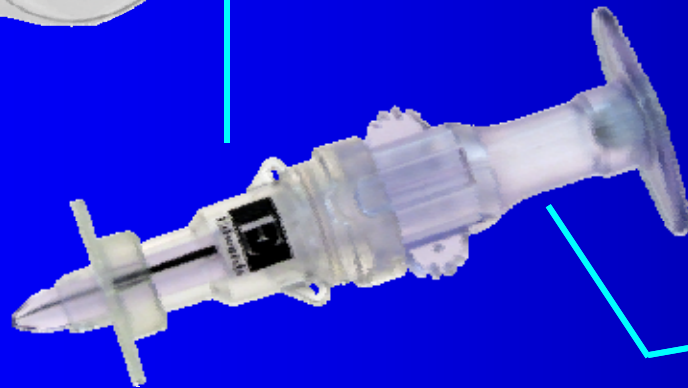
(Kahlert 2010, Ghanem 2011, Astarci 2011, Stolz 2004, Rodes Cabau 2011)

Parameter	DEFLECT-I N=20	Historical Data N=150
Proportion of Patients with New Lesions	70%	76%
Number of New Lesions	5.1 (0 - 28)	4.4 (0 -39)
Average New Lesion Volume	0.12 (0 - 0.39) cm <sup>3</sup>	0.34 cm <sup>3</sup>
Max Single New Lesion Volume	0.39 cm <sup>3</sup>	6.45 cm <sup>3</sup>
Total New Lesion Volume	0.70 (0 – 3.94) cm <sup>3</sup>	1.64 (0 – 70.3) cm <sup>3</sup>

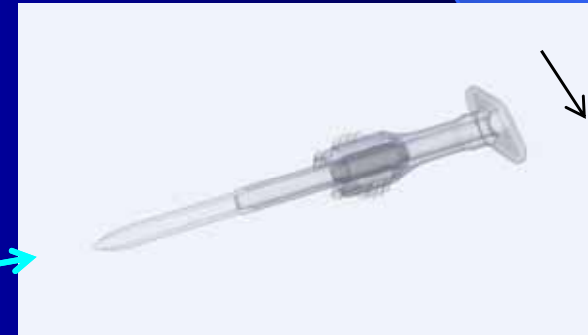
# EMBOL-X Intra-aortic Filter



Filter



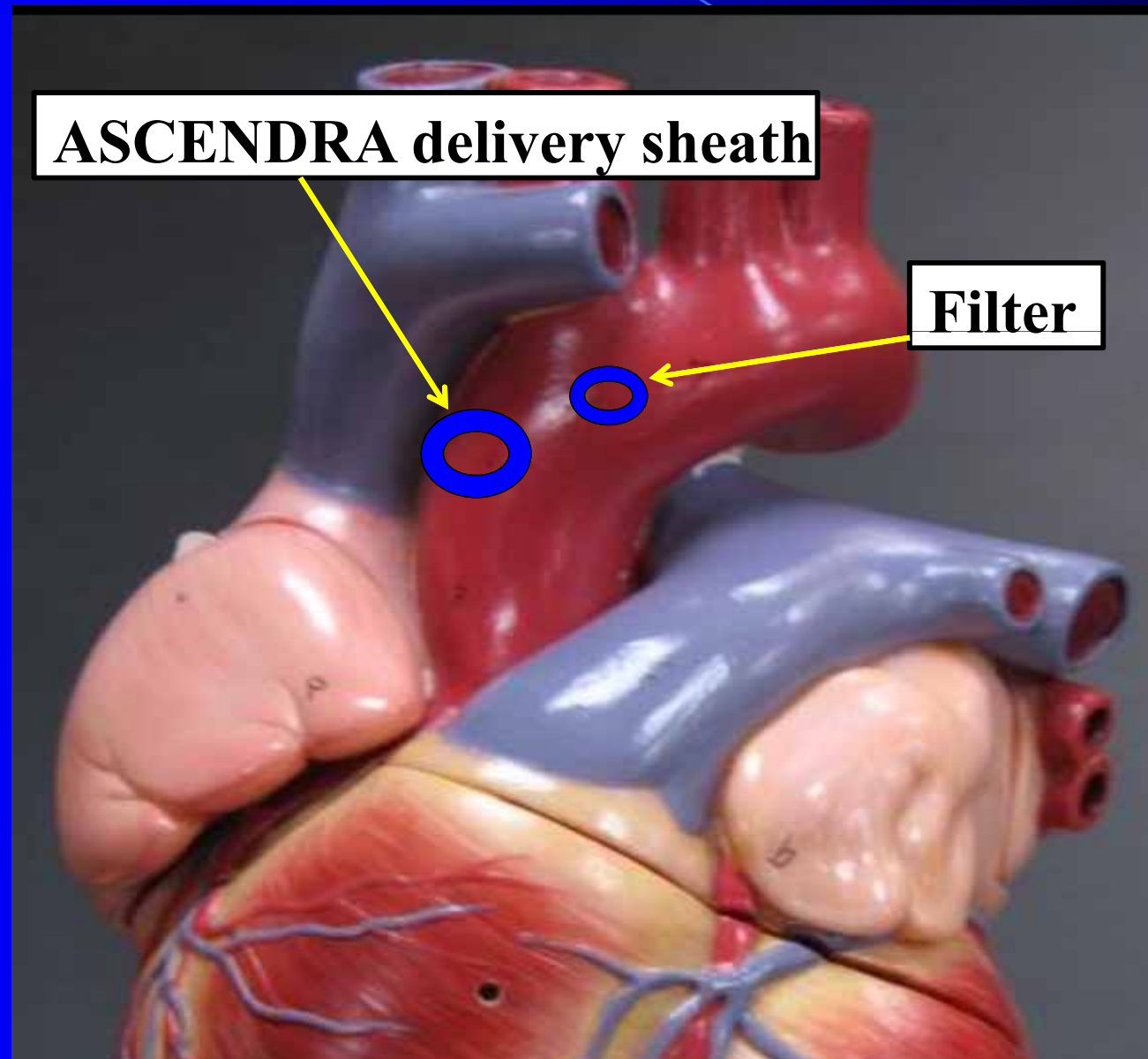
Introducer Sheath



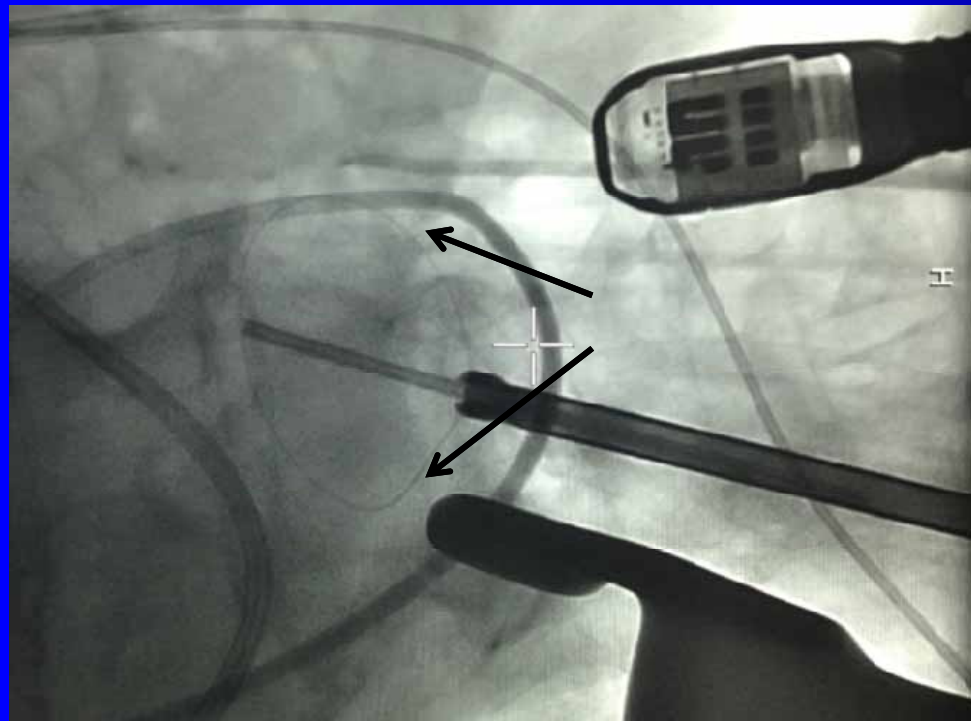
# EMBOL-X Intra-aortic Filters

<b>Filter Sizes</b>	<b>Minimum Aortic Inner Diameter (mm)</b>	<b>Maximum Aortic Inner Diameter (mm)</b>
X-Small (26mm)	22 mm	26 mm
Small (29 mm)	26 mm	29 mm
Medium (32 mm)	29 mm	32 mm
Large (34 mm)	32 mm	35 mm
X-Large (37 mm)	35 mm	40 mm

# Placement of EMBOL-X filter during Transaortic TAVI

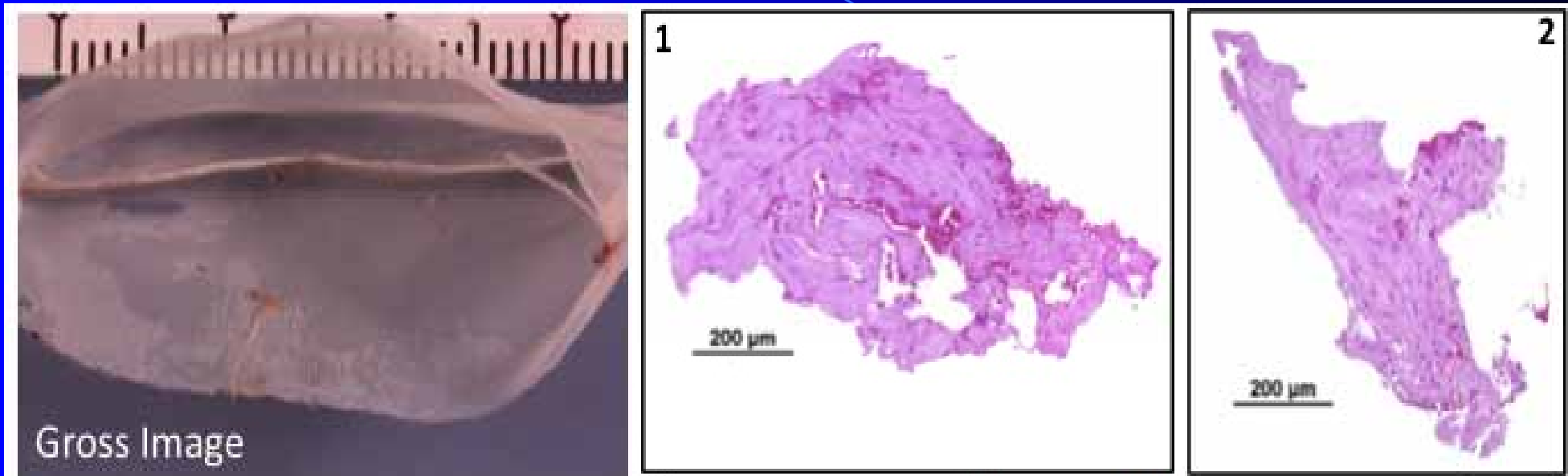


# EMBOL-X Intra-aortic Filter – FIH study

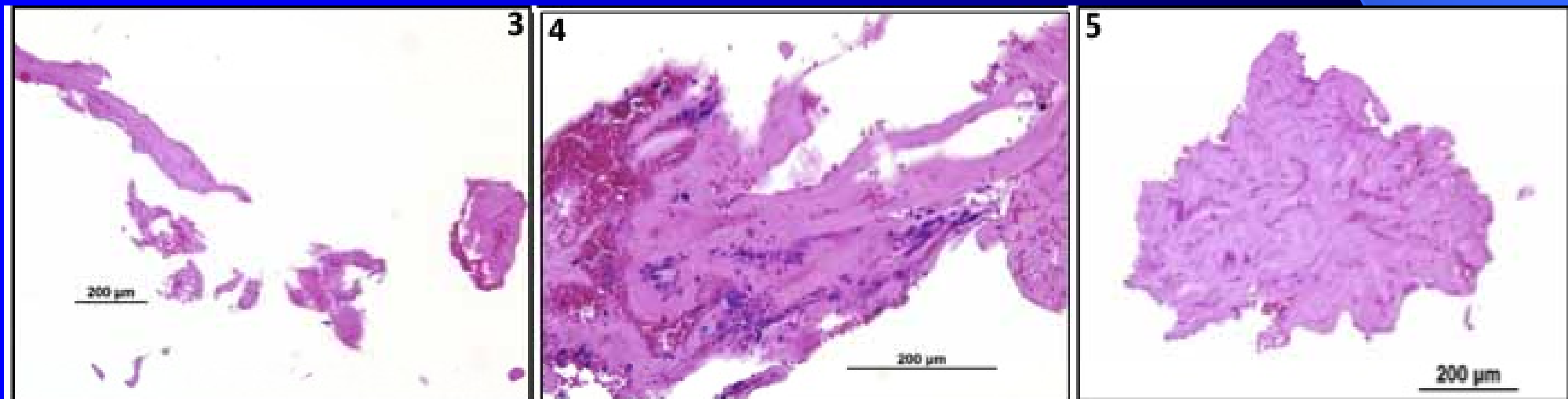




# Captured Embolic Material TAo TAVI case



**Elastic arterial wall**



elastic arterial wall and  
intimal tissue

**Thrombus**

# Conclusion

- **Cerebral embolization was observed in the majority of TAVI patients. Emboli are unavoidable with current TAVI technologies.**
- **I believe the majority of embolic events is related to TAVI procedure.**
- **Embolic protection devices are important during TAVI.**
- **Limited clinical data suggested that embolic protection devices may reduce cerebral embolic events. Large controlled clinical trials are required to confirm clinical benefits of these devices.**