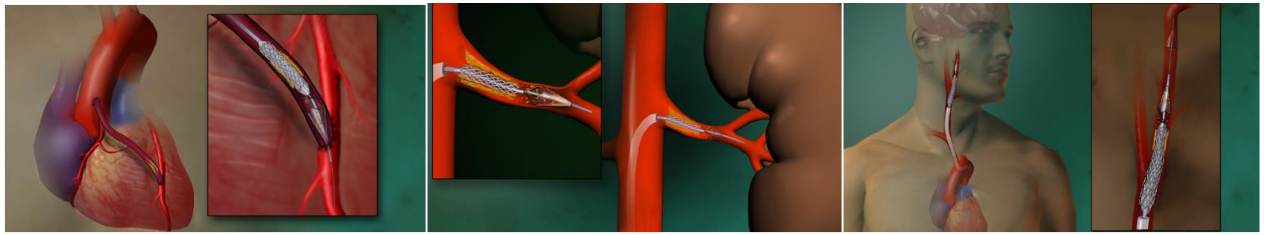
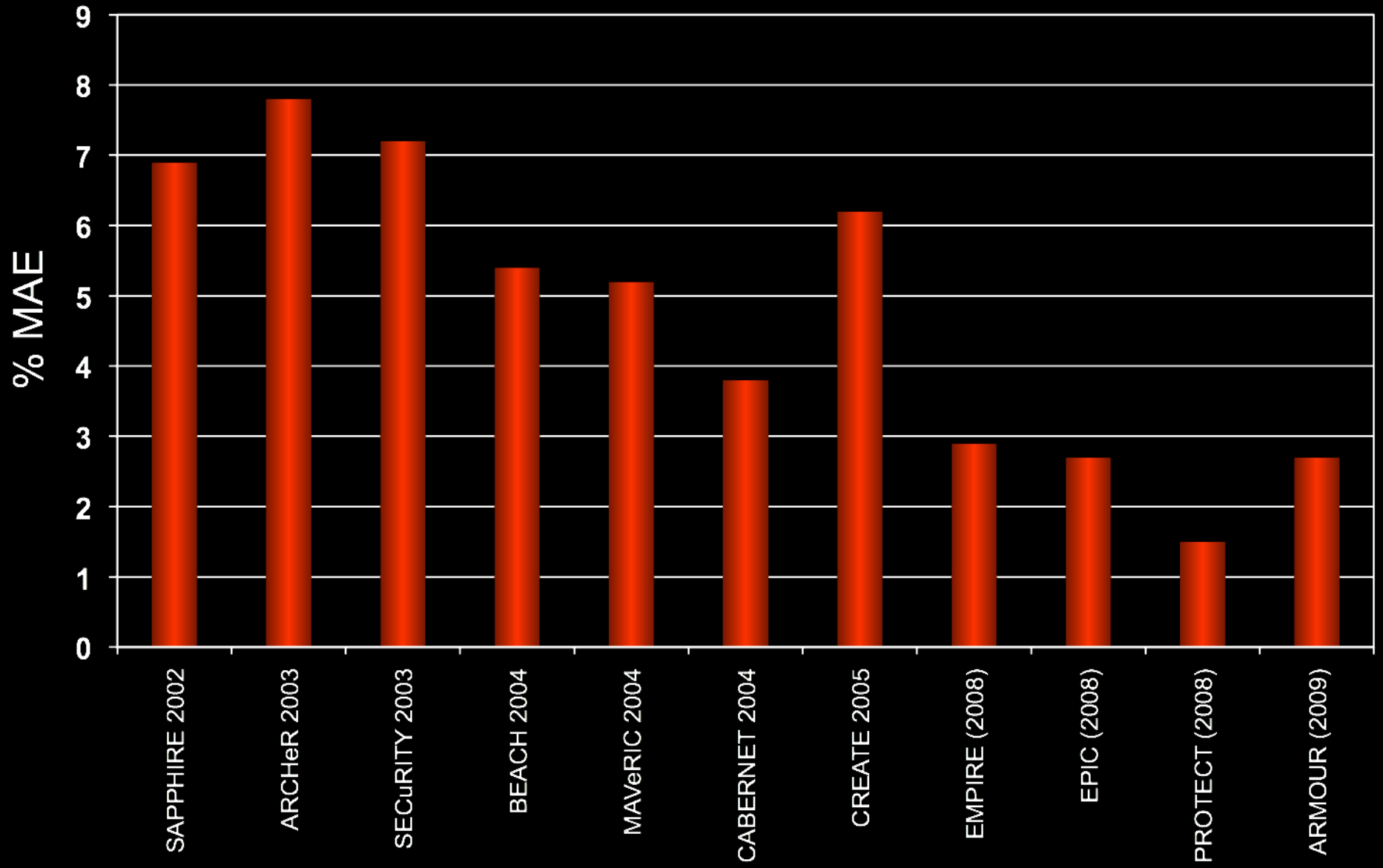
Double Filtration During Carotid Artery Stenting



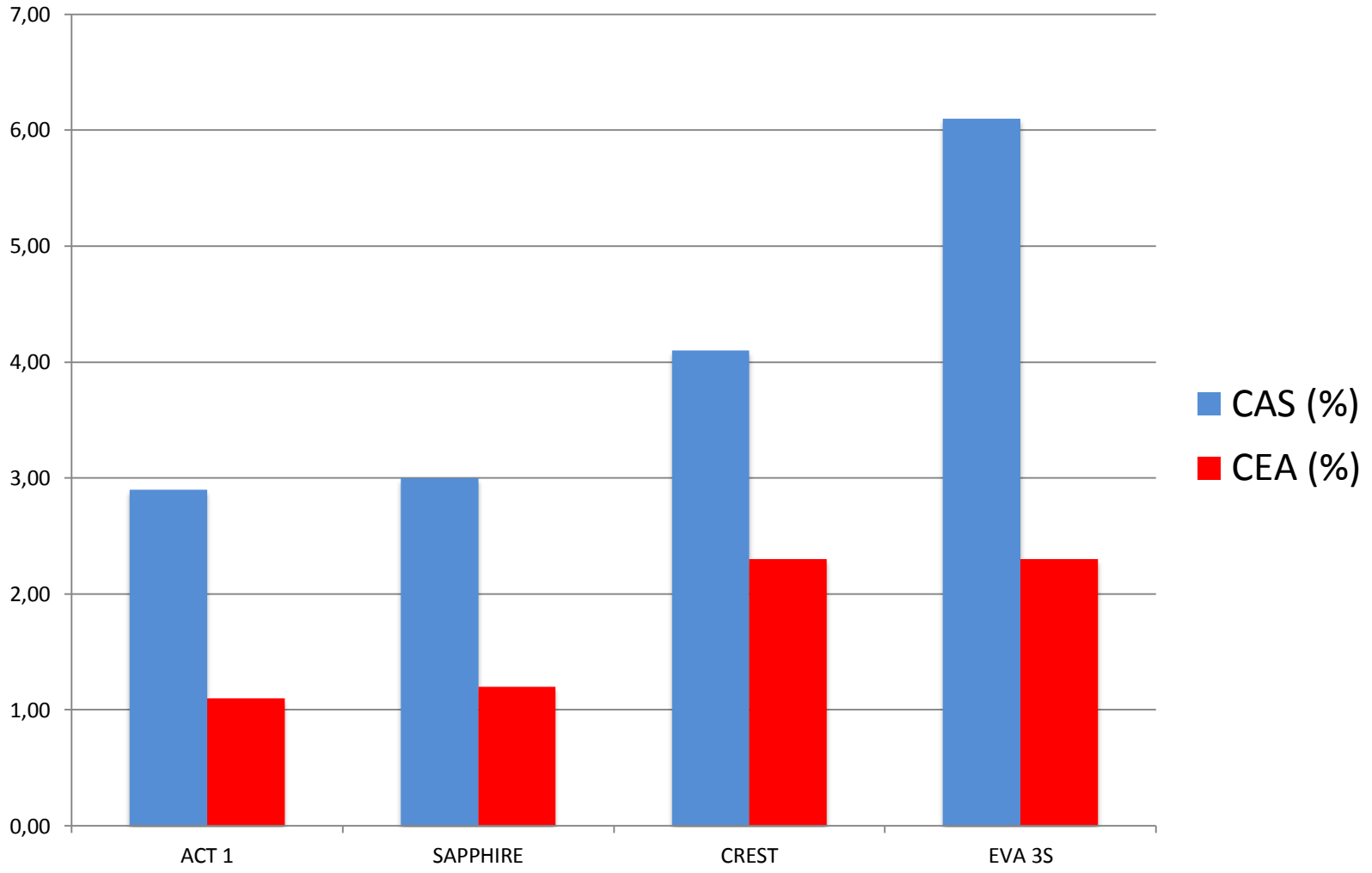
The PALADIN Carotid Post-Dilation Balloon with Integrated Embolic Protection

Disclosures

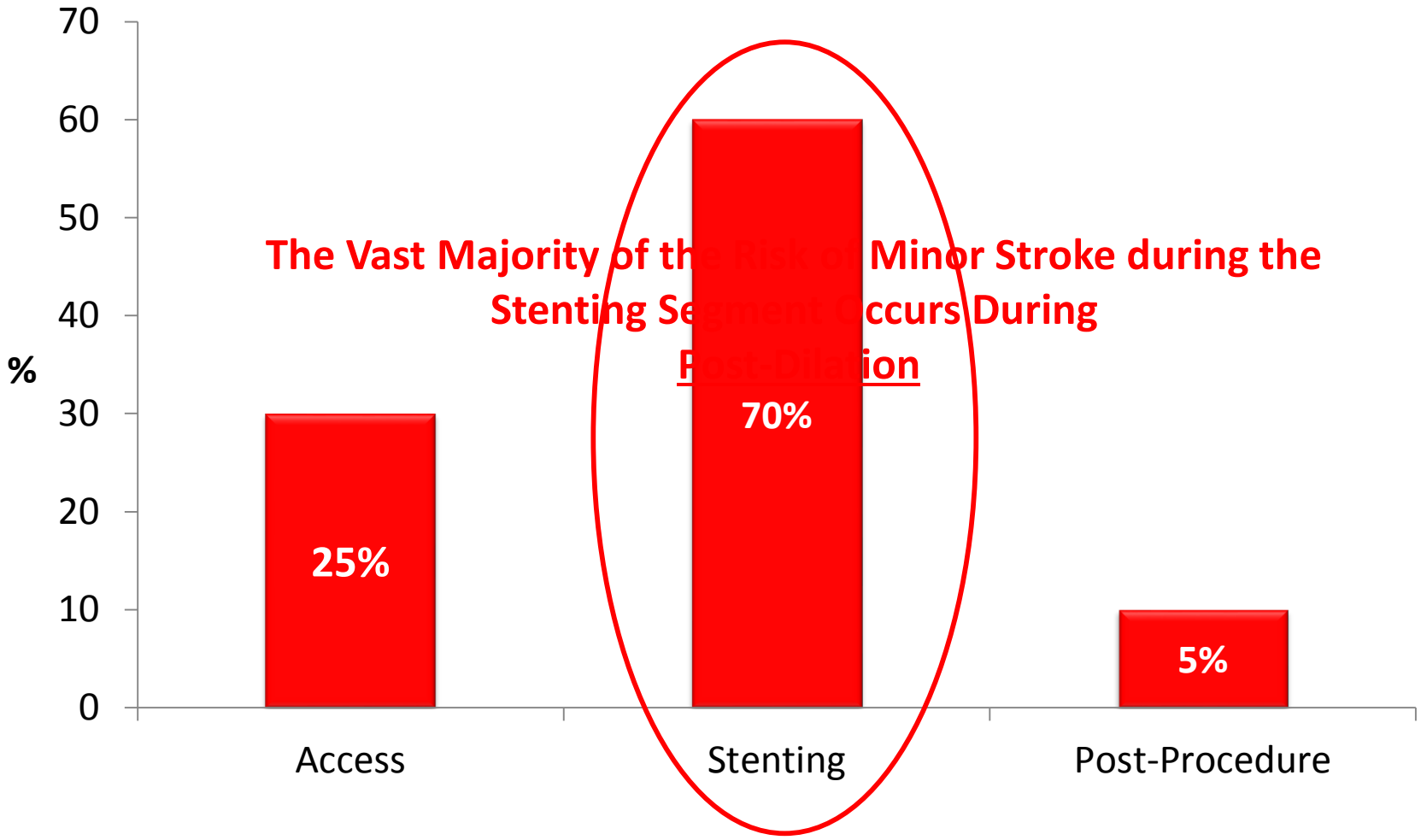
CAS Results are steadily Improving

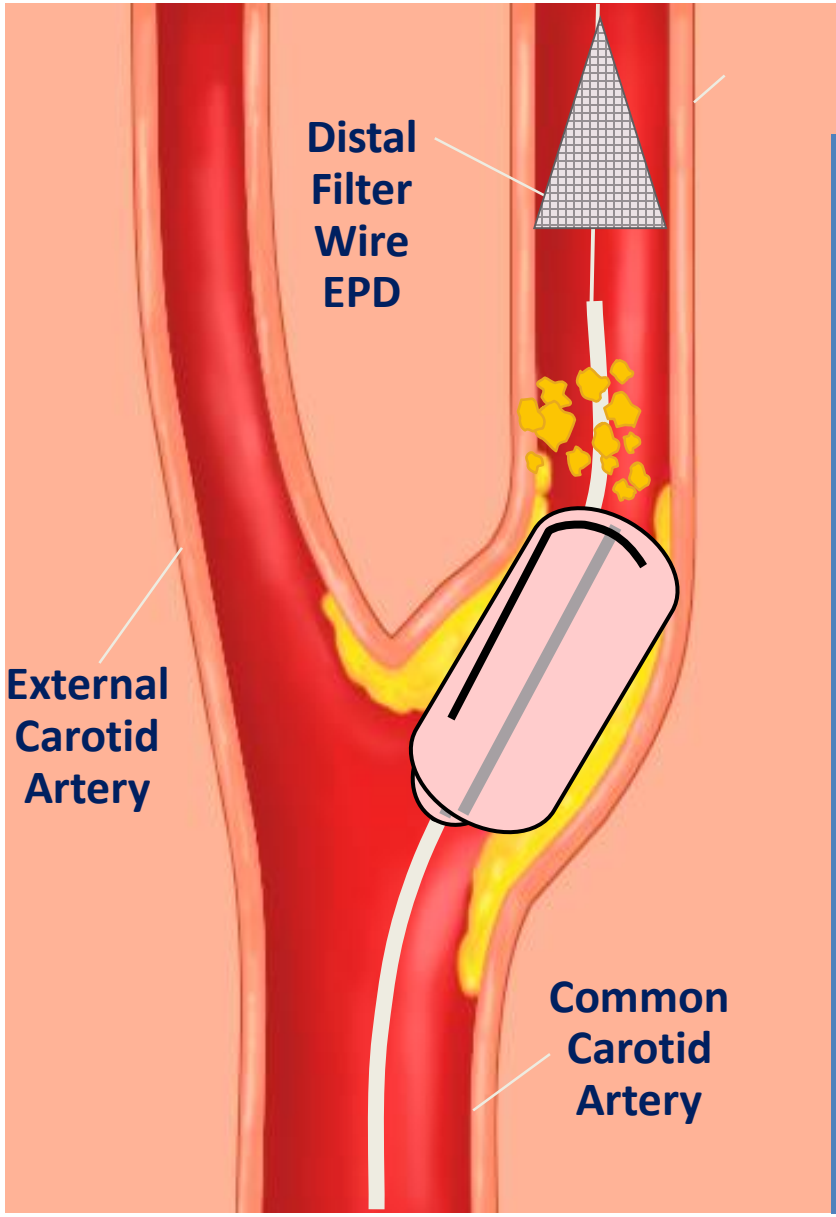


However, Minor Stroke at 30 days: An Unsolved Problem During CAS



When Do Minor Strokes Occur During Carotid Artery Stenting?





Why Do Minor Strokes Occur Despite EPD use?

- Pore Size (100-280 microns)
- Filter Malapposition
  - Improper Sizing
  - Shape Mismatch
  - Patient Movement
- Overwhelming Debris Burden

Hypothesis

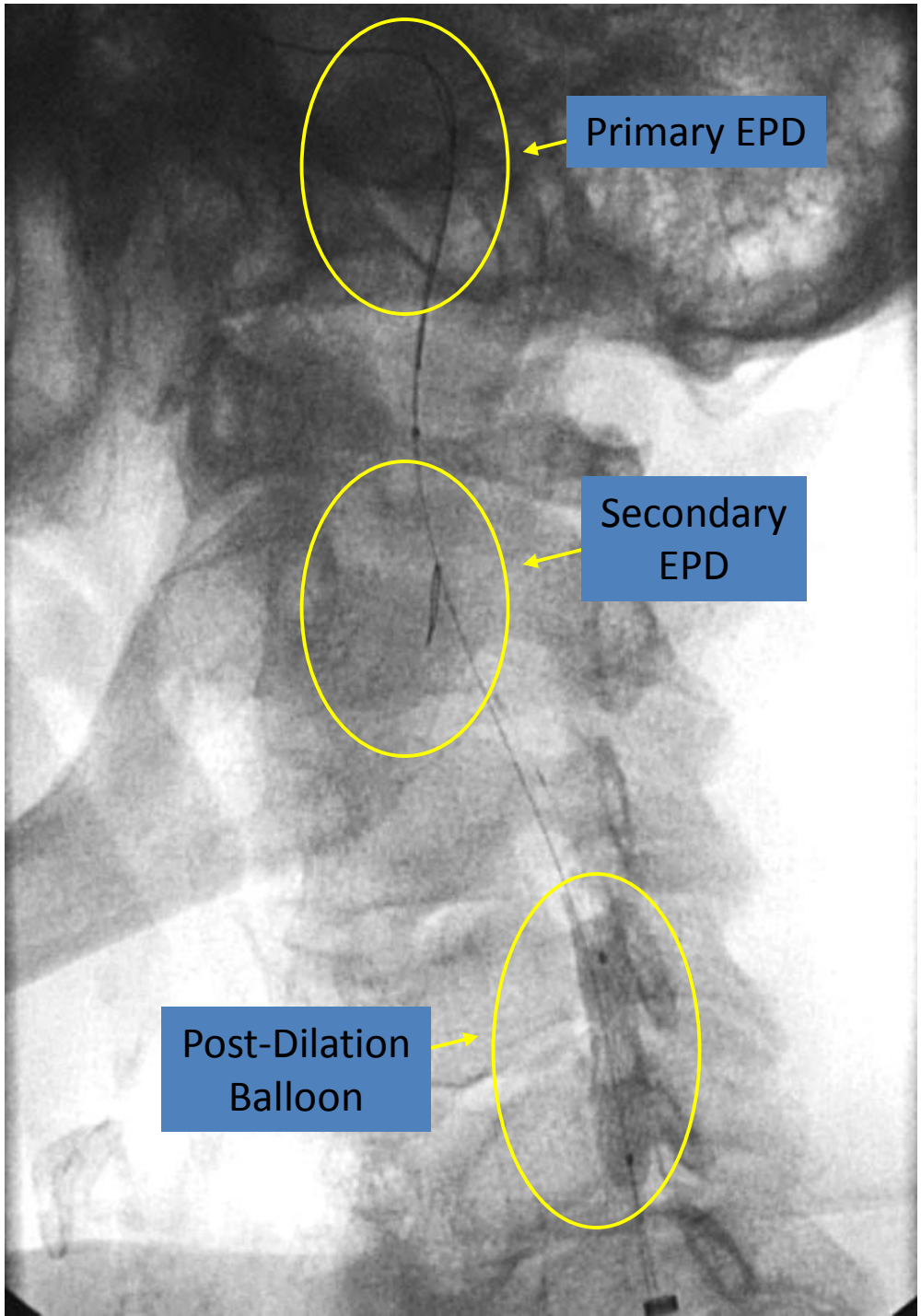
•Problem: Risk of stroke is maximal during the post-dilation phase

•Solution: Increase protection during the post-dilation phase

Double Filtration – Symptomatic LICA

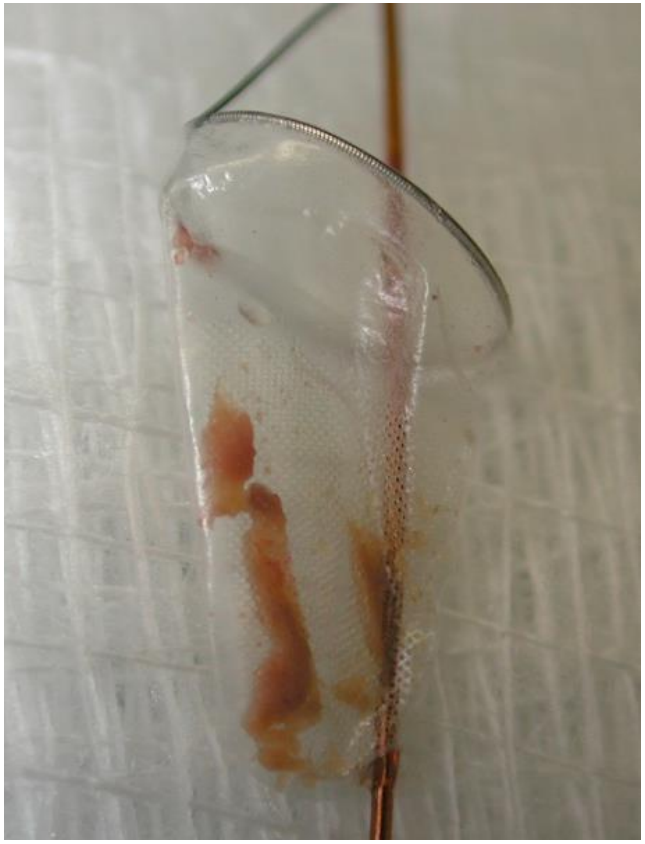
Double Filtration

- 221 Non-consecutive Patients
- 2 Centers, Prospective, Non-Randomized
- Double Filtration using a variety of primary filters and stents
- FilterWire used for all secondary filter
- 30 Day Neurological Death, Stroke, MI



Filter Analysis

- 36 Paired Filters Sent to Pathology
- Debris noted in BOTH filters in ALL 36 cases



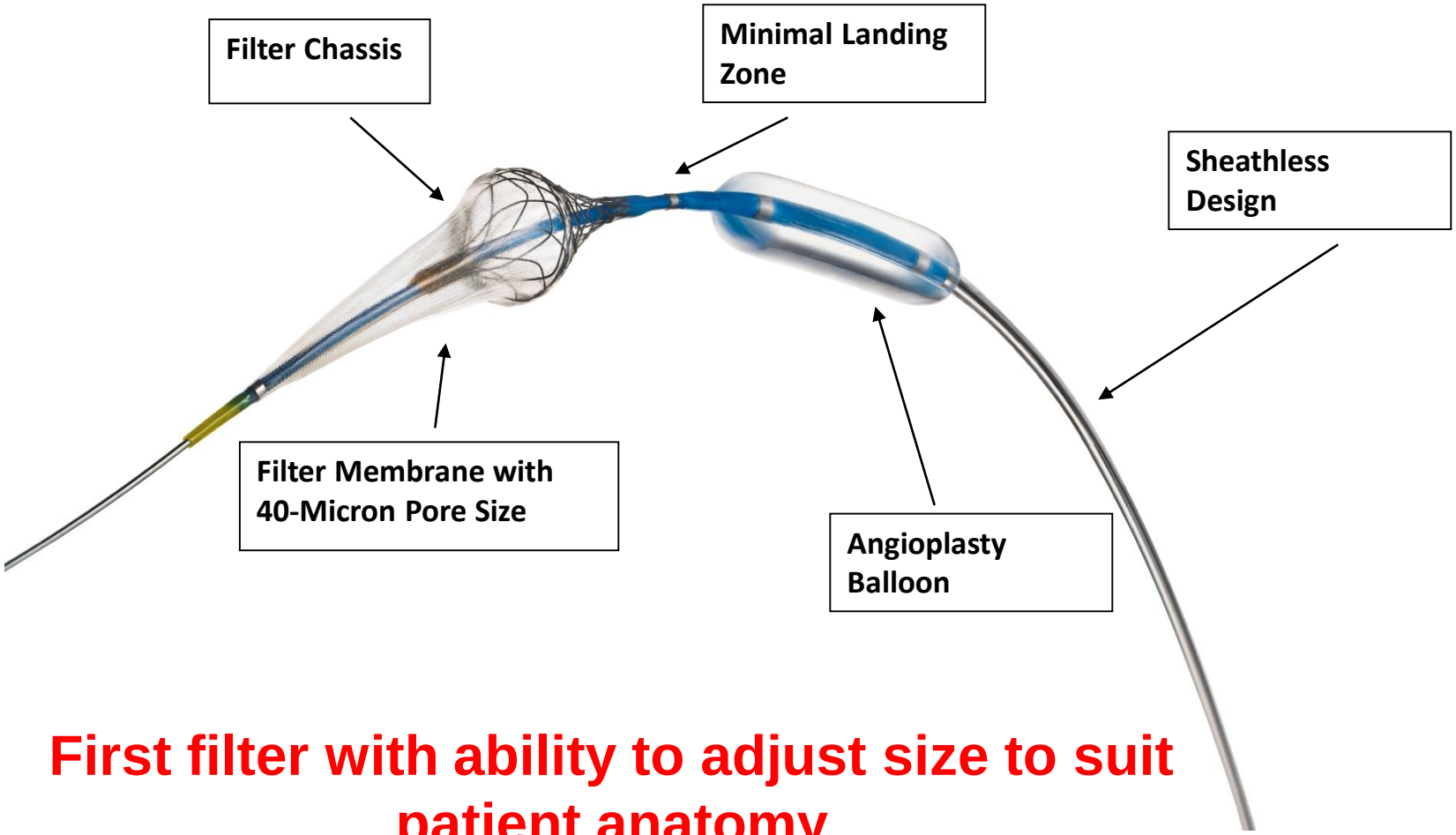
Double Filtration:
Procedural and 30 day Results

N=221	Number	%
Procedural Events		
Myocardial Infarction	0	0%
Stroke	1	0.48%
Neurological Death	0	0%
30-Day Events		
Myocardial Infarction	1	0.48%
Neurological Death	0	0%
Stroke	0	0%
Total Neurological Death/Stroke/MI	2	0.96%

Limitations of Double Filtration using Two Separate Filters

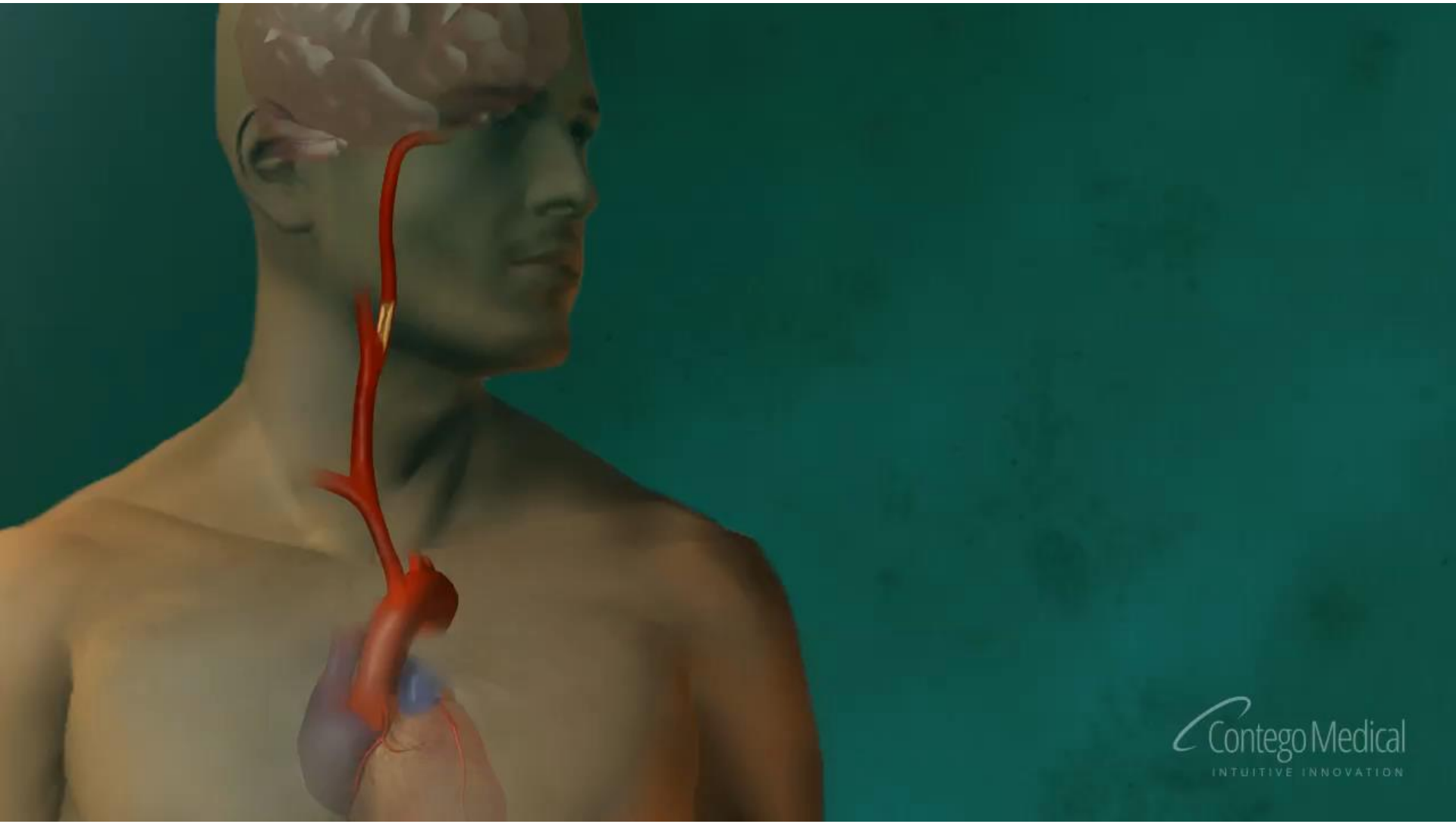
- Cost of an extra filter
- Extra time require to deploy a second filter
- 36% of patients with insufficient landing zone for a second filter

PALADIN®
Carotid Post-Dilation Balloon with Integrated Embolic Protection (IEP) Technology

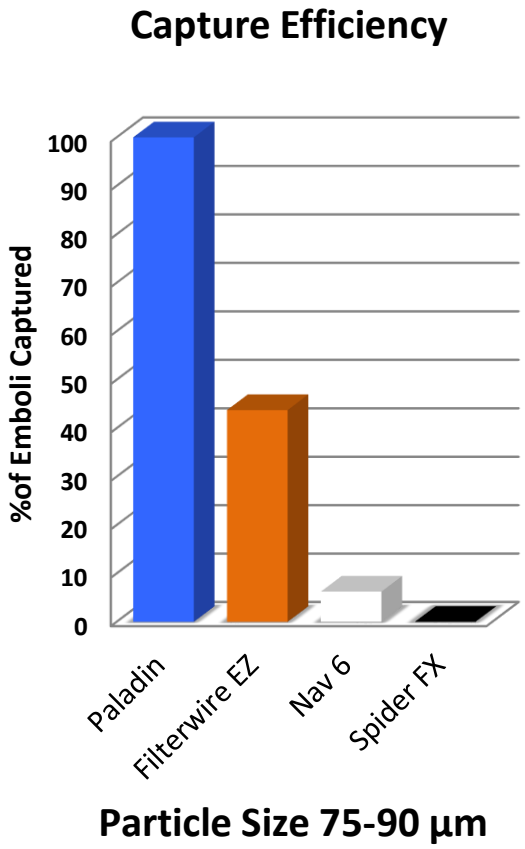


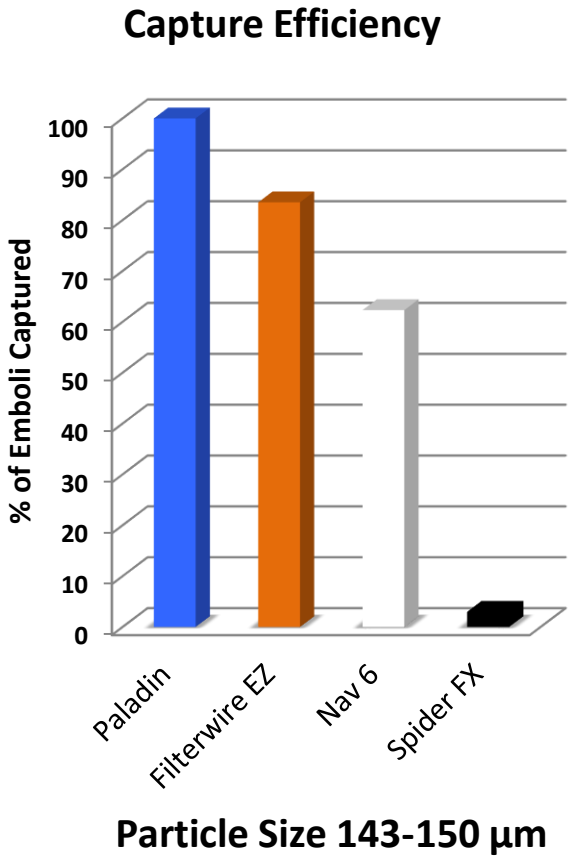
First filter with ability to adjust size to suit patient anatomy

PALADIN®



Capture Efficiency Testing



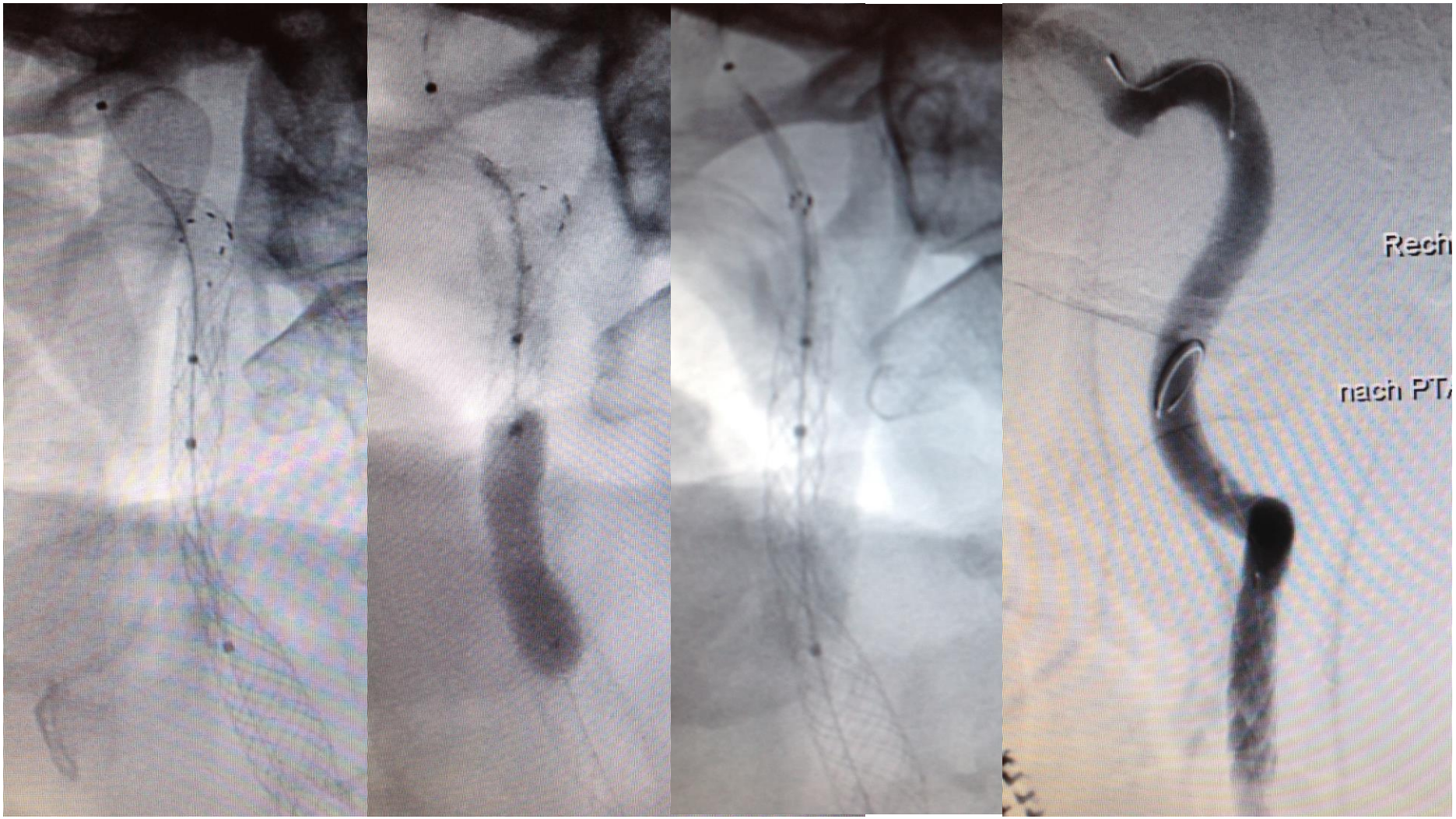


Data on file: Contego Medical LLC

PALADIN® Balloon Registry

- 100 patients
- 6 Sites in Germany
- Any Primary Distal Filter or Proximal Protection
- Any Approved Carotid Stent
- Paladin used for Post-Dilation according to IFU
- Primary Endpoint
  - Acute Success
  - 30 day MACE
- MRI sub-study – 31 patients – 2 sites

PALADIN® Balloon Registry



Images Courtesy Dr Ralf Langhoff

Preliminary Registry Clinical Experience

Baseline Characteristics	Registry (n=87)
Age (mean)	70
Gender (male)	75.9%
Asymptomatic	82.8%
Symptomatic	17.2%
Hypertension	81.6%
Hyperlipidemia	83.9%
Diabetic (Type II)	36.8%
Smoker: Current/Former	34.5/44.8%
Prior MI	12.6%
Prior TIA/Stroke	11.5/2.3%

Preliminary Registry Clinical Experience

Procedure Results	Registry* (n=87)
Paladin Technical Success	100%
Procedure Success	100%
MACE (through D/C)	0%
MACE (through 30 days)	1.1%*

*1 Stroke at day 12 due to stent thrombosis in a patient with a mesh covered stent who did not take ASA or clopidogrel. Treated with thrombolytic therapy

Preliminary Registry Clinical Experience

Procedure Results	Registry (n=87)
Femoral Access	100%
Target Vessel: Left ICA Right ICA	47.9 52.1
Lesion Length (mm) RVD (mm)	14.3±5.35 5.3±0.65
Diameter Stenosis (%DS)	83.5±8.9
Primary EPD: Distal Filter Proximal	95.8% 4.2%
Stent Deployed	100%

Preliminary Registry Clinical Experience

Procedure Results	Registry* (n=50)
Paladin Technical Success	100%
Procedure Success	100%
MACE (through D/C)	0%
MACE (through 30 days)	2%*

*1 Stroke at day 12 due to stent thrombosis in a patient with a mesh covered stent who did not take ASA or clopidogrel. Treated with thrombolytic therapy

DW-MRI Evaluation: Preliminary Results

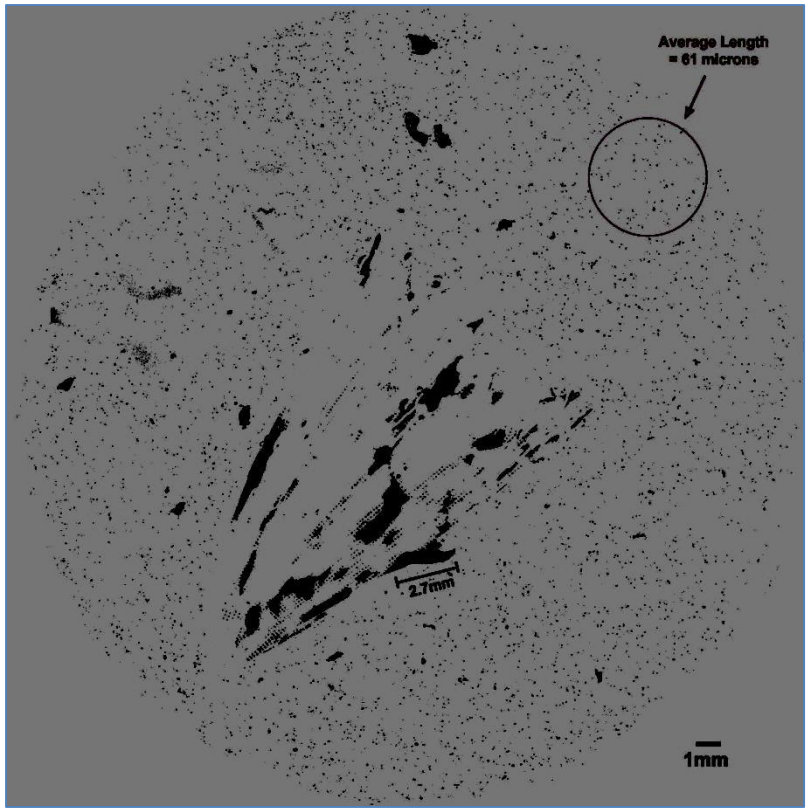
DW-MRI Results	Paladin (n=15)
Incidence of New Lesions	13%
# Lesions per patient	0.13
Mean Lesion Volume (cm^3)	0.01

Comparative DW-MRI Results Across Studies	Paladin (n=15)	CARENET[1] CGuard (n=26)	PROFI[2] Proximal group (n=31)	PROFI[2] Filter group (n=31)	ICSS[3] Filter group (n=37)
Incidence of New Lesions	13%	48%	45%	87%	73%
Mean Lesion Volume (cm^3)	0.01	0.06	0.16	0.59	NA

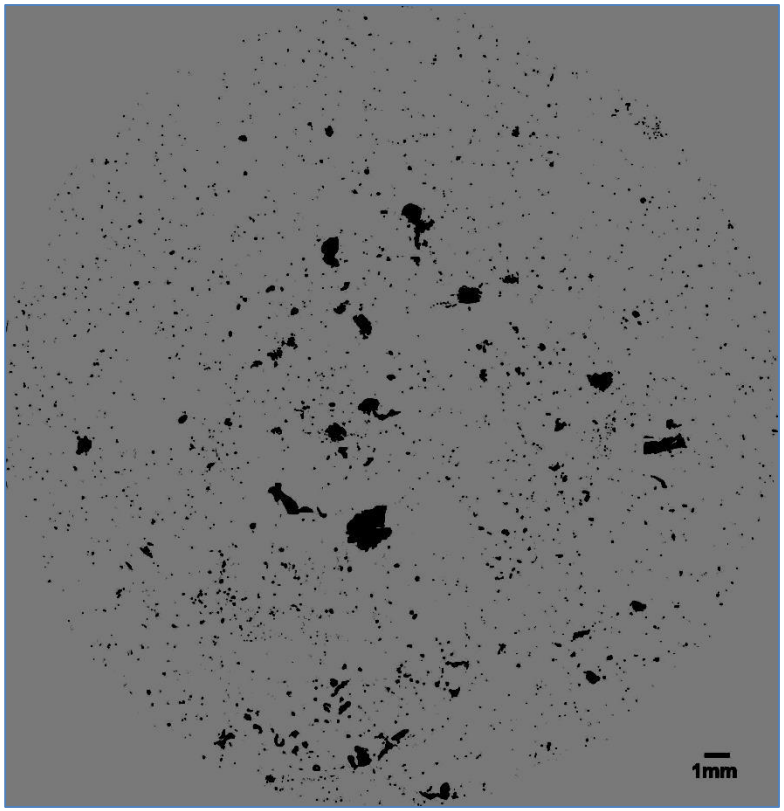
1. Schofer . TCT 2014
2. JACC. April 2012
3. Lancet, March 2010

Filter Histological Analysis: Preliminary Results Example #1

Paladin Filter



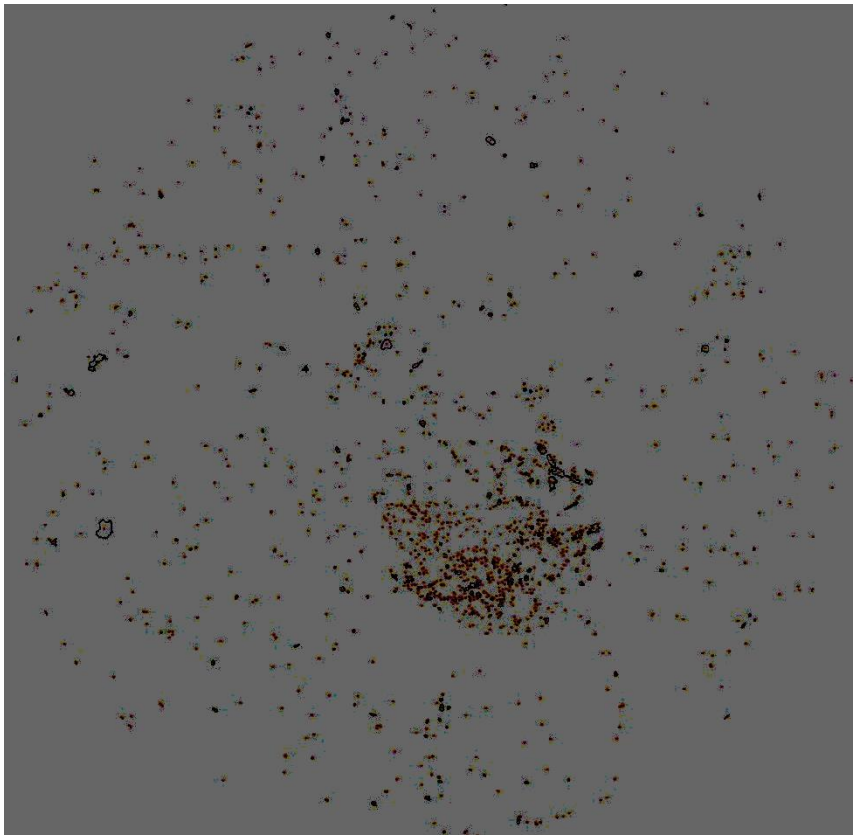
Distal Filter



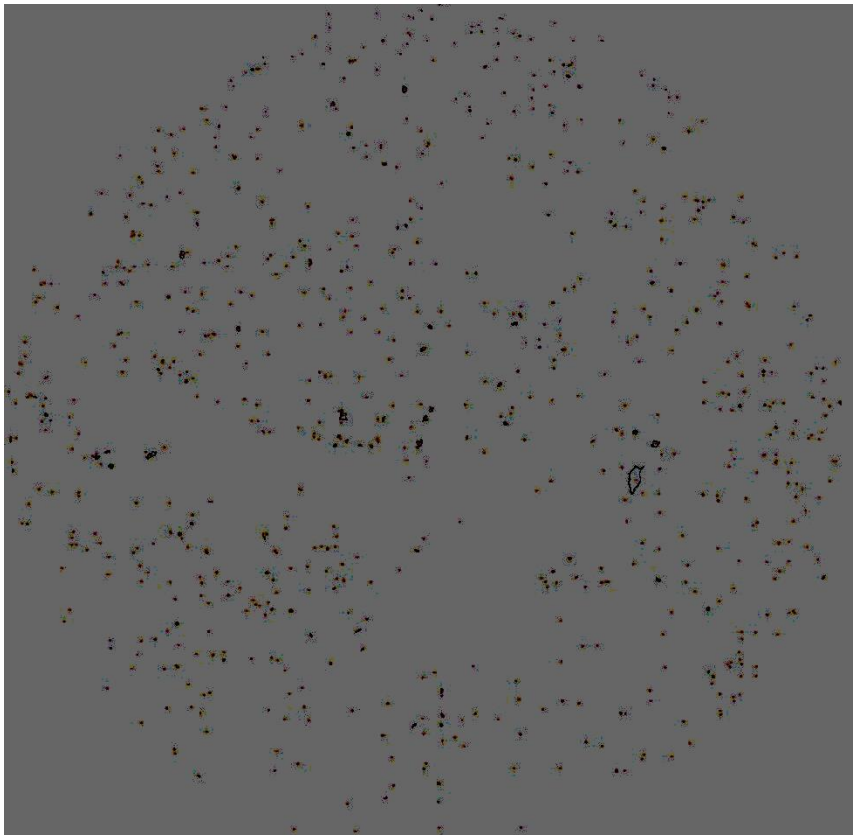
Sample Patient Filter Analysis Measurement (mm)	Paladin	Distal
Number of particles > 40 microns	732	531
Percent Count 40-80 microns vs >40	78%	60%

Filter Histological Analysis: Preliminary Results Example #2

Paladin Filter

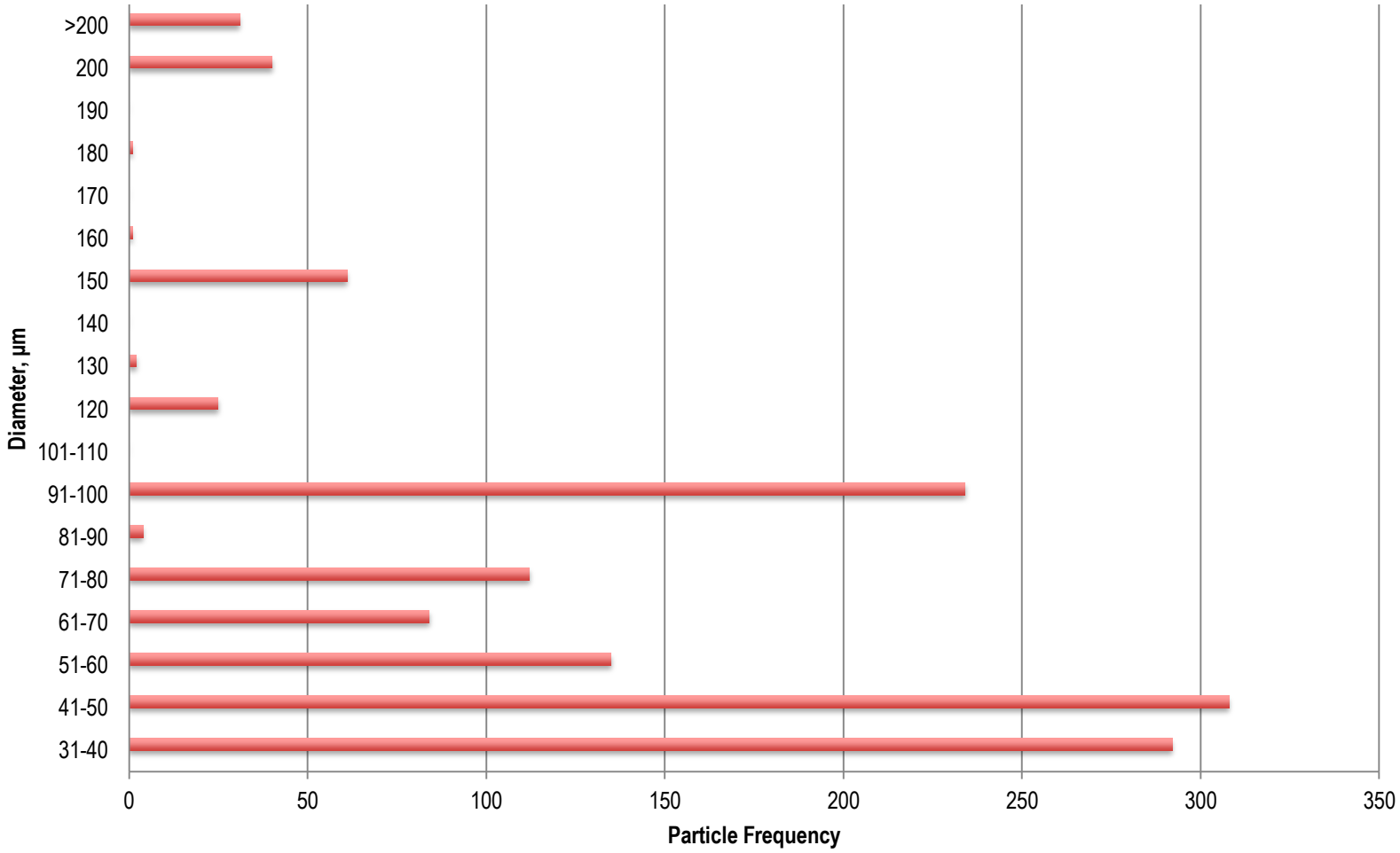


Distal Filter



Sample Patient Filter Analysis Measurement (mm)	Paladin	Distal
Number of particles	1513	824
Percent Count 40-80 microns vs >40	94%	54%

Particle size distribution in a typical Paladin Filter

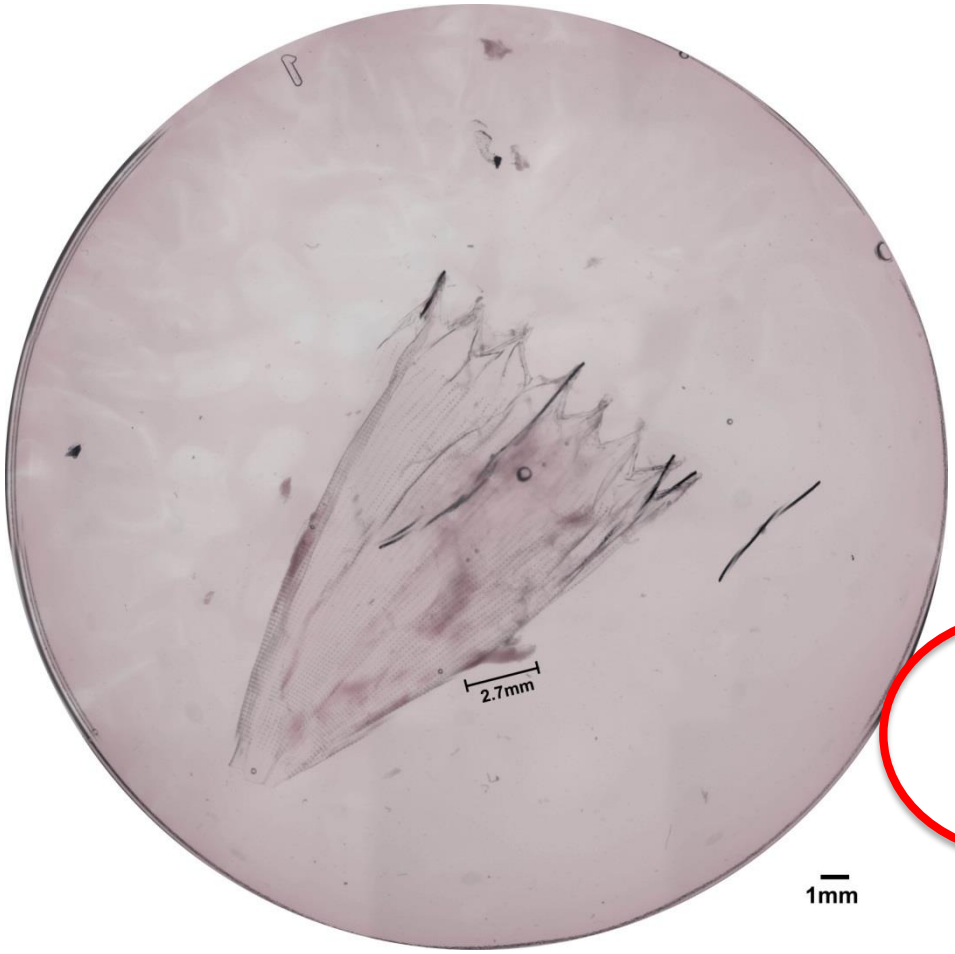


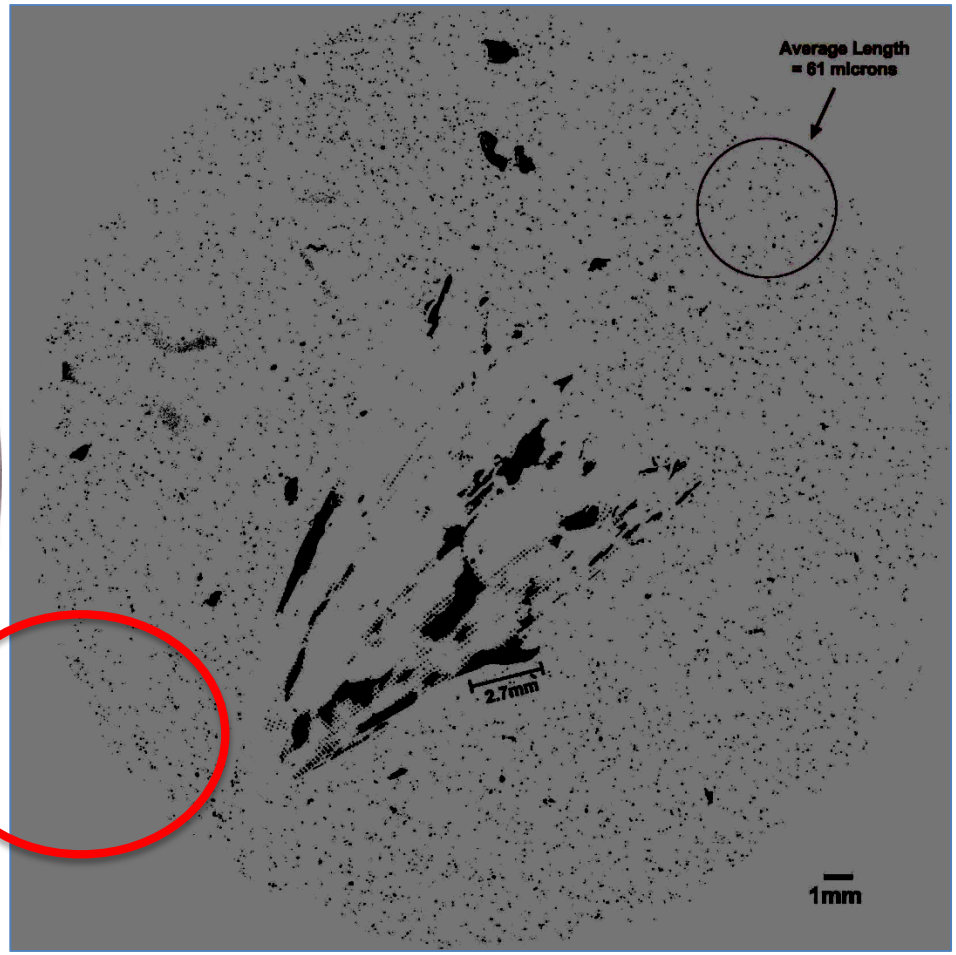
Conclusions

- Initial data for double filtration using the Paladin balloon demonstrated excellent safety and technical success
- Majority of the particles captured in the PALADIN filter are less than 100 microns
- Double filtration appears to reduce the incidence and volume of new ischemic DW MRI lesions
- Double filtration may help to reduce the problem of minor stroke during CAS
- This hypothesis needs to be studied further

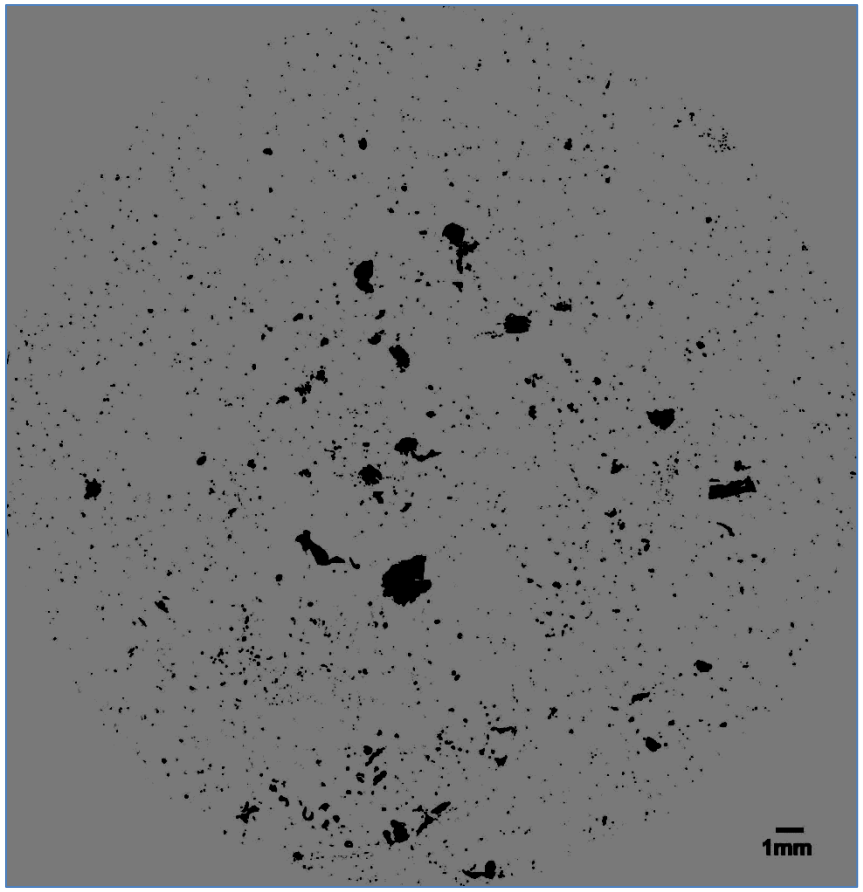
Thank You

Paladin Filter

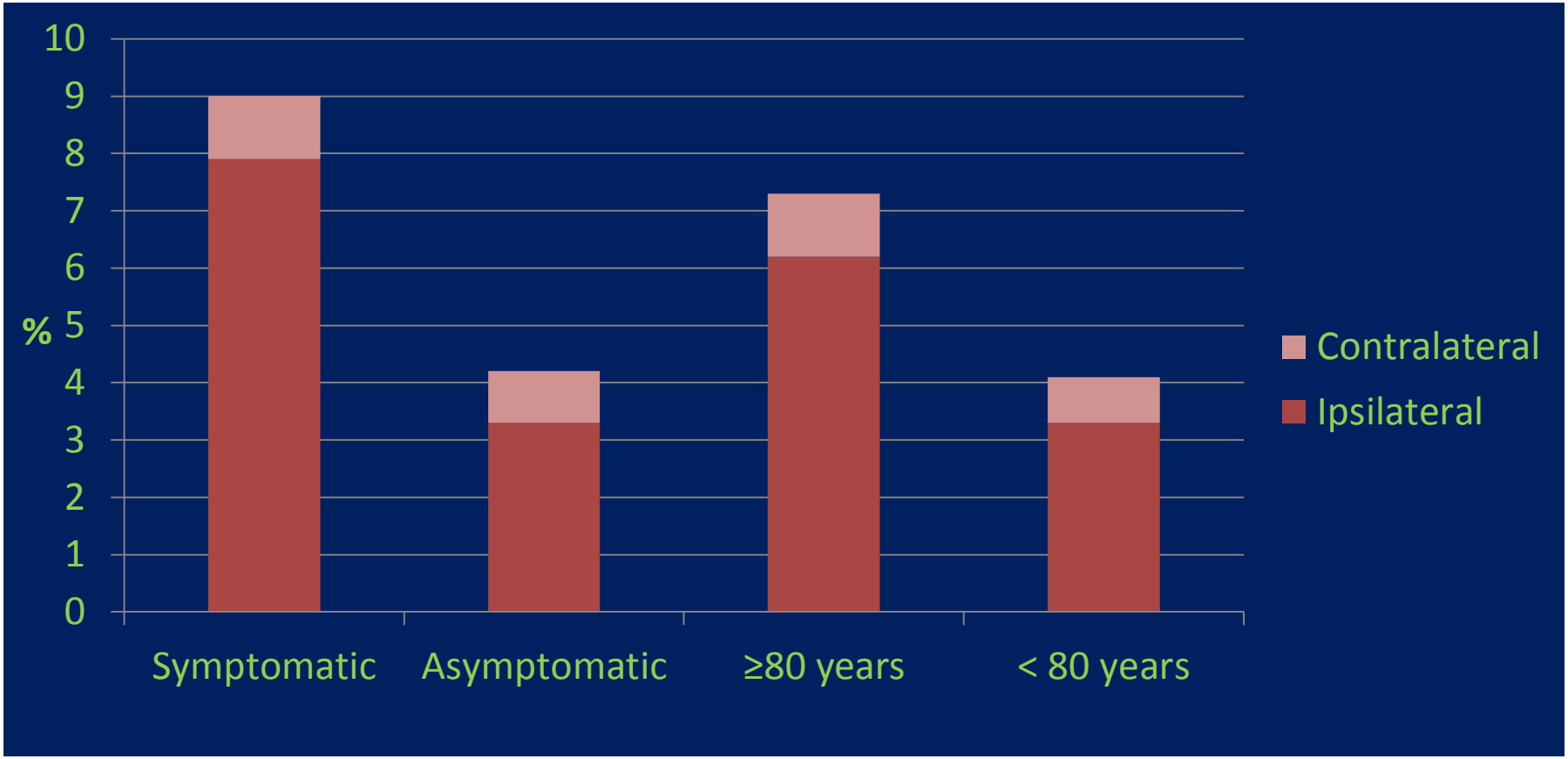




Distal Filter



However, Stroke Remains the Achilles Heal of Carotid Artery Stenting



CAPTURE 3500:
Stroke by Symptoms, Age, and Location