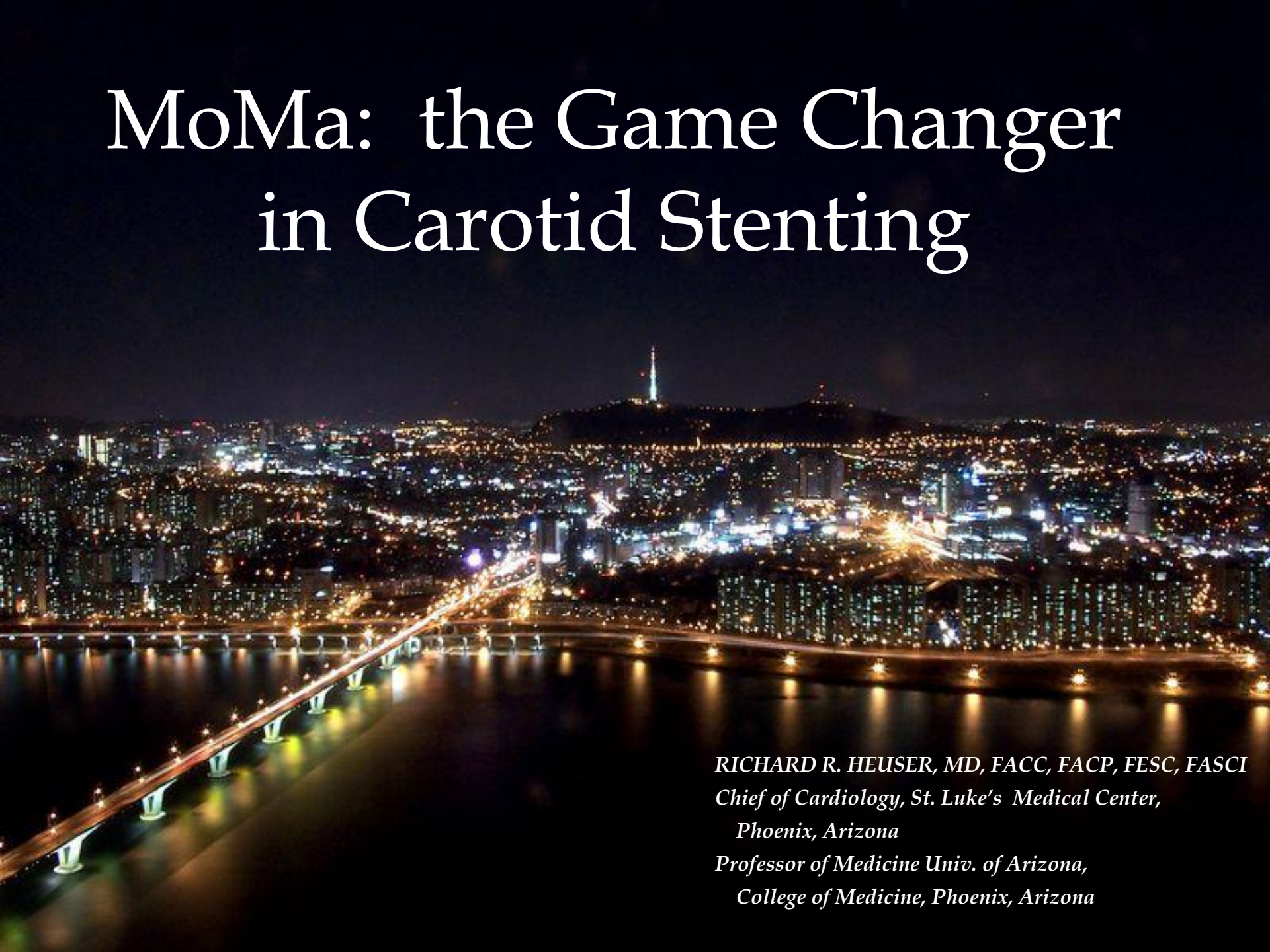
MoMa: the Game Changer in Carotid Stenting



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Presenter Disclosure Information

Name: ***RICHARD R. HEUSER M.D.***

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

- ***QuantumCor, Major Stock Holder/Medical Director;***
- ***Radius Medical, Avinger and Claret Medical, Major Stock Holder;***
- ***PQ ByPass, Founder and Major Stock Holder;***
- ***CSI, Stockholder;***
- ***Spectranetics, Abbott, Medtronic, Bard, Abiomed, Honorarium;***
- ***Medtronic, Abbott, AngioScore, Speaker;***
- ***Acist Medical Systems Grant; and***
- ***Verve Medical, Inc., Major Stockholder***

Patents *-- RF, Snares, Wires, Balloon Catheters, Covered Stents, Devices for Arterial Venous Connection, Devices for LV and RV Closure*

Stroke

- *731,000 strokes each year*
- *160% increase in incidence by the year 2050*

CAS: Procedure Steps

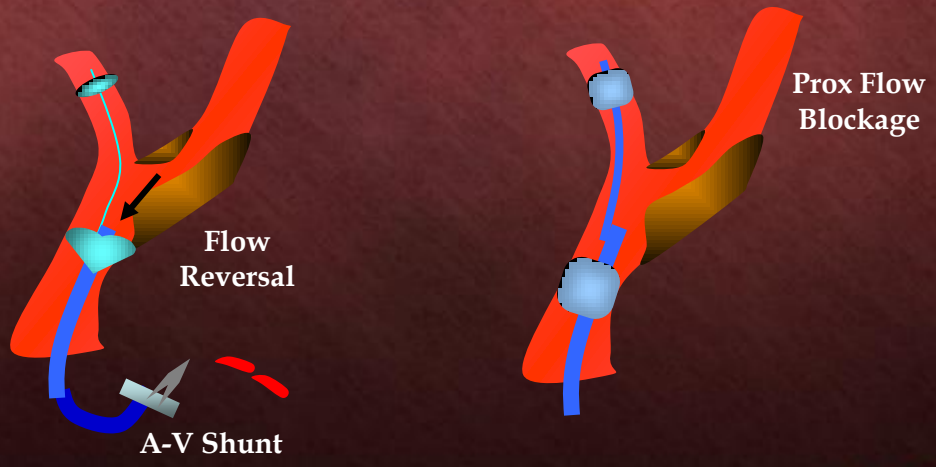
Embolic protection management: embolic protection device (EPD)

Distal Protection

- Filter device
- Distal balloon occlusion

Proximal Protection

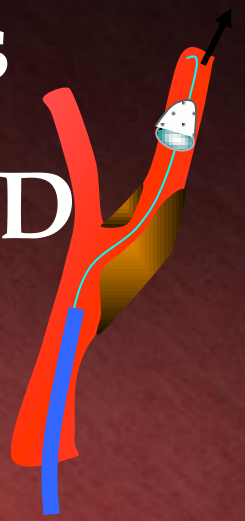
- Occlusion
- Flow reversal



Characteristics of Ideal CAS EPD System

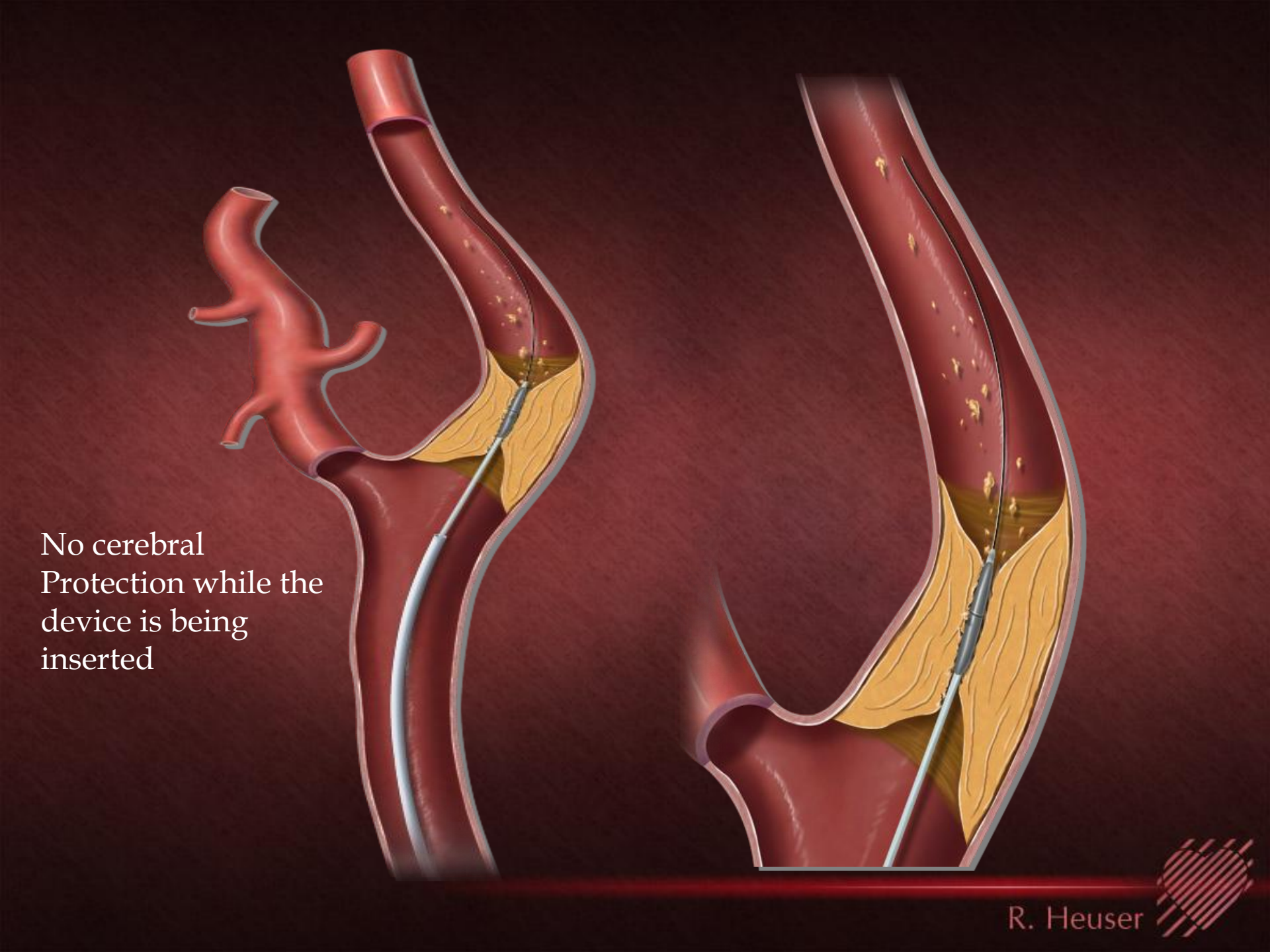
- Ease of use
- Stable device position
- Maintains cerebral perfusion
- Complete protection for all parts of CAS procedure (including lesion crossing and placing EPD)
- Use of preferred guidewire
- Minimal/no restrictions on landing zone
- Applicable to all plaque morphologies
- Captures debris of all sizes; effective aspiration
- Documented results in high-risk lesions and patients

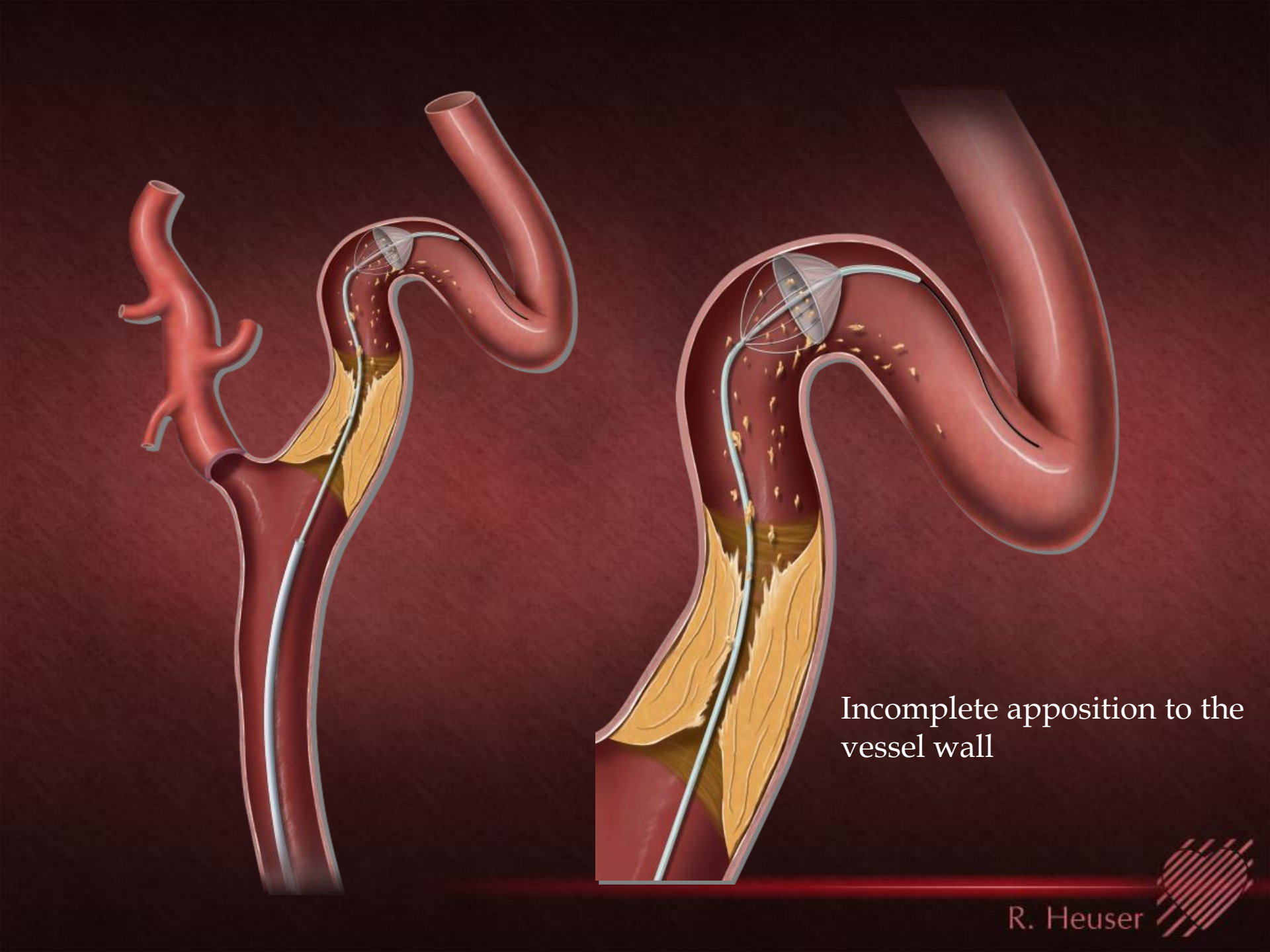
EPD: Embolic Filter Devices

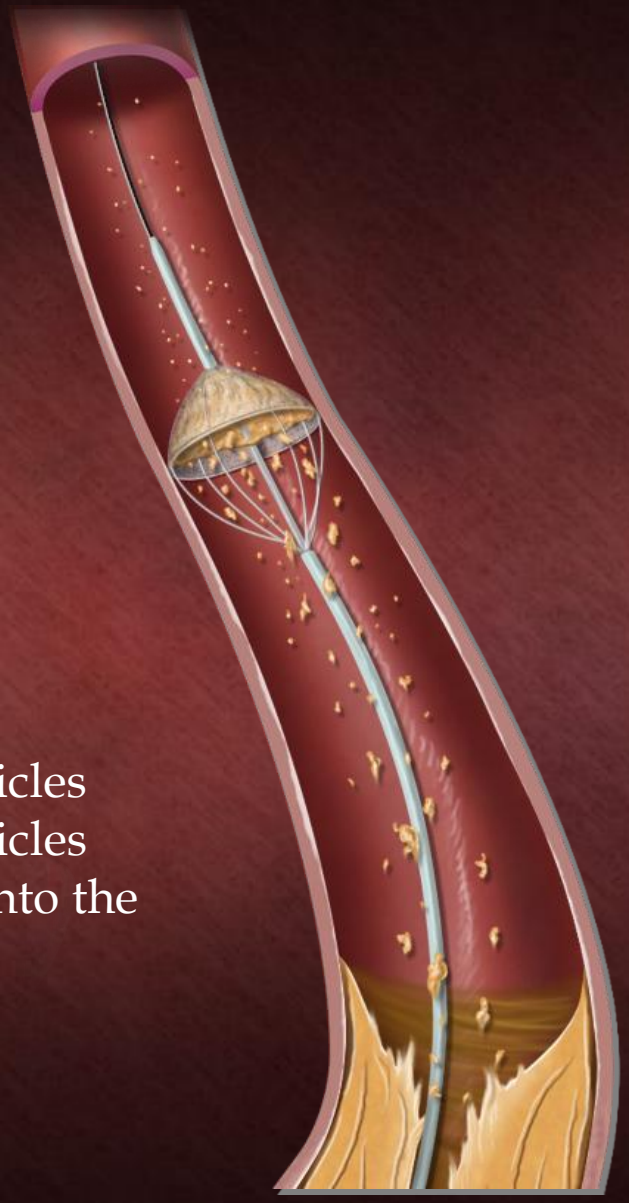


Distal filters are most common EPD used

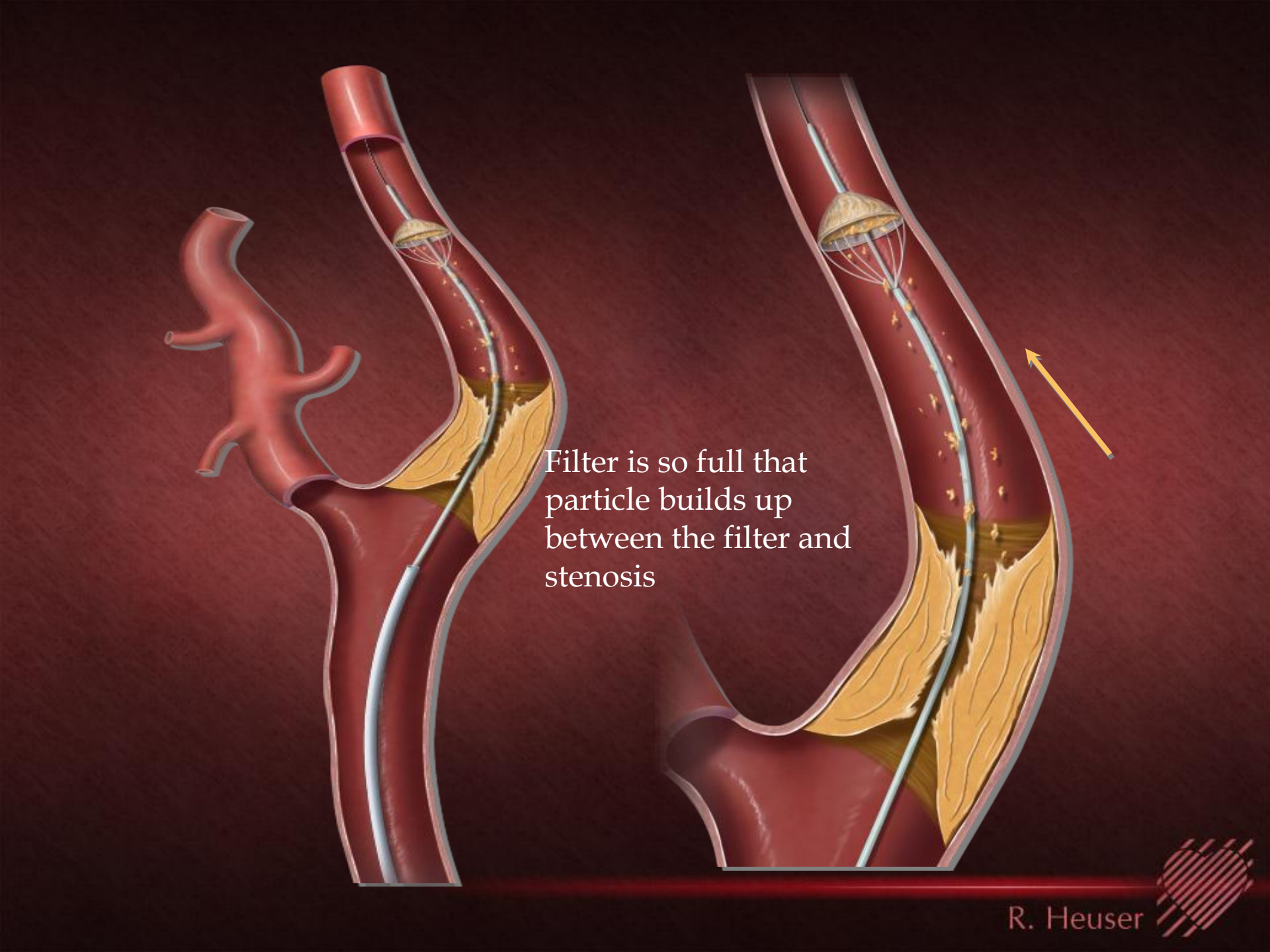
- Relatively easy to use
- Angiographic visualization available
- Cerebral perfusion maintained
- Generally well tolerated and does not require collateral flow to treated hemisphere
- Overall favorable results

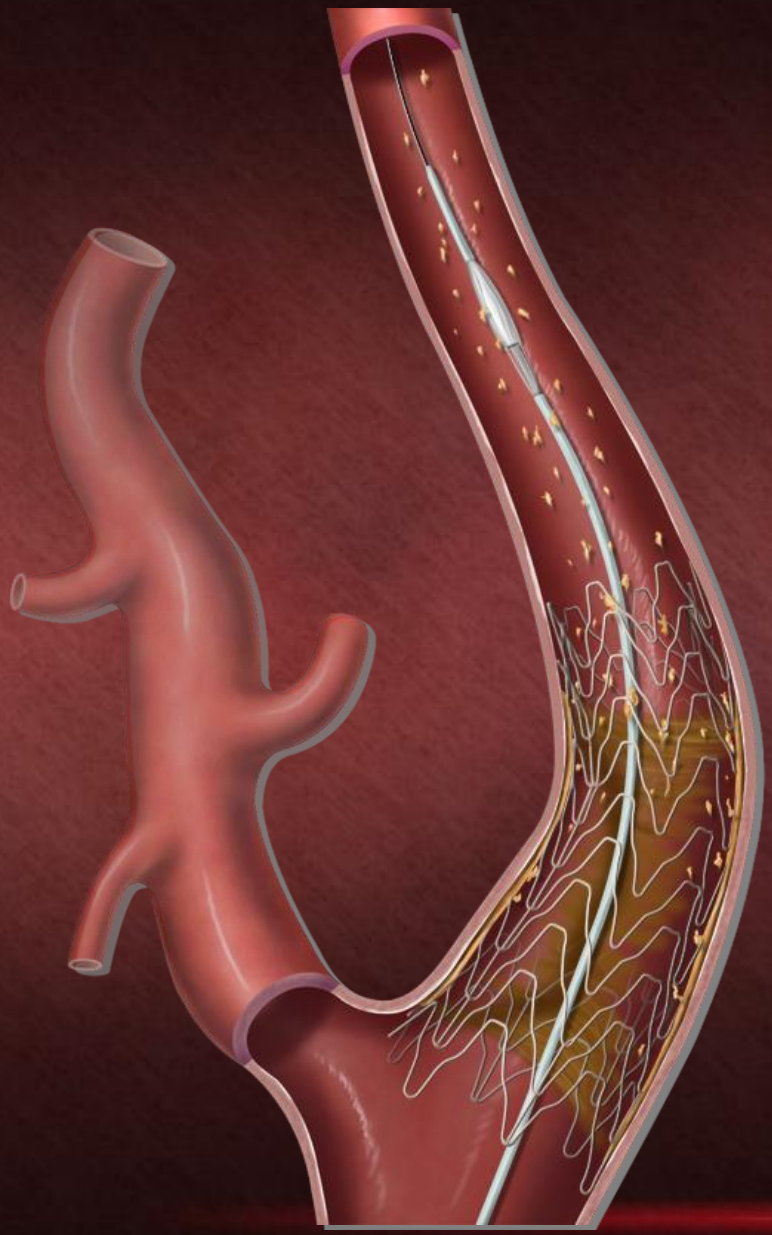

No cerebral
Protection while the
device is being
inserted
R. Heuser


Incomplete apposition to the vessel wall
R. Heuser



Filters exclude large particles >100 microns. Small particles may pass through filter into the brain


Filter is so full that particle builds up between the filter and stenosis
R. Heuser

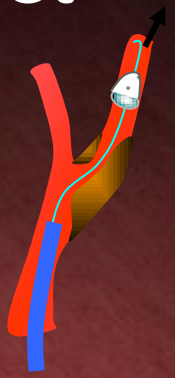


When the filter is full of debris, particles suspended between the filter and stent may be expelled when the filter is removal

R. Heuser

Embolic Protection Filters

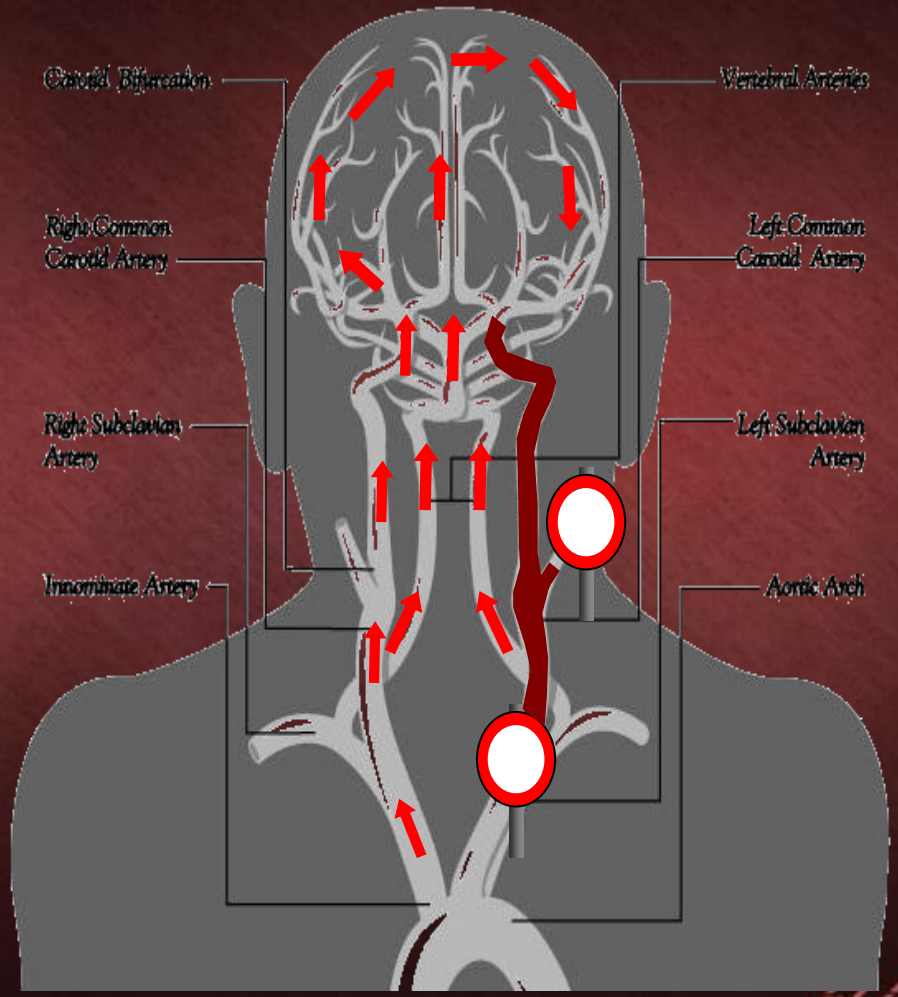
EPD: Filter Devices - NOT a perfect EPD



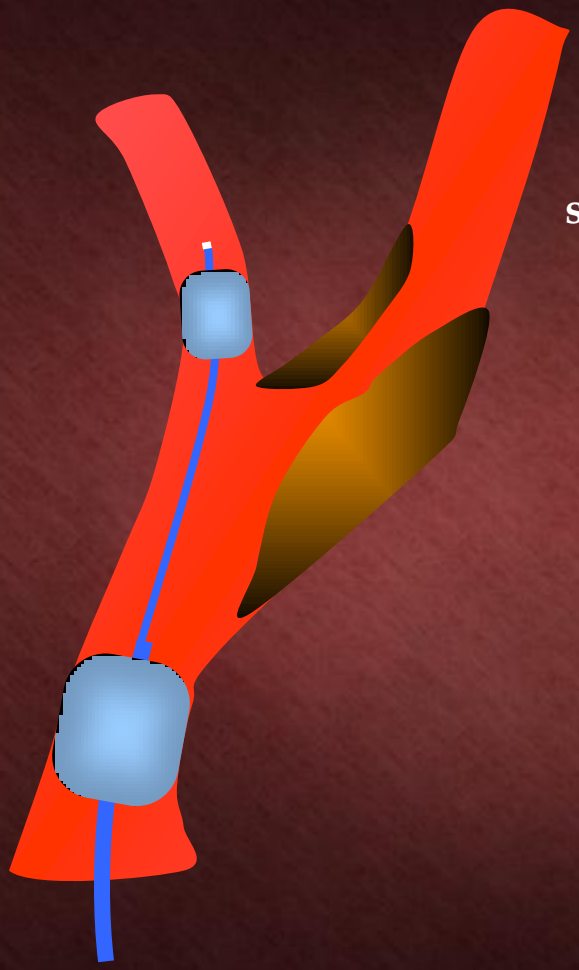
- No cerebral protection while crossing lesion
- Requires straight landing zone
- Difficult to deliver and use in tortuous ICAs
- Filter may not provide complete cerebral protection -malapposition
- Filter may allow passage of particles < 100-150 µm
- Filter may become filled with debris and require aspiration
- May cause spasm/dissection
- Difficult to retrieve through newly placed stents

EPD: Mo.Ma® Ultra Proximal Cerebral Protection Device

- Common carotid artery (CCA) clamping
  - Suspends antegrade blood flow for CCA
- External carotid artery (ECA) clamping
  - Suspends retrograde blood flow from ECA
- Combined to stop flow of ICA
- Remove debris via syringe aspiration



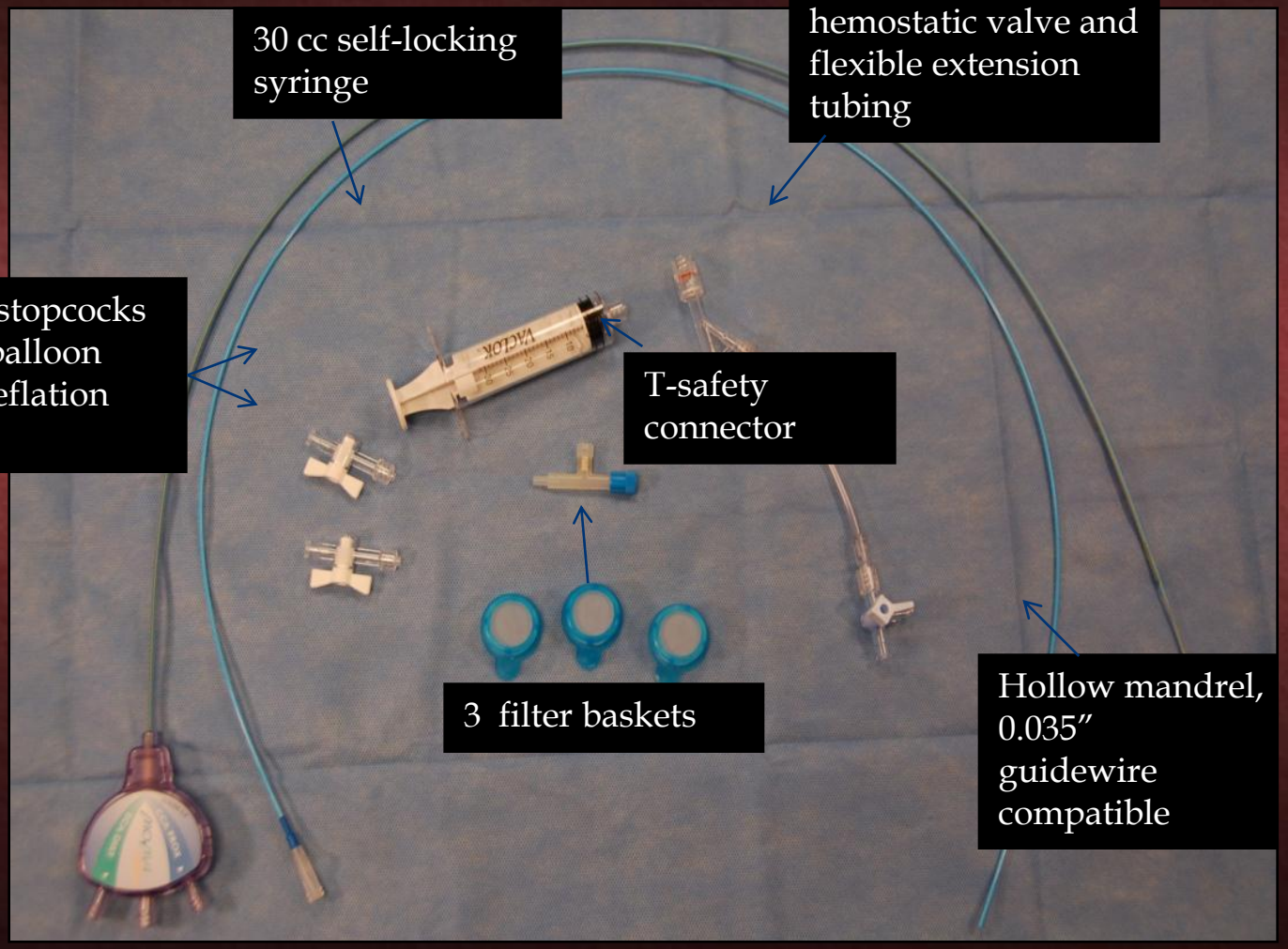
EPD: Concept of Proximal Cerebral Protection



Flow suspension during CAS

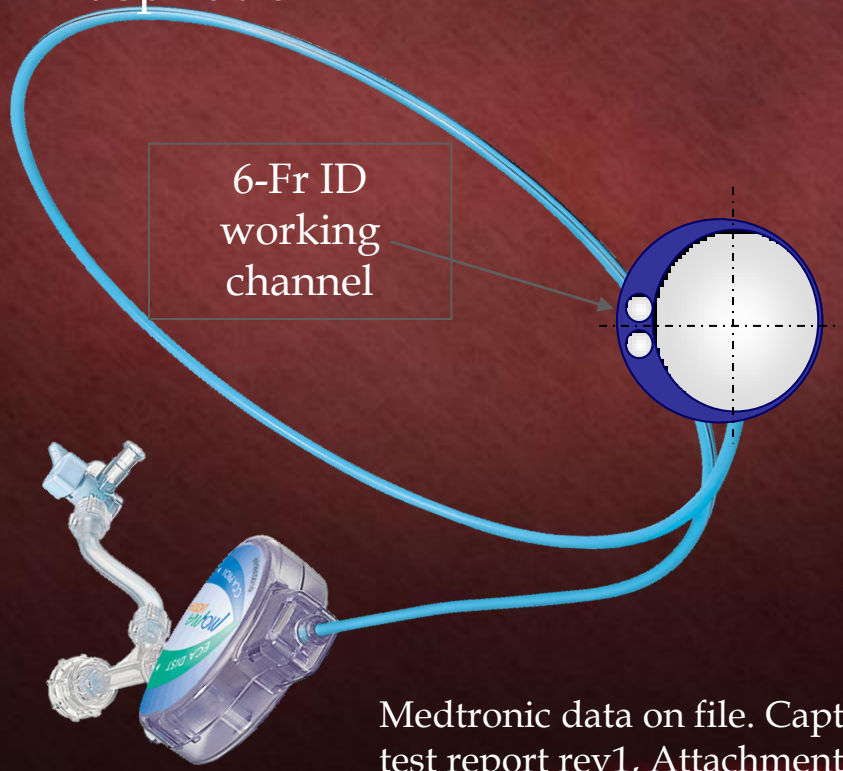
- Protection established before crossing ICA lesion
- No distal landing zone required
- 0.014″ guidewire wire of choice for ICA intervention
- Backup support/device stability due to two occlusion balloons and braided catheter
- Effectively captures debris of various sizes
- Cerebral protection by debris aspiration through 6-Fr working channel

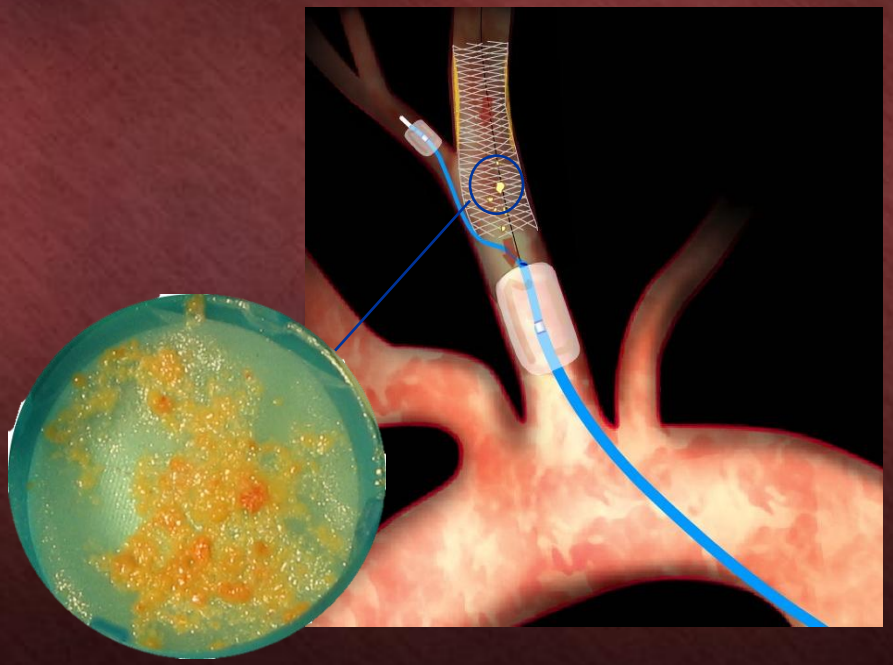
Mo.Ma Ultra Proximal Protection System Components



Mo.Ma Ultra Proximal Cerebral Protection Device

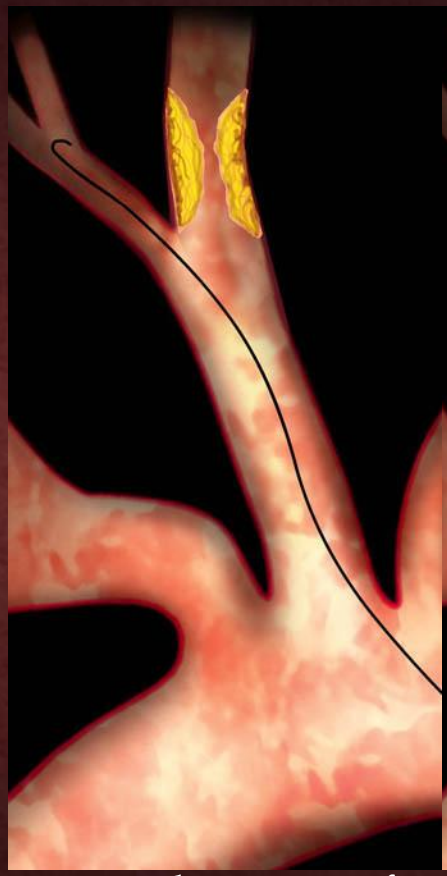
- 9-Fr outer diameter (OD) shaft
- 6-Fr inner diameter (ID) working channel port provides lesion access and effective, efficient aspiration of debris
  - Efficiently contains and removes debris of various sizes through aspiration



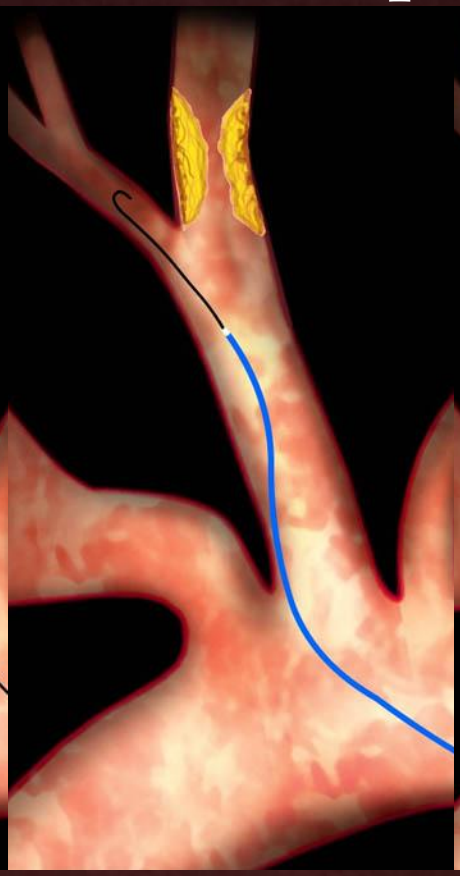


Medtronic data on file. Capture Efficiency. CP071TP02 in vitro test report rev1, Attachment 7-1.

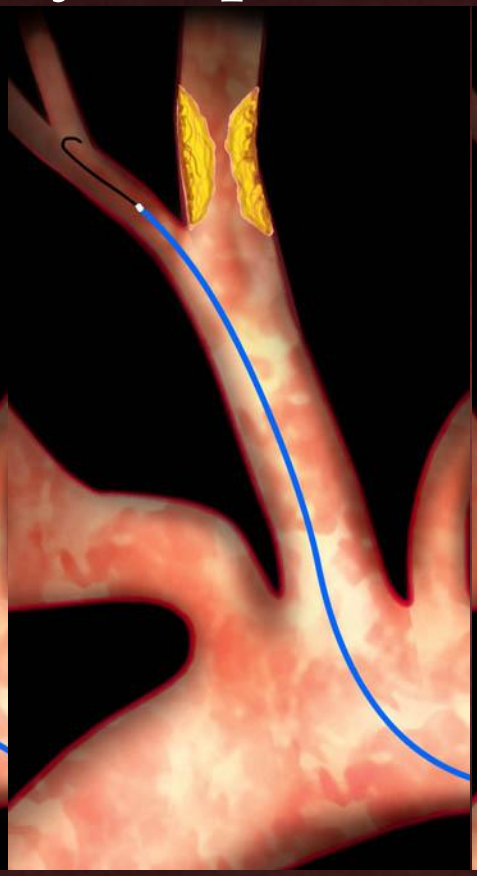
Mo.Ma Ultra Proximal Protection Device: Step by Step



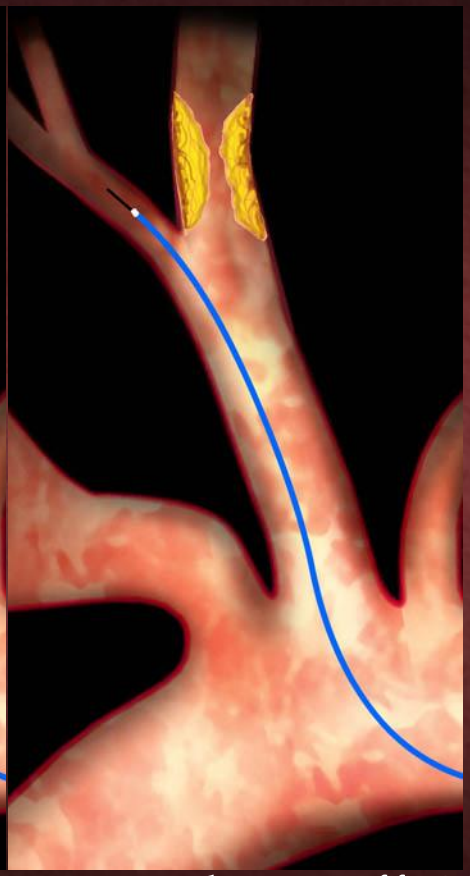
Introduction of steerable 0.035" wire into ECA



Introduction of diagnostic catheter into ECA



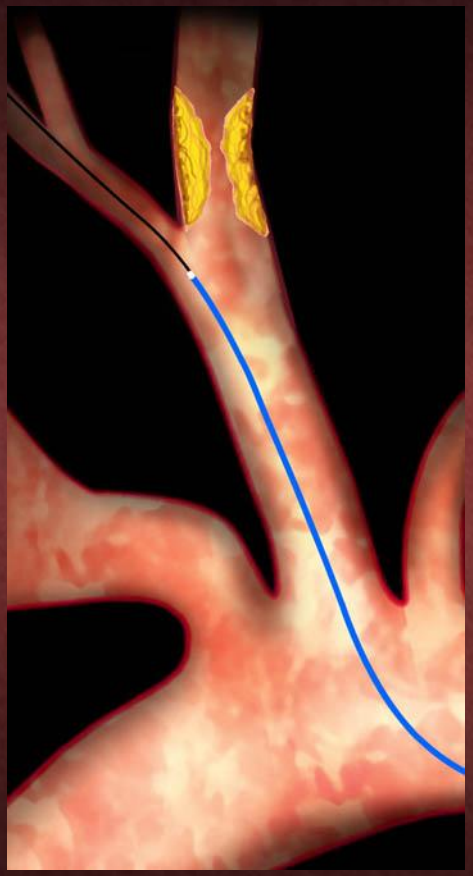
Remove steerable 0.035" guidewire



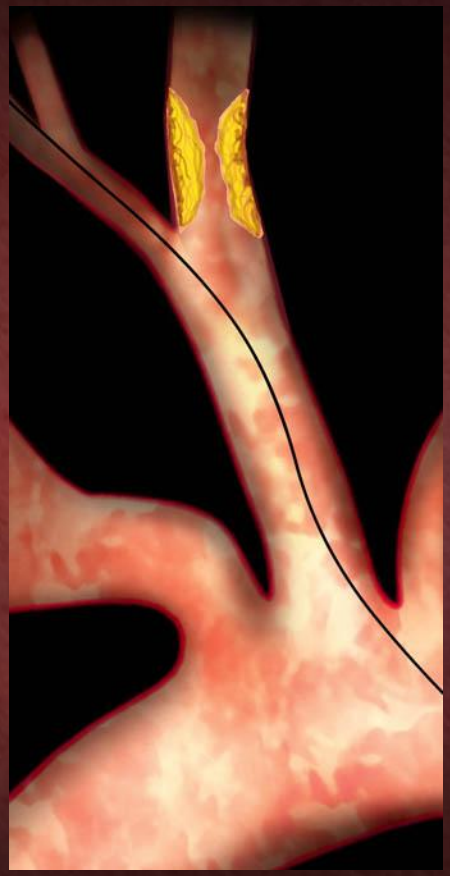
Introduce stiff .035" guidewire

R. Heuser

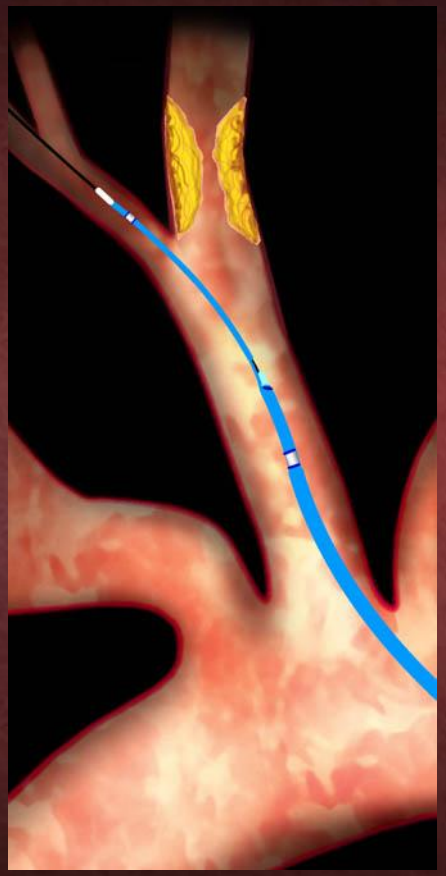
Mo.Ma Ultra Proximal Protection Device: Step by Step



Remove diagnostic catheter



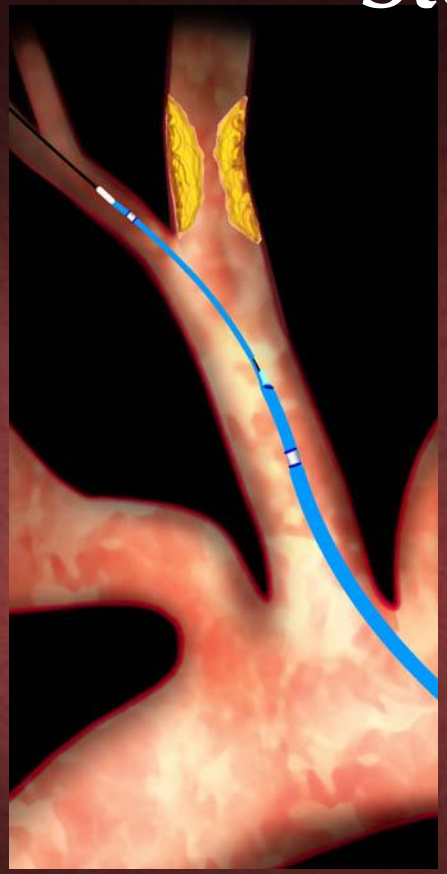
Retain 0.035” wire to introduce Mo.Ma Ultra device



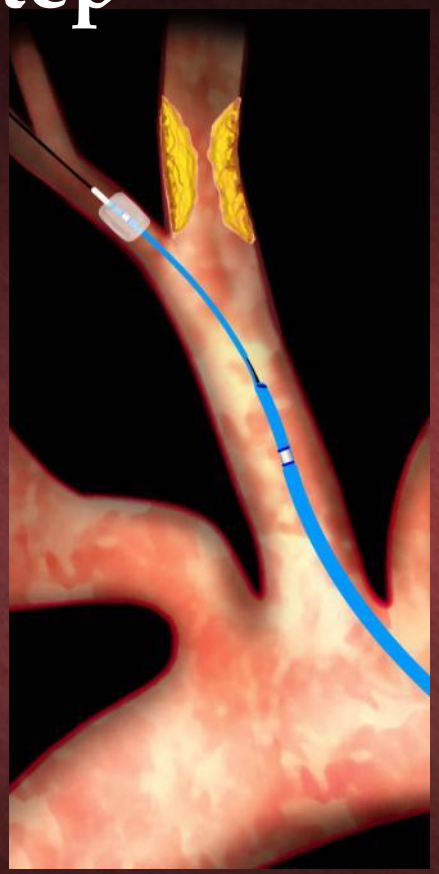
Introduce Mo.Ma Ultra device

R. Heuser

Mo.Ma Ultra Proximal Protection Device: Step by Step

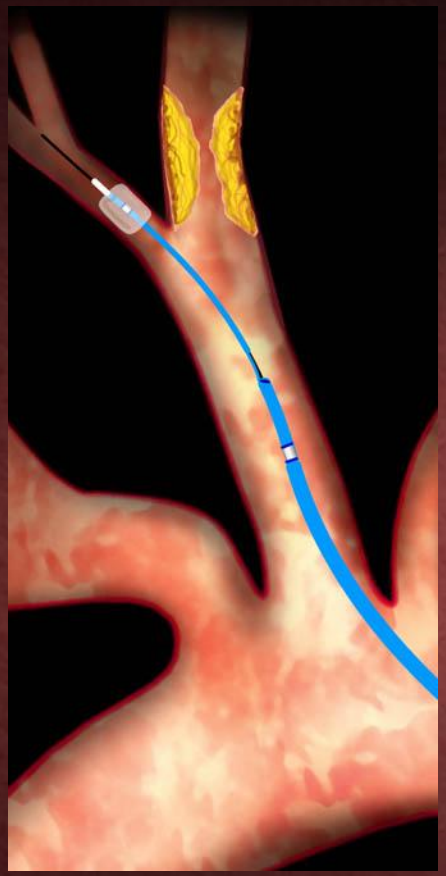


Advance Mo.Ma Ultra Device 1 cm - 1.5 cm into ECA

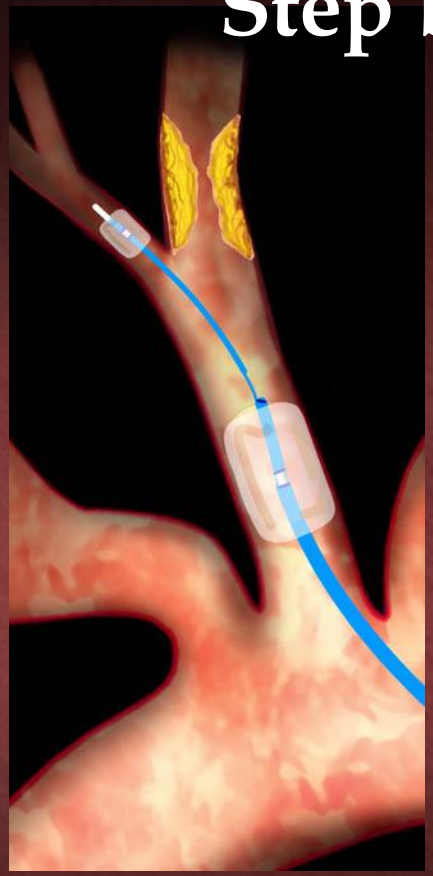


Remove mandrel; leave 0.035″ guidewire in place. Inflate distal balloon in ECA.

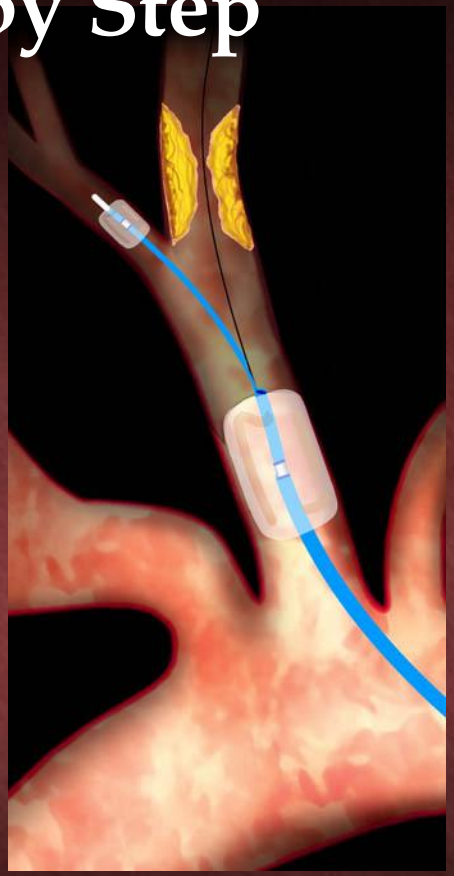
Mo.Ma Ultra Proximal Protection Device: Step by Step



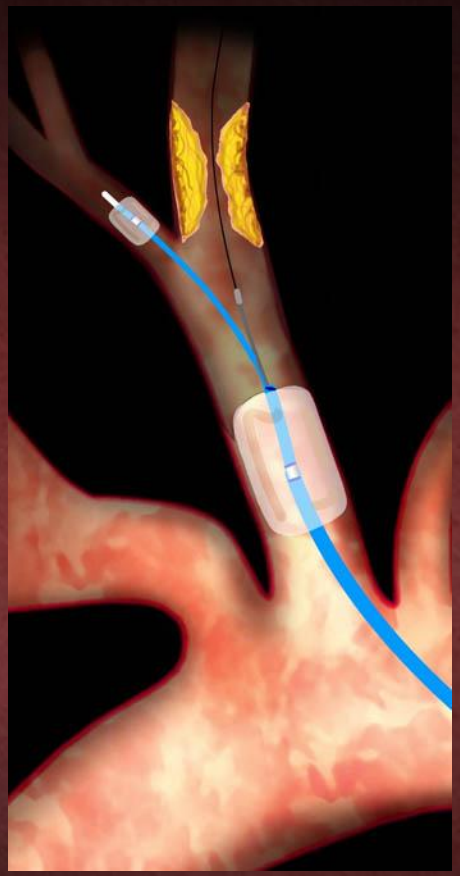
Remove 0.035" stiff guidewire



Inflate proximal balloon in the CCA



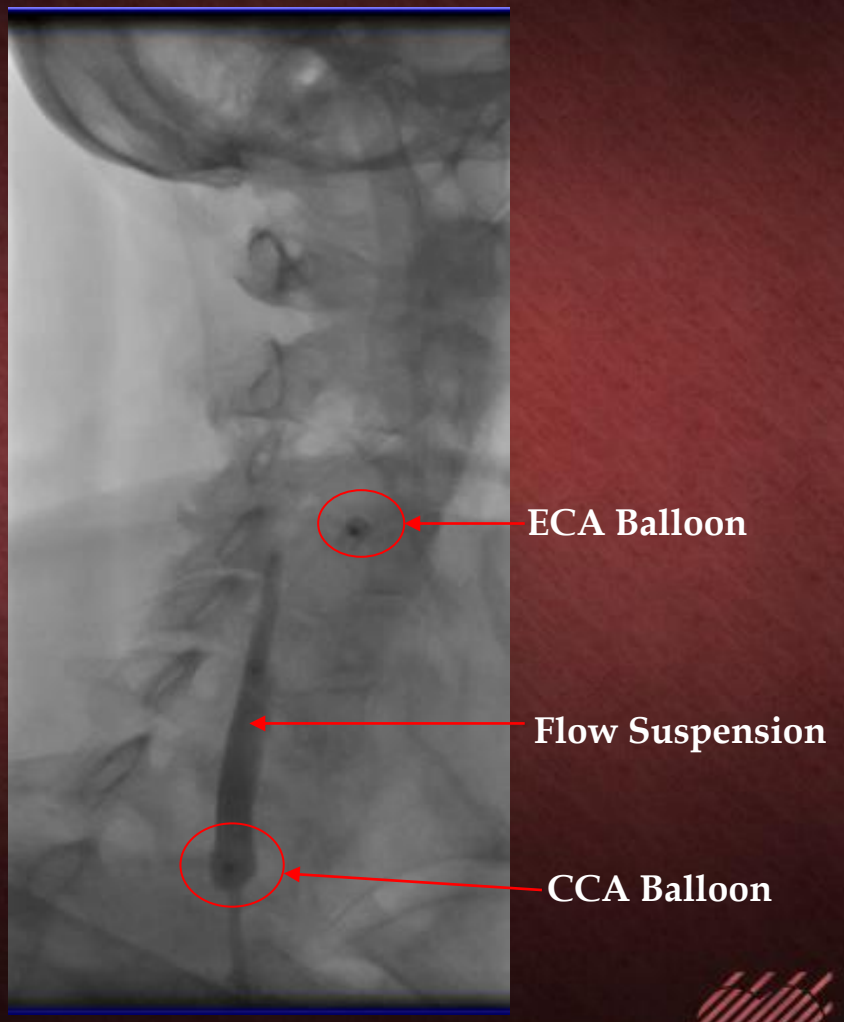
Advance 0.014" guidewire through lesion



Predilate or primary stent

Mo.Ma Ultra Proximal Cerebral Protection Device

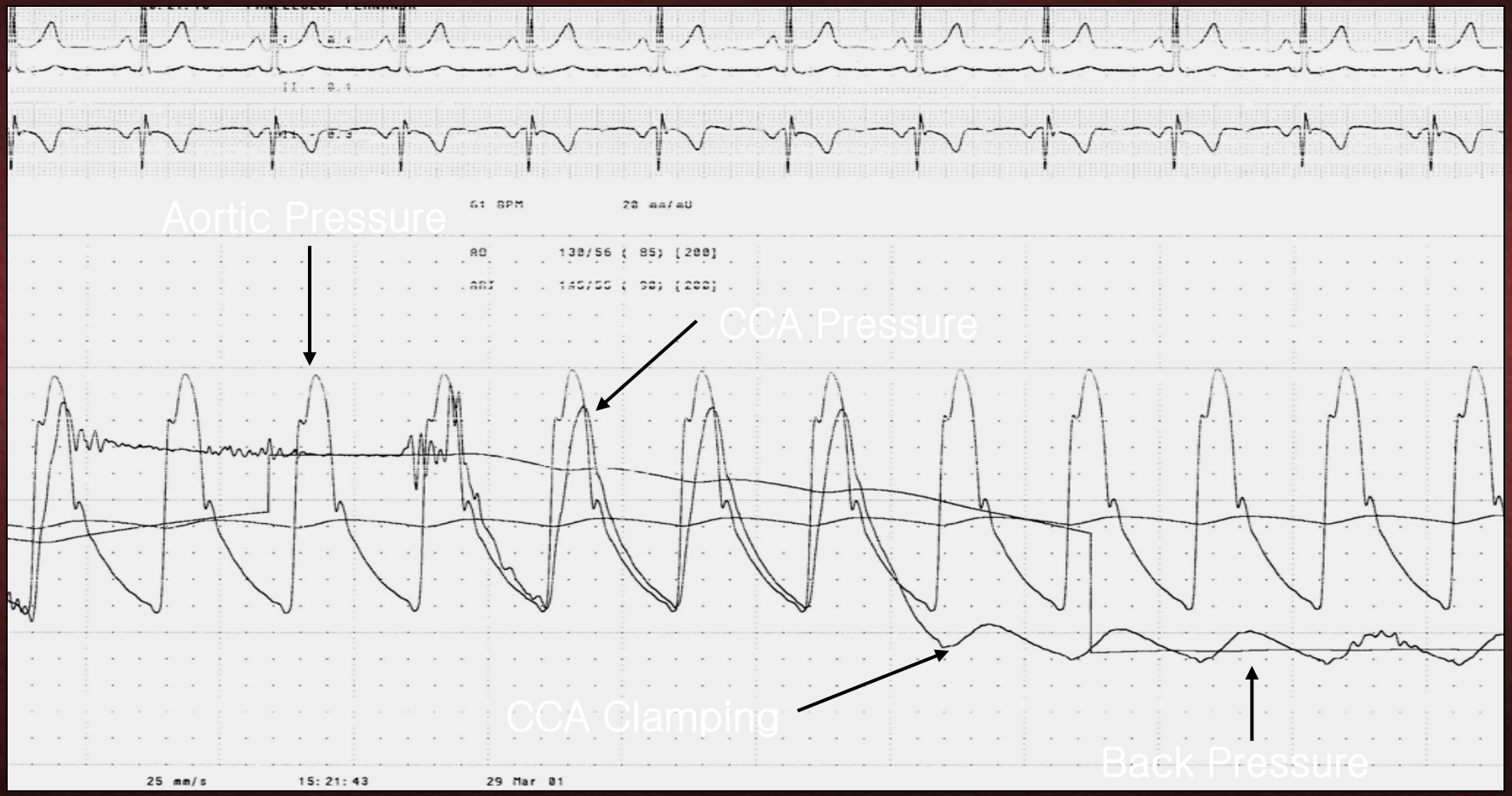
- Dual balloon inflations establish full-time proximal cerebral protection
- Temporarily suspends antegrade CCA flow and ECA retrograde flow
- Check for absence of flow after both balloons are inflated



Pressure Measurement: Mo.Ma Ultra Device

Back Pressure:

Wedge Pressure Waveform Represents CCA Occlusion



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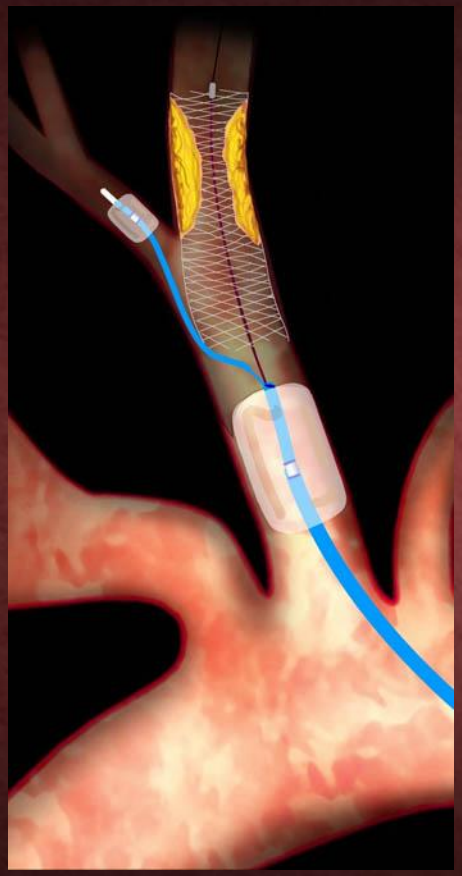
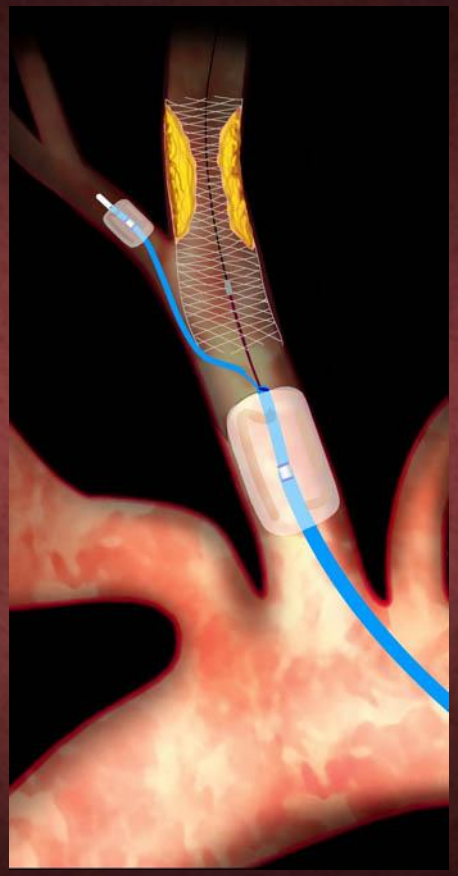
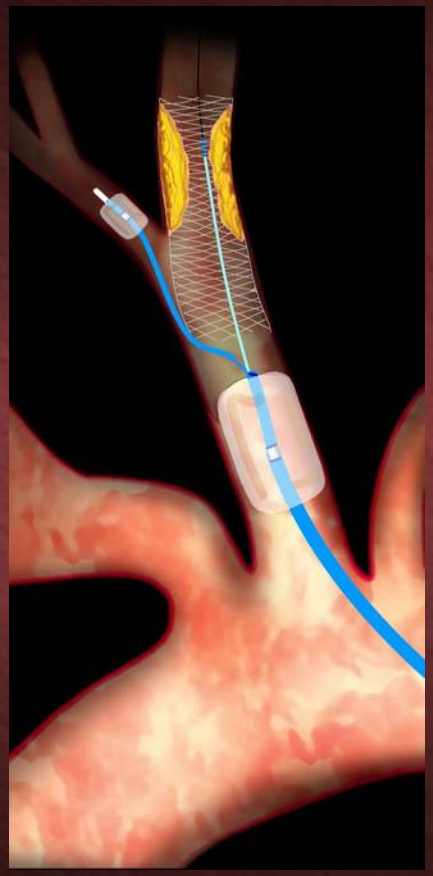
Mo.Ma Ultra Proximal Protection Device: Step by Step



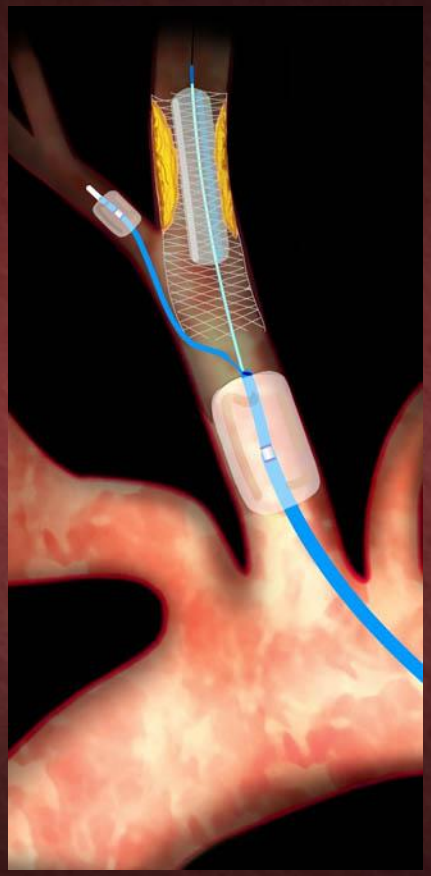
Place stent



Remove stent delivery system



Insert post-dilatation balloon



Inflate PTA balloon

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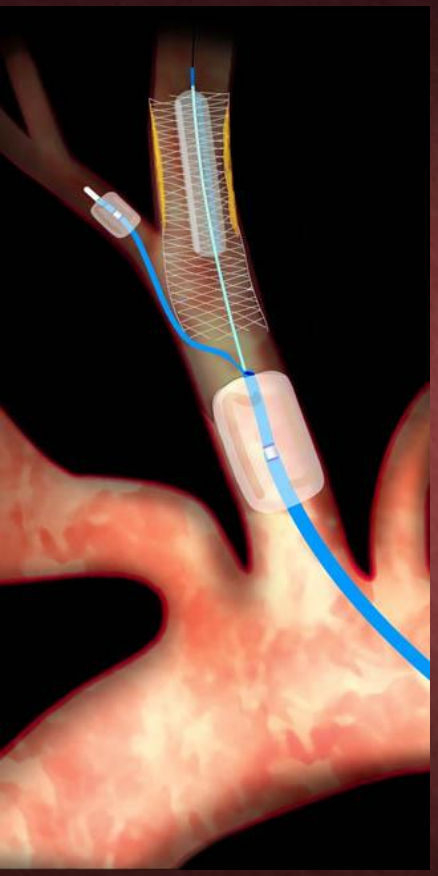
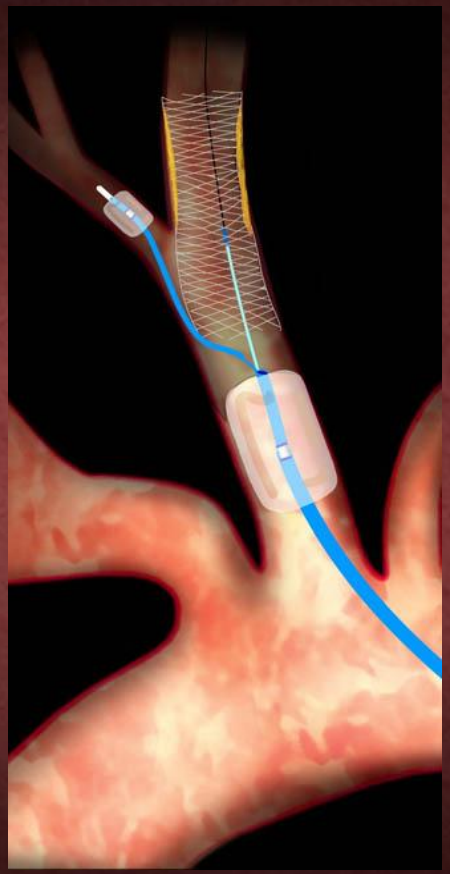
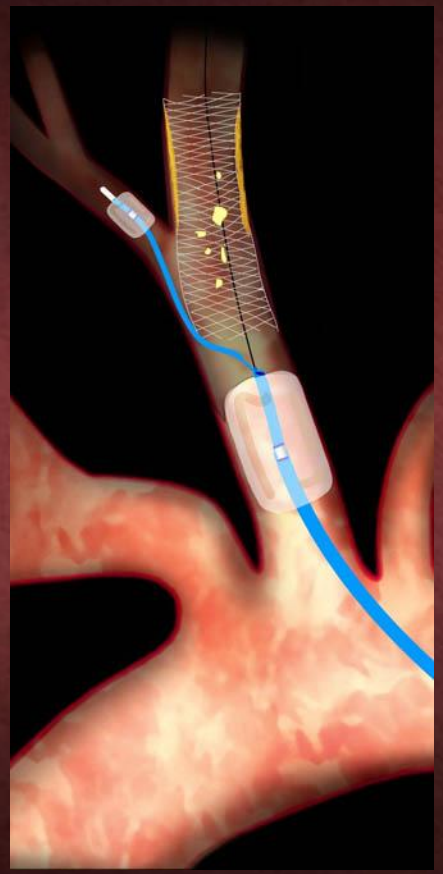
Mo.Ma Ultra Proximal Protection Device: Step by Step



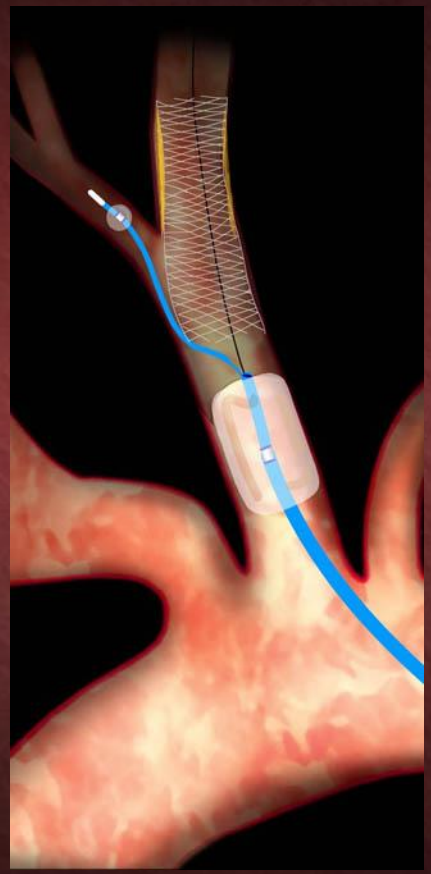
Deflate
PTA balloon



Retract
PTA balloon



Aspirate to
remove debris



Deflate distal
(ECA) balloon

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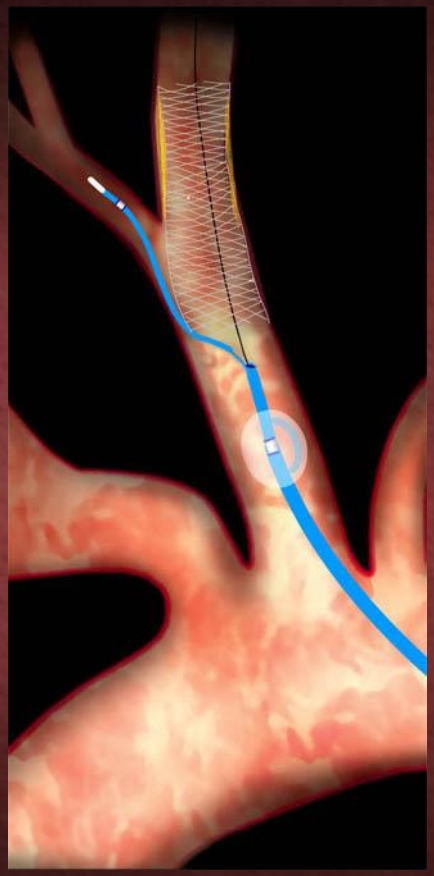
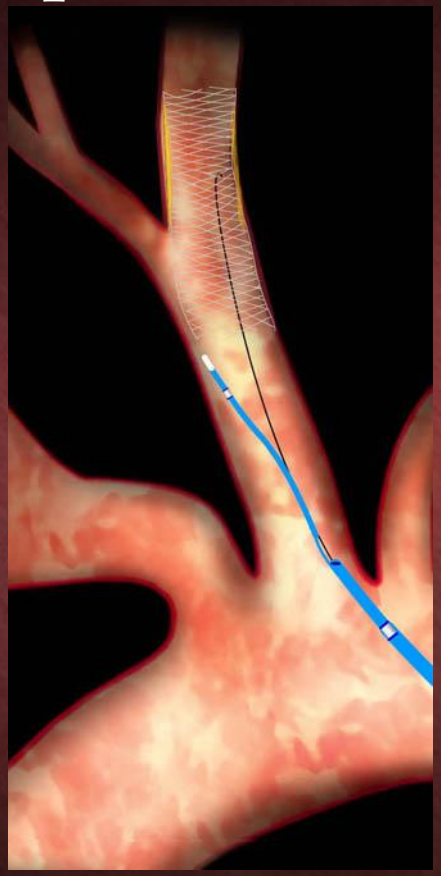
Mo.Ma Ultra Proximal Protection Device: Step by Step



Deflate proximal (CCA) balloon

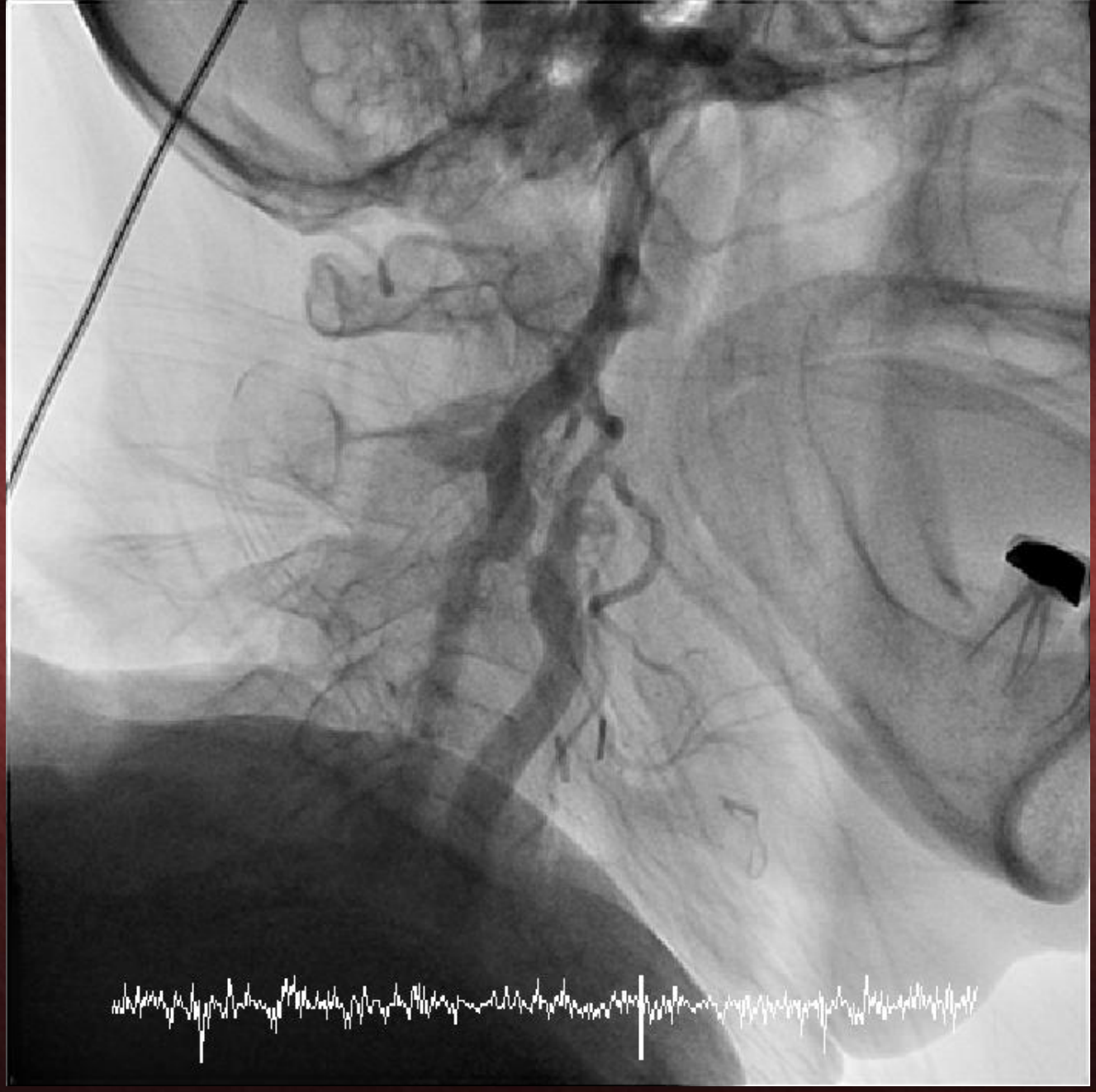


Retract Mo.Ma Ultra device and guidewire

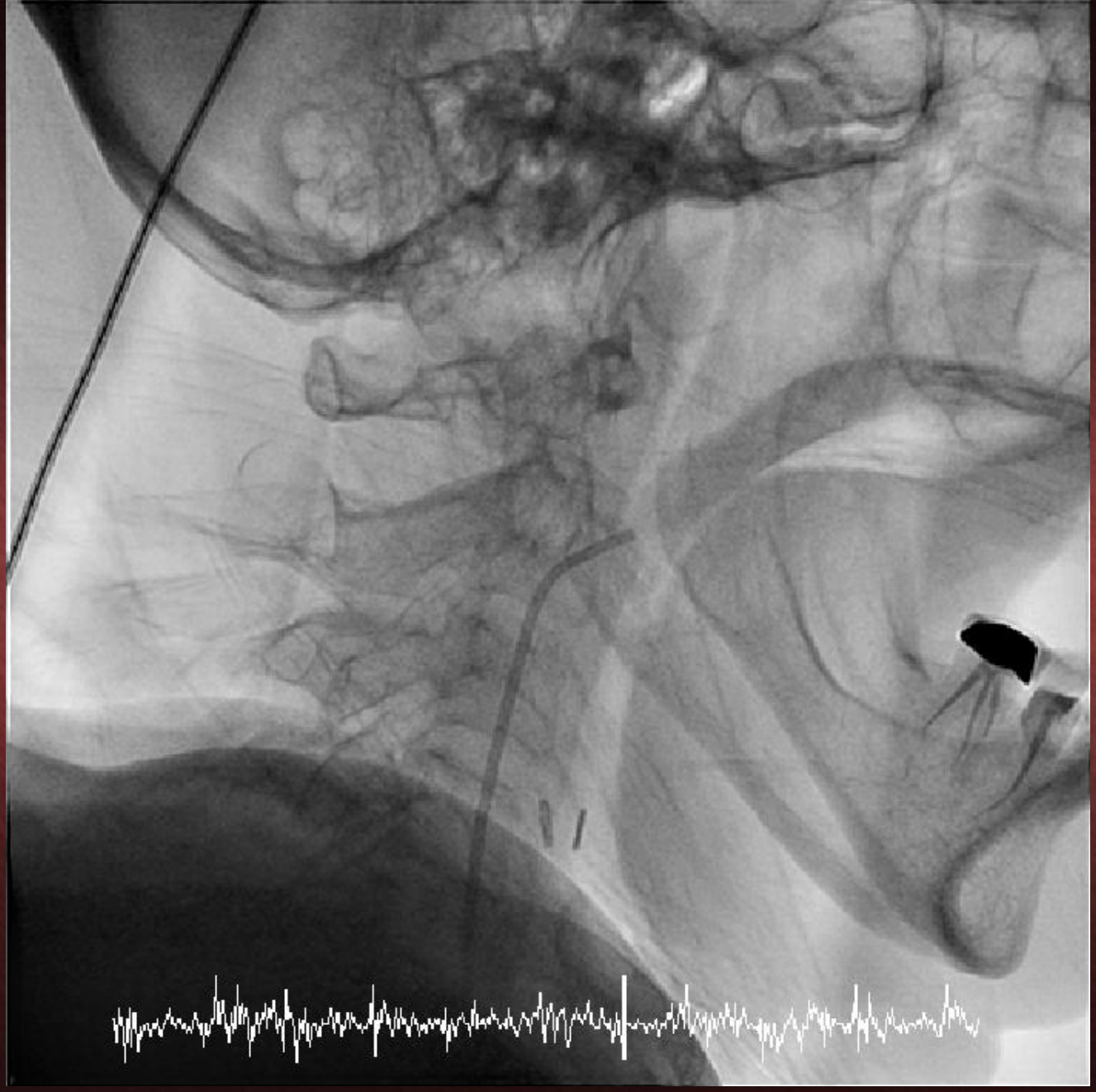
ARMOUR: Clinical Trail Overview

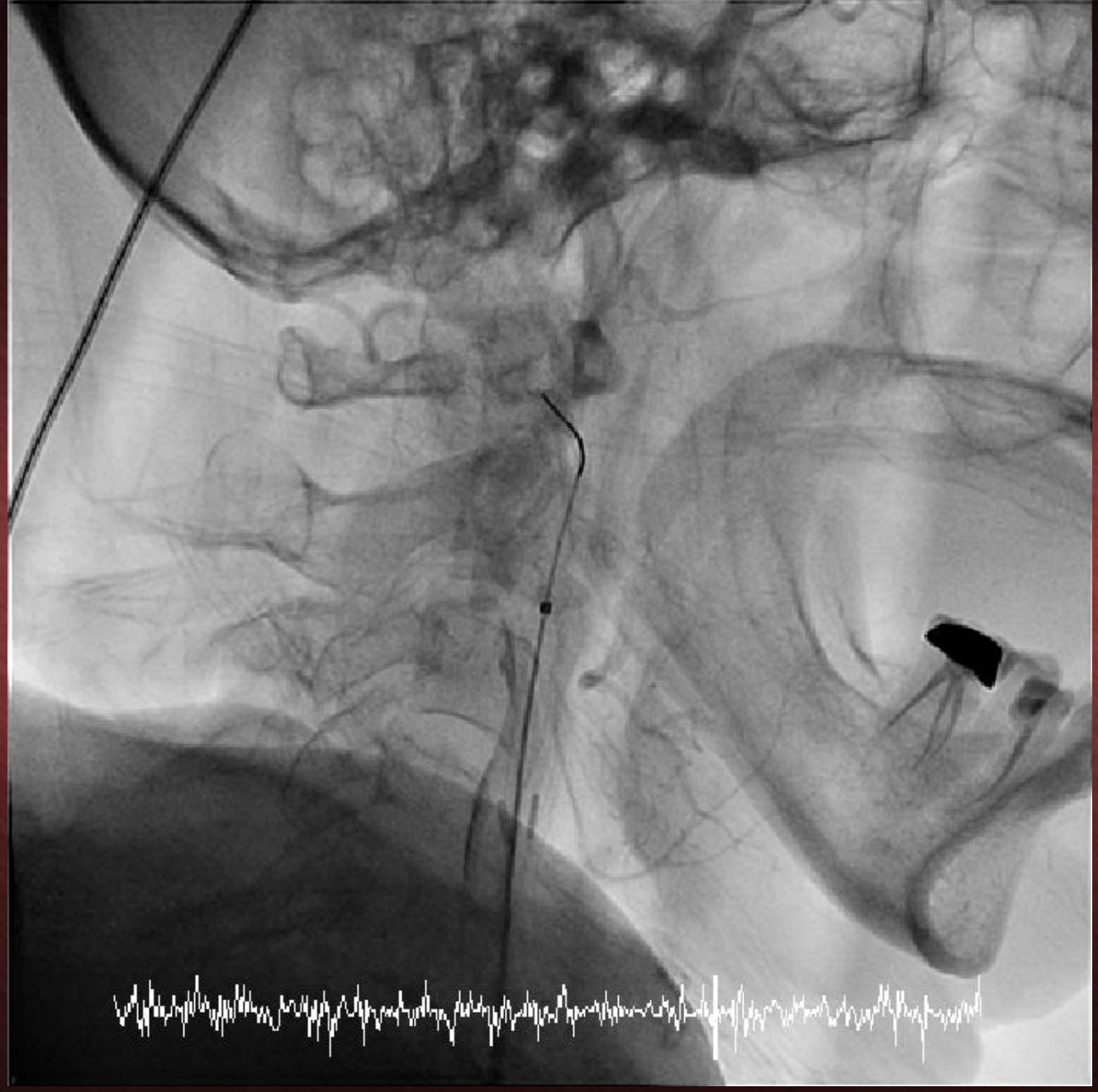
- Prospective, multicenter (US/EU), single-arm IDE trial
- To evaluate the safety and effectiveness of the Mo.Ma Ultra device for cerebral protection in high-surgical-risk CAS candidates with any FDA-approved carotid stent
  - Primary Endpoint: Major adverse cardiac and cerebrovascular events (MACCE: MI, stroke, death) at 30 days
  - 25 investigational sites (20 US; 5 EU)
  - 262 patients: 225 study subjects (ITT) + 37 roll-in
  - Independent Clinical Event Committee, Data Safety Monitoring Board, angiographic and duplex ultrasound core labs

RS is a 58 y/o patient with TIA's. She has had previous bi-lateral carotid endarterectomy and severe COPD

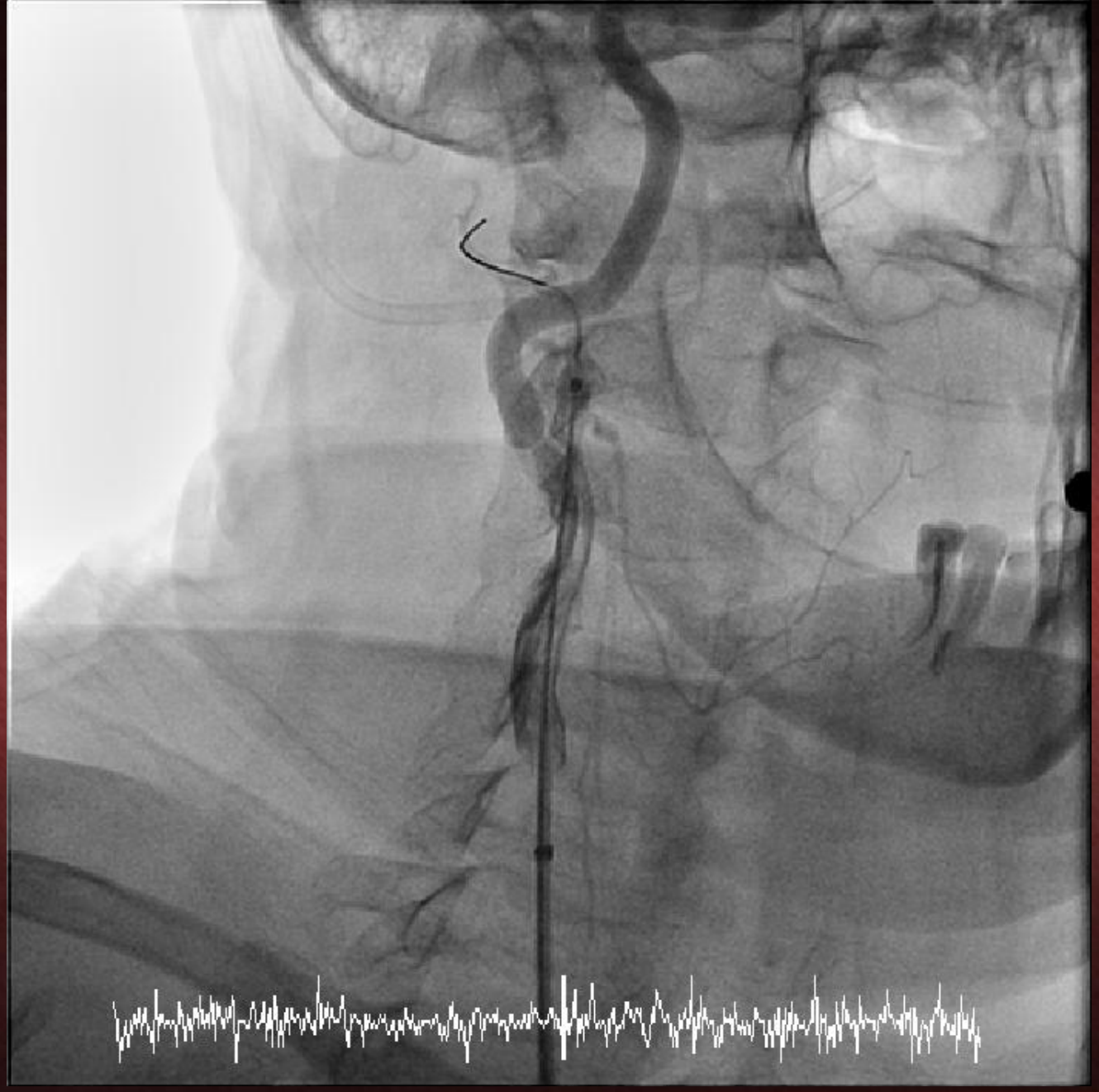


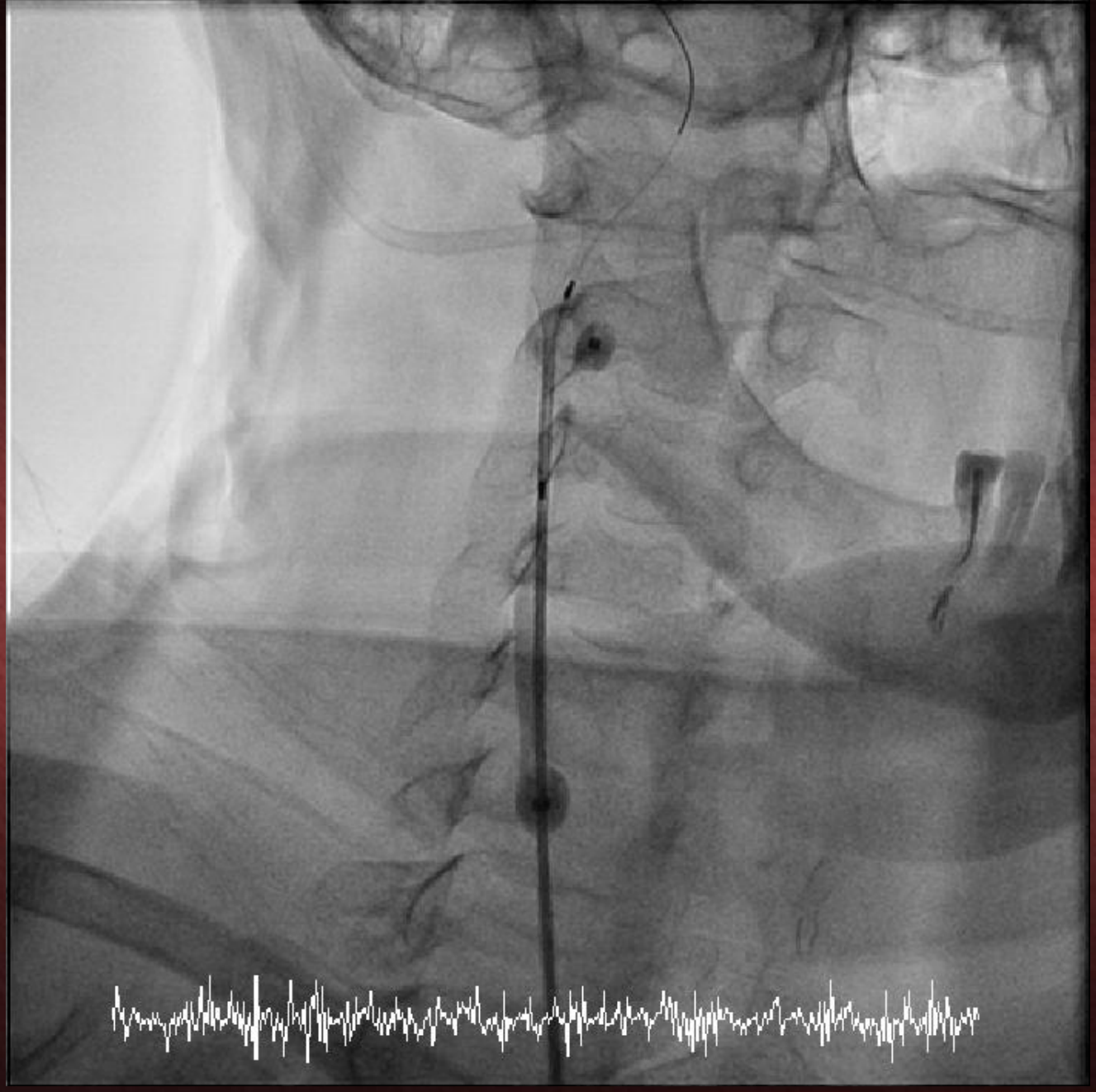
R. Heuser



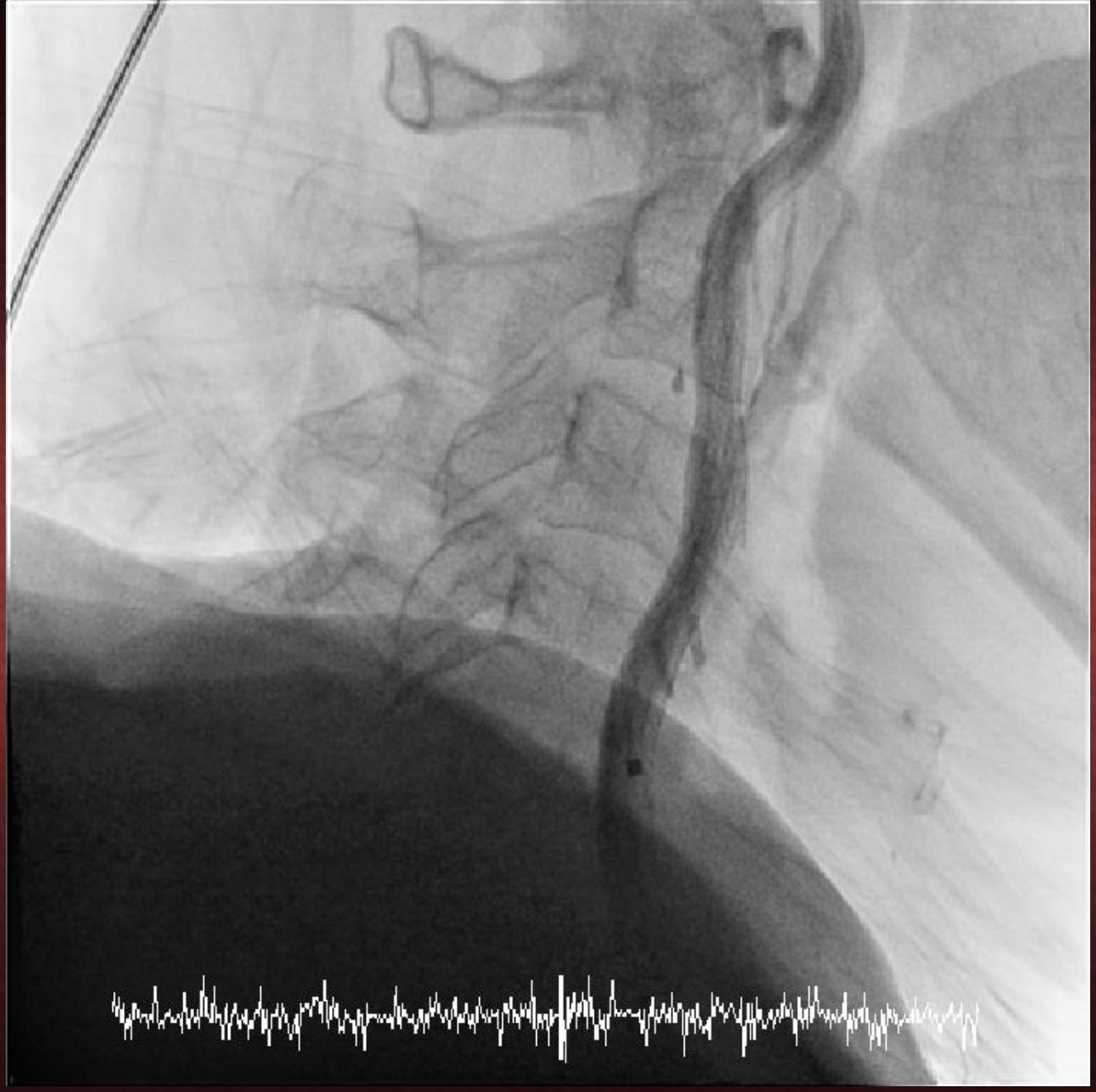


R. Heuser





R. Heuser

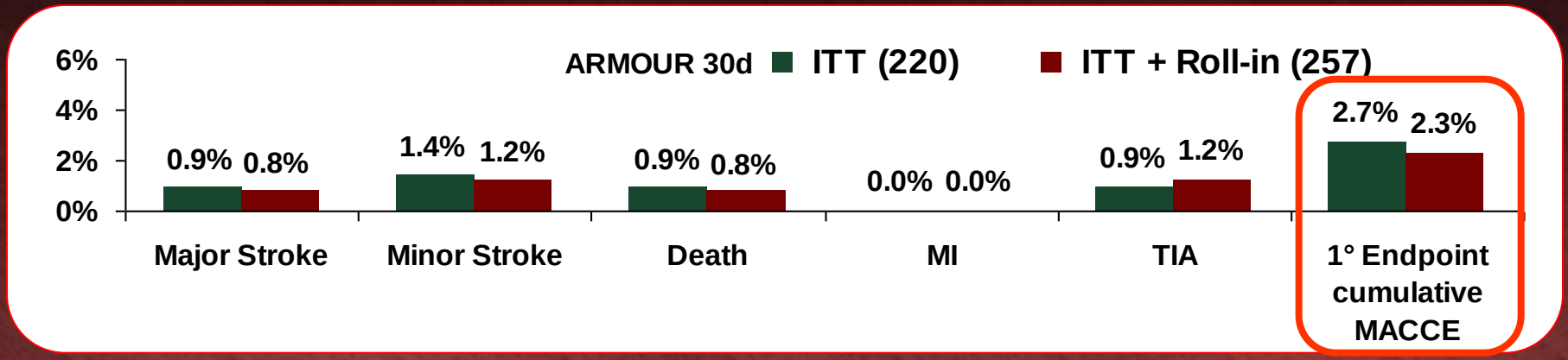


ARMOUR: Results 1° Endpoint

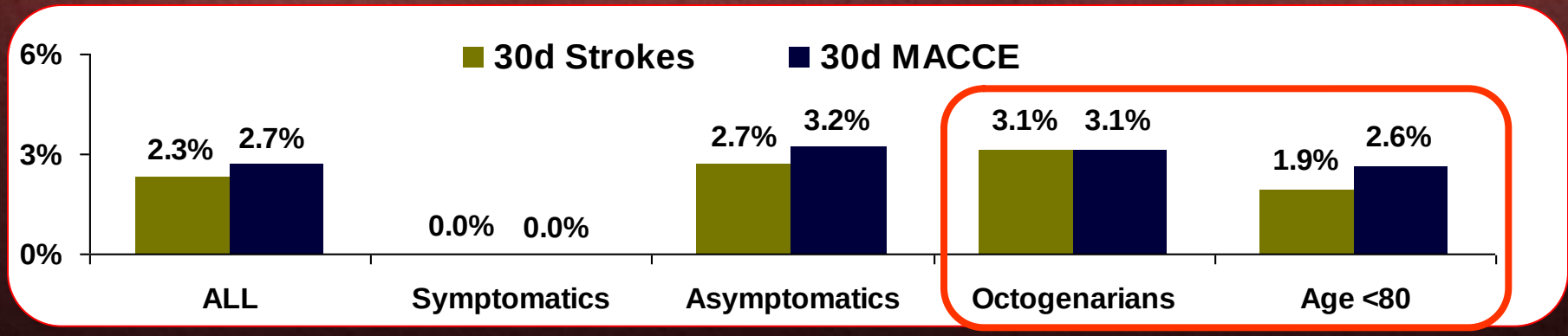
	ITT (N=220)	Roll-In (N=37)	Full Analysis (N=257)
30d MACCE rate	2.7% (6/220)	0.0% (0/37)	2.3% (6/257)
Any MI	0.0% (0/220)	0.0% (0/37)	0.0% (0/257)
Stroke	2.3% (5/220)	0.0% (0/37)	1.9% (5/257)
- Minor Stroke	1.4% (3/220)	0.0% (0/37)	1.2% (3/257)
- Major Stroke	0.9% (2/220)	0.0% (0/37)	0.8% (2/257)
Death	0.9% (2/220)	0.0% (0/37)	0.8% (2/257)
MACCE rate (procedural)	1.8% (4/225)	0.0% (0/37)	1.5% (4/262)
MACCE rate (at discharge)	1.8% (4/225)	0.0% (0/37)	1.5% (4/262)

ARMOUR: Results 1° Endpoint

30-Day Results (ITT & Full Population)



30-Day Results by Symptoms and Age (ITT)



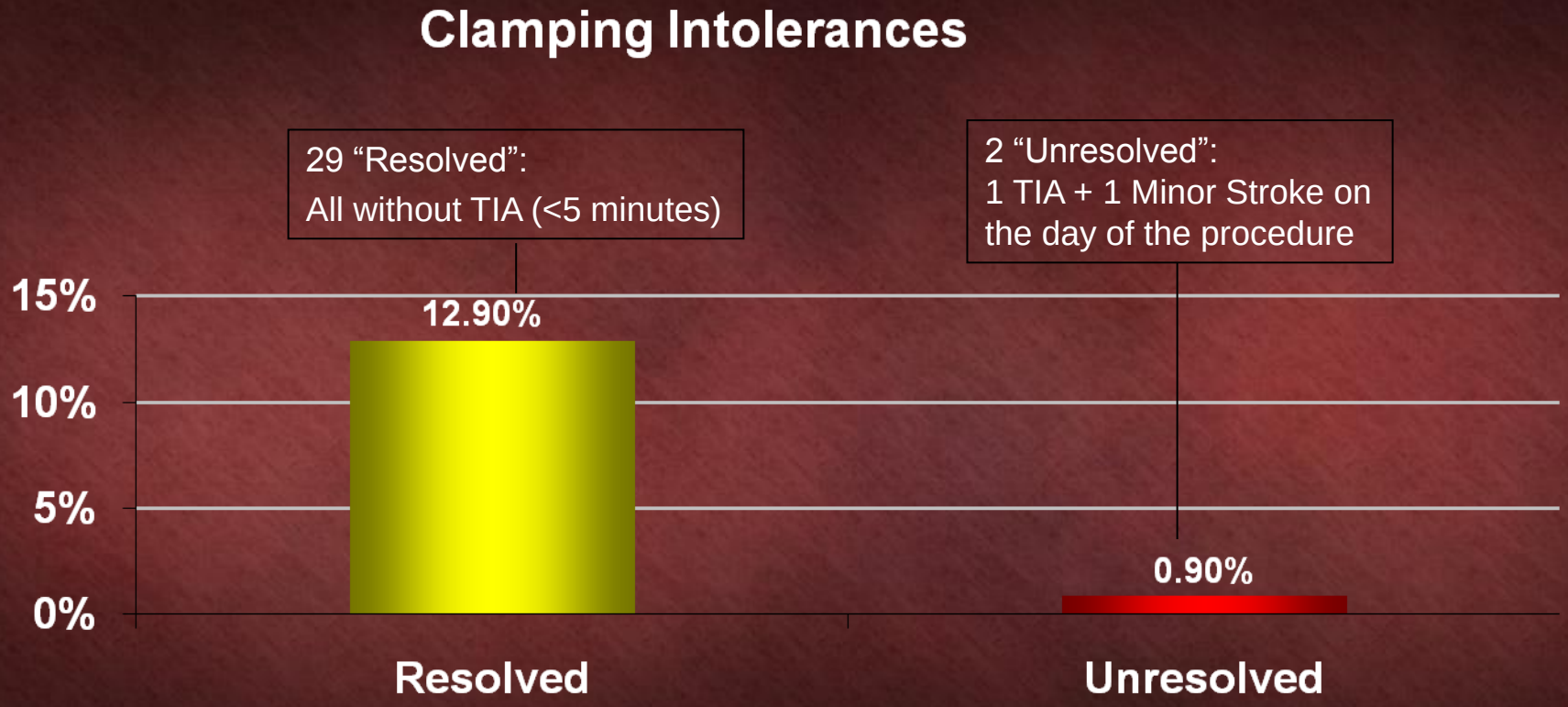
R. Heuser

ARMOUR: Results 2° Endpoint (ITT)

- Mo.Ma Device Success 98.2%
- Technical Success 94.6%
- Procedural Success 93.2%
- Restenosis at 30 days 1.6%
- TLR at 30 days 0%
- Access Site Complications 3.1%

ARMOUR: Clamping Intolerances

CEC adjudicated: unresolved clamping intolerances, TIAs, and Strokes



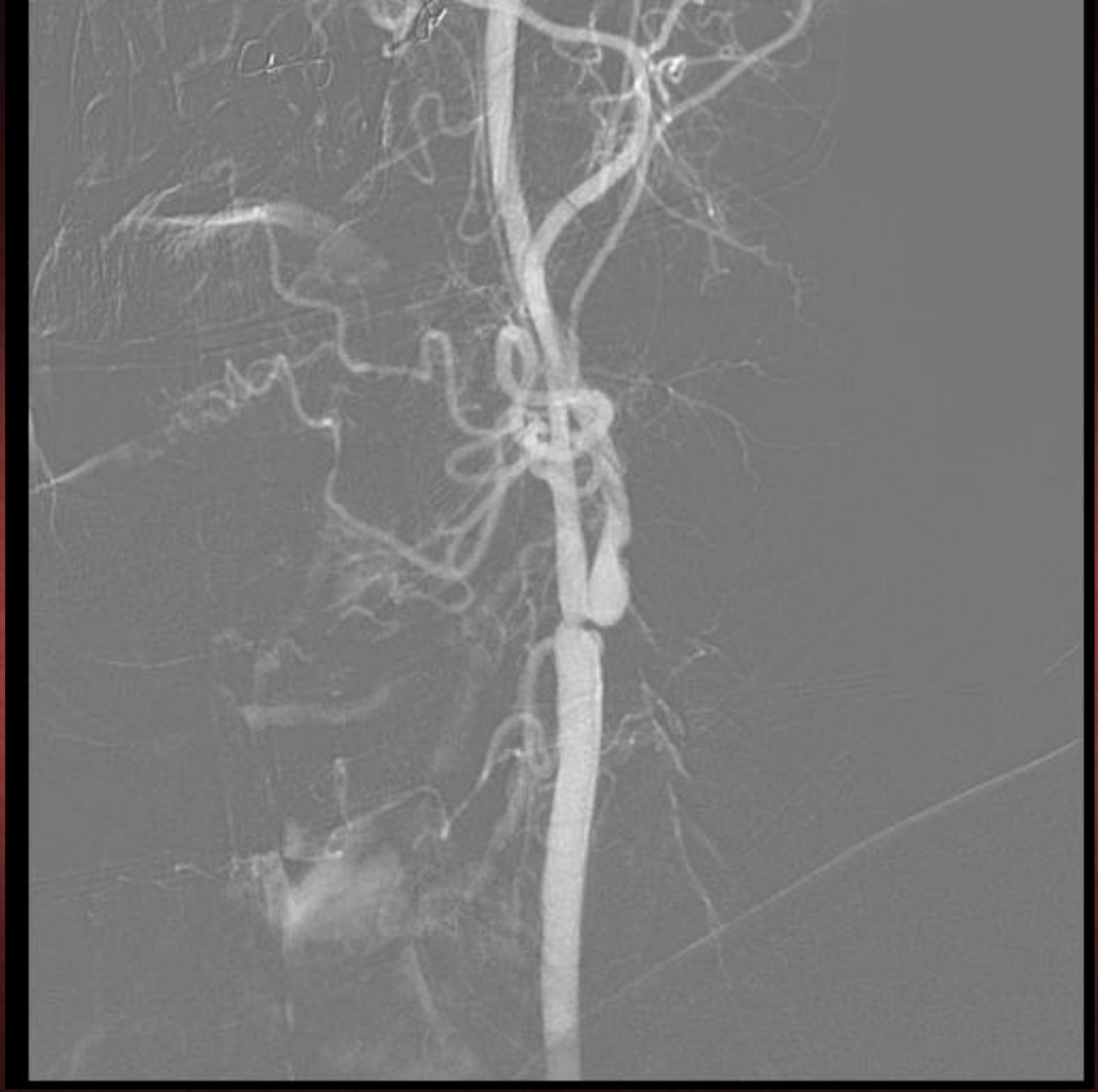
ARMOUR Study definitions of endovascular clamping intolerances:

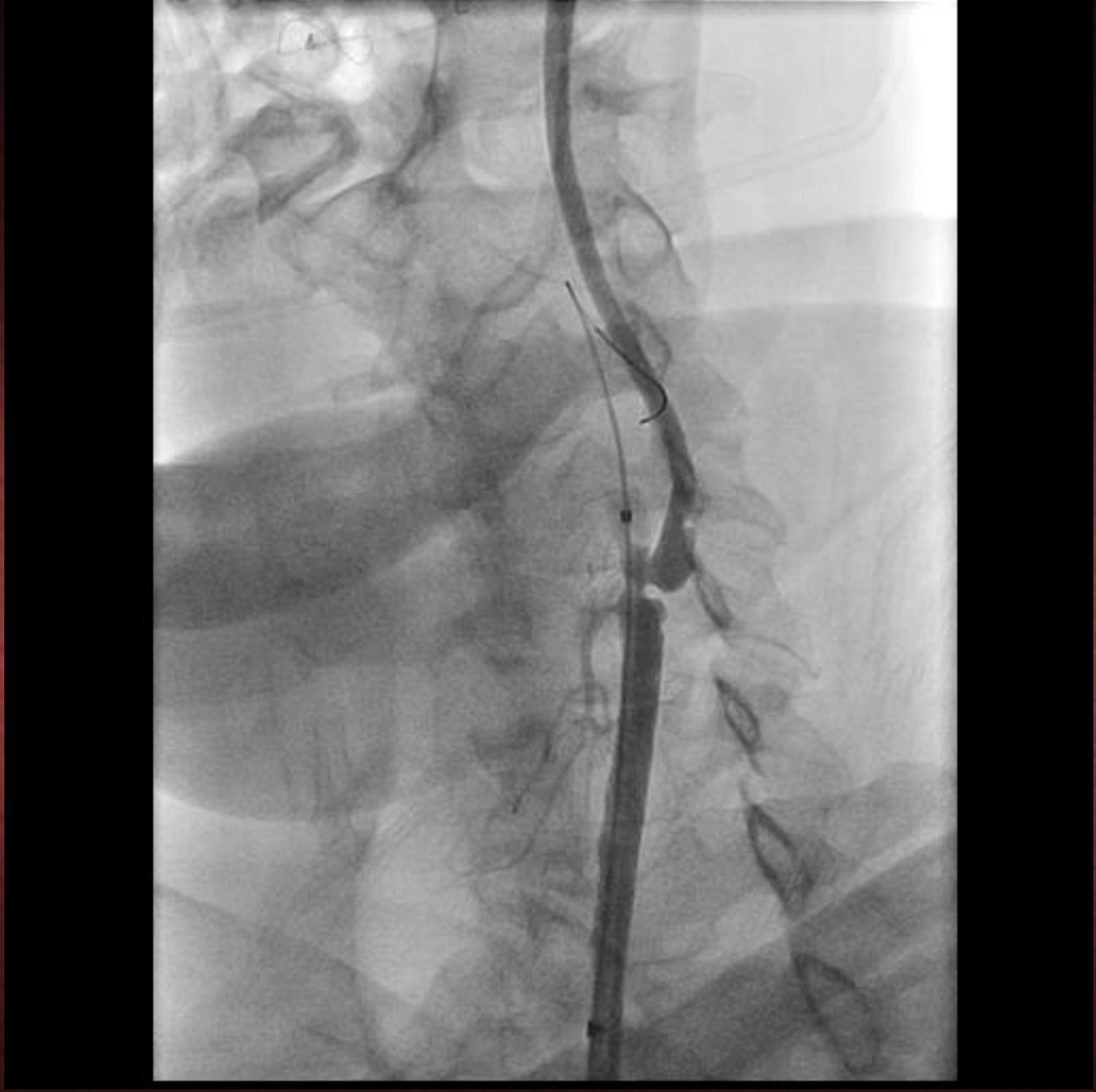
- Resolved intolerance: temporary symptoms lasting < 20 min after declamping
- Unresolved intolerance: temporary symptoms lasting > 20 min after declamping

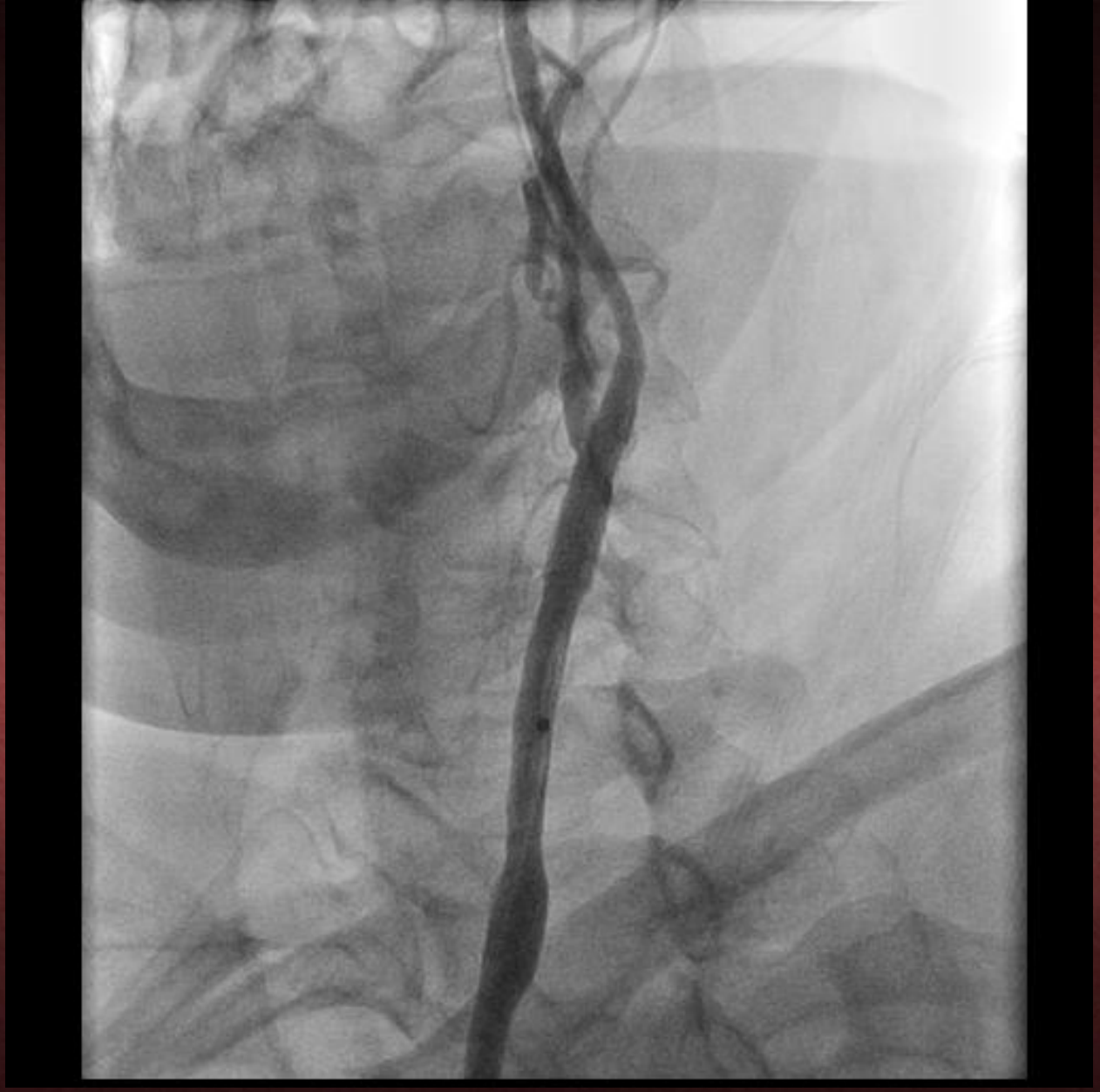
ARMOUR: Conclusions

- ARMOUR confirmed 30-day safety of Mo.Ma Proximal Protection Device for CAS in high-surgical-risk patients with a variety of FDA-approved carotid stents
- Cumulative, 30-day event rate of 2.7% compares very favorably with historical and recent CAS study results

70 year old male with COPD and severe CAD and TIA's undergoes carotid stenting







Proximal Endovascular Occlusion for Carotid Artery Stenting

Results From a Prospective Registry of 1,200 Patients

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Mercogliano, Italy

Objectives This single-center registry presents the results of proximal endovascular occlusion (PEO) use in an unselected patient population.

Background In published multicenter registries, the use of PEO for carotid artery stenting (CAS) has been demonstrated to be safe and efficient in patient populations selected for anatomical and/or clinical conditions.

Methods From July 2004 to May 2009, 1,300 patients underwent CAS using PEO. Patients received an independent neurological assessment before the procedure and 1, 24 h and 30 days after the procedure.

Results Procedural success was achieved in 99.7% of patients. In-hospital, major adverse cardiac or cerebrovascular events included 5 deaths (0.38%), 6 major strokes (0.46%), 5 minor strokes (0.38%), and no acute myocardial infarction. At 30 days of follow-up, 2 additional patients died (0.15%), and 1 patient had a minor stroke (0.07%). The 30-day stroke and death incidence was 1.38% (n = 19). Symptomatic patients presented a higher 30-day stroke and death incidence when compared with asymptomatic patients (3.04% vs. 0.82%; $p < 0.05$). No significant difference in 30-day stroke and death rate was observed between patients at high (1.88%; n = 12) and average surgical risk (1.07; n = 7) (p = NS). Operator experience, symptomatic status, and hypertension were found to be independent predictors of adverse events.

Conclusions The use of PEO for CAS is safe and effective in an unselected patient population. Anatomical and/or clinical conditions of high surgical risk were not associated with an increased rate of adverse events. (J Am Coll Cardiol 2010;55:1661–7) © 2010 by the American College of Cardiology Foundation

Total Event Rate of 1.38%

R. Heuser

Peripheral Vascular Disease

Carotid artery stenting in octogenarians using a proximal endovascular occlusion cerebral protection device: A multicenter registry†

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†Conflict of interest: No conflicts of interest exist, with exception of Prof G. Biamino, who is scientific consulting of Invatec.

KEYWORDS

carotid angioplasty • carotid stenosis • cerebrovascular disease

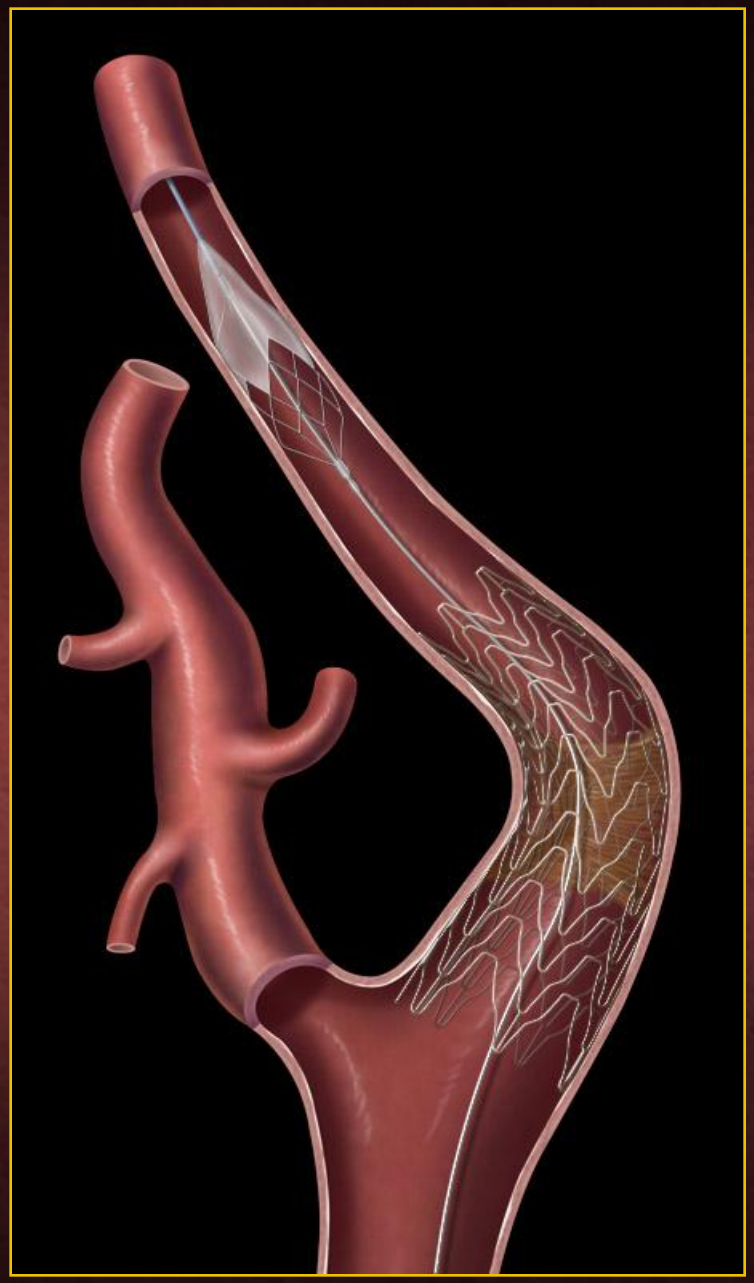
ABSTRACT

Background: Carotid stenting (CAS) has been proposed as an alternative to carotid endoarterectomy also in elderly patients with discrepant results. However, the use of proximal neuroprotection devices have not been evaluated in octogenarians. Purpose: The aim of this multicenter prospective registry was to demonstrate that CAS in octogenarians is safe and effective if performed in high-volume centers by experienced operators. Methods: From July 2005 to May 2009, a total of 198 octogenarians patients, in three different institutions, were included in this registry. All patients underwent CAS using a proximal endovascular occlusion device (Mo.Ma. device Invatec, Roncadelle, Italy). An independent neurologist evaluated all patients. The primary endpoint was death and stroke rate at 30 days. Results: 198 octogenarians (135 men, mean age: 83.2 years) were included in the registry. 39.4% of the patients were symptomatic. Procedural success was 100%. In-hospital complications: Two minor and two major strokes (2.02%) occurred. No device-related complications and no serious access site complication were noted. Between discharge and 30-day follow-up, one patient died due to a cardiac arrest. The overall 30-day combined stroke/death rate was 2.52%, resulting in 1.61% event incidence in asymptomatic and 3.9% in symptomatic patients (P = ns). Logistic regression did not identify independent predictor of neurological events, except in the female gender. Conclusion: This multicenter prospective registry shows that CAS performed with proximal flow blockage is safe and feasible also in octogenarians. Thirty days death/stroke rates are similar to those of the overall population and within the International guidelines. © 2010 Wiley-Liss, Inc.

Success Rate 100% Event Rate of 2.52%

R. Heuser

In spite of issues
filters are used
in carotid therapy
almost exclusively



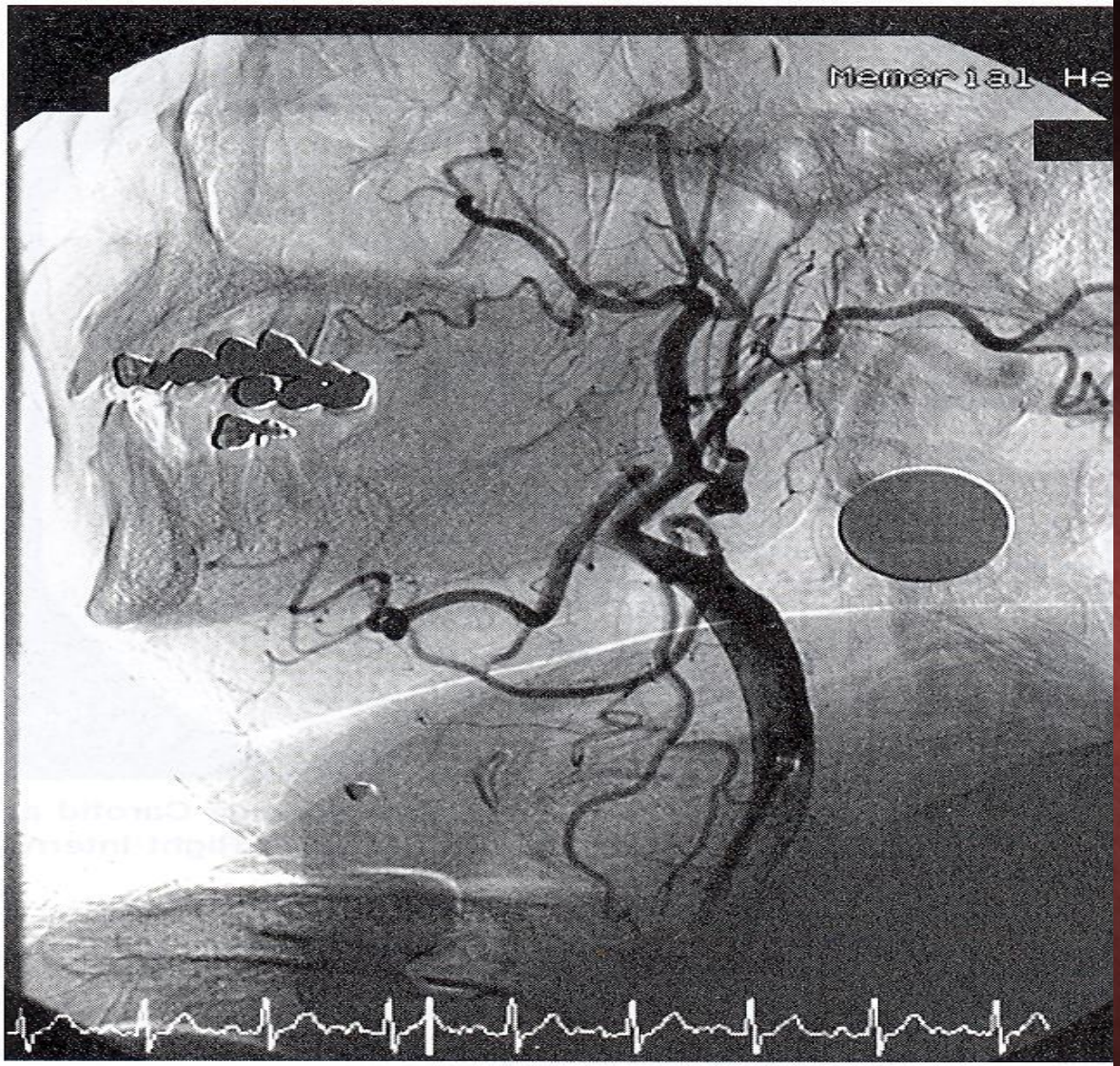
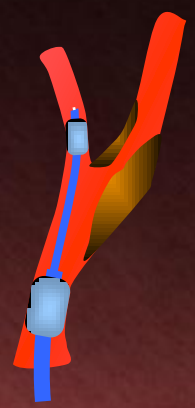


Fig. 1. Selective angiogram of the Right Common Carotid a
tery in the lateral view showing an angiographic string sig
(SS) at the ostium of the Right Internal Carotid artery.

When do you use Proximal Protection?

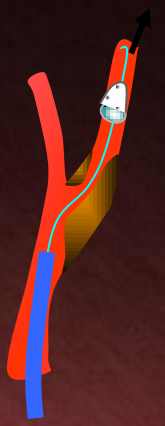


- When the ICA is tortuous
- Poor landing zones in the ICA
- When ICA lesion would be difficult to cross with a filter
- Symptomatic patients and octogenarians with suitable anatomy
- When distal filters won't cross the lesion

(Relative) Requirements for Proximal Protection

- Intact ECA on ipsilateral side
- Collateral support to the Treated Hemisphere
- CCA and arch anatomy for 9F OD device

When do you use Distal Filter Wire?



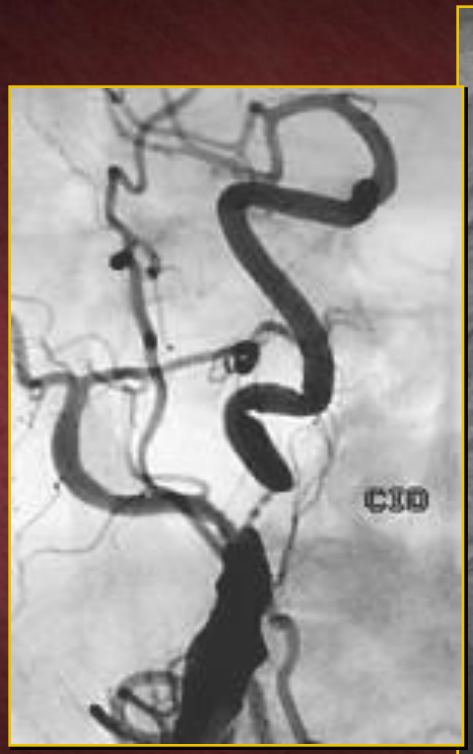
- Clinical trial protocol requires it
- Lesion is easy to cross
- Vessel has a good landing zone
- ~Asymptomatic patients
- Contralateral ICA occlusion
- No collateral support to treated hemisphere
- Poor ipsilateral ECA

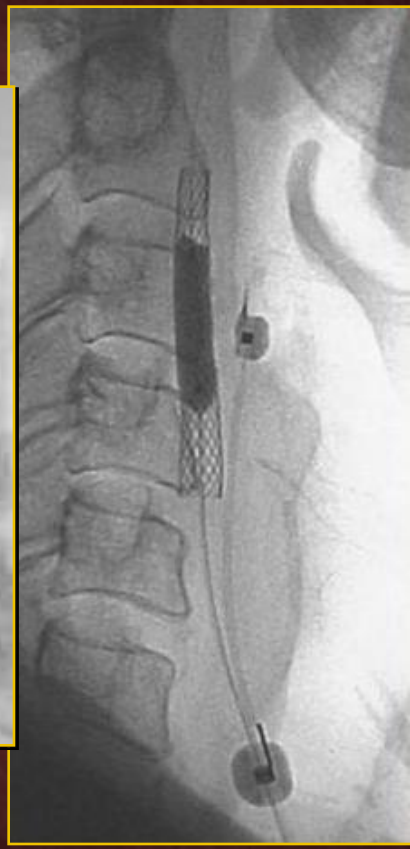
When NOT to Use Proximal Protection?

- ECA occluded or bad anatomy
- Carotid lesion at or before the bifurcation
- Contralateral occlusion, esp. if no Posterior ommunicating artery support
- No collateral support to carotid being treated
- Severe arch or CCA disease
- Insufficiently trained operators

Mo.Ma Ultra: System Benefits

- Protected lesion crossing
- No ICA landing zone requirement
- Treat broad range of anatomies and lesion types
- Debris capture efficiency
  - Flow suspension
  - Device trackability and stability
  - Lesion access and debris aspiration
  - Precise positioning and orientation





Summary

- CAS is a safe and effective alternative to CEA for treatment of carotid artery disease in appropriate patients
- Careful attention to patient and lesion selection, coupled with meticulous attention to procedure detail by experienced operators, will ensure optimal outcomes in patients treated with CAS