THE PROTECHTOR DEVICE:

A Simple System for Embolic Protection in Carotid and SVG Intervention

RICHARD R. HEUSER, MD, FACC, FACP, FESC

Director Of Cardiology, St. Luke's Medical Center, Phoenix, Arizona

Medical Director, Phoenix Heart Center, Phoenix, Arizona

Clinical Professor of Medicine Univ. of Arizona, College of Medicine, Tucson, Arizona

TCT2007
TRANSCATHETER CARDIOVASCULAR THERAPEUTICS

CARDIOVASCULAR RESEARCH FOUNDATION

No-Reflow: Lasting Consequences

- Complicates 10–15% of SVG PCI[1]
- 31% rate of acute myocardial infarction[2]
- Increases in-hospital mortality by 10-fold[2]
- Atheroembolization is a key contributor[3]

Image courtesy of Dr. Donald S. Baim

1 Sdringola, *et al.,* Cathet Cardiovasc Intervent. 2001; 54(3):325-326.
2 *Abbo, et al*., American Journal of Cardiology, 1995; 74(12) 15: 778-782
3 Rezkalla, *et al.,* Circulation. 2002;105:656-662.

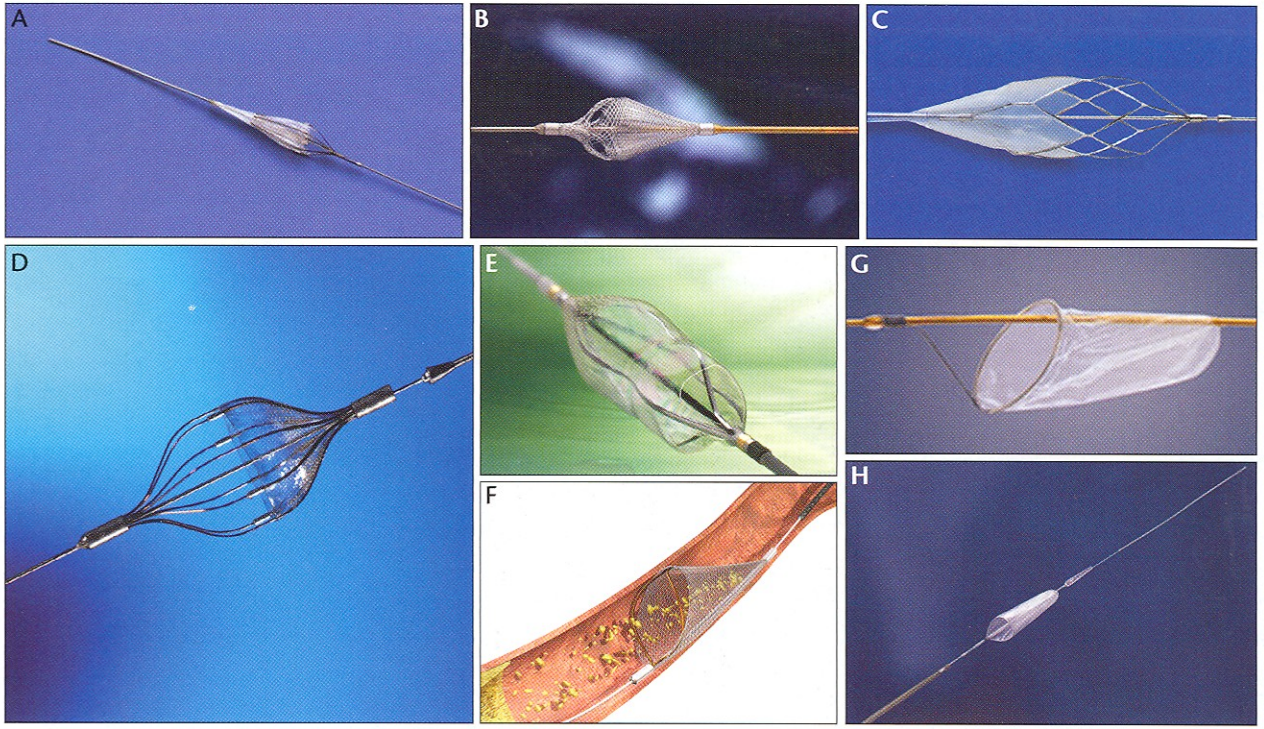
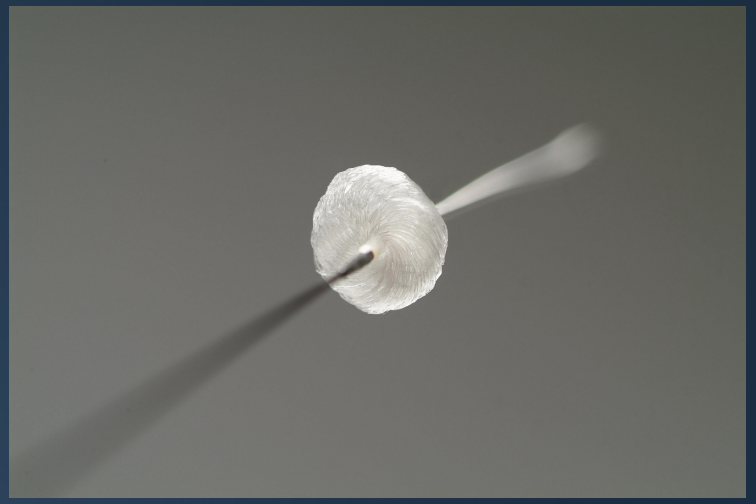


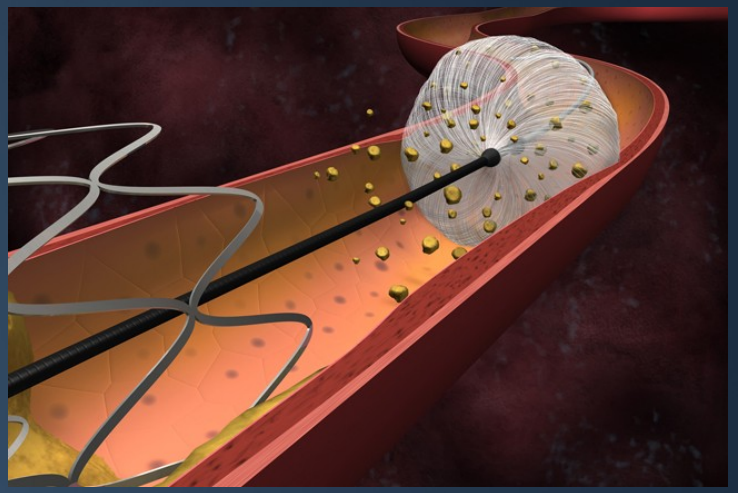
Figure 2. Distal filter devices. The Rubicon Filter (A). The InterceptorPlus Filter (B). The Accunet Filter (C). The AngioGuard XP filter (D). The Emboshield (E). The SpideRX (F). The FilterWire EZ (G). The FilterWire EX (H).

Endovascular Today October 2006

Fibernet

- Fiber based filter
- Low crossing profile
- 40 micron
- Vessel conformable
- EPIC- US pivotal trial
- RETRIEVE-US IDE
- Enrollment began in March 2007





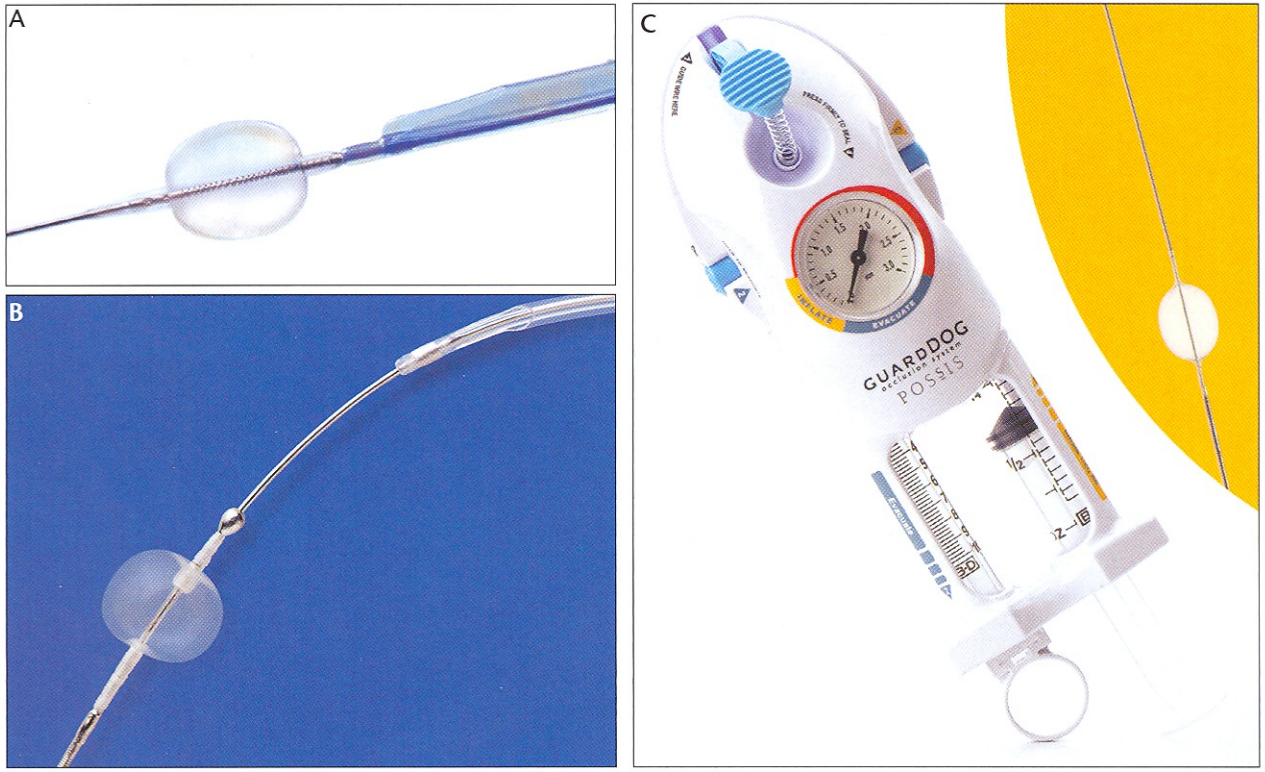


Figure 1. Distal occlusion devices. The PercuSurge GuardWire (A). The TriActiv FX Embolic Protection System (B). The Possis GuardDog (C).

Endovascular Today October 2006

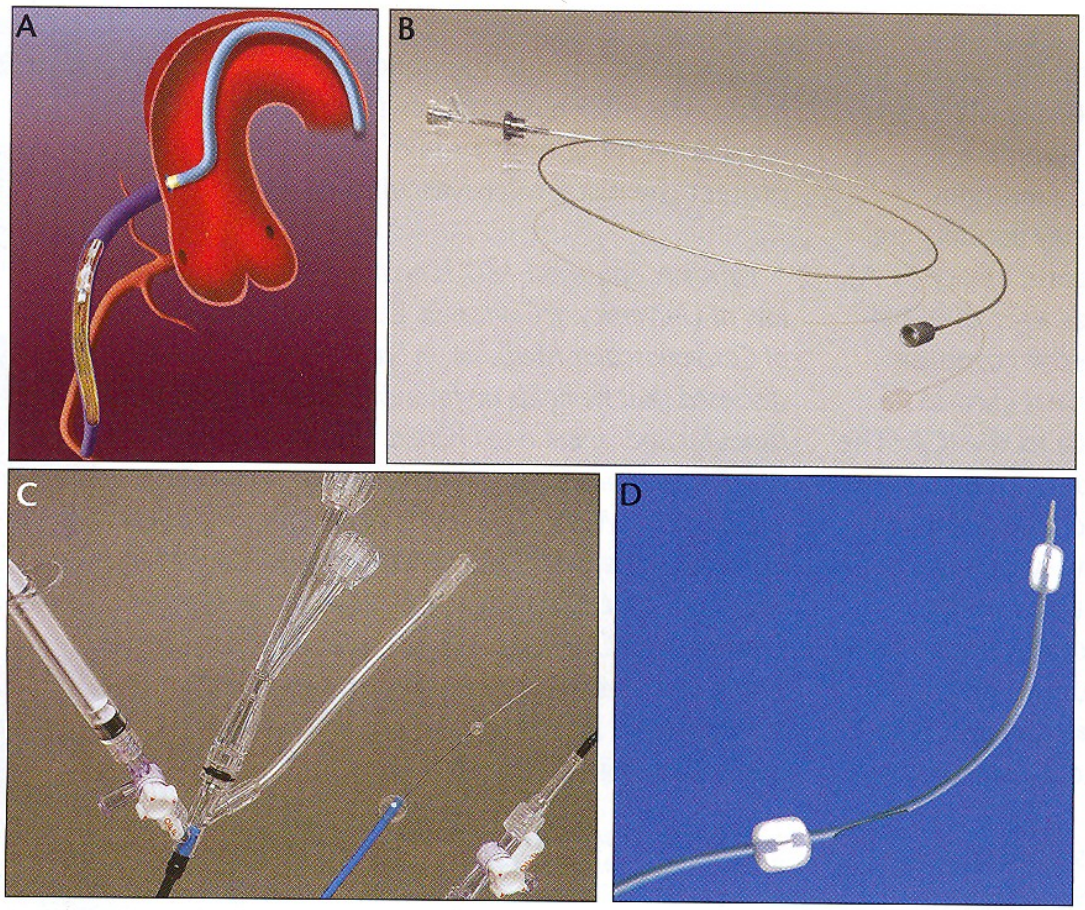
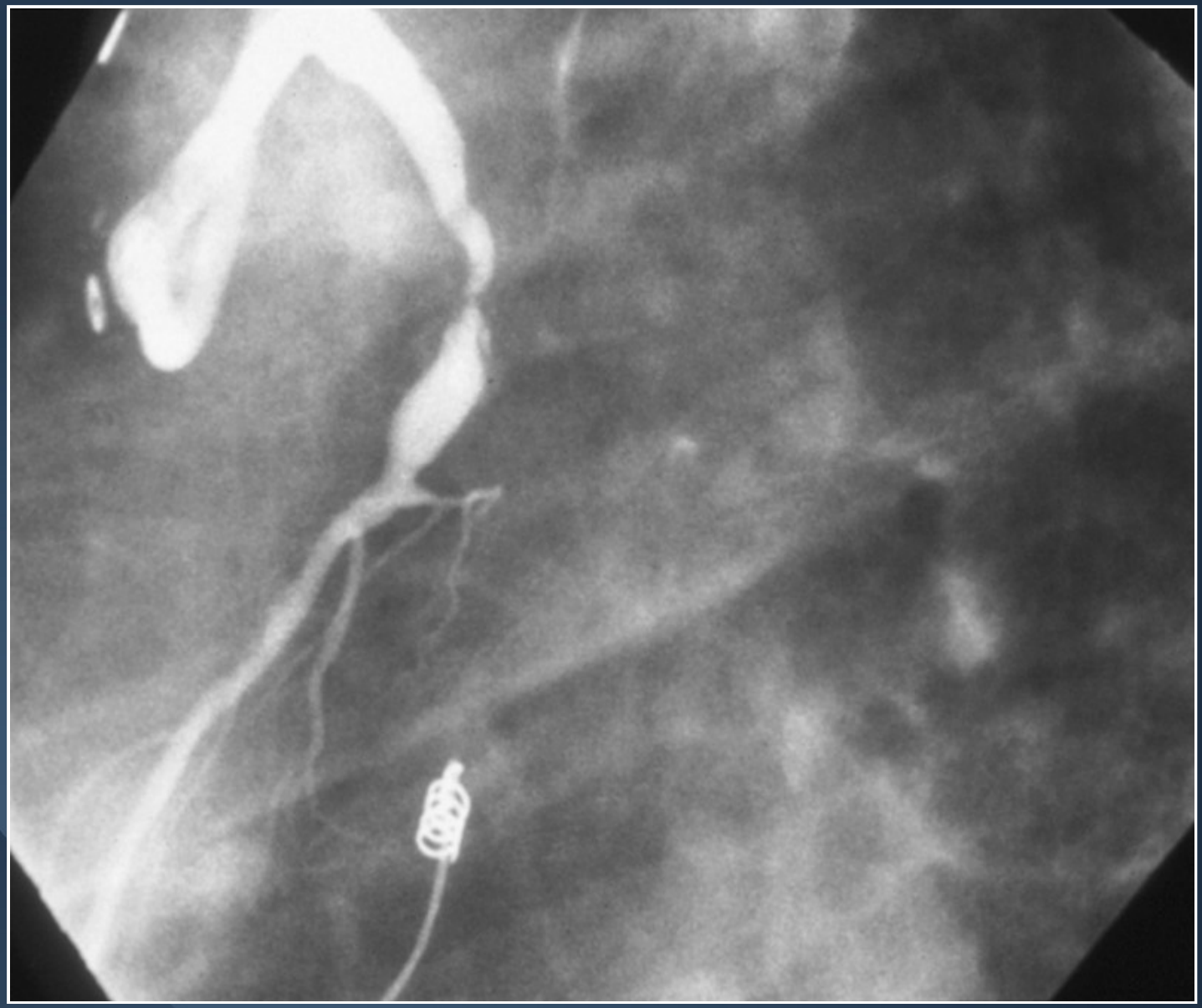
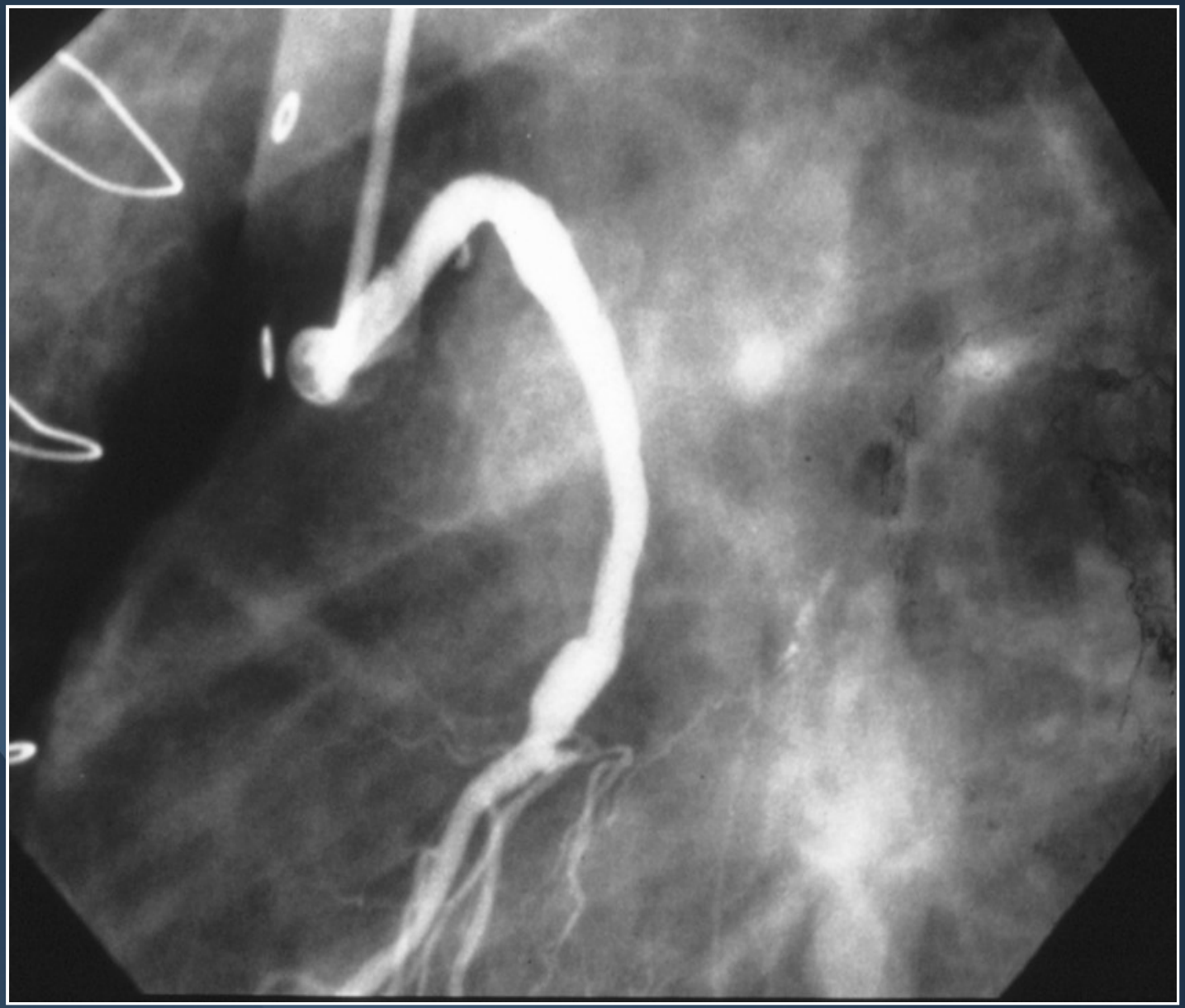


Figure 3. Proximal occlusion/reversal of flow devices. The Proxis Embolic Protection System (A). The Genesis Funnel Catheter (B). The Gore Neuro Protection System (C). The Mo.Ma Cerebrovascular Protection Device (D).

Endovascular Today October 2006



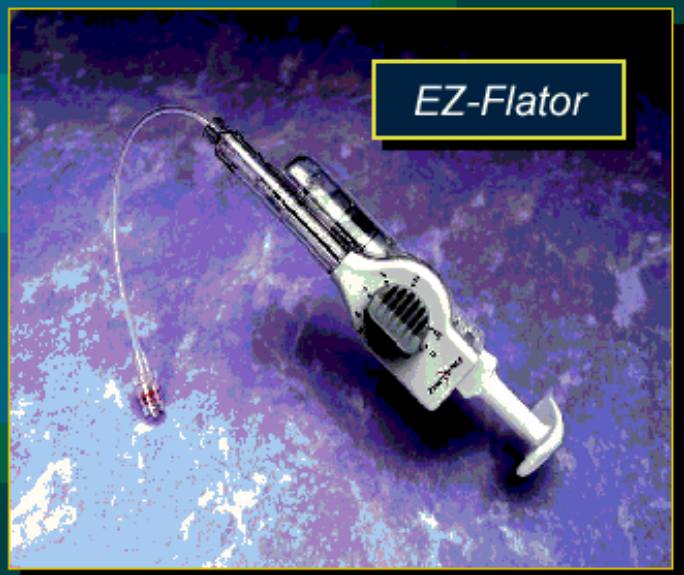


The PercuSurge GuardWire System

Consists of 4 components: the GuardWire®, the EZ-Flator™, the MicroSeal® Adapter, and the Export® catheter

MicroSeal Adapter

EZ-Flator



The Cardiovascular Research Foundation

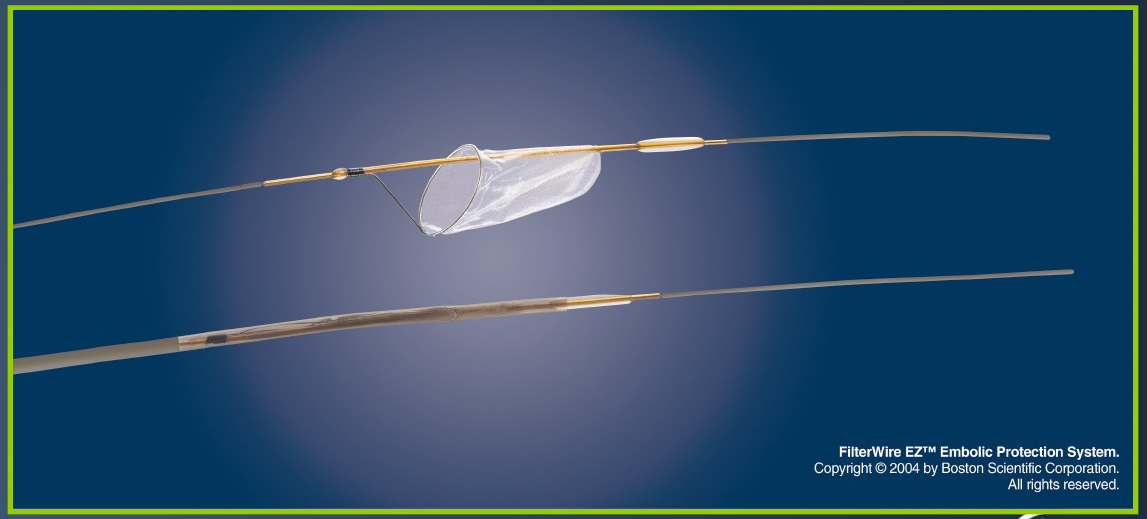
Lenox Hill Heart and Vascular Institute of New York

SAFER Trial

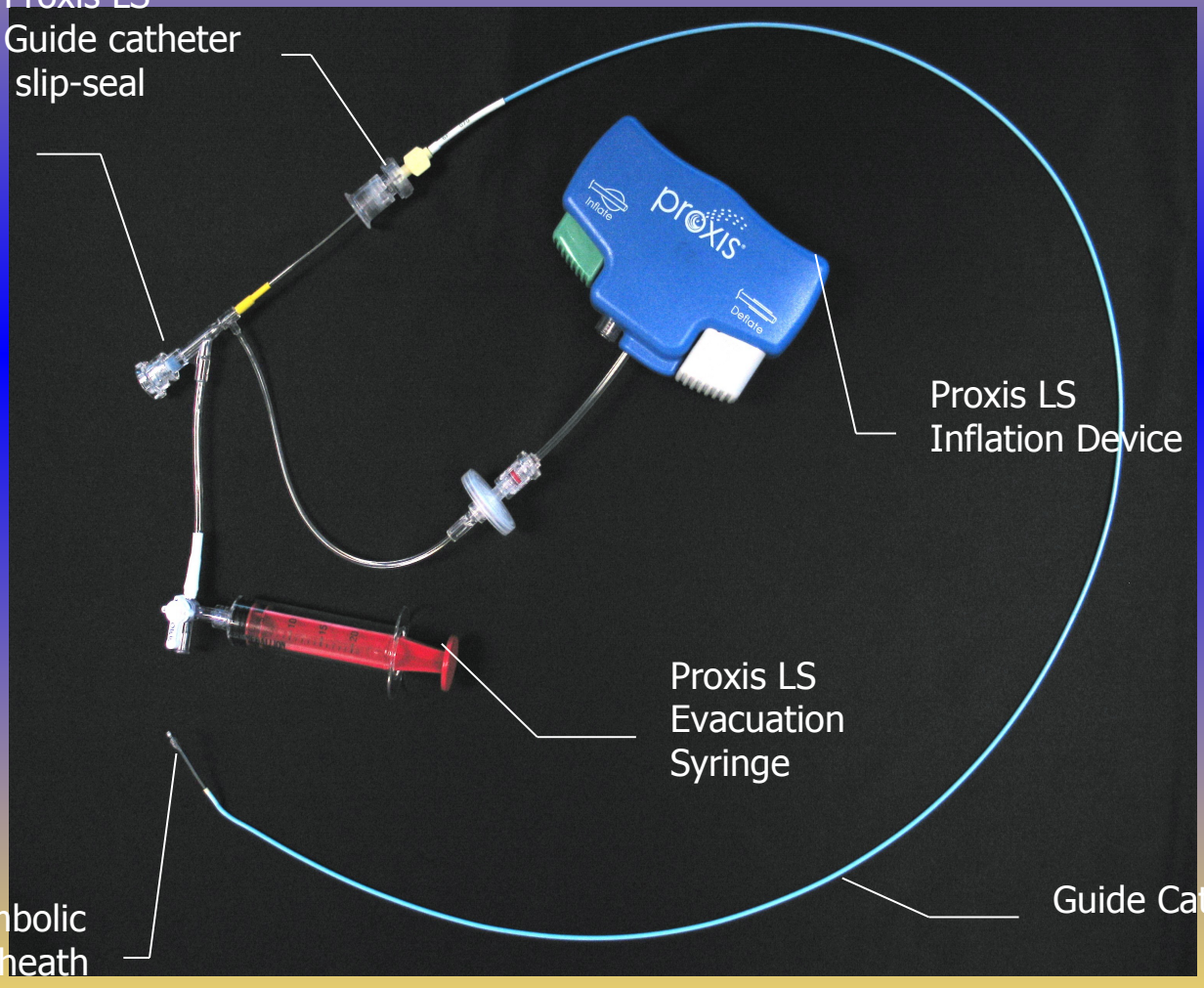
- Confirmed embolic protection and resulted in improvement in clinical endpoints
- It was difficult to predict embolic risk

FilterWire EZ™ System

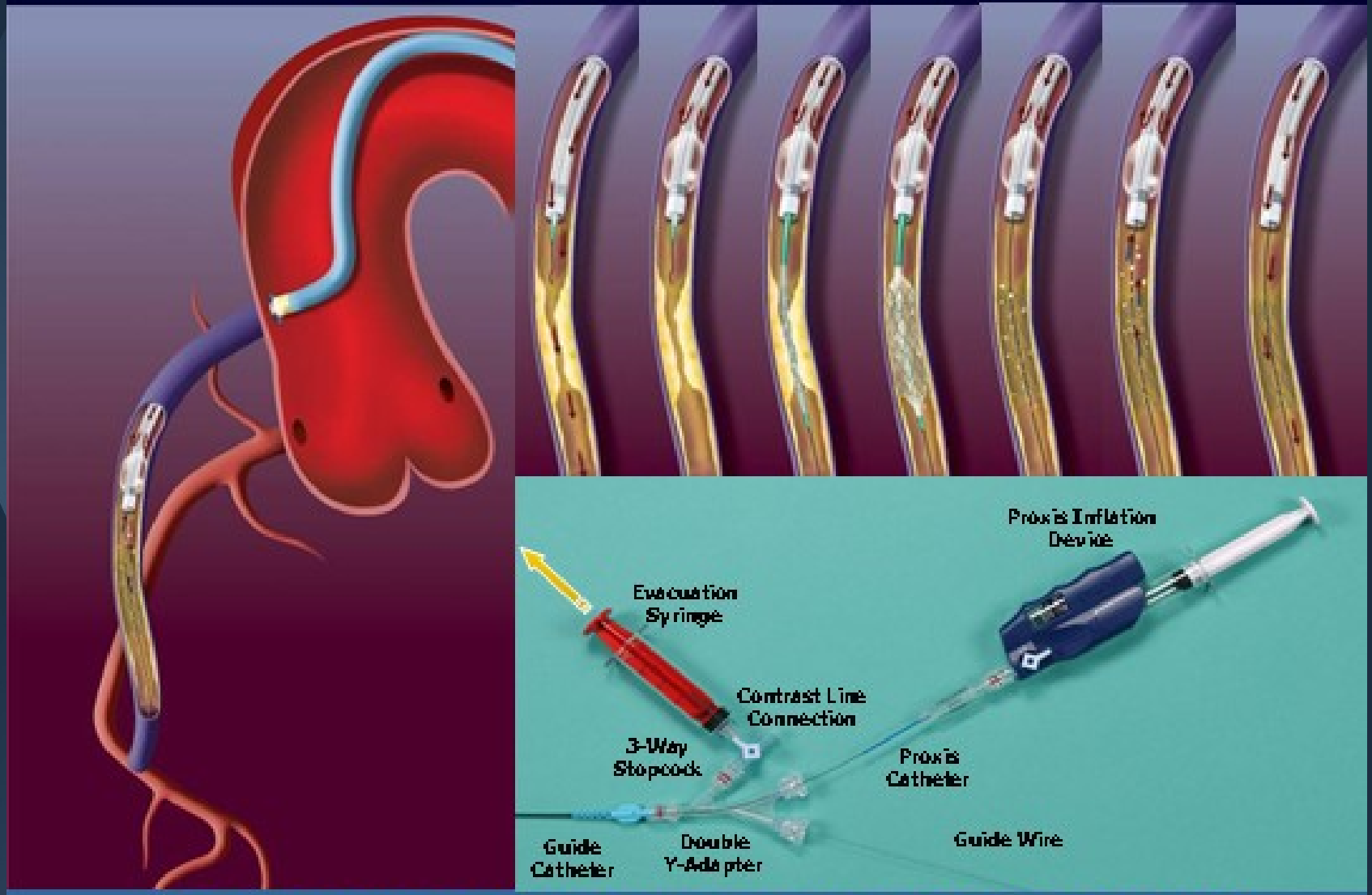
- Suspended Loop Design
- .014" guide wire with silicone coated spring tip, delivery sheath and retrieval sheath
- Pre-loaded, peel-away delivery sheath
- 3.2F delivery profile
- Soft-Tip Retrieval Sheath
- Tapered nosecone



System Set-up



Proxis™ Procedure

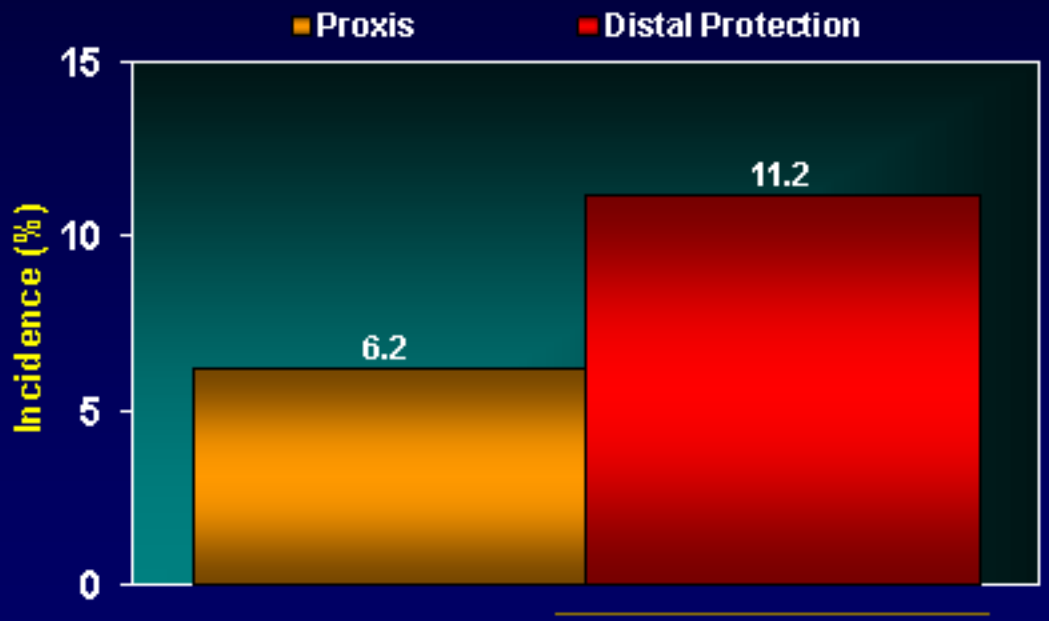


Use of the Proxis System as a proximal embolic protection device is currently under review by the FDA

30 Day MACE: Lesions Amenable to Either Proximal or Distal Protection

Δ = -3.1 [-8.2, +2.0]

P = 0.089 for superiority, P = 0.0001 for NI

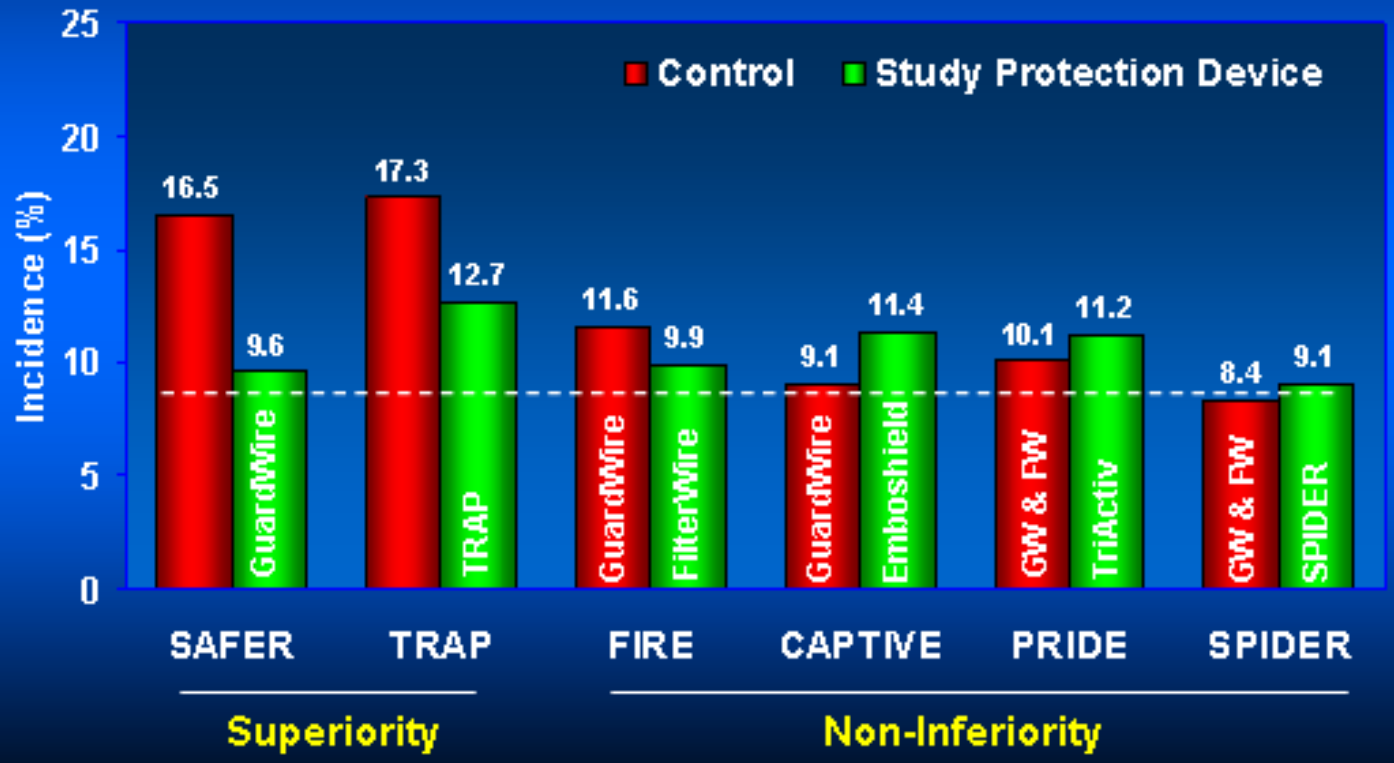


Brigham and Women's Hospital, Harvard Medical School

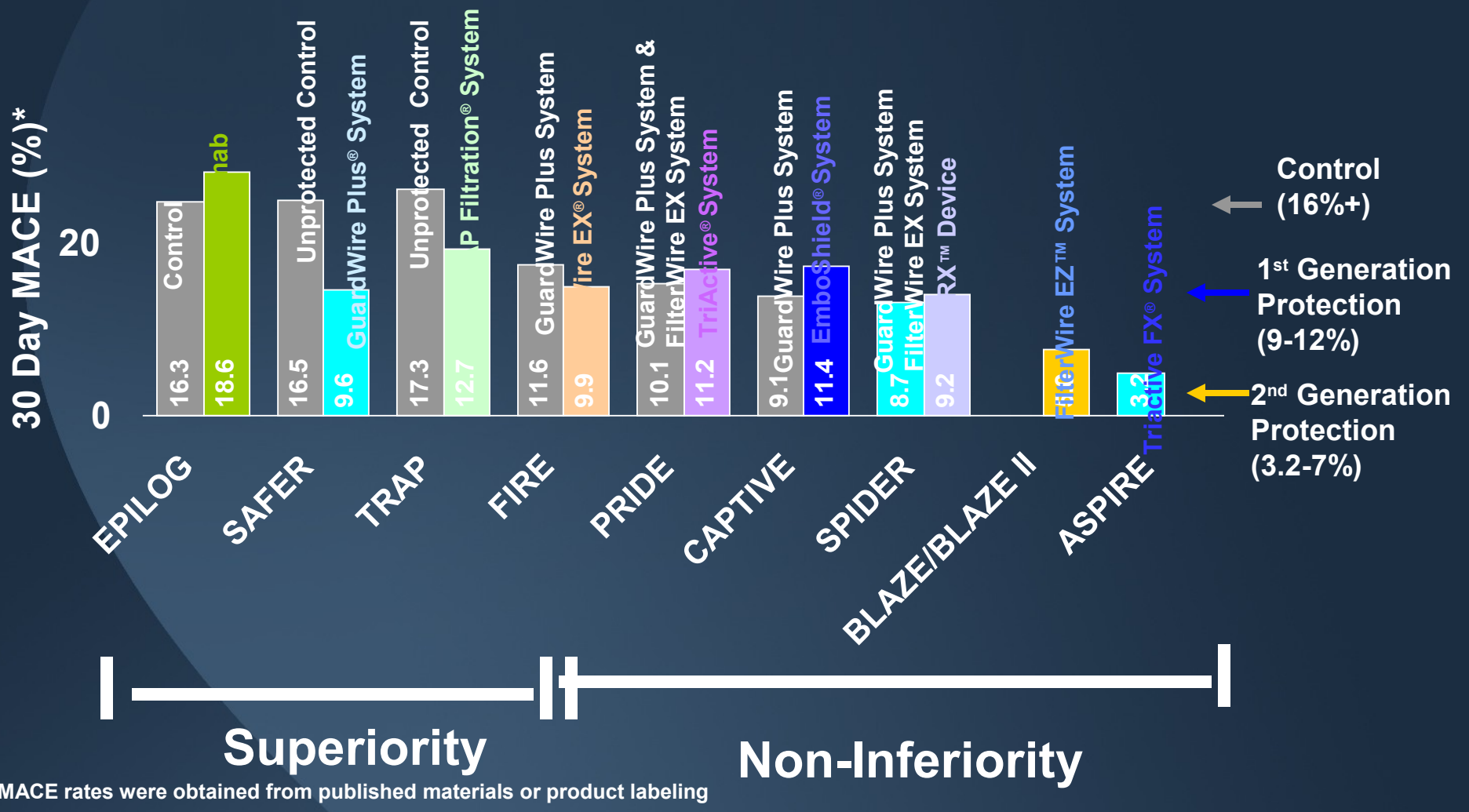
PROXIMAL TRIAL

SPIDER

30-Day MACE In Other Studies



SVG MACE Rates

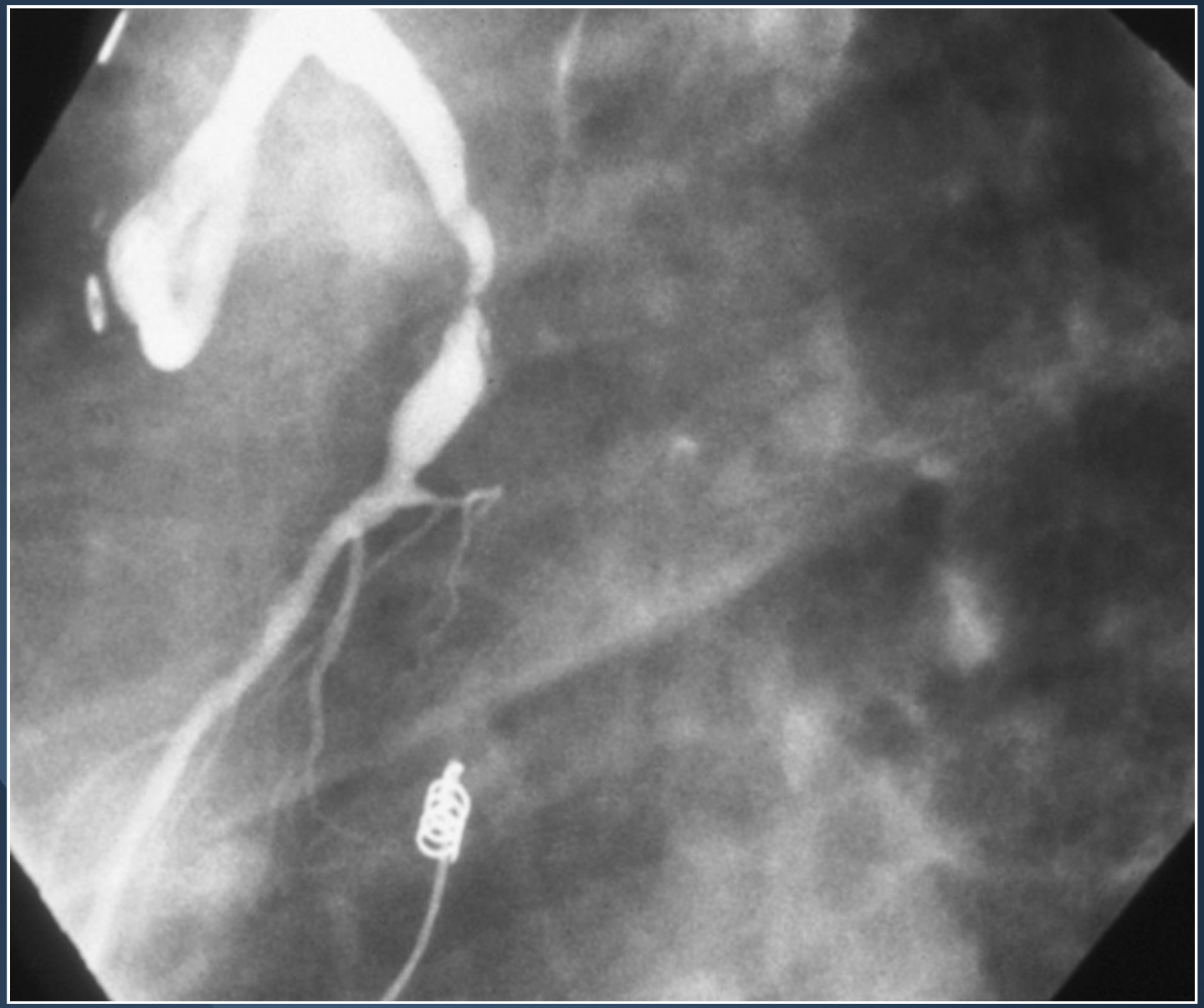


*** MACE rates were obtained from published materials or product labeling**

Ellis, *et al.,* JACC 1998; Vol. 32, No. 6: 1619-23 Baim DS, *et.al.,* Circulation. 2002;105:1285-1290. Stone GW, *et.al., Circulation*. 2003;108:548-553. Cox, D. presented September 2003; TCT.

Prediction is very difficult, especially about the future.

-Niels Bohr



Prediction of Distal Embolization During Percutaneous Coronary Intervention in Saphenous Vein Grafts

William Joseph van Gaal, MBBS[a,*], Robin Patrick Choudhury, DM[a], Italo Porto, MD[a], Keith Channon, MD[a], Adrian Banning, MD[a], Vladimir Dzavik, MD[c], Rachael Ramsamujh, MD[c], Sanh Bui, BSc[c], and Daniel James Blackman, MD[b]

Distal protection devices have been proved to decrease distal embolization and improve outcome in unselected patients undergoing percutaneous coronary intervention (PCI) in saphenous vein grafts (SVGs). However, it remains uncertain whether distal protection is necessary in all patients. We investigated whether clinical or angiographic variables can predict distal embolization and, hence, need for a distal protection device. Fifty-eight consecutive SVGs that underwent PCI with a FilterWire distal protection device were studied. After the procedure, the FilterWire was fixed in formalin and photographed, and embolic debris area (square millimeters) was quantified by semi-automated edge-detection analysis. Debris area was correlated with 6 prespecified variables: clinical presentation, SVG age, reference lumen diameter, plaque volume, SVG degeneracy, and presence of a filling defect. Embolic debris was identified in 57 of 58 grafts (98%). Median debris area was 4.0 mm^2 (range 0.0 to 25.1). None of the prespecified variables predicted the occurrence of distal embolization or the amount of captured embolic debris. In conclusion, distal embolization during SVG PCI is universal. Embolic burden cannot be predicted by clinical or angiographic variables, and embolic protection should be used in all patients. (Am J Cardiol 2007;99:603–606)

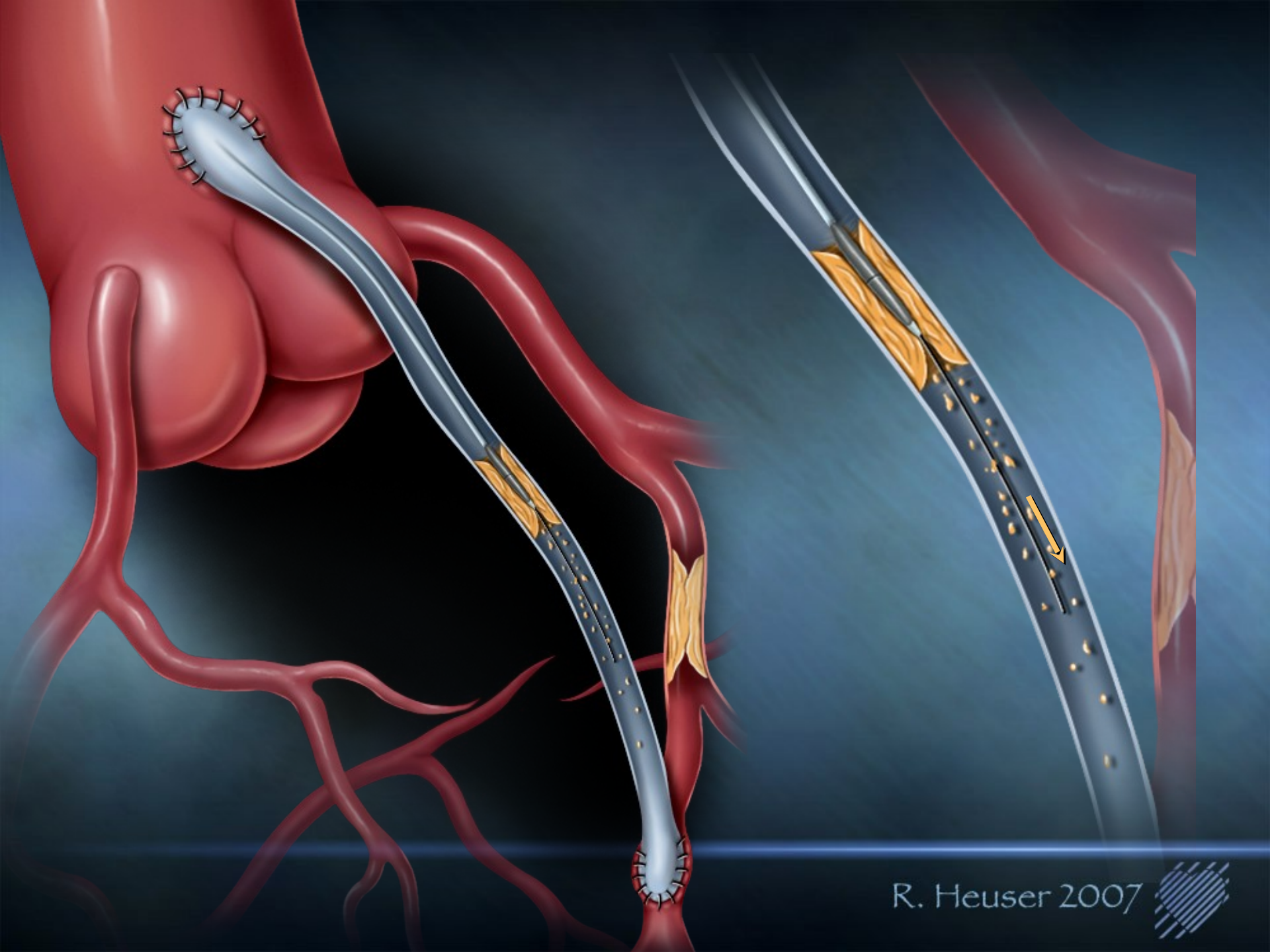
Predicting Emboli in SVGs

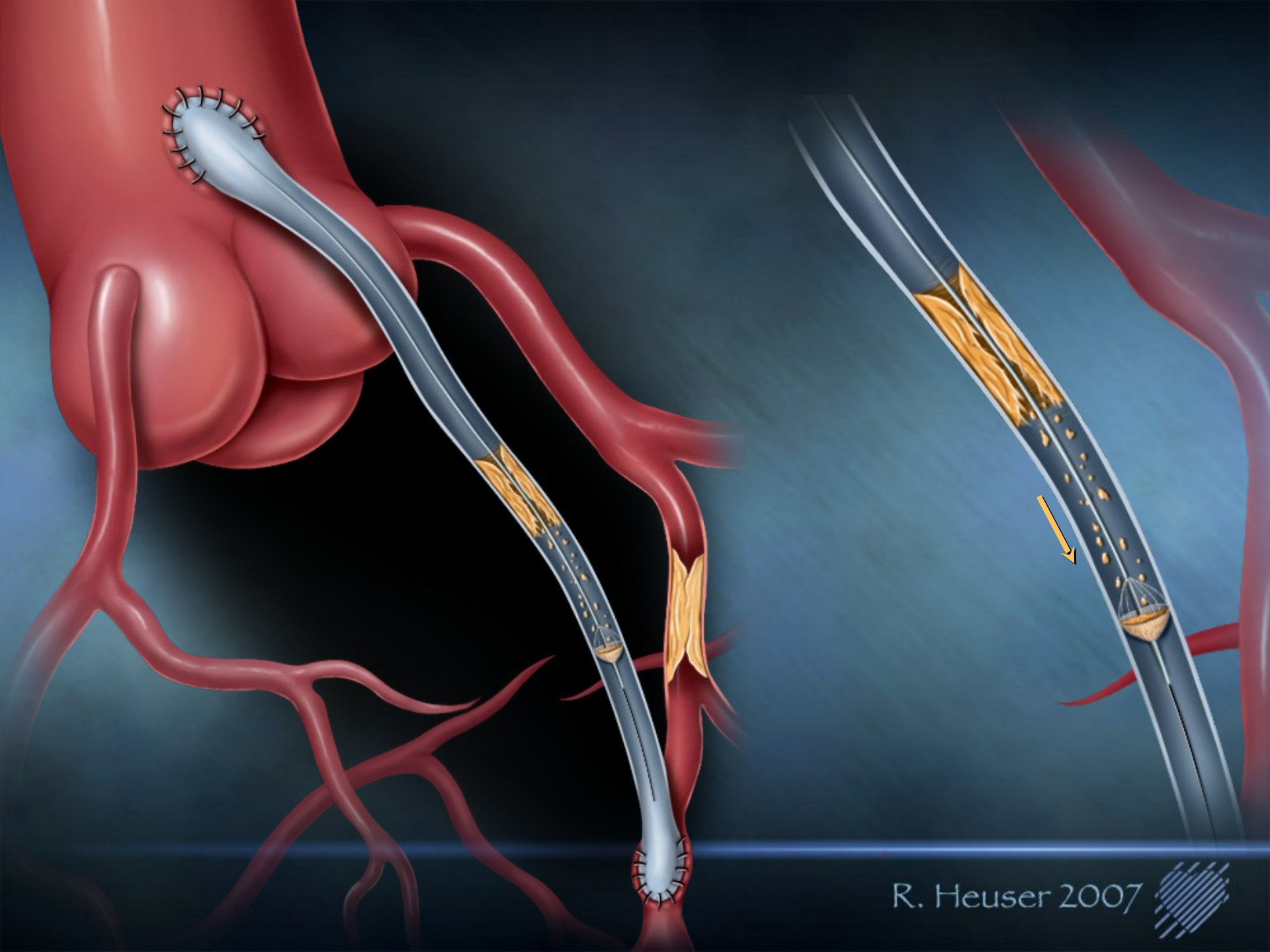
- All lesion subsets benefit as embolization appears unpredictable:
  - **regardless of lesion characteristics**
  - **with or without direct stenting**
  - **with or without IIb/IIIa inhibitors**

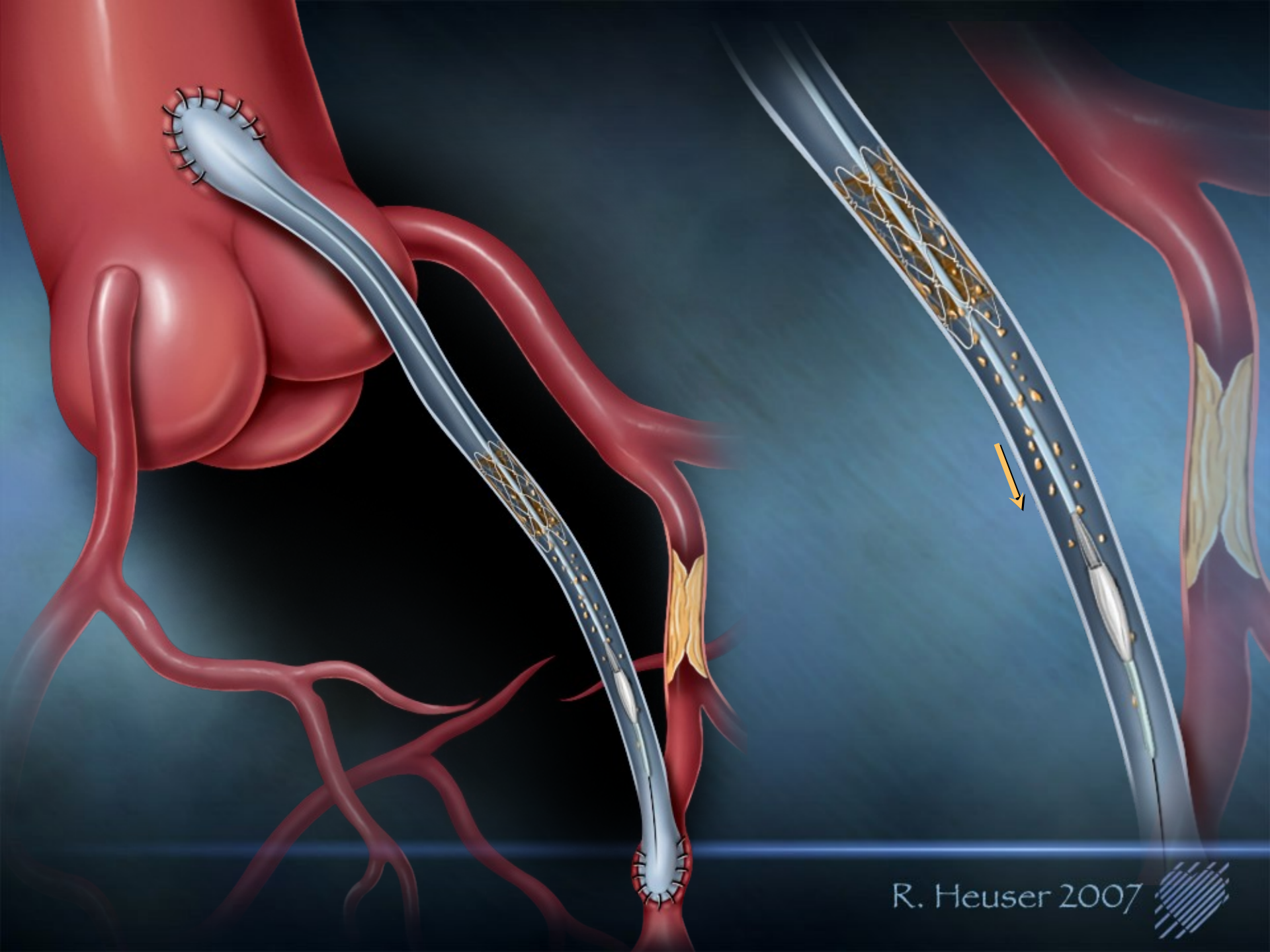
Baim DS. SAFER subset analysis presented November 18, 2002; AHA.

Technical Concerns

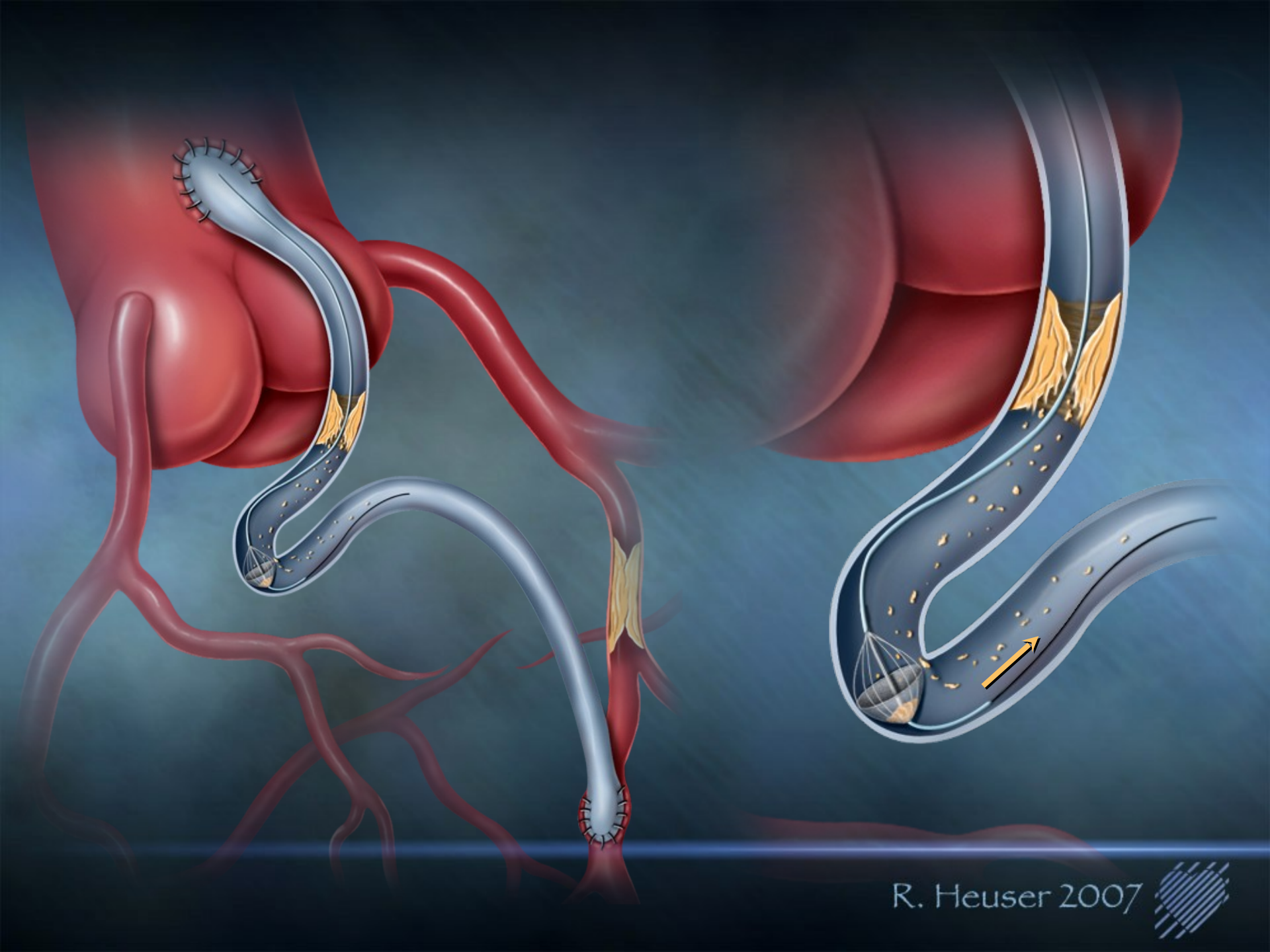
- Failure to cross the lesion
- Positioning
- Sizing the device
- Side-branch protection
- Persistent embolization
- Retrieval
- Use in small vessels
- Use in large vessels
- Uncertain clinical scenarios

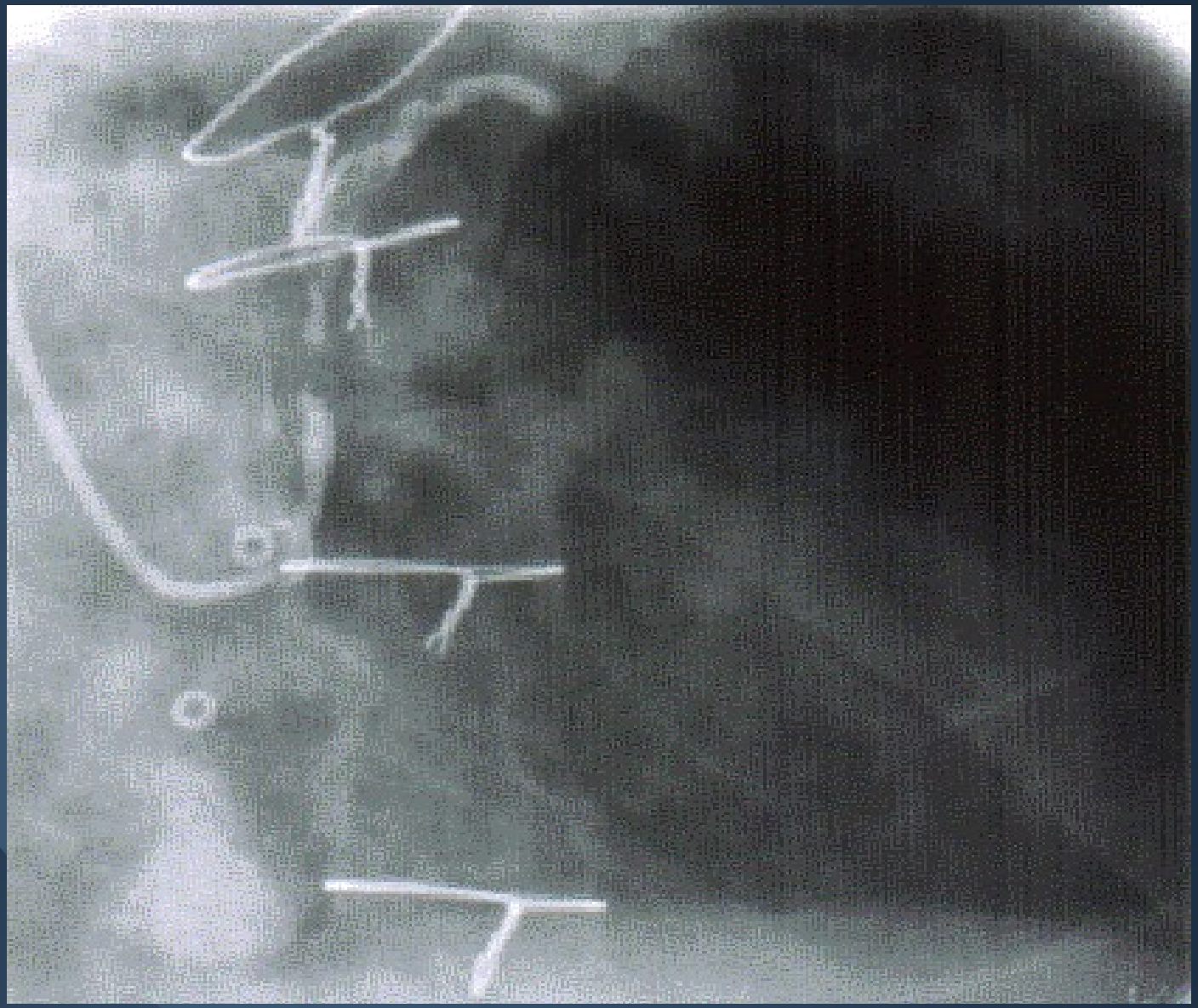

R. Heuser 2007

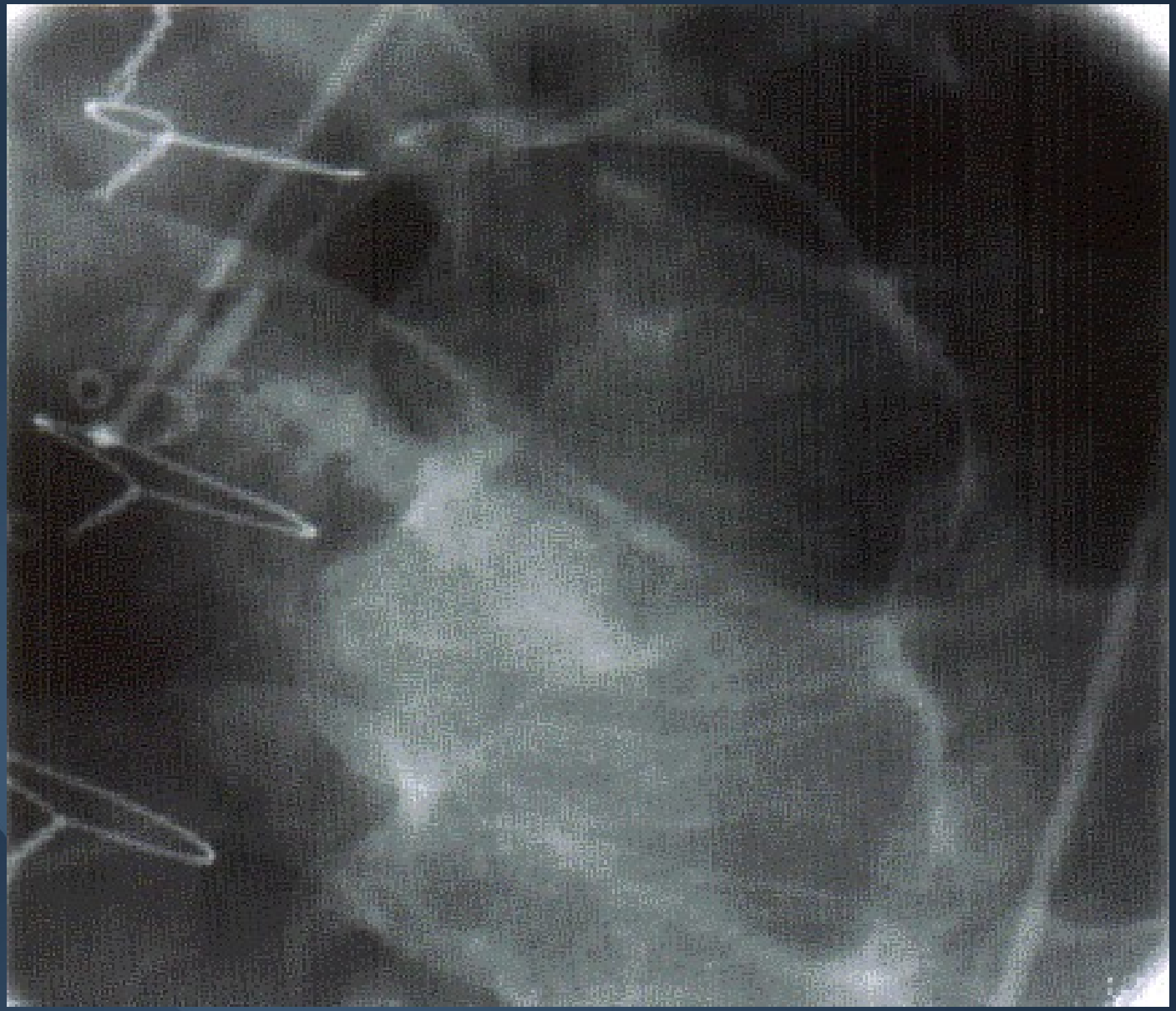

R. Heuser 2007


R. Heuser 2007

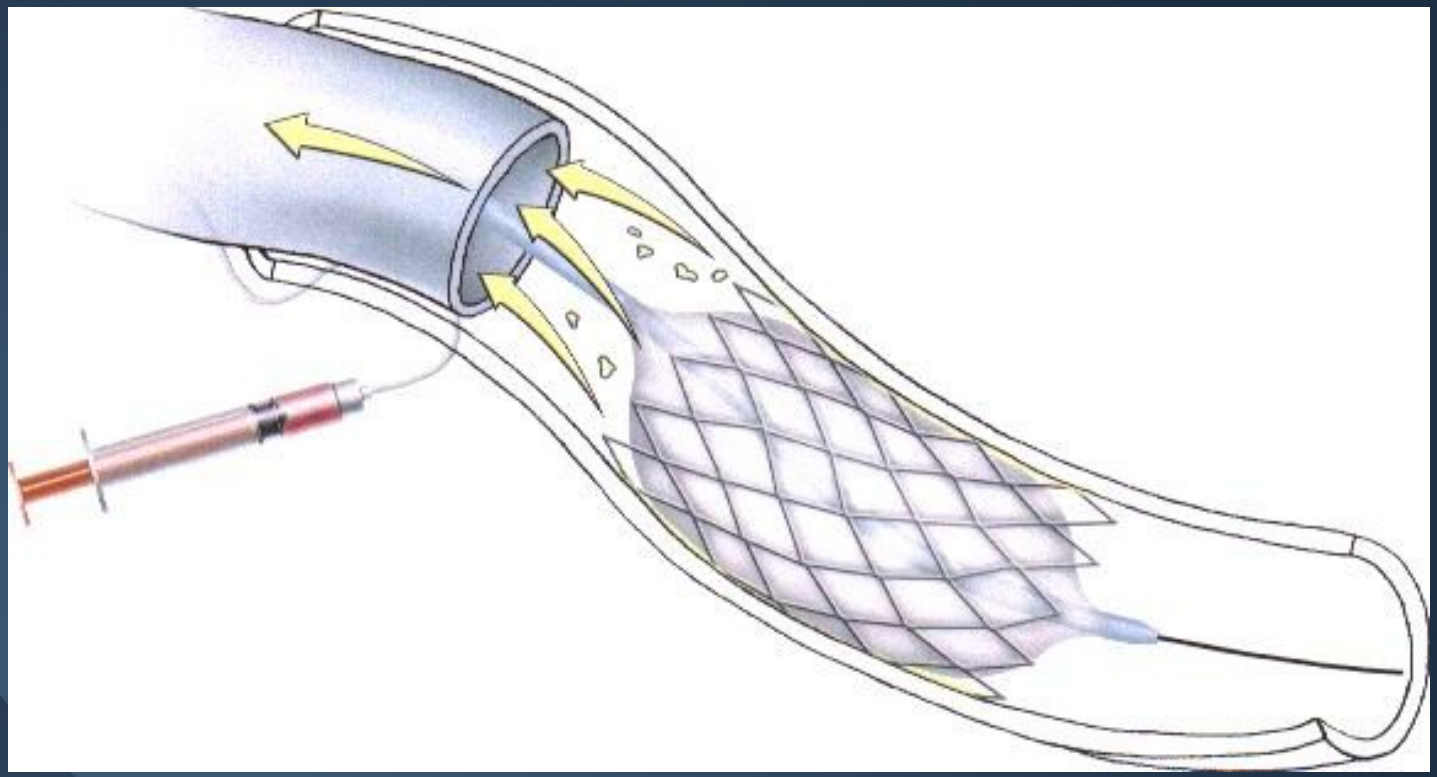

R. Heuser 2007

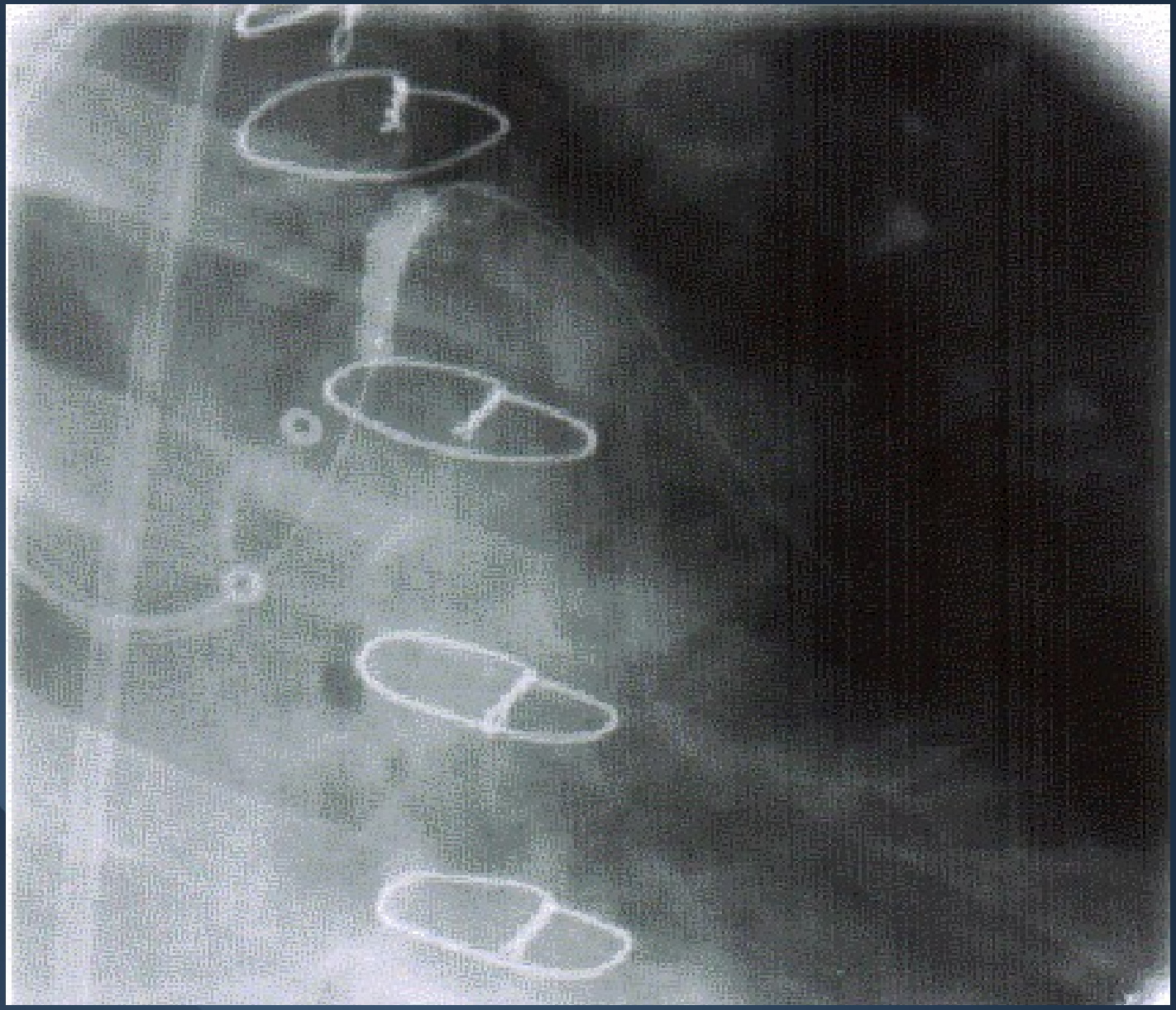

R. Heuser 2007





SUCK-U-SURGE





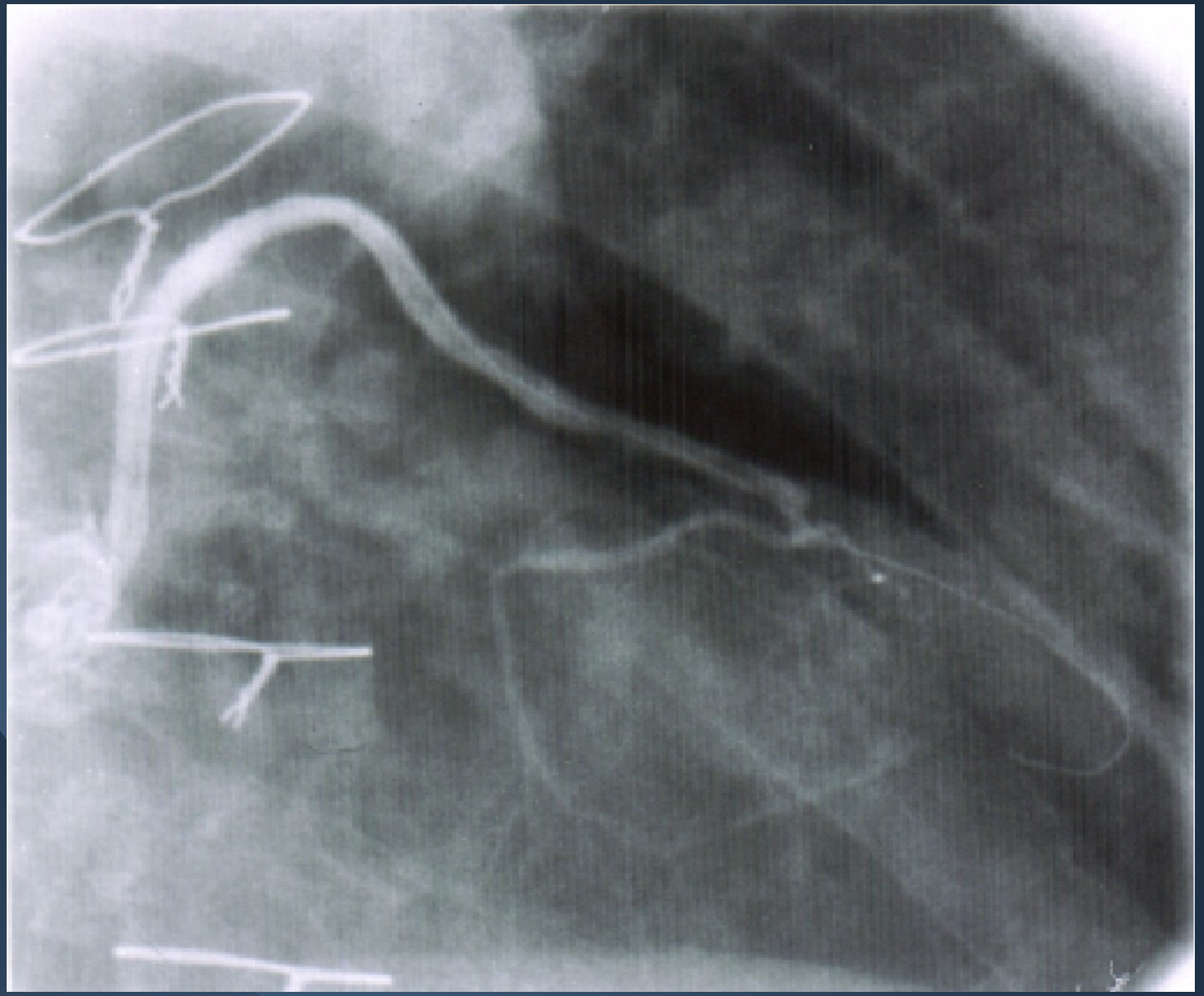
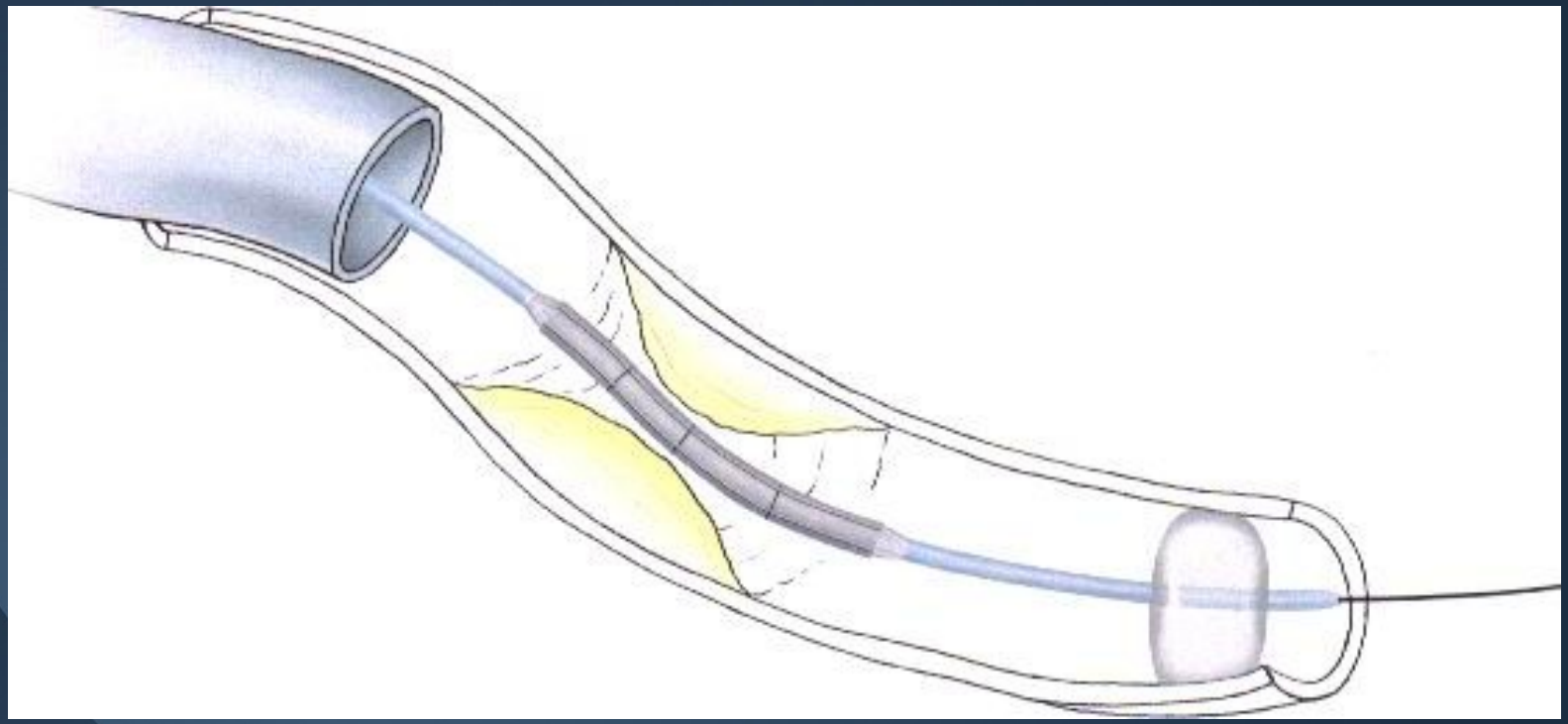


Table. Baseline characteristics and results of the patients who underwent intervention of their saphenous vein graft with guiding catheter aspiration technique

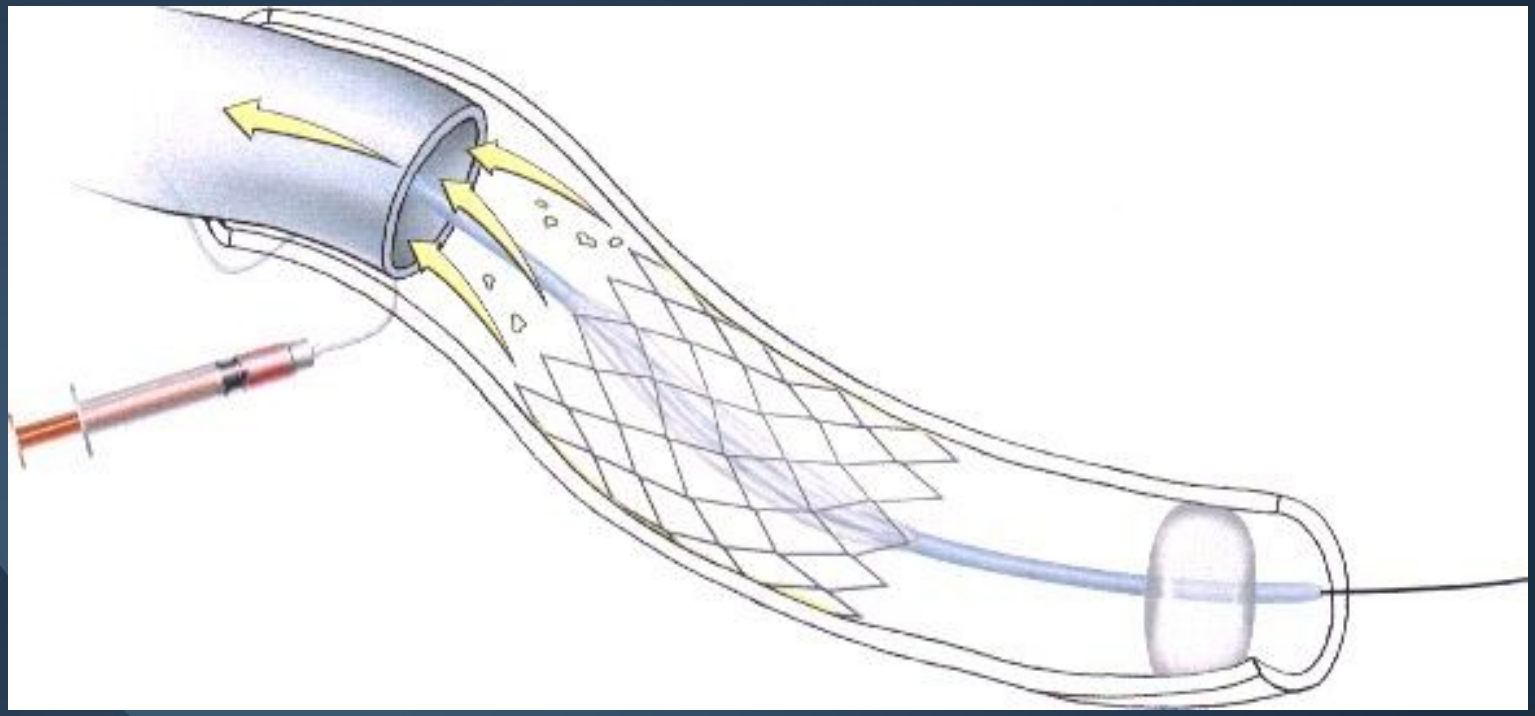
Pt	Gender	Age	DM	Vein Graft (yr)	Vein Graft Target	Stent Placed	P.P. Elevated Age (yr)	30-day CK-MB
Follow-up								
1	M	59	N	RCA	13	Y	N	No event
2	M	58	N	LCX	13	N	N	No event
3	M	66	Y	LCX	6	N	N	No event
4	M	76	Y	LAD	21	Y	N	No event
5	M	83	Y	RCA	7	Y	N	No event
6	M	82	Y	LAD	23	N	N	No event
7	M	66	Y	RCA	12	Y	N	No event
Avg.		70 ± 6			14 ± 6			

Defintions: DM, diabetes mellitus; CK-MB, Creatine Kinase- MB fraction; N, no; Y, yes; M, male; yr, year; P.P., post-procedure

J Interven Cardiol 2002;15:491-498



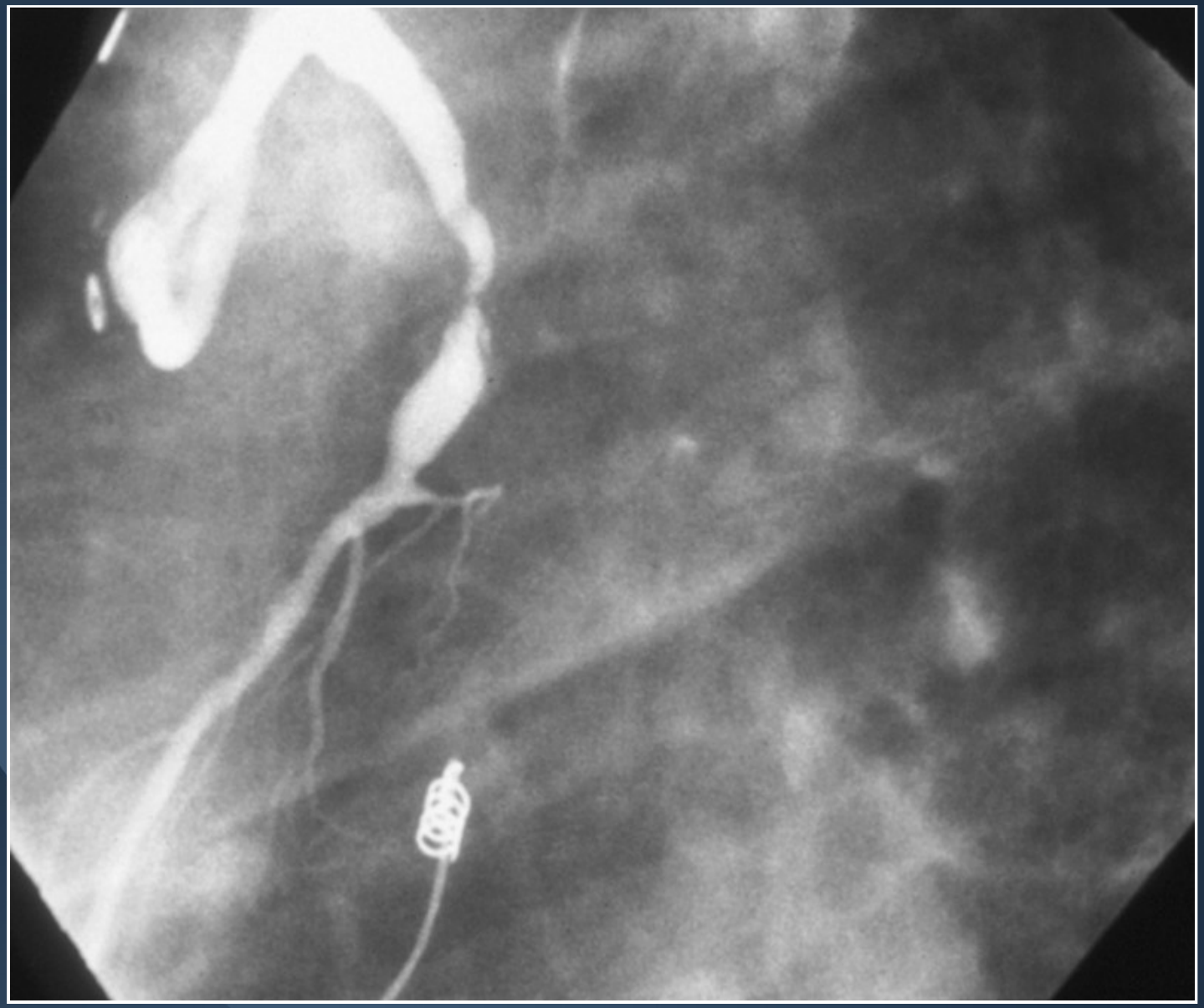
Patent # 6,364,900 Embolism Prevention Device



Patent # 6,364,900 Embolism Prevention Device

SVG Intervention 2007

- *Probably All Should Have Embolic Protection*
- *Filter or Balloon System depends on cost, experience, availability*



ACC/AHA SVG Recommendation

ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention)

5.5. Percutaneous Intervention in Patients With Prior Coronary Bypass Surgery

Class I

1. When technically feasible, PCI should be performed in patients with early ischemia (usually within 30 days) after CABG. *(Level of Evidence: B)*
2. It is recommended that distal embolic protection devices be used when technically feasible in patients undergoing PCI to saphenous vein grafts. *(Level of Evidence: B)*

Smith, et al., **ACC/AHA/SCAI Practice Guidelines** 2005; 56-58.

EMBOLIC PROTECTION DEVICES

- What % of patients have EPD paced during PCI of SVG's?

EMBOLIC PROTECTION DEVICES

- **What % of SVG lesions COULD have either Distal Protection Filters or Proximal Protection…**

77%

Webb, H, J. Int. Cardiology, 2005, April, 18(2): 81-2; (Class IB Indication by ACC/AMA Guidelines) Circ. 2006; 113: 156-175

EMBOLIC PROTECTION DEVICES

ACC DATABASE

- 19,562 Patients
- 452 Centers

22% of cases

Mehta S, et al, ACC 2007

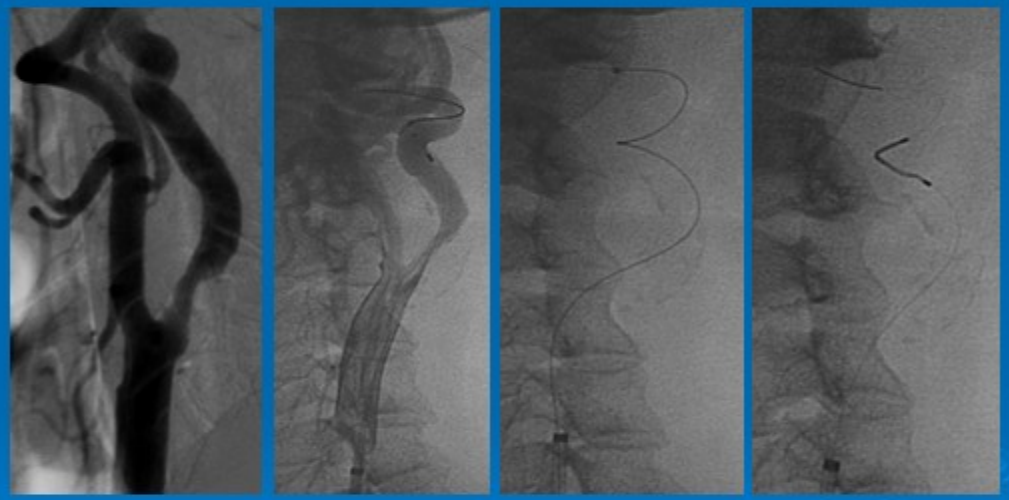
EMBOLIC PROTECTION DEVICES

LACK OF PROTECTION

- **Lack of understanding of the effectiveness**
- **Lack of understanding of cost effectiveness**

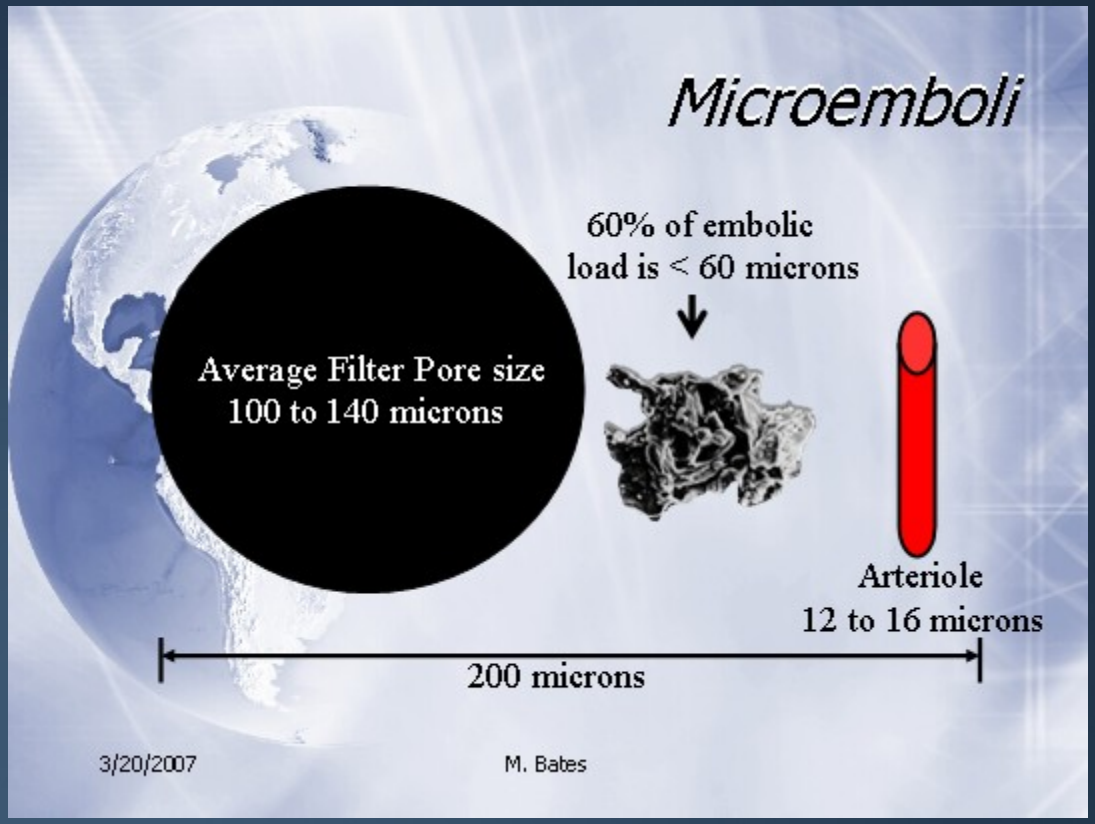
  -- 15 lives are saved at 30 days per 1,000 patients
- **Lack of understanding that it is an ACC/AHA Class 1 indication**
- **The fact that the devices are not always easy to use by the "lowest common denominator" physician**

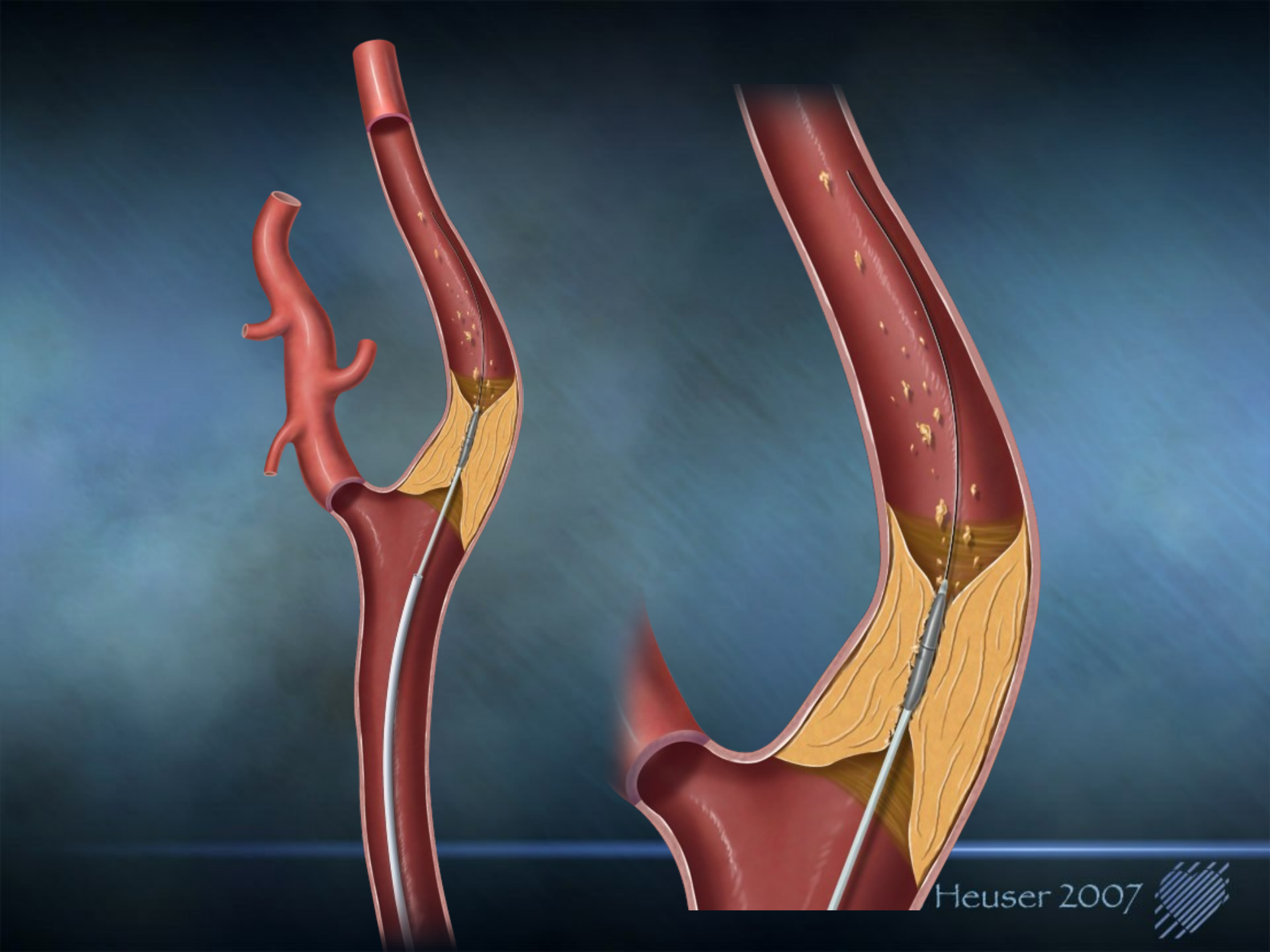
Distal Tortuosity

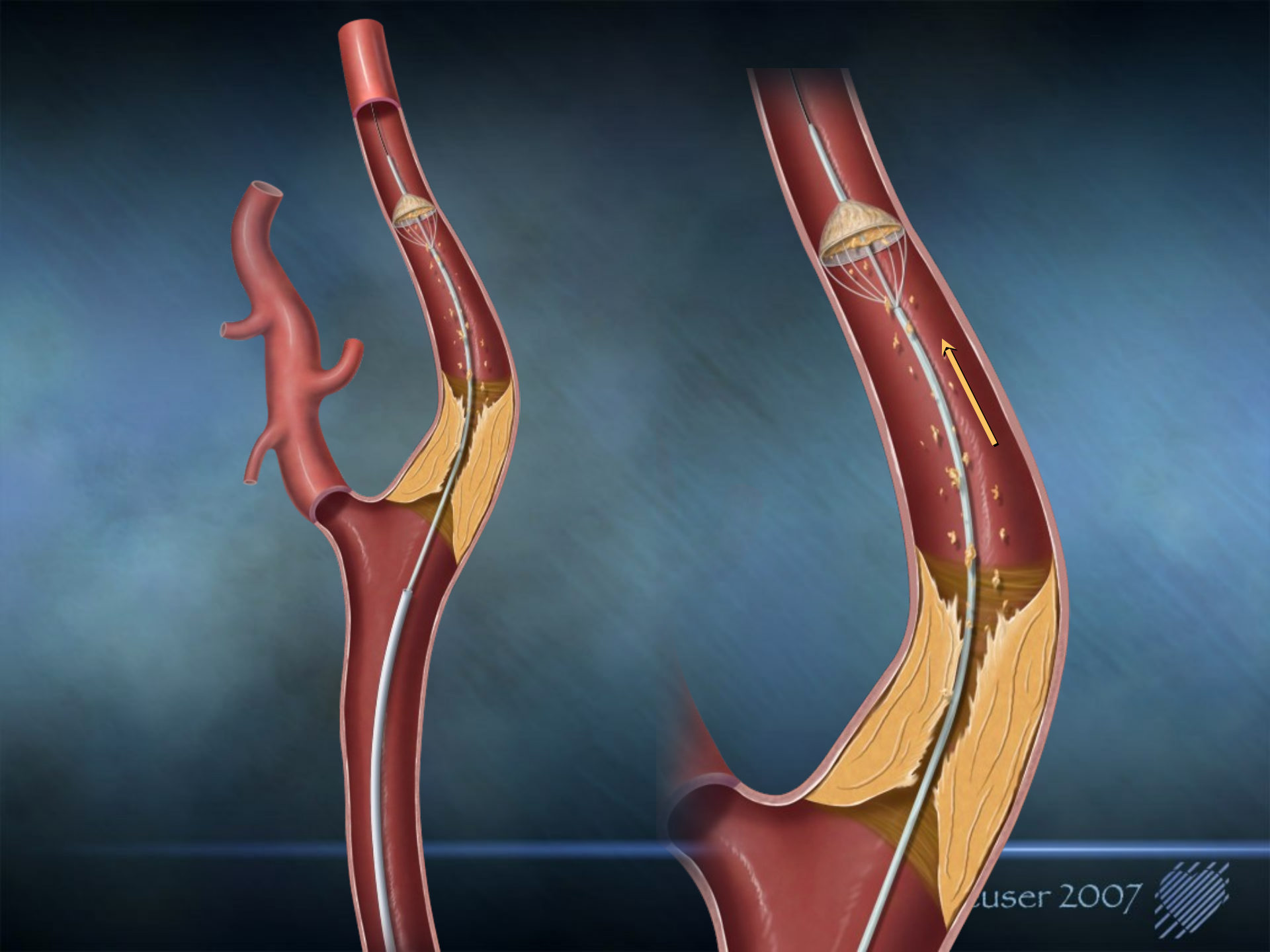


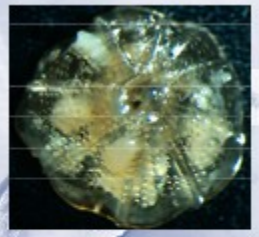
Good support from sheath. Angioguard and Filterwire did not cross despite buddy-wire; Spider delivery catheter crossed but filter could not be advanced

041573


Microemboli
60% of embolic load is < 60 microns
Average Filter Pore size 100 to 140 microns
Arteriole 12 to 16 microns
200 microns
3/20/2007
M. Bates


Heuser 2007


user 2007



Filter threshold

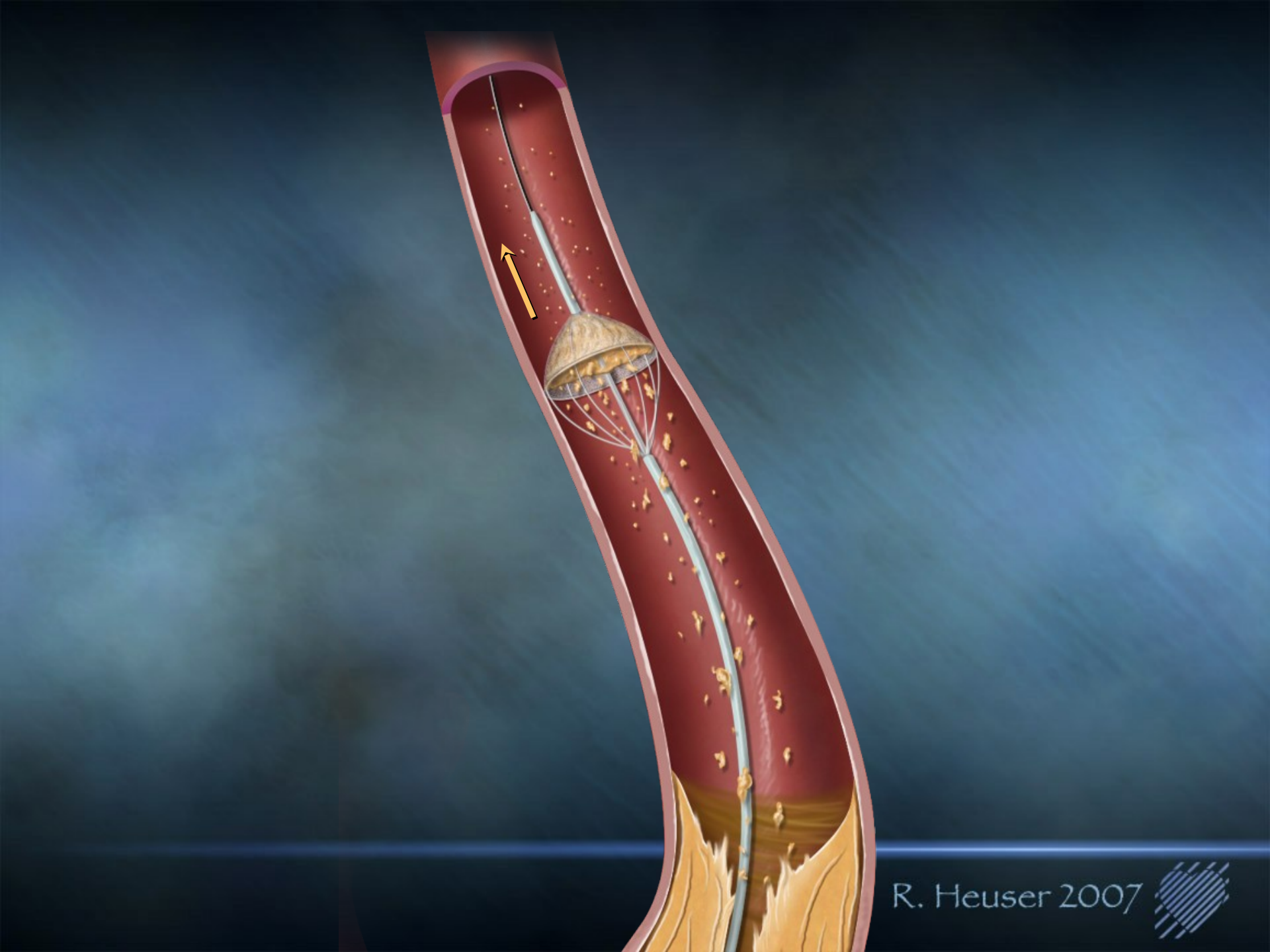
- Static column of blood with suspended particles that will embolize when filter is collapsed
- "Concentrated particles may be more harmful than small amounts of emboli distributed throughout the case"

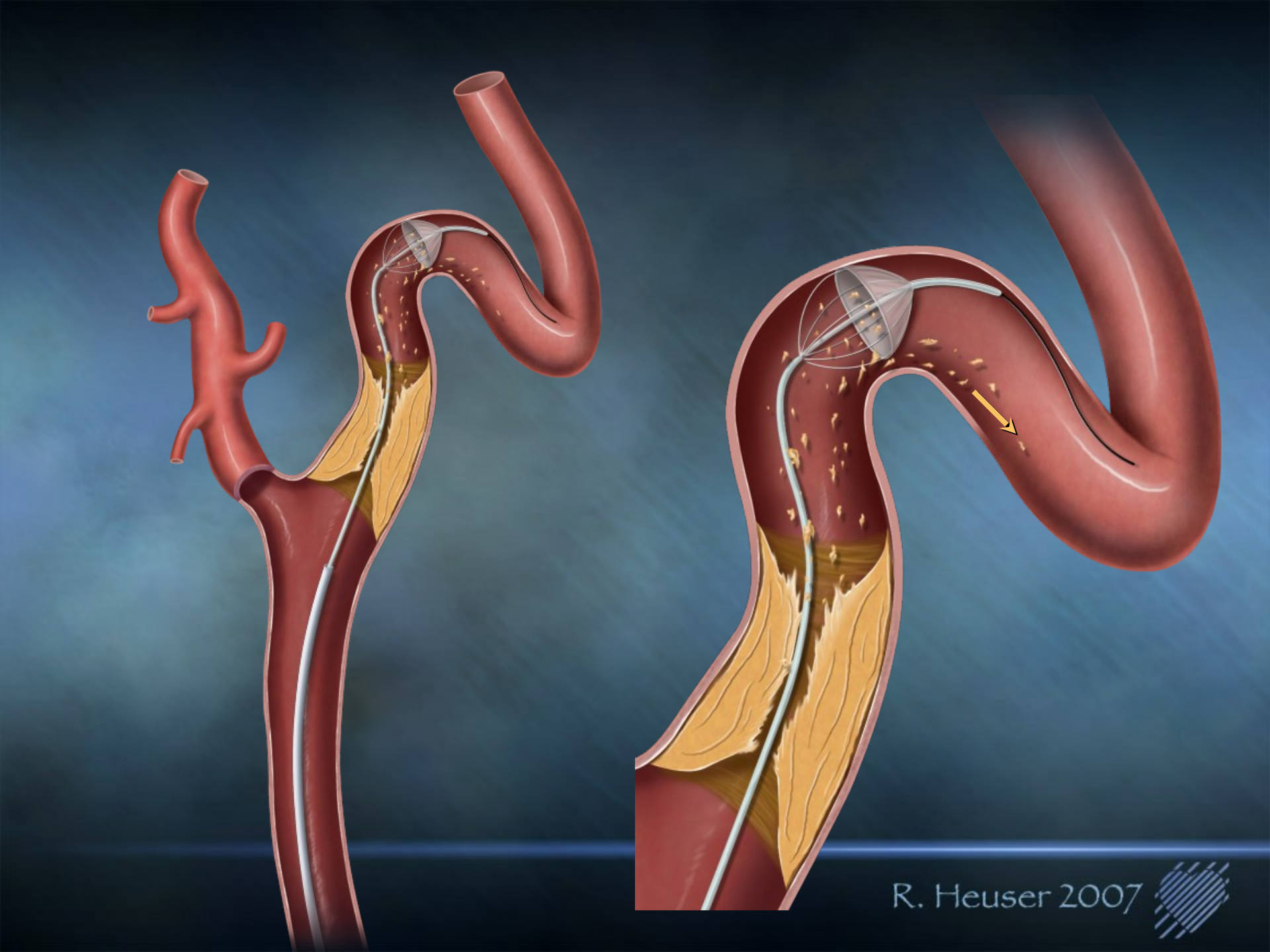
  Tak Ohki

Filter occluded with embolic load

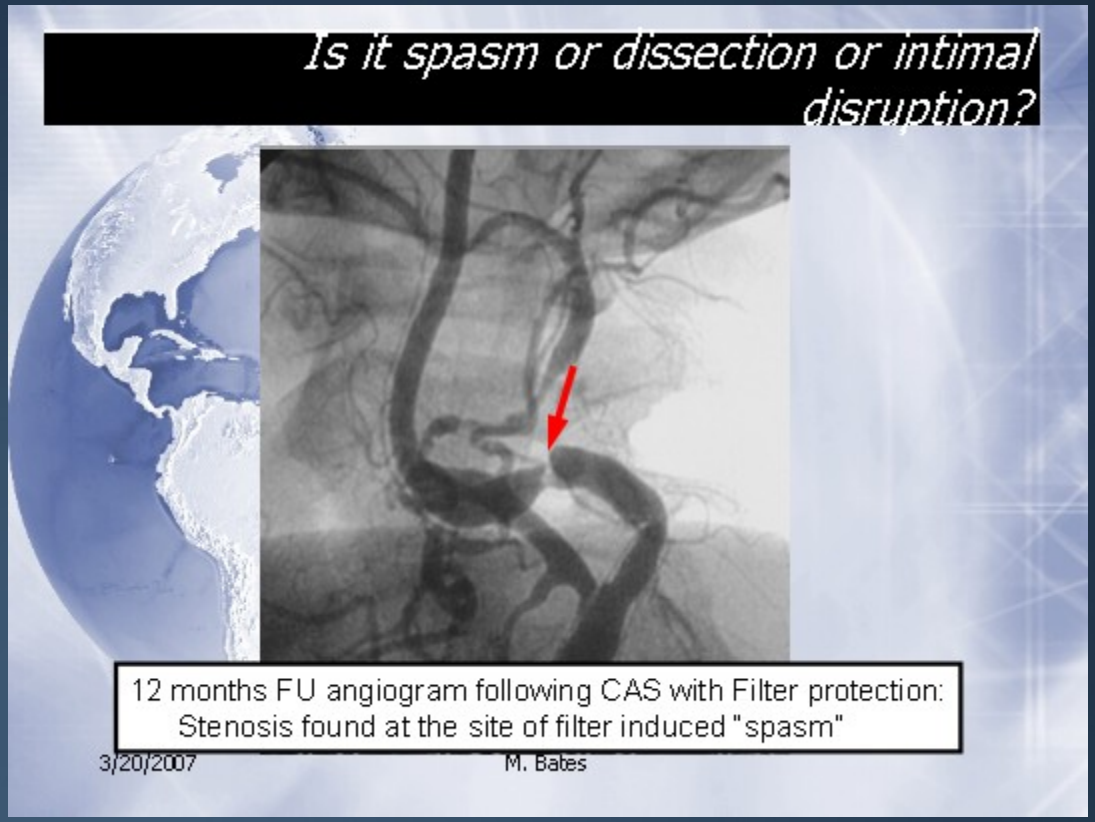
3/20/2007 M. Bates


R. Heuser 2007


R. Heuser 2007


R. Heuser 2007

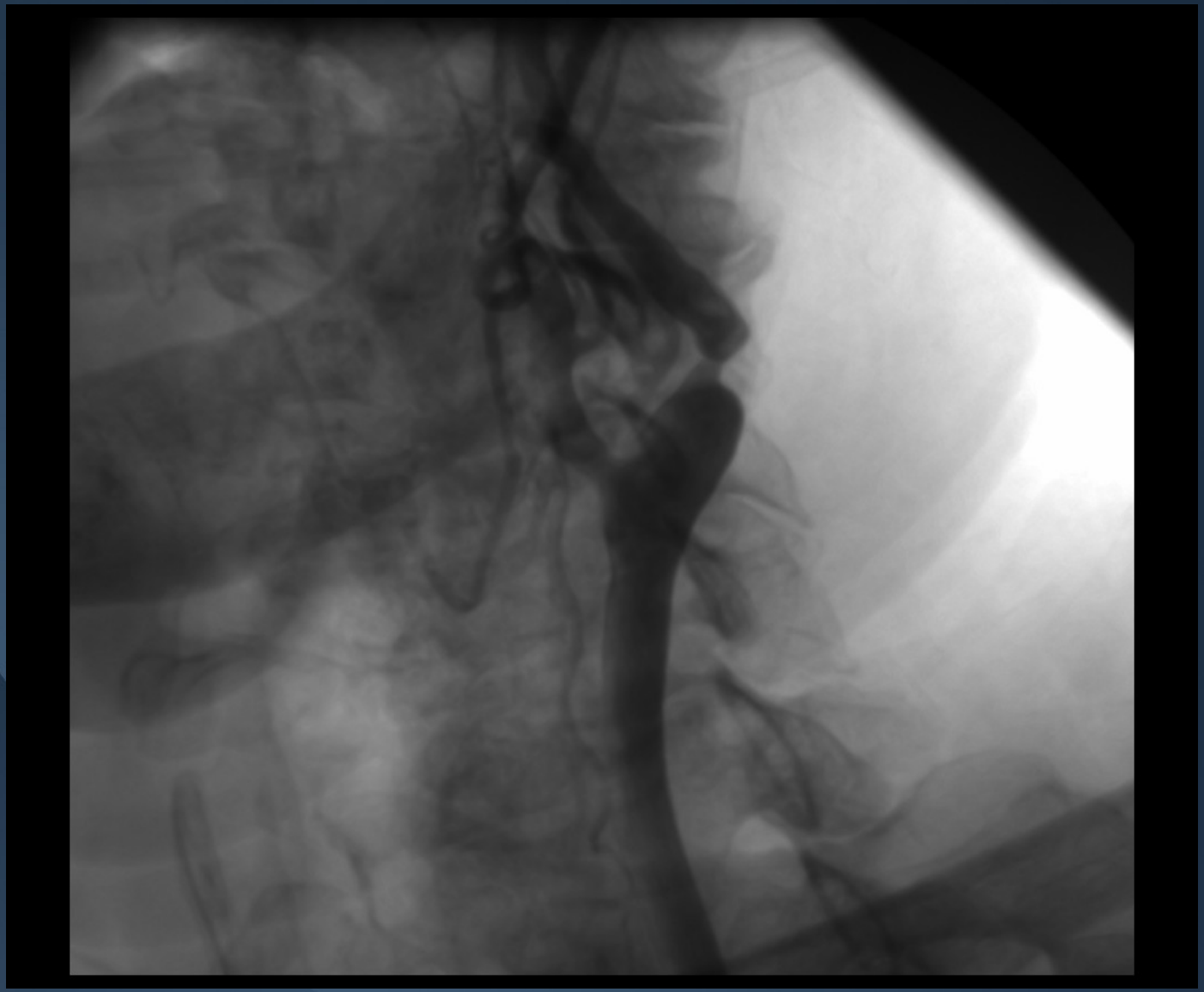
Is it spasm or dissection or intimal disruption?

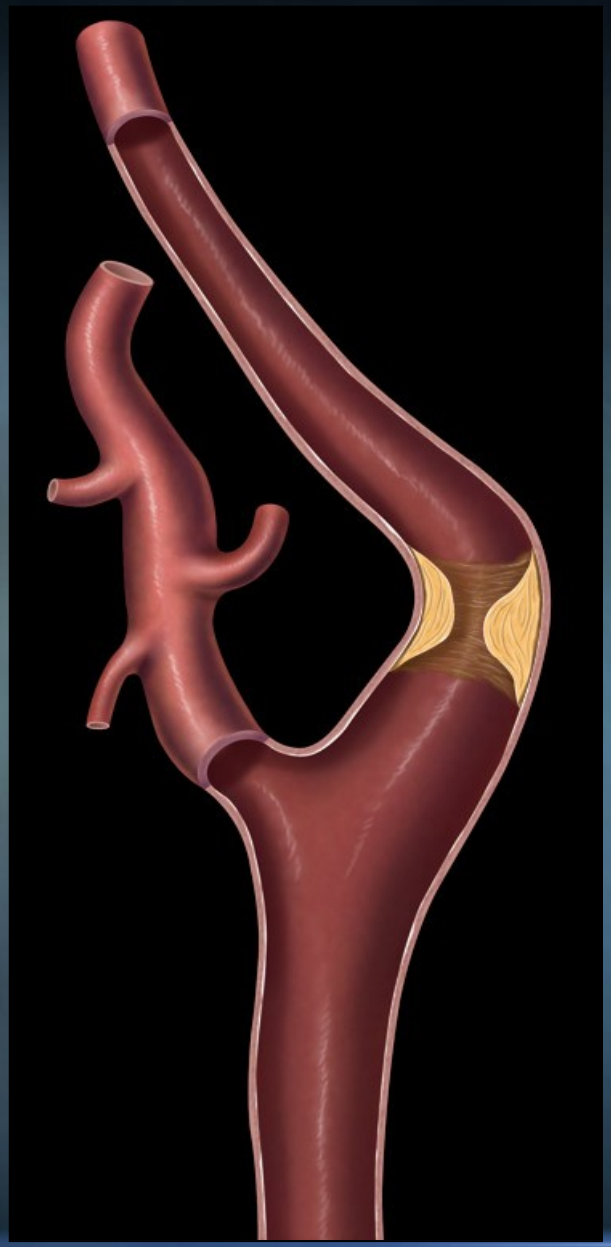


12 months FU angiogram following CAS with Filter protection:
Stenosis found at the site of filter induced "spasm"

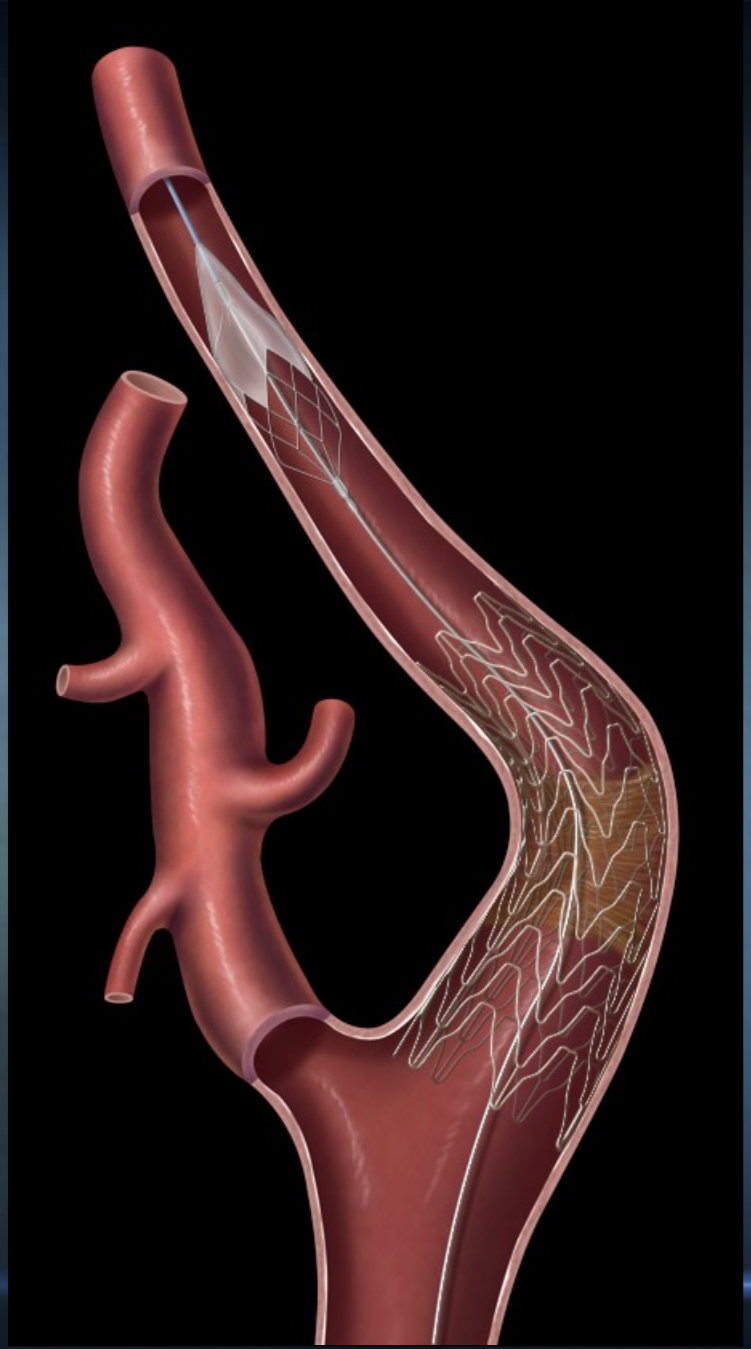
82 year old gentleman with symptomatic carotid artery stenosis and severe COPD and coronary artery disease

First View

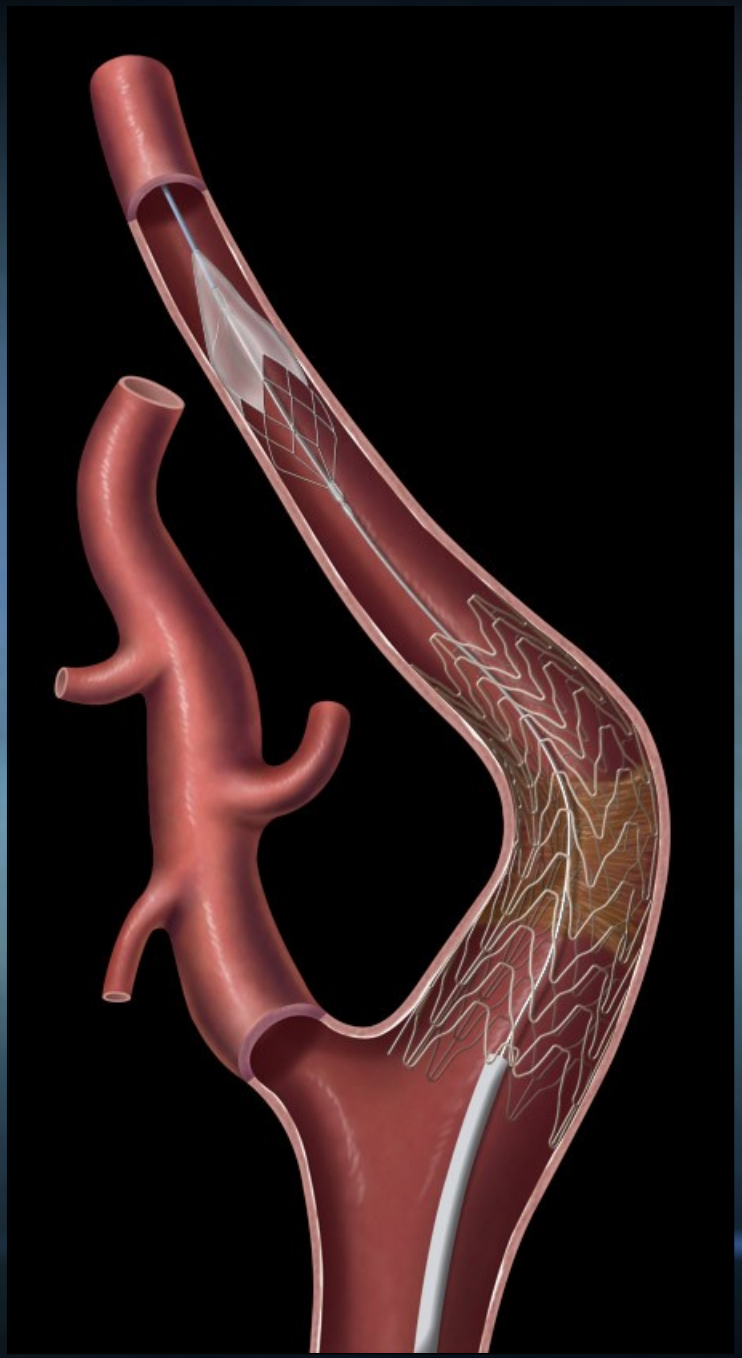


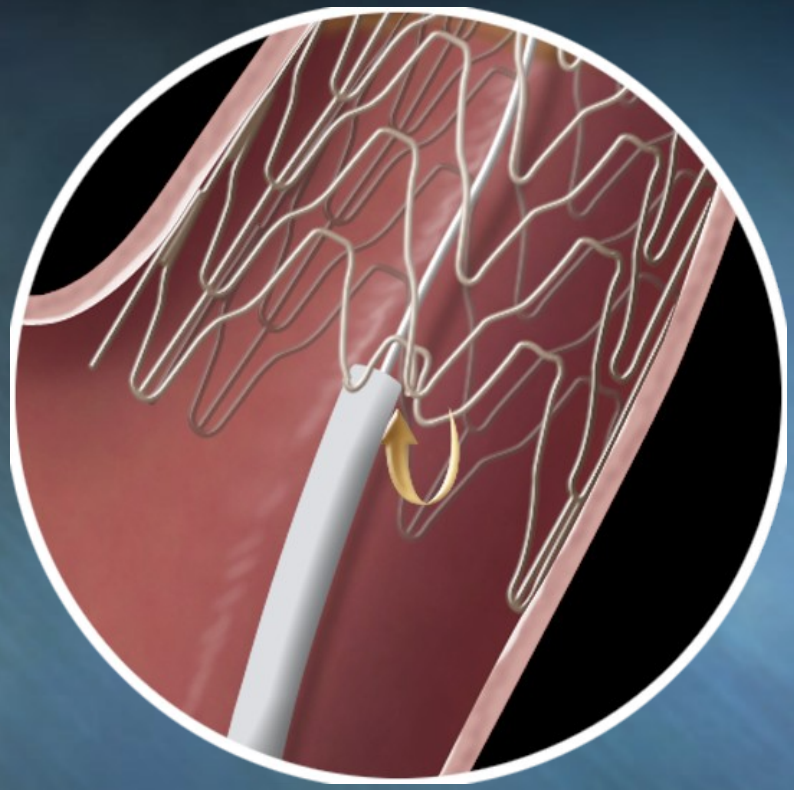


R. Heuser 2007

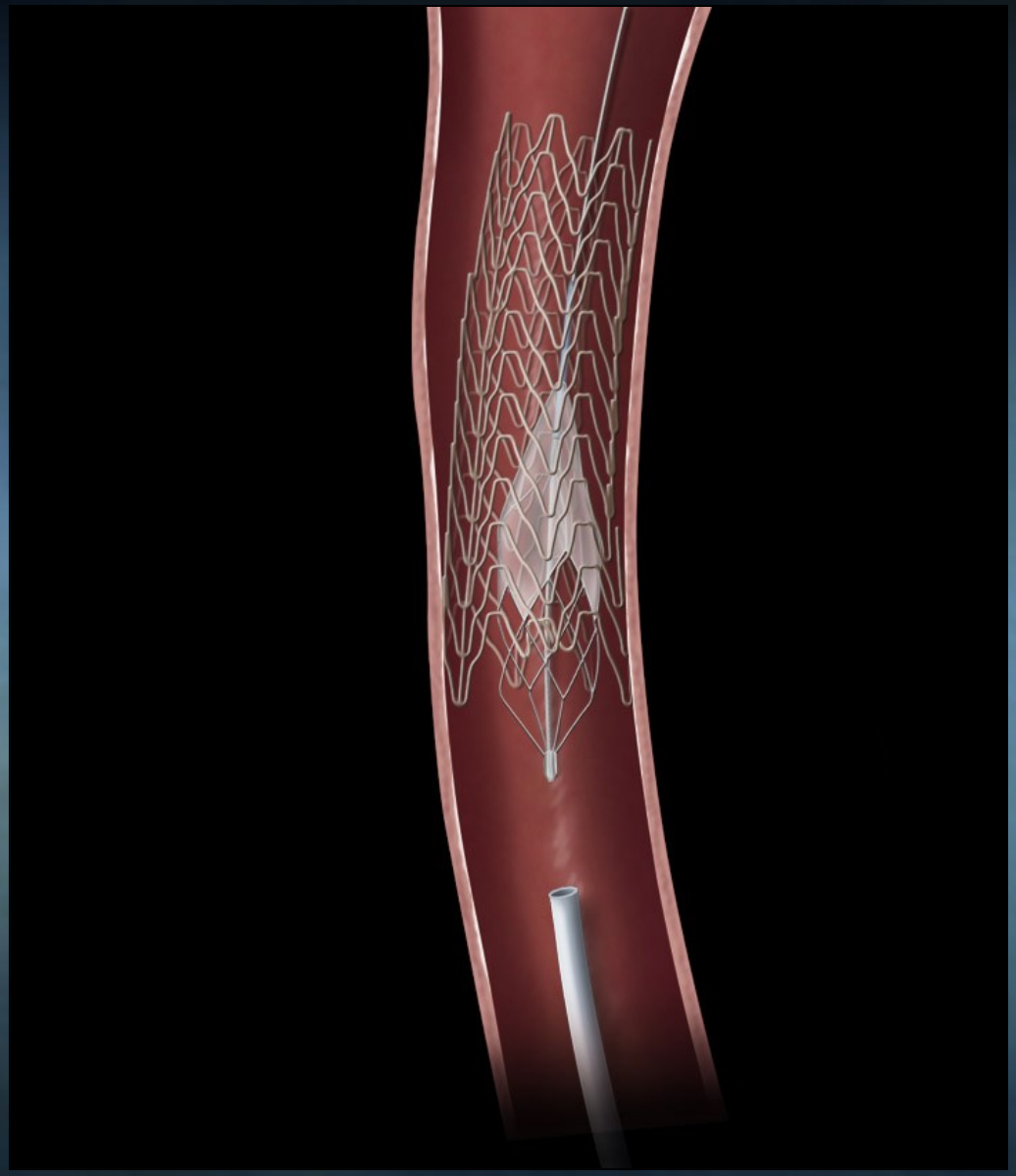


R. Heuser 2007

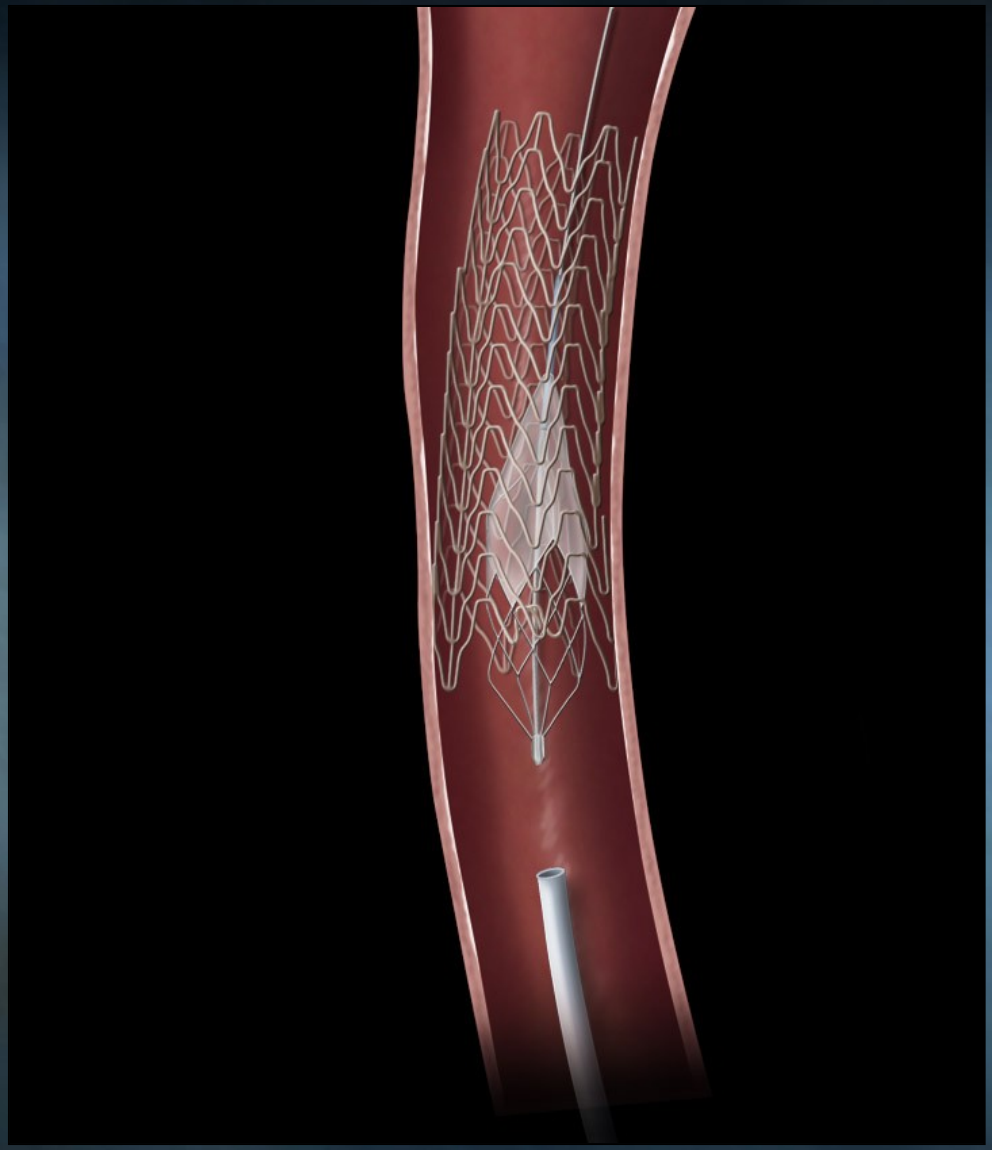


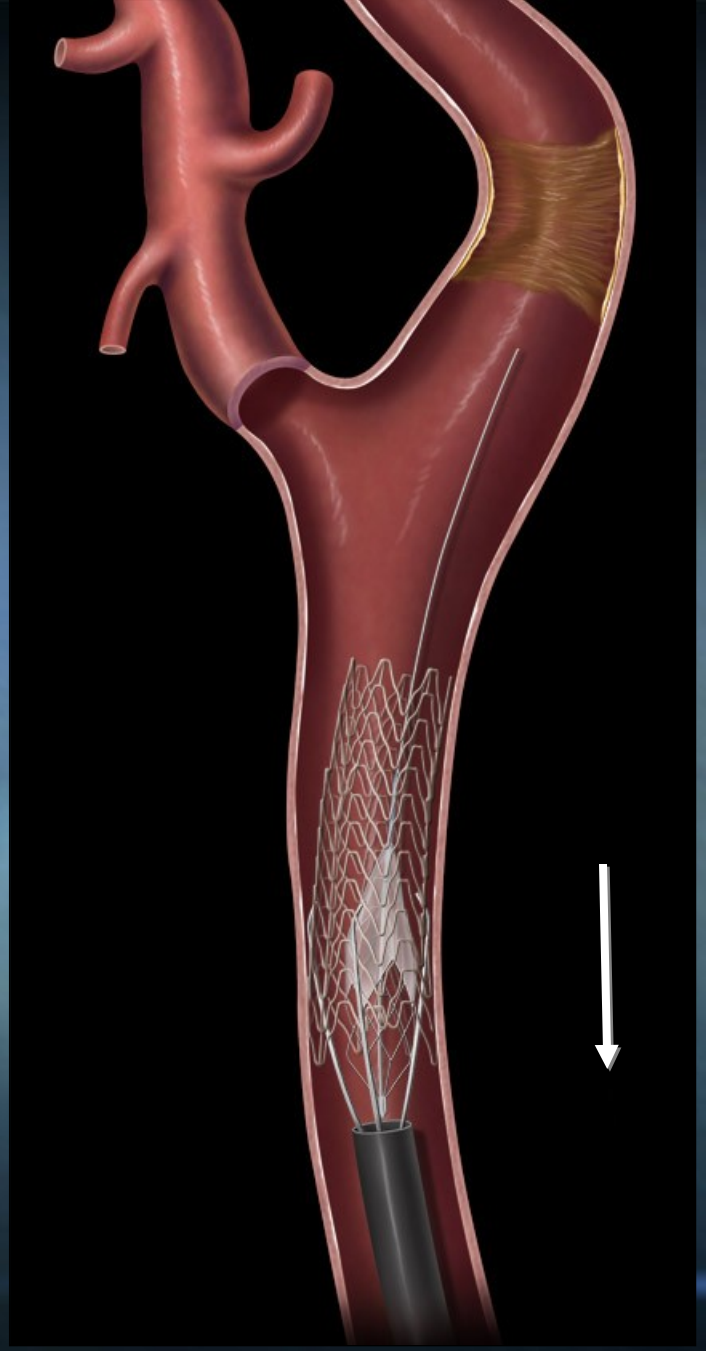


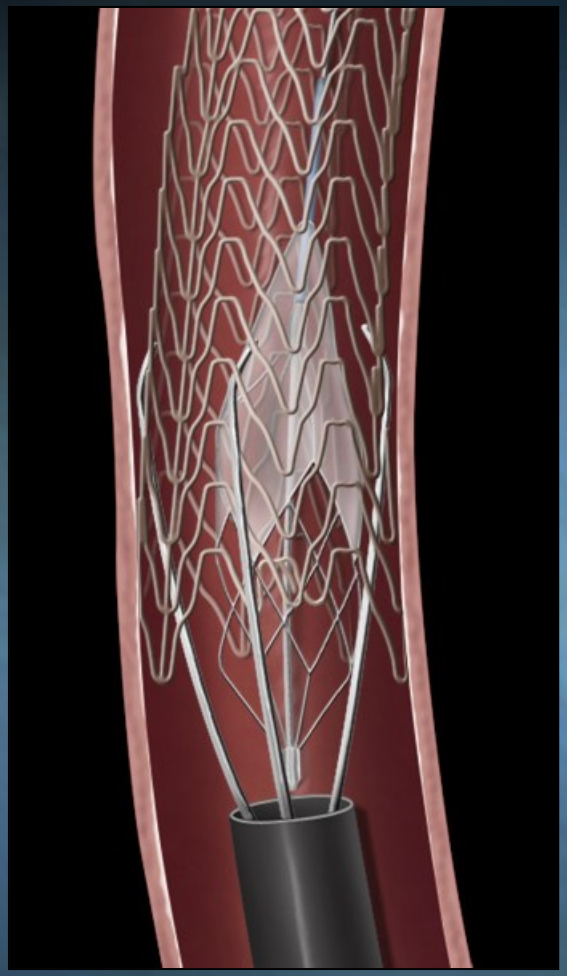
R. Heuser 2007



Filter Wire Disconnected







R. Heuser 2007

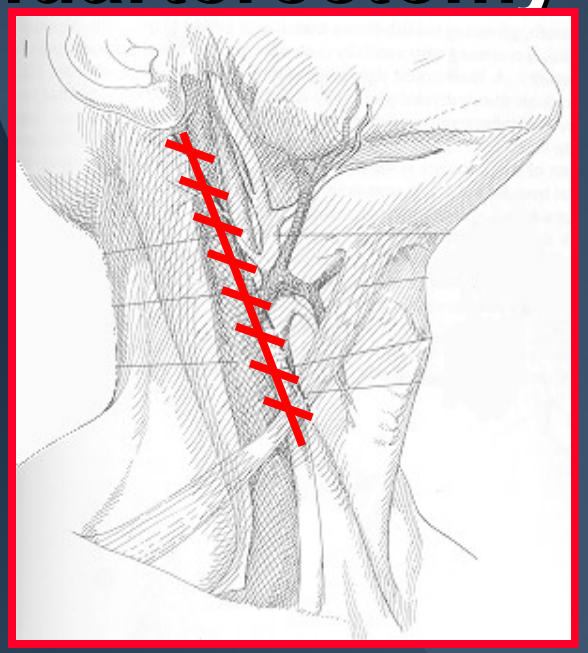
Post Removal Dissection

Zoom Post

C.R.E.S.T.

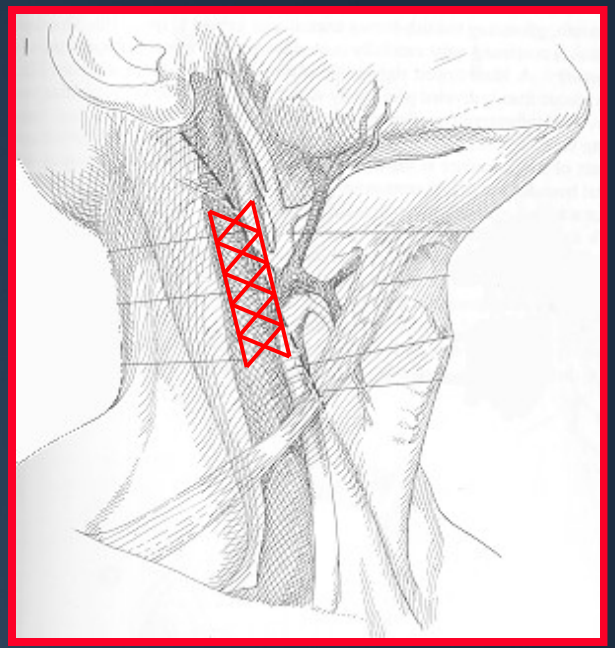
N.I.H.-N.I.N.D.S.

Carotid **R**evascularization **E**ndarterectomy



vs.

Stent **T**rial

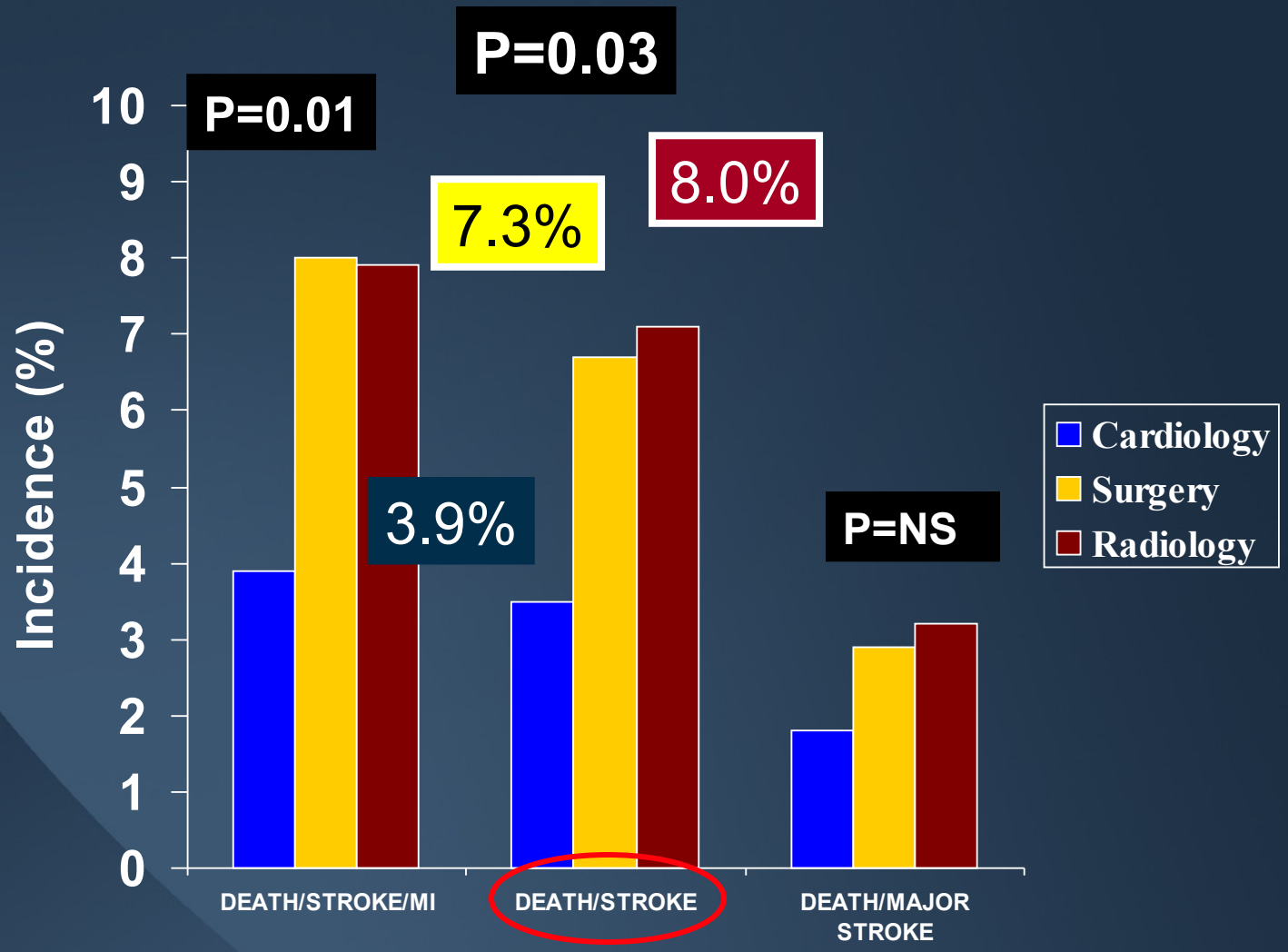


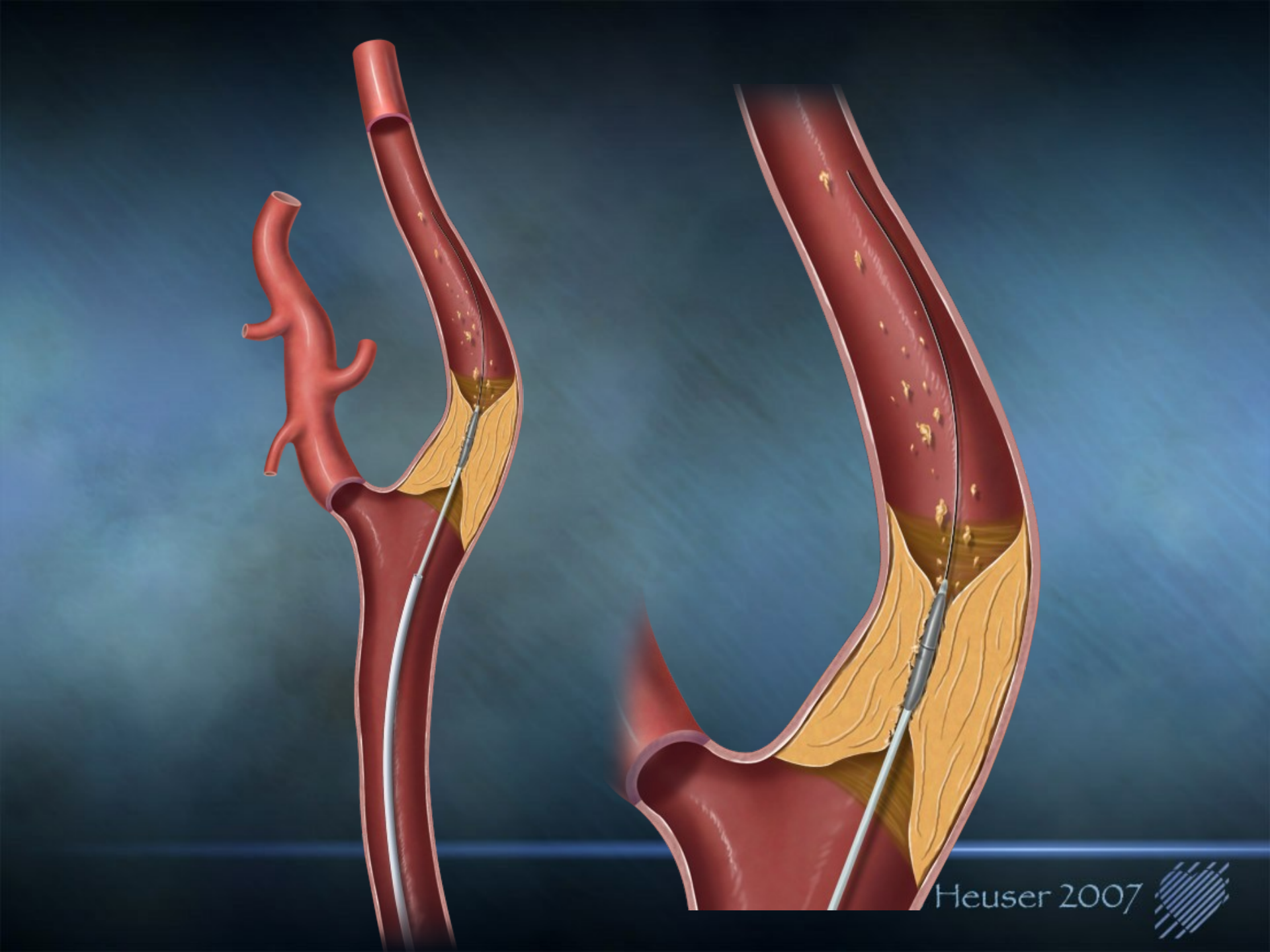
CREST Lead-in Registry

N=1479 Patients.

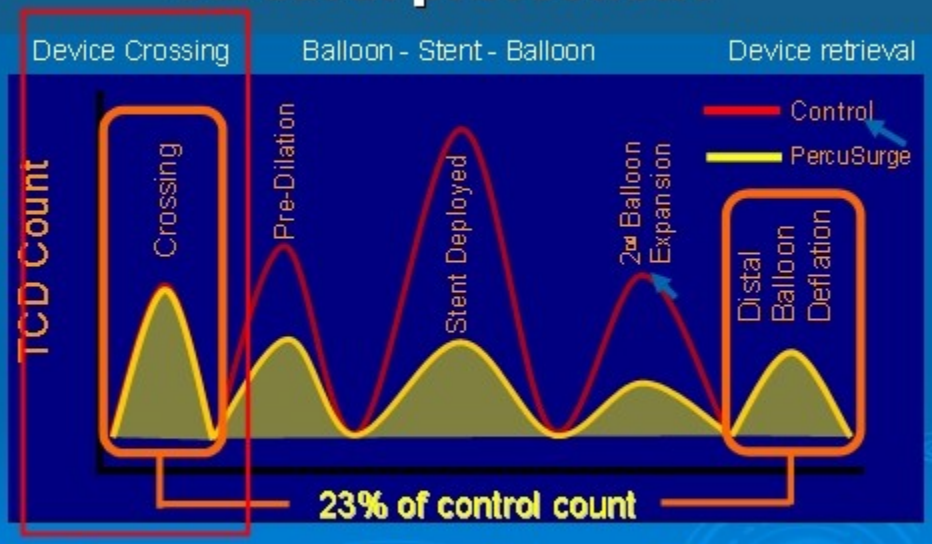
- Cardiology 567(38%)
- Surgery 450(30%)
- Radiology 251(17%)
- Neuroradiology 136(9%)
- Neurology 11
- Unclassified 60

CREST Lead-in: 30 day Events By Specialty




Heuser 2007

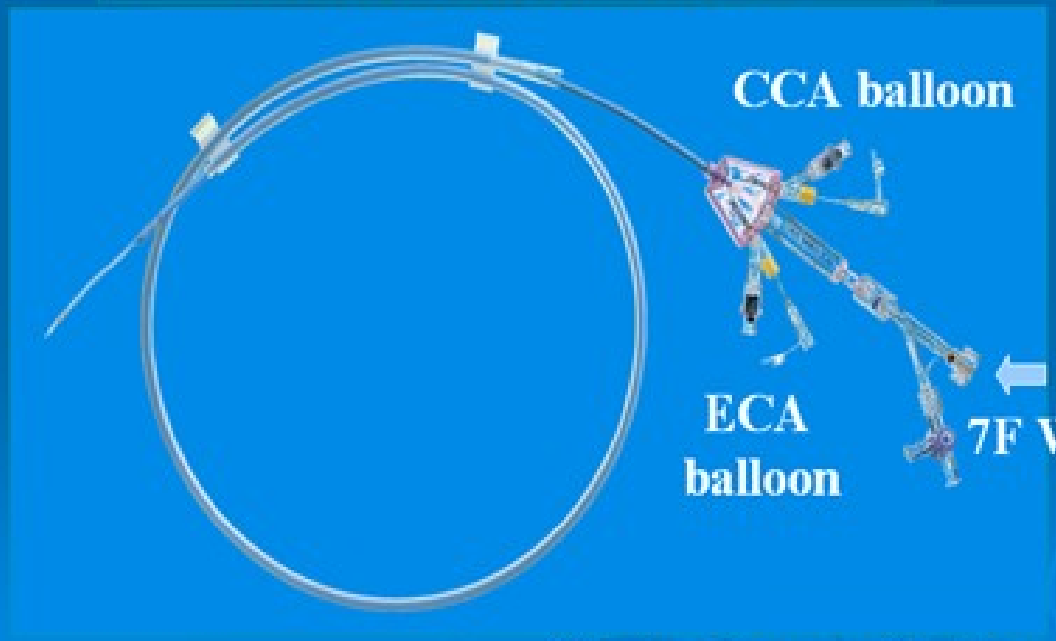
Why pursuing a new concept of cerebral protection?



Embolism may occur during all phases fo the procedure

MO.MA

Single Device consisting of long 90 cm sheath and 2 occlusion balloons



9F device available

Journal of the American College of Cardiology
© 2004 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 44, No. 10, 2004
ISSN 0735-1097/04/$30.00
doi:10.1016/j.jacc.2004.08.049

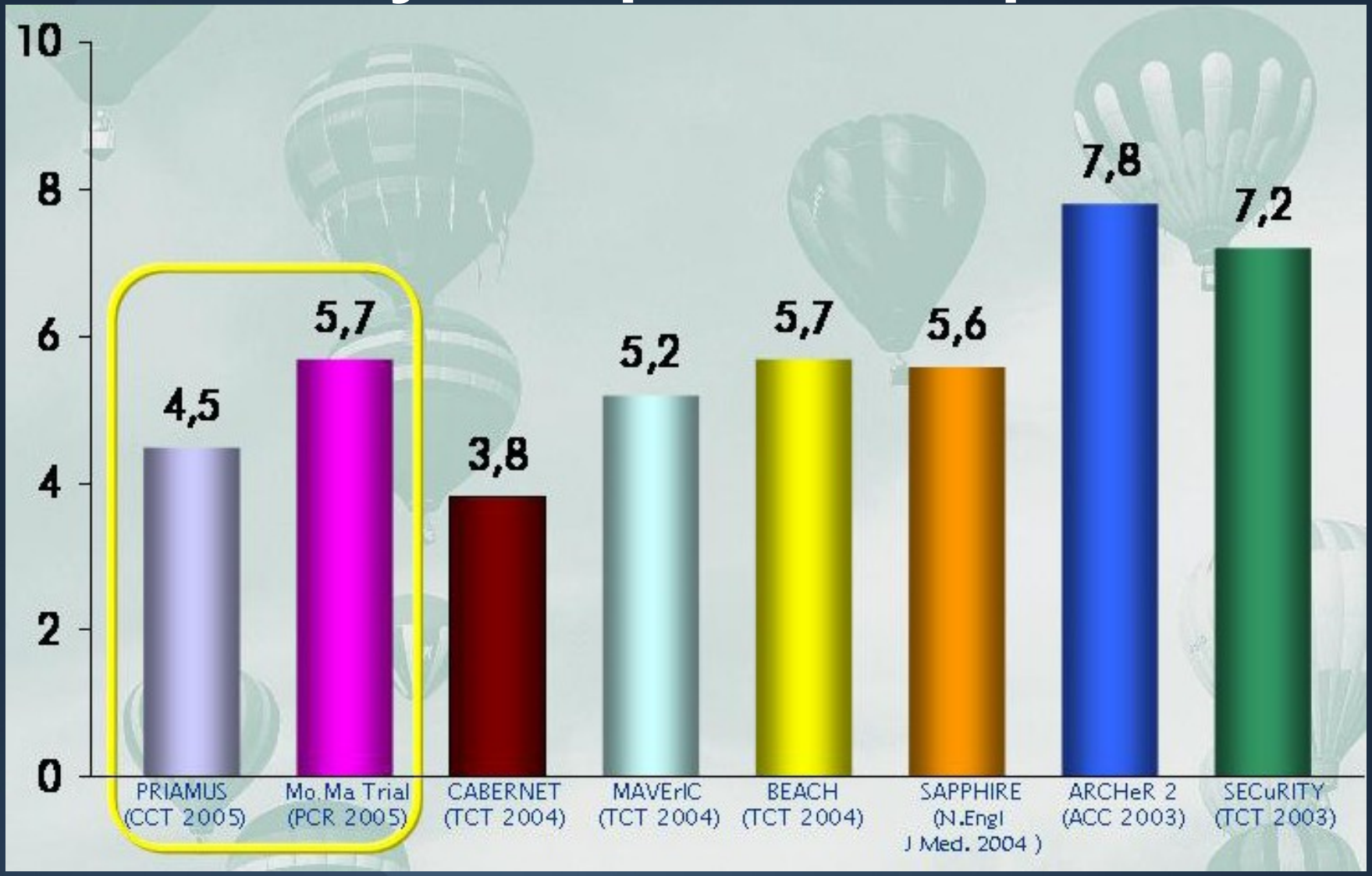
CLINICAL RESEARCH **Interventional Cardiology**

Effect of Two Different Neuroprotection Systems on Microembolization During Carotid Artery Stenting

Andrej Schmidt, MD, Klaus-Werner Diederich, MD, Susanne Scheinert, MD, Sven Bräunlich, MD, Tatjana Olenburger, Giancarlo Biamino, MD, Gerhard Schuler, MD, Dierk Scheinert, MD
Leipzig, Germany

Study Type	Single Center comparative - non random. MO.MA vs Filters	
	MO.MA	Filters
Nr of Patients	21	21
Symptomatic	7 (33%)	6 (29%)
Degree of Stenosis	86±9%	85±8%
Evidence of Macroscopic Debris	18 (89%)	14 (67%)
Stroke & Deaths procedural	0	0
Total MES Counts	57±41	196±84
	$p < 0.0001$	

30-Day Composite Endpoints

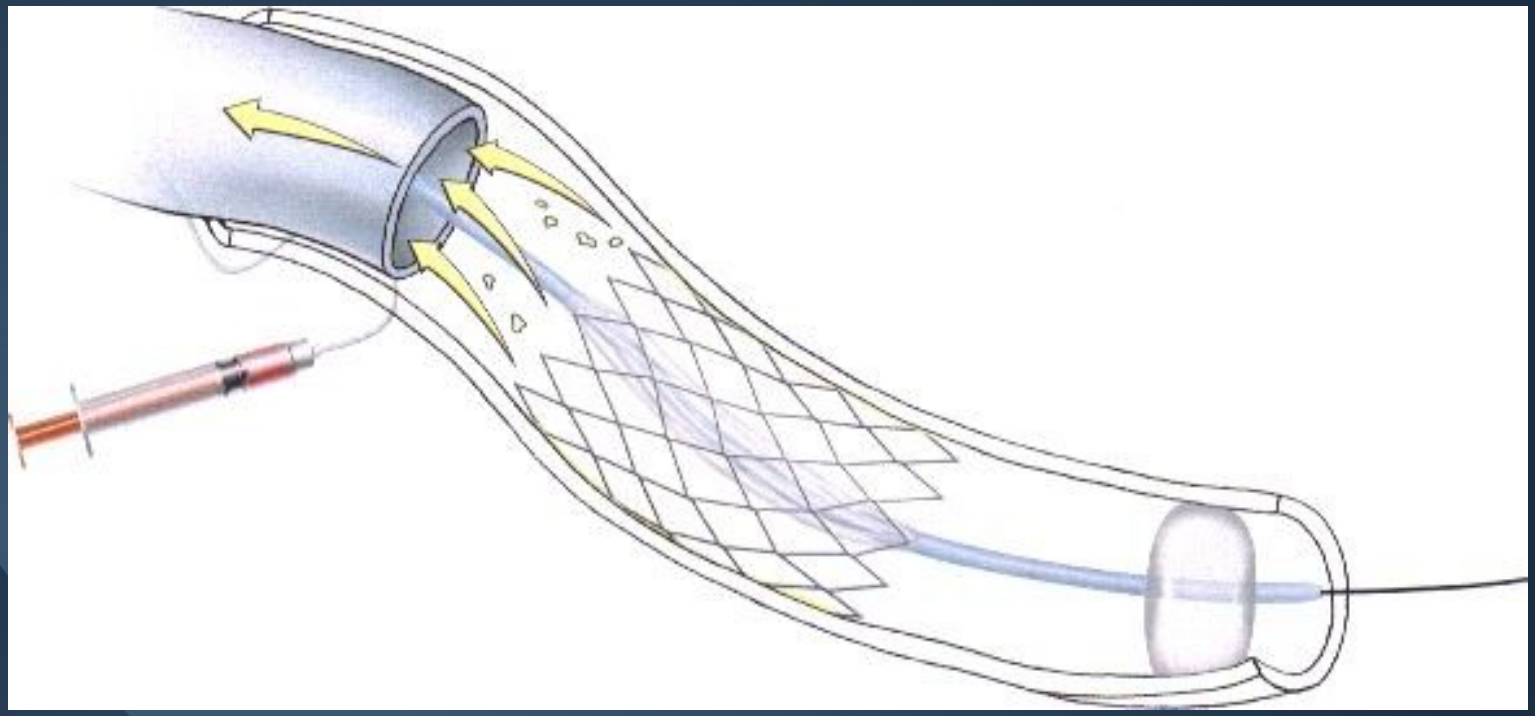


EMBOLIC PROTECTION DEVICES

- **Whether proximal**
- **Filter based**
- **Reversal of Flow**
- **Balloon Occlusive**

ALL ARE BASED ON THE KLETSCHKA PATENT

THE PROTECHTOR



CURRENT EMBOLIC PROTECTION DEVICES

ALL HAVE SEVERAL FEATURES IN COMMON

- They are under utilized (22% in SVG)
- They are stiff and sometimes difficult to use
- They are relatively expensive and add cost and time to the procedure
- They appear not to be effective in MI patients
- They all are based on the original Kletschka Patents

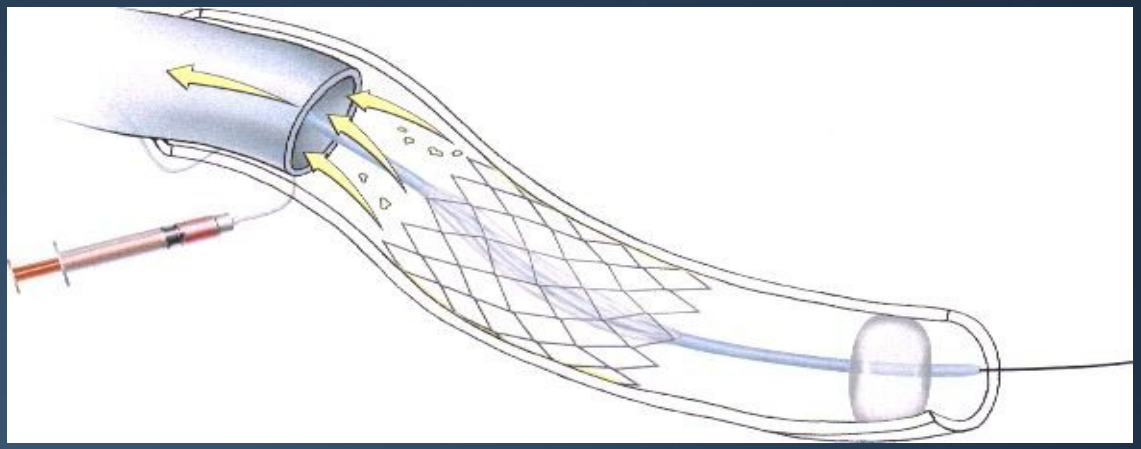
EMBOLIC PROTECTION DEVICES COULD BE IMPROVED WITH THE FOLLOWING

- An integrated system including embolic protection and treatment
- A system familiar to everyone performing PTCA/PTA including novices…*i.e.*, surgeons
- A system that is quick, simple, inexpensive to manufacture and intuitively obvious

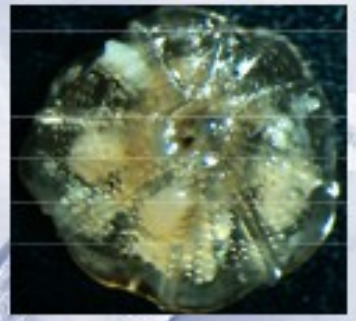
EMBOLIC PROTECTION DEVICES

- All devices are cumbersome
- Filter devices are still too stiff
- Studies confirm you can't predict whether a SVG is more or less likely to embolize
- What about carotids, renals and PVD

PROTECHTOR



BEGINNING CLINICAL TRIALS SOON



Filter threshold

- Static column of blood with suspended particles that will embolize when filter is collapsed
- "Concentrated particles may be more harmful than small amounts of emboli distributed throughout the case"

  Tak Ohki

Filter occluded with embolic load

3/20/2007

M. Bates

EMBOLIC PROTECTION MAY HAVE A ROLE IN THE FUTURE

- Femorals (particularly with Atherectomy)
- Renals
- Perhaps with devices that are as quick as balloon angioplasty in MI's
- As a source for medical malpractice if not utilized in SVG's and carotids because even you can reproduce the horrible results of SPACE & EVA-3S.

What is going on?

- High Risk Intervention patients?
  - Older patients (>70 yrs.) have a greater incidence of adverse (contraindicated) anatomy – arch , lesion tortuosity and calcification
  - Patient selection and technical skills and technology are being challenged in these patients.

- Operator Experience?

Conclusions

- Distal protection during SVG PCI with the Boston Scientific FilterWire EZ™ System is safe (MACE 5.0%, 98% device success, no SAT)
- FilterWire technology has been clinically proven to reduce MACE.
- Embolic protection with improved devices should be the standard of care in SVG PCI.