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# Is Protection Device of Benefit or Not

Propose of CS

- Plaque scaffolding to reduce embolism
- Lumen enlargement to improve perfusion
- Clinical impact: prevent ischemic stroke

- Acceptable complication (death/stroke) rate
  - Asymptomatic <3%; symptomatic <6%

Emboli, emboli, more emboli

- Emboli are released in all steps of CS

mean emboli count

| | sheath | wire | pre-dil | stent | post-dil | final angio |
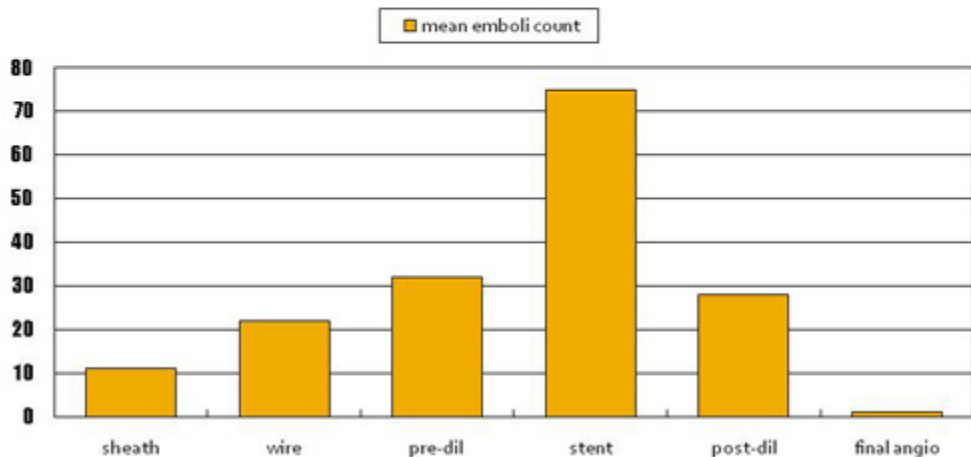
TcD HITS during CS

	Filter Group	MO.MA Group	p Value
Sheath placement-protection device placement	20 ± 15	18 ± 10	NS
Wiring of the stenosis	25 ± 22	2 ± 3	< 0.0001
Stent deployment	73 ± 49	11 ± 19	< 0.0001
Balloon dilation	70 ± 31	12 ± 21	< 0.0001
Retrieval of the protection device	14 ± 15	19 ± 15	NS
Total	196 ± 84	57 ± 41	< 0.0001

Data are mean values ± SD or n (%).
Abbreviations as in Table 3.

Culprit of CS (vs. CE)

- Where do the debris go?
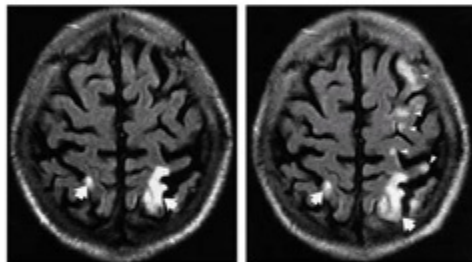
Postprocedural Clinical Signs and MR Imaging Findings

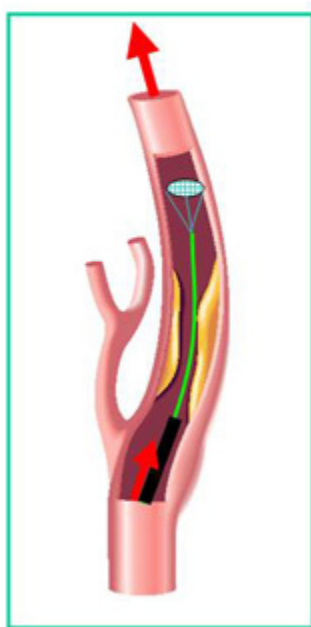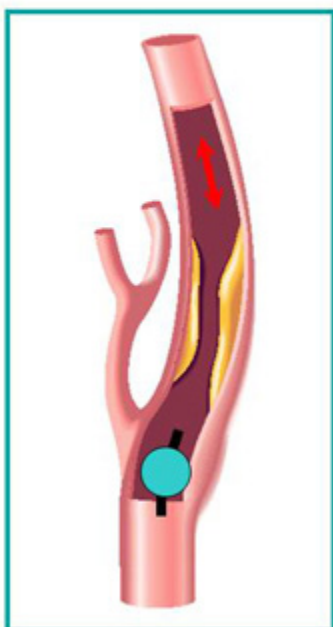| Clinical Signs	MR Imaging Findings		Total
	No New Lesions	New Lesions	
No clinical signs	55	6	61
Transient monocular blindness	3	. . .	3
TIA	2	2	4
Major stroke	. . .	2	2
Minor stroke	1	1	2
Total	61	11	72

Note.—Data are numbers of patients.

Van Heesewijk et al. Radiology 2002

- Even micro-emboli counts

| Particel size	Number of Injections	Neurological Deficit
15μ	25	no
50μ	1	yes

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Heistadt DD et al. in: Cerebral metabolism and neural function. Williams and Wilkins,1980; 2002

What can we do?

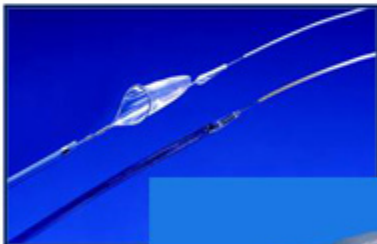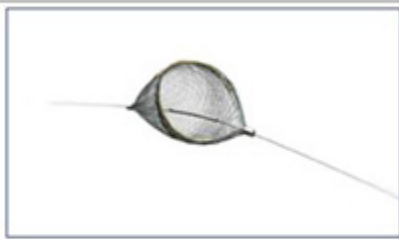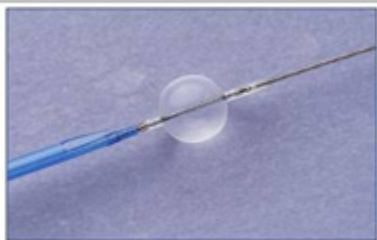Paul HL Kao

Classification of EPD

- Distal occlusion
  - PercuSurge
  - TwinOne

- Proximal occlusion
  - MoMA
  - Parodi FR

- Filter
  - AngioGuard
  - EmboShield
  - Accunet
  - FilterWire
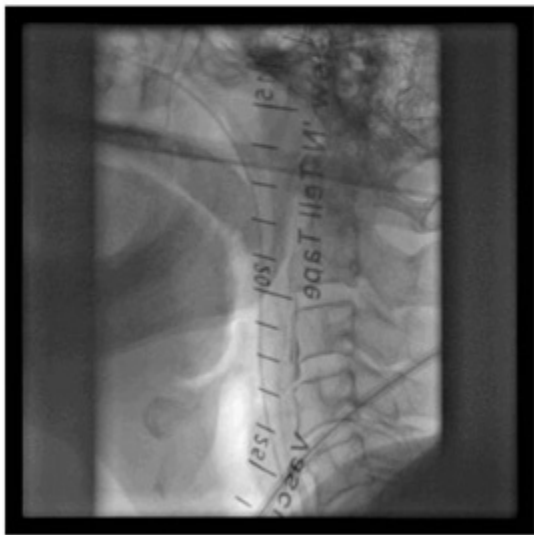 - Spider
  - Fibernet
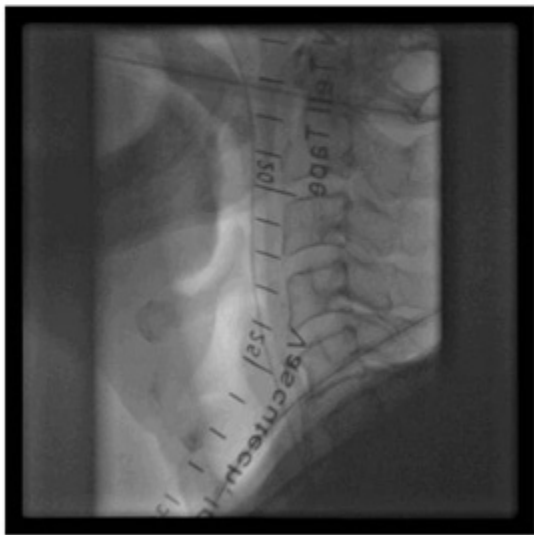
Personal experience with EPD

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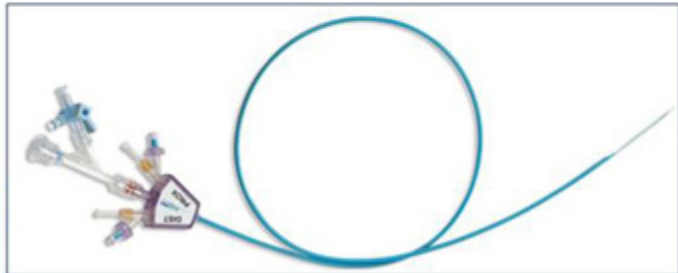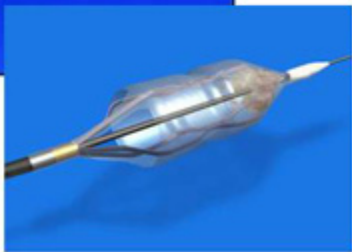
Comparison – distal occlusion

- Low profile
- Small particles and soluble factors are kept back

- Cannot choose wire
- No protection during crossing
- Distal landing zone required
- No angiography during protection
- Patient intolerance and operator stress

PurcuSurge
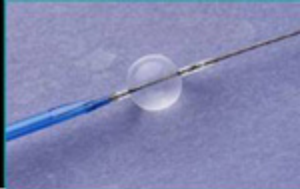
PurcuSurge
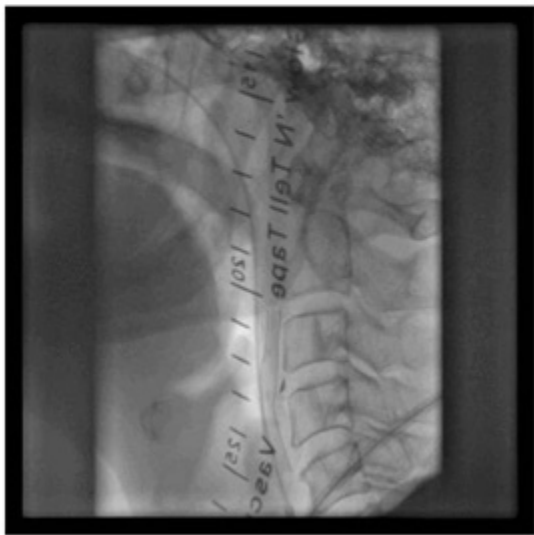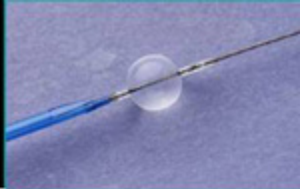
Comparison – proximal occlusion

- Protection starts before crossing
- Wire of your choice
- Small particles and soluble factors are kept back

- No angiography during protection
- Patient intolerance and operator stress
- Large vascular access

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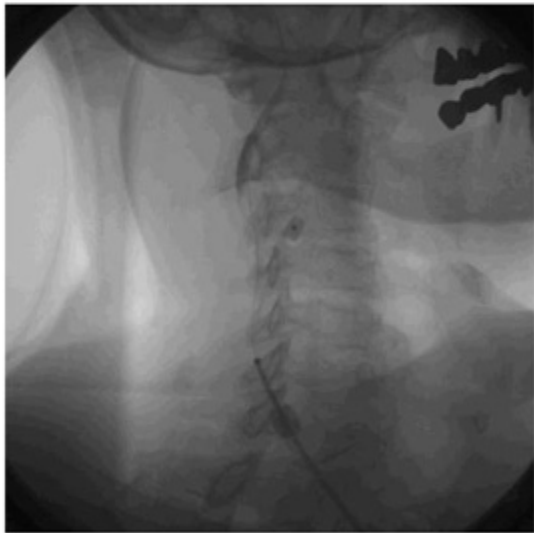
MoMA

MoMA
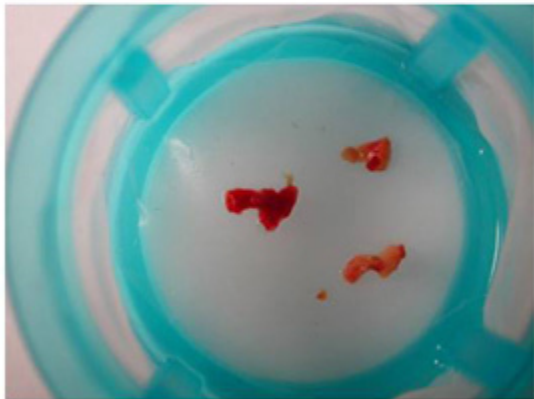
Comparison – filter

- Less operator stress/better patient tolerance
- Angiography possible during procedure

- Cannot choose wire (ex. Spider)
- No protection during crossing
- Distal landing zones required
- Possible mal-apposition
- Particles <100μ nay escape
- Filter capacity limited and risk of thromboembolic occlusion
- Potential retrieval problem

FilterWire
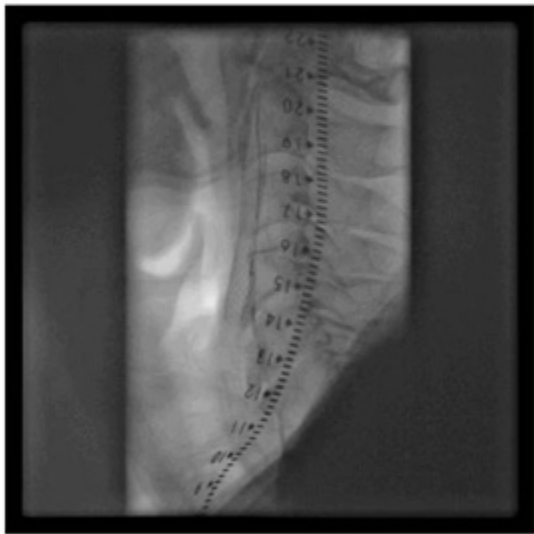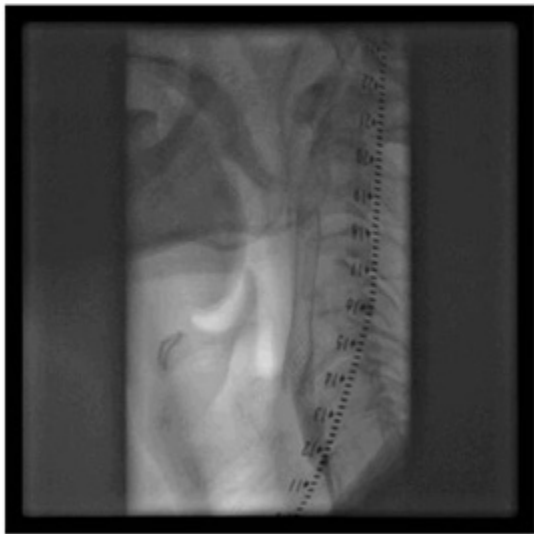
FilterWire
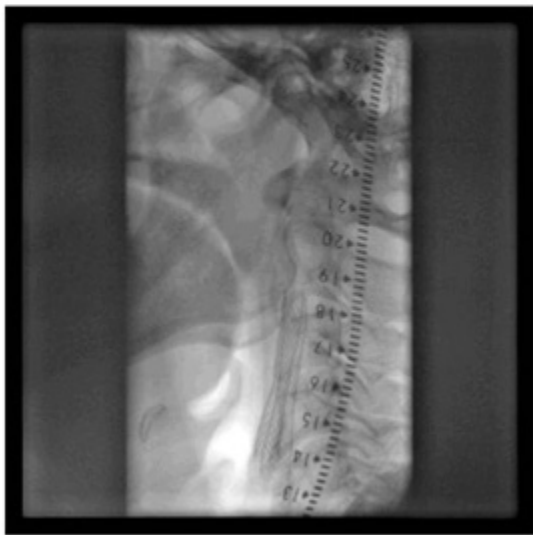
EPD choices – rule of thumb

- Inadequate collateral/intolerance
- Filter

- Difficult arch access
- Distal occlusion

- High risk plaque
- Distal landing issues
- Proximal occlusion

Global CS registry

Wholey M et al. CCI 2003
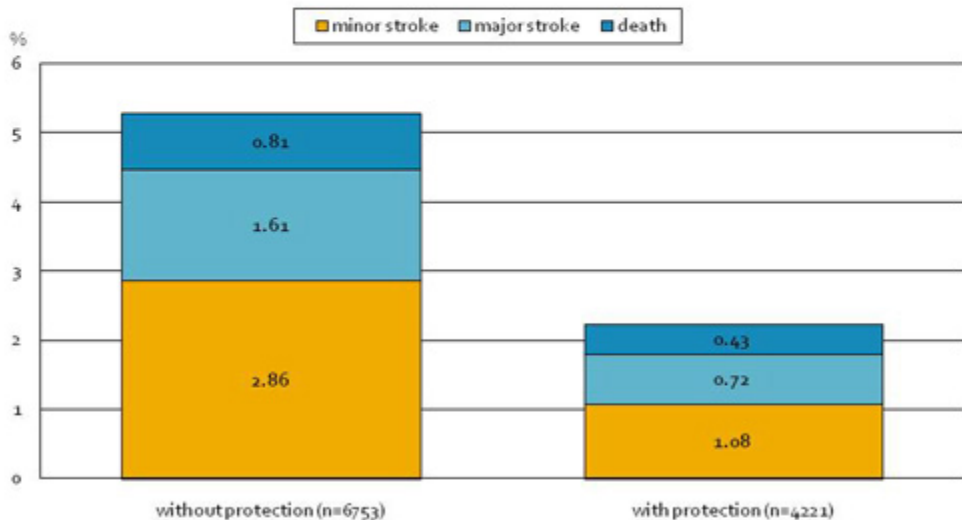
Meta-analysis on 30d outcome

- Systemic review of 26 CS studies from 1996 to 2002 reporting 30d outcome

	EPD (-) (N=2537)	EPD (+) (N=896)	P
Minor stroke	94 (3.7%)	5 (0.6%)	<0.001
Major stroke	28 (1.1%)	3 (0.3%)	<0.05
Death	18 (0.7%)	8 (0.9%)	0.6
Any stroke or death	140 (5.5%)	16 (1.8%)	<0.001

Registry of CS under EPD

- 815 CS from 1999 to 2002 under routine EPD
- Filter 79.2%, distal occlusion 17.8%, proximal occlusion 3%

30d events	N (%)
Major stroke	7 (0.8)
Minor stroke	17 (2.0)
Death	4 (0.5)
All stroke or death	27 (3.3)
EPD-related complication	9 (1.1)
EPD success rate	793 (98.2)

Reimers B et al. Am J Med 2004

EVA-3S

- Safety committee of EVA-3S analyzed first 80 CS, recommended to stop unprotected CS

30d events	CS with EPD N=58	CS without EPD (N=15)	Unadjusted OR (95% CI)	Age-adjusted OR (95% CI)
Any stroke	5 (8.6%)	4 (26.7%)	3.9 (0.9-16.7)	2.8 (0.6-12.8)
Major stroke	1 (1.7%)	2 (13.3%)	8.8 (0.7-100)	5.8 (0.5-71.0)
Any stroke or death	6 (10.3%)	4 (26.7%)	3.2 (0.8-13.0)	2.5 (0.6-10.8)
Any major stroke or death	2 (3.4%)	2 (13.3%)	4.3 (0.6-33.3)	3.8 (0.5-31.6)
Any procedural (<24h) stroke	3 (5.2%)	2 (13.3%)	2.8 (0.4-18.7)	2.3 (0.3-15.7)

EPD specific problems

- 422 CS in a high volume center
- 91% filters, 6% distal occlusion, 3% proximal occlusion EPD

	N (%)	Management	Complication
Dissection	2 (0.5)	Extra stent	Nil
Spiral dissection and occlusion	1 (0.2)	Nil	Nil
EPD wire trapping	1 (0.2)	Surgery	Nil
Vessel spasm	35 (7.9)	Vasodilator	Nil
Full basket	58 (13.1)	Aspiration/retrieval	Nil
Consciousness change	6 (1.4)		Nil

Observational DWI evidence

- Is EPD really helping?

	Filter EPD (+) (N=18)	No EPD (+) (N=18)	P
Any diffusion defect	13 (72%)	8 (44%)	0.09
Any ipsi. perfusion defect	12 (67%)	7 (39%)	0.09
Average No. of defects	6.1	6.2	NS
DW defect size (mean mm^3)	16.63	15.61	NS

- Small number and inexperienced operator

RCT of EPD vs. no EPD

	Filter (+)	Filter (-)	P
Procedural HITS			
Showers	73	19.4	NS
Gaseous emboli	103.2	48.4	NS
Particulate emboli	251.3	92	0.03
Total recorded events	427.5	165.2	0.01
New DWI lesions			
Procedural (<24h)	7/24 (29%)	4/22 (18%)	0.4
Total (<30d)	9/33 (27%)	4/33 (12%)	0.1

Proximal vs. distal EPD

- Randomized study of proximal vs. distal EPD using MRI/DWI

	Proximal (N=25)	Distal (N=19)
New lesion/patient	0.72	2.26
Consistent	0.51	2.05
Inconsistent	0.21	0.21
New lesion/patient in patients with NL	2.57	7.12
Consistent	1.81	6.5
Inconsistent	0.76	0.67

Filter vs. proximal occlusion

- Randomized study of filter vs. MoMA using TCD/HITS

	Filter	Proximal occlusion	P
Lesion wiring	20.9 ± 14	5.7 ± 9.3	<0.0001
Pre-dilatation	8.4 ± 5.1	2.2 ± 5.2	0.26
Stent crossing	30.5 ± 30	1 ± 2.2	<0.0001
Stent deployment	24.3 ± 15	1.4 ± 3.9	<0.0001
Post-dilatation	20.0 ± 14	2.7 ± 6	<0.0001
Device retrieval	3.6 ± 4.5	10.7 ± 10	<0.0001
Total	101 ± 53	22.5 ± 19	<0.0001

Second thoughts

- Remember that some 30d embolic events are post-procedural
  - Medication, stent design
- Not all EPD's are born equal
  - Filter the worst?
- Technique/experience and device, which is more important?
  - Routine EPD users are most likely experienced
- More RCT of EPD vs. non-EPD?

Conclusion

- Embolism is the nemesis of CS
- If we want to benefit our patients, EPD is probably mandatory
- Various EPD's are available, operator should understand and choose carefully according to clinical scenario
- No overwhelming evidence, but intuitively compelling

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Which EPD? That's The Question.

Q1

- What should be the endpoint for evaluating EPD?
  - New DWI lesion
  - HITS
  - Clinical stroke/death
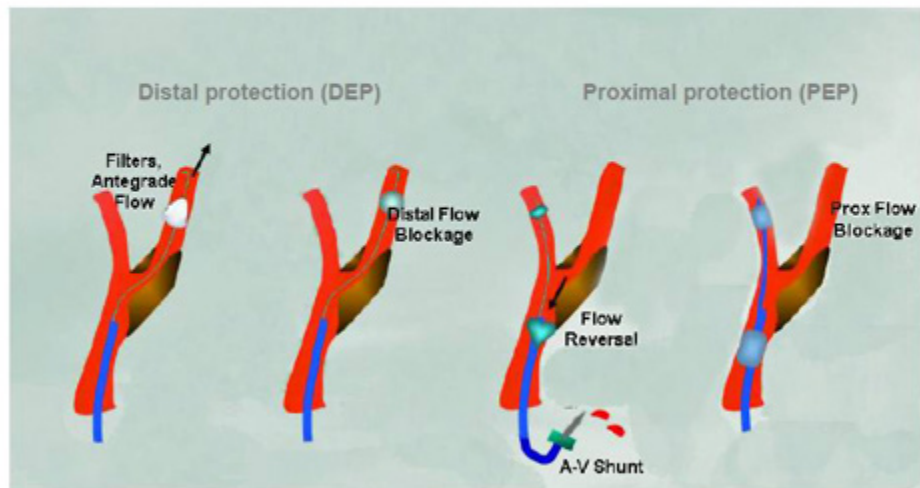 - Neuro-cognitive assessment
  - Other

Q2

- What are the characteristics that affect your EPD choice?
  - Arch/artery morphology
  - Symptomatic status
  - Plaque morphology
  - Willis circle
  - Other

Q3

- Do you think there are cases where EPD is not indicated or contra-indicated?

What can we do?

Filter spec & pore size

	Vessel size (mm)	Crossing profile	Capture cath profile	Pore diameter (μ)
AngioGuard	4-8	0.042-52"	0.066"	100
Emboshield	4-6	0.038"	0.084"	120
Accunet	4.5-7.5	0.045-48"	0.071"	115
Trap	2.5-7	0.042"	0.066"	200
FilterWire	3.5-5.5	0.042"	0.055"	110
Spider	3-7	0.038"	0.054-63"	80
Rubicon	4-6	0.028-36"	0.047"	100