How to Choose Among Carotid Embolic Protection Devices?

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Conflicts / Disclosures

- Consultant/Advisory Board member/research support:

  - Abbott Vascular
  - Cordis
  - Medtronic

Carotid Stenting: Intracranial Complications

- Distal Embolization- TIA, CVA
  - Most are embolic, cannot be identified by angiography
  - Some are due to air emboli (preventable!)
  - Probably more common in symptomatic patients
  - Can occur with CEA restenosis

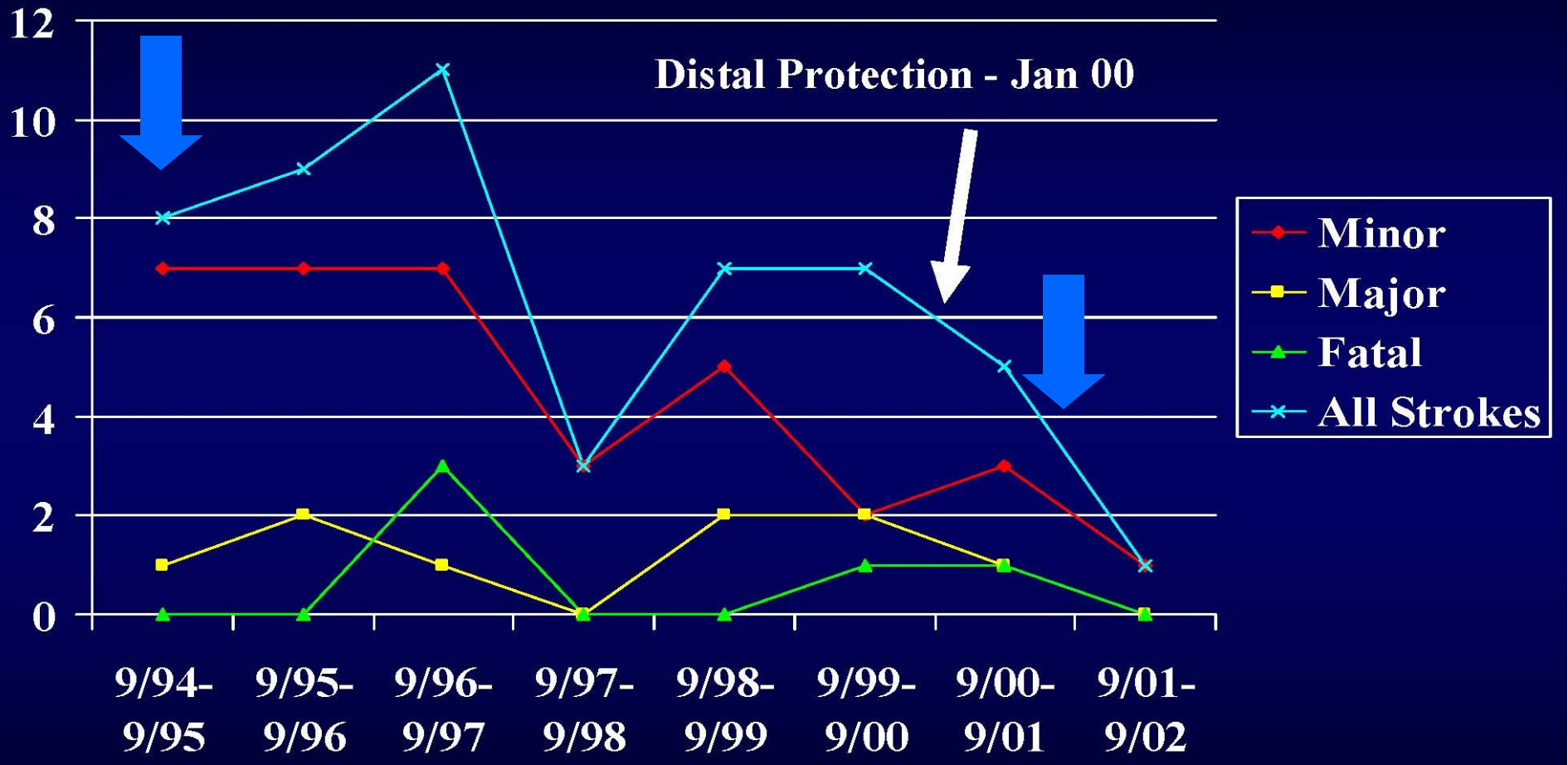
  - Causes
    - Guiding catheter or sheath placement
    - Incomplete embolic protection
    - Most common cause of stroke with stenting

Cerebral embolism

Patient selection is crucial as stroke is most common in:

- Age > 80
- Complex anatomy of aortic arch, carotid artery
- Severe proximal or distal tortuousity
- Vessel and/or lesion calcification
- Thrombotic lesions
- String-sign
- Failure of the embolic protection device

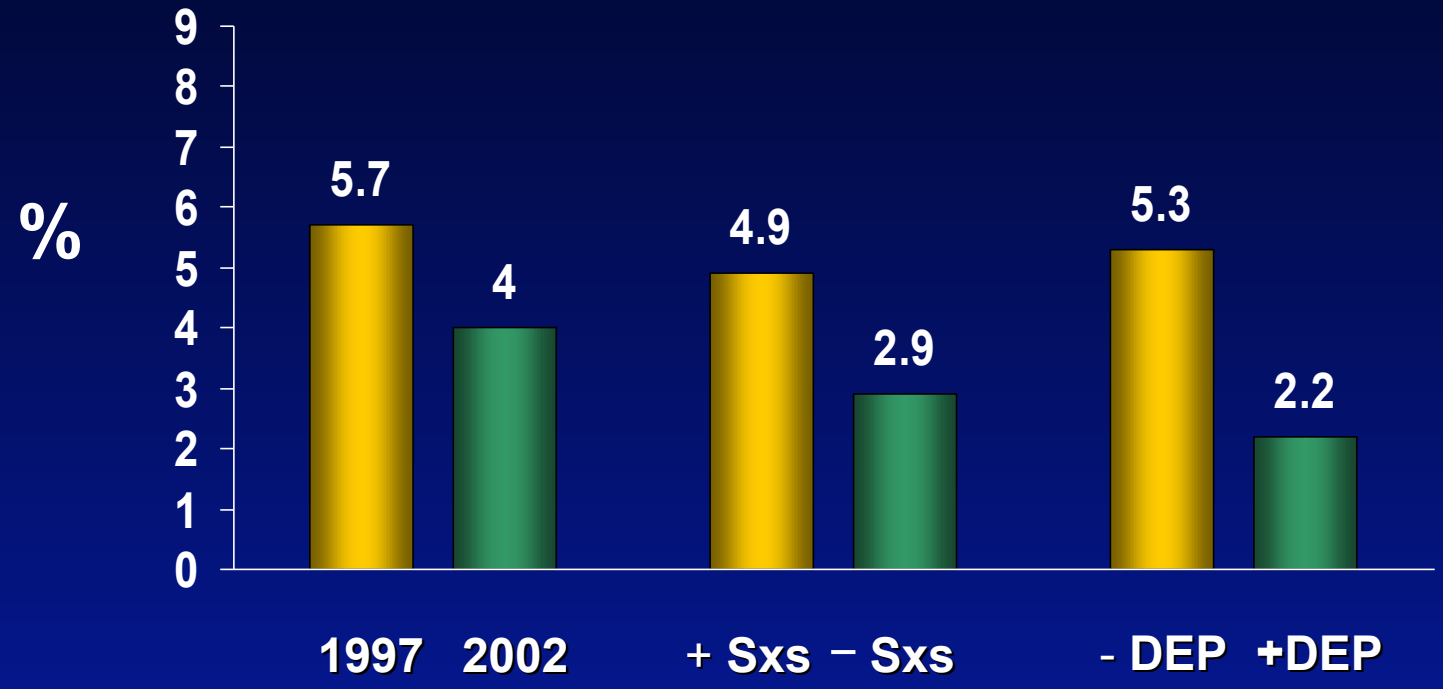
Improving Results of Carotid Stenting



N =	100	124	126	94	159	207	214	178

New, Roubin et al. JACC Suppl. 41. 79a. 2003

Global Carotid Artery Stent Registry (GCASR): 30-Day Death/ All CVA *



*Wholey M et al. TCT 2003; n>12,000

Devices for Distal Protection

Balloon Occlusion Devices

- PercuSurge GuardWire **
- TriActiv System

Catheter Occlusion Devices

- Parodi Guiding KJ
- Coppi Invatec Guiding KT
- Kachel catheter
- VelociMed

Filter Devices

- Cordis Angioguard**
- Abbott/Guidant Accunet**
- BSC EPI Filterwire EZ **
- Medtronic Interceptor
- Abbott Mednova**
- Microvena TRAP
- EV3 Spider**

** FDA-approved (carotid and SVG)

PercuSurge GuardWire® System

Components:

GuardWire®

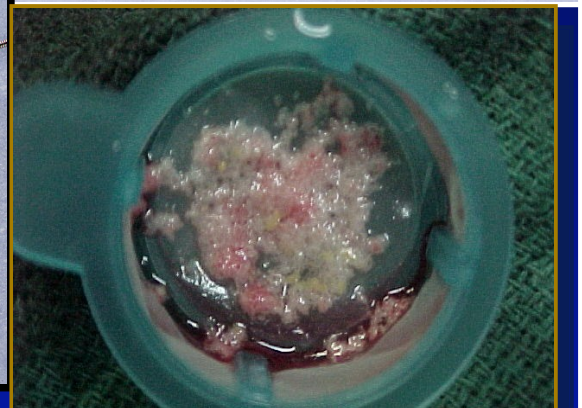
EZ-Flator™

MicroSeal® Adapter

Export®catheter

The PercuSurge GuardWire™ System

PercuSurge Export™ Aspiration Catheter Mounted on GuardWire™



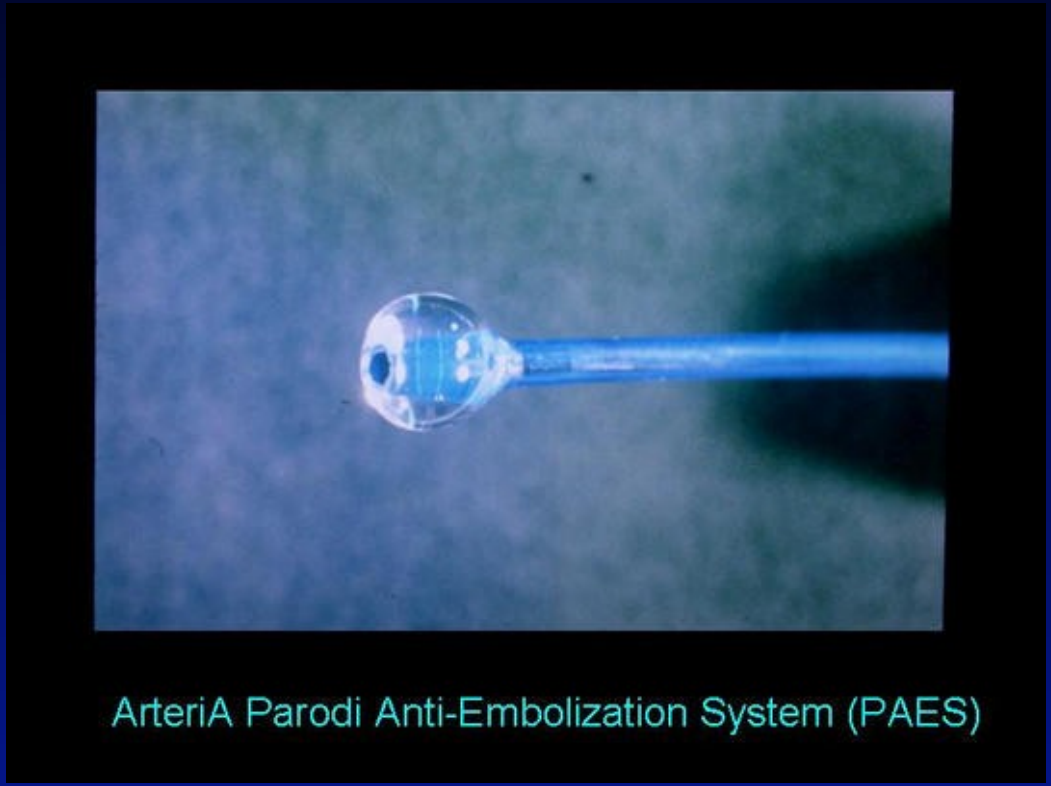
Pro's and Con's versus other systems

Advantages

- Complete occlusion
- Proven effect in SVG's
- Flexible, low-profile stent delivery system
- Crosses most lesions
- Small parking space

Disadvantages

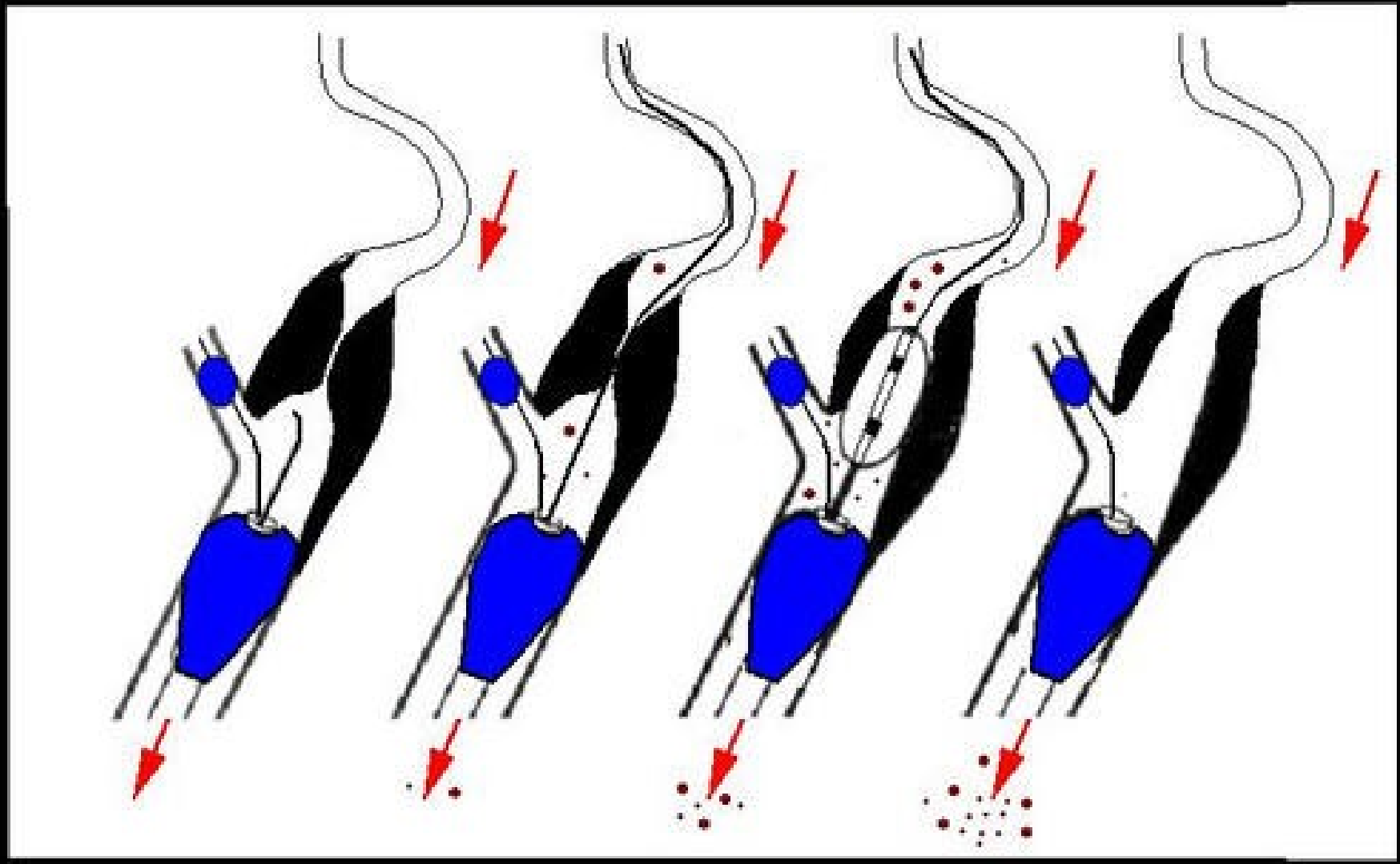
- Complete occlusion
- Excludes pts with contralateral lesions
- Failure may cause stroke
- Speed is important
- OTW design



ArteriA Parodi Anti-Embolization System (PAES)

ArteriA Parodi Antiembolization System (PAES)

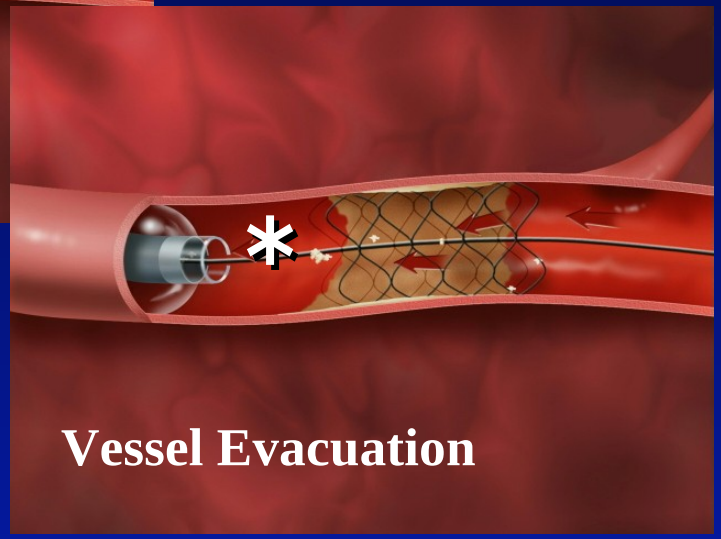
Complete Protection



Distal Protection with *Proximal* Occlusion: Proxis System

Protection During Initial Wire Crossing

Protection During Device Placement



Vessel Evacuation

* Evacuation sheath

Proximal Occlusion Devices*

Advantages

- Transient reversal of flow in distal artery
- Operator can select a guidewire of choice
- Avoids embolization during initial passage of guidewire and throughout procedure

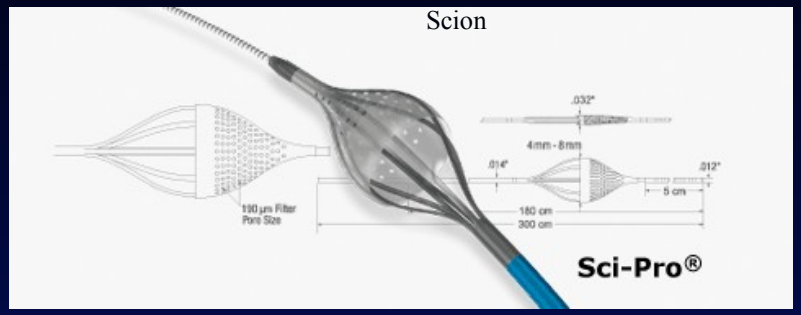
Disadvantages

- More cumbersome to use than other devices; large profile
- Imaging via stagnant contrast during device advancement
- Intermittent vessel occlusion

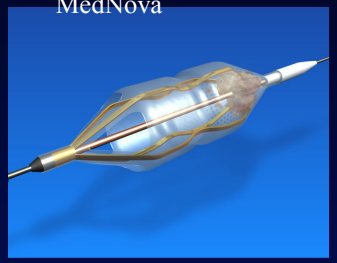
**** Velocimed Proxis studied in SVGs-PROXIMAL Trial***

More EPDs/ Filters Dominate

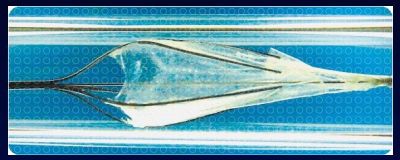
Scion



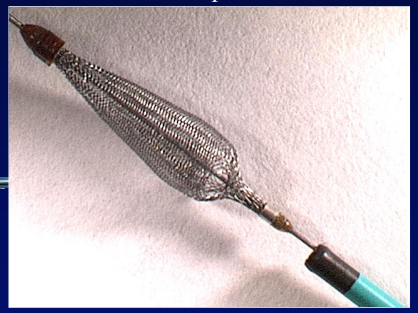
MedNova

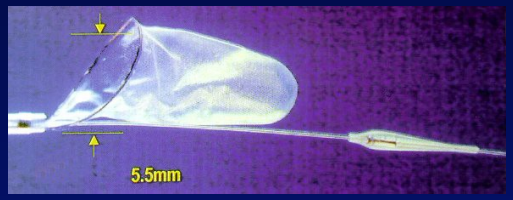


BSX/Rubicon



MDT/Interceptor



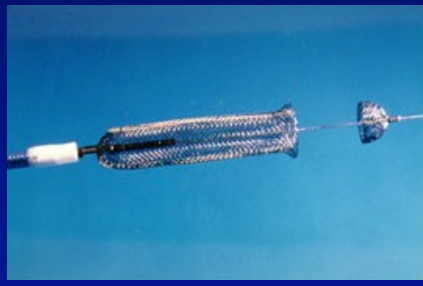


BSX/FilterWire Gen I

BSX/FilterWire Gen II

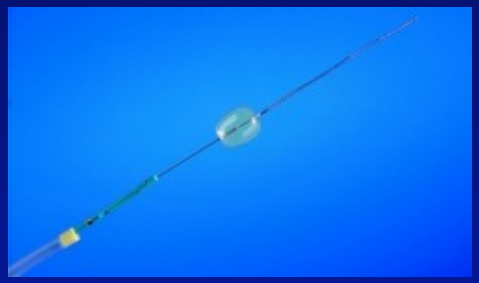
Guidant AccuNet

MicroVena - Trap



MDT/PercuSurge

Abbot/Rubicon - Guardian



Kensey Nash

Distal Protection with Filter Devices

Advantages

- Preserve antegrade flow
- Contrast imaging is possible throughout the procedure
- Spider device allows operator to select a guidewire to cross target lesion

Disadvantages

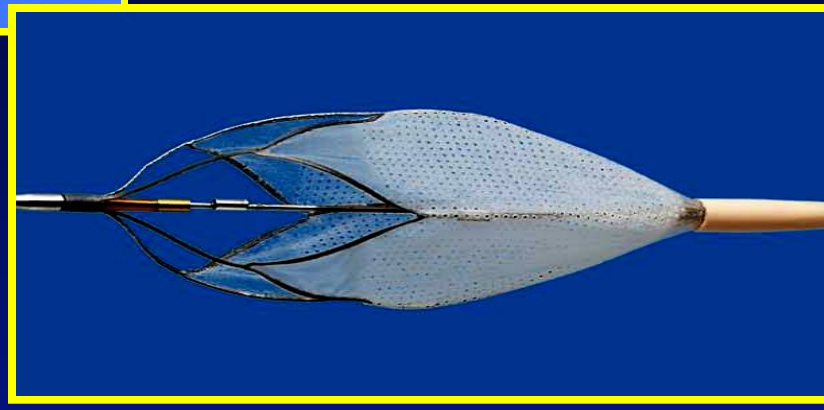
- May not capture all debris
- Difficult to evaluate retrieval of debris during the procedure
- Filters may clog
- Delivery/retrieval catheters may cause embolization
- Fair support/steerability/profile

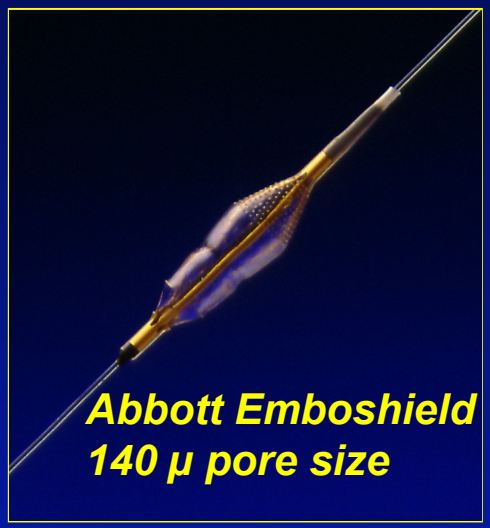
CAS - Distal Protection Devices

AngioGuard XP
100µ pore size

FilterWire EX
80-110µ pore size

ACCUNET
≤150 µ pore size





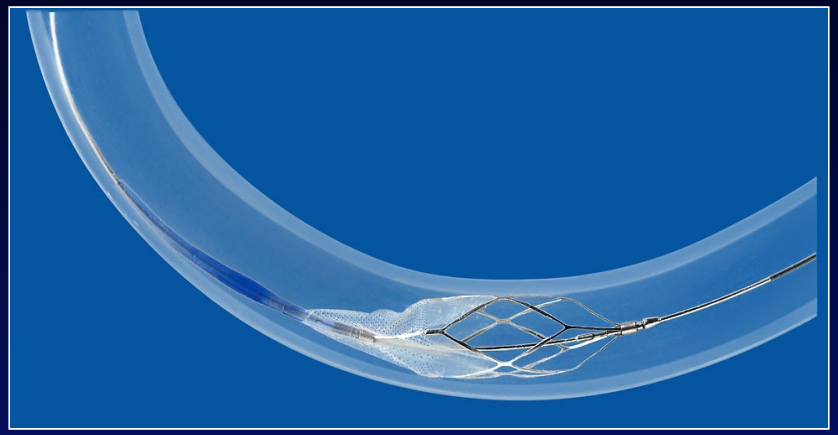
Abbott Emboshield
140 µ pore size

EV3 Spider
167-209µ pore size

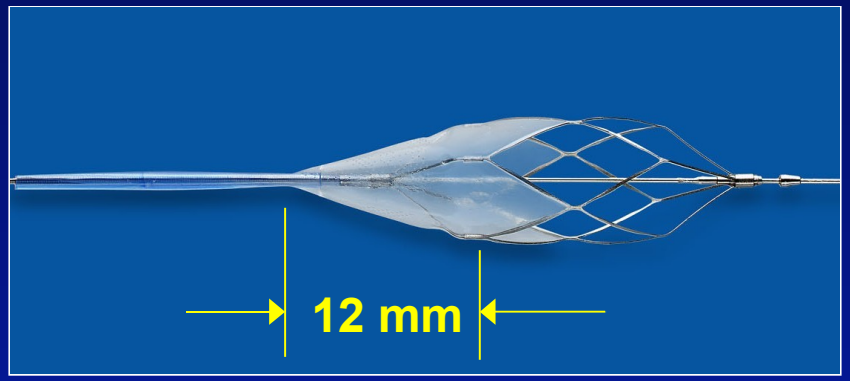
Rx Accunet DPF-

Designed for Capture Efficiency

Deployment in Tortuosity



7.5 mm RX ACCUNET™

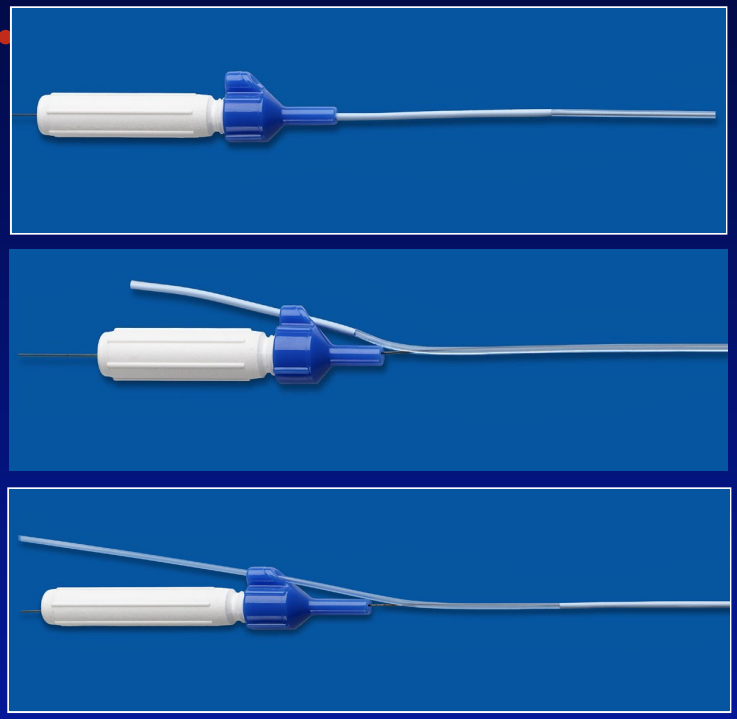


- Designed to protect in challenging anatomy
  - Dual strut filter configuration
  - Flexible distal obturator
  - Concentric filter design with guide wire centered in filter
  - 4 radiopaque markers to visualize wall apposition
- Capture Capabilities
  - Designed to capture a large embolic load
  - 4.5, 5.5, 6.5, and 7.5 cm sizes

Peelable Delivery Sheath

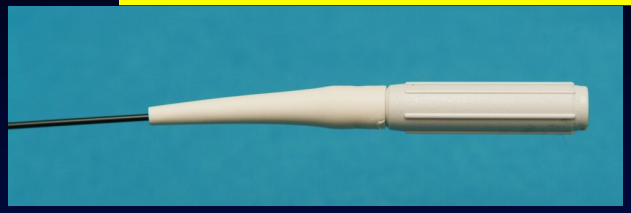
Controlled Delivery and Deployment

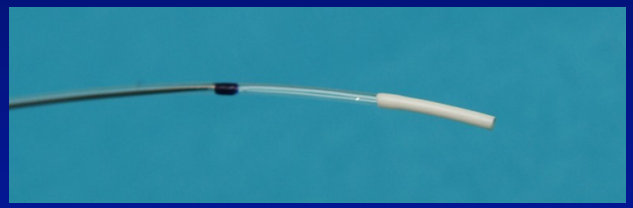
- Enter body as a single unit → Exit as a rapid exchange catheter
- Helps stabilize ACCUNET™ Filter during unsheathing
-



Delivery sheath is peeled away during deployment

RX ACCUNET™ 2 Recovery Catheter

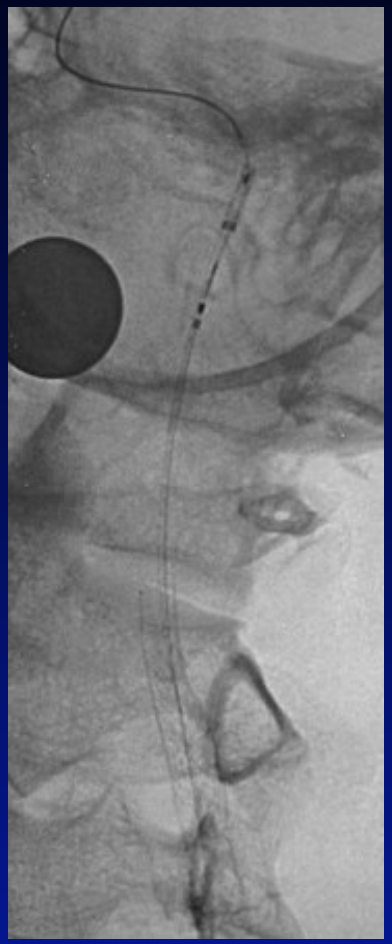




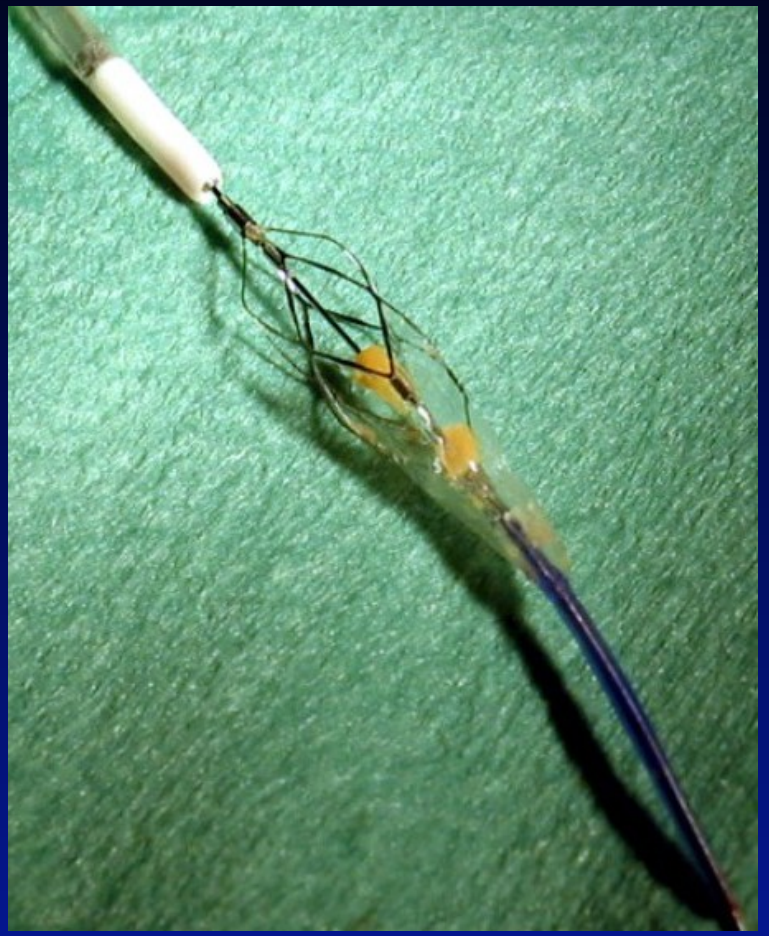
- Dedicated catheter for filter recovery
- 141 cm working length
- Rapid exchange (RX) design
- 0.014” guide wire compatible
- Radiopaque tip
- Soft, lower profile, flexible tip (ID= .038”) to allow for deflection during advancement
- Flexible catheter shaft optimized for challenging GC/sheath access
- Catheter shaft markers: 95 cm, 105 cm

Rx Accunet DPF

Carotid lesion
prior to treatment

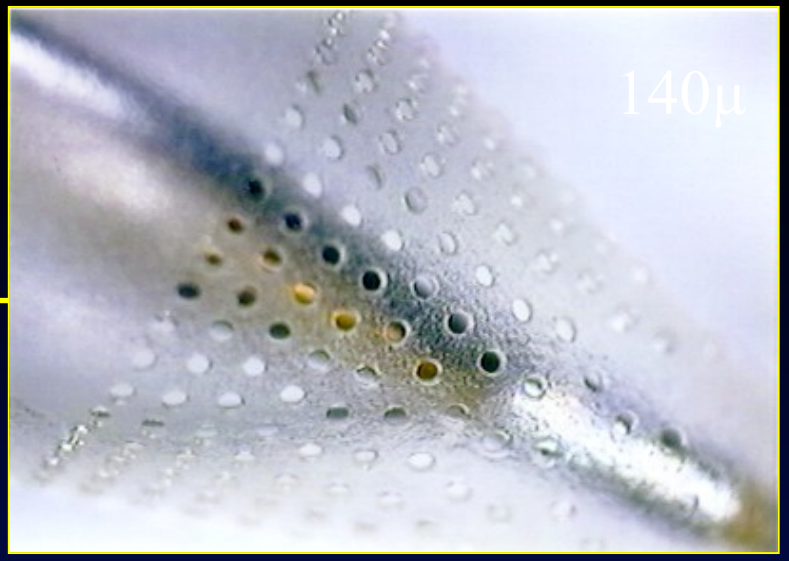


Retrieval of
RX ACCUNET



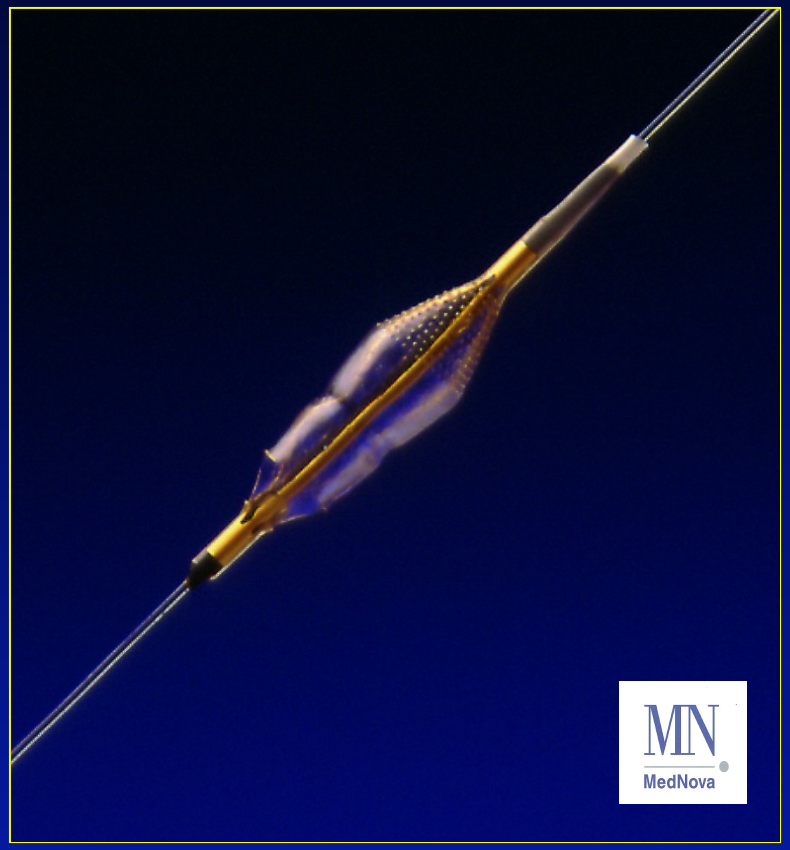
RX ACCUNET with captured material

Abbott EmboShield™

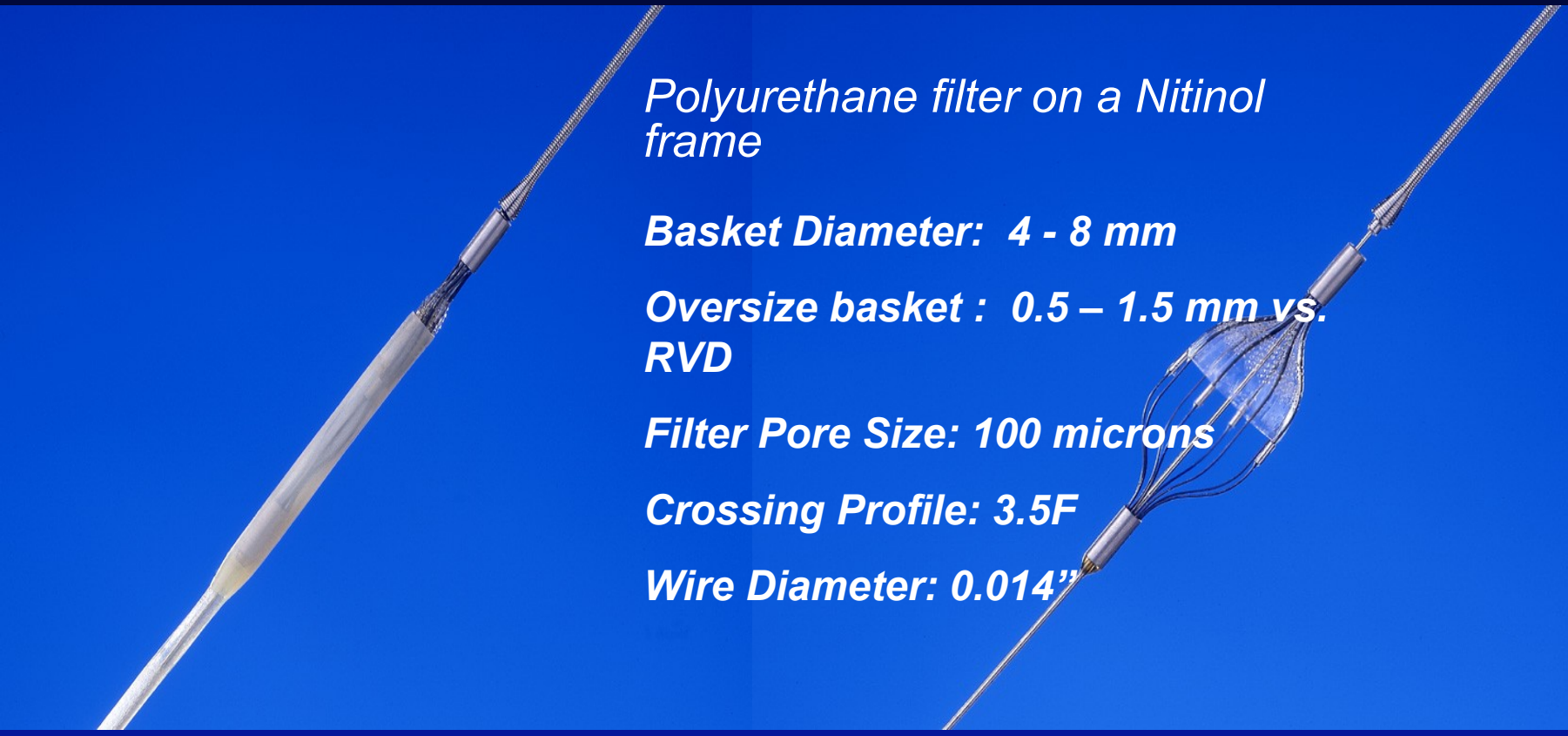


Gen V 2.9 - 3.2 Fr

Independent wire access (4 wires)



Cordis ANGIOGUARD™ XP Emboli Capture Guidewire



Polyurethane filter on a Nitinol frame

Basket Diameter: 4 - 8 mm

Oversize basket : 0.5 – 1.5 mm vs. RVD

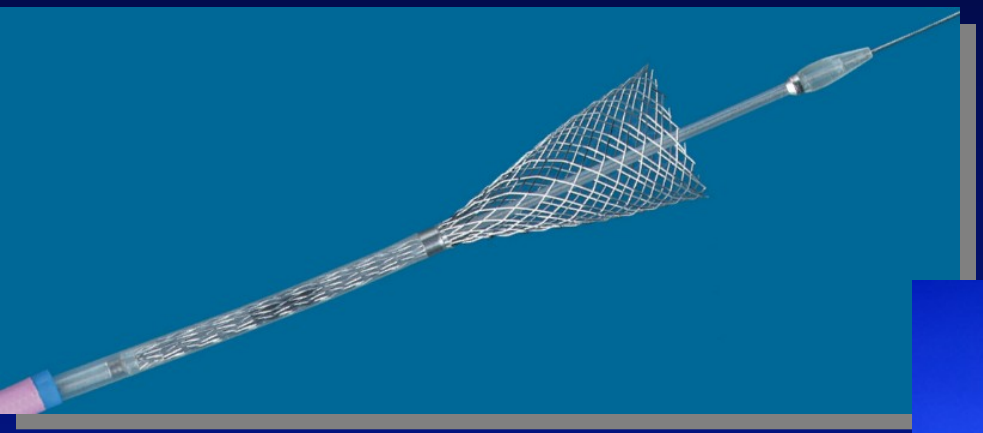
Filter Pore Size: 100 microns

Crossing Profile: 3.5F

Wire Diameter: 0.014”

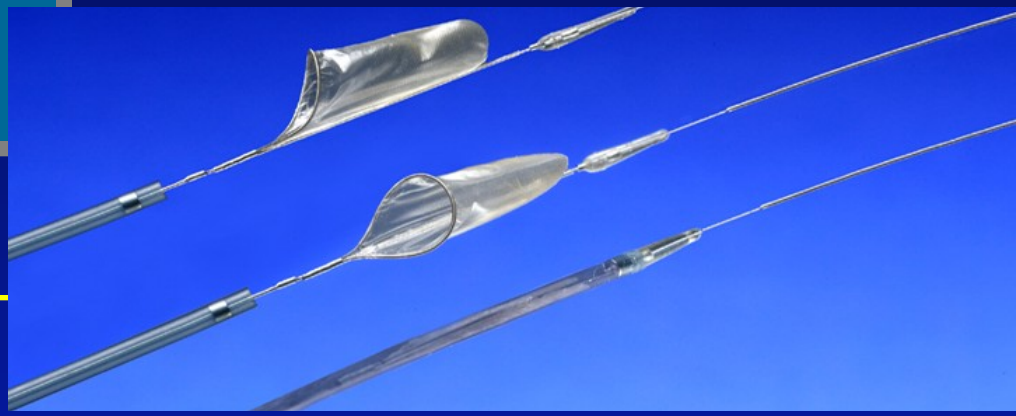
BEACH

Boston Scientific EPI: A Carotid Stenting Trial for High-Risk Surgical Patients

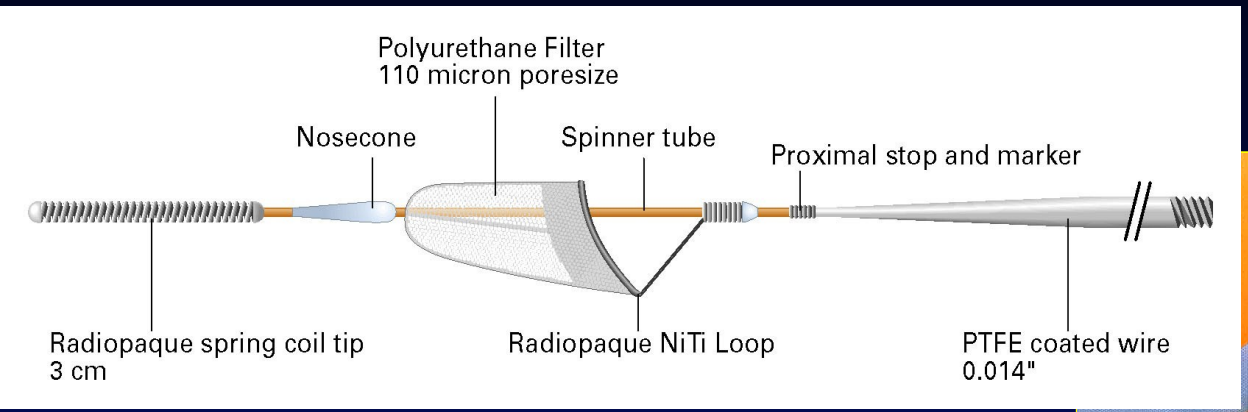


Carotid Wallstent® Monorail™

FilterWire EX™



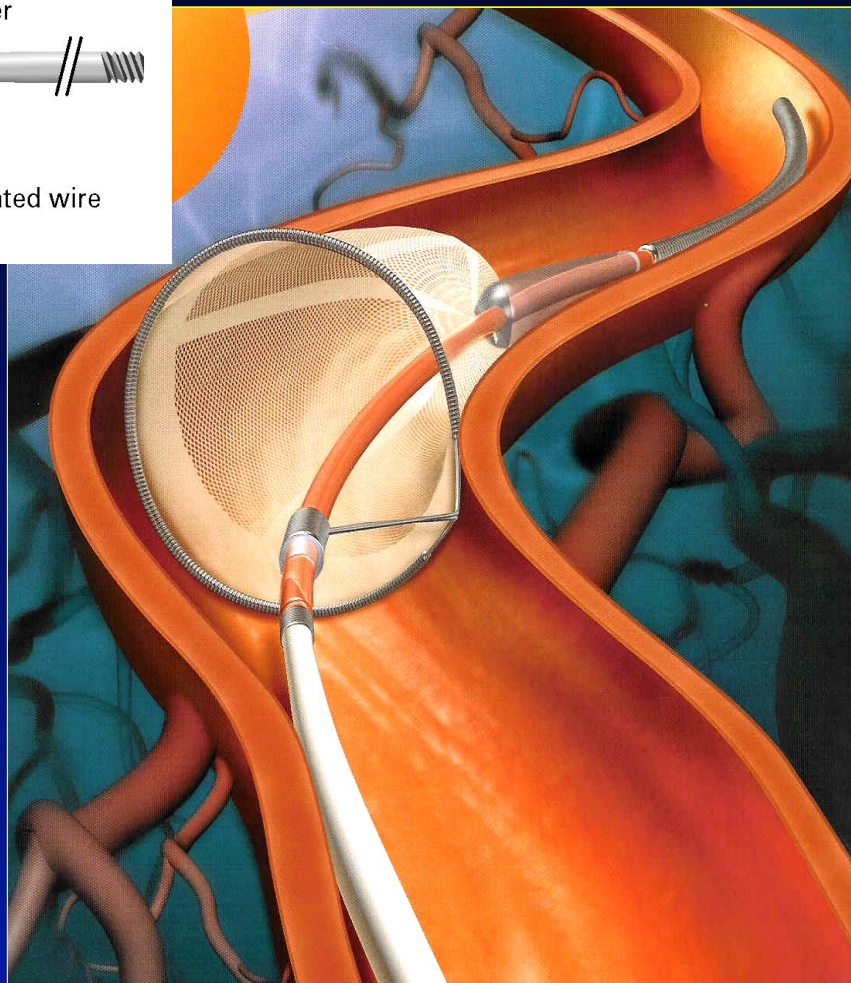
The Filterwire EZ



3.2 French Crossing Profile

4.3 French Retrieval Catheter

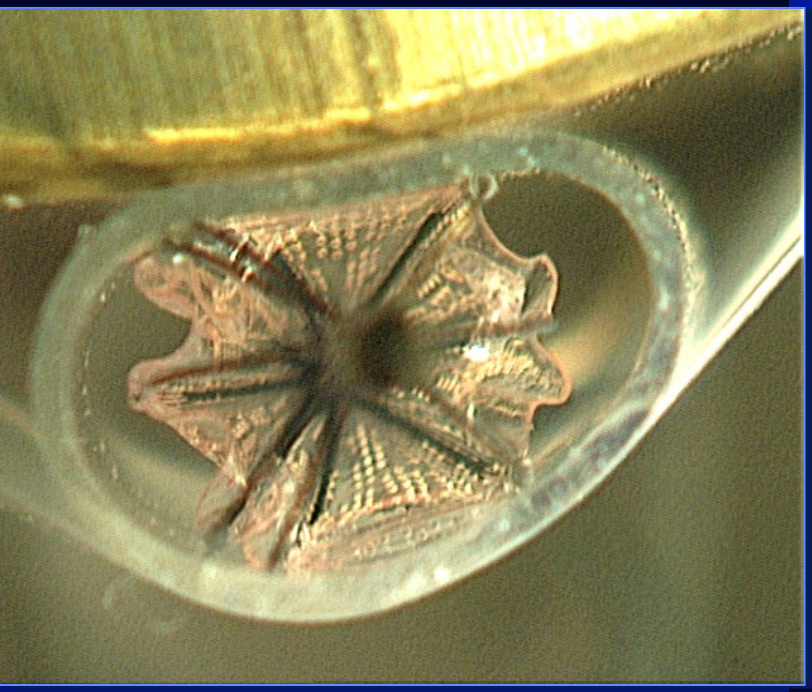
110 µm Pore Size



Distal Embolic Protection Filters

	Spider	FW EZ	A-guard	Accunet	Embosh	Intercep
Co	ev3	BSC	CJJ	GDT	ABT	MDT
Material	N	N, PU	N, PU	N, PU	N, PU	N
GW (in)	18	14	14	14	18	14
Rx	Yes	Yes	Yes	Yes	Yes	No
Ind wire	Yes	No	No	No	Yes	No
Sheath (Fr)	6	6	6	6	6	7
Size (mm)	4-7	3.5-5.5	4-8	4.5-7.5	3-6	5.5-6.5
Profile (Fr)	3.2	3.2	3.2-3.9	3.5-3.7	3.7-3.9	2.9
Pores (u)	167-209	110	100	120	140	100

How Can Distal Protection Fail?



- Inability to deliver device
  - Profile, steerability, landing zone
- Device induced complications
  - Vessel injury, distal embolization
- Procedural ischemia or intolerance
- Incomplete capture or retrieval of debris
  - By device design (filter vs. balloon occlusion)
  - Overwhelming burden of debris
- Embolization into proximal branches
  - External carotid (Ophthalmic artery)
  - Preventable with catheter-occlusion devices

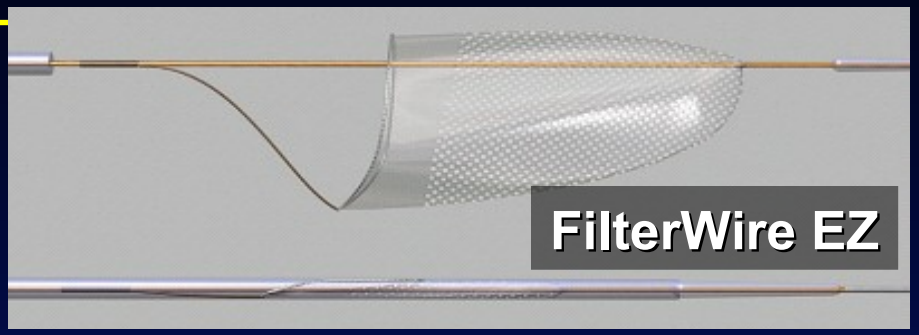
Filter Features

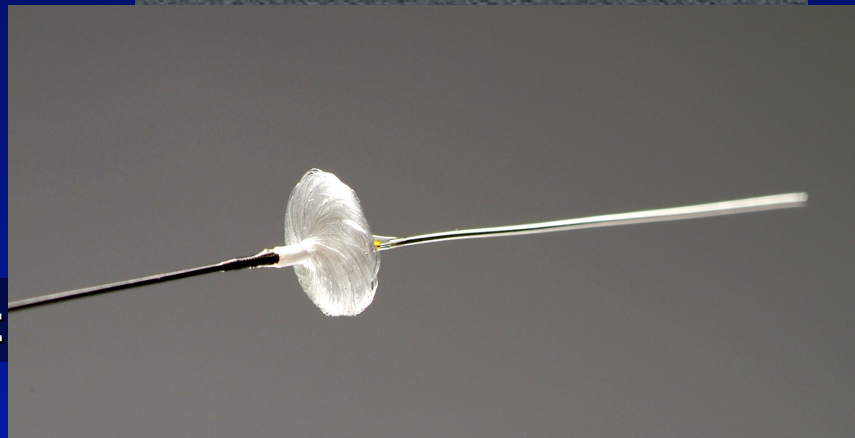
- Delivery profile and flexibility
- Steerability
- Vessel wall apposition
- Pore size
- In vitro capture efficiency
- Ease of retrieval
- Clinical event rates

Distal Protection Advances

- Lower profile- 7Fr-> 4Fr -> 2.5 Fr
- Improved centering
- Improved transitions
- Independent wire movement – EmboShield, Spider
- Independent wire use

Filters: Newer Devices

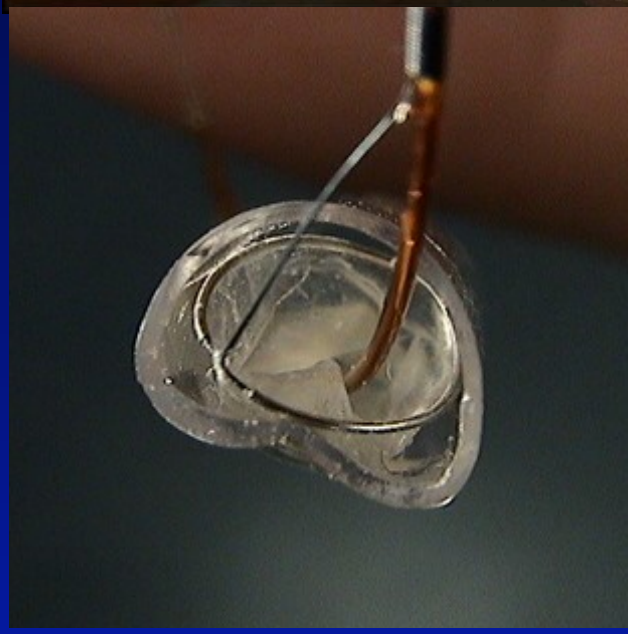




FiberNet®
Embolic Protection System

Vessel conforming 3-dimensional fiber filter

- Particulate capture as low as 40 microns while maintaining blood flow during the procedure
- Filter mounted on .014” guidewire
- No delivery sheath required
- Low crossing profile (1.7-3.1F)
- Retrieval catheter with focal-suction during device removal
- Filter sizes to cover vessel diameters from 1.75-7.0mm
- Epic US Carotid Study:
- High surgical risk, multicenter, single arm registry, 30 day follow-up
- Epic European Carotid Study:
- Multicenter, single arm registry, 30 day follow-up



Carotid EPDs

- Filters should be the default mode
- Accunet, Angioguard and BSC Filterwire are all workhorse devices
- Abbott Emboshield and EV3 Spider offer the ability to wire independent of filter – may be especially helpful with tortuosity and high grade lesions, reduces need for buddy wire
- Percusurge has a limited EPD role as the filter technology improves and nano-sizes
- Careful case selection, thoughtful preparation and execution are the keys to minimizing complications