

# ProCatic MEDICAL®

UniGrd (WIRION)

The Optimal Embolic Protection Device

March 2026



# Procatid History Highlights



Year	Highlight	Details
2007	Gardia founded	Three founders closed an investment of $\approx$ 6M\$ with Medica (Ehud Geller)
2008	Feasibility, and animal trial completed	Caesarea. Rambam, Haifa
2009	FIH completed	Leipzig Germany. Prof. Scheinert (20 pt.)
2009	Manufacturing upscale	Creganna, Ireland
2010	CE for Carotid	50 more patients in Europe
2012-14	FDA study in US	
2012-3	Gardia sold to Allium	
2015	FDA approval	
2020	CSI buy Gardia from ALMD	Prereferral right only, name changed to Procatid
2023	ABBOT buy CSI	ALMD get rest of money



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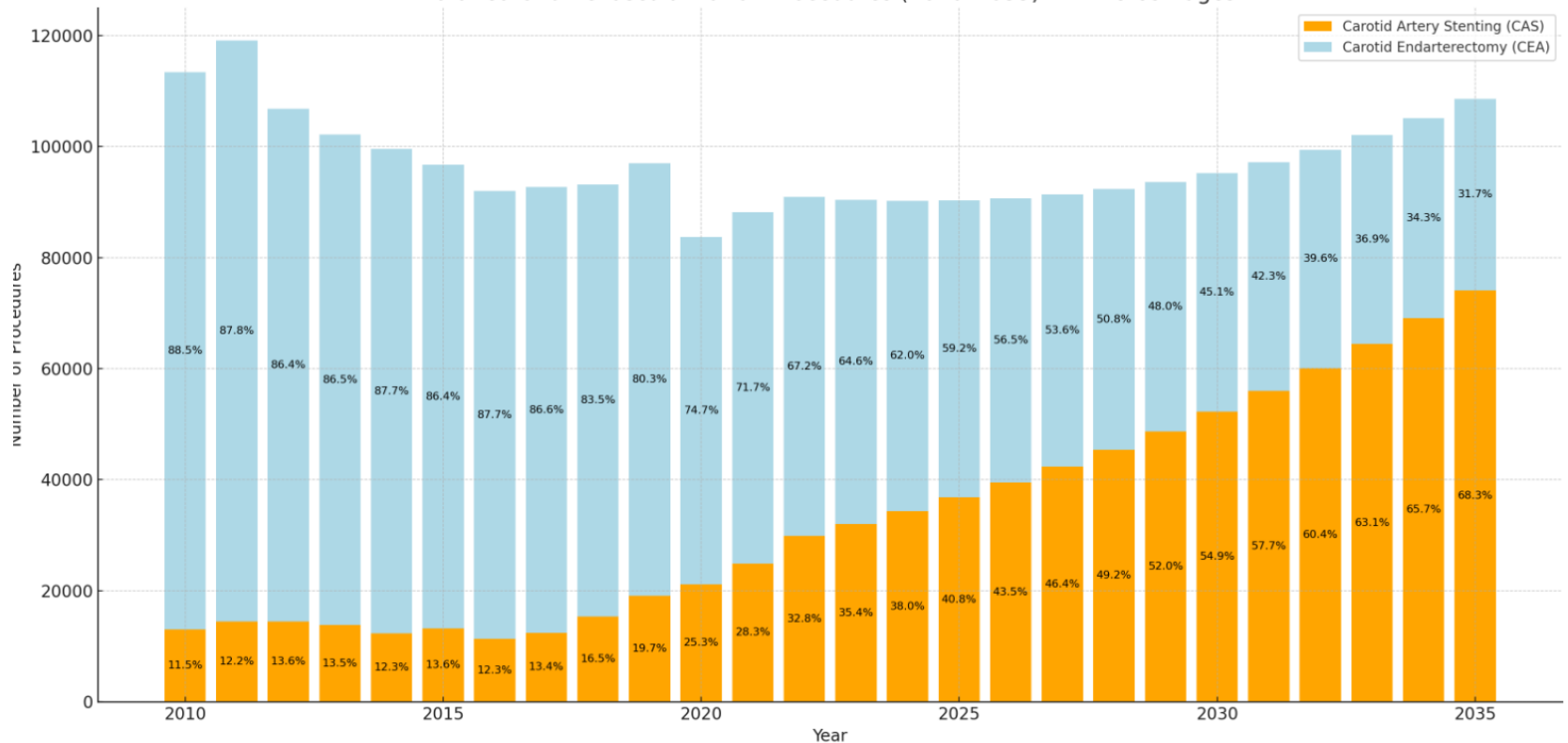
# Carotid Artery Stent vs. Carotid Endarterectomy



- Significant change in practice due to improved stent technology and routine use of Embolic Protection Device (EPD)
  - Increasing volume of CAS
  - Stable / decreasing volumes of CEA

## US Market Analysis

Total Carotid Revascularization Procedures (2010-2035) with Percentages

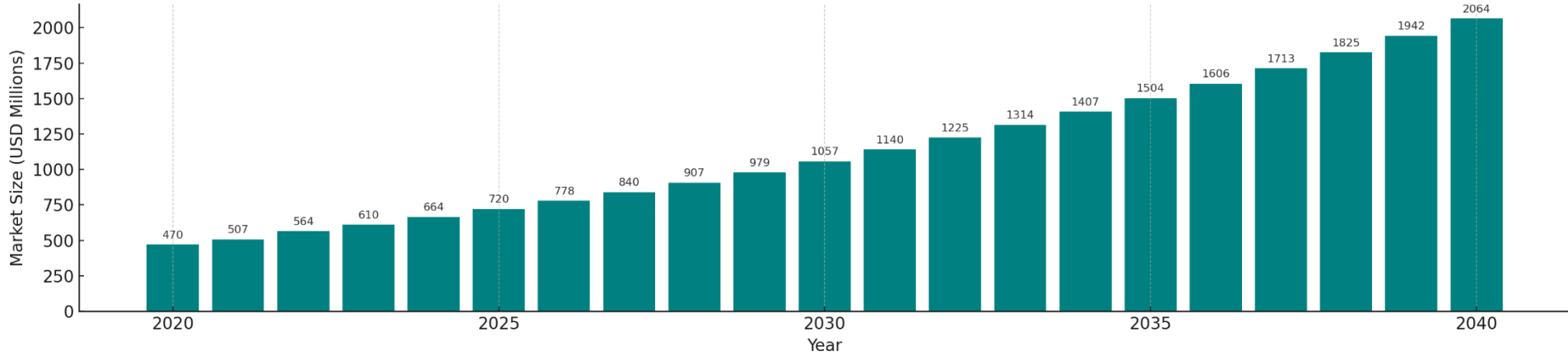


# Global and Segmented EPD Market 2020-2040

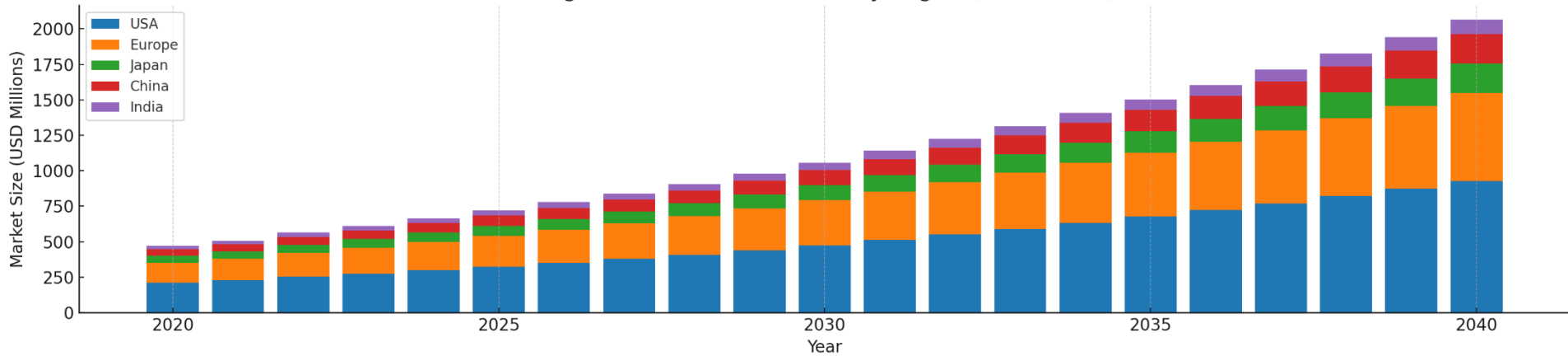


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### Global Market Size for Embolic Protection Devices (2020-2040)

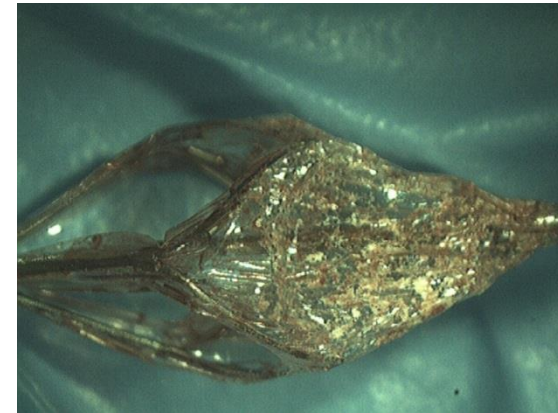


### Segmented EPD Market Size by Region (2020-2040)

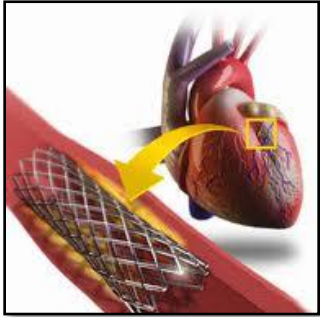


## Next Generation Embolic Protection Device

- FDA approved for the Lower Extremities (2018)
- FDA (2015) and TGA (2016) approved for Carotid
- CE and AMAR approved for all interventional vascular procedures including: LE, Carotid, Renal, TAVI, SVG
- Publications in the JACC and Circulation Journals
- Exceptional safety profile demonstrated in FDA studies
- Over 1,300 successful clinical procedures
- Scalable production structure with Creganna as main SC
- Huge market opportunity



**Innovative delivery, locking and retrieval technology**

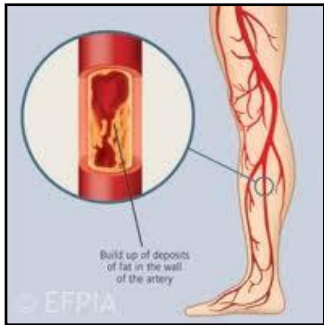


## Coronary Stenting

- SVG stenting
- Coronary stenting

### EPD use may reduce

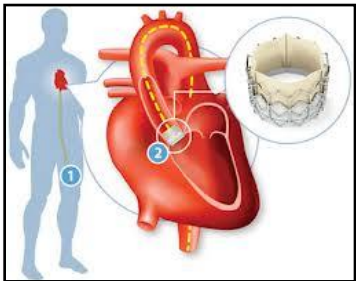
- MI, death
- Stroke, death



## Peripheral Stenting

- Carotid stenting
- Renal stenting
- Lower limbs stenting

- Stroke, death
- Kidney failure
- Amputations

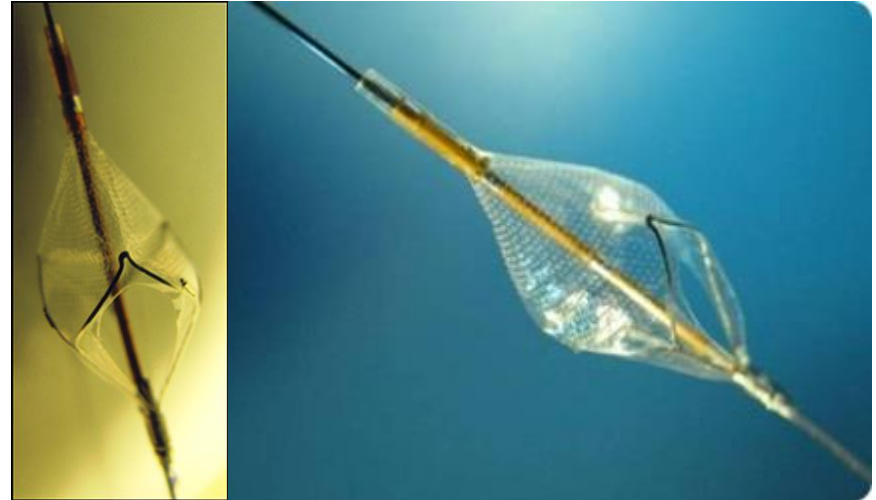


## Trans Aortic Valve Implantation (TAVI)

- MI, stroke, death

**>1,300 cases in a range of indications**

- The **only** embolic filter that can be used with **any** guide wire throughout the entire procedure
- Allows optimal filter positioning:  
*anywhere* on the guide wire  
*anywhere* along the vessel
- Wide vessel size range
- Excellent deliverability
- High capture efficacy
- Great support and stability
- Clear visibility
- Superior retrieval technology



**Excellent feedback from the medical community**

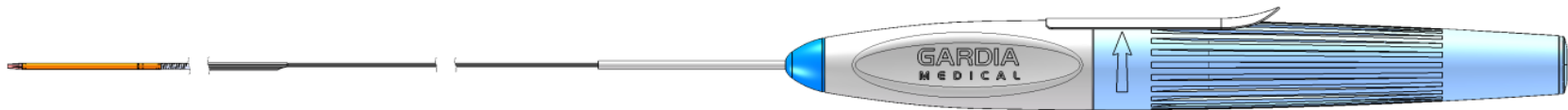
- ✓ **Simple and easy to use**
- ✓ **Any-wire is a critical feature**
- ✓ **Optimal wall apposition**
- ✓ **Strong capturing ability**

**Delivery Catheter:** Rapid exchange, 3.2F - contains and delivers the filter unit

- **Delivered over any 0.014” guidewire**
- **Proprietary locking mechanism** secures the filter to the wire
- Filter deploys by withdrawing the delivery catheter

**Filter Unit:** Nylon mesh and Nitinol frame, Concentric design with 120 $\mu$  pore size

- Compatible with vessels from 3.5-6.0mm



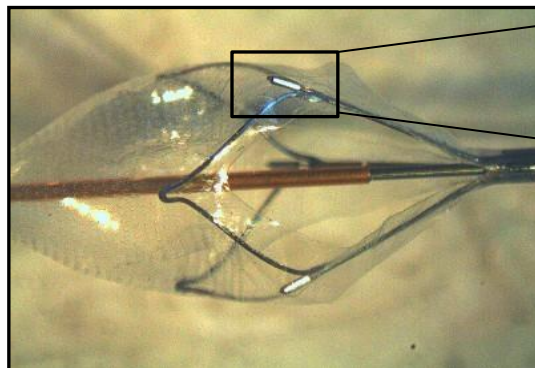
**Retrieval Catheter:** Rapid exchange, 4.8F with **retractable tip**

- Captures and retrieves the filter unit with any embolic debris
- Retractable tip improves deliverability, then allows smooth capture



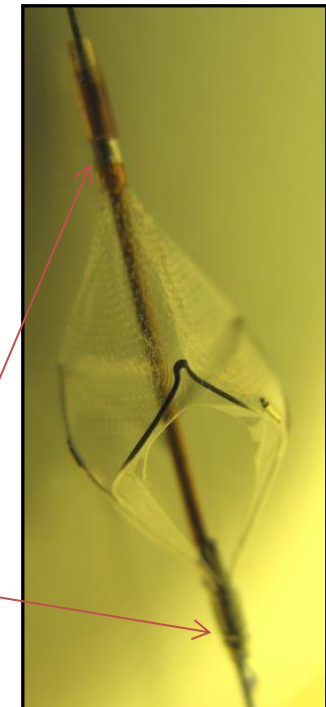
- The filter unit is a **Nylon membrane on a Nitinol frame**
- **3 marker bands** identify the proximal edge of the filter membrane
- Distal and proximal marker bands identify filter landing zone
- The locking mechanism is integral to the proximal edge of the Nitinol frame and secures the filter **unit to any 0.014” guidewire**
- **Filter can lock anywhere on the guidewire anywhere in the vessel**

Target Blood Vessel Diameter	Filter Unit Length	Pore Size ( $\mu\text{m}$ )
3.5-6.0 mm	22.5 mm	120



Radiopaque Markers on Filter

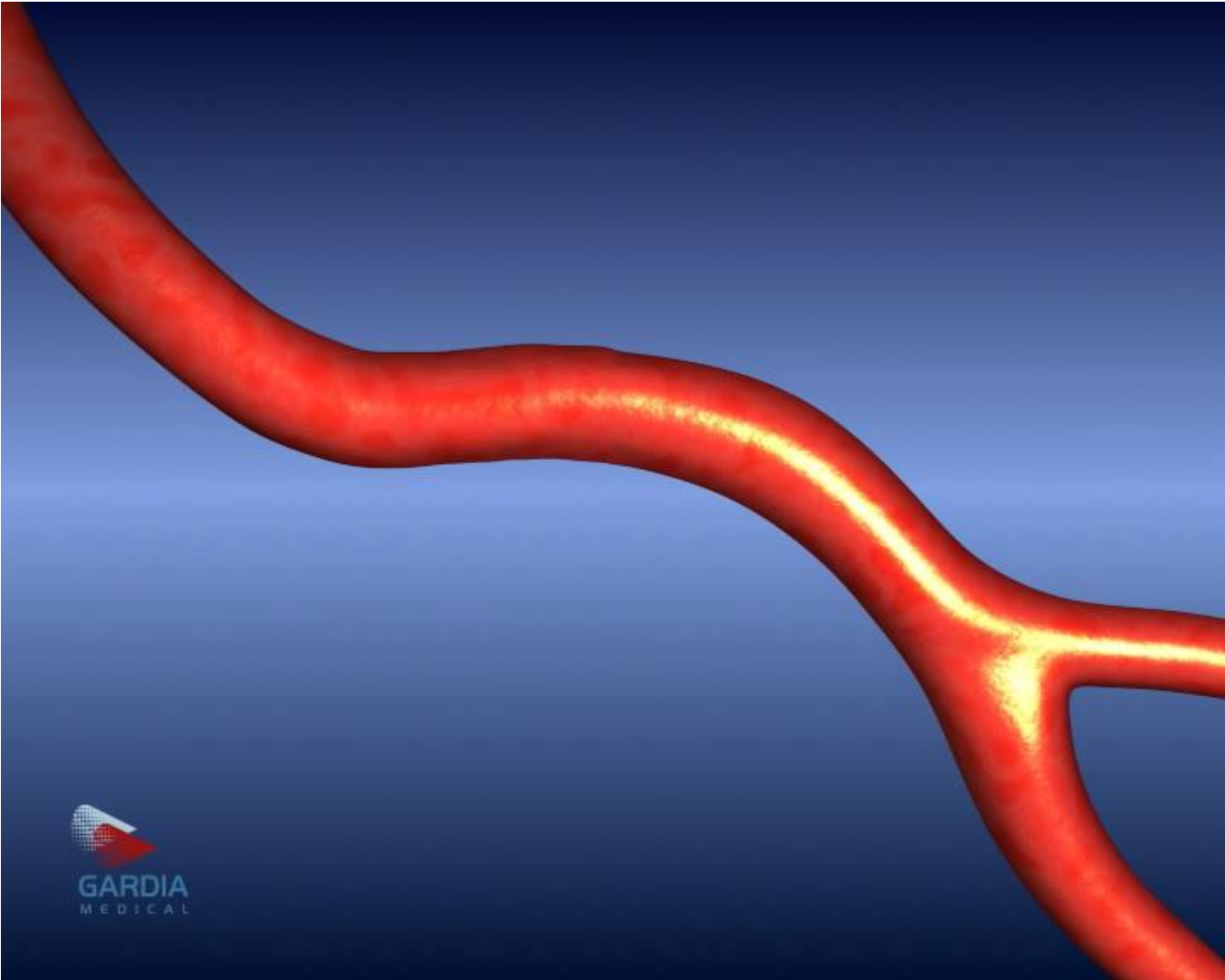
Proximal and Distal Radiopaque Markers



# Animation



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## Market Share

> 50 %

< 35 %

### 1<sup>st</sup> Generation:

- Dedicated wire
- Fixed filter location

### 2<sup>nd</sup> Generation:

- Wire exchange to a dedicated wire
- Fixed filter location

### Potential market leader

### 3<sup>rd</sup> Generation:

- Any wire throughout the entire procedure
- Desired location



COVIDIEN

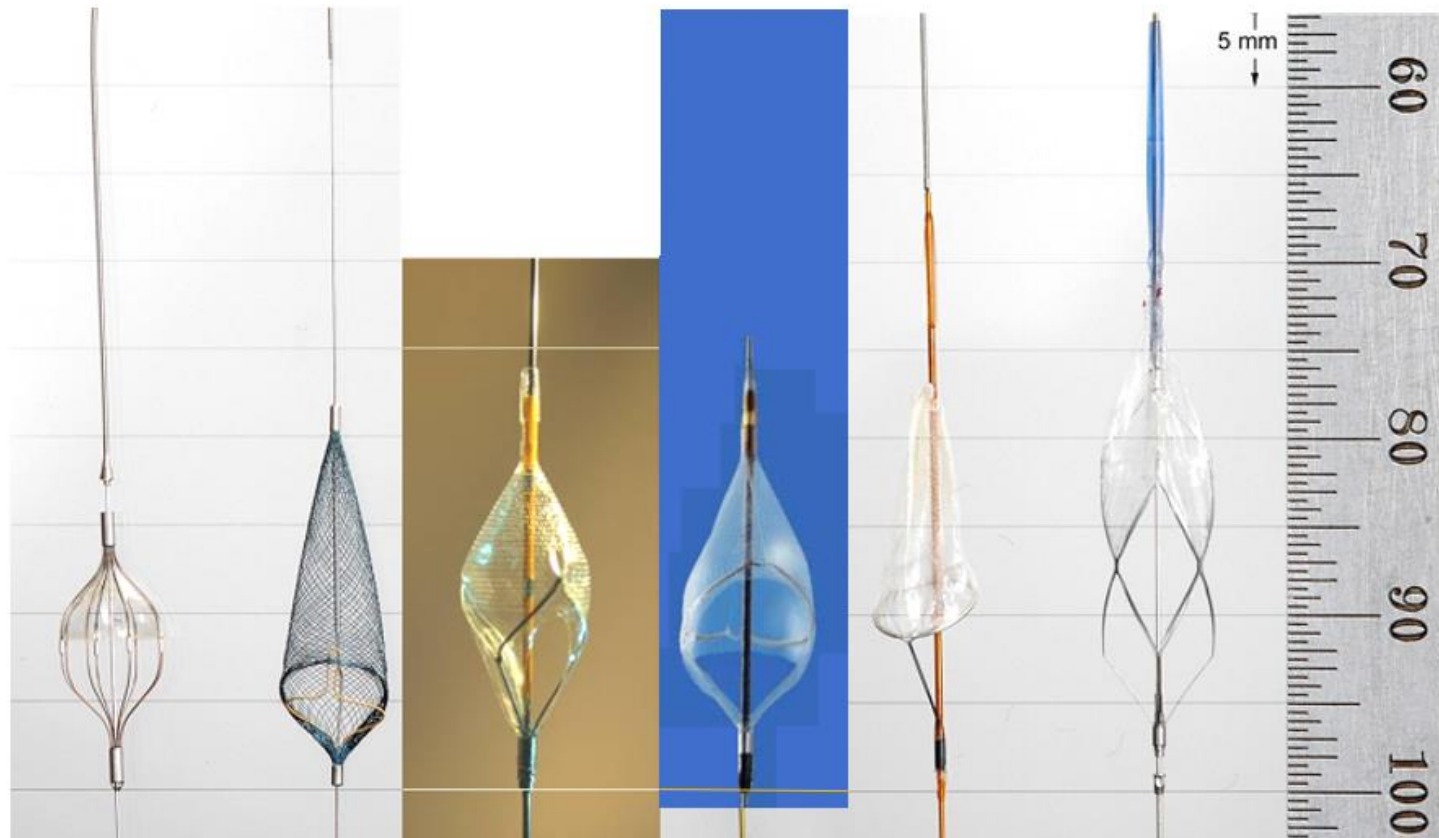
**WIRION™**  
Embolic Protection Device

# Compare filters



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Picture of filters in proportional scale



AngioGuard

Spider

Wirion

NAV6

Filterwire

Accunet



## Circulation

Cardiovascular Interventions

- Objective: Comparing the safety and performance of WIRION™ in patients undergoing CAS to a performance goal based on an analysis of the results of previous US carotid stents with embolic protection studies.
- Demography: Similar to that of the historical control population. Similar age and similar prevalence of co-morbidities including hypertension, diabetes mellitus and heart failure. The majority of the patients were asymptomatic in both WISE study (88.3%) and historical control (73%).
- Primary endpoint: A composite of Major Adverse Cardiac and Cerebrovascular Events (MACCE) including Death, Stroke, and Myocardial Infarction (DSMI) occurring within 30±7 days post-procedure.

**The WIRION system successfully met the primary endpoint. MACCE rate was 3.3% compared to an historic control MACCE rate of 6.3%. 0% death.**



- Objective: Demonstrate the safety and performance of the WIRION™ in subjects undergoing Lower Extremity atherectomy for the treatment of PAD
- Indication of USE: Atherectomy *independent labeling* (unique) for all atherectomy devices (orbital, rotational, directional, laser)
- Design- 103 patients, 30 days FU
- Primary endpoint: Absence of major adverse events (MAE) to 30 days post procedure
- Performance goal study: based on Covidien DEFINITIVE LE & DEFINITIVE Ca++ trials

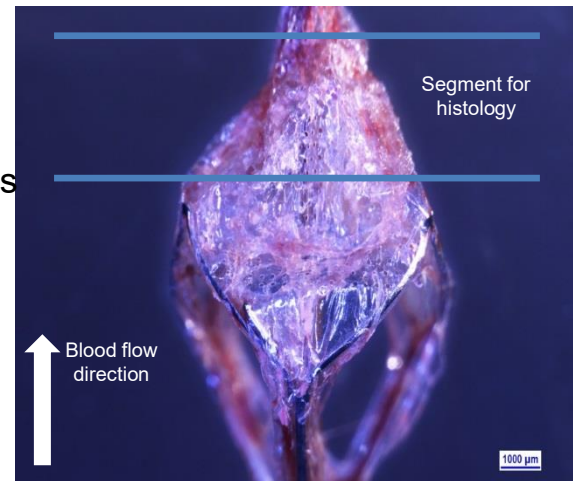
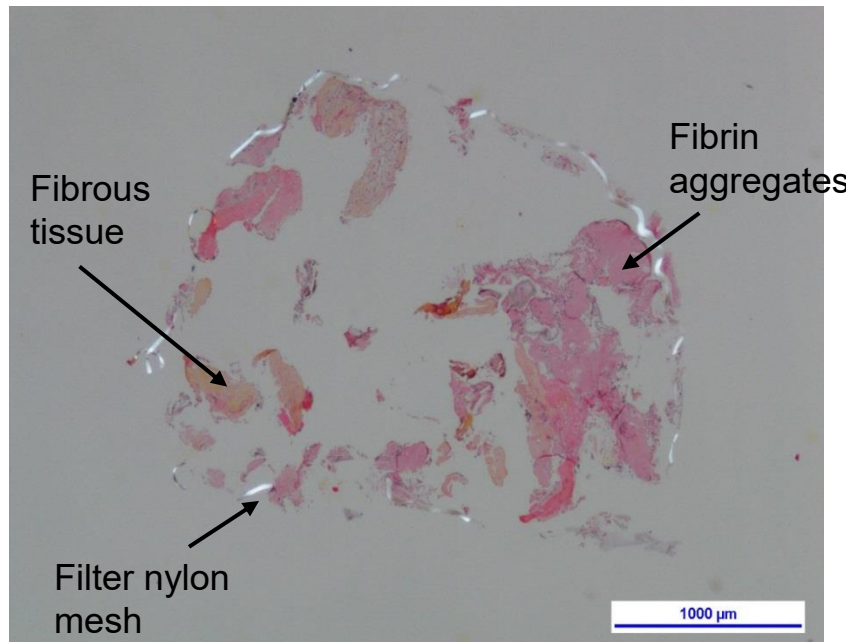
The WIRION system successfully met the primary endpoint. MAE was **1.9%** *compared to an historic control MAE rate of 10.6%.*

# Histology analysis of the filters



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- The purpose of the histology analysis was to evaluate the debris captured by the WIRION.
- The histopathologic analysis for the filters demonstrated that WIRION **successfully captured debris in 100% of filters analyzed. Large thrombi ranged >1mm was found in 31% of the filters.**



NAMSA®



- ProCatid has a unique embolic protection system (WIRION) that truly enables “wire of choice” in a variety of indications
- UniGrd (WIRION) has FDA Peripheral indication and FDA & TGA clearances for the carotid indication and it is CE marked and AMAR approved for all vascular indications
- While historically the market for EPD’s was largest in Carotid Stenting, the use of EPD’s in peripheral vessels has grown rapidly, and is currently the larger market segment with the highest growth rate
- Procatid has clinical experience in carotid stenting, lower limb peripheral atherectomy and stenting, renal, SVG as well as TAVI procedures
- Physician feedback has been very positive regarding the clinical data, the handling of the device and the simplicity of operation

# ProCatid Medical – competitor analysis



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UniGrd (WIRION™) vs. Spider, leading protection device by MDT

	<b>WIRION</b>	<b>Spider</b>
Start with Wire of Choice	Yes	Yes
Exchange to Dedicated Wire	<b>No</b>	<b>Yes</b>
Filter	Nylon Membrane (120μ)	Nitinol Mesh (190μ nominal pore size, <b>up to 400μ proximal</b> )
Filter Frame	<b>Concentric Frame</b>	<b>Eccentric Frame</b>
Delivery Catheter	3.2F	3.2F
Landing Zone	3.5cm	4-5cm

The Spider EPD by MDT (formerly Covidien) is the only other EPD claiming “wire of choice”. However, the “wire of choice” must be exchanged for the Spider dedicated wire prior to filter deployment, and the rest of the case is performed over that wire.

Despite this, the Spider is the leading EPD. The WIRION improves upon this design by using the wire of choice for the entire case, eliminating an exchange step, allowing filter positioning anywhere on the wire, and potentially improving capture efficiency and retrieval.