# Lumen Fibernet EPD

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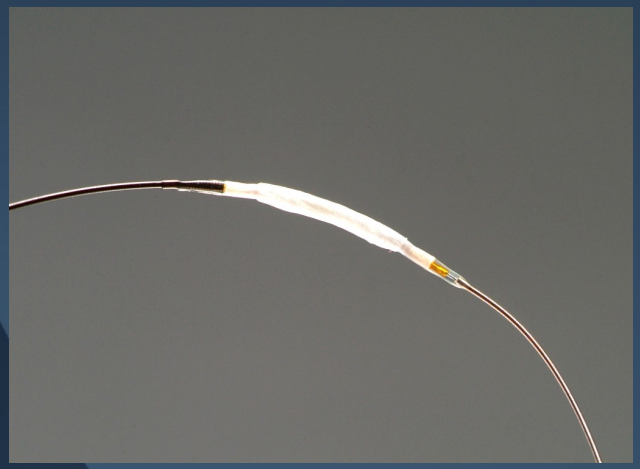
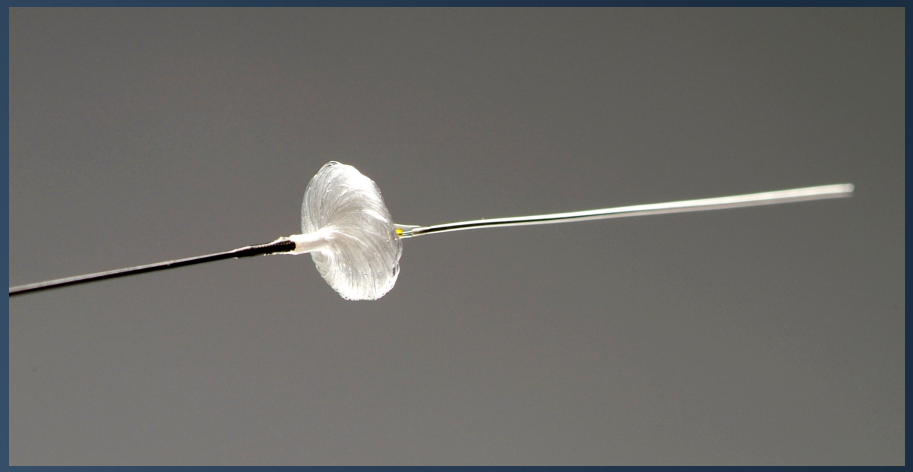
# Limitations of Current Protection Devices

- Difficult to deliver, due to crossing profile, stiffness, etc. – frequent need for predilation, aggressive guide, buddy wire, etc.
- Pore sizes of ≥100 um allow smaller particles through filter
- Not apposed to wall in eccentric or diseased landing zones
- Restrictive landing zone requirements
- Filter clogging reduces flow, makes it difficult to withdraw
- Visualization, perfusion not possible with balloon occlusion, other devices

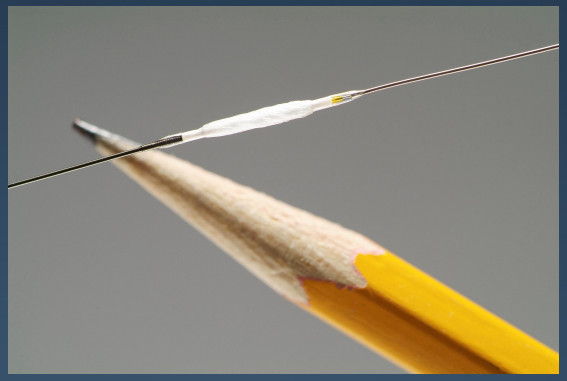
# FiberNet® Embolic Protection System



**Lumen Biomedical, Inc.**



# FiberNet: Low Crossing Profile



| FiberNet | Vessel Size | Crossing Profile |
|---|---|---|
| 2.5mm | 1.75-2.5 mm | 1.7F |
| 3.5mm | 2.5-3.5 mm | 2.1F |
| 5.0mm | 3.5-5.0 mm | 2.4F |
| 6.0mm | 5.0-6.0 mm | 2.7F |
| 7.0mm | 6.0-7.0 mm | 3.1F |

**Other Device Specifications** →

| Device | Vessel Size | Crossing Profile |
|---|---|---|
| EmboShield | 3.0-6.0 mm | 3.7-3.9F |
| AccuNet RX | 3.5-5.0 mm | 3.5-3.7F |
| FilterWire EZ | 3.5-5.5 mm | 3.2F |
| SpideRX | 3.0-7.0 mm | 3.2F |
| GuardWire | 3.0-5.0 mm | 2.7F |

# FiberNet®

## Embolic Protection System

- 3-dimensional fiber mesh filter
- Conforms to vessel wall for maximum wall contact
- PET fibers with groove the size of RBc

# FiberNet®

## Embolic Protection System

Key Product Specifications:

- **Vessel conforming 3-dimensional fiber filter**
- **Particulate capture as low as 40 microns while maintaining blood flow during the procedure**
- **Filter mounted on a high performance .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**

# Bench Top Tests

**FiberNet:**

- Captured 99% of particles >100 microns
- Captured 96% of particles >40 microns

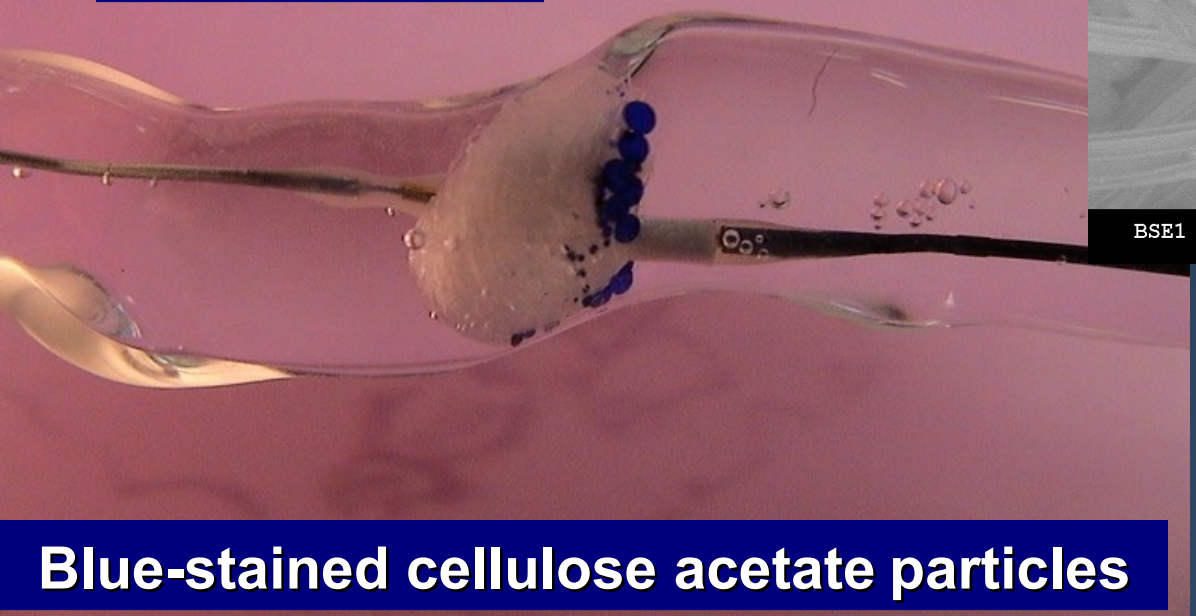
# FiberNet Porcine Model

- captured 94% of particles >40 microns in diameter
- 81% of the particulate captured was <96 microns
- FiberNet did not demonstrate decreased flow

# Embolic Protection
## Bench Test

cellulose acetate syringe filter


Environmental electron micrograph showing 40 µm particulate within the FilterNet



Blue-stained cellulose acetate particles

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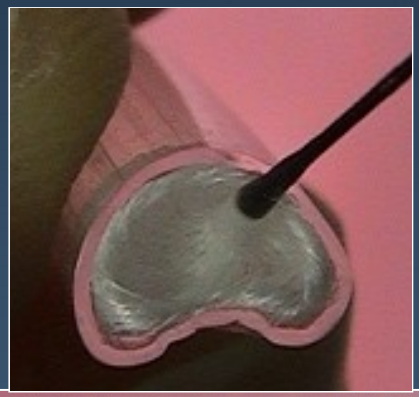
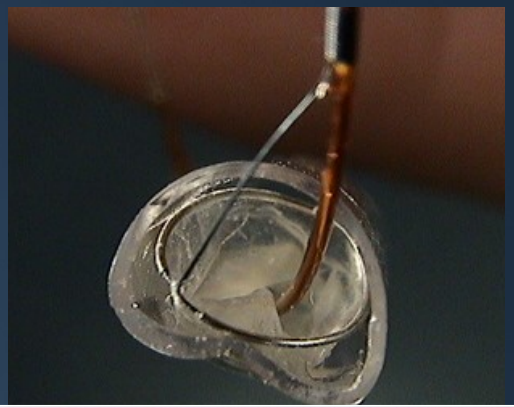
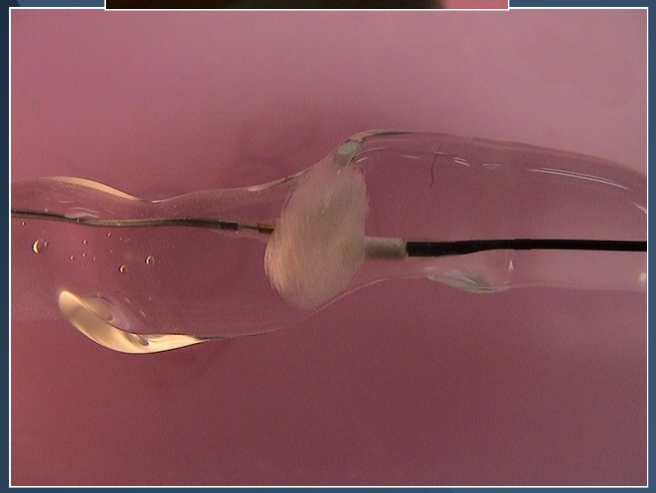
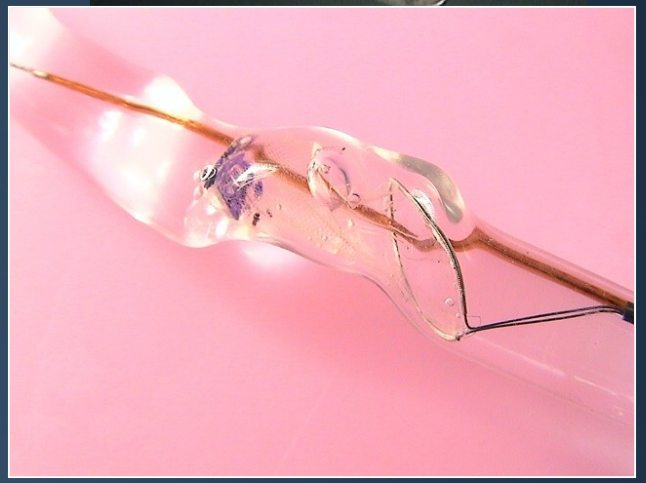
# Wall Apposition in Eccentric Landing Zones

## FiberNet



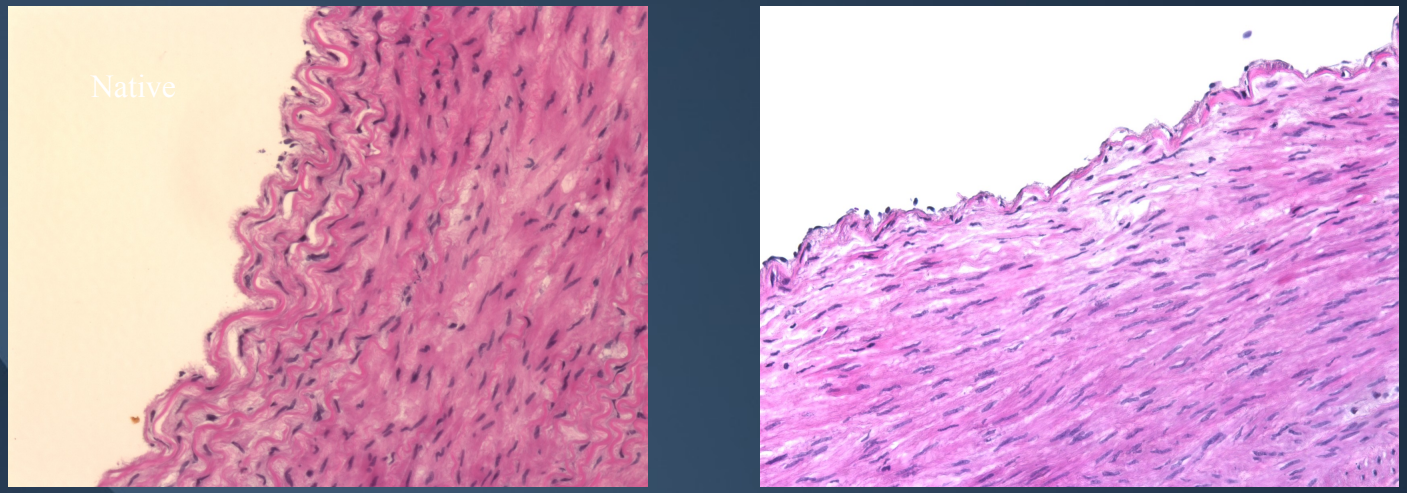






# FiberNet
# Lack of Injury to the Vessel Wall

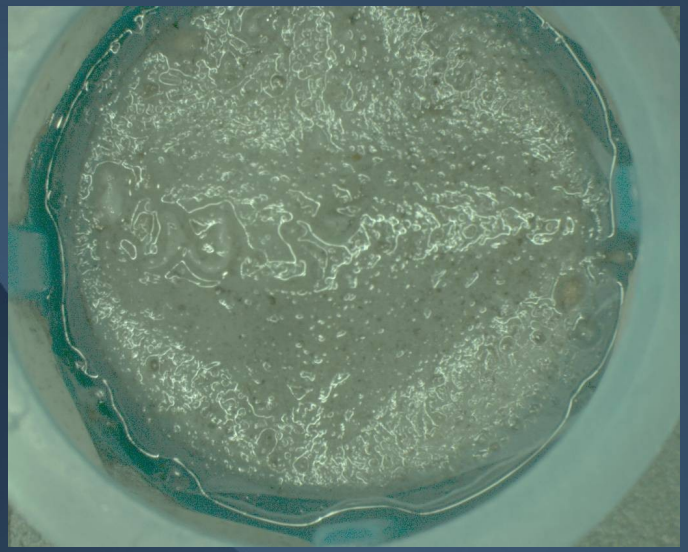
## Carotid Wall Histopathology

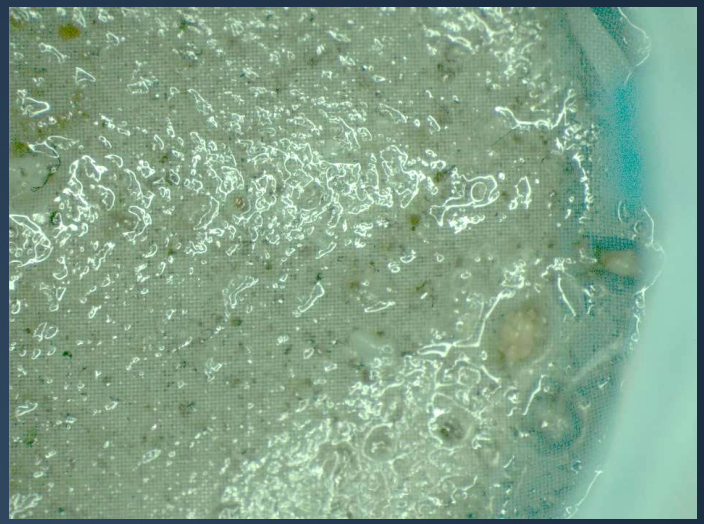



H&E 200X

# High Capture Efficiency:
## Clinical Cases – Greece, Germany, US

Visible debris has been removed in **100%** of the cases to date.





# FiberNet Procedures Done in Greece with Dr. Henry and Dr. Polydorou

"CAUTION – Not commercially available: INVESTIGATIONAL DEVICE"
90-1003,B

# Greece Baseline Characteristics

**N = 46 Carotid Patients and 4 Renal Patients**

| | |
|---|---|
| **Mean Age at Procedure** | **69 years** |
| **Percent Male** | **68%** |
| **Mean Percent Stenosis** | **84.6%** |

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# Greece FiberNet Results

Patients N = 50 subjects (51 lesions)

| | |
|---|---|
| **Procedure Success** | **96%** |
| **% Cases Visible Debris Caught** | **100%** |

**Two Instances of TIMI 1 flow and one instance of TIMI 0 flow. TIMI 3 flow restored after suction in all cases.**

**Three vessel spasm treated with nitro (not at the location of distal protection device)**

**No Changes noted in 30 day follow-up CT/MRI**

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# Greece FiberNet Carotid Results

| | |
|---|---|
| Death | 0% (0/46) |
| Major Stroke | 0% (0/46) |
| Permanent Amourosis | 4% (2/46) |
| Amourosis Fugax | 2% (1/46) |
| Q-Wave MI | 2% (1/46) |
| Non Q-Wave MI | 2% (1/46) |

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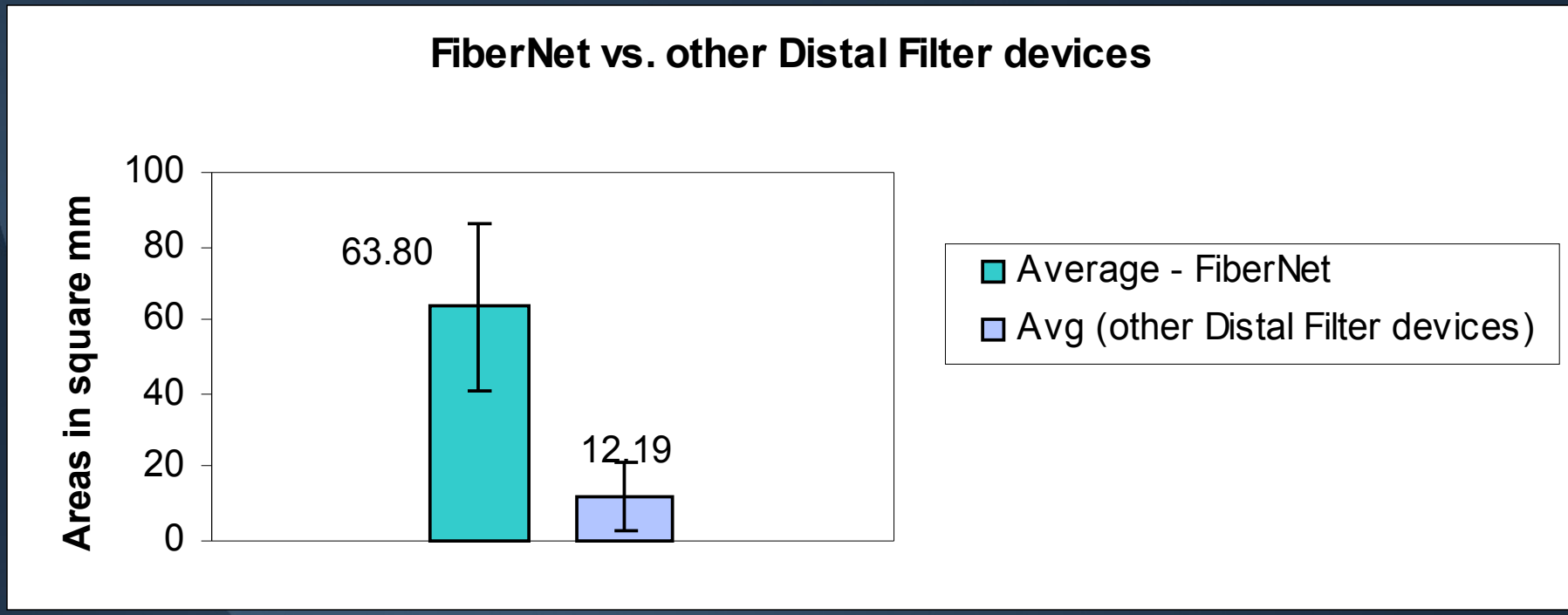
# Debris Analysis
# Area of Debris Captured ($mm^2$)

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# Evaluating the Use of the FiberNet® Emboli Protection Device in Carotid Artery Stenting:

# The EPIC US Feasibility Study

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# EPIC Study Objective

**Multicenter, prospective, feasibility study designed to demonstrate the performance and safety of the Lumen Biomedical, Inc. FiberNet® Embolic Protection System as an adjunctive device during carotid artery percutaneous intervention in high risk patients.**

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# EPIC Study Endpoints

Primary Endpoint: **the rate of all death, stroke, and MI within 30 days of the procedure.**

Secondary Endpoints:

- **All death and stroke rates**
- **Non-stroke neurological event rates**
- **Technical success rates**
- **Procedural success rates**
- **Access site complication rates**

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# CLINICAL TRIAL (EPIC)

- Feasibility completed
- Pivotal underway in US