FIH Experience with the EnCompass F_2 Filter: a Novel Cerebral Embolic Protection Device

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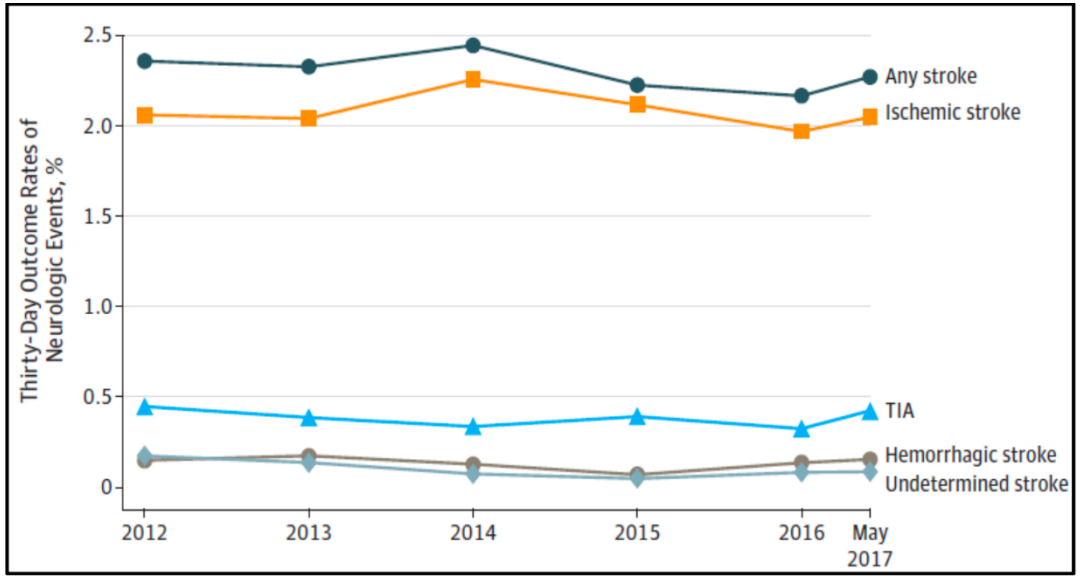
Disclosure Statement of Financial Interest

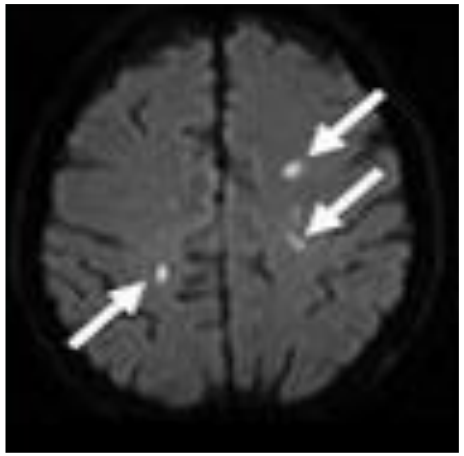
Within the past 12 months, I or my spouse/partner have had a financial interest, arrangement, or affiliation with the organization(s) listed below:

- *Boston Scientific – consulting fees*
- *Medtronic – consulting fees*
- *Abbott – consulting fees*
- *Teleflex – consulting fees*

Background

- Stroke remains an important complication of TAVR occurring in 2-3% of cases[1,2]
- DW-MRI studies reveal ischemic brain injury in majority of patients (68-93%)[3]
- Existing CEPD devices have failed to demonstrate efficacy in reducing stroke or brain injury after TAVR[2,4]
- There remains an unmet clinical need for safe and efficacious CEPD for TAVR





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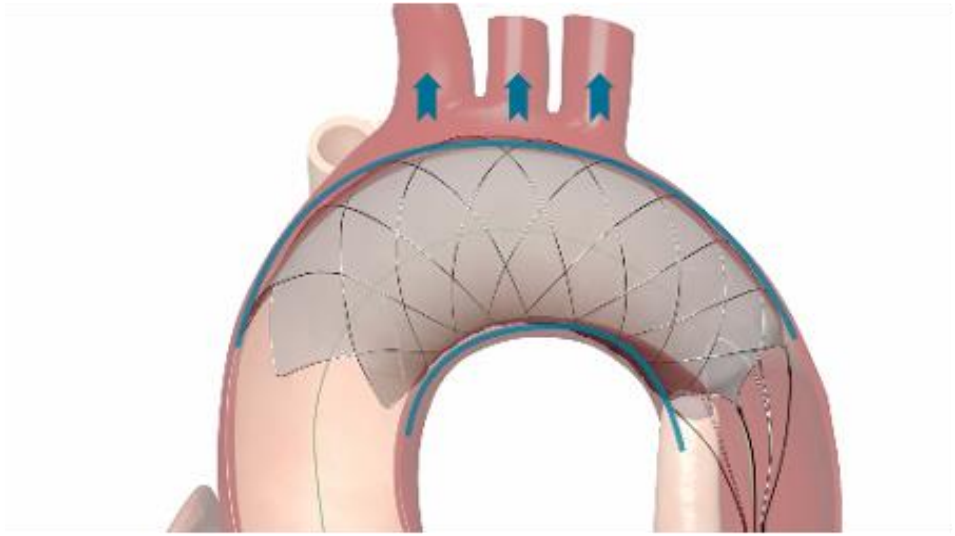
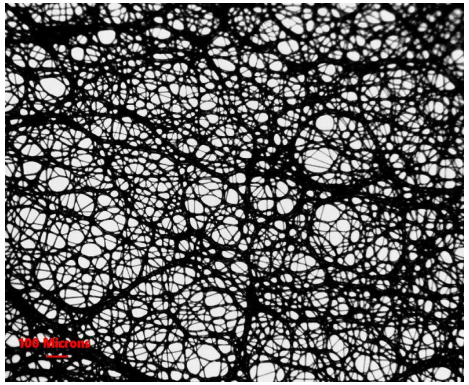
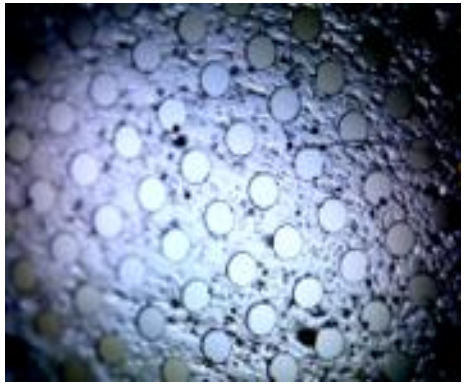
EnCompass F_2 Technology



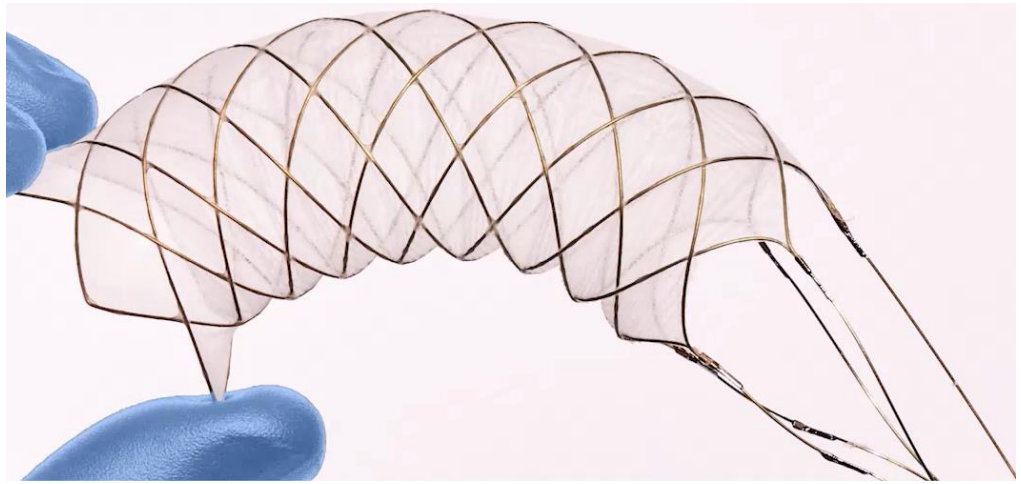
- F_2 Filter is a deflector that protects all 3 arch vessels, allows passage TAVR through center
- Self-expanding nitinol frame achieves 360° wall apposition for stability
- Electrospun polyurethane filter with 30µm avg. pore size
- Ipsilateral or contralateral femoral access (14F)



F_2 Filter
(30µm avg pore size)

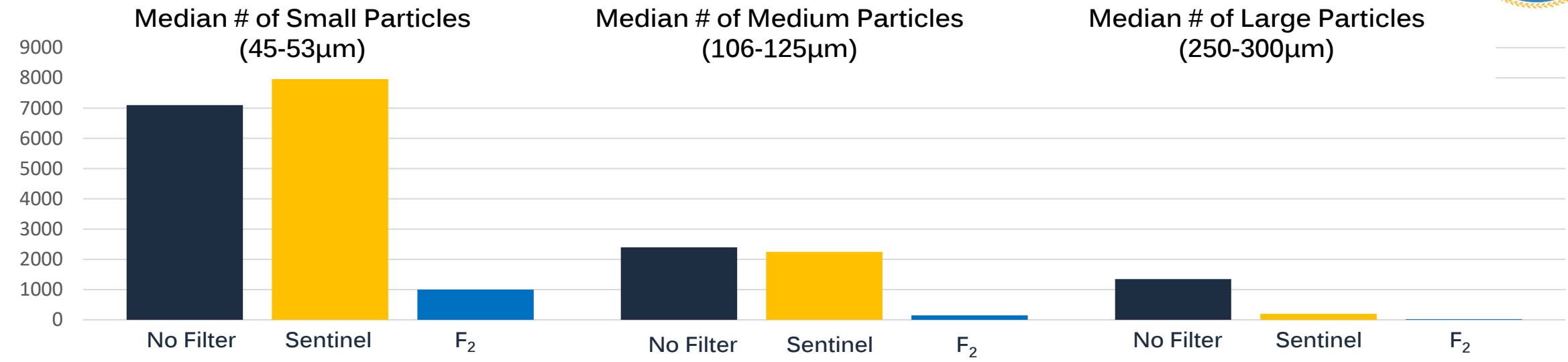


Sentinel Filter
(140µm avg pore size)



Scientific Foundation: F_2 vs Standard of Care

F_2 prevented 94% more brain emboli than Sentinel or Unprotected Control



No Filter | Sentinel CPS | EnCompass F_2

EnCompass F_2 First-in-Human Study

Objectives

- To evaluate the feasibility and safety of cerebral embolic protection with the F_2 filter during TAVR
- Exploratory efficacy analysis of DW-MRI brain lesion number and volumes (8-72h)

Methods

- Enrolled adult subjects w/ SOC indication for TAVR for native AS
- Excluded: TIA or stroke within 6 months or contraindication to MRI
- Excluded: Unsuitable aortic arch and iliofemoral anatomy by CTA
- Subjects treated (49) at 1 site in Republic of Georgia and 4 sites in Australia
- Single MRI 8-72 hours post TAVR
- Core labs for MRI review and neurocognitive assessment

F_2 FIH Study Endpoints

Technical Success

- Successful F_2 Filter device deployment, stable device positioning, complete coverage during TAVR, and successful retrieval

Primary Safety: 30-day MACCE* (VARC3)

- All-cause death, all stroke, major vascular complications, type 2-4 bleeding, or acute kidney injury (AKI) stage 3 or 4 within 7 days

DW-MRI at 8-72h (preferred within 24h)

- Median total new lesion volume
- Media individual new lesion volume
- Median number of new lesions

F_2 FIH Study Population (ITT)

- 49 subjects enrolled and underwent TAVR with F_2 Filter (including 2 no MRI), ITT population
- F_2 filter delivered by ipsilateral (N=17) or contralateral (N=32) femoral access
- TAVR performed with both balloon-expandable (N=39) and self-expanding (N=10) THV
- Per Protocol Analysis (N=45): 2 strokes occurred in patients determined not per protocol (Intraprocedure Type 2 MI, with CPR. Decompensated patient prior to F_2 deployment)

	N=49
Age - years	75.8 +/- 6.14
Female Sex – no. (%)	30 (61.2%)
STS Score	2.7 +/- 1.56
BMI > 30 – no. (%)	21 (42.9%)
Diabetes – no. (%)	15 (30.6%)
Cr – mg/dL	0.9 +/- 0.25
Prior PCI or CABG – no. (%)	12 (24.5%)
Prior TIA of stroke – no. (%)	2 (4.1%)
Atrial Fibrillation – no. (%)	7 (14.3%)

EnCompass F_2 FIH Study Results (ITT)

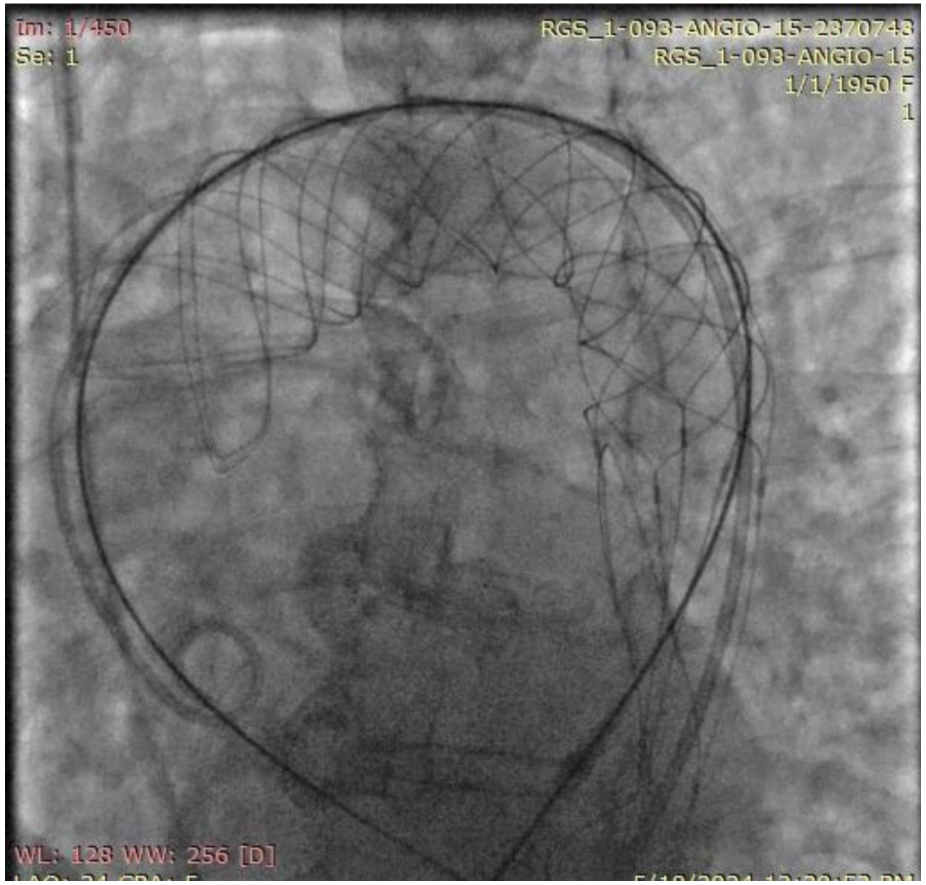
Technical Success: 93.9% (46 of 49 patients)

- Single F_2 filter used in 48 of 49 cases
- Average time for F_2 filter deployment - 2.8 +/- 2.4 min

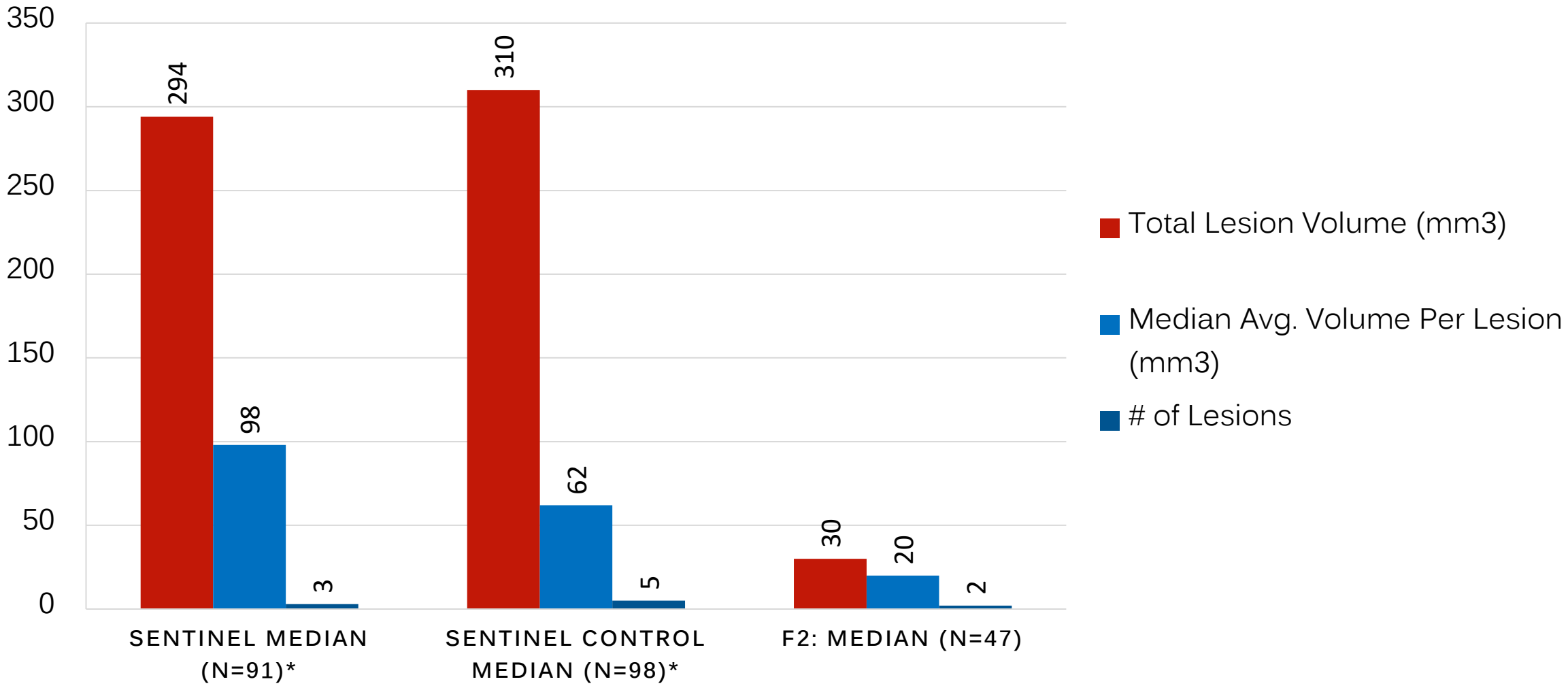
Primary Safety: 30-Day MACCE rate 6.1%*

ITT
- Death – 0
- Strokes – 2
- TIA – 0
- 1 Vascular complication in non-MRI case

*CEC-adjudicated 30-day data available for all cases



EnCompass F_2 FIH Study MRI Results (PP)

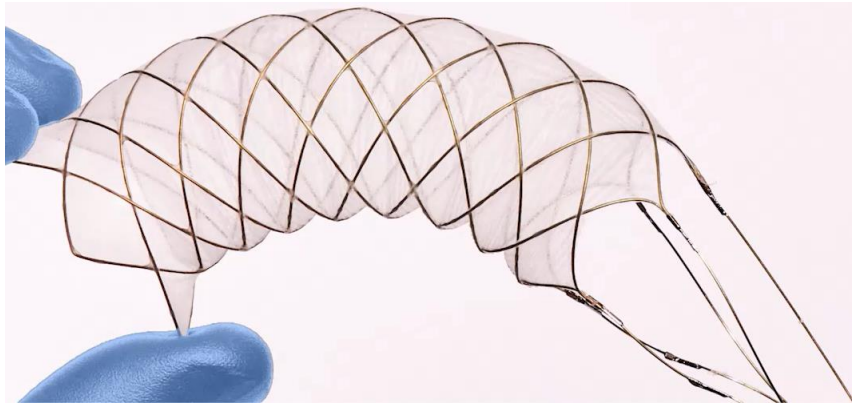


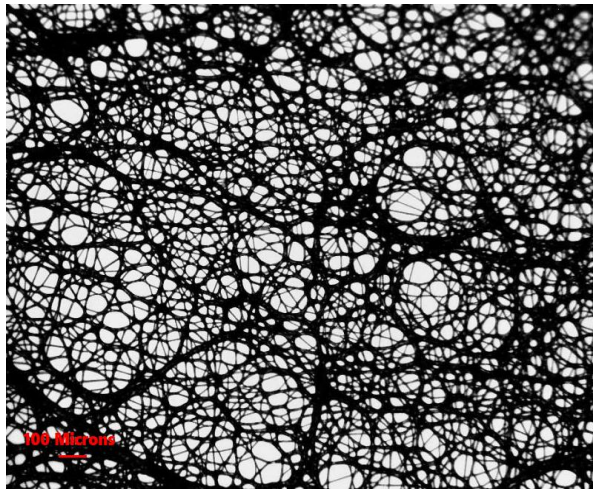
EnCompass F_2 Clinical Study Program

- EFS enrolled at 5 sites in Georgia and Australia
- EFS results support US IDE Pivotal Trial (400 patient randomized to standard of care at site: Sentinel or unprotected)

Conclusions

- The EnCompass F_2 is a novel CEPD that features a cylindrical nitinol frame and Electrospun filter with very small pore size (30μm)
- In this FIH experience, 49 subjects underwent TAVR with the F_2 filter, and technical success was achieved in 93.9%
- The F_2 filter was safe with 6.1% 30-day MACCE
- DW-MRI results were favorable with median total new lesion volume 30mm^3 and median volume per lesion 20mm^3, both much lower than historical controls





F_2 Filter
(30μm avg pore size)