FIH Experience with the EnCompass F2 Filter: a Novel Cerebral Embolic Protection Device

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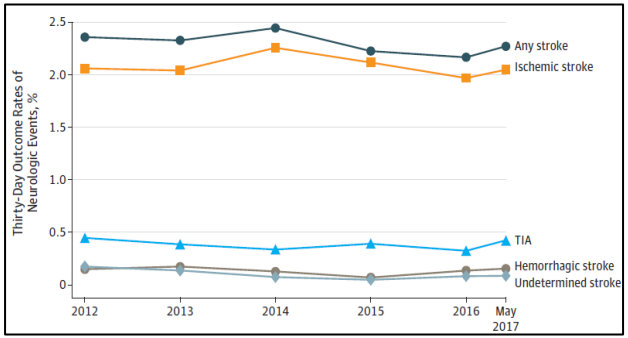
Disclosure Statement of Financial Interest

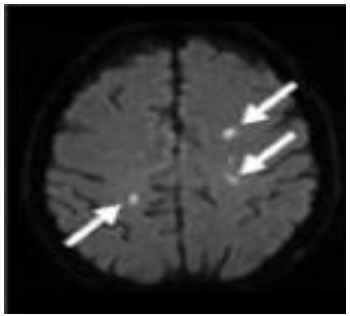
Within the past 12 months, I or my spouse/partner have had a financial interest, arrangement, or affiliation with the organization(s) listed below:

Affiliation/Financial Relationship	Company
Consulting Fees/Honoraria	Boston Scientific
Consulting Fees/Honoraria	Medtronic
Consulting Fees/Honoraria	Teleflex
Consulting Fees/Honoraria	EnCompass

Background

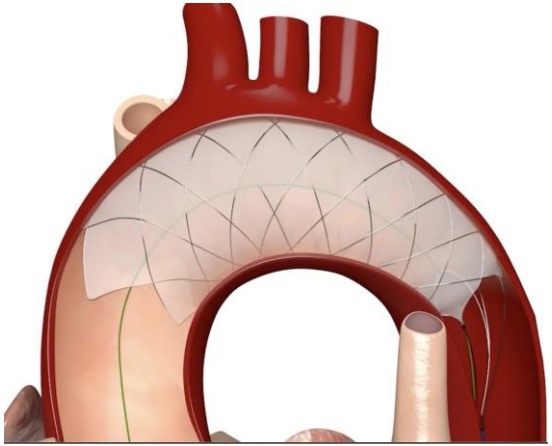
- Stroke remains an important complication of TAVR occurring in 2-3% of cases[1,2]
- DW-MRI studies reveal ischemic brain injury in the majority of patients (68-93%)[3]
- Existing CEPD devices have failed to demonstrate efficacy in reducing stroke or brain injury after TAVR[2,4]
- There is an unmet clinical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

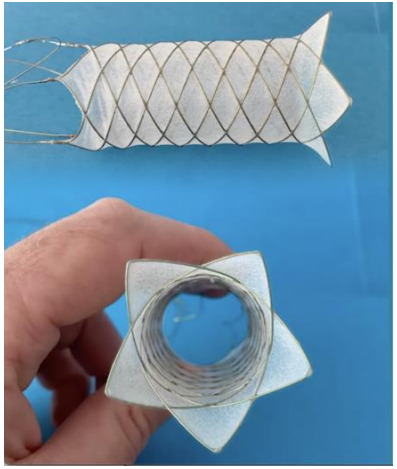




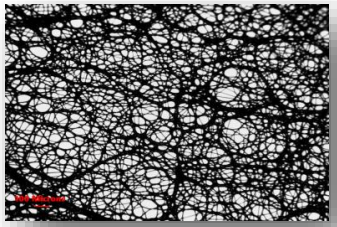
1. Carroll, JD. et al. J Am Coll Cardiol. 2020;76:2492-2516. 2.Kapadia SR. et al. N Engl J Med. 2022;387:1253-1263. 3. Lansky, A. et al. J Am Coll Cardiol. 2017;69:679–91. 4.Kapadia SR. et al. J Am Coll Cardiol. 2017;69:367-377, 5. Ghanem, A. et al. J Am Coll Cardiol. 2010;55:1427-32.

EnCompass F_2 Technology

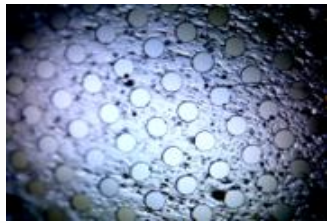




- F2 Filter is an arch deflector that protects all 3 vessels, allows passage TAVR through center
- Self-expanding nitinol frame achieves 360˚ wall apposition for stability
- Electrospun filter with 30 µm avg. pore size
- Ipsilateral or contralateral femoral access (14F)

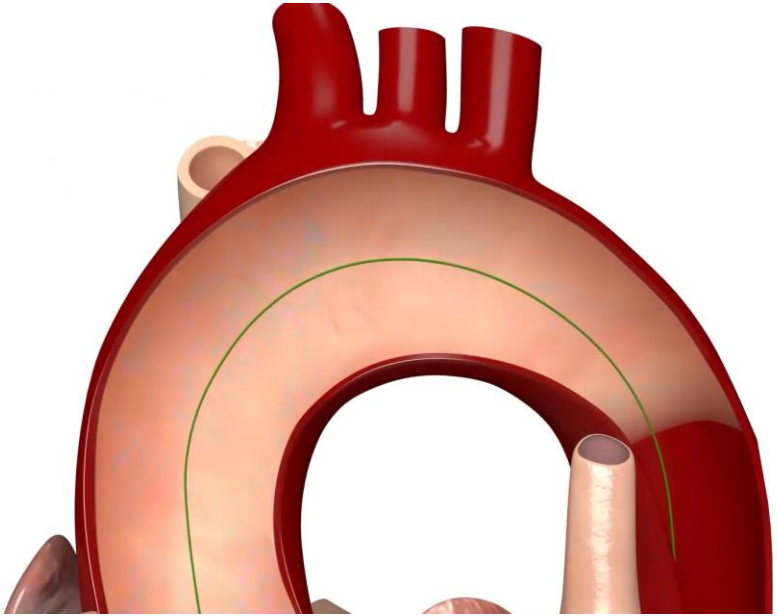


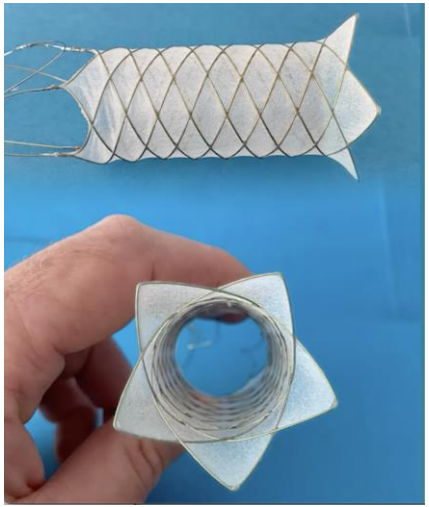
F_2 Filter
(30 µm average pore size)



Sentinel Filter
(140 µm average pore size)

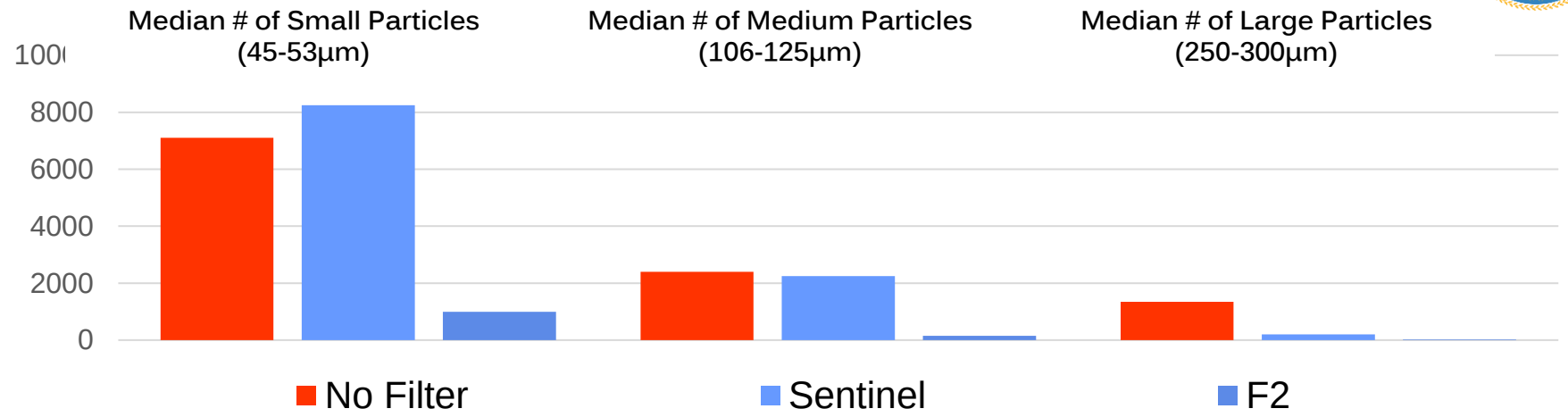
EnCompass F_2 Animation





Preclinical evaluation: 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

Ghowati M. et al. J NeuroIntervent Surg 2023;15(Suppl 1):A128-129.

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 by single team of operators at the Israeli-Georgian Medical Research Clinic, Tbilisi, Georgia

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)**
  - Total new lesion volume
  - Average individual new lesion volume
  - Average number count of new lesions

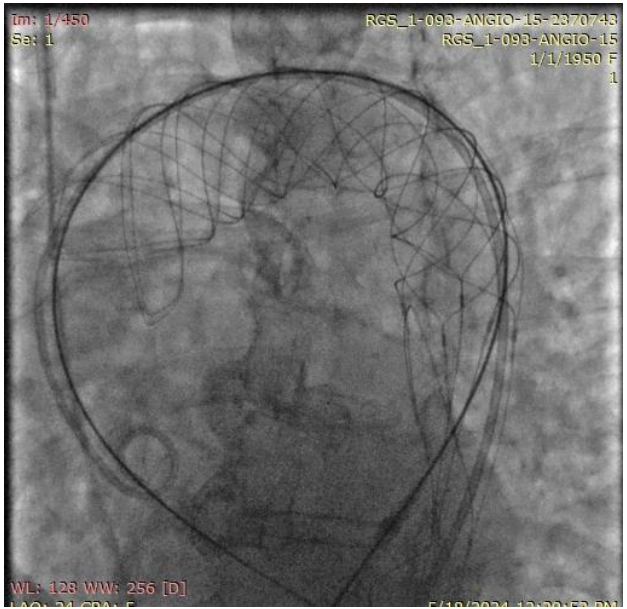
F_2 FIH Study Population

- 12 subjects enrolled and underwent TAVR with F_2 Filter
- F_2 filter delivered by ipsilateral (N=5) or contralateral (N=7) femoral access
- TAVR performed with both balloon-expandable (N=9) and self-expanding (N=3) THV

	N=12
Age - years	73.0 +/- 5.0
Female Sex – no. (%)	7/12 (58)
STS Score	3.2 +/- 2.0
BMI > 30 – no. (%)	5/12 (42)
Diabetes –no. (%)	3/12 (35)
Cr – mg/dL	0.9 +/- 0.23
Prior PCI or CABG – no. (%)	1/12 (8.3)
Prior TIA or stroke – no. (%)	1/12 (8.3)
Atrial Fibrillation – no. (%)	1/12 (8.3)

EnCompass F_2 FIH Study Results

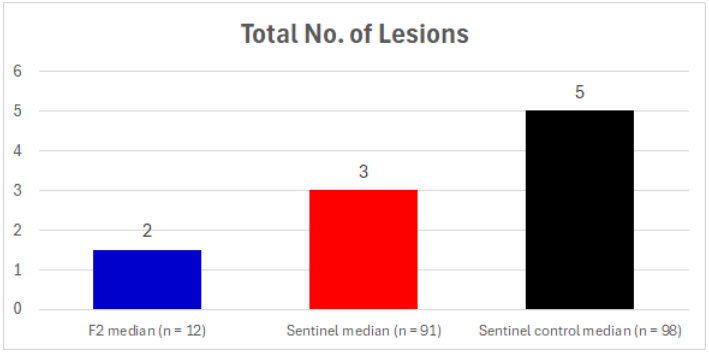
- Technical success achieved 100%
  - Single F_2 filter used in all cases
  - Average time for F_2 filter deployment 1.6 +/- 1.3 min

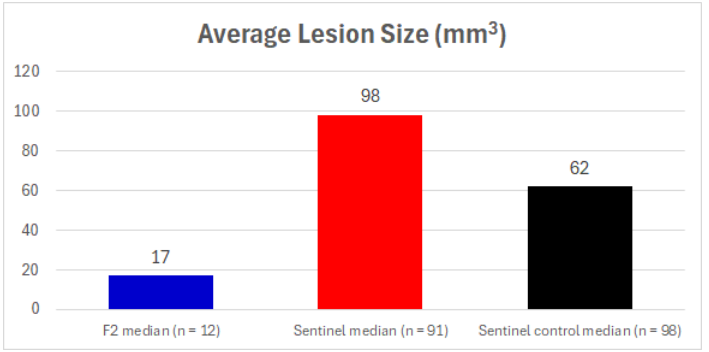


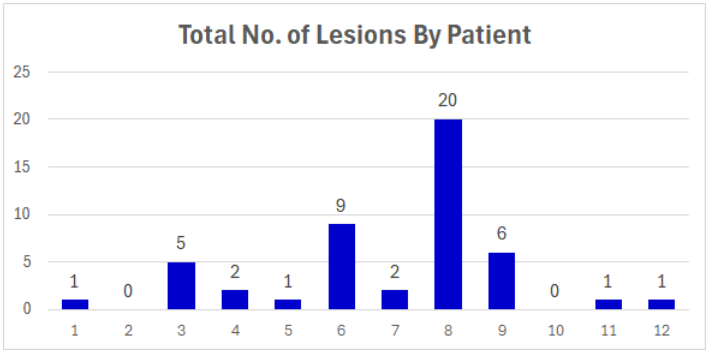
- 30-day MACCE rate 0%*
  - Death 0%, Stroke 0%, TIA 0%
  - No vascular complications

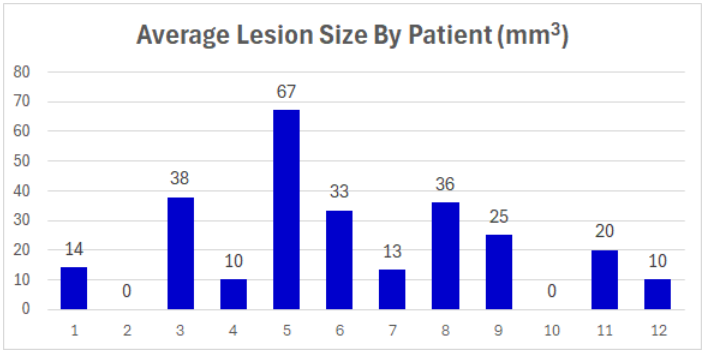
*CEC-adjudicated 30-day data available for 9 cases

EnCompass F_2 FIH Study MRI Results

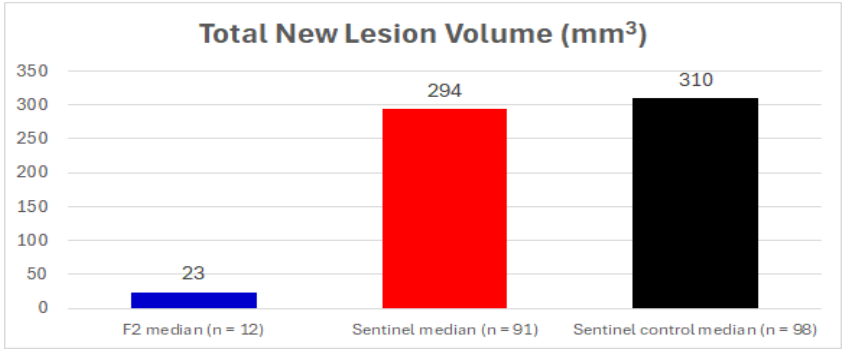


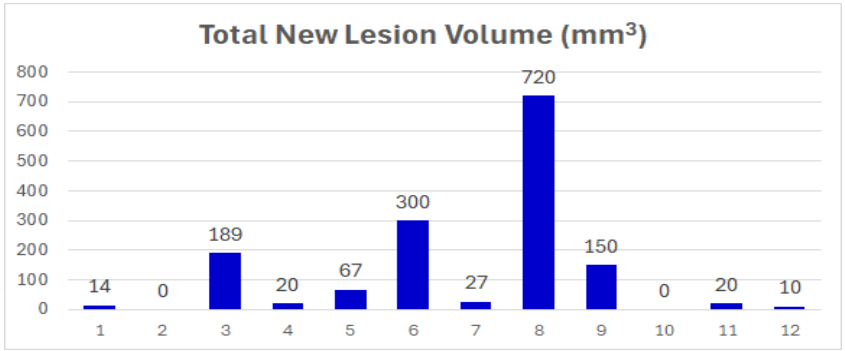






EnCompass F_2 FIH Study MRI Results



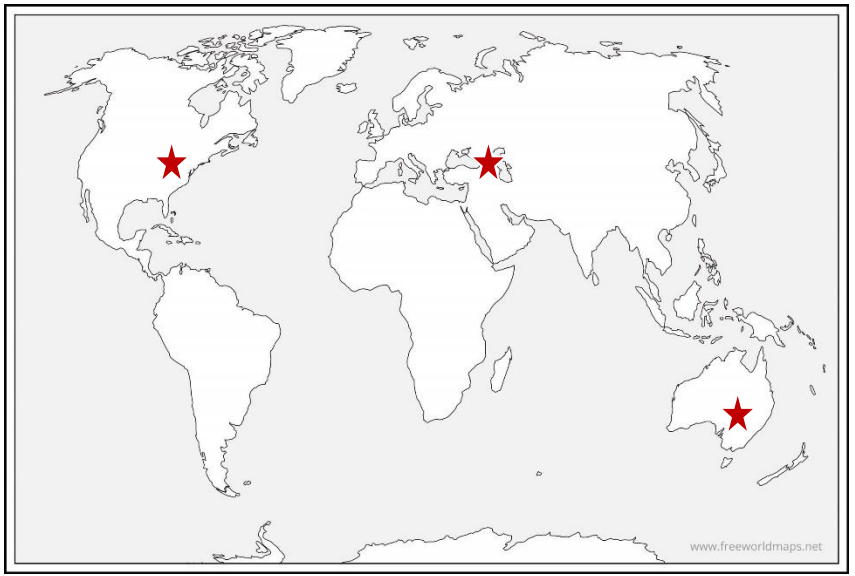


Kapadia SR. et al. J Am Coll Cardiol. 2017;69:367-377. FDA De Novo Summary (DEN160043).

EnCompass F2 Clinical Study Program

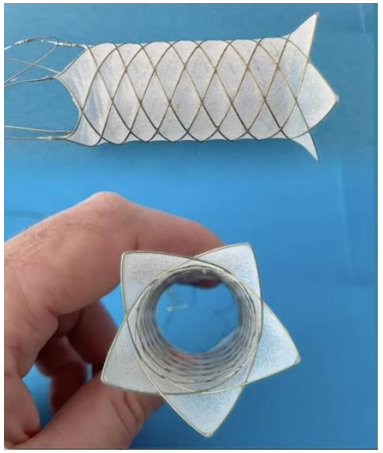
- EFS actively enrolling at 5 sites in Georgia and Australia
- ~40 cases performed to date

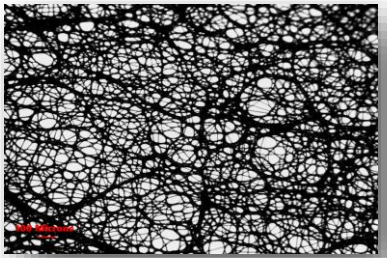
- EFS results will support planned US IDE pivotal trial



Conclusions

- The EnCompass F_2 is a novel CEPD that features a cylindrical nitinol frame and electrospun filter with very small pore size (30 um)
- In this FIH experience, 12 subjects underwent TAVR with the F_2 filter, and technical success was achieved in 100%
- The F_2 filter was safe with no 30-day MACCE
- DW-MRI results very favorable with median total new lesion volume 23 mm^3 and volume per lesion 14 mm^3, both much lower than historical control





F_2 Filter
(30 μm average pore size)

Thank you to the entire team!