FLOWer – The Complete Embolic Protection Device - Nautilus Study

FLOWer - Device Description

FLOWer is an innovative Embolic Protection Device ("EPD") by AorticLab **that filters and removes the debris normally released during TAVI procedures** without compromising the normal patient's blood flow

- 12Fr femoral access site
- CATCH&FLOW proprietary technology: advanced fabric with **mesh pore size of 60 µm** even captures the smallest embolic debris
- 3 sizes covering >95% of the aortic arch geometries

FLOWer contributes to performing **safer TAVI procedures** by reducing serious adverse events incidence

FLOWer CE Mark Nautilus Study

Safety Endpoints:
- MACCEs rate [Timeframe: 30 days]
- Cumulative occurrence of serious clinical events [Timeframe: 7 days and 30 days]

Performance Endpoints:
- Technical success & system usability [Time Frame: immediately after procedure]
- Debris capture post-TAVI by **FLOWer** with gross and histopathological evaluation including particle size and composition

Clinical Benefit Endpoints:
- Brain imaging (DW-MRI) [Timeframe: within 2-5 days after procedure vs. baseline].
- Neurocognitive protection assessed by NIHSS, Montreal Cognitive Assessment and mRS [Timeframe: 2-7 days and 30-days vs. baseline]

75 pts enrolled in 7 Centers in EU — CE MARK

First **23** Pts — TAF - Early safety assessment

Completion **52** Pts — FLOWer Early safety assessment

Investigators	
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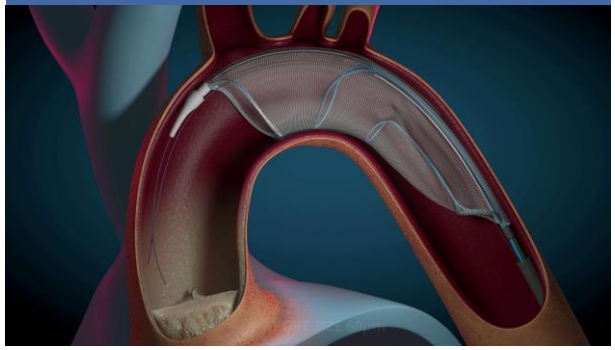
Matteo Montorfano - Milan, Italy	5
Eugenio Stabile – Potenza, Italy	4
Elvin Kedhi - Brussels, Belgium	3
Pierfrancesco Agostoni - Antwerp, Belgium	2

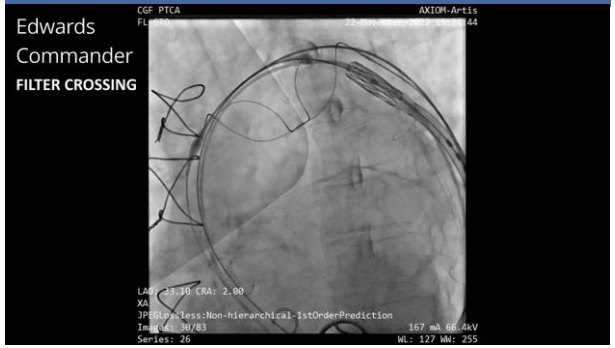
TAVI Models	
Accurate Neo - Boston Sci.	28
Evolut R/PRO - Medtronic	21
Portico/Navitor - Abbott	14
Sapien 3 – Edwards LS	9
Myval - Meril	2

Nautilus Study involved **TOP centers** in Italy and Belgium
FLOWer device is used in combination with all TAVI devices available in EU Market

Protected TAVI Procedural Video

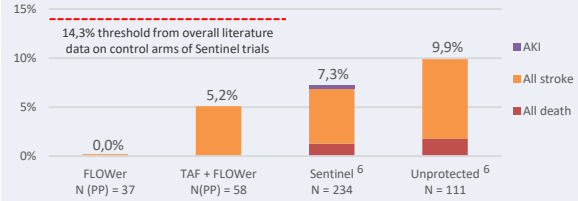


Case in the Box



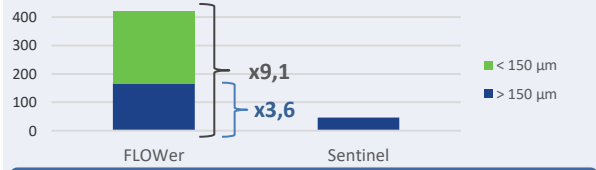
Nautilus Trial – Interim Study Results[1]

MACCE rate @ 30 days follow-up[3]



Nautilus trial overall MACCE 30 days events rate is promising compared to literature data from a predicate device.

Average number of debris captured per filter (15 pts)[2]



FLOWer captures 9 times more debris than Sentinel
(3,6 times more debris over 150 µm) with an average of 420 debris/filter

Additional Interim Study Results[1]

Vascular access compl.: 0 (0.0%)[5]
Avg. Positioning time: 2,5 min[7]
Optimal stability[7]

72h Disabling Stroke: 0 (0.0%)[7]
72h Non-Disabling Stroke: 1 (1.5%)[7]
30 Days Disabling Stroke: 0 (0.0%)[4]
30 Days Non-Disabling Stroke: 3 (5.2%)[4]

Conclusion

Nautilus Study MACCE outcomes at 30 days show that **FLOWer is safe and effective** in catching emboli as small as 60 µm. It can be a **great ally for cardiologists to minimize the risk of stroke during TAVI**, without adding additional time to the procedure. **FLOWer** remains stable in the aortic arch during TAVI procedures **protecting the brain and the peripheral organs**.

1: 30 days Follow-up not completed for all the patients, calculation on Per Protocol population
2: Histopathological analysis from CVPath Institute Inc.
3: Rate of Major Adverse Cardiac and Cerebrovascular Events (MACCEs) related to FLOWer device and procedure as adjudicated by a Clinical Event Committee. [Timeframe: 30 Days]
4 : 58pts PP
5: 75pts
6: Sentinel IDE Trial
7: 66pts PP