

NAUTILUS STUDY



A single-arm, prospective, multicenter non-randomized clinical study



To assess the **safety** and **performance** of **AorticLab FLOWer® EPD**, in preventing cerebral thromboembolic complications during TAVI procedure



76 patients enrolled



7 sites in Europe

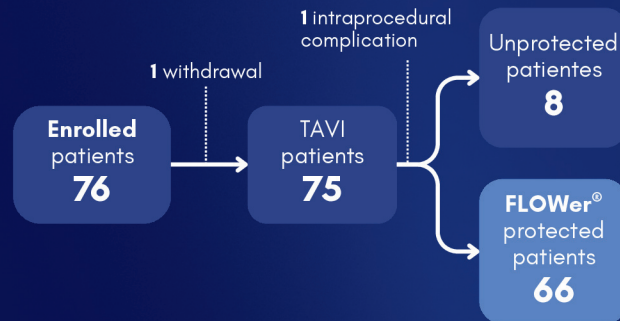


AORTICLAB

FLOWer

WITH CATCH & FLOW TECHNOLOGY

Discover
FLOWer®
Scan to explore
clinical data,
technology and
product information



Baseline patients demographic data

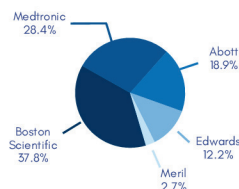
		ITT 75		PP 66	
Gender (N(%))	N				
Gender (N(%))	Female	41	54.7%	36	54.5%
	Male	34	45.3%	30	45.5%
Age at Enrollment (years)	Mean	81.6		81.3	
	SD	6.0		6.0	
	Min	63		63	
	Max	96		96	

ITT: Intention to Treat; PP: Per Protocol

Sites and number of patients

Policlinico di Monza, Italy	33
Policlinico San Donato, Italy	15
IRCCS San Raffaele, Italy	5
Centro Cardiologico Monzino, Italy	14
Azienda Ospedaliera San Carlo, Italy	4
Erasmus Hospital, Belgium	3
ZNA Middelheim, Belgium	2

TAVI platforms used



Distributor



AORTICLAB
YOUR HEART, YOUR TRUST, OUR MISSION

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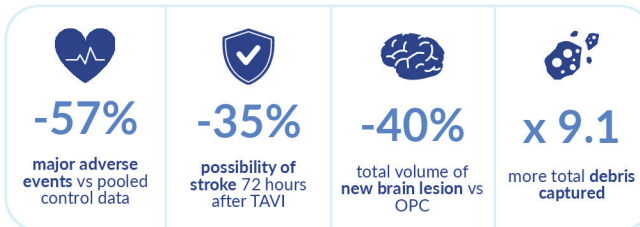


EMBOLIC PROTECTION DEVICE
FOR **TAVI** AND OTHER
TRANSCATHETER
CARDIOVASCULAR
PROCEDURES

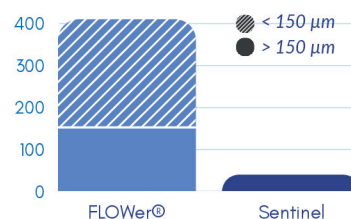
THE NEW FRONTIER OF EMBOLIC PROTECTION



STUDY RESULTS



Debris captured



FLOWer® filter gets:

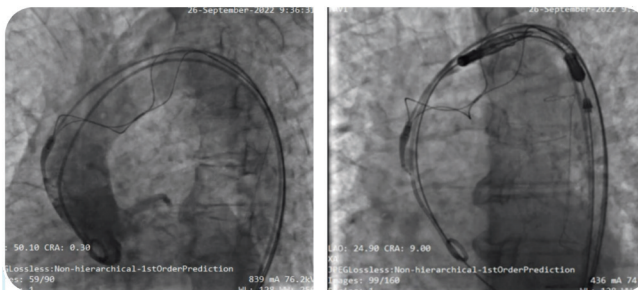
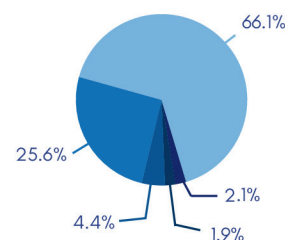
x 3.6
more >150 µm debris captured

x 9.1
more total debris captured

Comparison of total number of particles captured by FLOWer and by Sentinel. (26 FLOWer® and 100 Sentinel filters analyzed by CVPPath Institute Inc (Gaithersburg, MD, USA)

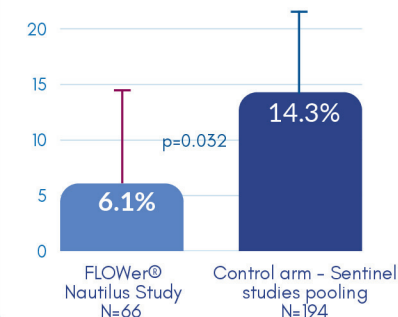
Distribution of particle dimensions captured by FLOWer®

- >2000µm
- 1000-2000µm
- 500-1000µm
- 150-500µm
- <150µm



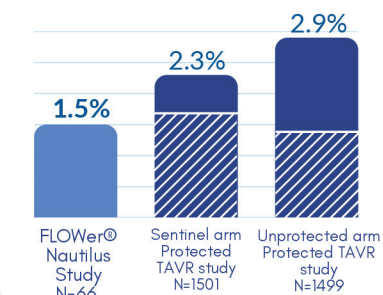
In a subset of patients, angiographic assessments were carried out by Dr. Alexandra Lansky (Yale University, USA) and shown an **excellent FLOWer® positioning, stability and wall apposition**

MACCE rate @30 days



MACCE rate (all death, all stroke, AKI) @30 days shows statistical significance (p=0.032) against the rate of the unprotected control arm of pooled Sentinel studies (CLEAN TAVI, MISTRAL-C and SENTINEL IDE)

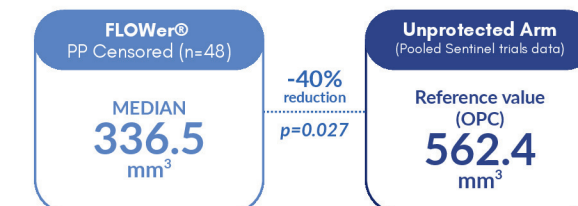
Stroke Rate at 72 hours after TAVI



Occurrence of disabling and not disabling strokes at 72 hours in FLOWer® protected population of Nautilus study compared to data from PROTECTED TAVI study (Sentinel device)

- Stroke not disabling
- Stroke disabling

Total volume of New Brain Lesions



Total new brain lesions volume in FLOWer® protected censored population in Nautilus study showed statistical significance (p= 0.027) against the selected Objective Performance Criteria (OPC).

Sources

(1) FLOWer - The Complete Embolic Protection Device - Nautilus Study.

EuroPCR 2023

(2) FLOWer Instruction for Use