

# Single-operator Implantation of the New Generation Vitaflow Liberty valve for Efficient Transcatheter Aortic Valve Implantation: The SINGLE-TAVI Study

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# Disclosure of Relevant Financial Relationships

I, Filippo Pensotti, DO NOT have any financial relationships to disclose.

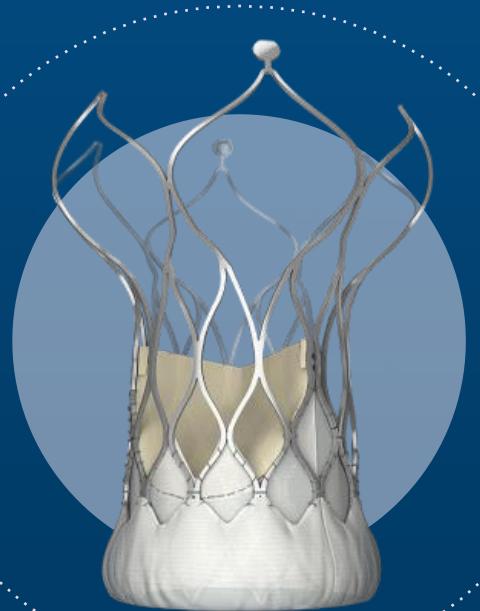
# Background: VitaFlow Liberty TAV

## *Supra-annular design*

- Preserves annulus circularity
- Large EOAs and low gradients

## *Tubular Shaped Frame*

- Large EOA



## *PET double layer skirt design*

- Reducing perivalvular leakage

## *Bovine pericardial leaflets*

# Background: VitaFlow Liberty Delivery System

## *Motorized delivery system*

### *Motorized handle*

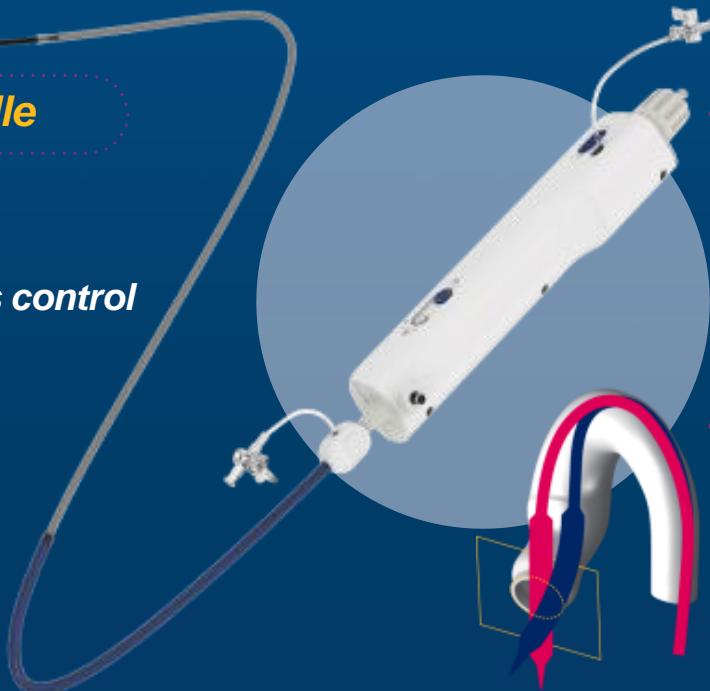
- Stable position during deployment
- Allows simultaneous control of guidewire during deployment

### *Accurate repositioning*

- Recapturable and repositionable to 75%

### *Capsule with 360°range of motion*

- Flexibility for coaxial alignment and valve positioning



# The single operator technique

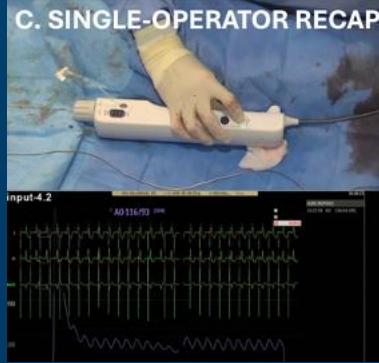
A. SINGLE-OPERATOR RELEASE



B. HIGH POSITION



C. SINGLE-OPERATOR RECAPTURE



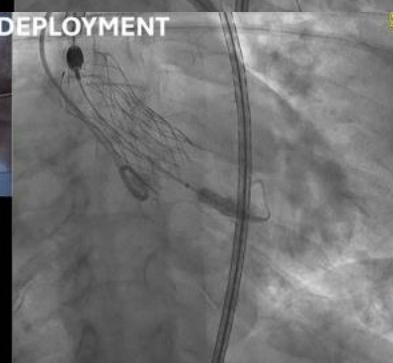
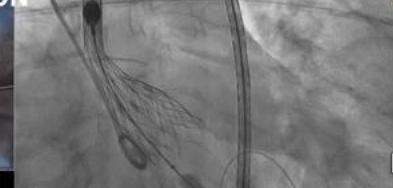
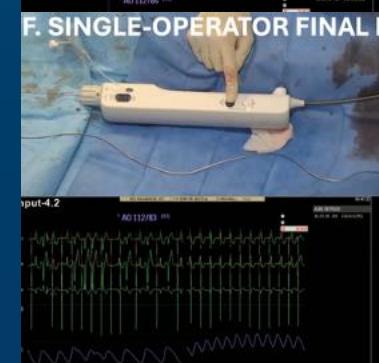
D. APPROPRIATE HEIGHT



E. REMOVAL OF WIRE TENSION



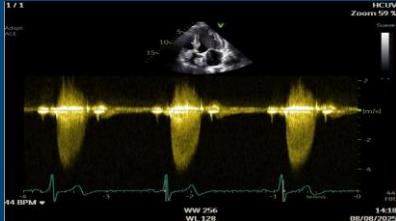
F. SINGLE-OPERATOR FINAL DEPLOYMENT



# Baseline characteristics

Variable	Global study population N=103
<b>CLINICAL CHARACTERISTICS</b>	
Age (years)	80.5 ± 5.9
Female sex	40 (38.8%)
Weight (kg)	72.0 ± 11.2
Height (m)	1.62 ± 0.12
EuroSCORE II (%)	3.4 ± 2.2
STS PROM (%)	3.8 ± 2.1
NYHA III-IV	23 (22.3%)
Angina CCS III-IV	7 (6.8%)
Previous Sincope	9 (8.7%)
Dialysis	9 (8.7%)
History of cancer	8 (7.8%)
Atrial fibrillation	47 (45.6%)
Peripheral artery disease	10 (9.7%)
Prior stroke	13(12.6%)
Previous Right Bundle Branch block	20 (19.4%)
Prior pacemaker	9 (8.7%)
Prior CABG	3 (2.9%)
Prior PCI	12 (11.7%)
Prior valve surgery (ViV candidate)	2 (1.9%)

# TTEcho and CT features



Variable	Global study population N=103
<b>ECHOCARDIOGRAPHIC CHARACTERISTICS</b>	
LVEF (%)	53.1 ± 13
Mean gradient (mmHg)	44.4 ± 11.6
AVA (cmq)	0.78± 0.19
Aortic Regurgitation III-IV	30 (19.1%)
Mitral Regurgitation III-IV	28(27.2%)
Tricuspid Regurgitation III-IV	11 (10.7%)
<b>COMPUTED TOMOGRAPHY CHARACTERISTICS</b>	
Aortic annular perimeter (mm)	76.4± 9.5
Perimeter Derived Diameter (mm)	23.9± 3.2
Aortic annular area (mm <sup>2</sup> )	458.6 ± 114
Maximum Annulus Diameter (mm)	26.0 ± 3.3
Minimum Annulus Diameter (mm)	21.8 ± 3.1
Mean Annulus Diameter (mm)	23.5± 2.8
Maximum Sinuses of Valsalva Diameter (mm)	33.6± 5.1
Minimum Sinuses of Valsalva Diameter (mm)	31.4+ 4.7
Agatston units	3138 ± 1743
Bicuspid valve	37 (35.9%)
Left main height (mm)	14.6± 2.8
Right coronary artery height (mm)	15.4± 3.5
Mean Right Femoral Artery (mm)	8.1± 0.9
Mean Left Femoral Artery (mm)	7.9± 1.1



# Procedural and In-Hospital outcomes



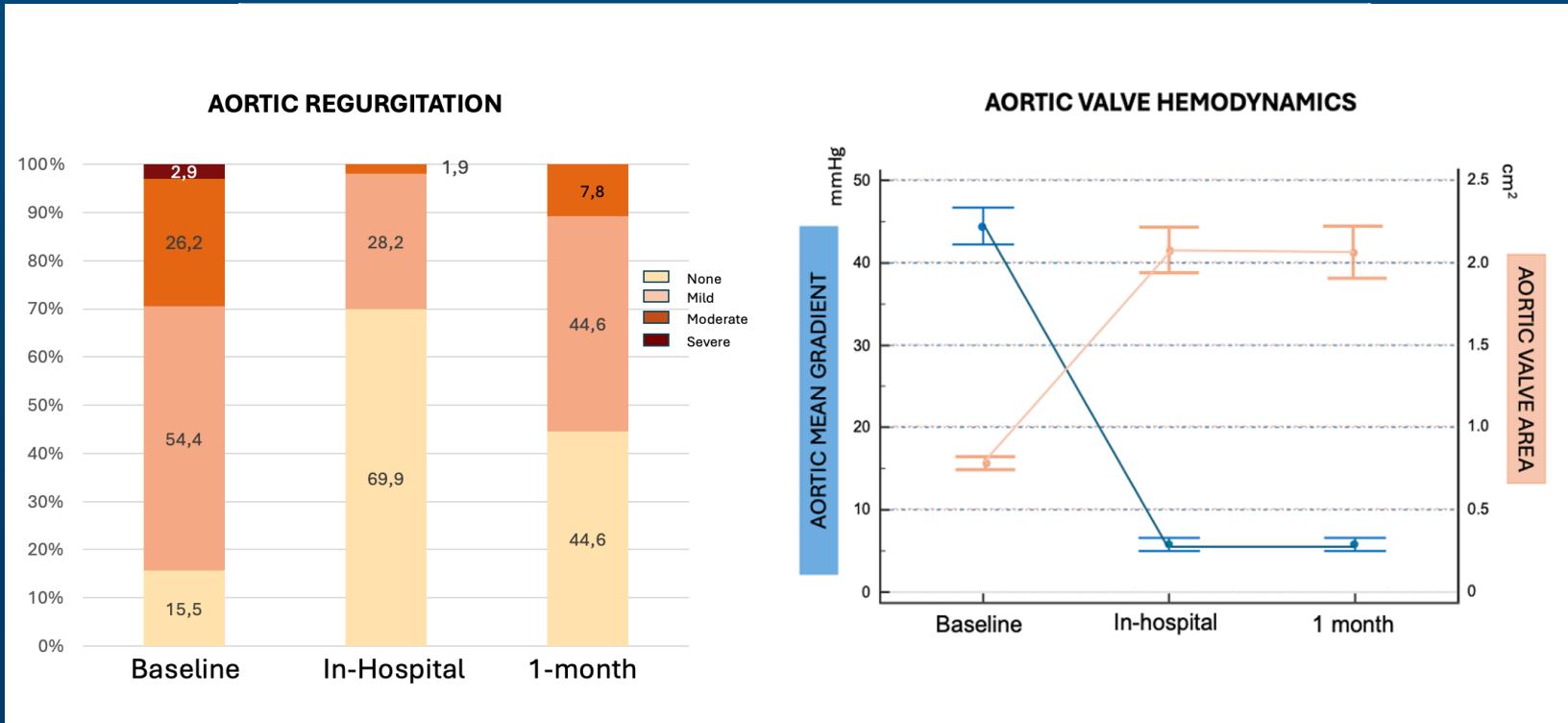
## PROCEDURAL CHARACTERISTICS

Femoral Access	103 (100%)
Pre-Dilatation (Yes)	69,9%
Valve Size	
24 mm	39 (37.8%)
27 mm	34 (33%)
30 mm	31(29.1%)
Need for Second Operator Bailout	8 (7.8%)
Post-Dilatation (Yes)	11 (10.7%)
Annulus Rupture (Yes)	0 (0%)
Coronary Occlusion (Yes)	0(0%)
Valve Embolization (Yes)	5 (4.9%)
Minor Vascular Complications (Yes)	10 (9.7%)
Minor Intraprocedural Bleeding (Yes)	9 (8.7%)
Technical Success (Yes)	98 (95,1%)
Procedure Duration (min)	64.7± 42.1

## IN-HOSPITAL OUTCOMES

In-Hospital Death	0 (0%)
Permanent Pacemaker Implantation (Yes)	23 (22.3%)
Acute Kidney Injury (Yes)	10 (9.7%)
Cerebrovascular Events (Yes)	0 (0%)
LVEF (%)	53.5± 12.3
Mean gradient (mmHg)	5.8 ± 3.9
AVA (cmq)	2.0± 0.6
Aortic Paravalvular Regurgitation III-IV	2 (1.9%)
Mitral Regurgitation III-IV	21 (20.4%)
Tricuspid Regurgitation III-IV	8 (7.8%)
TAPSE	18.2± 3.3

# 30-day Outcomes and Valve Performance



# Take Home Messages

- Single-operator TAVR is feasible and safe with the VitaFlow Liberty system
- Excellent valve performance with low gradients and minimal paravalvular leak
- Streamline the procedure, reduce its complexity, and optimize resource utilization, “PCI”-like procedure