



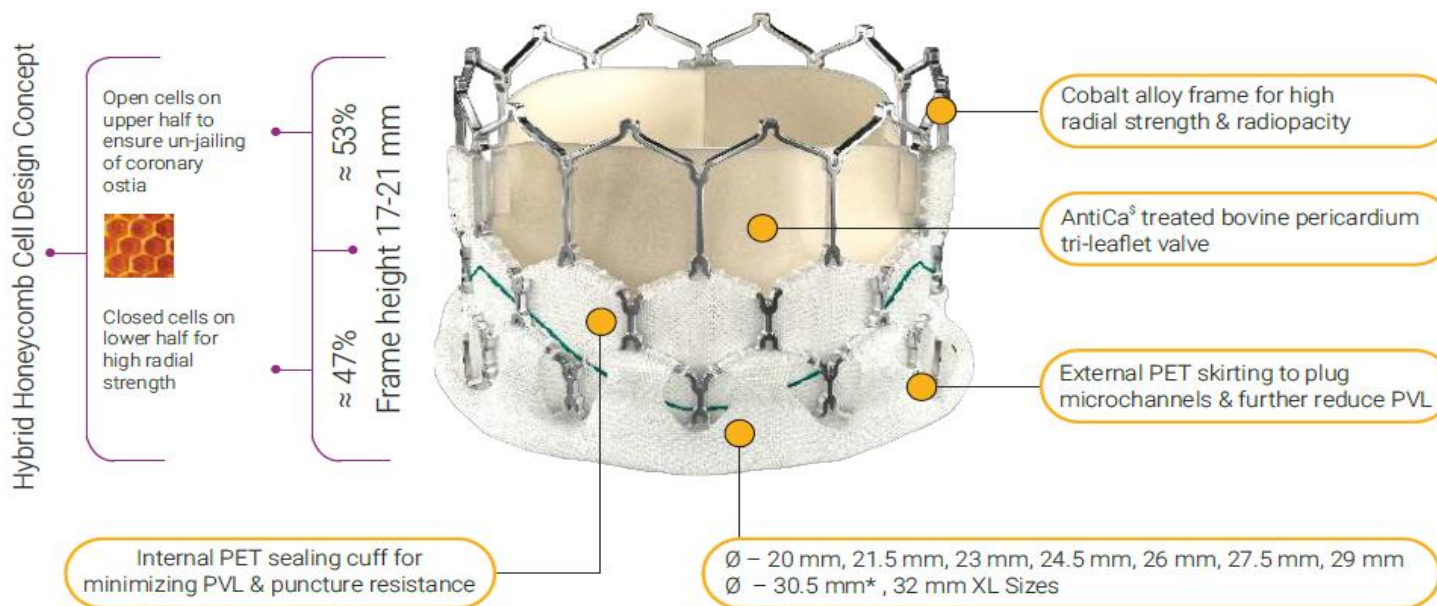
# TAVI Myval Meril Lifesciences



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## Myval THV: Designed for Precision in Outcomes



Myval THV has been indigenously developed by Meril Life Sciences Pvt. Ltd.

AntiCa<sup>s</sup> - Meril's proprietary anti-calcification treatment technology  
All Myval THV sizes are currently CE approved.  
\*30.5 mm is currently awaiting CDSCO approval

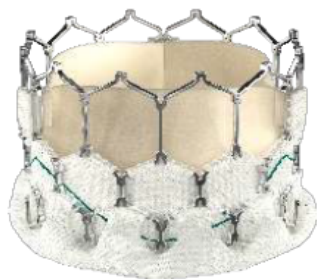
**CE Marked April 2019**

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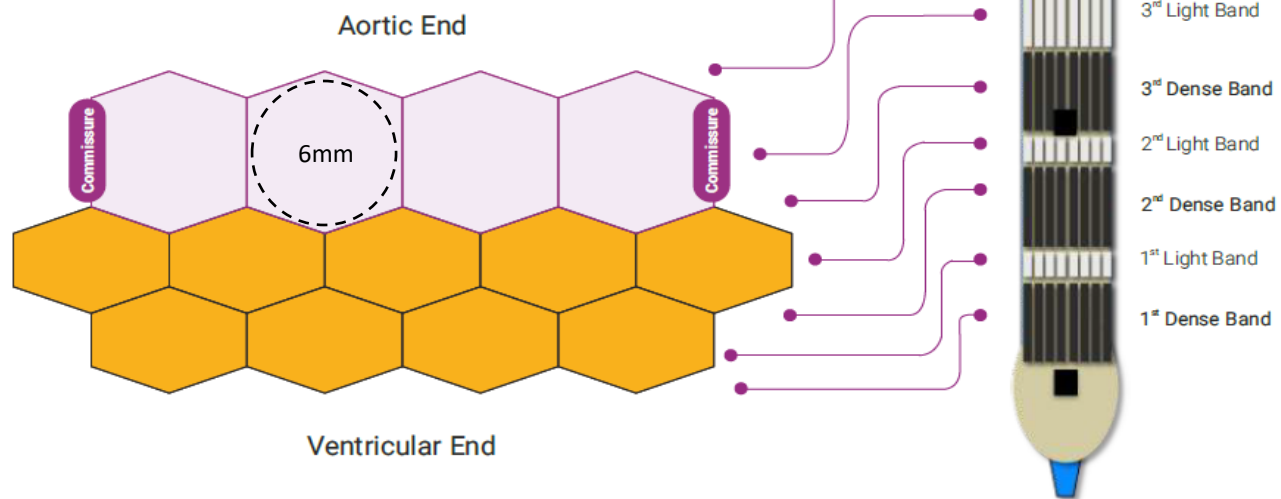
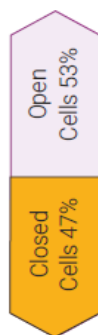
## Myval THV: Unique Crimping Outcome



### Upon Crimping:

- V-shaped hinges on hexagonal frame fold, generating the dense bands on fluoroscopy
- Vertical connectors 'I' give rise to light bands
- Alternating V-folds & vertical connectors give Myval THV a unique 'Zebra Crossing' appearance on fluoroscopy for ease of positioning

Largest circumscribable diameter in Open Cell (for all Myval THV Diameters 20mm to 32mm)



Myval THV is recommended to be crimped over Navigator THV Balloon Delivery System prior to insertion within patient's vasculature.



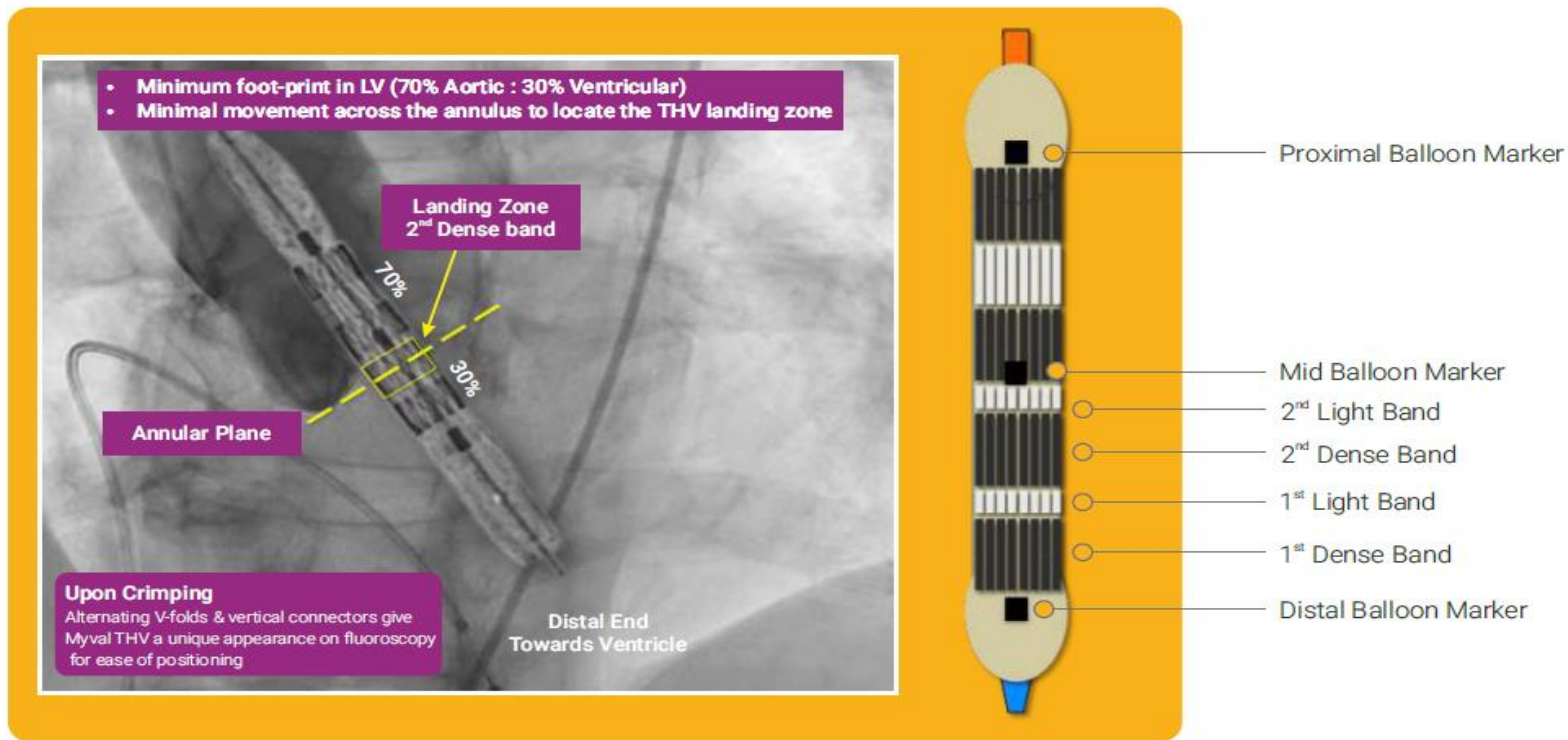
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## Myval THV: Precise Placement Technique

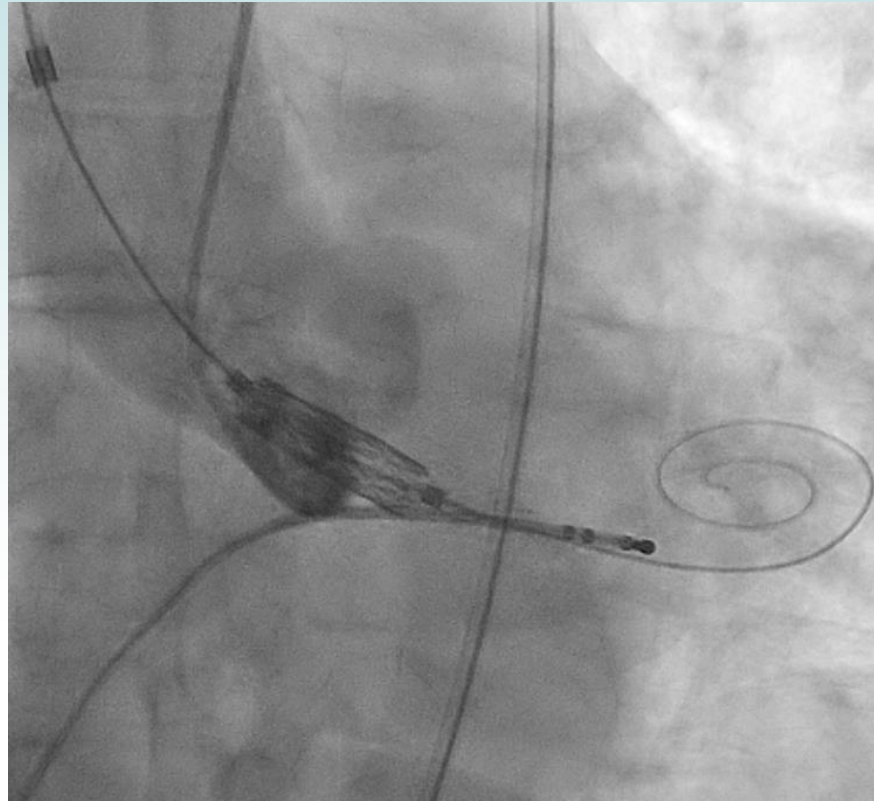
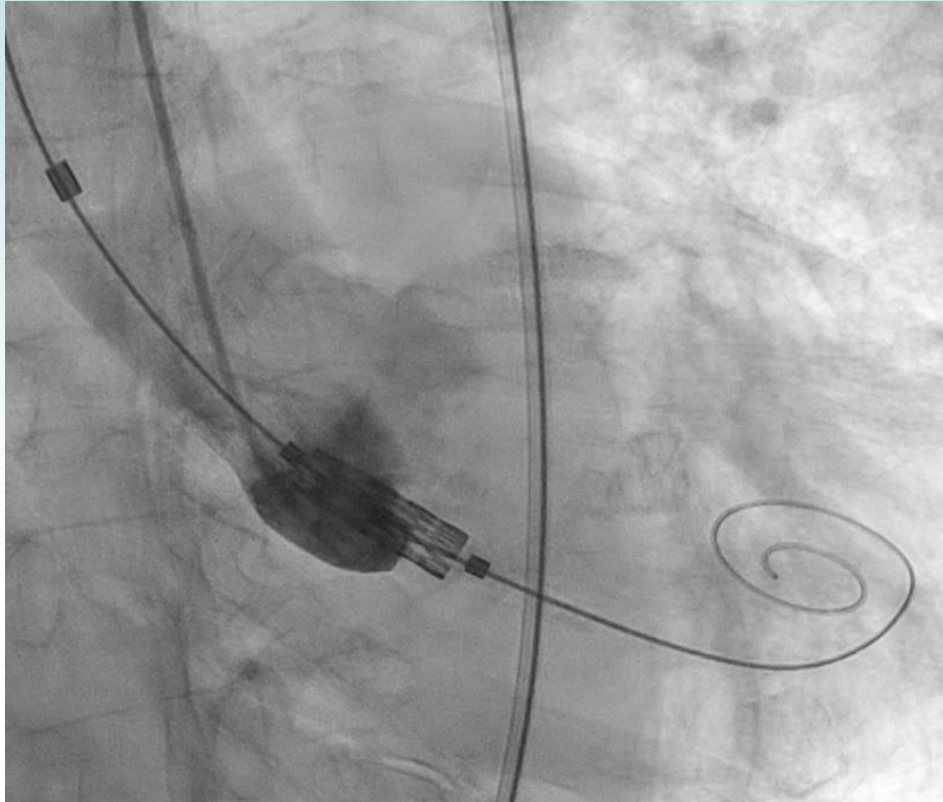
Schematic of Myval THV - Ideal Landing Zone



Elimination of THV frame parallax promptly ensures visualisation of characteristic dark-light bands







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# Size chart of Myval THV



Myval THV size (mm)	TEE annulus size (mm)	MSCT derived Native annulus area (mm <sup>2</sup> )	MSCT Area-derived diameter (mm)
20.0	16.0-19.0	270-330	18.5-20.5
21.5	17.5-20.5	314-380	20.0-22.0
23.0	18.0-22.0	360-440	21.4-23.7
24.5	19.5-23.5	410-500	22.8-25.2
26.0	21.0-25.0	460-560	24.2-26.7
27.5	22.5-26.5	510-630	25.5-28.3
29.0	24.0-28.0	570-700	26.9-29.9

MSCT: multi-slice computed tomography; TEE: Transesophageal Echocardiogram; THV: transcatheter heart valve.

2	2	2	3	3	3	3	3	3	3	4	4	4	4	4	5	5	5	5	5	6	6	6	6	7	7	7	7	8	8
7	8	9	1	1	3	4	5	6	8	0	1	4	5	6	0	1	2	6	7	2	3	5	6	0	6	7	8	0	4
0	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20								23								26				29				32					
								21.5				24,5				27.5				30.5									



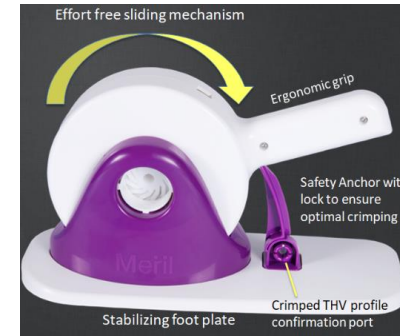
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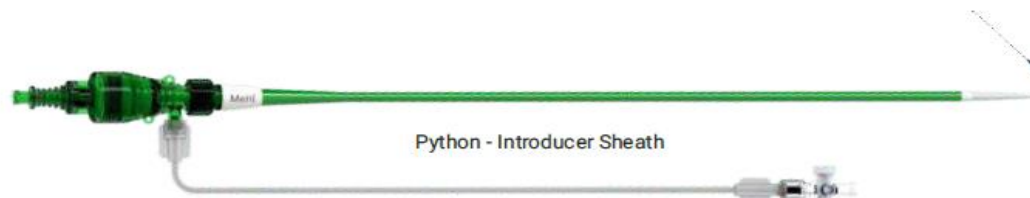
## Myval THV System and Components



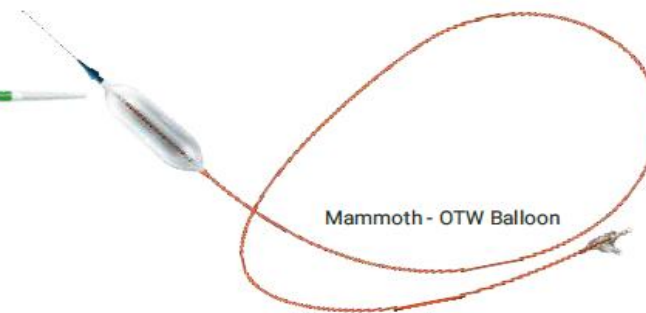
Myval - THV



Navigator - THV Delivery System



Python - Introducer Sheath



Mammoth - OTW Balloon

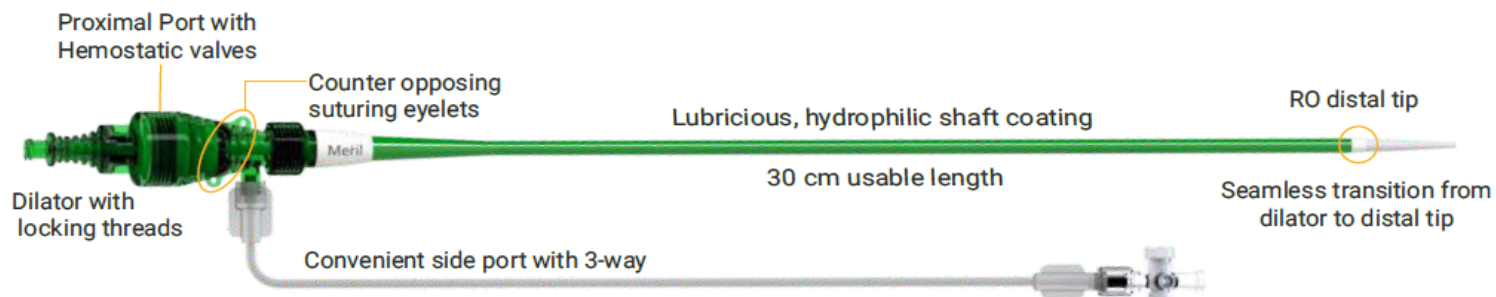


## 14Fr Python – Introducer Sheath Compatible with all Myval THV diameters (20 mm to 32 mm)

Sheath expands momentarily like a python swallowing its prey  
Conveniently allows passage of crimped Myval THV System

14Fr Entry Profile, Allows Atraumatic Percutaneous Access

**High convenience for full retrievability of an un-deployed Myval THV System**



Two separate, calibrated loading tubes ensure temporary opening of hemostatic valves in proximal port allowing smooth passage of crimped Myval THV System

Common Femoral Artery* Ø (mm)	Myval THV Ø (mm)
≥ 5.50 mm	20 mm, 21.5 mm, 23 mm, 24.5 mm
≥ 6.00 mm	26 mm, 27.5 mm, 29 mm
≥ 6.50 mm	30.5 mm, 32 mm

\*CFA Ø must be MSCT derived. Excluding circumferential Ca<sup>2+</sup>

Python - Introducer Sheath has been indigenously developed by Meril Life Sciences Pvt. Ltd.



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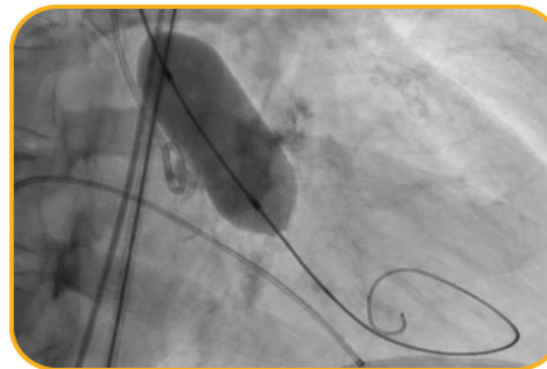
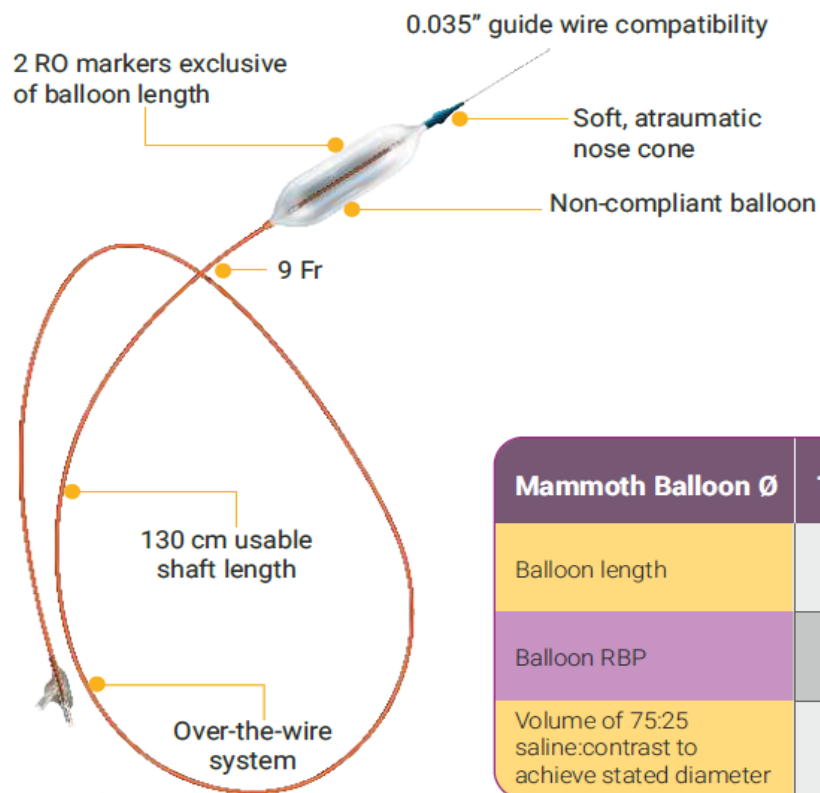
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## Mammoth - OTW Balloon Catheter

It is not mandatory to pre-dilate the native annulus prior to Myval THV implantation.  
Operators may consider pre-dilatation based on anatomical considerations.



Mammoth Balloon Ø	14 mm	16 mm	18 mm	20 mm	23 mm	25 mm
Balloon length	← 40 mm →					
Balloon RBP	← 6 atm →					
Volume of 75:25 saline:contrast to achieve stated diameter	7 ml	10 ml	13 ml	16 ml	23 ml	25 ml

Mammoth – OTW Balloon Catheter has been indigenously developed by Meril Life Sciences Pvt. Ltd.



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## Navigator THV Delivery System Delivering TAVI Made Easy

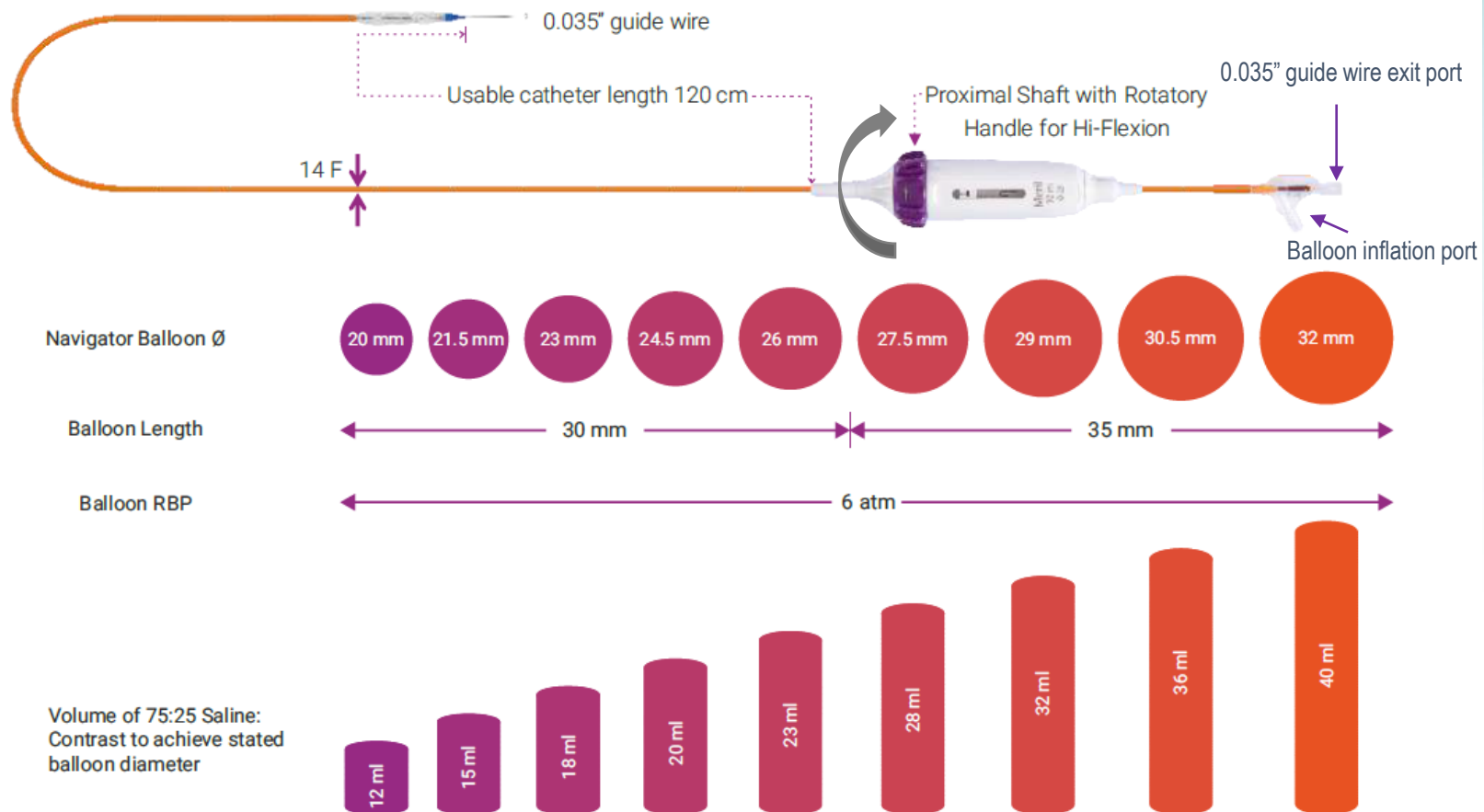
- Myval THV is recommended to be crimped over Navigator THV Delivery System prior to insertion within patient's vasculature.
- The crimped valve with delivery system is then loaded through 14Fr Python – Introducer Sheath.



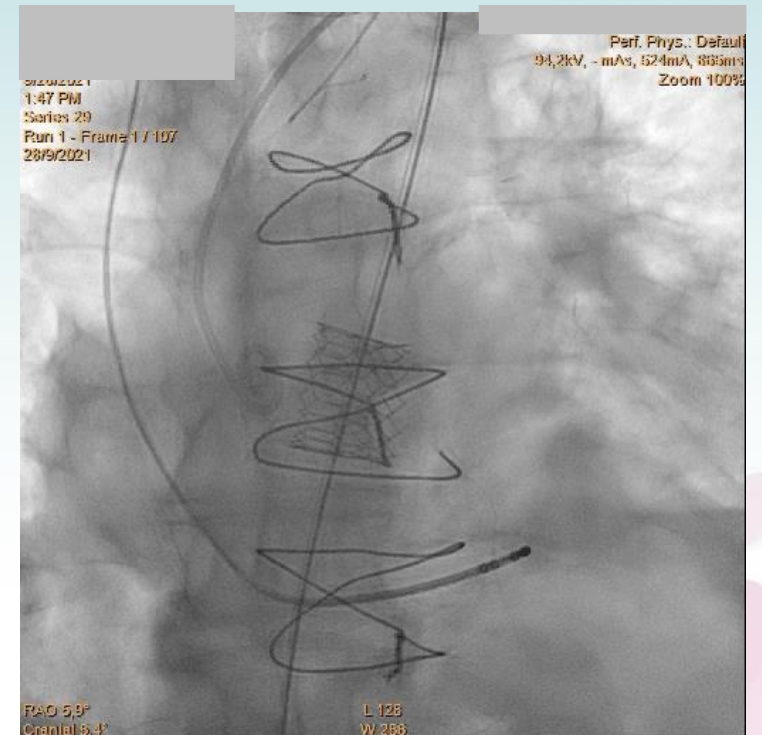
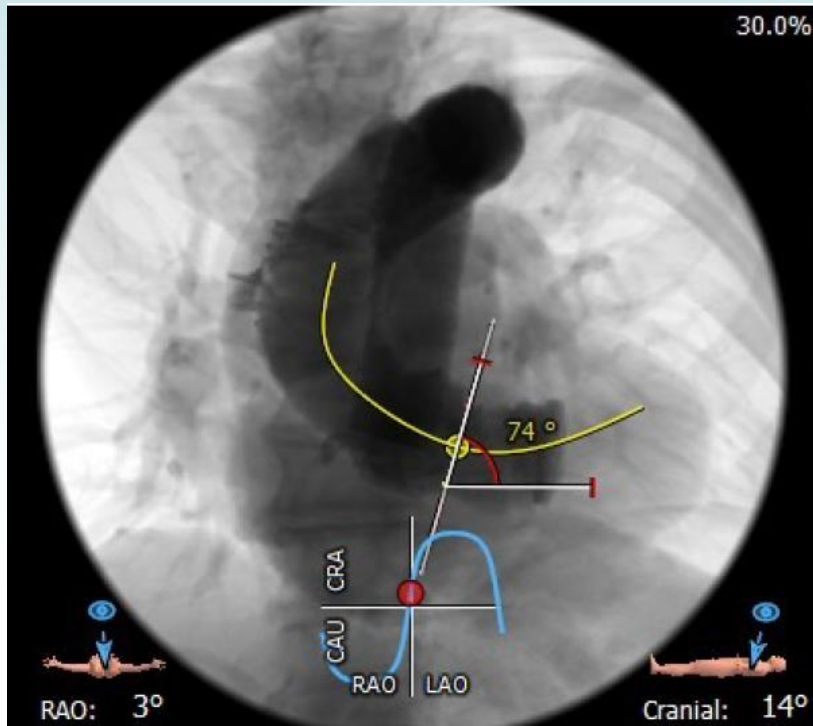
- Navigator delivery system has a set of proximal and distal stoppers which ensure that valve crimping is precise and snug.
- Visual confirmation of crimped valve can be ensured before entering the sheath to avoid any crimping errors/defects.
- The stoppers prevent inadvertent migration of the valve & ensure there is no risk of valve dislodgement (embolization) during entry through the sheath or while negotiating the loaded delivery system across the aorta.
- Myval THV direct crimping on the balloon makes TAVI delivery simple, intuitive and eliminates unwarranted procedural steps.



## Navigator THV Delivery System





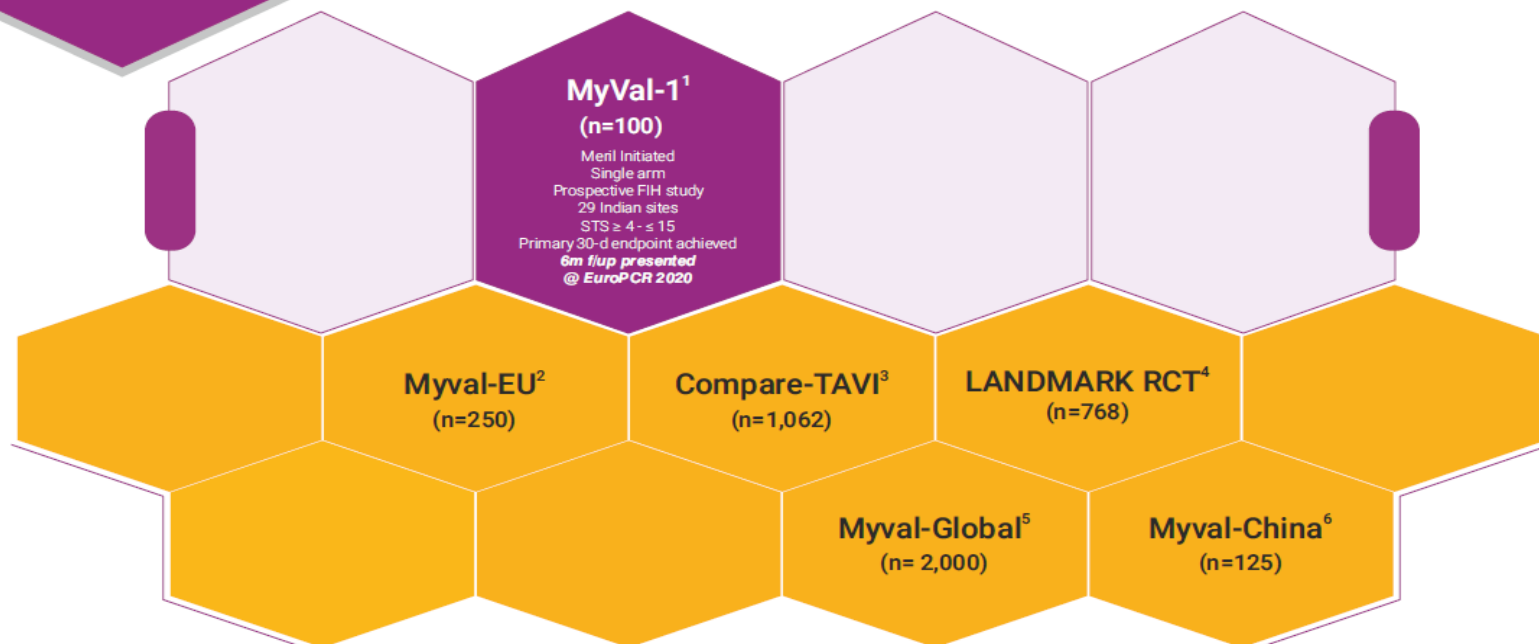


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## Myval THV: Global Clinical Program



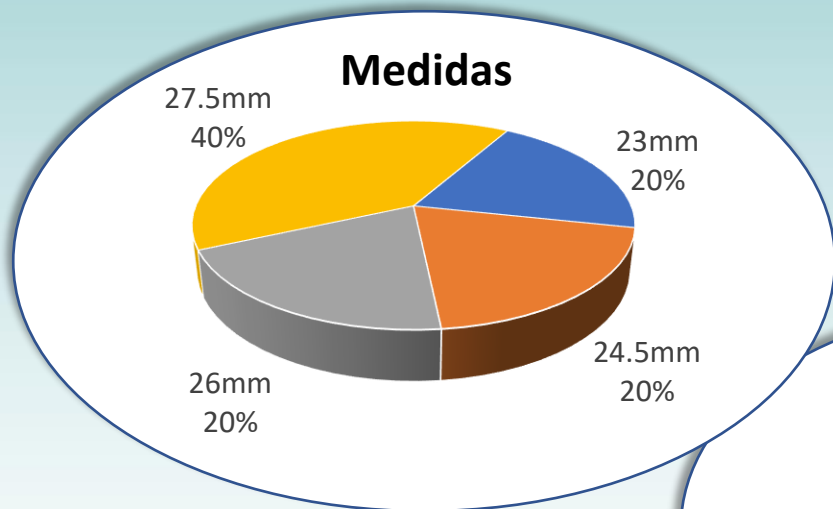
<sup>2</sup> Meril Initiated Single arm	<sup>3</sup> Investigator Initiated RCT – 1:1 Myval : Sapien 3 THV	<sup>4</sup> Meril Initiated RCT – 2:1:1 Myval : Sapien : Evolut THV series	<sup>5</sup> Meril Initiated Single arm	<sup>6</sup> Meril Initiated Single arm
Retrospective EU Registry	Prospective study	Prospective study	Prospective study	Prospective study
20 EU sites	10 Nordic + EU sites	50+ EU/ANZ sites	100 Global sites	10 China sites
Real world STS	Real world STS	Real world STS	Real world STS	Real world STS
Data collection in progress <b>30-day f/up est.</b> @ EuroPCR 2021	Enrollment has started <b>1-year f/up est.</b> @ EuroPCR 2023	EC/IRB approvals in progress <b>First patient first visit est.</b> @ QIV 2020	Under planning <b>First patient first visit est.</b> @ QIII 2021	Pre-study activities initiated <b>First patient first visit est.</b> @ QI 2022



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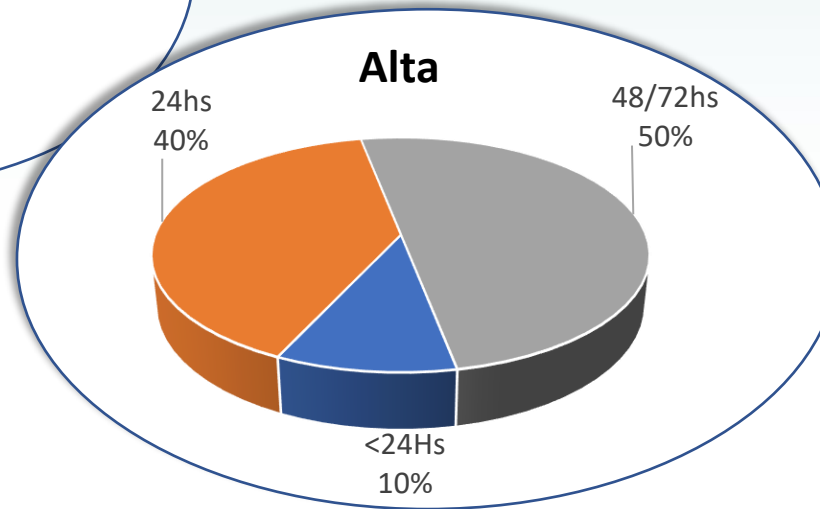
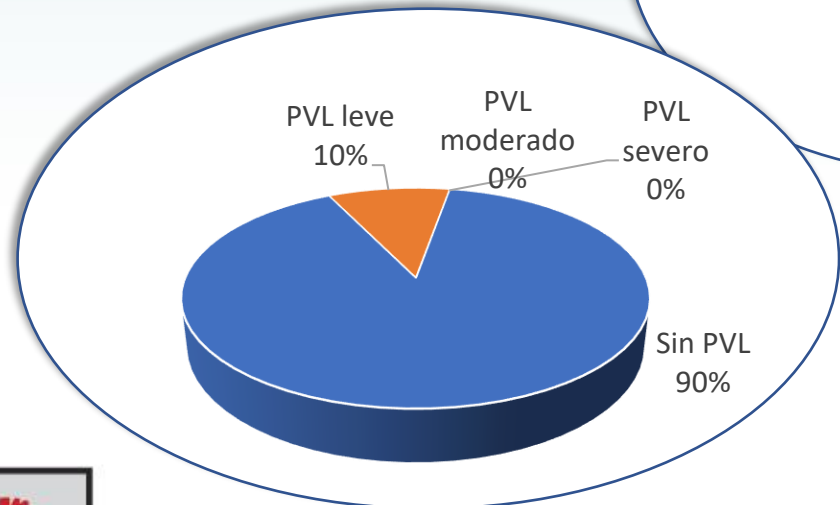




**0% Tasa de marcapasos**

**0% Complicaciones vasculares**

**10 pacientes**





Muchas gracias !!!  
Zemp Laura  
Especialista Clínica



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