Myval™

TRANSCATHETER HEART VALVE

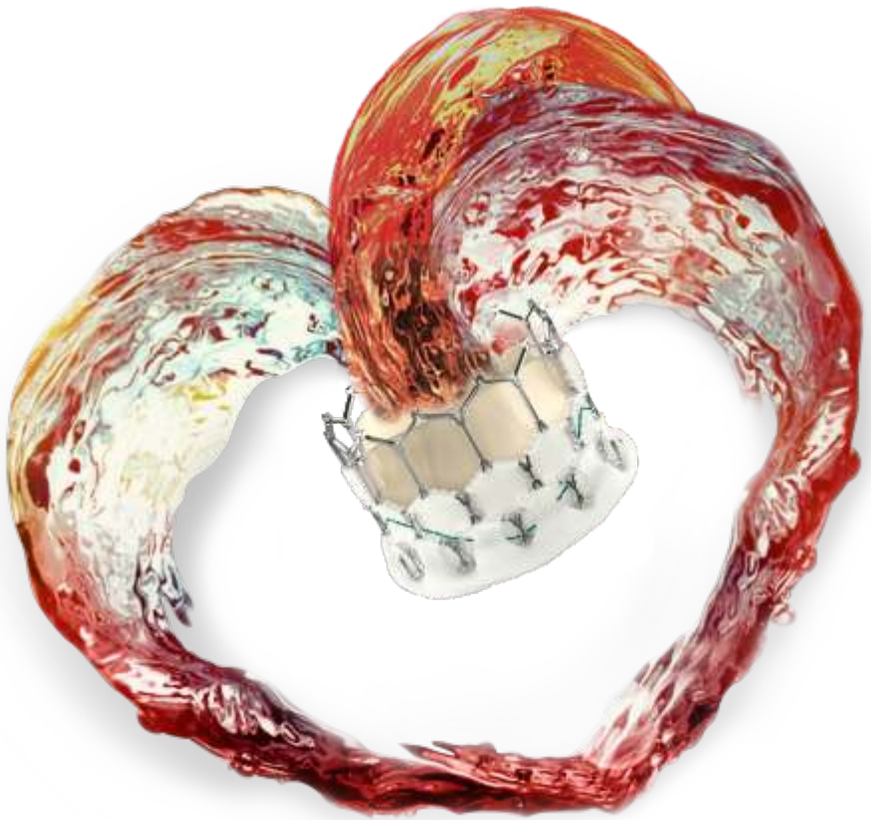
PRECISION AT HEART

Meril

CE APPROVED

At the heart of life.
At the heart of precision.

Myval™
TRANSCATHETER HEART VALVE
PRECISION AT HEART



MyVal-1 Study
6-month Outcome

Low* Device Related Mortality
Incidence of Stroke
New Permanent Pacemaker

*6-month outcome data presented by Dr. Ravinder Singh Rao at PCR e-Course 2020.

Myval THV: Designed for Precision in Outcomes

Hybrid Honeycomb Cell Design Concept

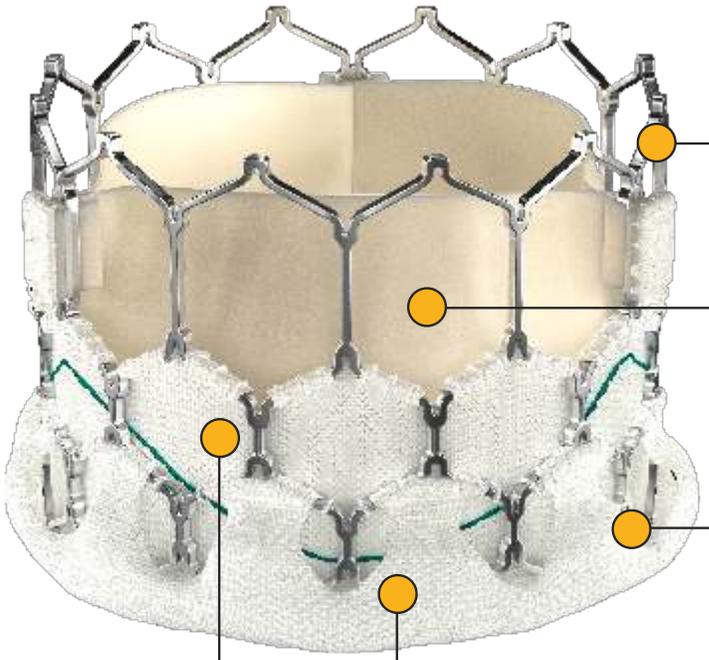
Open cells on upper half to ensure un-jailing of coronary ostia

Closed cells on lower half for high radial strength

≈ 53%

≈ 47%

Frame height 17-21 mm



Cobalt alloy frame for high radial strength & radiopacity

AntiCa[$] treated bovine pericardium tri-leaflet valve

External PET skirting to plug microchannels & further reduce PVL

Internal PET sealing cuff for minimizing PVL & puncture resistance

Ø – 20 mm, 21.5 mm, 23 mm, 24.5 mm, 26 mm, 27.5 mm, 29 mm
Ø – 30.5 mm , 32 mm XL Sizes

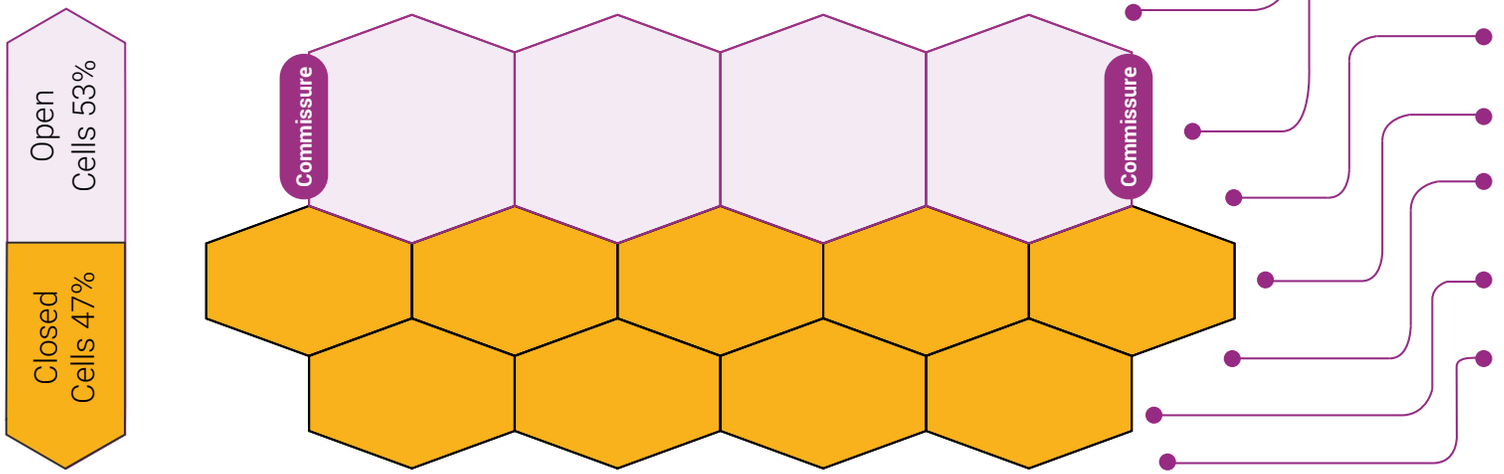
Myval THV has been indigenously developed by Meril Life Sciences Pvt. Ltd.

AntiCa[$] - Meril's proprietary anti-calcification treatment technology
All Myval THV sizes are currently CE approved.

Myval THV: Unique Crimping Outcome

Upon Crimping:

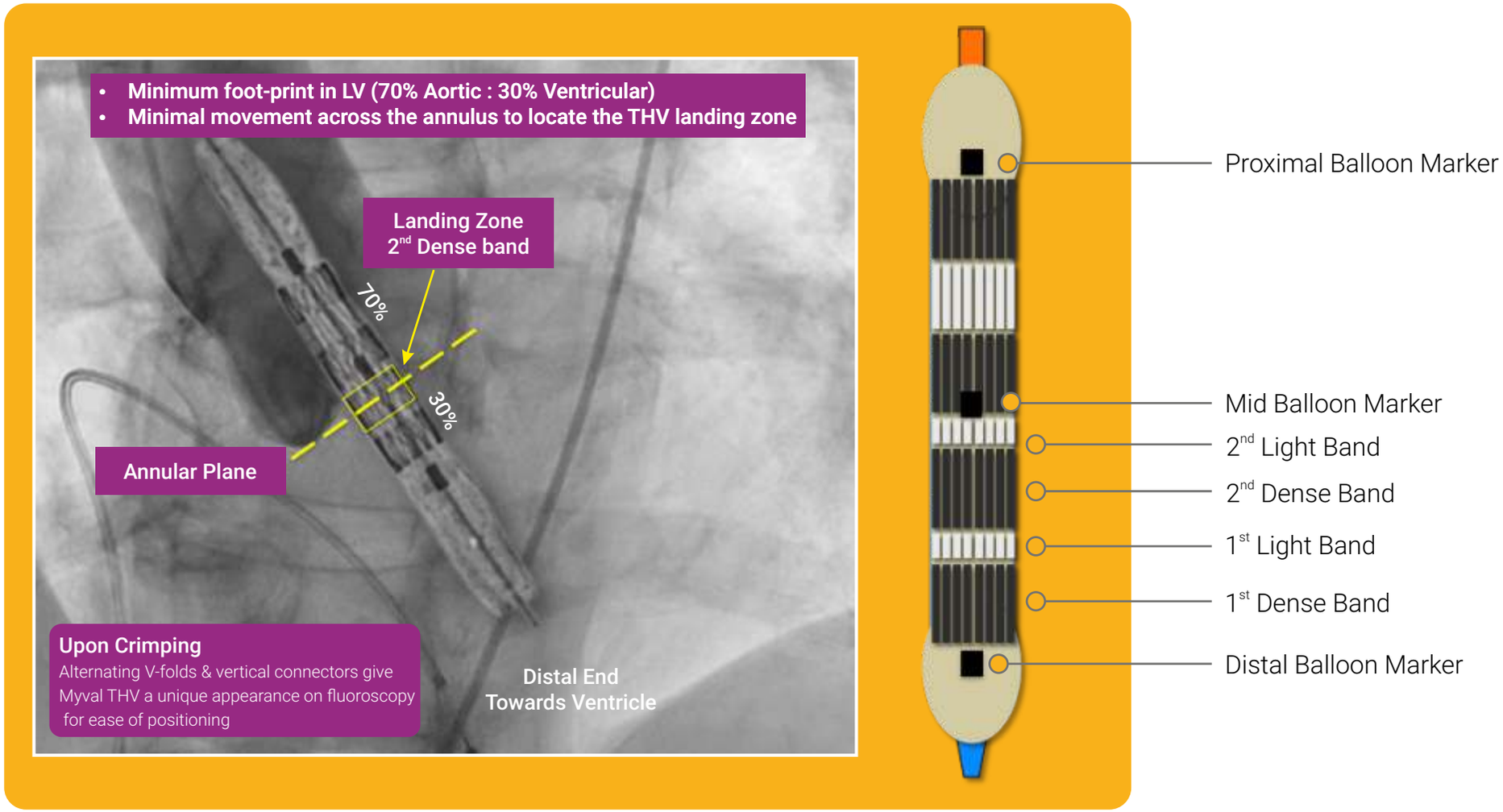
- **V-shaped hinges** on hexagonal frame fold, generating the dense bands on fluoroscopy
- **Vertical connectors** '|' give rise to light bands
- Alternating V-folds & vertical connectors give Myval THV a unique ***'Zebra Crossing'*** appearance on fluoroscopy for ease of positioning



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

Myval THV: Precise Placement Technique

Schematic of Myval THV - Ideal Landing Zone

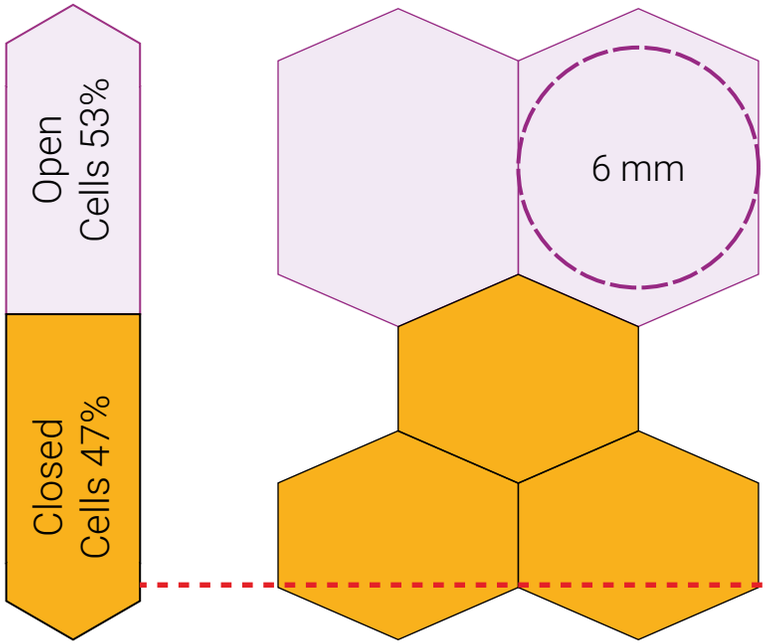


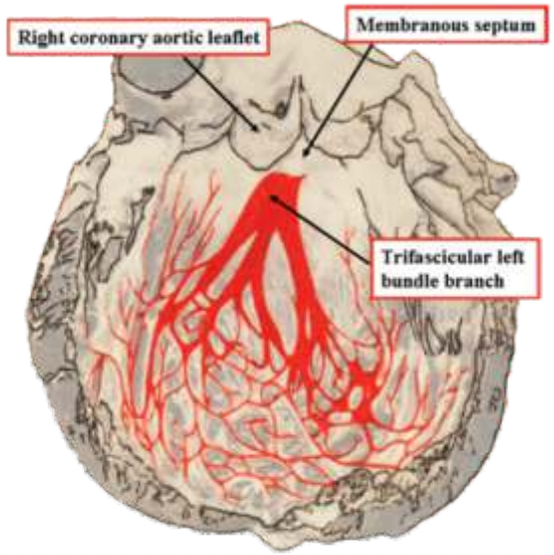
Elimination of THV frame parallax promptly ensures visualisation of characteristic dark-light bands

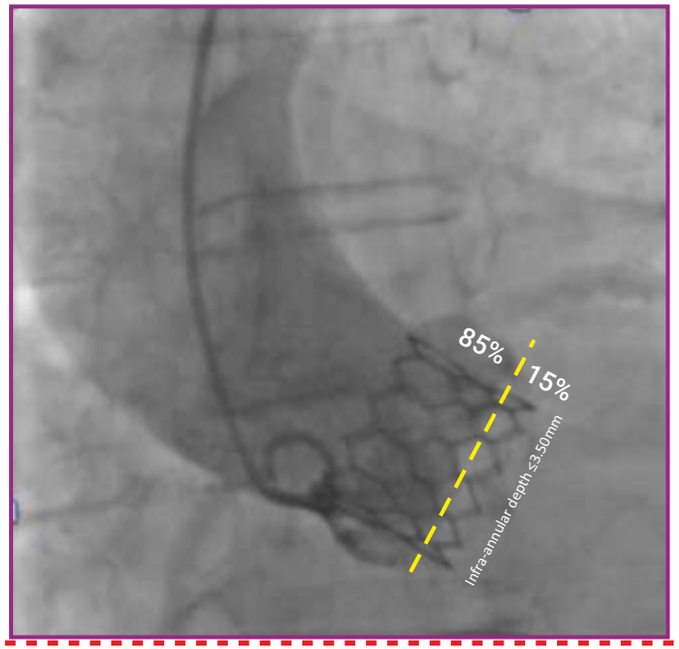
Myval THV: Ground Zero Deployment

- Shallow deployment of Myval THV with least engagement within LVOT is possible.
- Optimal orthotopic anchorage of Myval THV with marginal LVOT foot-print without risk of THV migration.
- Minimal infra-annular depth ≤3.50mm avoids conduction system interference (thus minimizing the need of new permanent pacemaker dependency).

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







Myval THV infra-annular depth ≤3.50mm based on THV Ø

Image ref : Tawara et al. JACC CardioVascular Interventions 2008; 1:310-316. Angio image reference : Dr. Ravinder Singh Rao, EHCC, Jaipur, India.

Myval THV: Detailed Sizing Guide

3D Annular area mm²		270	280	290	300	310	314	320	330	340	350	363
3D area derived diameter mm		18.5	18.9	19.2	19.5	19.9	20.0	20.2	20.5	20.8	21.1	21.5
% Annular area over/under	20 mm	16.4%	12.2%	8.3%	4.7%	1.3%	0.1%	-1.8%	-4.8%	-7.6%	-10.2%	-13.5%
	21.5 mm	34.5%	29.7%	25.2%	21.0%	17.1%	16%	13%	10%	7%	4%	0.0%
	23 mm	53.9%	48.4%	43.3%	38.5%	34%	32.3%	29.8%	25.9%	22.2%	18.7%	14.5%

3D Annular area mm²		370	380	390	400	410	415	420	430	440	450	460	471
3D area derived diameter mm		21.7	22.0	22.3	22.6	22.8	23.0	23.1	23.4	23.7	23.9	24.2	24.5
% Annular area over/under	23 mm	12.3%	9.3%	6.5%	3.9%	1.3%	0.1%	-1.1%	-3.4%	-5.6%	-7.7%	-9.7%	-11.8%
	24.5 mm	27.4%	24.1%	20.9%	17.9%	15.0%	13.6%	12.2%	9.6%	7.1%	4.8%	2.5%	0.1%
	26 mm	43.5%	39.7%	36.1%	32.7%	29.5%	27.9%	26.4%	23.5%	20.7%	18.0%	15.4%	12.7%

3D Annular area mm²		480	490	500	510	520	531	540	550	560	570	580	594
3D area derived diameter mm		24.7	25.0	25.2	25.5	25.7	26.0	26.2	26.5	26.7	26.9	27.2	27.5
% Annular area over/under	26 mm	10.6%	8.4%	6.2%	4.1%	2.1%	0.0%	-1.7%	-3.5%	-5.2%	-6.9%	-8.5%	-10.6%
	27.5 mm	23.7%	21.2%	18.8%	16.5%	14.2%	11.9%	10.0%	8.0%	6.1%	4.2%	2.4%	0.0%
	29 mm	37.6%	34.8%	32.1%	29.5%	27.0%	24.4%	22.3%	20.1%	17.9%	15.9%	13.9%	11.2%

3D Annular area mm²		600	610	620	630	640	650	661	670	680	690	700	710
3D area derived diameter mm		27.6	27.9	28.1	28.3	28.5	28.8	29.0	29.2	29.4	29.6	29.9	30.1
% Annular area over/under	29 mm	10.1%	8.3%	6.5%	4.8%	3.2%	1.6%	-0.1%	-1.4%	-2.9%	-4.3%	-5.6%	-7.0%
	30.5 mm	37.6%	37.6%	37.6%	37.6%	14.2%	12.4%	10.5%	9.0%	7.4%	5.9%	4.4%	2.9%
	32 mm	34.0%	31.8%	29.7%	27.7%	27.7%	23.7%	21.7%	20.0%	18.3%	16.6%	14.9%	13.3%

3D Annular area mm²		720	731	740	750	760	770	780	790	804
3D area derived diameter mm		30.3	30.5	30.7	30.9	31.1	31.3	31.5	31.7	32.0
% Annular area over/under	32 mm	11.7%	10.0%	8.7%	7.2%	5.8%	4.4%	3.1%	1.8%	0.0%

Area derived diameter based on MSCT cross-sectional measurements.

Myval THV: Size Matrix

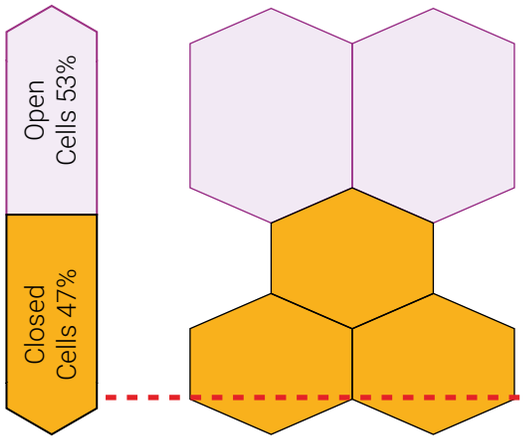
Myval THV Size Matrix & Technical Specifications	Area 314 mm^2 17.35 mm  20 mm	Area 363 mm^2 18.35 mm  21.5 mm	Area 415 mm^2 17.85 mm  23 mm	Area 471 mm^2 18.75 mm  24.5 mm
Perimeter	62.83 mm	67.54 mm	72.26 mm	76.97 mm
Native annulus area	270 - 330 mm^2	314-380 mm^2	360 - 440 mm^2	410-500 mm^2
Area-derived diameter	18.5 - 20.5 mm	20-22 mm	21.4 - 23.7 mm	22.8-25.2 mm
Native annulus size by TEE	16 - 19 mm	17.5-20.5 mm	18 - 22 mm	19.5-23.5 mm

All Myval THV diameters (20 mm to 32 mm) are compatible with 14Fr Python - Introducer Sheath

Myval THV XL Sizes

Area 531 mm²	Area 594 mm²	Area 661 mm²	Area 731 mm²	Area 804 mm²
18.85 mm  26 mm	19.25 mm  27.5 mm	20.35 mm  29 mm	20.9 mm  30.5 mm	21.14 mm  32 mm
81.68 mm	86.39 mm	91.11 mm	95.82 mm	100.53 mm
460 - 560 mm²	510-630 mm²	570 - 700 mm²	630-770 mm²	700-840 mm²
24.2 - 26.7 mm	25.5-28.3 mm	26.9 - 29.9 mm	28.3-31.3 mm	29.9-32.7 mm
21- 25 mm	22.5-26.5 mm	24 - 28 mm	25.5-29.5 mm	27-31 mm

Myval THV: Post Deployment Dimension Chart



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

Myval THV Diameters (Ø)	20 mm	21.5 mm	23 mm
Total frame height	17.35 mm	18.35 mm	17.85 mm
Open cell height (53%)	9.20 mm	9.73 mm	9.46 mm
Closed cell height (47%)	8.15 mm	8.62 mm	8.39 mm
Infra-annular depth	3.05 mm	3.20 mm	2.85 mm
Supra-annular height of closed cells	5.10 mm	5.42 mm	5.54 mm
Recommendation for coronary protection	10 mm	10 mm	10 mm

• A balloon occlusion test may be considered to assess the propensity for coronary occlusion. Balloon diameter approximated to shortest axis of CT derived annular diameter to be considered.

Myval THV XL Sizes

24.5 mm	26 mm	27.5 mm	29 mm	30.5 mm	32 mm
18.75 mm	18.85 mm	19.25 mm	20.35 mm	20.90 mm	21.14 mm
9.94 mm	9.99 mm	10.20 mm	10.79 mm	11.08 mm	11.21 mm
8.81 mm	8.86 mm	9.05 mm	9.56 mm	9.82 mm	9.94 mm
2.95 mm	3.05 mm	3.15 mm	3.35 mm	3.45 mm	3.55 mm
5.86 mm	5.81 mm	5.90 mm	6.21 mm	6.37 mm	6.39 mm
10 mm	10 mm	10 mm	10 mm	10 mm	10 mm

- Consider protection of coronary arteries with a DES especially if height of coronary ostium is < 10 mm from the annular plane and in conjunction with sinus of valsalva dimensions i.e. height & diameters.

Navigator THV Delivery System

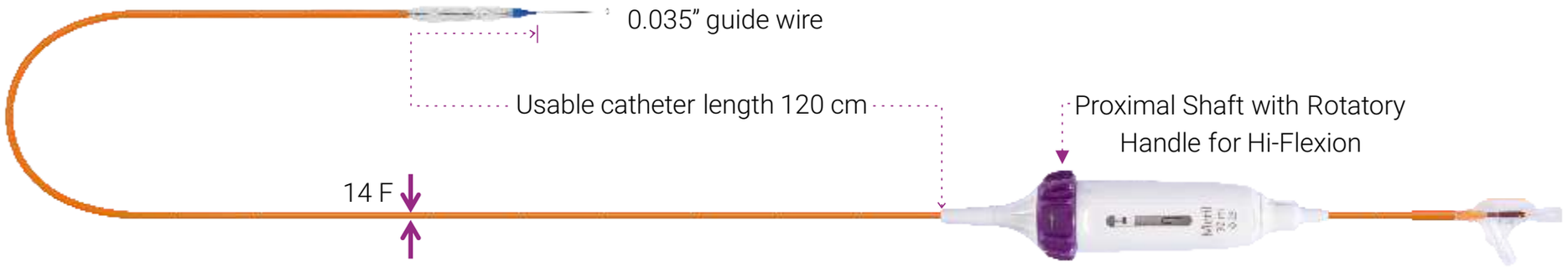
Delivering TAVI Made Easy

- 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.

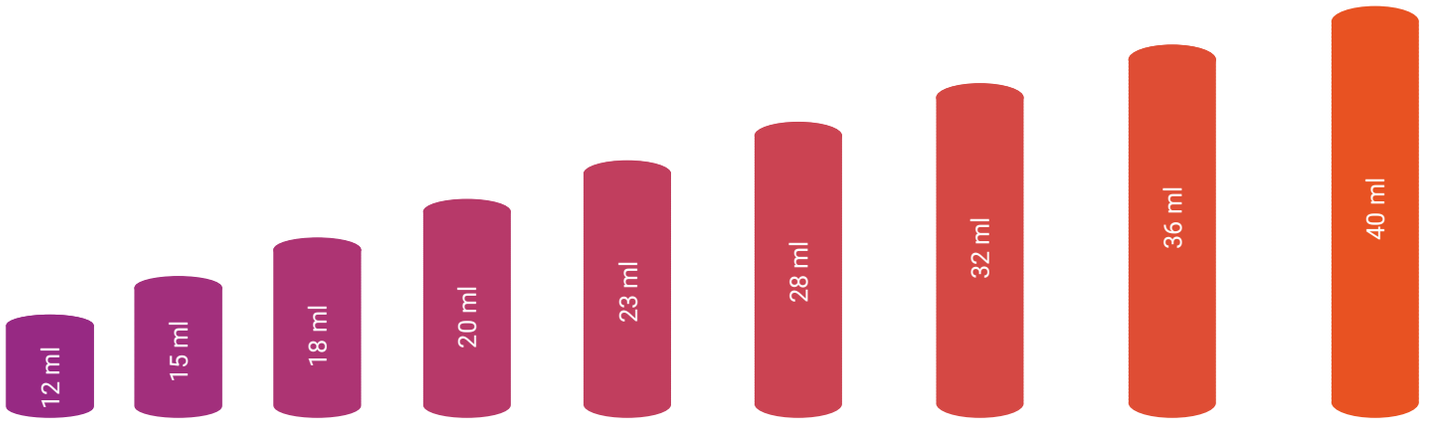
Navigator with Myval THV

- 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



Navigator Balloon Ø	20 mm	21.5 mm	23 mm	24.5 mm	26 mm	27.5 mm	29 mm	30.5 mm	32 mm
Balloon Length	30 mm					35 mm			
Balloon RBP	6 atm								



Navigator – THV Delivery System has been indigenously developed by Meril Life Sciences Pvt. Ltd.

Navigator THV Delivery System
Characteristic Balloon Expansion

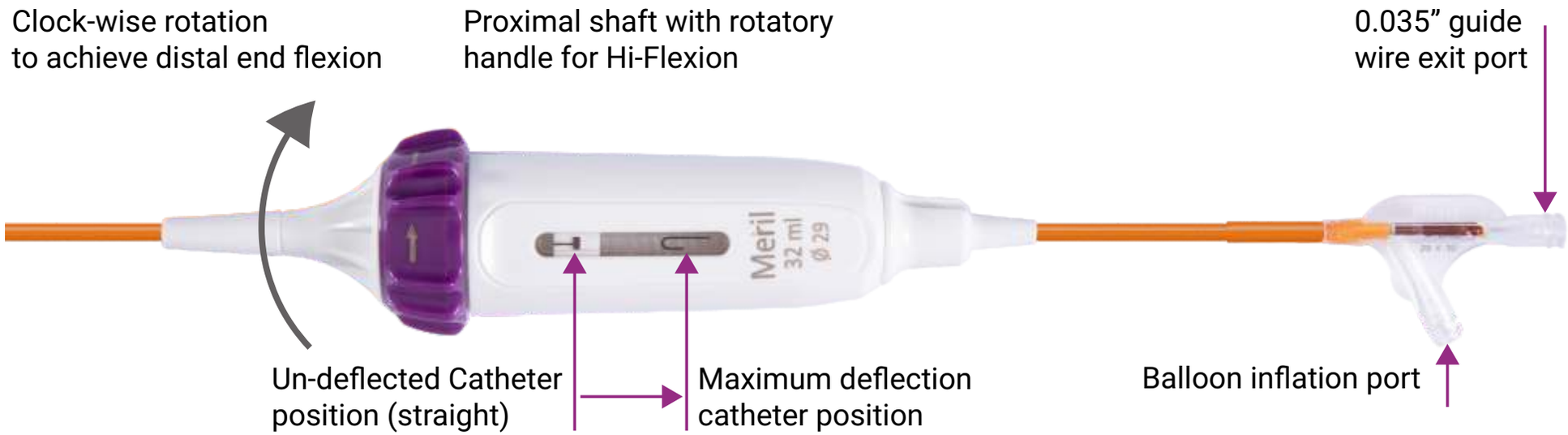
Navigator balloon with dual expansion ports at each end ensures rapid, simultaneous, controlled expansion (dog-boning) of distal and proximal ends

This typical dog bone pattern of inflation steadies the valve during expansion phase, ensuring its precise annular position and deployment without any risk of valve migration

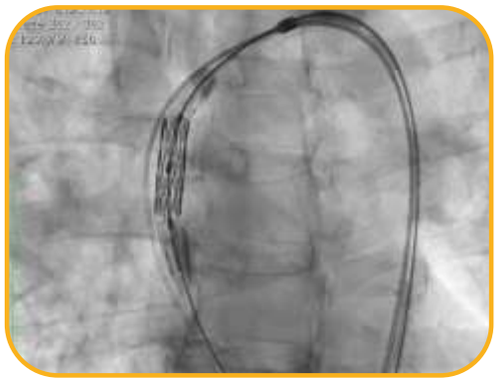
Rapid balloon inflation, using an inflation device is possible with controlled palm thrust

Rapid balloon deflation within 3-5 sec ensures procedural safety and compliance

Navigator THV Delivery System: Proximal Assembly



Hi-flexion feature ensures tracking the THV delivery system
via inner aortic arch curve thereby avoiding contralateral wall scraping.



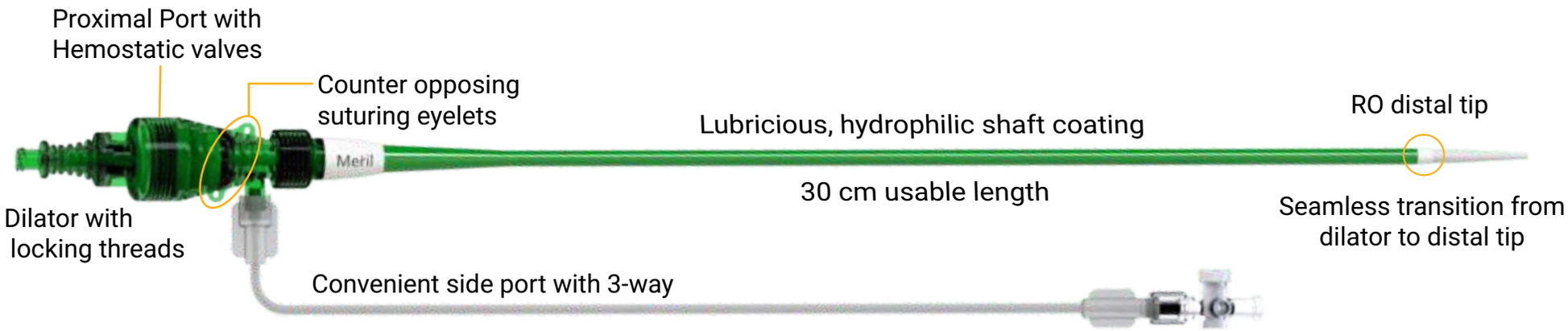
Caution: Always remember to fully un-flex the Navigator system while withdrawing

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



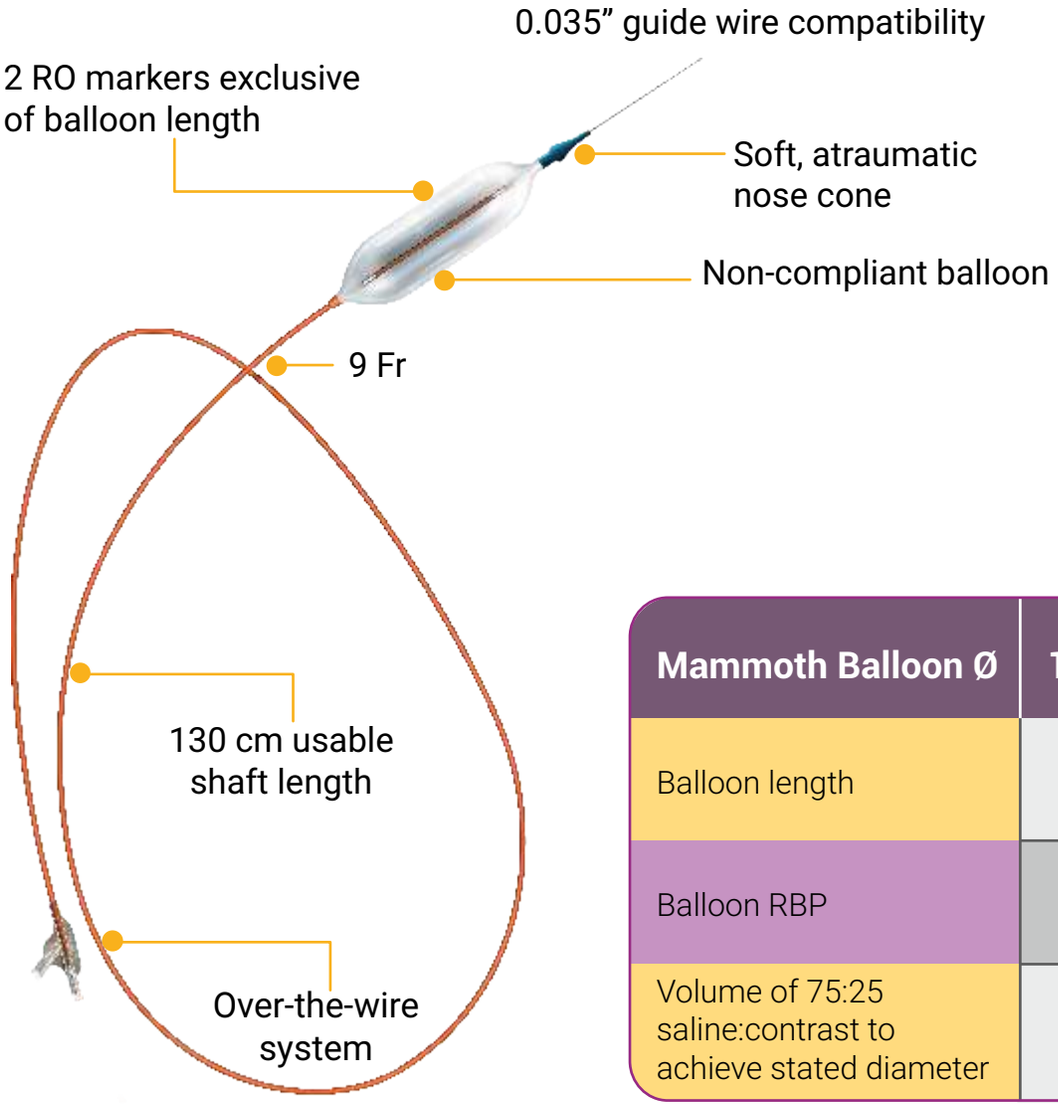
Two separate, calibrated loading tubes ensure temporary opening of hemostatic valves in proximal port allowing smooth passage of crimped Myval THV System

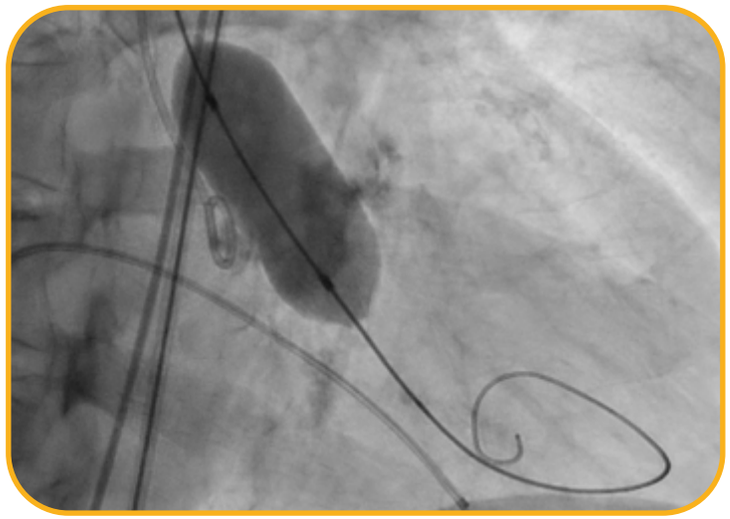
Common Femoral Artery* Ø (mm)	Myval THV Ø (mm)
≥ 5.50 mm	20 mm, 21.5 mm, 23 mm, 24.5 mm
≥ 6.00 mm	26 mm, 27.5 mm, 29 mm
≥ 6.50 mm	30.5 mm, 32 mm
*CFA Ø must be MSCT derived. Excluding circumferential Ca^{2+}	

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

Mammoth - OTW Balloon Catheter

Pre-dilatation is entirely operator's discretion and not mandatory.





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.

Myval THV: Global Clinical Program

~4000 Patients

MyVal-1[1]
(n=100)

Meril Initiated
Single arm
Prospective FIH study
29 Indian sites
STS ≥ 4 - ≤ 15
Primary 30-d endpoint achieved
6m f/up presented @ EuroPCR 2020

Myval-EU[2]
(n=250)

Compare-TAVI[3]
(n=1,062)

LANDMARK RCT[4]
(n=768)

Myval-Global[5]
(n= 2,000)

Myval-China[6]
(n=125)

[2]Meril Initiated	[3]Investigator Initiated	[4]Meril Initiated	[5]Meril Initiated	[6]Meril Initiated
Single arm	RCT – 1:1 Myval : Sapien 3 THV	RCT – 2:1:1 Myval : Sapien : Evolut THV series	Single arm	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	Enrollment has started	EC/IRB approvals in progress	Under planning	Pre-study activities initiated
30-day f/up est. @ EuroPCR 2021	***1-year f/up est. @ EuroPCR 2023***	***First patient first visit est. @ QIV 2020***	***First patient first visit est. @ QIII 2021***	***First patient first visit est.@ QI 2022***

MyVal-1: Study Design

A prospective, multicentre, single-arm, open-label study of Myval THV in the treatment of severe symptomatic native aortic valve stenosis.

Total number of patients: 100

Device Sizes – 20, 21.5, 23, 24.5, 26, 27.5 and 29 mm

CLINICAL FOLLOW-UP

Follow-up	100	100	100	100
Clinical Follow-up	100	100	100	100
Echocardiographic Follow-up	100	100	100	100
Quality of Life Measurement	100	100	100	100

Dr. Samin Sharma - Chairman
New York, USA

Dr. Ashok Seth - Principal Investigator
New Delhi, India

Dr. Praveen Chandra - Co-ordinating PI
New Delhi, India

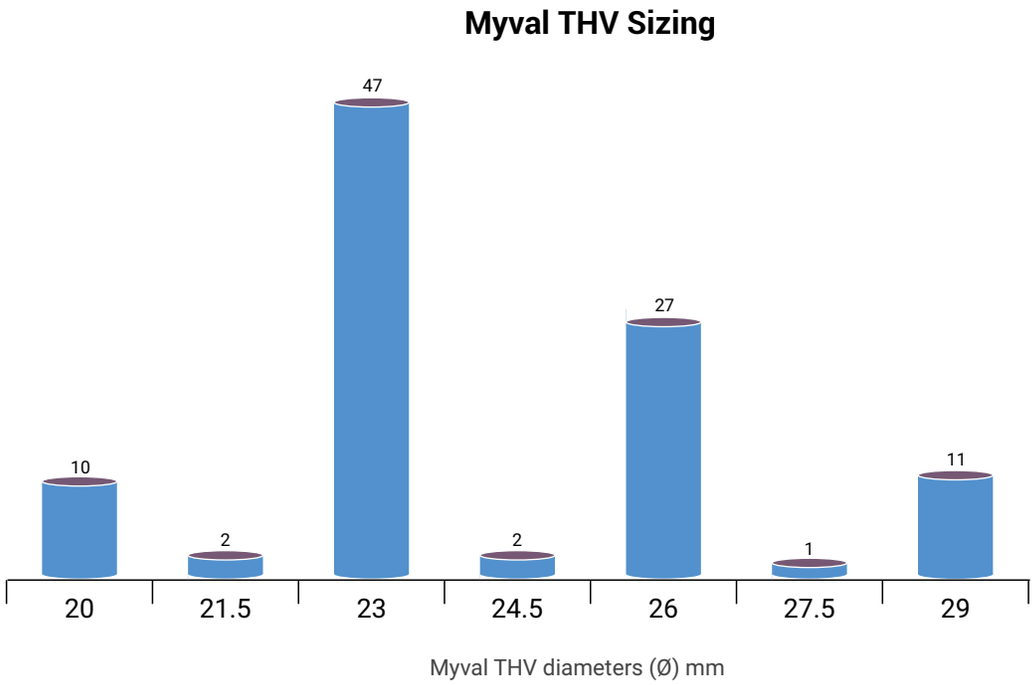
Dr. Ravinder Singh Rao - Co-PI
Jaipur, India

Dr. P. K. Goel - Scientific Advisor
Lucknow, India

Study Investigators: Sharma Samin[1], Chandra Praveen[2], Ashok Seth[3], Rao Ravinder Singh[4], Goel P. K.[5], Bharadwaj Prashant, Sethi Rishi, Sengottuvelu G., Mahajan Ajaykumar, Jose John, Abhaichand Rajpal, Ajit Kumar V K, Manjunath C N, Mehtrotra Sanjay, Rao Suryaprakash, Chaurasia Amit Kumar, Bahl V K, Kaul Upendra, Jain R K, Gopalamurugan AB, Rath P C, Trehan Vijay, Vivek Kumar, Roy Sanjeeb, Mantri R R, Sharma S M, Kler T S, Nair R C, Mehta Ashwin 1. Chairman; 2. Principal Investigator; 3. Co-ordinating PI, 4. Co-PI, 5. Scientific Advisor.
*6-month outcome data presented by Dr. Ravinder Singh Rao at PCR e-Course 2020.
MyVal-1: Study (CTRI/2016/11/007512).

MyVal-1: Baseline Characteristics

Patient History	
Average Age (years)	73 ± 7.49
Mean STS	5.12%
History of Coronary Artery Bypass Graft surgery	17%
History of Previous PCI	13%
History of previous Aortic Valvuloplasty	1%
Cerebral vascular disease	3%
Perpheral vascular disease	1%



- Intermediate sizes were introduced after 90% of enrollment completion.

MyVal-1: Clinical outcomes up to 6-month follow-up

Excellent clinical safety & efficacy

Events	Post-procedure	1-Month Follow-Up	6-Month Follow-Up
Survival	98%	97%	91%
All-cause mortality	2%	3%	9%
Stroke	1%	2%	2%
Acute renal failure	2%	2%	2%
Life-threatening or disabling bleeding	1%	1%	1%
Endocarditis	0%	0%	1%
Myocardial infarction	0%	0%	0%
Major vascular complications	1%	1%	1%
Minor vascular complications	2%	2%	2%
Repeat hospitalization	NA	8%	10%[#]
New permanent pacemaker	2%*	2%	2%

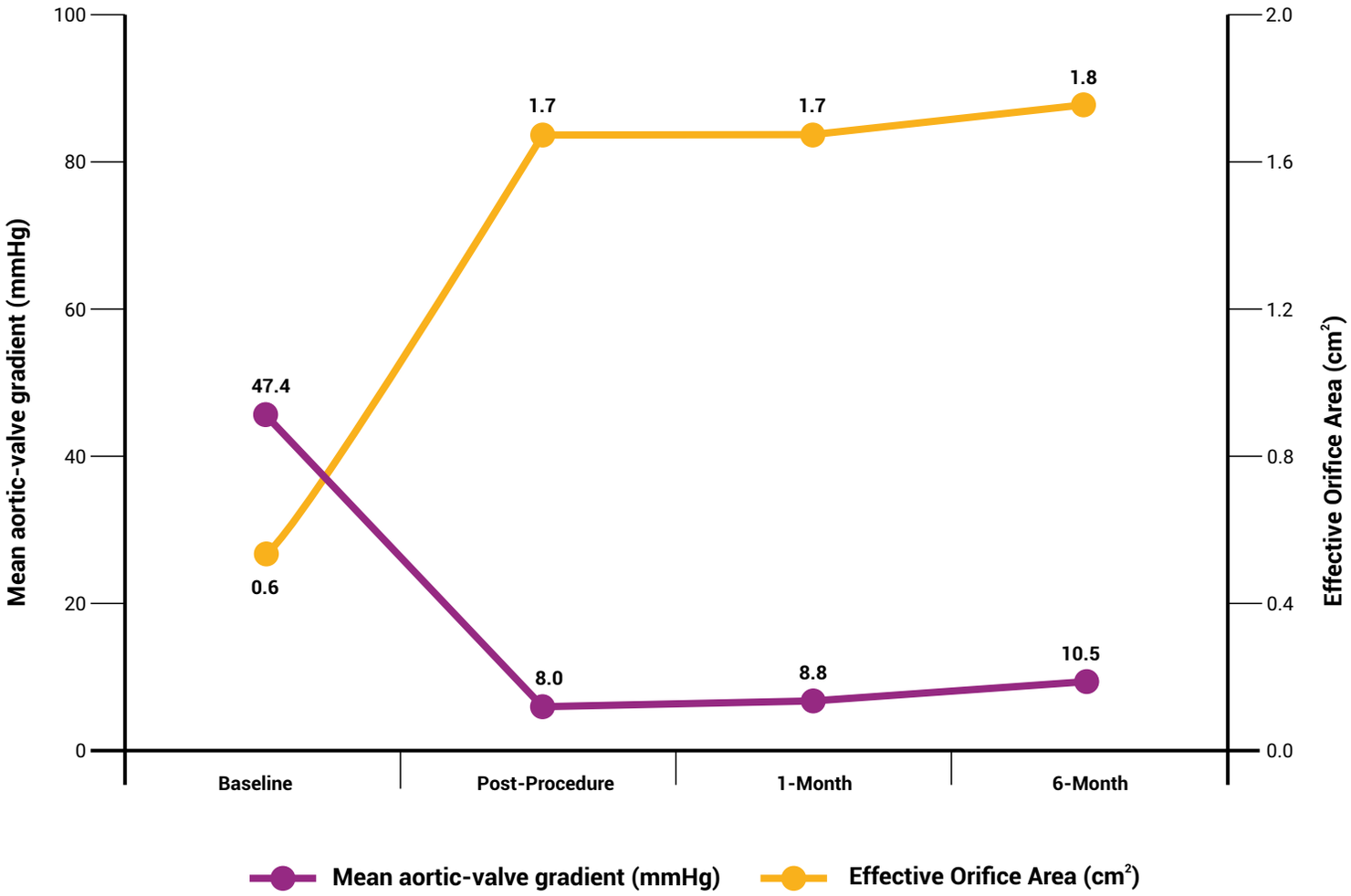
*One patient had RBBB pre-procedure
[#]5 patients had repeat hospitalization due to non-device/procedure related conditions

MyVal-1: Echocardiographic Findings at 6-month Follow-up

Echocardiographic findings				
Parameters	**Baseline**	**Post Procedure**	**30-day FU**	**6-month FU**
Effective orifice area, (cm^2)	0.6 ± 0.2	1.7 ± 0.3	1.7 ± 0.5	1.8±0.5
Mean aortic-valve gradient, (mmHg)	47.4 ± 8.8	8.0 ± 2.7	8.8 ± 2.5	10.5±2.6
Peak aortic-valve gradient, (mmHg)	71.7 ± 13.0	14.4 ± 2.4	15.7 ± 2.8	17.9±2.9
Trans-aortic velocity, (m/s)	4.5 ± 0.4	1.9 ± 0.4	1.8 ± 0.4	1.8±0.3
Mean LVEF, (%)	45.5 ± 11.5	47.8 ± 11.1	48.6 ± 8.9	48.8±8.0
Moderate or severe mitral regurgitation, (n)	2	0	0	0
Aortic regurgitation, (n)	-	0	0	0

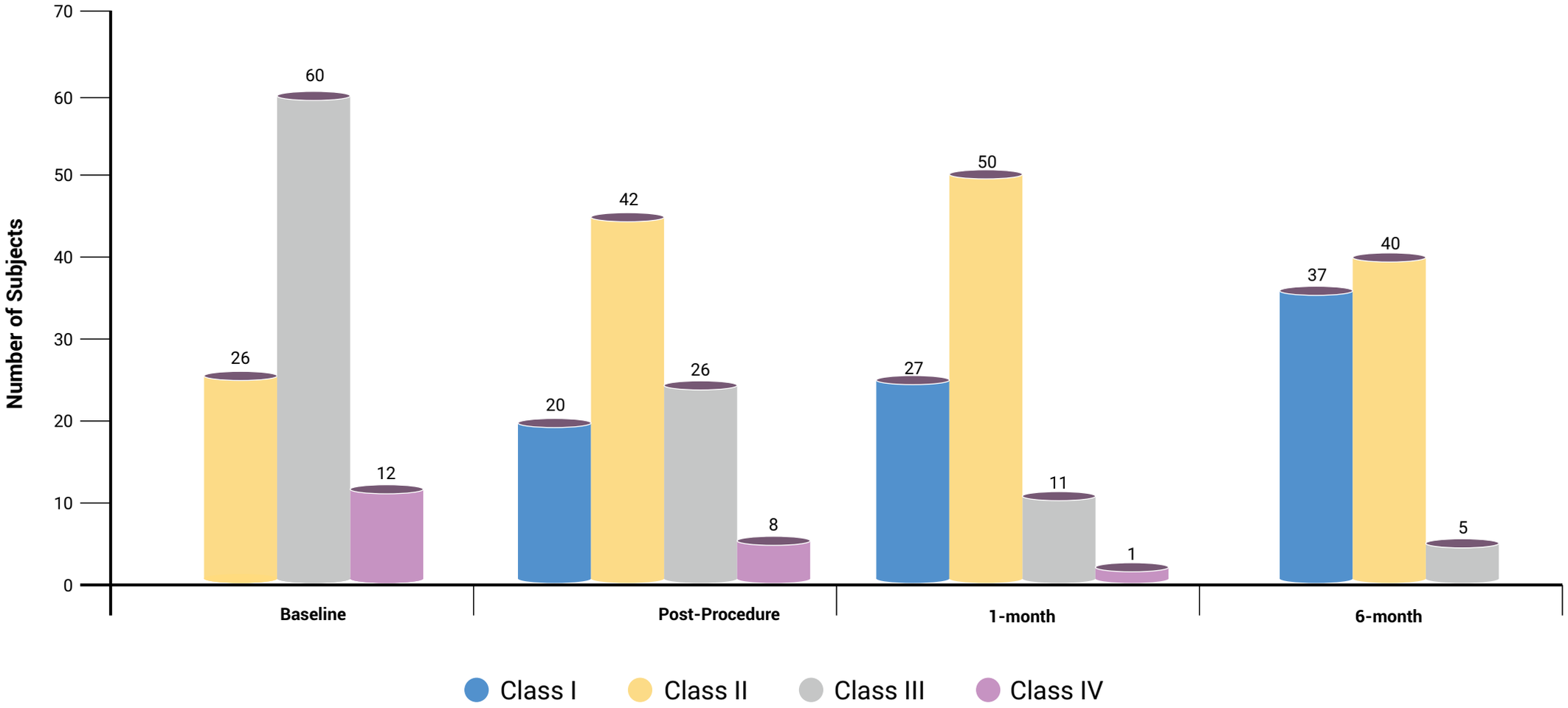
Values are mean ±SD (n) or % (n); FU: follow-up, LVEF: left ventricular ejection fraction.

Sustained Low Mean Gradients Post-Procedure and ~1.8cm^2 Large EOA at 6-month Follow-up (p<0.0001)



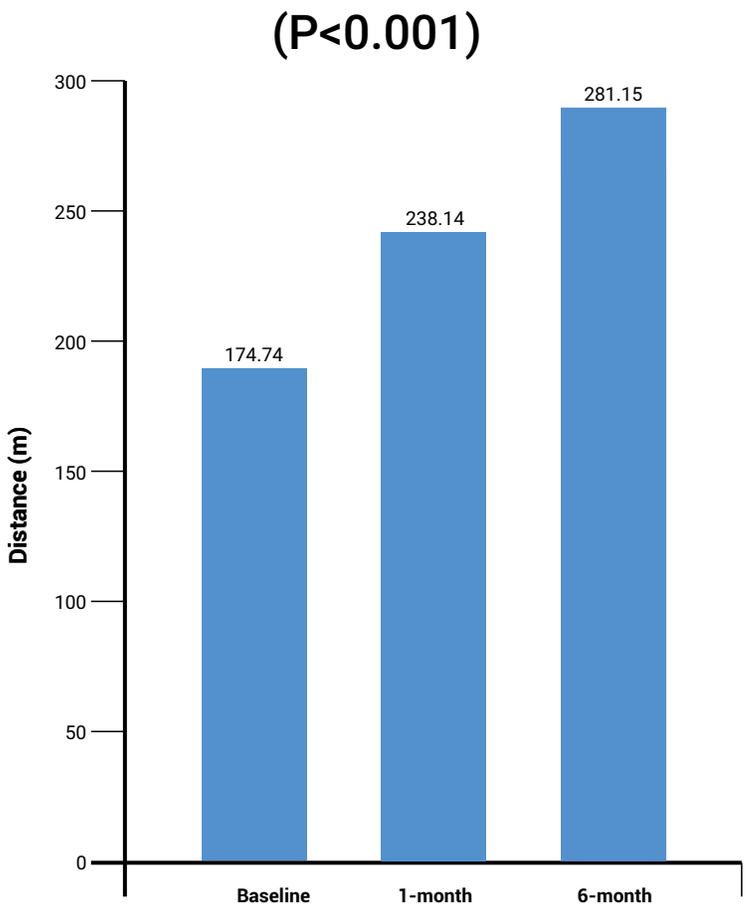
MyVal-1: Marked improvement in Quality of Life (QoL) parameters

NYHA Classification

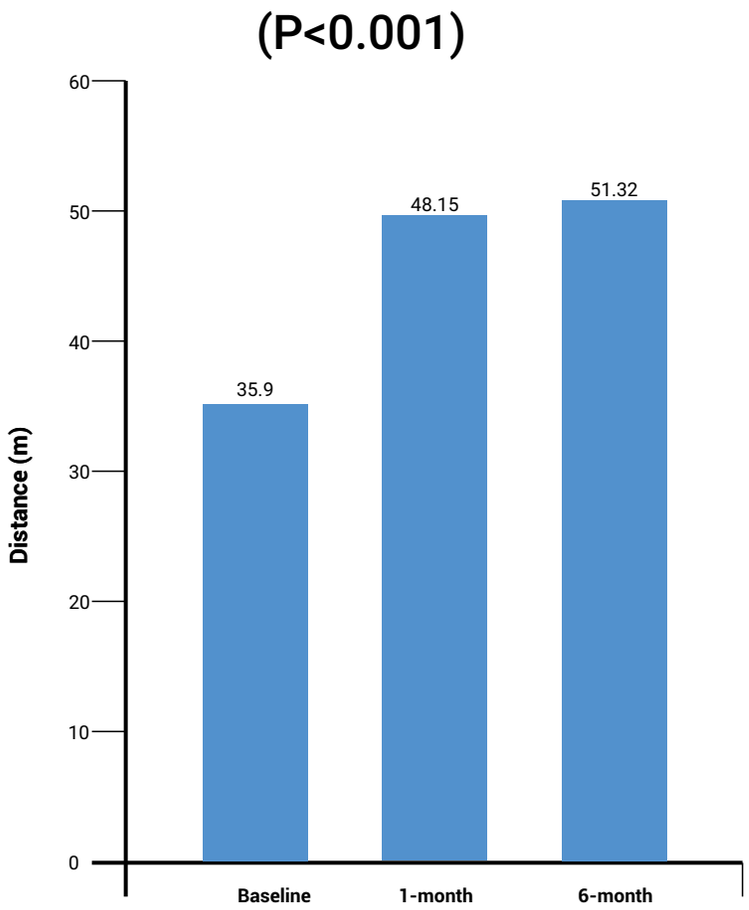


MyVal-1: Marked improvement in Quality of Life (QoL) parameters

Six-minute walk test



Kansas City Cardiomyopathy Questionnaire Score

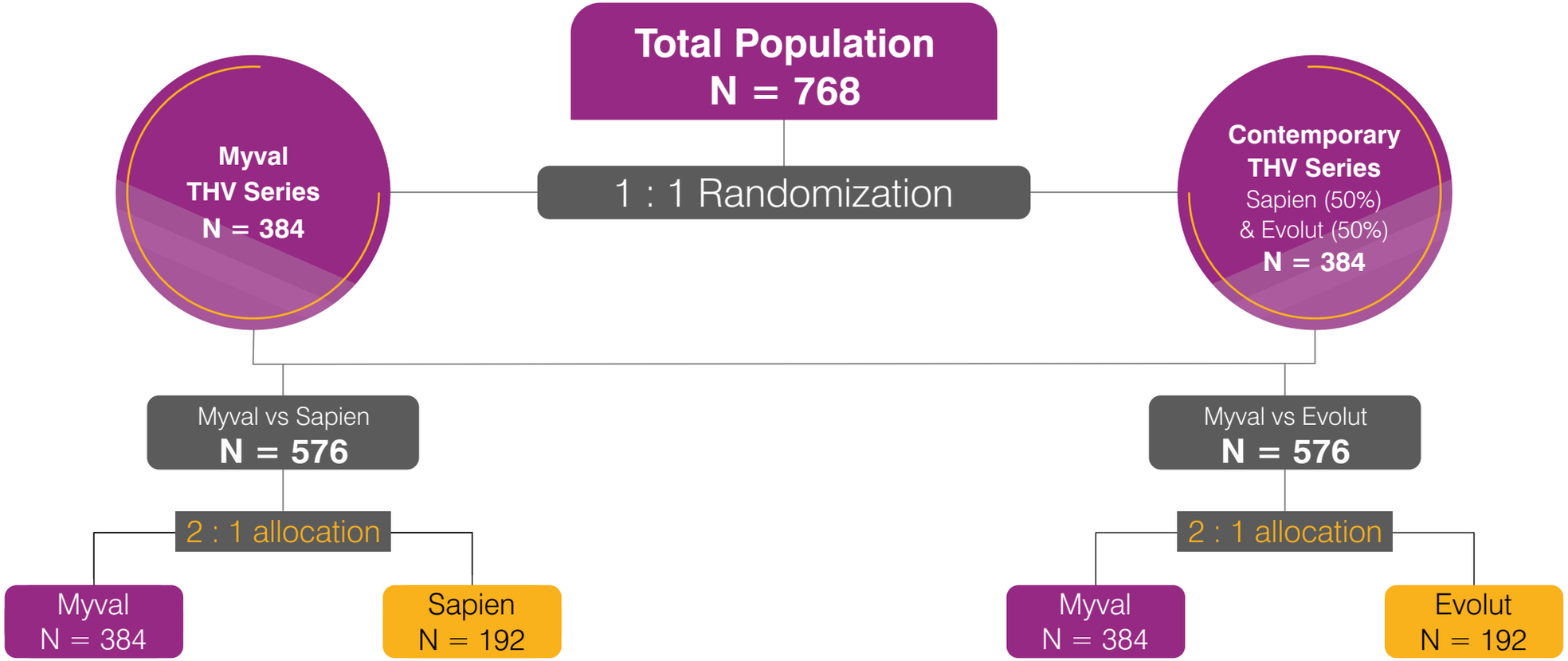


MyVal-1: Study Conclusion

- In 100 intermediate and high-risk patients of MyVal-1 FiH study, Myval THV system demonstrated excellent clinical and hemodynamic outcomes at 6-month:
  - 91% survival & low incidence of stroke (2%)
  - Low 2% rate of new permanent pacemaker implantation post-procedure
  - High procedural success (97%) due to precise orthotopic valve positioning
  - Significant improvement in quality of life of patients at 6-month follow-up

- In real world global experience of ≈1000 cases; Myval THV has been consistently demonstrating high procedural success and clinical performance
  - Unique hybrid honey-comb geometry for precise positioning and orthotopic deployment.
  - Preserve THV geometry & respect patient's anatomy; Intermediate Ø 21.5, 24.5, 27.5 mm & XL Ø 30.5, 32 mm
  - Direct THV crimping on Navigator balloon makes TAVI delivery simple, intuitive and eliminates unwarranted procedural steps.
  - Compatibility of novel 14Fr Python Introducer sheath for all Myval THV Øs; with high convenience of full retrievability of an un-deployed Myval THV system

LANDMARK RCT – 50+ Sites EU+ANZ



Primary Endpoint – 30 Days

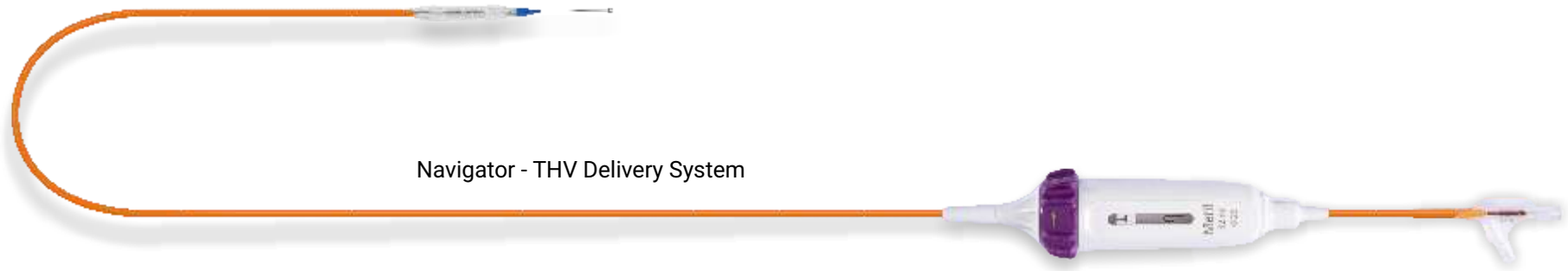
All cause mortality | All stroke | Life threating bleeding | Vascular complications
Acute Kidney Injury | Paravalvular leak (PVL) | New permanent pacemakers

ECG/Echo Follow-up	**Baseline | Post Procedure | 30 D | 1 Y | 3 Y | 5 Y**
Video Densitometry	**Post Procedure**
Clinical Follow-up	**Upto 10 years**

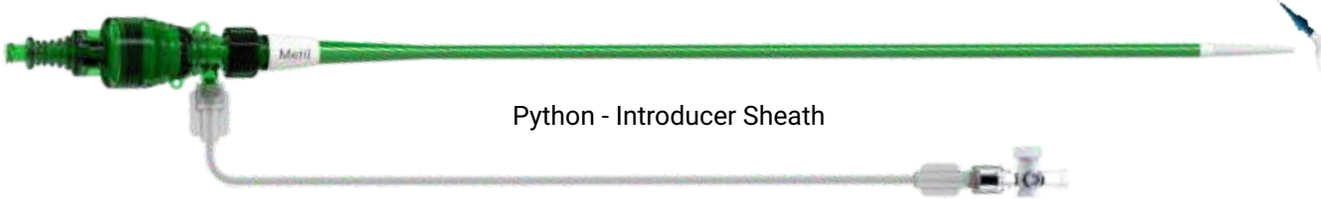
LANDMARK RCT EC/IRB work initiated. First patient enrollment expected Q4, 2020.

Myval THV System and Components

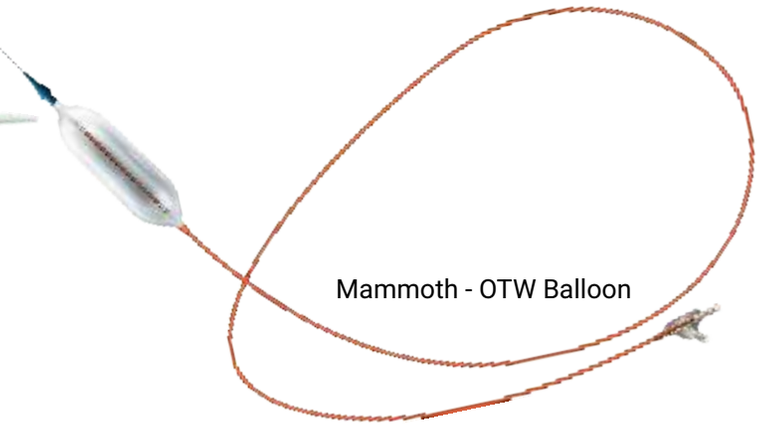
Myval - THV



Navigator - THV Delivery System



Python - Introducer Sheath



Mammoth - OTW Balloon

Myval THV System and Components - Ordering Information

Myval - THV Ordering Information

Diameters	20.0 mm	21.5 mm	23.0 mm	24.5 mm	26.0 mm	27.5 mm	29.0 mm	30.5 mm	32.0 mm
Product code	MVL200	MVL215	MVL230	MVL245	MVL260	MVL275	MVL290	MVL305	MVL320

Navigator - THV Delivery System Ordering Information

Diameters	20.0 x 30 mm	21.5 x 30 mm	23.0 x 30 mm	24.5 x 30 mm	26.0 x 30 mm	27.5 x 35 mm	29.0 x 35 mm	30.5 x 35 mm	32.0 x 35 mm
Product code	NVT20030	NVT21530	NVT23030	NVT24530	NVT26030	NVT27535	NVT29035	NVT30535	NVT32035

Mammoth - OTW Balloon Ordering Information

Diameters	16.0 x 40 mm	18.0 x 40 mm	20.0 x 40 mm	23.0 x 40 mm	25.0 x 40 mm
Product code	MTV1640	MTV1840	MTV2040	MTV2340	MTV2540

Python - Introducer Sheath Ordering Information

Product code	PHT14

Val-de-Crimp - Heart Valve Crimping Tool Ordering Information

Product code	VLDC

Myval™
TRANSCATHETER HEART VALVE
PRECISION AT HEART

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