Myval™

TRANSCATHETER HEART VALVE

PRECISION AT HEART

Meril

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

CE APPROVED

Myval™
TRANSCATHETER HEART VALVE
PRECISION AT HEART

MyVal-1 Study Favourable Outcomes at 1-year*

Low

Device-related Mortality
Incidence of Stroke
New Permanent Pacemaker

*MyVal-1 study, one year results presented by Dr. Ravinder Singh Rao at PCR Valves e-Course 2020

Myval THV: Designed for Precision in Outcomes

Hybrid Honeycomb Cell Design Concept

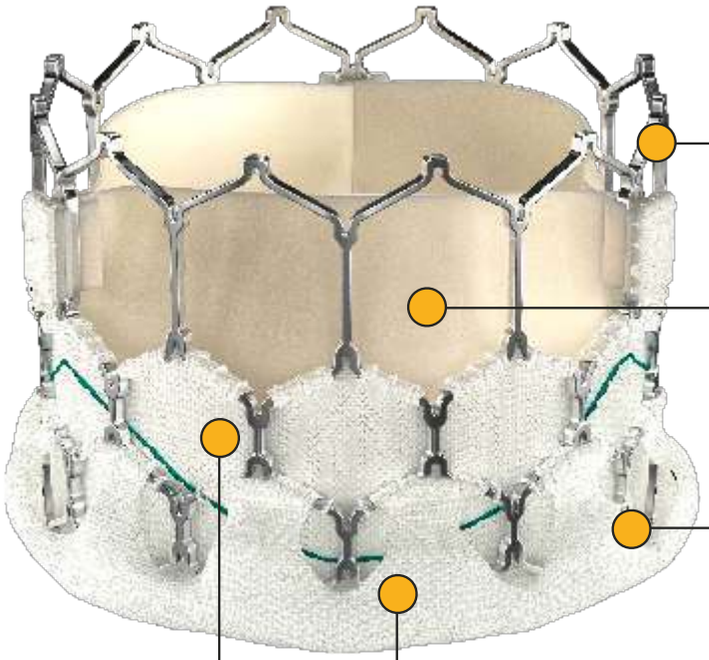
Open cells on upper half to ensure un-jailing of coronary ostia

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

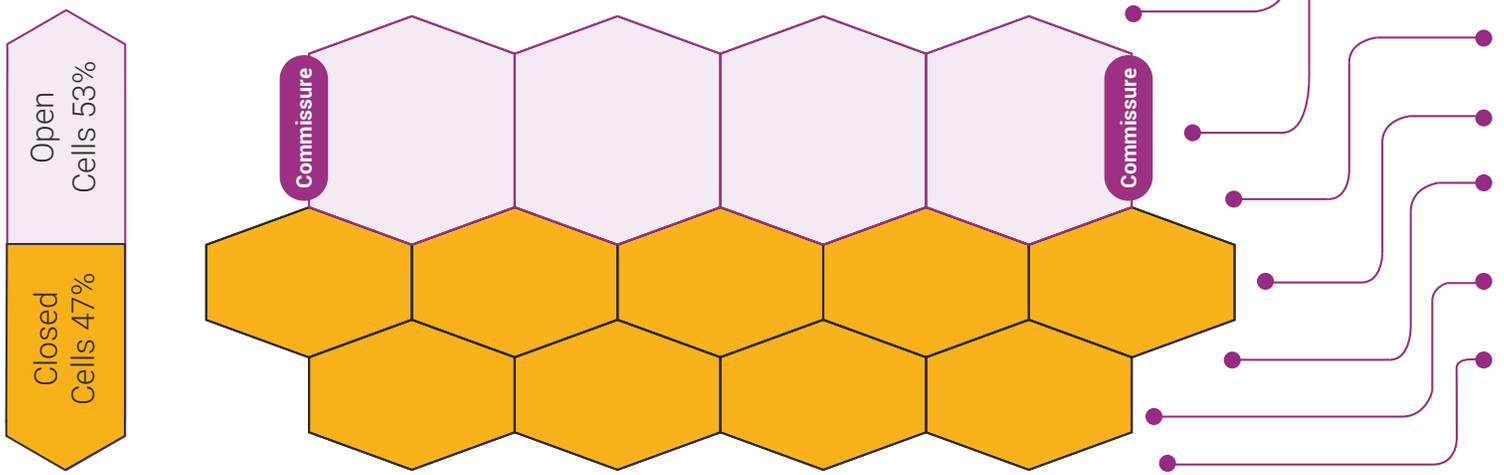
Myval THV has been indigenously developed by Meril Life Sciences Pvt. Ltd.

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

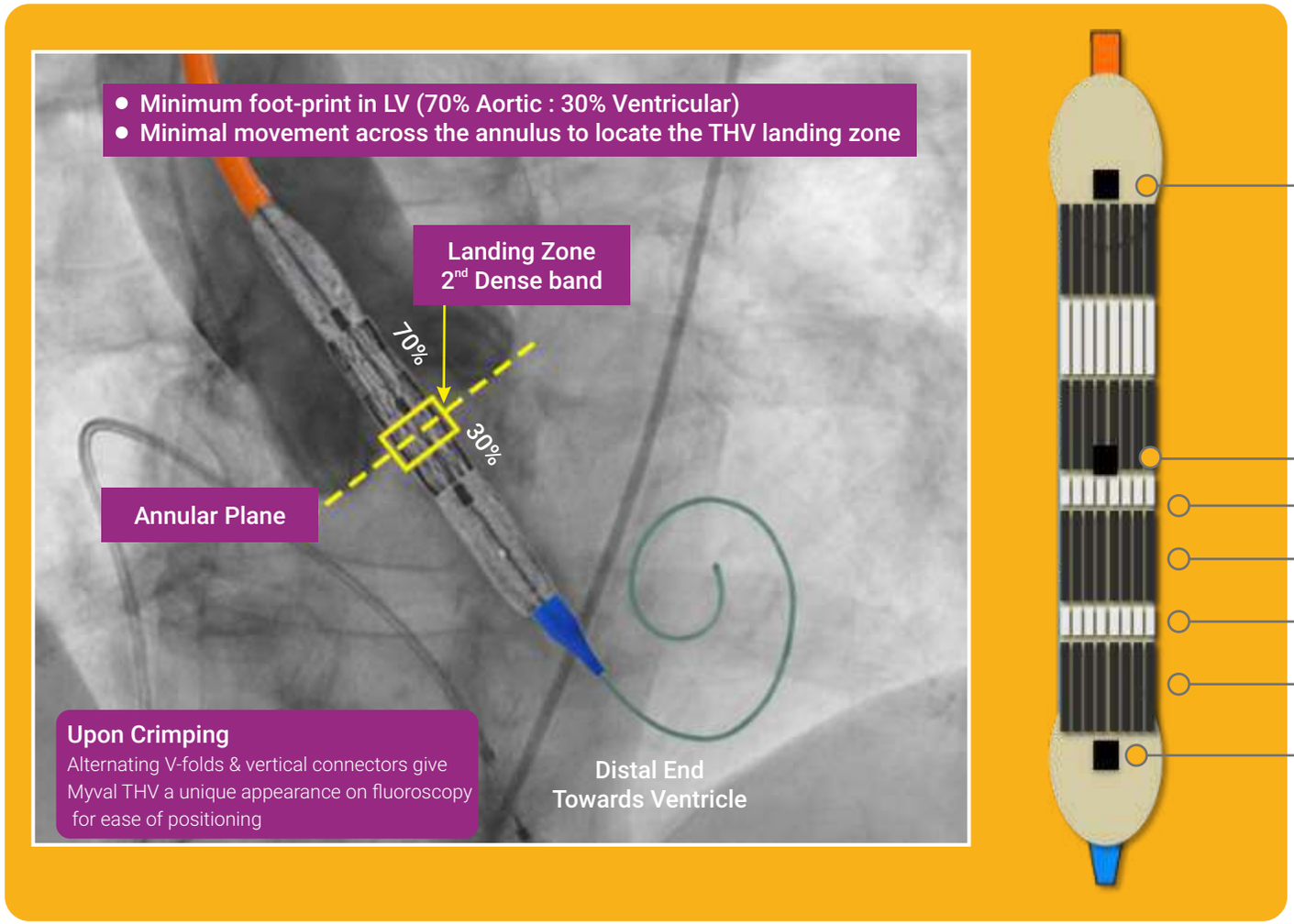


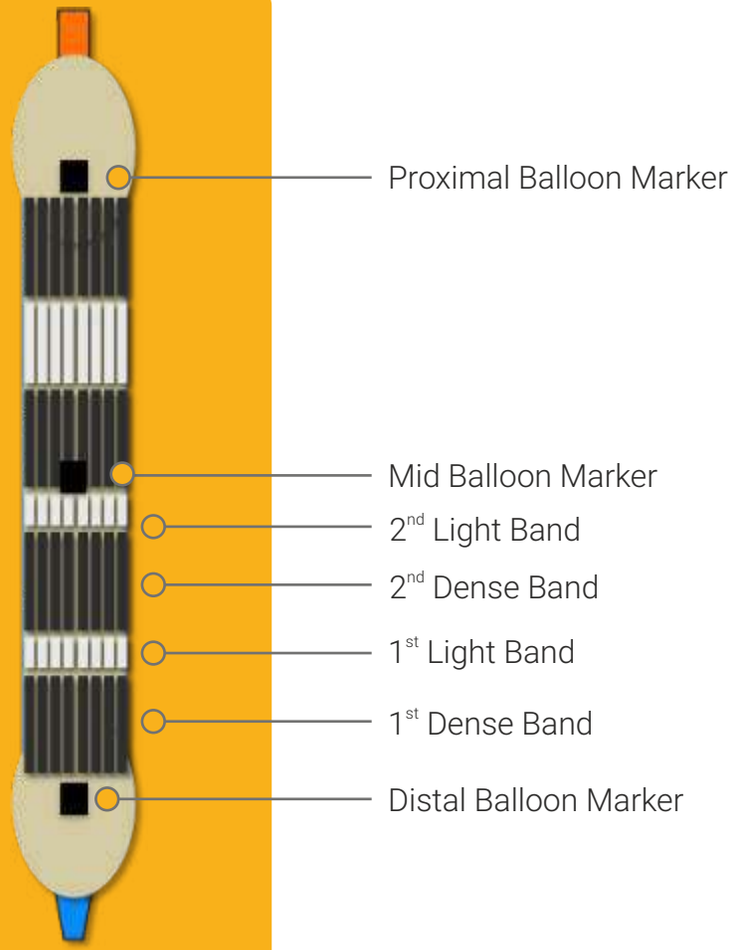
Myval THV is recommended to be crimped over Navigator THV Balloon Delivery System prior to insertion within introducer sheath

Illustrations are artist's representation and should not be considered as engineering drawings or photographs

Myval THV: Precise Placement Technique

Schematic of Myval THV - Ideal Landing Zone





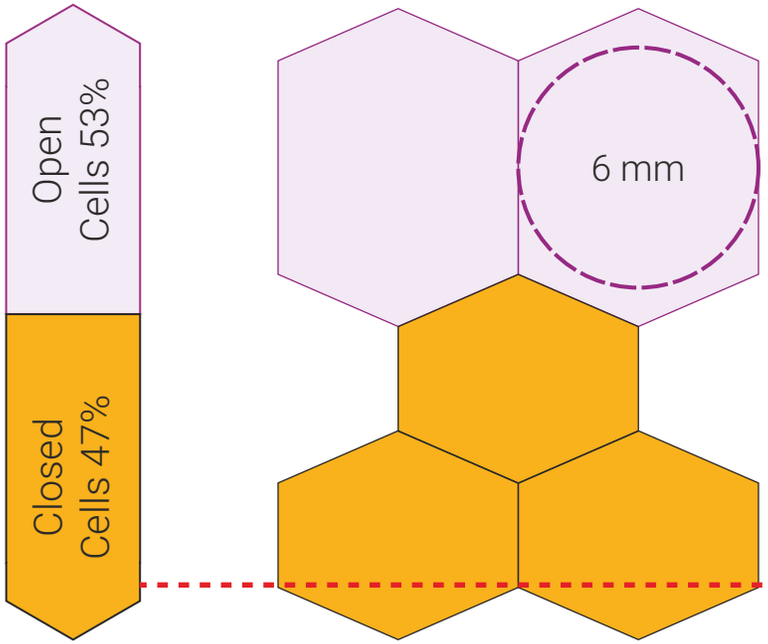
Elimination of THV frame parallax promptly ensures visualisation of characteristic dark-light bands
Fluoroscopic images have been dramatized & and may not be in 1:1 ratio

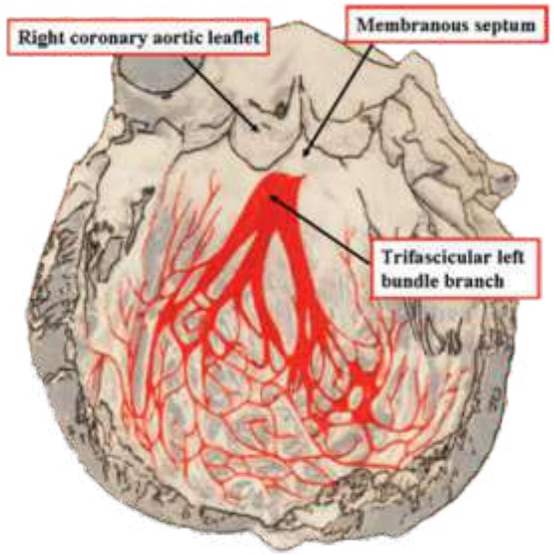
Illustrations are artist's representation and should not be considered as engineering drawings or photographs

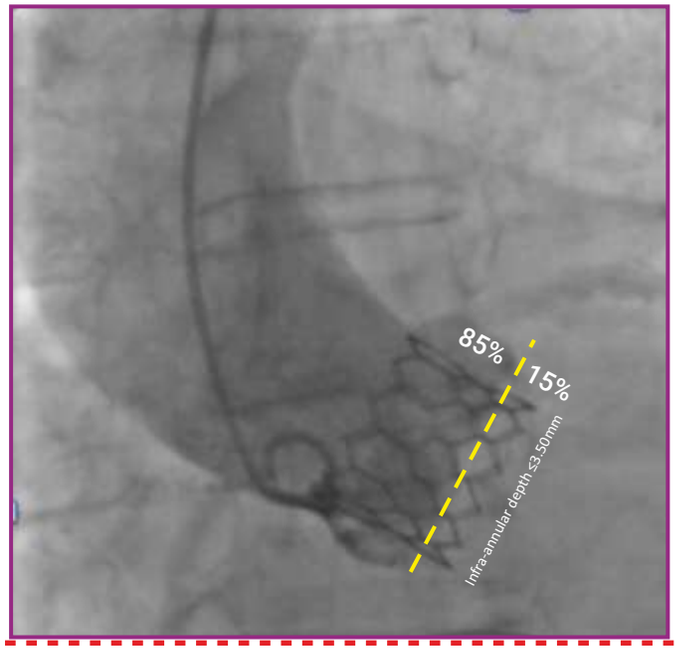
Myval THV: Ground Zero Deployment

- 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 courtesy Dr. Luigi Salemme, Montevergine Hospital Napoili, Italy.

Myval THV: Detailed Sizing Guide

3D Annular area mm²		270	280	290	300	310	314	320	330	340	350	360
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	21.4
% 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%	-12.7%
	21.5 mm	34.5%	29.7%	25.2%	21.0%	17.1%	16%	13%	10%	7%	4%	0.8%
	23 mm	53.9%	48.4%	43.3%	38.5%	34.0%	32.3%	29.8%	25.9%	22.2%	18.7%	15.4%

3D Annular area mm²		370	380	390	400	410	415	420	430	440	450	460	470
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%	-11.6%
	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%	0.3%
	26 mm	43.5%	39.7%	36.1%	32.7%	29.5%	27.9%	26.4%	23.5%	20.7%	18.0%	15.4%	13.0%

3D Annular area mm²		480	490	500	510	520	530	540	550	560	570	580	590
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	27.4
% Annular area over/under	26 mm	10.6%	8.4%	6.2%	4.1%	2.1%	0.2%	-1.7%	-3.5%	-5.2%	-6.9%	-8.5%	-10.0%
	27.5 mm	23.7%	21.2%	18.8%	16.5%	14.2%	12.1%	10.0%	8.0%	6.1%	4.2%	2.4%	0.7%
	29 mm	37.6%	34.8%	32.1%	29.5%	27.0%	24.6%	22.3%	20.1%	17.9%	15.9%	13.9%	12.0%

3D Annular area mm²		600	610	620	630	640	650	660	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	21.8%	19.8%	17.8%	16.0%	14.2%	12.4%	10.7%	9.0%	7.4%	5.9%	4.4%	2.9%
	32 mm	34.0%	31.8%	29.7%	27.7%	25.7%	23.7%	21.9%	20.0%	18.3%	16.6%	14.9%	13.3%

3D Annular area mm²		720	730	740	750	760	770	416	790	800	810	820	830	840
3D area-derived diameter mm		30.3	30.5	30.7	30.9	31.1	31.3	23.0	31.7	31.9	32.1	32.3	32.5	32.7
% Annular area over/under	32 mm	11.7%	10.2%	8.7%	7.2%	5.8%	4.4%	93.3%	1.8%	0.5%	-0.7%	-1.9%	-3.1%	-4.3%

Area-derived diameter based on MSCT cross-sectional measurements

Myval THV: Size Matrix

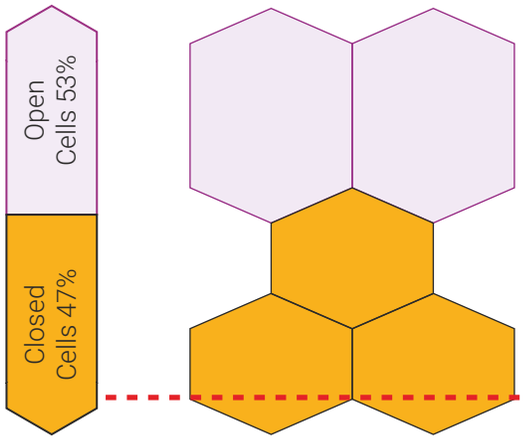
Myval THV Size Matrix & Technical Specifications	Area 314 mm^2 17.35 mm  20 mm	Area 363 mm^2 18.35 mm  21.5 mm	Area 415 mm^2 17.85 mm  23 mm	Area 471 mm^2 18.75 mm  24.5 mm
Perimeter	62.83 mm	67.54 mm	72.26 mm	76.97 mm
Native annulus area	270 - 330 mm^2	314 - 380 mm^2	360 - 440 mm^2	410 - 500 mm^2
Area-derived 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 Dimensions 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

* Infra-annular depth may depend on final landing zone position prior to valve deployment. The values mentioned are indicative range.

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 introducer sheath
- 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

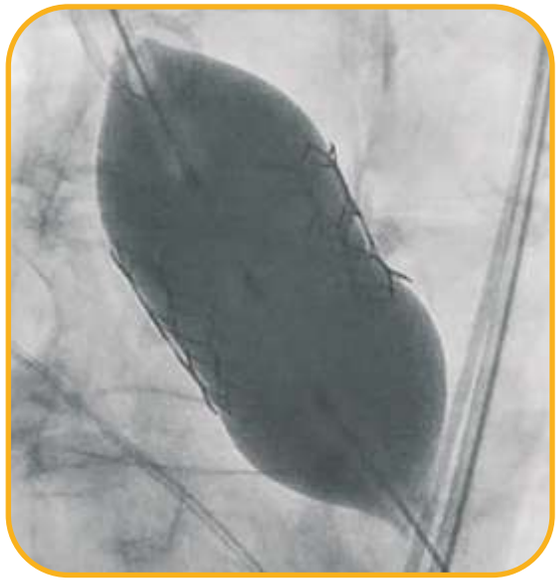
Navigator THV Delivery System
Characteristic Balloon Expansion

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

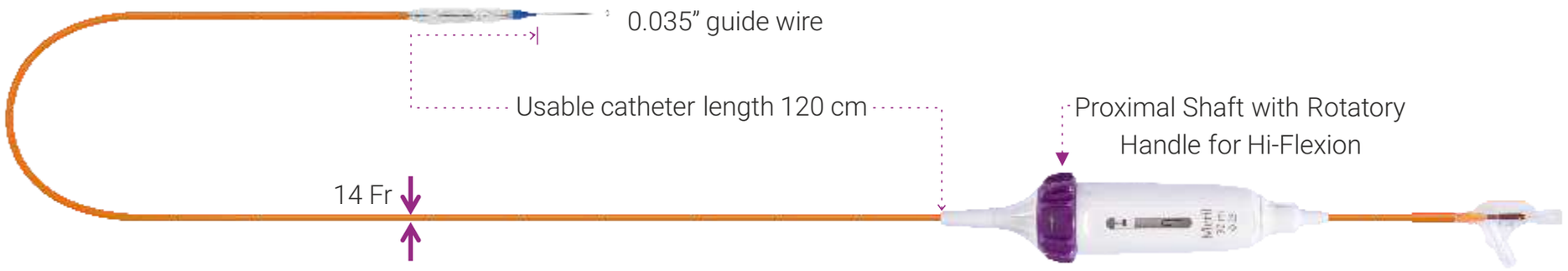
- This typical dog bone pattern of inflation steadies the valve during expansion phase, ensuring its precise annular position and deployment without any risk of valve migration

- 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

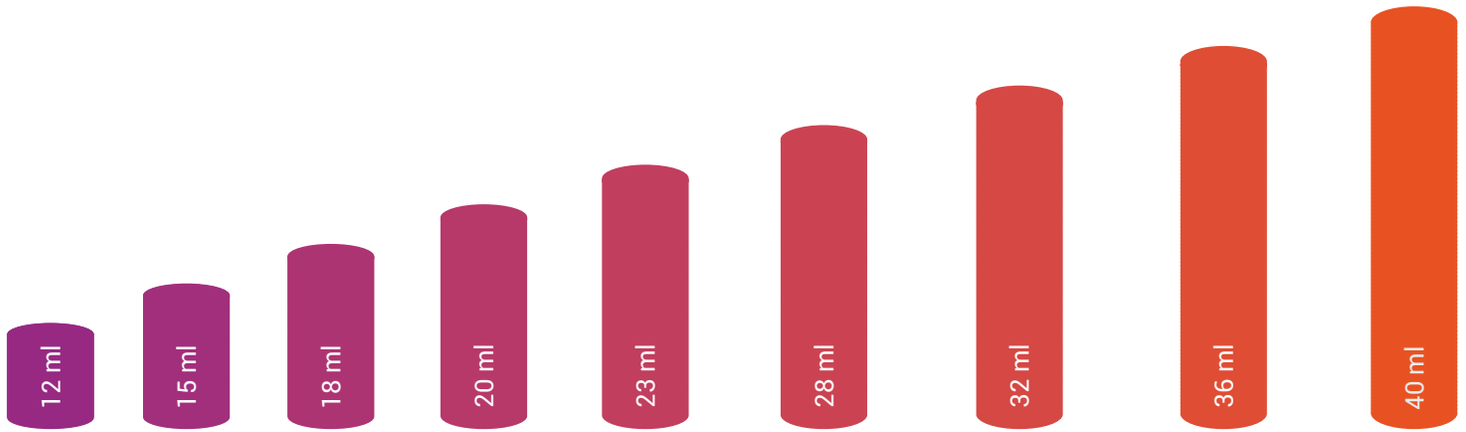


Navigator THV Delivery System



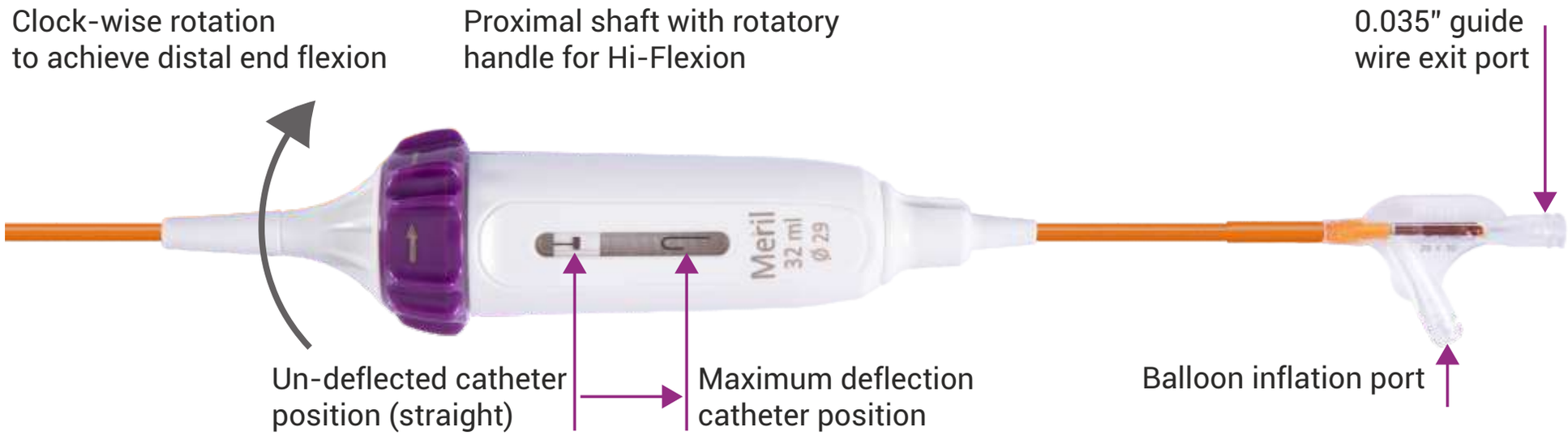
Navigator Balloon Ø	20 mm, 21.5 mm, 23 mm, 24.5 mm, 26 mm, 27.5 mm, 29 mm, 30.5 mm, 32 mm
Balloon Length	30 mm, 35 mm
Balloon RBP	6 atm

Volume of 75:25 Saline: Contrast to achieve stated balloon diameter

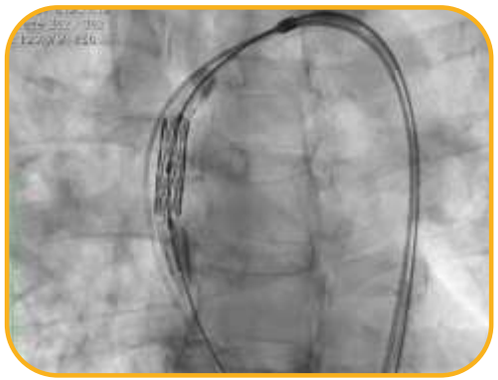


Navigator – THV Delivery System has been indigenously developed by Meril Life Sciences Pvt. Ltd.

Navigator THV Delivery System: Proximal Assembly



Hi-flexion feature ensures tracking the THV delivery system
via inner aortic arch curve thereby minimizing the risk of contralateral wall scraping



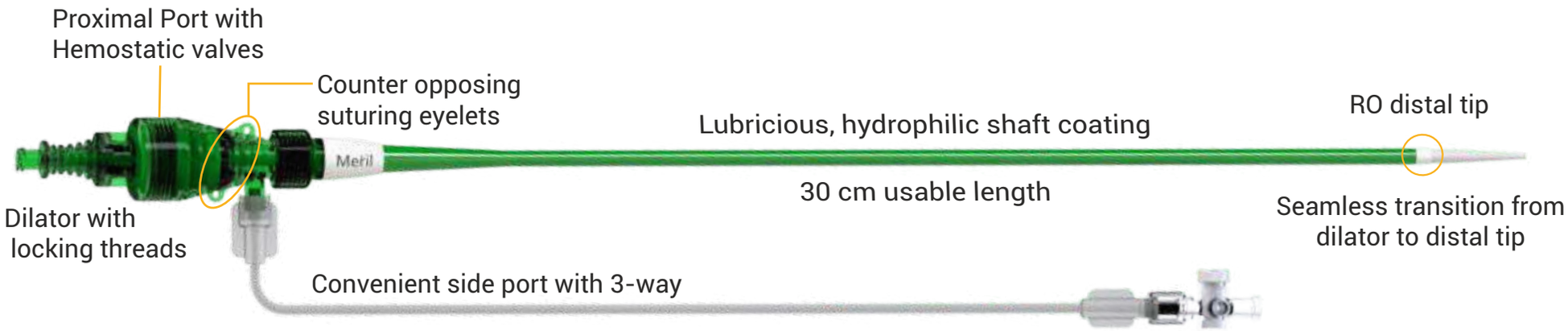
Caution: Always remember to fully un-flex the Navigator system while withdrawing

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



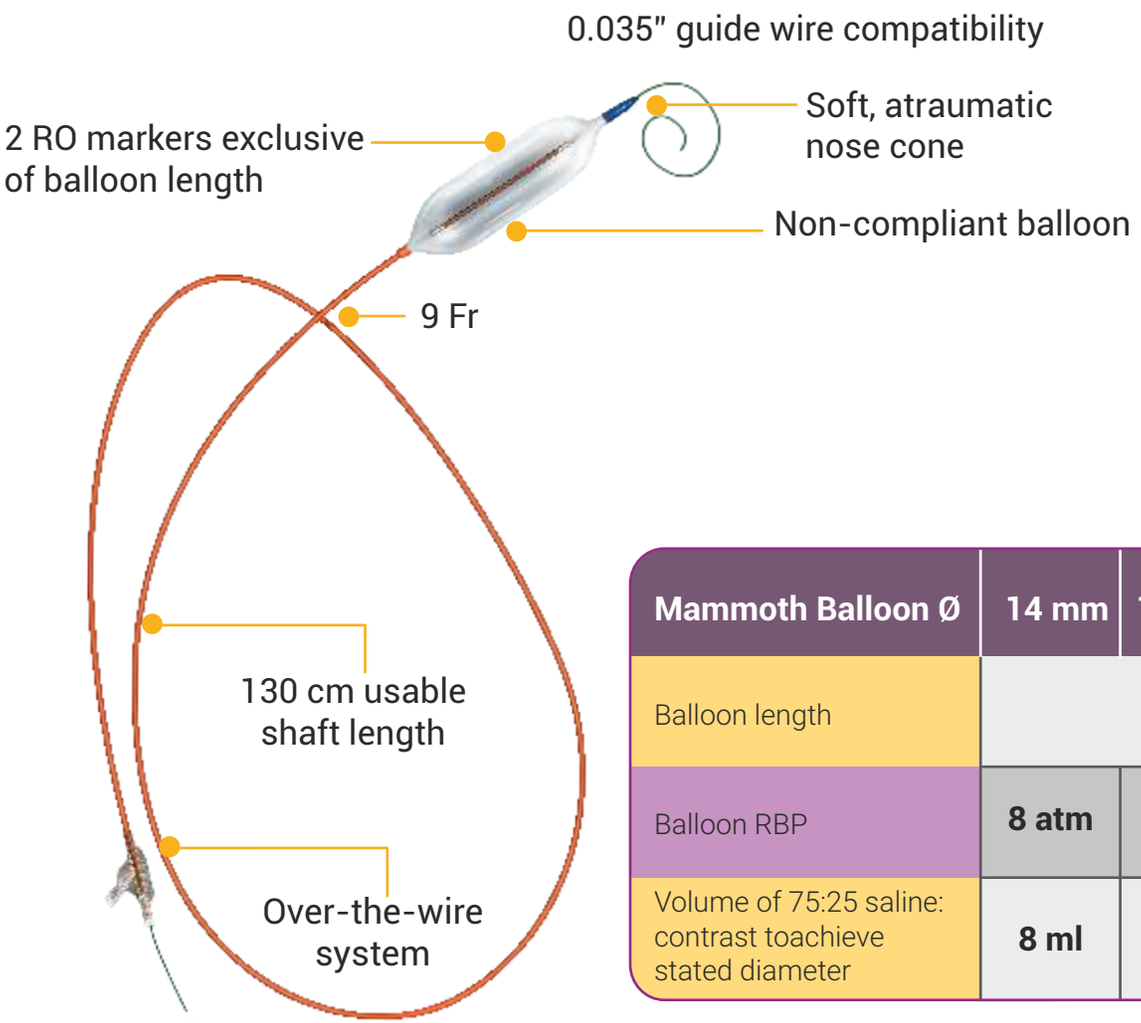
Two separate, calibrated loading tubes ensure temporary opening of hemostatic valves in proximal port allowing smooth passage of crimped Myval THV System

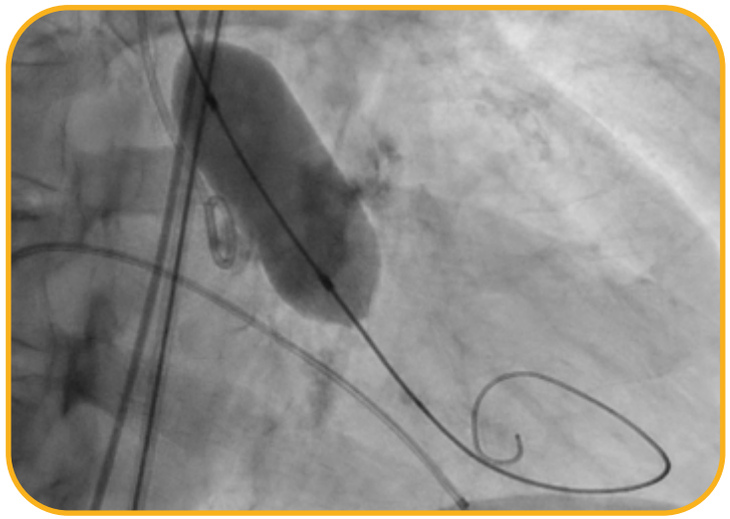
Common Femoral Artery* Ø (mm)	Myval THV Ø (mm)
≥ 5.50 mm	20 mm, 21.5 mm, 23 mm, 24.5 mm
≥ 6.00 mm	26 mm, 27.5 mm, 29 mm
≥ 6.50 mm	30.5 mm, 32 mm
*CFA Ø must be MSCT derived. Excluding circumferential Ca^{2+}	

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



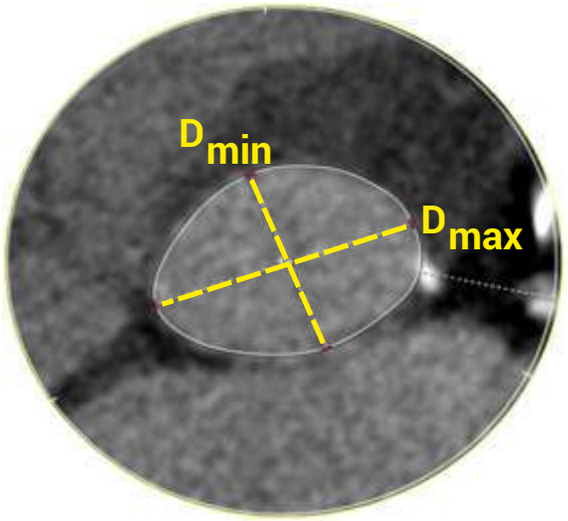


Mammoth Balloon Ø	14 mm	16 mm	18 mm	20 mm	23 mm	25 mm	28 mm	30 mm
Balloon length	← 40 mm →							
Balloon RBP	8 atm	← 6 atm →						
Volume of 75:25 saline: contrast toachieve stated diameter	8 ml	10 ml	13 ml	16 ml	23 ml	25 ml	34 ml	42 ml

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

Pre-Dilatation & Balloon Sizing Rationale

- **Balloon diameter approximated to shortest axis of annular diameter measured on MSCT to be considered in order to -**
  - Ensure controlled crossing of THV across the diseased, narrowed annulus (AVA)*(prevent abrupt jumping into LV)*
  - Minimize unwarranted risk of AR due to pre-dilatation
  - Reduce propensity for iatrogenic damage to the conduction system
  - Simulate expansion behavior of the diseased native leaflets
    - Assess potential risk of ostial jailing and estimate coronary perfusion



AoV Annulus Cross-sectional View

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

100 pt. 1-year follow-up presented by Dr. Ravinder Singh Rao at PCR Valves e-Course 2020

Myval European Study[2]
(n=200)

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

LANDMARK Trial[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	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	Currently enrolling	Under planning	Pre-study activities initiated
30-day f/up est. @ PCR-LV 2021	***1-year f/up est. @ EuroPCR 2023***	***1-year f/up est. @ EuroPCR 2023***	***First patient first visit est. @ QIV 2021***	***First patient first visit est.@ QIV 2022***

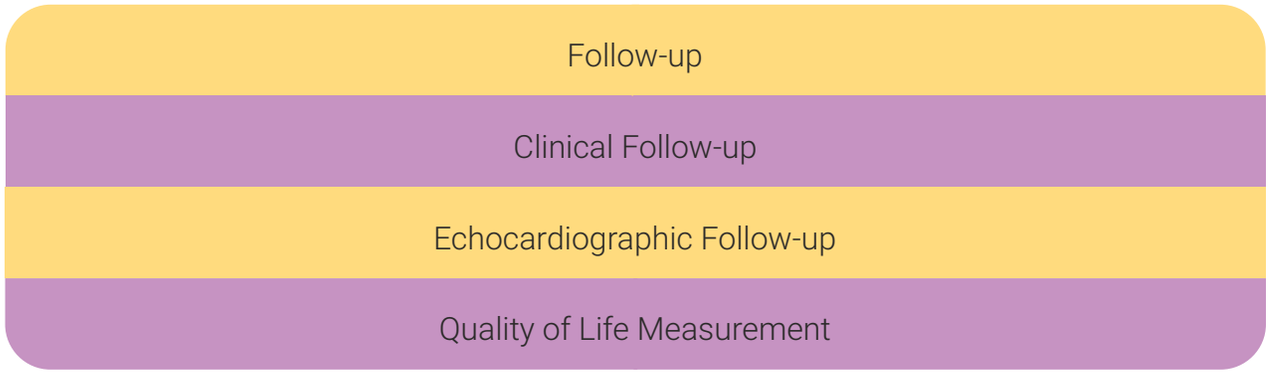
MyVal-1: Study Design

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



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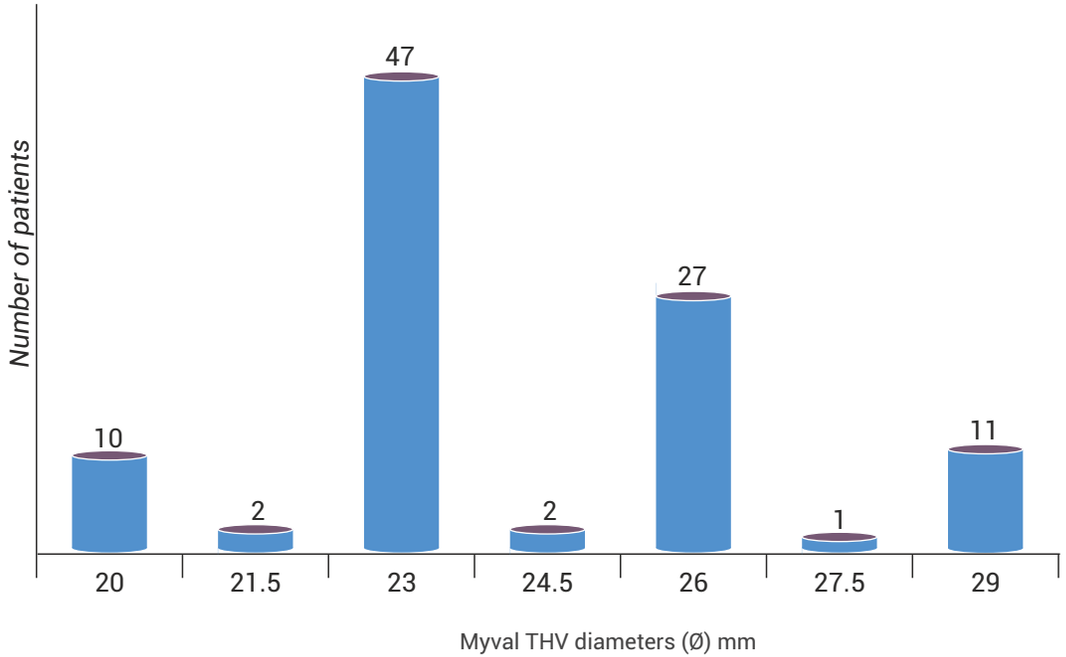
Study Investigators: Samin Sharma, Ravinder Singh Rao, John Jose, Praveen Chandra, Pravin K. Goel, G. Sengottuvelu, Prashant Bharadwaj, C. N. Manjunath, P. C. Rath, Rajiv Chandrasekharan Nair, Rajpal Abhaichand, Ajit Mullasari, V. K. Ajith Kumar, Ajaykumar U. Mahajan, Ganesh Kumar, Jaspal Singh Arneja, Keyur Parikh, R. K. Jain, S. M. Sharma, B. B. Chanana, Jagdish Parikh, M. S. Hiremath, Rishi Sethi, Rony Mathew Kadavil, R. R. Mantri, Sanjay Mehrotra, Tarlochan Singh Kler, T. R. Murlidharan, Vijay Trehan, Ashok Seth
MyVal-1 study, one year results presented by Dr. Ravinder Singh Rao at PCR Valves e-Course 2020
MyVal-1 Study (CTRI/2016/11/007512)

Sharma SK, et.al. First-in-human evaluation of a novel balloon-expandable transcatheter heart valve in patients with severe symptomatic native aortic stenosis: the MyVal-1 study. EuroIntervention. 2020 Aug 28;16(5):421-9. PMID: 31566572. doi: 10.4244/EIJ-D-19-00413
Erratum for: EuroIntervention. 2020 Aug 28;16(5):421-429. PMID: 32855114. doi: 10.4244/EIJ-D-19-00413C

MyVal-1: Baseline Characteristics

Patient History	
Average Age (years)	73.51 ± 7.49
Mean STS	5.12 ± 1.64
History of Coronary Artery Bypass Graft surgery	17%
History of Previous PCI	13%
History of Previous Aortic Valvuloplasty	1%
History of Cerebro-Vascular Events	3%
Peripheral Vascular Disease	3%

Based on the annular size,
a bioprosthetic valve of specific size was decided for each patient



- When novel intermediate sizes of the transcatheter heart valves were introduced, recruitment of only 10% of patients was remaining (of 10 patients, 5 patients were implanted with the intermediate-size study device)
- 23 mm transcatheter heart valve was implanted in 47% of the patient population- reflective of the Indian aortic annulus anatomy

MyVal-1: Cumulative Clinical Outcomes up to 1-Year Follow-up

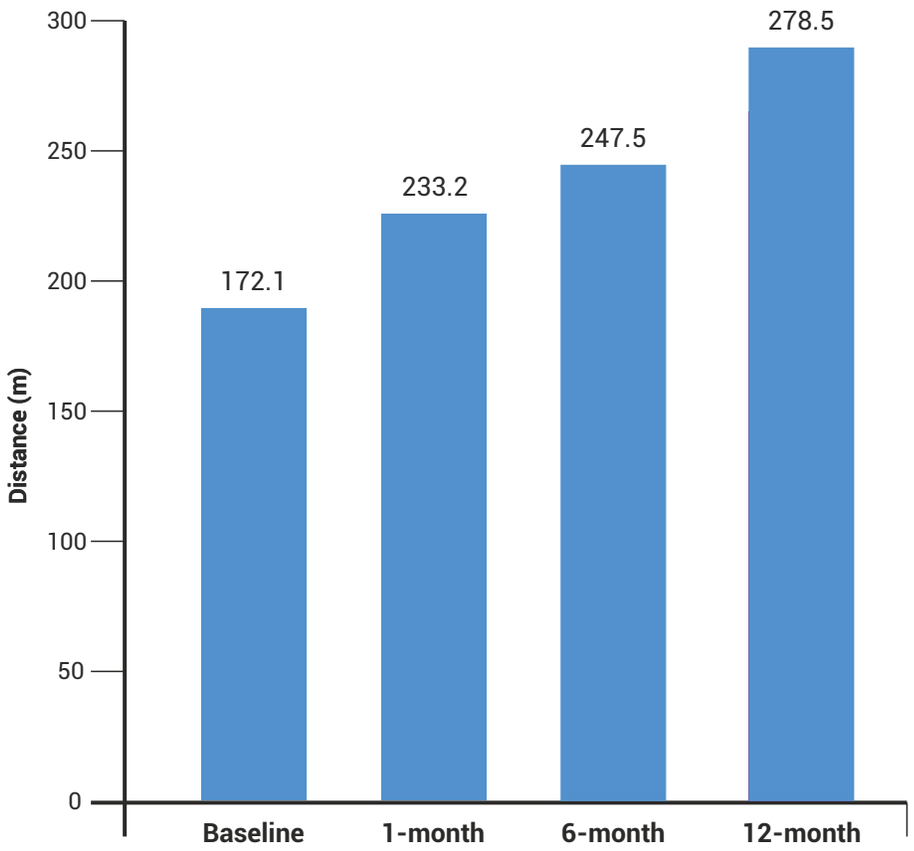
Clinical Events[#]	Post-procedure (n=100)	1-Month Follow-Up (n=100)	6-Month Follow-Up (n=100)	12-Month Follow-Up (n=100)
Survival	98%	97%	91%	87%
All-cause Mortality	2%	3%	9%	13%
All Stroke	1%	2%	2%	2%
Disabling	0%	1%	1%	1%
Non-disabling	1%	1%	1%	1%
Acute Renal Failure	2%	2%	2%	2%
Life-threatening or disabling bleeding	1%	1%	1%	1%
Endocarditis	0%	0%	1%	1%
Myocardial Infarction	0%	0%	0%	1%
Vascular Complications	3%	3%	3%	3%
Repeat Hospitalization	NA	8%	11%	17%
New Permanent Pacemaker	2%*	2%	2%	2%

*One patient had RBBB pre-procedure

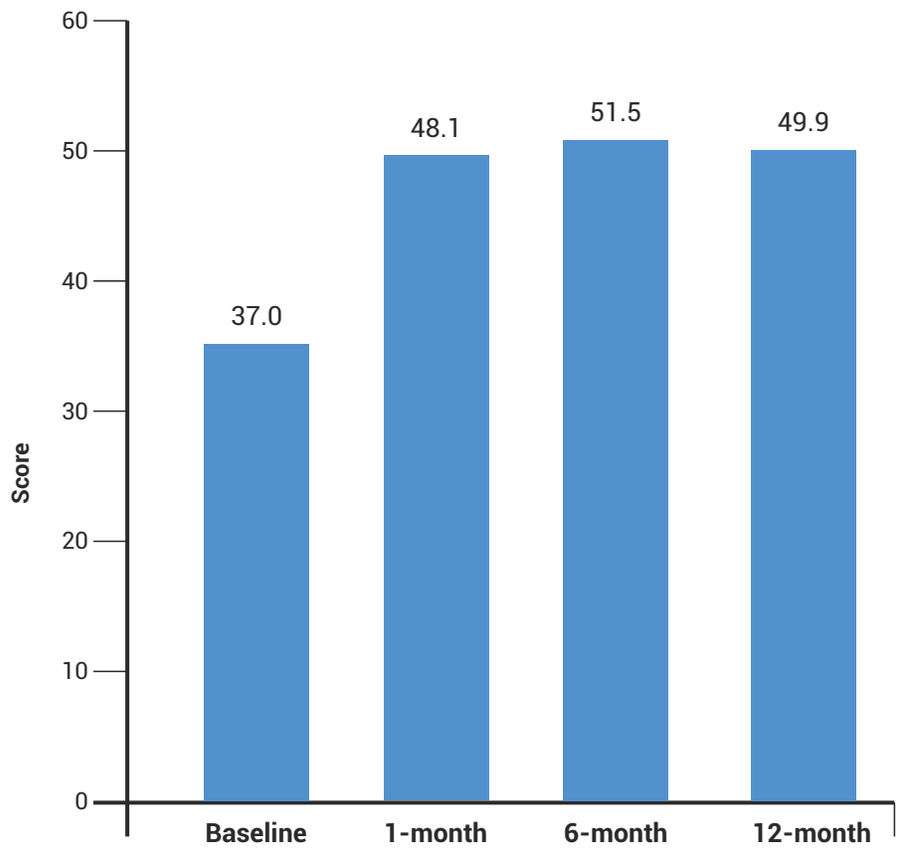
[#]Kappetein AP, Head SJ, Généreux P, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. Eur Heart J. 2012;33:2403-2418.

MyVal-1: Marked Improvement in Quality of Life Parameters

Six-minute walk test



Kansas City Cardiomyopathy Questionnaire Score



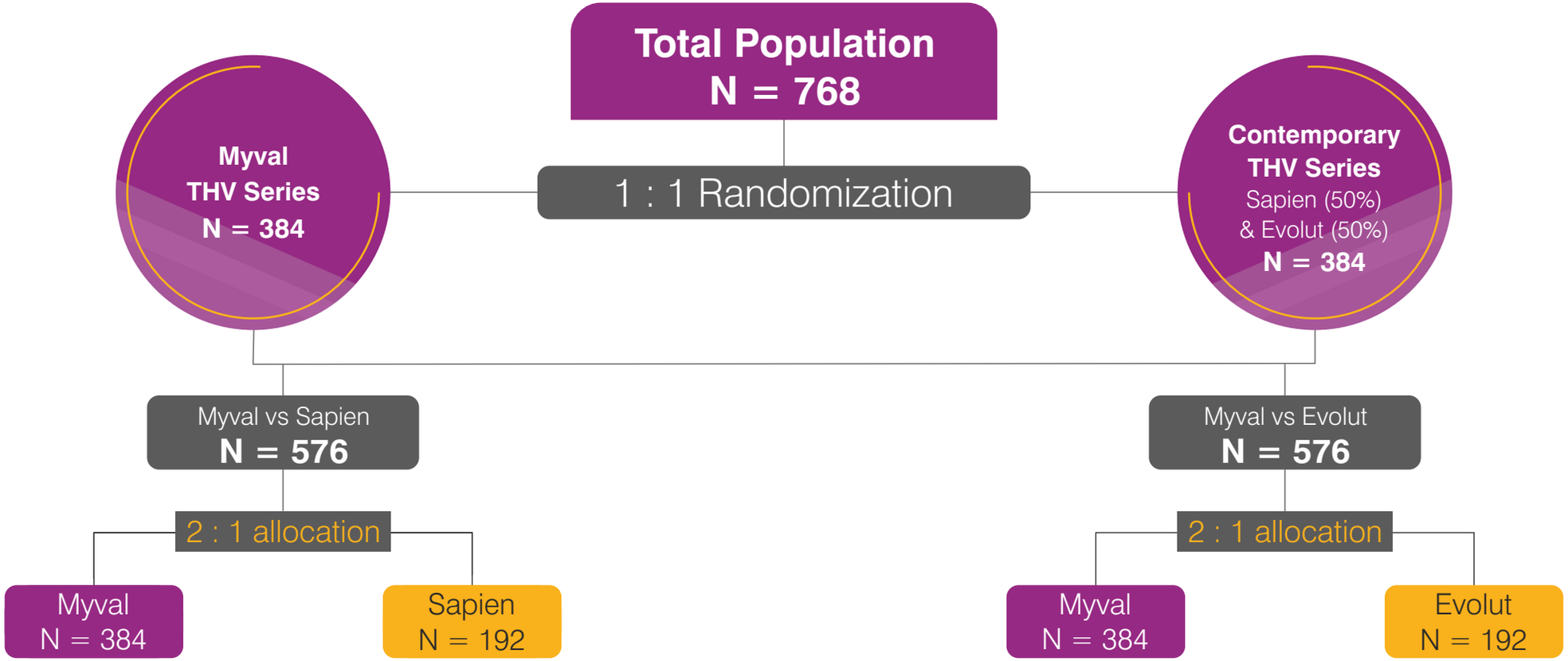
There was significant improvement in six-minute walk test and Kansas City Cardiomyopathy Questionnaire score from baseline to 12 months

MyVal-1: Study Conclusion

- **In 100 intermediate to high-risk patients of MyVal-1 study,** the next-generation balloon-expandable transcatheter heart valve system demonstrated favourable clinical and haemodynamic outcomes at 12-month follow-up
  - **87% survival and low incidence of all stroke (2%)**
  - **Low rate (2%) of new permanent pacemaker implantation**
  - High procedural success that can be attributed to precise orthotopic valve positioning

- In real-world global experience of 2500+ 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. Large size matrix : Conventional Ø 20, 23, 26, 29 mm, 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 (20-32 mm); with high convenience of full retrievability of an un-deployed Myval THV system

LANDMARK Trial – 50+ Sites EU+ANZ



Primary Endpoint – 30 Days

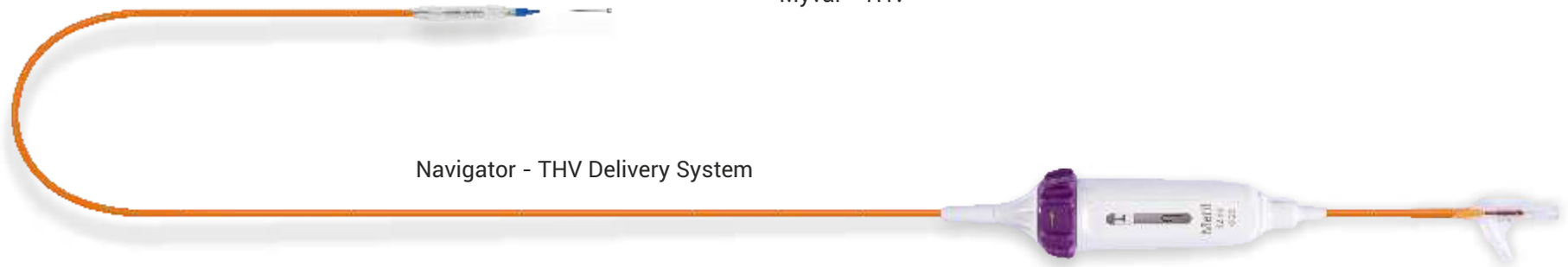
All cause mortality | All stroke | Life-threatening bleeding | Vascular complications
Acute kidney injury | Paravalvular leak | New permanent pacemakers

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**

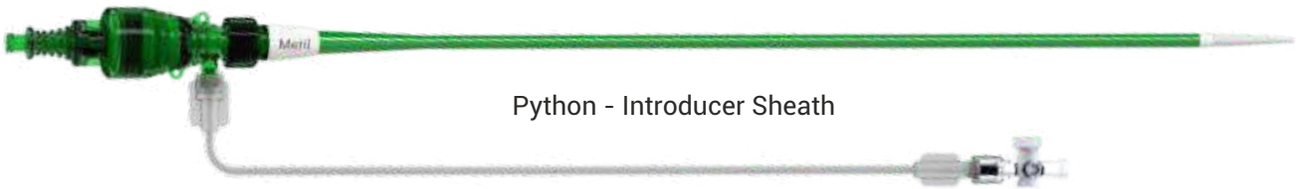
Currently enrolling

Myval THV System and Components

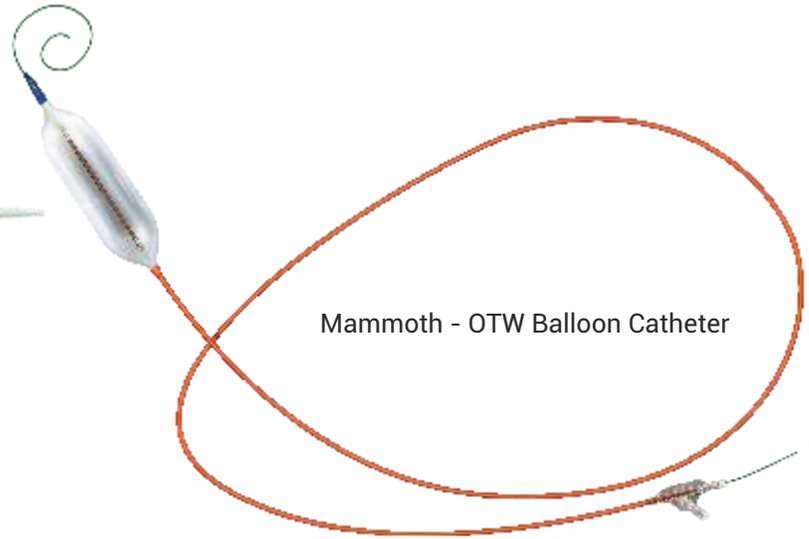
Myval - THV



Navigator - THV Delivery System



Python - Introducer Sheath



Mammoth - OTW Balloon Catheter

Myval THV System and Components - Ordering Information

Myval - THV

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

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 35mm	30.5 x 35 mm	32.0 x 35 mm
Product code	NVT20030	NVT21530	NVT23030	NVT24530	NVT26030	NVT27535	NVT29035	NVT30535	NVT32035

Mammoth - OTW Balloon Catheter

Diameters	14.0 x 40 mm	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	28.0 x 40 mm	30.0 x 40 mm
Product code	MTV1440	MTV1640	MTV1840	MTV2040	MTV2340	MTV2540	MTV2840	MTV3040

Python - Introducer Sheath

Product code	PHT14

Val-de-Crimp - Heart Valve Crimping Tool

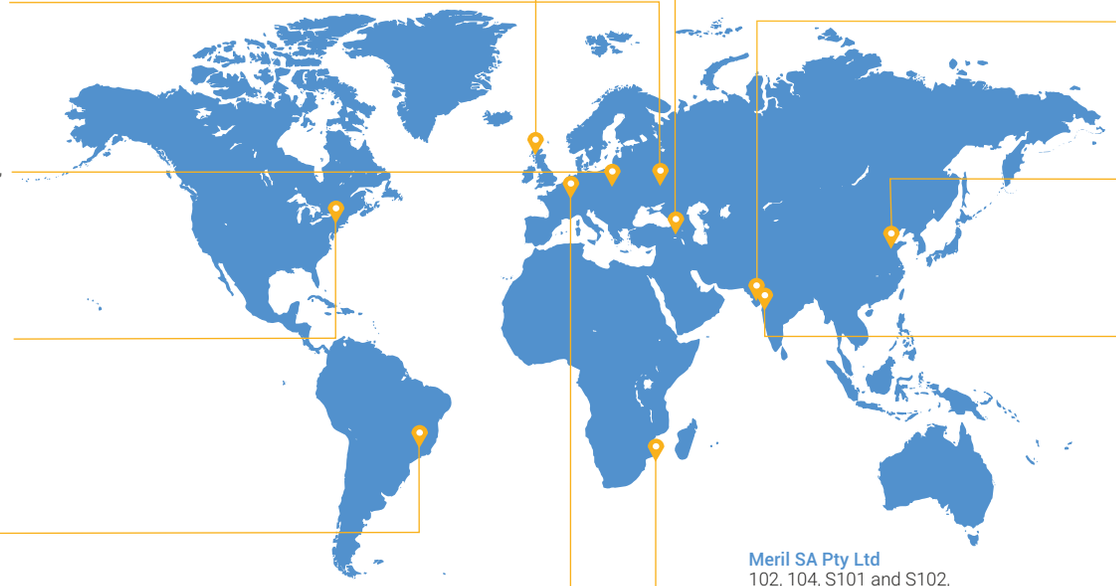
Product code	VLDC

Myval™
TRANSCATHETER HEART VALVE
PRECISION AT HEART

Meril
More to Life

Check availability of Myval THV in your country

Meril's Global Presence



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