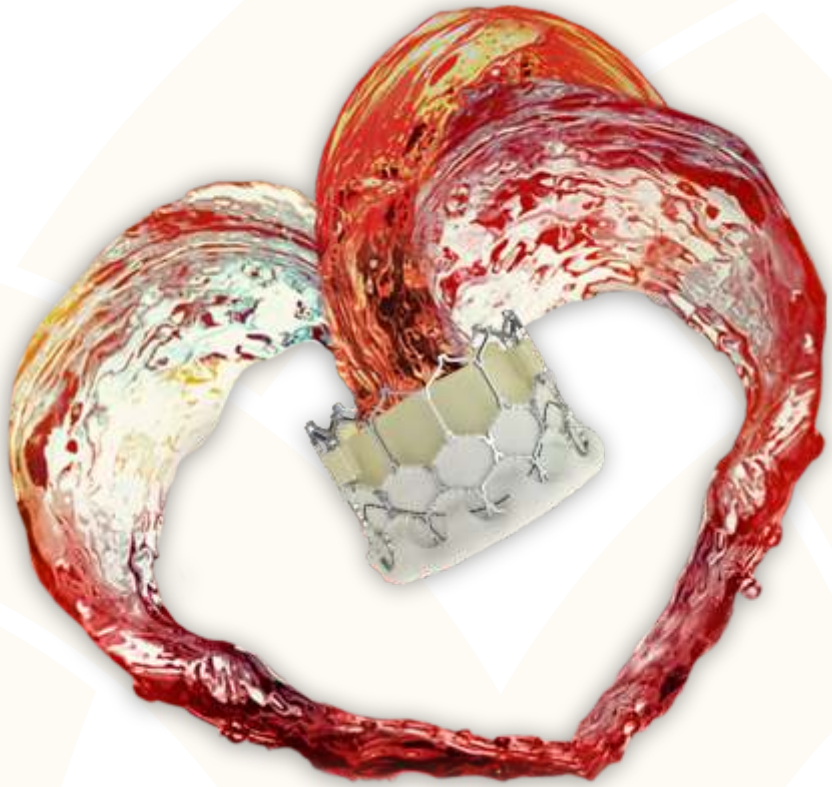
Myval™
TRANSCATHETER HEART VALVE SYSTEM
PRECISION AT HEART

Meril
Cardiovascular

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

CE APPROVED

Myval™
TRANSCATHETER HEART VALVE SYSTEM
PRECISION AT HEART



MyVal-1 Study
30 days Outcome

Low* Device-Related Mortality
New Permanent Pacemaker
Incidence of Stroke

97% Device Success*

*30-day primary outcome data presented by Dr. Ravinder Singh Rao at PCR London Valves 2019.

Myval THV: Designed for Precision in Outcomes

Hybrid Honeycomb Cell Design Concept

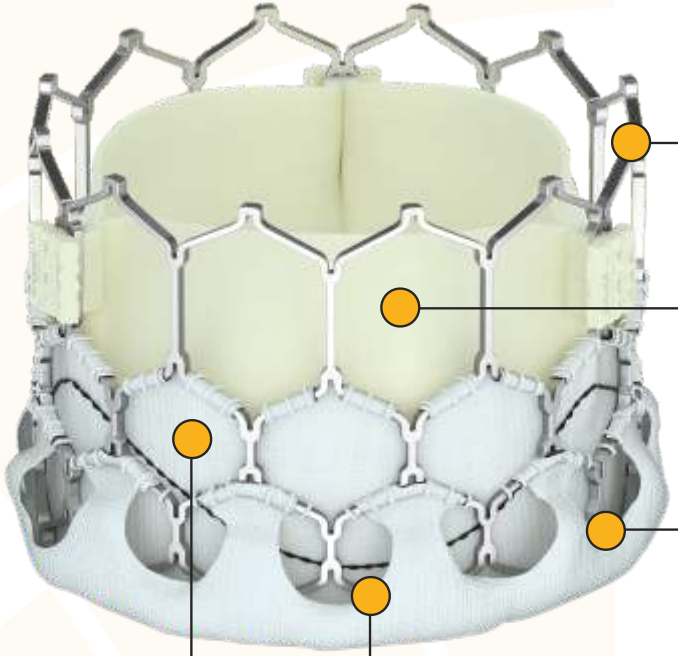
Open cells on upper half to ensure un-jailing of coronary ostia

Closed cells on lower half for high radial strength

≈ 53%

≈ 47%

Frame height 17-21 mm



Cobalt alloy frame for high radial strength & radiopacity

Bovine pericardium tri-leaflet valve

External PET buffing to minimize para-valvular leaks

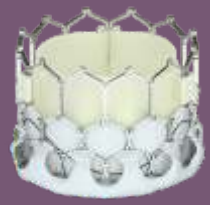
Internal PET sealing cuff for lower profile & puncture resistance

Ø – 20mm, 23mm, 26mm, 29mm# - Standard sizes
Ø – 21.5mm, 24.5mm, 27.5mm - Intermediate Sizes
Ø – 30.5 mm, 32 mm* - XL Sizes

Myval THV has been indigenously developed by Meril Life Sciences Pvt. Ltd. & is CDSCO approved.

- Sizes available now
* - Contact Meril Representative for information and availability in your country.
Myval THV diameter sizes 30.5 mm and 32 mm are currently not CE approved. Myval THV diameter size 30.5 mm is currently pending approval from CDSCO.

Myval THV: Size Matrix

Myval THV Size Matrix & Technical Specifications	Area 314 mm^2 17.50 mm  20 mm	Area 415 mm^2 18 mm  23 mm	Area 531 mm^2 19 mm  26 mm	Area 661 mm^2 20.50 mm  29 mm
Perimeter	62.83 mm	72.26 mm	81.68 mm	91.11 mm
Native annulus area	270 - 330 mm^2	360 - 440 mm^2	460 - 560 mm^2	570 - 700 mm^2
Area-derived diameter	18.5 - 20.5 mm	21.4 - 23.7 mm	24.2 - 26.7 mm	26.9 - 29.9 mm
Native annulus size by TEE	16 - 19 mm	18 - 22 mm	21- 25 mm	24 - 28 mm

Myval THV: Additional* Size Matrix

Myval THV Size Matrix & Technical Specifications	← Myval Intermediate Size →			← Myval XL Size →	
	Area 363 mm^2 18.50 mm  21.5 mm	Area 471 mm^2 18.90 mm  24.5 mm	Area 594 mm^2 19.40 mm  27.5 mm	Area 731 mm^2 21.05 mm  30.5 mm	Area 804 mm^2 21.30 mm  32 mm
Perimeter	67.54 mm	76.97 mm	86.39 mm	95.82 mm	100.53 mm
Native annulus area (mm^2)	314-380 mm^2	410-500 mm^2	510-630 mm^2	630-770 mm^2	700-840 mm^2
Area-derived diameter	20-22 mm	22.8-25.2 mm	25.5-28.3 mm	28.3-31.3 mm	29.9-32.7 mm
Native annulus size by TEE	17.5-20.5 mm	19.5-23.5 mm	22.5-26.5 mm	25.5-29.5 mm	27-31 mm

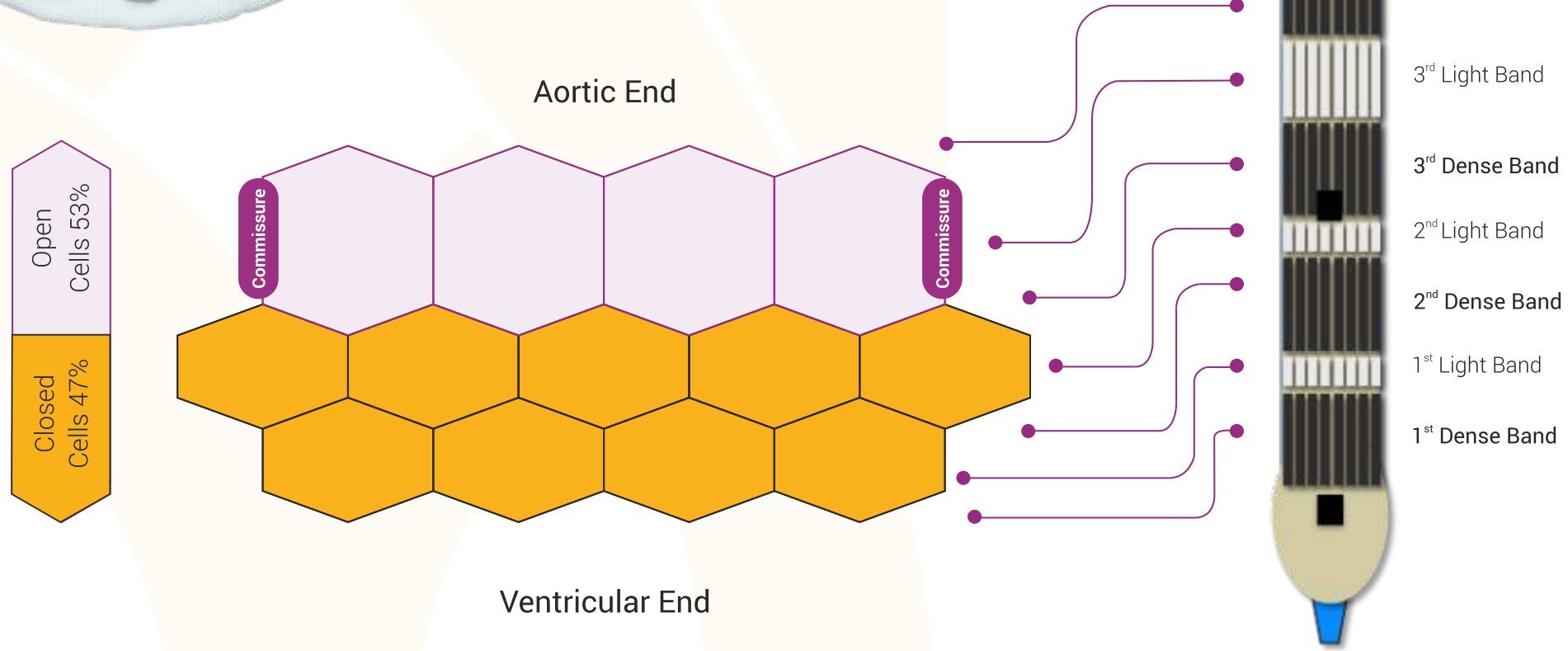
14Fr Python - Expandable Introducer Sheath can be used for all Myval THV diameter sizes up to 32 mm.

* Contact Meril Representative for information and availability in your country. Myval THV diameter sizes 30.5 mm and 32 mm are currently not CE approved.
Myval THV diameter size 30.5 mm is currently pending approval from CDSCO.

Myval THV: Precise Crimping

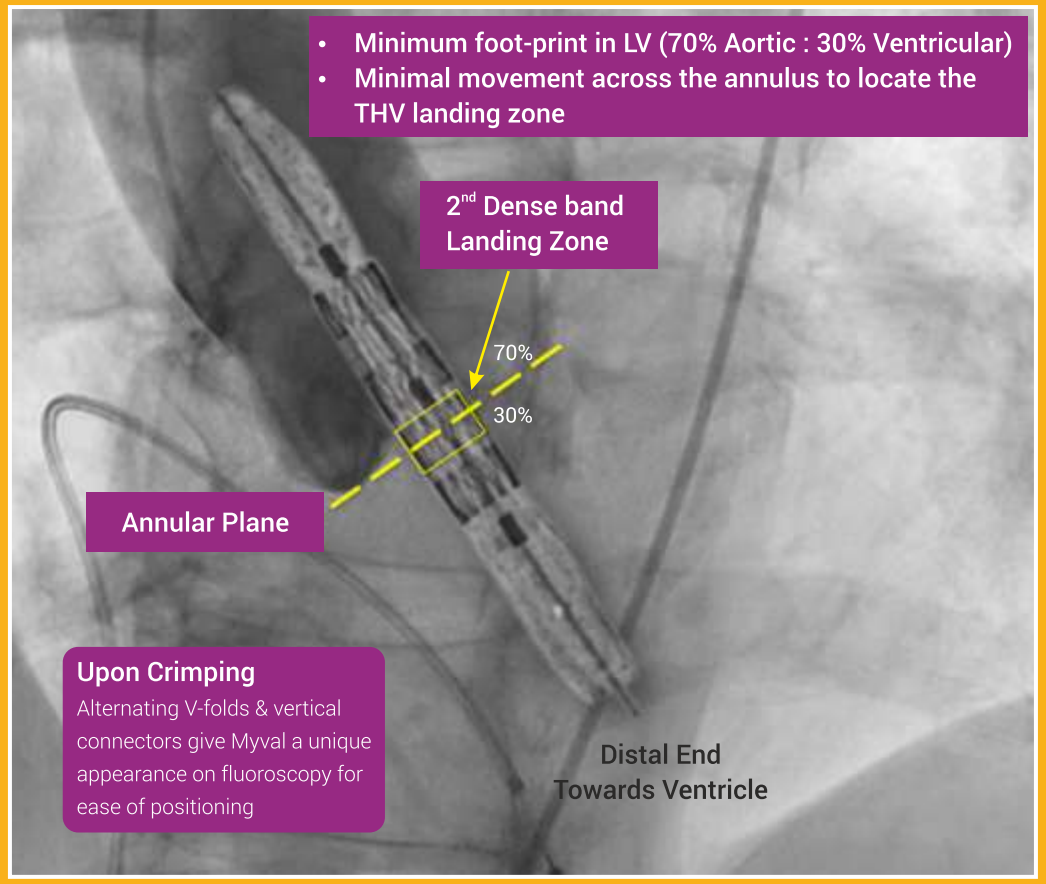
Upon Crimping:

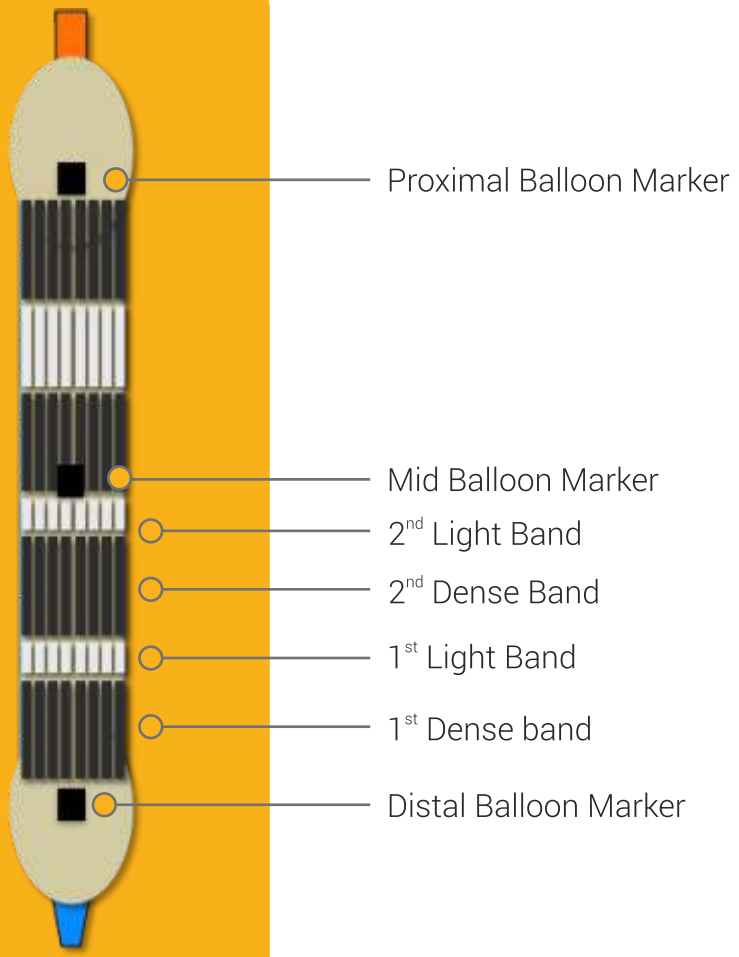
- **V-shaped hinges** on hexagonal frame fold, generating the dense bands on fluoroscopy
- **Vertical "I" connectors** give rise to light bands
- Alternating V-folds & vertical connectors give Myval a unique appearance on fluoroscopy for ease of positioning



Myval THV: Precise Placement Technique

Schematic of Myval THV - Ideal Landing Zone

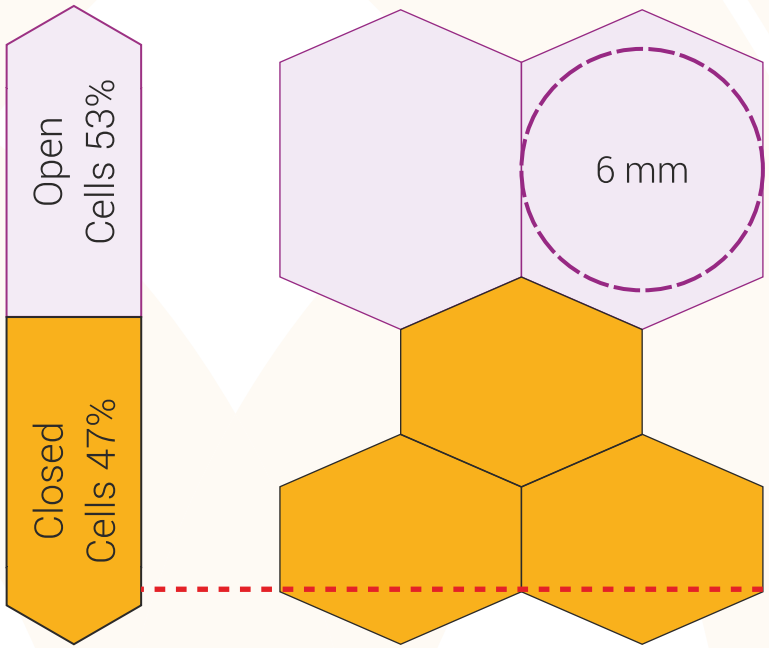




The characteristic bands may not be visible in-case the THV system is not co-axial to the annular plane.
In this case, THV landing zone must be referenced using Mid-Balloon marker which has to be ~ 3 mm above the annular plane.

Myval THV: Ground Zero Deployment

- Shallow deployment of Myval with least engagement within LVOT is possible
- Optimal orthotopic anchorage of THV post deployment (80:20) without risk of THV migration
- Minimal infra-annular depth (range of 3-3.50 mm) to avoid conduction system interference (thus minimizing the need of new permanent pacemaker dependency)



Largest circumscribable diameter in Open Cell

Myval THV infra-annular depth range
3 – 3.50 mm based on THV Ø

Angiography 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%						
	21.5 mm						16%	13%	10%	7%	4%	
	23 mm											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%							
	24.5 mm					15.0%	13.6%	12.2%	9.6%	7.1%	4.8%	2.5%	
	26 mm												12.7%

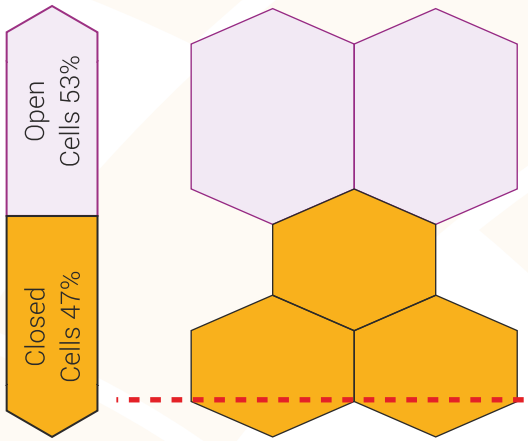
3D Annular area mm²		480	490	500	510	520	531	540	550	560	570	580	594
3D area derived diameter mm		24.7	25.0	25.2	25.5	25.7	26.0	26.2	26.5	26.7	26.9	27.2	27.5
% Annular area over/under	26 mm	10.6%	8.4%	6.2%	4.1%	2.1%							
	27.5 mm					14.2%	11.9%	10.0%	8.0%	6.1%	4.2%		
	29 mm											13.9%	11.2%

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%								
	30.5 mm					14.2%	12.4%	10.5%	9.0%	7.4%	5.9%	4.4%	
	32 mm											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 Post Deployment Dimension Chart

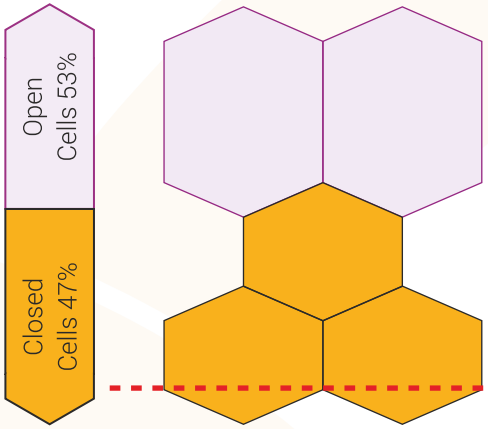


Largest circumscribable diameter in Open Cell

Myval Sizes	20 mm	23 mm	26 mm	29 mm
Myval total height	17.50 mm	18 mm	19 mm	20.50 mm
Myval open cells 53%	9.20 mm	9.46 mm	9.99 mm	10.79 mm
Myval closed cells 47%	8.15 mm	8.39 mm	8.86 mm	9.56 mm
Myval Infra-annular height	3.05 mm	2.85 mm	3.05 mm	3.35 mm
Supra-annular height of closed cells	5.10 mm	5.54 mm	5.81 mm	6.21 mm
Recommendation for coronary protection	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.

Myval THV Post deployment Dimension Chart: Additional Sizing

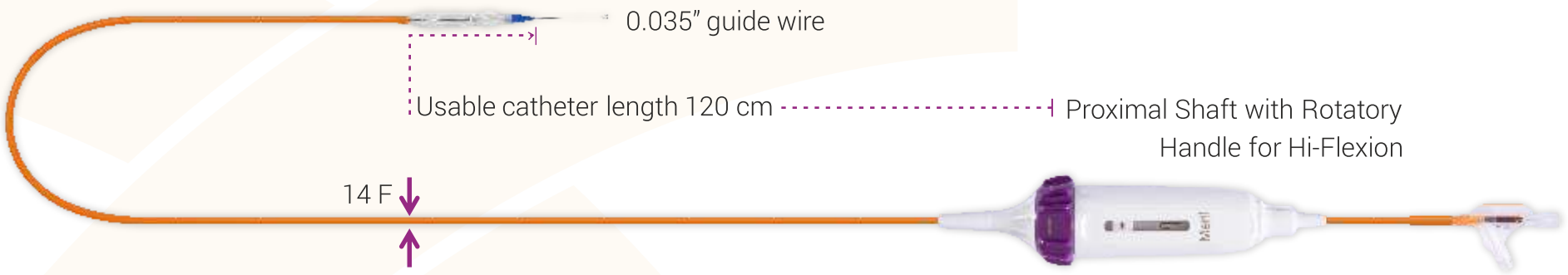


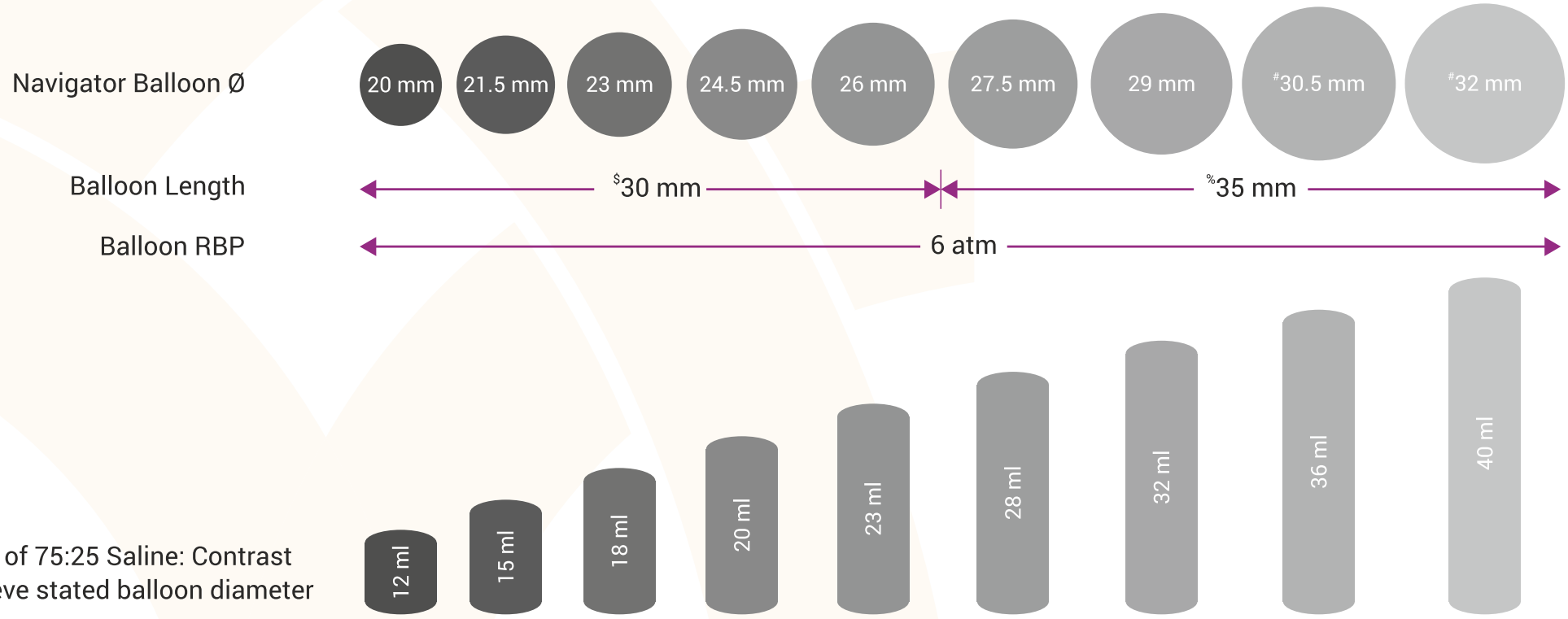
Largest circumscribable diameter in Open Cell

Myval Sizes	← Myval Intermediate Size →			← Myval XL Size →	
	21.5 mm	24.5 mm	27.5 mm	30.5 mm	32 mm
Myval total height	18.50 mm	18.90 mm	19.40 mm	21.05 mm	21.30 mm
Myval open cells 53%	9.73 mm	9.94 mm	10.20 mm	11.08 mm	11.21 mm
Myval closed cells 47%	8.62 mm	8.81 mm	9.05 mm	9.82 mm	9.94 mm
Myval Infra-annular height	3.20 mm	2.95 mm	3.15 mm	3.45 mm	3.55 mm
Supra-annular height of closed cells	5.42 mm	5.86 mm	5.90 mm	6.37 mm	6.39 mm
Recommendation for coronary protection	10 mm	10 mm	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.

Navigator THV Delivery System





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

30.5mm & #32mm dia. are currently not CE approved and approval pending from CDSCO for 30.5mm dia.
% 35mm length is currently not CE approved.
$ For Balloon length of 30mm, balloon diameters of 20mm, 21.5mm, 23mm, 24.5mm, 26mm, 27.5mm and 29mm are CE approved.

Navigator THV Delivery System: Proximal Assembly

Clock-wise rotation
to achieve distal end flexion

Proximal shaft with rotatory
handle for Hi-Flexion

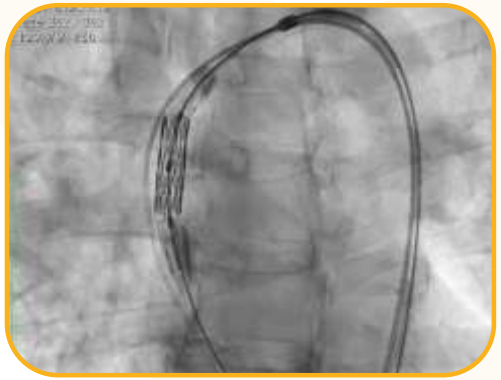
0.035" guide
wire exit port

Un-deflected Catheter
position (straight)

Maximum deflection
catheter position

Balloon inflation port

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

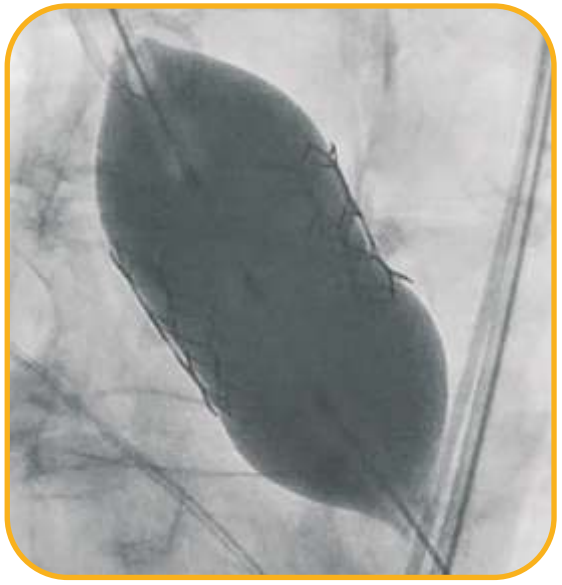
Navigator Balloon Expansion

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 or embolization

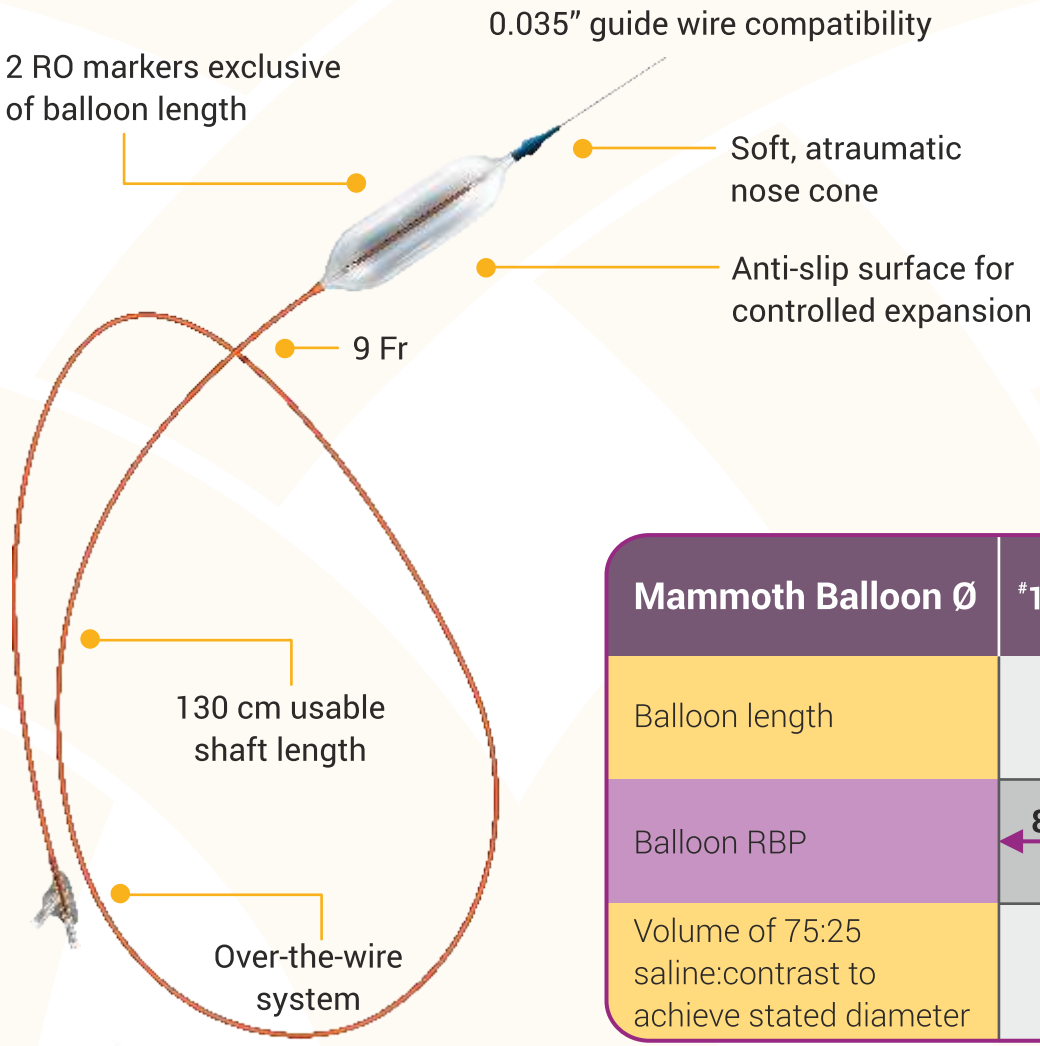
Rapid balloon inflation using an inflation device is possible with controlled palm thrust

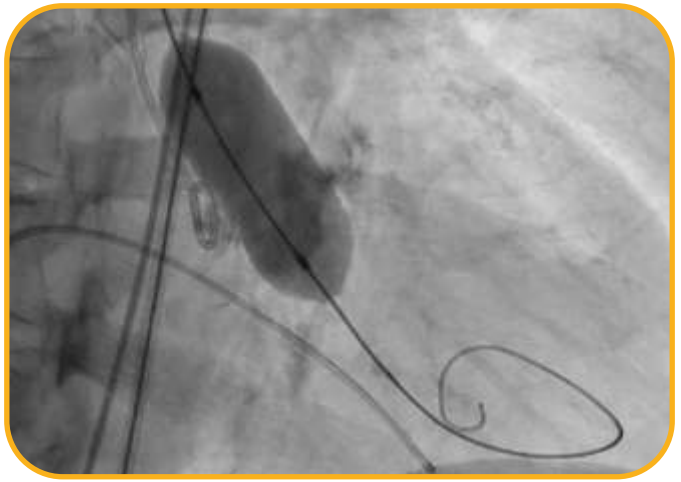
Rapid balloon deflation within 3-5 sec ensures procedure safety and compliance



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	#28 mm	#30 mm
Balloon length	40 mm							
Balloon RBP	8 atm	6 atm						
Volume of 75:25 saline:contrast to achieve 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. India.

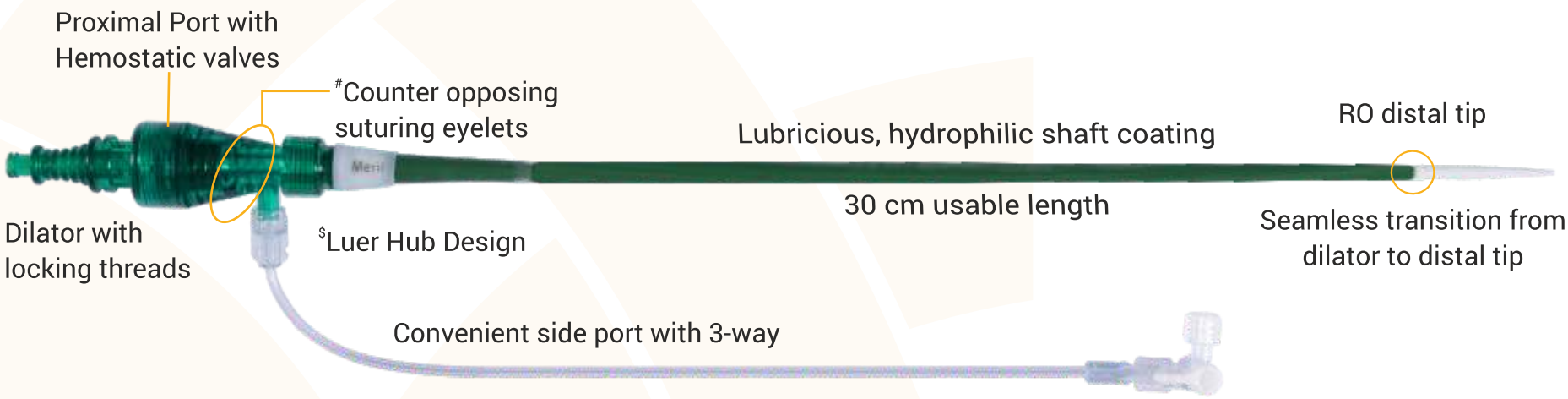
#14 mm, 28 mm, 30 mm dia. are currently not CE approved.
Balloon RBP is 8 ATM for 14 mm Mammoth Balloon

Python – Introducer Sheath
14Fr Profile for all Myval Ø 20 mm to 32 mm

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

14Fr Distal Entry Profile, Allows Atraumatic Percutaneous Access

Easy retrieval of crimped valve in case of inability to cross annulus



A separate loading tube ensures 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., India.

#Suture eyelets are not yet CE approved.
$Luer hub design is still not yet CE approved.

Myval THV Global Clinical Program

2000 Patients

Myval Global[4] (n=1,000)
Low, Intermediate to High surgical risk subjects. Real-world registry. 100 participating sites.

Myval-China[5] (n=110)
High surgical risk subjects
10 participating sites

MyVal-1[1] (n=100)
FiM Study. Intermediate to high surgical risk subjects.
29 Indian participating sites.

LANDMARK Trial[3] (n=768)
1:1 RCT Myval THV series : Contemporary Valves (Sapien and Evolut THV series)
Low, Intermediate to High surgical risk subjects.
EU/AUS/NZ 50+ participating sites.

Myval European Study[2] (n=200)
Retrospective registry of real-world EU population. 15 EU participating sites.

1. Primary endpoint achieved. Presented at PCR LV 2019.

2. 30-days results to be presented at EuroPCR 2020.

3. Initiated. First Patient First Visit expected Apr 2020.

4. Initiated. First Patient First Visit expected Jun 2020.

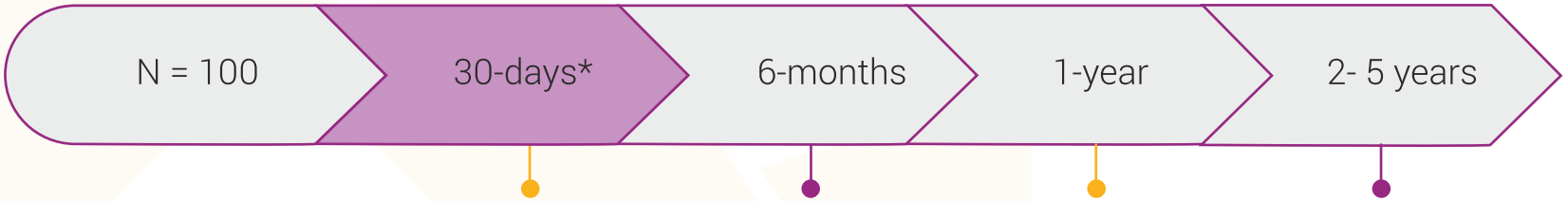
5. Pre-study activities initiated.

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

CLINICAL FOLLOW-UP



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

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

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-ordinating PI, Jaipur - India

Dr. PK Goel - Scientific Advisor, Lucknow, India

Study Investigators: Samin K. Sharma, Ravinder Singh Rao, Praveen Chandra, Gunasekaran Sengottovelu, Prashant Bharadwaj, Pravin Kumar Goel, George Joseph, John Jose, Pratap C. Rath, Rajpal K. Abhaichand, Rajiv C. Nair, Ajit S. Mullasari, V.K. Ajith Kumar, Bijulal S, Cholenahally N Manjunath, B.C. Srinivas, T.R. Raghu, Ajaykumar U. Mahajan, Ganesh Kumar, Jaspal Arneja, Keyur Parikh, Rajendra Kumar Jain, Shashi Mohan Sharma, Bharat Bhushan Chanana, M.S. Hiremath, Jagdish Parikh, Manik Chopra, S. Nagendra Boopathy, Rajneesh Jain, Rony Mathew Kadavil, Rishi Sethi, Sanjay Mehrotra, T.R. Murlidharan, T.S. Kler, Vijay Trehan, Ashok Seth. *30-day primary outcome data presented by Dr. Ravinder Singh Rao at PCR London Valves 2019

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

Excellent clinical safety & efficacy

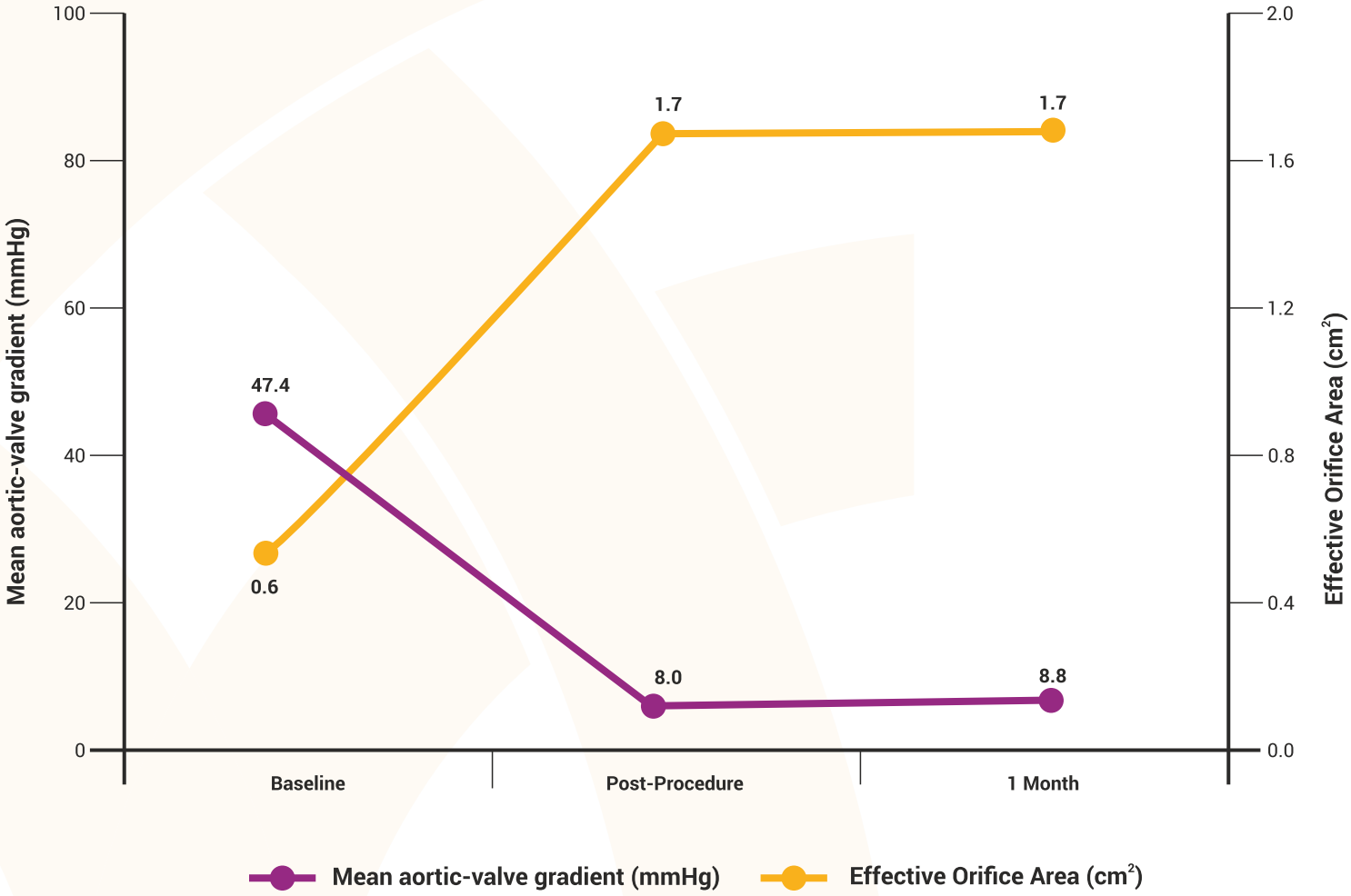
Major Adverse Cardiac, Cerebrovascular Renal Events (MACCRE)	Post-procedure	1-Month Follow-Up
Survival	98%	97%
Stroke	1%	2%
Acute renal failure	2%	2%
Life-threatening or disabling bleeding	1%	1%
Myocardial infarction	0%	0%
Major vascular complications	1%	1%
Minor vascular complications	2%	2%
Repeat hospitalization	NA	8%
New permanent pacemaker	2%*	2%

*One patient had RBBB pre-procedure

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

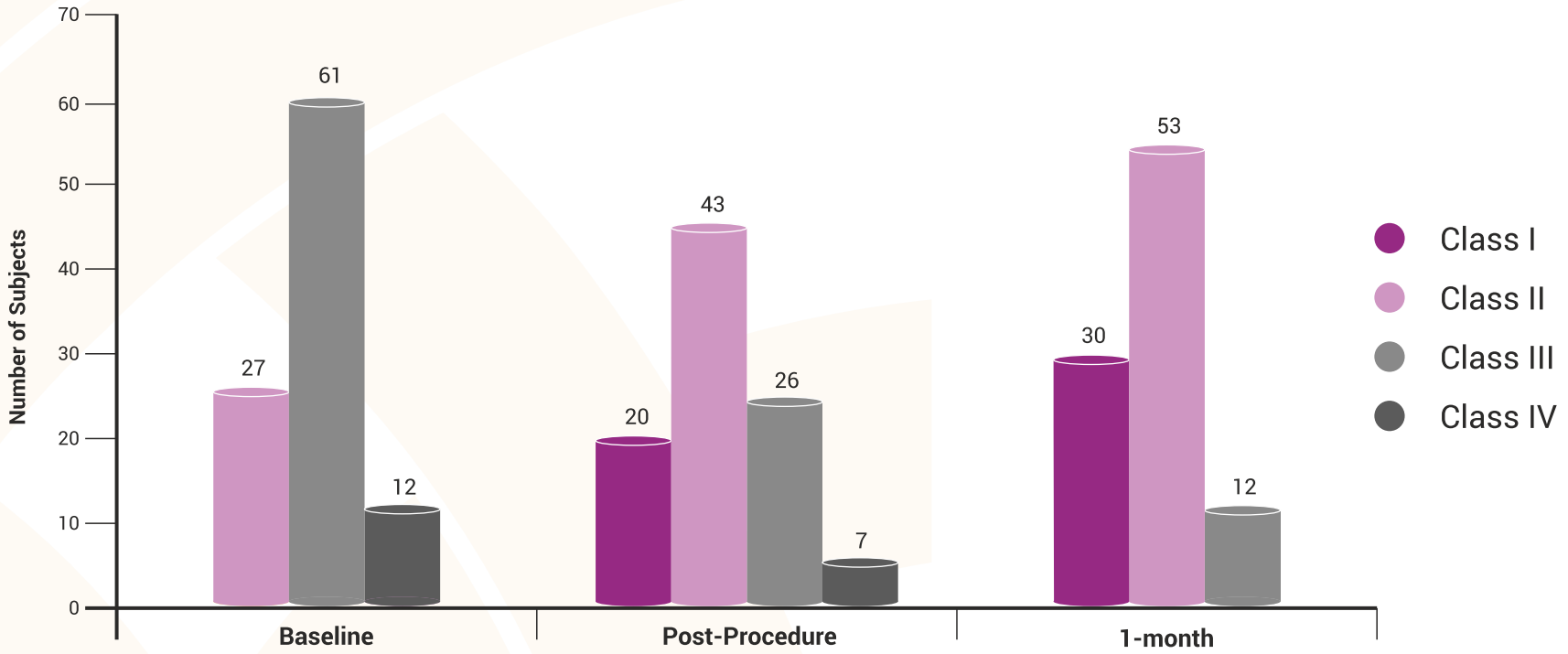
Echocardiographic findings			
Parameters	**Baseline**	**Post-procedure**	**30-day**
Effective orifice area, (cm^2)	0.6 ± 0.2	1.7 ± 0.3	1.7 ± 0.5
Mean aortic-valve gradient, (mmHg)	47.4 ± 8.8	8.0 ± 2.7	8.8 ± 2.5
Peak aortic-valve gradient, (mmHg)	71.7 ± 13.0	14.4 ± 2.4	15.7 ± 2.8
Trans-aortic velocity,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

Sustained Low Mean Gradients Post-Procedure and ~1.7cm^2 Large EOA at 1-month Follow-up (p<0.0001)



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

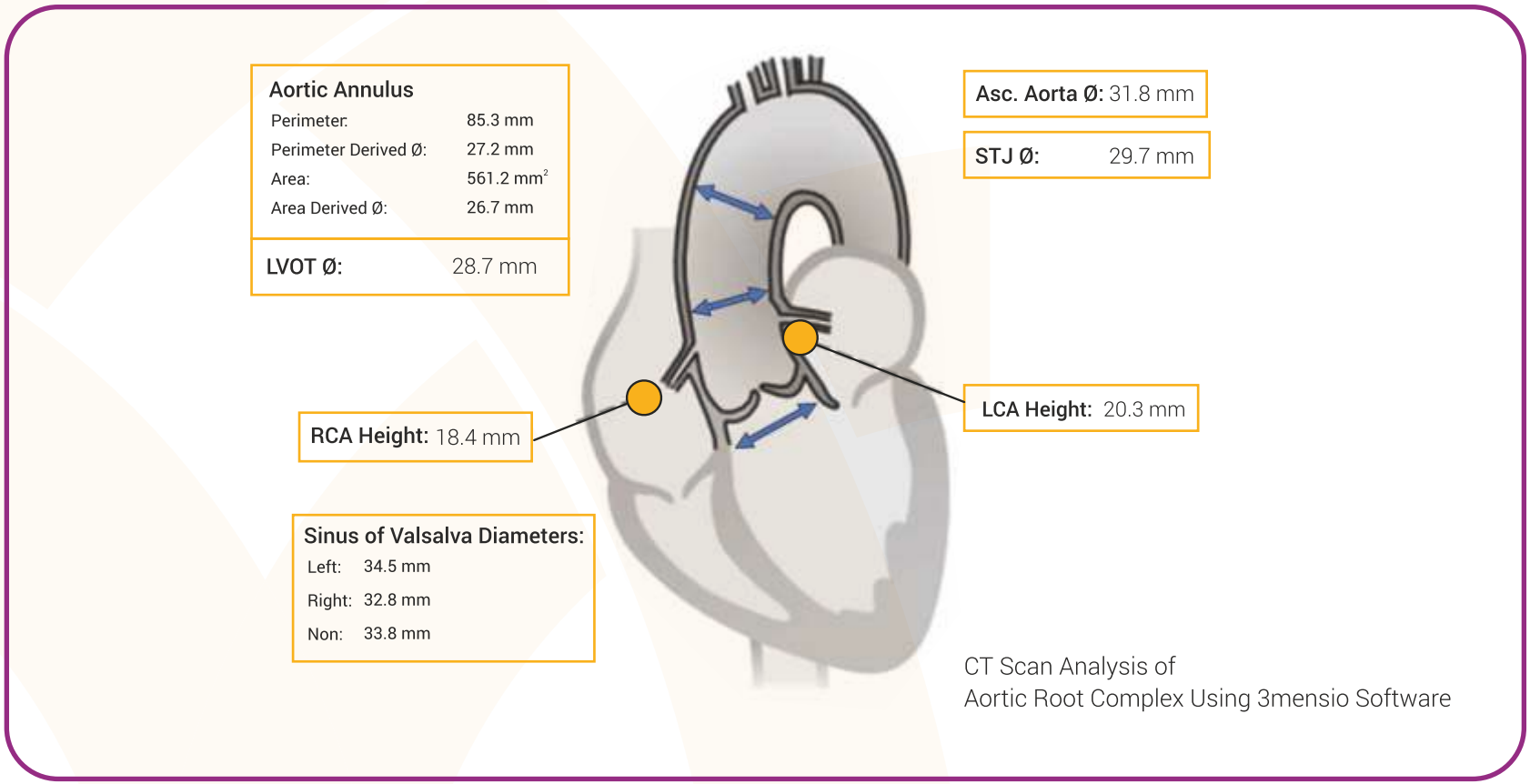
NYHA Functional Class



Parameters	Baseline (n=100)	1 Month (n=96)
Six minute walk test (p<0.0001)	171.7	230.69
Kansas city cardiomyopathy Questionnaire (p<0.0001)	35.27	47.91

Interesting Case with Myval THV

71 Years/Male | Symptomatic AS | NYHA class IV | LVEF 25% | Normal Renal Function | Hypertensive, AF on treatment | Moderate Pulmonary Disease | STS Score 7.97% | Valve Type Tri-Leaflet | Peak Velocity 4.59 m/s | Mean gradient 55 mmHg | Peak Gradient 84 mmHg | EOA 0.5 cm^2 | EF 25%



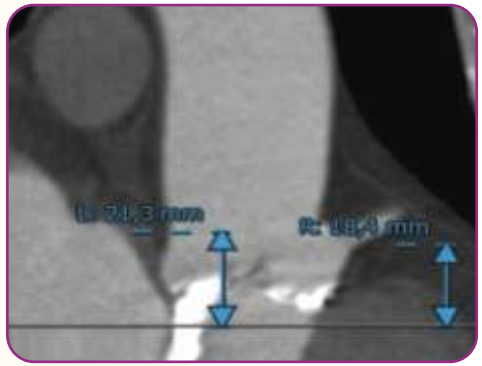
CT Scan Analysis of
Aortic Root Complex Using 3mensio Software

Clinical case, images and videos courtesy: Dr. Samin Sharma & Dr. Ravinder Singh Rao, EHCC, Jaipur, India

Myval THV: Sizing Rationale

- Ideal valve sizing may be in the range of 10-15% higher than area derived annulus diameter to have a good valve apposition
- For an area of 561.2mm^2, a 29mm Myval would be 17.5% over sized
- Considering there is a large Ca^{2+} at the LCC running towards LVOT, it was considered to use 2cc less volume to avoid risk of annular rupture

3D Annular area mm^2		546	550	560	570	580	590	600	610	615	620	630	640	650	660
3D area derived diameter mm		26.4	26.5	26.7	26.9	27.2	27.4	27.6	27.9	28.0	28.1	28.3	28.5	28.8	29.0
29mm % Annular area over/under	20 mm	-42.7%	-43.1%	-44.1%	-45.1%	-46.0%	-46.9%	-47.8%	-48.7%	-49.1%	-49.5%	-50.3%	-51.1%	-51.8%	-52.6%
	23 mm	-24.2%	-24.7%	-26.1%	-27.4%	-28.6%	-29.8%	-31.0%	-32.1%	-32.7%	-33.2%	-34.3%	-35.3%	-36.3%	-37.3%
	26 mm	-3.1%	-3.8%	-5.5%	-7.2%	-8.8%	-10.3%	-11.8%	-13.3%	-14.0%	-14.7%	-16.0%	-17.3%	-18.6%	-19.8%
	29 mm	**20.5%**	**19.6%**	**17.5%**	**15.4%**	**13.4%**	**11.5%**	**9.7%**	**7.9%**	**7.0%**	**6.1%**	**4.4%**	**2.8%**	**1.2%**	**-0.3%**



Analysis done using CT images and 3mensio software

Clinical case, images and videos courtesy: Dr. Samin Sharma & Dr. Ravinder Singh Rao, EHCC, Jaipur, India

Case Summary

Baseline - Aortogram

Myval 29mm Positioning

Myval 29mm Final Result

Baseline Echo Results

Parameters	Values
Valve type	Tri-leaflet
Peak Trans-aortic velocity	4.59 m/s
Mean Trans-aortic gradient	55 mmHg
Peak gradient	84 mmHg
Calculated EOA	0.5 cm^2
Severity of AR	Mild
Severity of MR	No
Ejection fraction	25%

Post-Procedure Echo Results

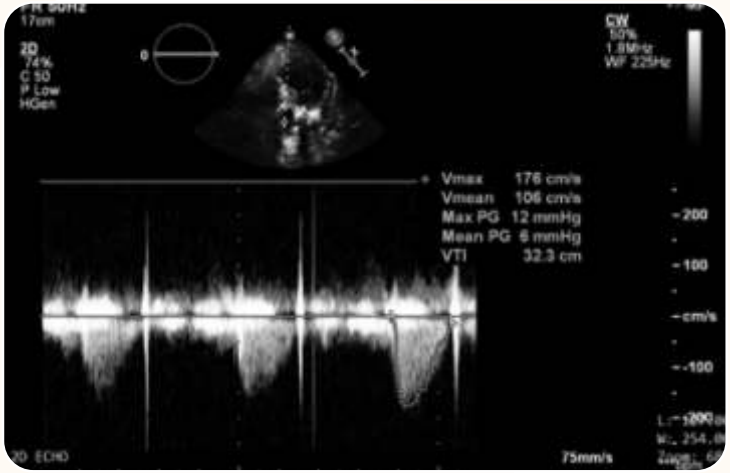
Parameters	Values
Valve type	Tri-leaflet
Peak Trans-aortic velocity	1.20 m/s
Mean Trans-aortic gradient	3.53 mmHg
Peak gradient	5.80 mmHg
Calculated EOA	>1.0 cm^2
Severity of AR	No
Severity of MR	No
Ejection fraction	25%

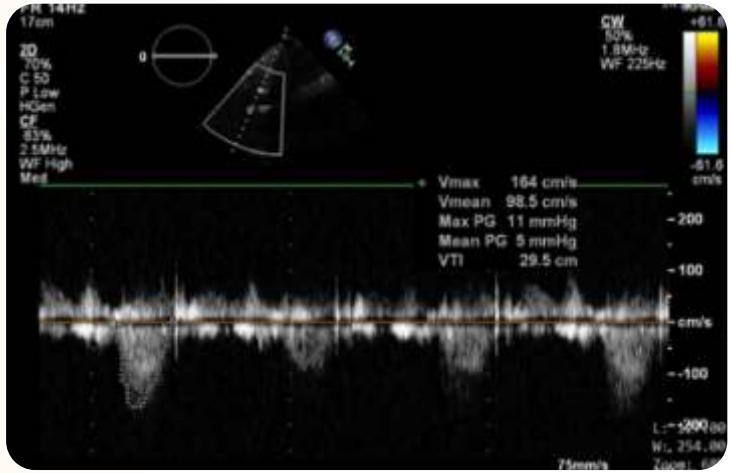
Clinical case, images and videos courtesy: Dr. Samin Sharma & Dr. Ravinder Singh Rao, EHCC, Jaipur, India

Case Follow-up

Echo TTE Results at 1 month follow-up	Values
Peak trans-aortic velocity	1.76 m/s
Mean trans-aortic gradient	6.0 mmHg
Peak gradient	12.0 mmHg
Calculated EOA	>1.0 cm^2

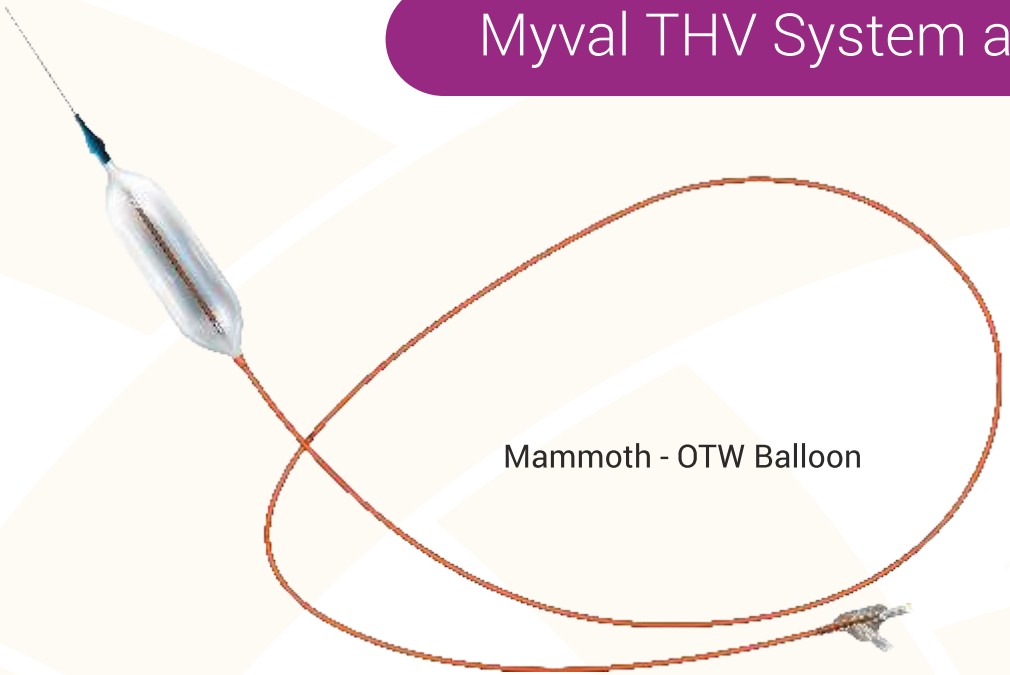
Echo TTE Results at 6 months follow-up	Values
Peak trans-aortic velocity	1.64 m/s
Mean trans-aortic gradient	5.0 mmHg
Peak gradient	11.0 mmHg
Calculated EOA	>1.0 cm^2





Clinical case, images and videos courtesy: Dr. Samin Sharma & Dr. Ravinder Singh Rao, EHCC, Jaipur, India

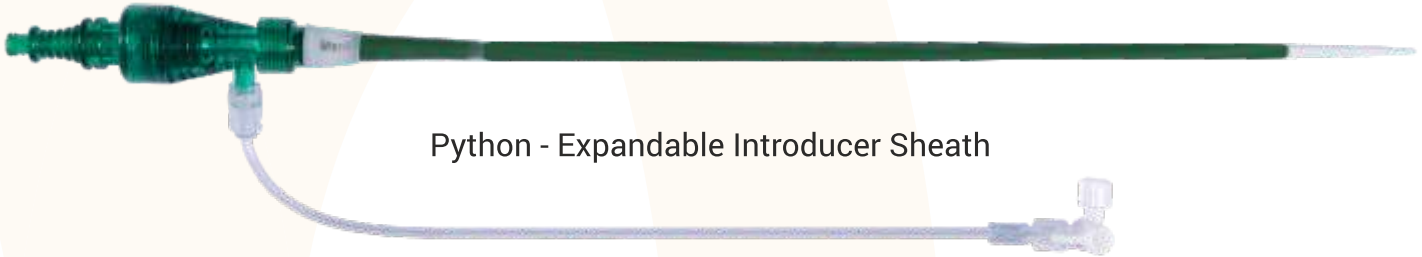
Myval THV System and Components



Mammoth - OTW Balloon

Myval THV

Navigator - THV Delivery System



Python - Expandable Introducer Sheath

Myval™

TRANSCATHETER HEART VALVE SYSTEM

PRECISION AT HEART

Myval THV Ordering Information

Diameters	20.0 mm	21.5 mm	23.0 mm	24.5 mm	26.0 mm	27.5 mm	29 mm
Product code	MVL200	MVL215	MVL230	MVL245	MVL260	MVL275	MVL290

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 30 mm	29 x 30 mm
Product code	NVT20030	NVT21530	NVT23030	NVT24530	NVT26030	NVT27530	NVT29030

Mammoth PTA Balloon Ordering Information

Diameters	14 x 40 mm	16 x 40 mm	18 x 40 mm	20 x 40 mm	23 x 40 mm	25 x 40 mm	28 x 40 mm	30 x 40 mm
Product code	MTV1440	MTV1640	MTV1840	MTV2040	MTV2340	MTV2540	MTV2840	MTV3040

Python 14 Fr Expandable Sheath Ordering Information

Product code	PHT14

CrocoDial - Heart Valve Crimping Tool

Product code	CCD

Val-de-Crimp - Heart Valve Crimping Tool

Product code	VLDC

Basix Touch Inflation Device 35 ATM (30 mL)

Product code	MVINF35A

Atrion QL4015 Inflation Device 15 ATM (40 mL)

Product code	MVINF15A

Syringe Luer Lock 50mL

Product code	MVSNG50ML

Syringe Luer Lock 60mL

Product code	MVSNG60ML

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

Meril

More to Life

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