

ABBOTT MECHANICAL HEART VALVES

Regent, Masters HP and Masters

AORTIC VALVE

MITRAL VALVE



IMPLANT CONFIDENTLY.

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**CONFIDENTLY
IMPLANT
THE MOST
TRUSTED
MECHANICAL
VALVES
IN THE WORLD**

**3 MILLION PATIENTS
TREATED WITH ABBOTT
MECHANICAL HEART VALVES**

**MORE THAN 1,000
PEER-REVIEWED
PUBLICATIONS PROVIDE
EVIDENCE FOR ABBOTT
MECHANICAL HEART VALVES**

**LOW THROMBOGENICITY AND
EXCELLENT PATIENT OUTCOMES**

**PROVEN DESIGN
TO RESTORE NATIVE VALVE
HEMODYNAMICS**

AN ABBOTT HALLMARK

Featured in all Abbott Mechanical Heart Valves the unique Pivot Guard Design offers benefits both during implant and post-implant.



Shields pivot mechanism from pannus ingrowth



Minimizes interaction with sub-annular native valve apparatus in the mitral position and ensure coronary ostia clearance in the aortic position



Enables for an 85° leaflet opening angle, minimizing leaflet flutter and leading to smoother laminar flow through the orifice*



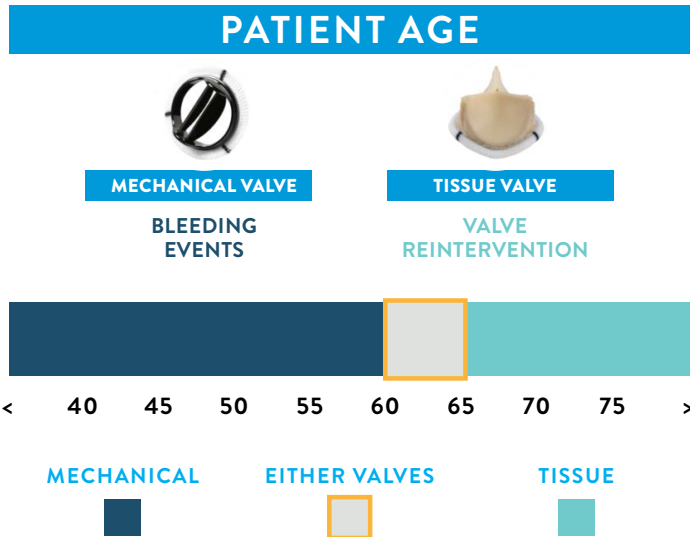
Can lessen thrombus formation by minimizing carbon surface area and thanks to the washout flow through the hinges*

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**FIND OUT MORE
ON ABBOTT
MHV DESIGN**



2017 ESC/EACTS GUIDELINES¹



Target INR for mechanical prostheses

Prosthesis thrombogenicity	Patient-related factors ^a	
	None	≥1 risk factor
Low ^b	2.5	3.0
Medium ^c	3.0	3.5
High ^d	3.5	4.0

INR = international normalized ratio; LVEF = left ventricular ejection fraction.

^a Mitral or tricuspid valve replacement; previous thromboembolism; atrial fibrillation; mitral stenosis of any degree; LVEF <35%.

^b Carbomedics, Medtronic Hall, ATS, Medtronic Open-Pivot, St Jude Medical, OnX, Sorin Bicarbon.

^c Other bileaflet valves with insufficient data.

^d Lillehei-Kaster, Omniscience, Starr-Edwards (ball-cage), Bjorik-Shiley and other tilting-disc valves.

OPERATE WITH THE FACTS

ABBOTT MECHANICAL HEART VALVES SHOW LOWER THROMBOEMBOLISM, THROMBOSIS AND BLEEDING EVEN AT A LOW INR RANGE

INR 1.5 ————— 2.0 ————— 2.5

LOWERING-IT² (target INR 1.5–2.5)

Randomized Study	197 patients implanted* (44 with Abbott valves, 153 with LivaNova valves), 5 years
Thromboembolism	0.09%/pt-year
Thrombosis	0%/pt-year
Bleeding Events	0.56%/pt-year



ESCAT III³ (target INR 1.6–2.1)

Randomized Study	1137 patients** (all Abbott valves), 2 years
Thromboembolism	0%/pt-year, 0.58%/pt-year***
Bleeding Events	0.58%/pt-year, 1.07%/pt-year†



PROACT⁴ (target INR 1.5–2.0)

Randomized Study	375 patients (all On-X Valves), 3 years
Thromboembolism	2.67%/pt-year
Bleeding Events	2.67%/pt-year



*44/197 patients in the Lowering-IT study were implanted with Abbott Valves. **This was further stratified into a control group, a very low INR (monitored 1x weekly), and a very low INR (monitored 2x weekly) group. ***Thromboembolic events for VL1 and VL2 groups are listed together, respectively. †Bleeding events for VL1 and VL2 groups are listed together, respectively.

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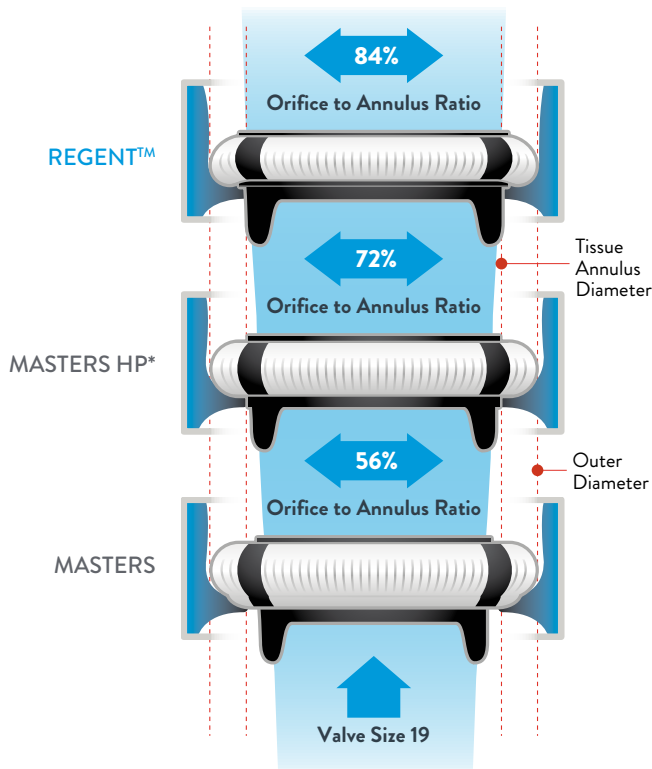
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FIND OUT MORE
ON LOW INR
CLINICAL EVIDENCE



A BROAD RANGE OF SOLUTIONS TO TAILOR THE IMPLANTATION TO EVERY PATIENT

AORTIC VALVE



Regent
EXCEPTIONAL HEMODYNAMICS
IN THE AORTIC POSITION IN SMALL
AORTIC ROOT PATIENTS

Masters HP
HEMODYNAMICS MEETS
IMPLANTABILITY IN BOTH THE
AORTIC AND MITRAL POSITION,
NOW AVAILABLE ALSO FOR BABIES
AND NEWBORNS

Masters
OPTIMAL IMPLANTABILITY IN BOTH
THE AORTIC AND MITRAL POSITION

FIND OUT HOW TO MINIMIZE AV BLOCK
WHEN IMPLANTING
A MECHANICAL HEART VALVE



TREATING THE TINIEST PATIENTS INCLUDING NEWBORNS AND BABIES IS NOW POSSIBLE...

with the world's smallest
mechanical heart valves



15mm MASTERS HP
MITRAL AND AORTIC VALVE

WATCH
SADIE'S STORY



VALVE ORDERING GUIDE

STANDARD CUFF

Compact, double velour Dacron

FLEXCUFF

Flanged and more conformable than the standard cuff, to accommodate variable anatomy

EXPANDED CUFF

25% more cuff material than the standard cuff, for even more anatomic accommodation

PTFE

Known for its low friction, very easy to suture

EXPANDED PTFE

Easy to suture with 16% more material, for extra anatomical conformability

AORTIC VALVE

SIZE (MM)	REGENT™ VALVE		MASTERS HP Series		MASTERS Series		
	STANDARD CUFF	FLEXCUFF™ 4	STANDARD CUFF	EXPANDED CUFF 1,3	STANDARD CUFF	EXPANDED CUFF 1,3	PTFE
15			15AHPJ-505				
17	17AGN-751	17AGFN-756	17AHPJ-505	17AEHPJ-505			
19	19AGN-751	19AGFN-756	19AHPJ-505	19AEHPJ-505	19AJ-501	19AECJ-502	19ATJ-503
21	21AGN-751	21AGFN-756	21AHPJ-505	21AEHPJ-505	21AJ-501	21AECJ-502	21ATJ-503
23	23AGN-751	23AGFN-756	23AHPJ-505	23AEHPJ-505	23AJ-501	23AECJ-502	23ATJ-503
25	25AGN-751	25AGFN-756	25AHPJ-505	25AEHPJ-505	25AJ-501	25AECJ-502	25ATJ-503
27	27AGN-751	27AGFN-756	27AHPJ-505	27AEHPJ-505	27AJ-501	27AECJ-502	27ATJ-503
29	29AGN-751	29AGFN-756			29AJ-501	29AECJ-502	29ATJ-503
31					31AJ-501	31AECJ-502	31ATJ-503

MITRAL VALVE

SIZE (MM)	MASTERS HP Series	MASTERS Series			
	STANDARD CUFF	STANDARD CUFF	EXPANDED CUFF 1,3	PTFE	EXPANDED PTFE 2
15	15MHPJ-505				
17	17MHPJ-505				
19	19MHPJ-505	19MJ-501	19MECJ-502	19MTJ-503	19METJ-504
21	21MHPJ-505	21MJ-501	21MECJ-502	21MTJ-503	21METJ-504
23	23MHPJ-505	23MJ-501	23MECJ-502	23MTJ-503	23METJ-504
25	25MHPJ-505	25MJ-501	25MECJ-502	25MTJ-503	25METJ-504
27	27MHPJ-505	27MJ-501	27MECJ-502	27MTJ-503	27METJ-504
29		29MJ-501	29MECJ-502	29MTJ-503	29METJ-504
31		31MJ-501	31MECJ-502	31MTJ-503	31METJ-504
33		33MJ-501	33MECJ-502	33MTJ-503	33METJ-504
35		35MJ-501			
37		37MJ-501			

1. The Expanded Aortic and Mitral Cuff has approximately 25% more cuff material than the standard cuff, for even more anatomic accommodation.
2. The Expanded PTFE Cuff easy to suture with 16% more material, for extra anatomical conformability
3. The Expanded HP Cuff has approximately 15% more cuff than the HP Series cuff.
4. The FlexCuff™ is flanged and more conformable than the standard cuff, to accommodate variable anatomy.

ACCESSORIES

ORDERING GUIDE

MECHANICAL VALVE SIZER SETS AND ACCESSORIES

Model No.	DESCRIPTION
905	Universal Sizer Set contains 17-33 mm valve sizers and valve holder handle model 905-HH.
905-15	Mitral and Aortic Double-Ended Sizer for Masters HP 15 mm.
905-35	35mm Masters Series valve sizer.
905-37	37mm Masters Series valve sizer.
905-MHH	Mitral valve holder handle.
905-RHH	Rigid valve holder handle.
907	Regent Sizer Set contains 17-29mm valve sizers and valve holder handle model 905-HH.
A-RHR	Contains sizes 19mm-31mm aortic Masters Series holder/rotators.
M-RHR	Contains sizes 19mm-37mm mitral Masters Series holder/rotators.
AHP-RHR	Contains sizes 17mm-27mm Masters Series Hemodynamic Plus holder/rotators.
AG-RHR	Contains sizes 17mm-29mm Regent™ holder/rotators.
LT100	Mechanical valve leaflet tester.

REFERENCES

1. European Heart Journal, Volume 38, Issue 36, 21 September 2017, Pages 2739–2791, <https://doi.org/10.1093/eurheartj/ehx391>
2. Torella, Michele, et al. “LOWERING the INTensity of oral anticoagulant Therapy in patients with bileaflet mechanical aortic valve replacement: results from the “LOWERING-IT” Trial.” American heart journal 160.1 (2010): 171-178.
3. Koertke, Heinrich, et al. “Efficacy and safety of very low-dose self-management of oral anticoagulation in patients with mechanical heart valve replacement.” The Annals of thoracic surgery 90.5 (2010): 1487-1493.
4. Puskas JD et al. Reduced anticoagulation after mechanical aortic valve replacement: interim results from the prospective randomized on-X valve anticoagulation clinical trial randomized Food and Drug Administration investigational device exemption trial. J Thorac Cardiovasc Surg 2014;147:1202-11

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