Abbott

TRIFECTA™ GT VALVE

Because your patients' lives matter.

HEMODYNAMICS MATTER.

INDICATION FOR USE: The Trifecta™ Valve with Glide™ Technology is intended as a replacement for a diseased, damaged, or malfunctioning native or prosthetic aortic heart valve.

CHOOSE THE VALVE DESIGNED FOR OPTIMAL FLOW.

HEMODYNAMICS MATTER.

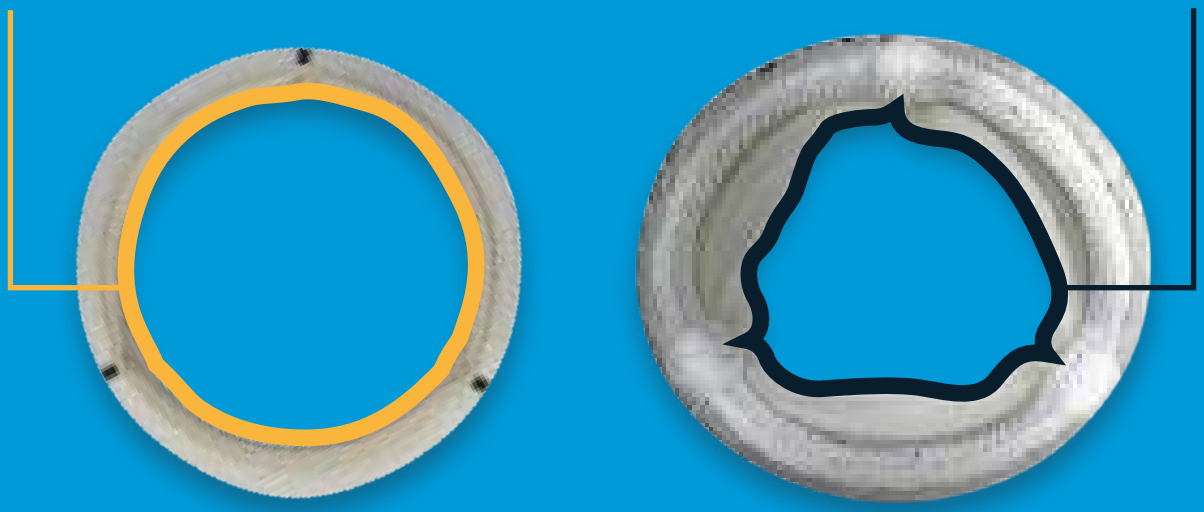
TRIFECTA™ VALVES:
EXPANSIVE, EXTERNALLY-MOUNTED LEAFLET DESIGN

Wide Valve Opening ..... Single-digit Gradients* ..... Large Effective Orifice Areas (EOAs)

*Across all valve sizes ≥ 21mm

Trifecta™ Valves:
Expansive, Externally-mounted
Leaflet Design

Perimount™ Valves:
Restrictive, Internally-mounted
Leaflet Design

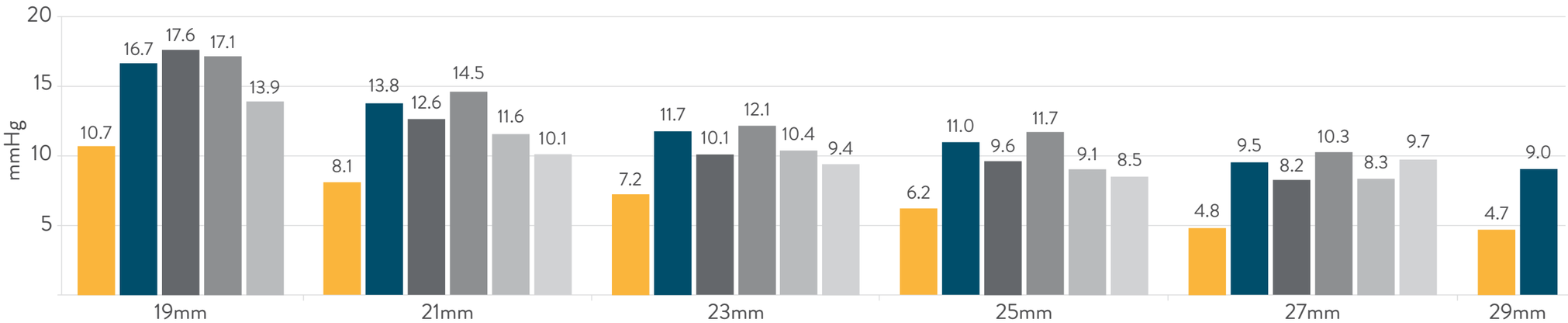


"The nearly cylindric opening of the Trifecta™ prosthesis on systole provides gradients and EOAs that surpass any other available stented aortic prosthesis."
– Bavaria et al.[6]

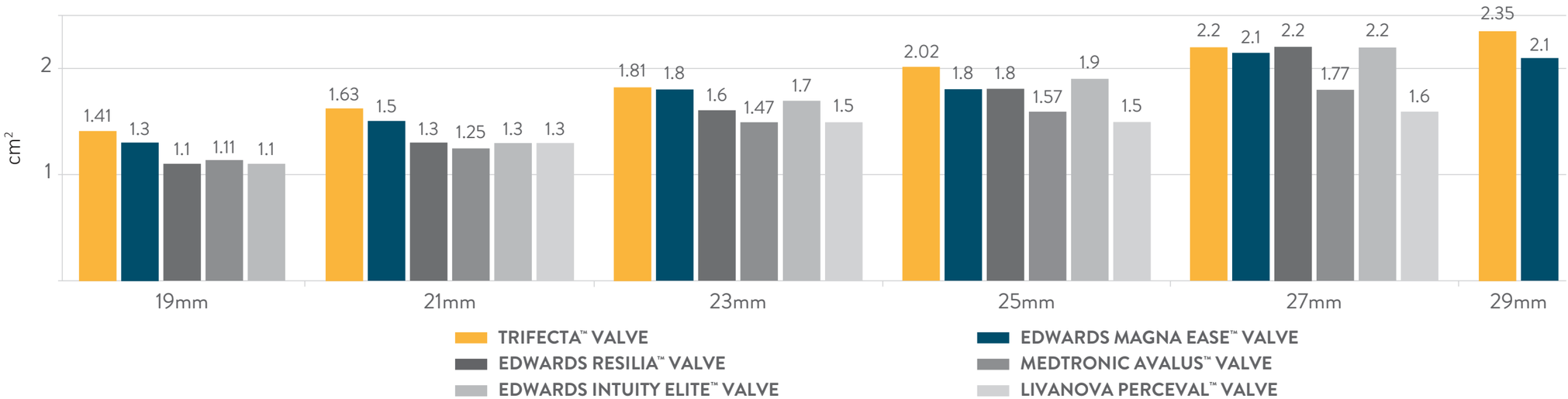
ONLY ONE SAVR VALVE DELIVERS SINGLE-DIGIT GRADIENTS ACROSS MOST VALVE SIZES.

HEMODYNAMICS MATTER.

AVERAGE MEAN GRADIENT BY VALVE SIZE AT ONE YEAR*[7-12]



AVERAGE EFFECTIVE ORIFICE AREA (EOA) AT ONE YEAR*[7-12]



*Results from different clinical trials are not directly comparable. Information provided for educational purposes only.

FOR EACH INCREASE OF 1 MMHG IN MEAN GRADIENT,

THE RELATIVE RISK OF HEART FAILURE (HF) RECURRENCE OR

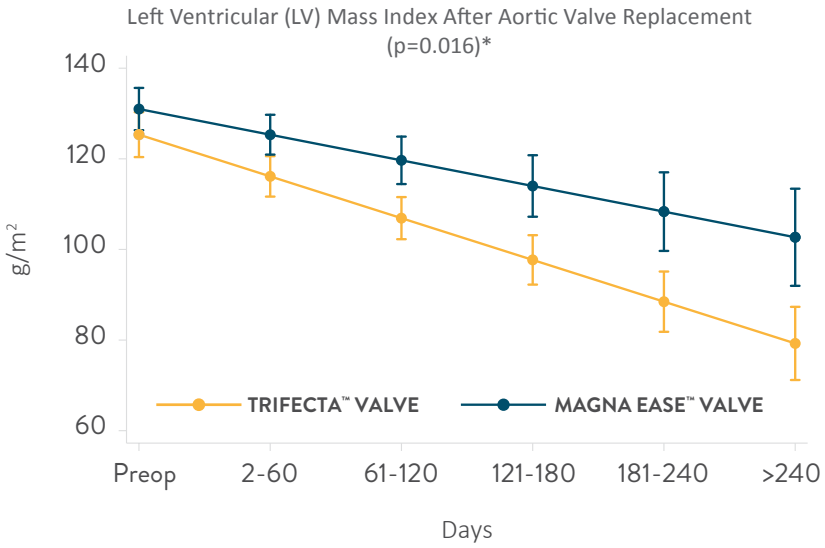
HF-RELATED DEATH IS INCREASED BY 6%[13]

BECAUSE LOWER GRADIENTS REDUCE RISK OF HEART FAILURE.

HEMODYNAMICS MATTER.

TRIFECTA™ VALVE: SIGNIFICANTLY GREATER LV MASS REGRESSION COMPARED WITH MAGNA EASE™ VALVE[14]

- Greater total mass regression
- Greater mass regression over time



An independent, propensity-matched, head-to-head study following 258 patients receiving either a Magna Ease™ Valve (n=141) or Trifecta™ Valve (n=117) demonstrates higher LV mass regression.

* Content adapted from original article content.

TRIFECTA™ VALVE: SIGNIFICANTLY REDUCED RISK COMPARED WITH MAGNA EASE™ VALVE[14]

76.5%

RELATIVE RISK REDUCTION OF READMISSION (CARDIAC-RELATED, P=.011)

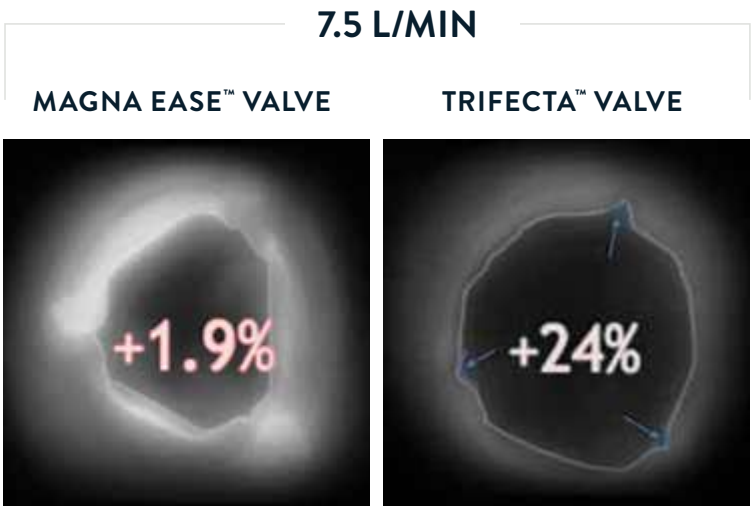
82.3%

RELATIVE RISK REDUCTION OF HF REQUIRING URGENT INTERVENTION (P=.016)

BECAUSE YOUR PATIENTS LEAD ACTIVE LIVES.
HEMODYNAMICS MATTER.

TRIFECTA™ VALVE:
INCREASED EOAs WITH INCREASED CARDIAC OUTPUT[14]

- Significantly greater hemodynamic reserve than Magna Ease™ Valve

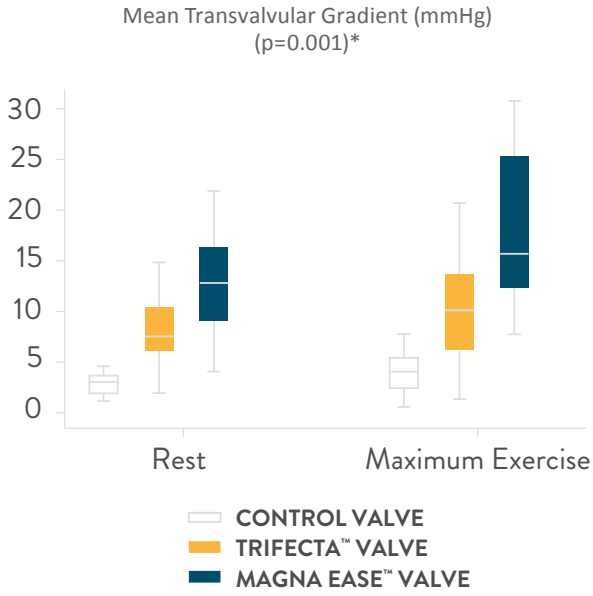


"During exercise, the EOAI in the Trifecta group increased significantly until maximum exercise."
– Hanke et al. P = 0.02[15]

TRIFECTA™ VALVE:
SIGNIFICANTLY LOWER GRADIENTS DURING EXCERCISE[16]

- Differences in hemodynamic performance even more pronounced

"The titanium stent has intrinsic distensibility, potentially allowing for further expansion of the prosthesis in highload conditions such as exercise."
– Bavaria et al.[6]



* Content adapted from original article content.

BECAUSE IT'S TIME TO MAKE PPM A THING OF THE PAST.

HEMODYNAMICS MATTER.

PPM MATTERS:
THE CLEAR LINK BETWEEN SEVERE PPM AND MORTALITY

6.5x

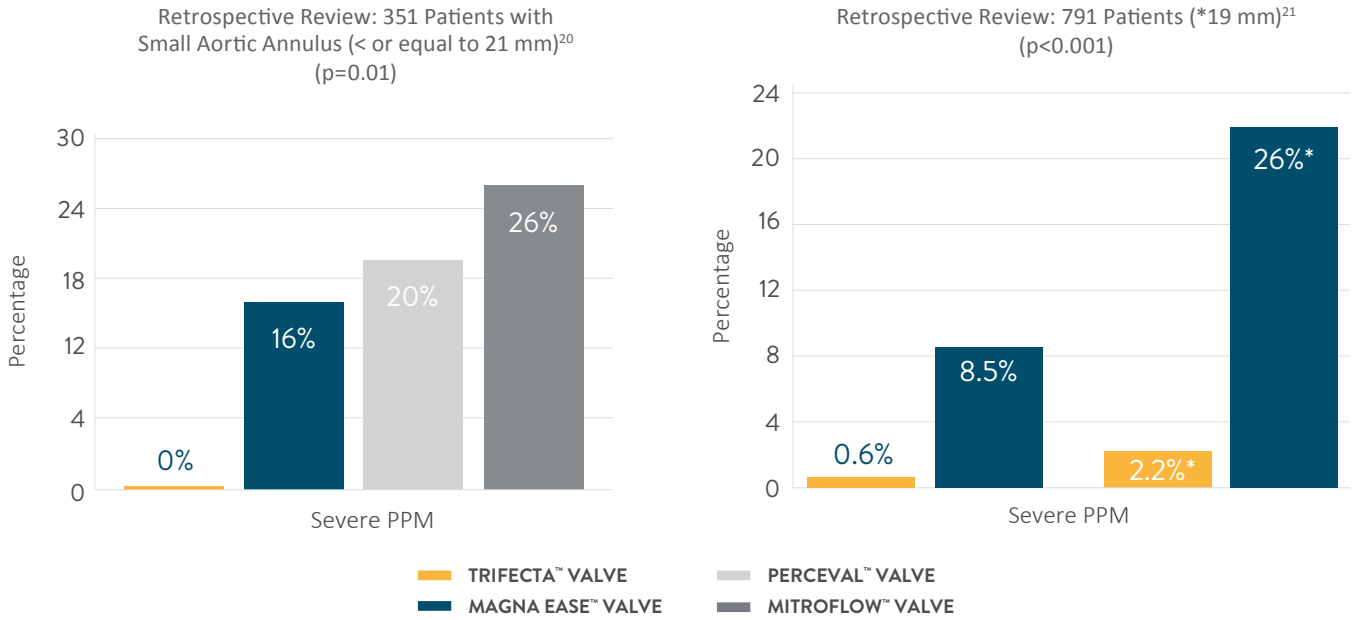
Increase in cardiac-related mortality with severe Patient Prosthesis Mismatch (PPM).[17]

<70

For patients under 70 years of age with LV dysfunction, PPM is associated with decreased survival and lower freedom from CHF.[18]

TRIFECTA™ VALVE:
CONSISTENTLY LOW RATE OF SEVERE PPM

- Meta-analysis across 13 studies with over 2,500 patients finds extremely low 2.7% severe PPM with Trifecta™ Valve[19]
- Significantly lower rate of severe PPM demonstrates advantage over other valves



BECAUSE PATIENTS DEMAND VALVE DURABILITY.
HEMODYNAMICS MATTER.

TRIFECTA™ VALVE:
EXCELLENT MID-TERM DURABILITY

• Consistently excellent clinical durability in multiple mid-term studies

NORTH AMERICA[22]

Published Freedom from Reop. SVD	**97.3%**
Subjects (n)	710
Implants Years	2007-2009
Patient Years	2873

GERMANY[23]

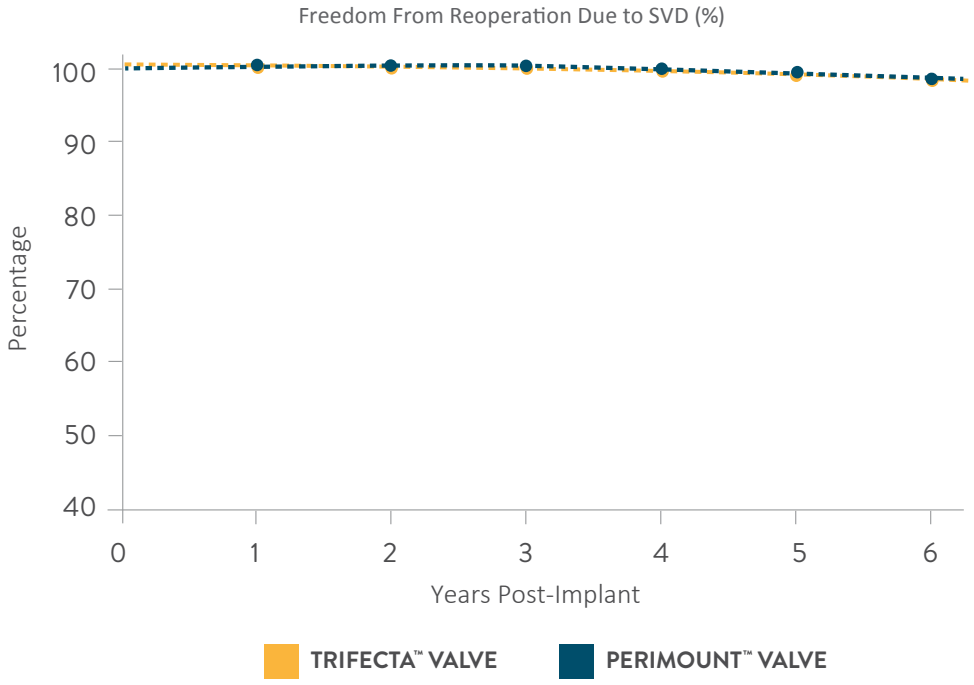
Published Freedom from Reop. SVD	**97.9%**
Subjects (n)	918
Implants Years	2007-2015
Patient Years	2357

FRANCE[24]

Published Freedom from Reop. SVD	**98%**
Subjects (n)	824
Implants Years	2008-2014
Patient Years	1748

TRIFECTA™ VALVE:
ON TRACK FOR EXCELLENT LONG-TERM DURABILITY

• Excellent mid-term durability compared to established aortic valves[22,25]



CLEVELAND CLINIC STUDY:

HEMODYNAMICS DETERMINE VALVE DURABILITY

- Increased PPM and higher gradients at implantation linked to valve deterioration and explant, especially in younger patients
- To maximize durability, optimize hemodynamics

"Our data suggest that strategies aimed at minimizing early postoperative gradients, such as use of valves with better effective orifice area...may be warranted..."

– Johnston et al.[26]

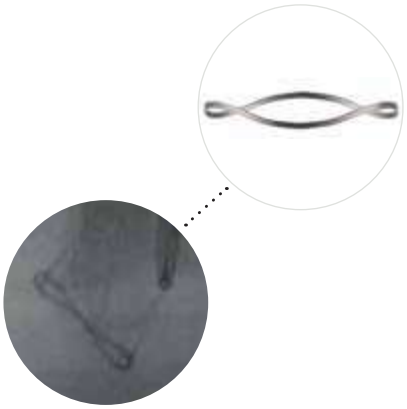
ADVANCING A PROVEN DESIGN TO ENHANCE EASE OF USE

TRIFECTA™ GT VALVE:
BUILT UPON THE TRIFECTA™ PLATFORM

- **Improved ease of implantability** for minimally-invasive and conventional procedures
- **Enhanced ease of placement** for challenging approaches and anatomies

SCALLOPED CUFF

- Follows contour of annulus, allowing valve to sit lower in anatomy



TITANIUM BAND

- Enhances strength and improves visualization for future valve interventions

SOFT SEWING CUFF

- Minimizes needle penetration, suture drag, and parachuting forces

SUTURE MARKERS

- Aids in optimal needle placement and spacing

*Size: 23 mm valve
†There is no clinical data currently available that evaluates the long-term impact of anticalcification tissue treatment in humans.
‡Abbott, Data on file.

STREAMLINED VALVE HOLDER

- A 38% reduction in footprint for better access and visibility*
- Screw-in attachment increases handle security
- Single-cut quick-release provides greater efficiency
- Backstops stabilize stent posts and minimize stent deformation during implantation
- Legs positioned in front of the leaflets for added protection

PERICARDIAL LEAFLETS

- Exterior mounted leaflets from a single pericardial sheet optimize coaptation
- LinxAC Antimineralization treatment for valve durability†

PRECISION MANUFACTURING

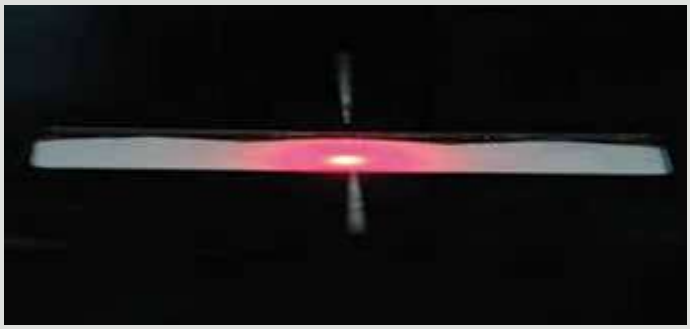
Ongoing improvements to our manufacturing process demonstrate commitment to advancing patient outcomes.

PRECISION CRAFTSMANSHIP

- Bovine pericardium hand-selected for quality
- Multiple operator certifications required for handmade valve production
- Suture depth and placement precisely controlled
- Each valve 100% functionally tested and 200% visually inspected

FIBER ALIGNMENT TECHNOLOGY

- Confirms optimal collagen fiber alignment of the pericardial tissue
- Ensures uniform tissue mechanical properties
- Delivers 3.4x resistance to fatigue related tissue degradation‡



TRIFECTA™ GT VALVE

BECAUSE YOUR PATIENTS' LIVES MATTER, HEMODYNAMICS MATTER.

- Best-in-class gradients and EOAs[7-12]
- Greater LV mass regression[14]
- Decreased risk of hospital readmission and heart failure[14]
- Improved performance during exercise[15,16]
- Consistently low rate of Severe PPM[19-21]
- Excellent durability[22-24]

For more information on the TRIFECTA™ GT Valve, contact your Abbott sales representative or visit TrifectaGTvalve.com.

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EPIC™ MITRAL

STENTED TISSUE VALVE
WITH LINX™ AC TECHNOLOGY

LEAFLET BEHAVIOR AND STENT MECHANICS

Epic. By Design.

Information contained herein for **DISTRIBUTION outside of the U.S. ONLY**.
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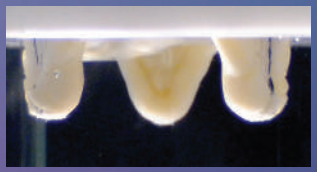
FLEXIBLE DESIGN
FOR NOW AND LATER

Built on the Biocor Platform that has been trusted for over 30 years, the Epic Platform has been reimagined to support options for today and tomorrow.

Curtaining is a characteristic of bioprosthetic valves in which the leaflets, when opened, stand tall or form a "curtain" between stent posts.[1a]

Epic™ Mitral leaflets are not prone to curtaining, which can result in less LVOT obstruction.[1a]

LEAFLET BEHAVIOR WHEN OPENED



Epic™ Mitral leaflets

C-E PERIMOUNT/ Magna Mitral Ease‡ pericardial leaflets

25 mm Epic™ Mitral (left) and Magna Mitral Ease‡ (right) with representative rods inserted

> In the bench test, we observed that the pericardial leaflets stand tall unlike the porcine leaflets which crumple. This will result in a greater degree of LVOT obstruction with pericardial leaflets. —*Bapat, et al.*[2]

[a]Results based on internal testing.

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PRESERVING THE **LVOT**

Can withstand approximately **8 atm** pressure during balloon valvuloplasty procedures[3]

Low overall stent post height mitigates LVOT obstruction[4]*

VENTRICULAR PROTRUSION*

Epic™ Mitral[5]	C-E PERIMOUNT Magna Mitral Ease‡[6]	Mosaic‡[7]
9 mm	**10.5 mm**	**14 mm**

> We observed that it may be the combination of height and type of leaflets—that is, porcine leaflets versus pericardial leaflets—than height alone which may be important. —*Bapat, et al.*[2]

*For 27 mm valve size, measured from the farthest point of the cuff.

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EPIC™ SUPRA

AORTIC STENTED TISSUE VALVE
WITH LINX™ AC TECHNOLOGY

Epic. By Design.

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INTUITIVE **IMPLANTABILITY**

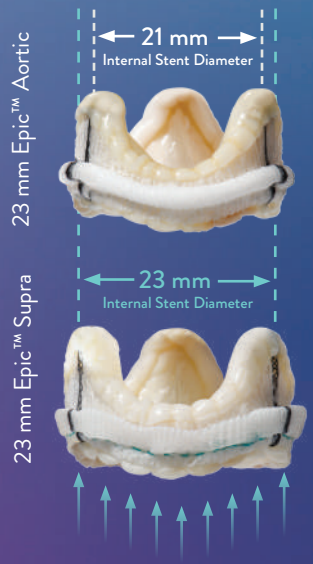
- FlexFit Stent allows for ease of implant in mini aortic procedures
- The Epic™ Supra silicone-filled cuff allows for supra-annular implantation
- Epic™ Aortic cuff options allow for secure suture placement while limiting suture drag and parachuting forces

FUTURE **FLEXIBILITY**

- Can withstand approximately 8 atm pressure during balloon valvuloplasty procedures[1]

OPTIMAL STENT-TO-ANNULUS RATIO

Inspired by the proven design of Biocor™, Epic™ Supra provides a larger stent-to-annulus ratio than the Epic™ Aortic Valve.[2]



LOW AORTIC PROTRUSION

23 mm Epic™ Supra

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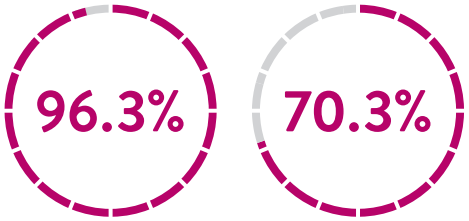
EXCEPTIONAL DURABILITY, **PROVEN PERFORMANCE**

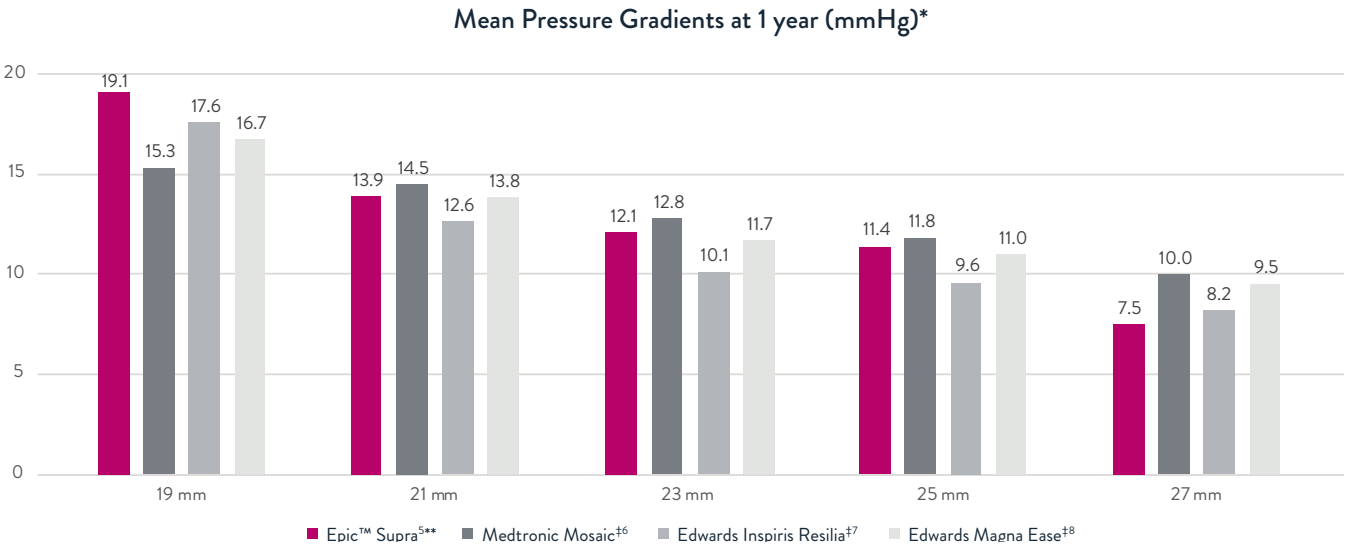
- Optimal leaflet design minimizes regurgitation
- Pericardial shield reduces abrasion by creating tissue-to-tissue interface
- 20-year Biocor™ durability data + Epic™ 10-year durability data shows outstanding Aortic freedom from failure[3,4]



Epic™ Aortic
Freedom from SVD
at 10 years[3]

Biocor™ Aortic
Freedom from SVD
at 20 years[4]

STRONG IN VIVO HEMODYNAMICS



*NOTE: For references 5–8, data not from head-to-head studies. Data differences depicted between these trials may not be directly comparable, statistically significant, or clinically meaningful due to differences in trial protocols, endpoints, and/or patient populations. Data provided for informational purposes only.
**Pressure Gradients approximated through Epic™ Aortic SSED data matched with stent size equivalencies for the Epic™ Supra. Per Abbott Internal engineering specifications, a 19 mm Epic™ Supra has the same stent size as a 21 mm Epic™ Aortic and this relationship continues across all Epic™ Supra valve sizes.

ABBOTT MECHANICAL HEART VALVES

Regent, Masters HP and Masters

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

FIND OUT MORE ON ABBOTT MHV DESIGN

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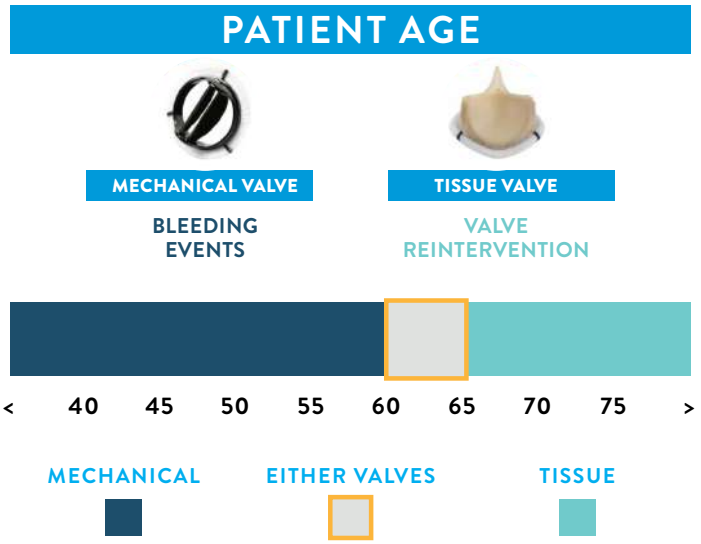
2017 ESC/EACTS GUIDELINES[1]



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-IT[2] (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 III[3] (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†

PROACT[4] (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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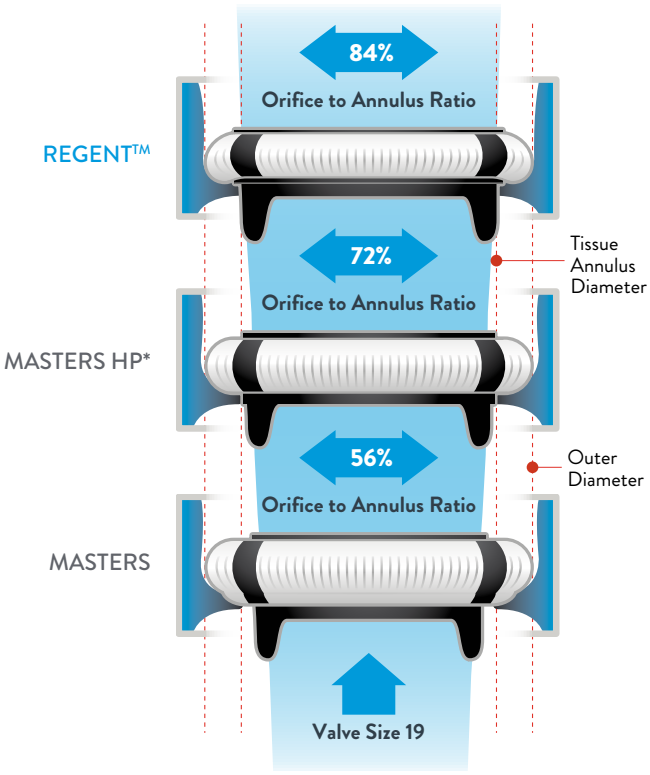
FIND OUT MORE ON LOW INR CLINICAL EVIDENCE

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 IMPLATABILITY 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 worlds'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

	REGENT™ VALVE		MASTERS HP Series		MASTERS Series		
SIZE (MM)	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

	MASTERS HP Series	MASTERS Series			
SIZE (MM)	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 RegentTM holder/rotators.
LT100	Mechanical valve leaflet tester.

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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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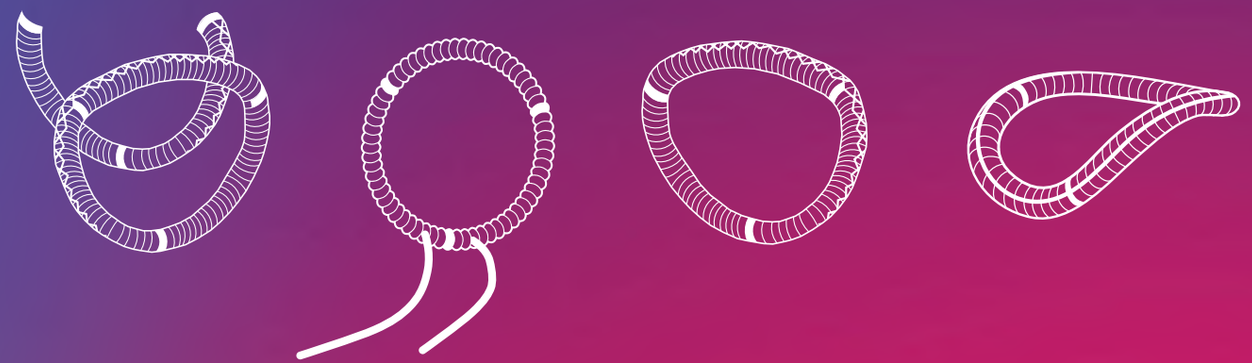
MITRAL VALVE
REPAIR SOLUTIONS



A comprehensive portfolio of mitral valve repair products from a single source.

See Important Safety Information referenced within.

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Abbott's customizable repair products are suitable for implant using open sternotomy and minimally invasive approaches such as robotic surgery.

Tailor Flexible Ring and Band

The Tailor Flexible Annuloplasty Ring and Band are designed to maintain the size of a repaired mitral or tricuspid annulus while sustaining physiologic movement.

- Customizable ring design can be tailored to address specific patient needs
- Pre-cut C band provides time savings simplicity

Attune™ Flexible Adjustable Ring

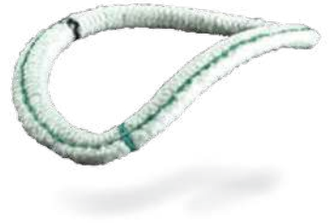
The symmetrical and asymmetrical adjustability of the Attune Ring allows the size and shape to be fine-tuned.

- The ability to make small adjustments to the ring after placement is designed to help eliminate residual mitral regurgitation
- Independent adjustability allows the annuloplasty to be localized to one side

Séguin Semi-Rigid Ring

The Séguin Semi-Rigid Ring provides surgeons a combination of rigidity and flexibility for mitral valve repair.

- Solid one-piece core resists needle penetration and reduces potential for suturing through the core
- More rigid anterior allows for annular remodeling
- One-step push button handle release simplifies the implantation process



Rigid Saddle Ring

A natural saddle-shaped ring designed for durable and complete remodeling.

- Titanium alloy core maintains anatomical shape and provides annular remodeling
- Saddle shape contributes to efficient distribution of leaflet stress and chordal tension[1-3]

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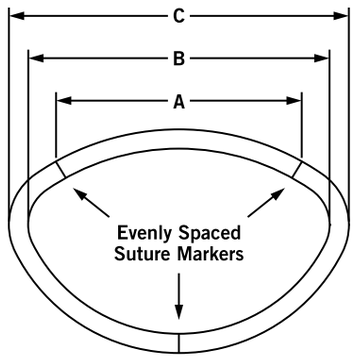
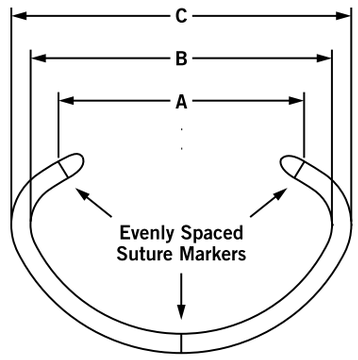
TAILOR FLEXIBLE RING AND BAND

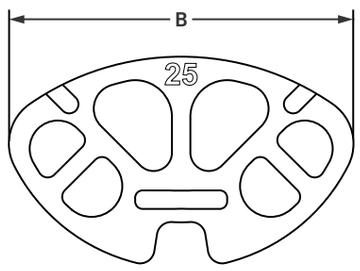
Ring Model Number	Band Model Number	Ring Size (mm)	Intertrigonal Dimension [A] (mm)	Inside Dimension [B] (mm)	Outside Dimension [C] (mm)
TARP-25	TAB-25	25	25	29	34
TARP-27	TAB-27	27	27	31	37
TARP-29	TAB-29	29	29	34	40
TARP-31	TAB-31	31	31	36	42
TARP-33	TAB-33	33	33	39	45
TARP-35	TAB-35	35	35	41	46

ACCESSORIES

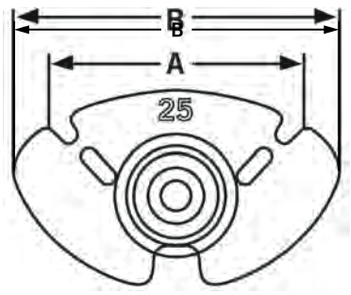
Model Number	Contents
TAR-505	Tailor Annuloplasty Ring Sizer Set One (1) malleable holder handle One (1) extension handle Six (6) sizers (25, 27, 29, 31, 33, 35) One (1) autoclavable tray for storage of components
TAR-510R	Tailor and Attune™ Ring Robotic Sizer Set Six low-profile robotic sizers in autoclavable tray
HH-05	Replacement Holder Handle
EX-05	Replacement Extension Handle







Robotic Sizer



Handled Sizer

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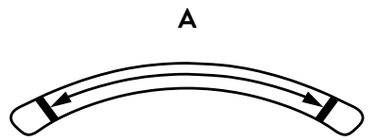
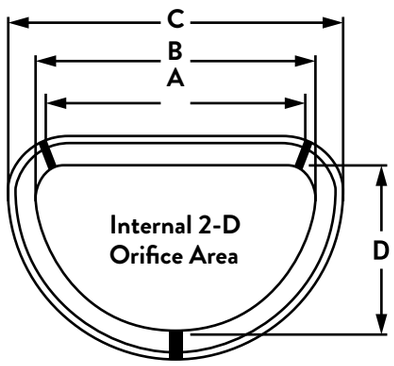
RIGID SADDLE RING

Ring Model Number	Ring Size [A] (mm)	Commissure Dimension [A] (mm)	Inside Dimension [B] (mm)	Outside Dimension [C] (mm)	A-P Dimension [D] (mm)	Internal 2-D Orifice Area (mm^2)
RSAR-24	24	24	22	30	21	227
RSAR-26	26	26	24	32	23	276
RSAR-28	28	28	26	34	24	331
RSAR-30	30	30	28	36	25	387
RSAR-32	32	32	30	38	27	450
RSAR-34	34	34	32	40	28	511

ACCESSORIES

Model/Reorder Number	Contents
RSAR-507A	RSAR Sizer Set Complete One (1) malleable holder handle One (1) extension handle Six (6) sizers (24, 26, 28, 30, 32, 34) One (1) autoclavable tray for storage of components One (1) autoclavable tray cover
HH-05	Replacement Holder Handle
EX-05	Replacement Extension Handle





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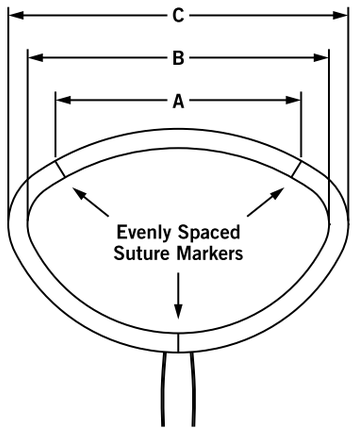
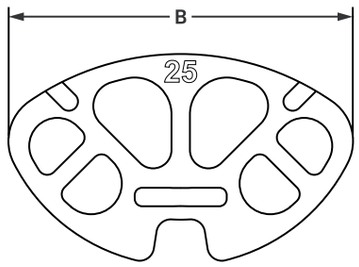
ATTUNE™ FLEXIBLE ADJUSTABLE RING

Model/Reorder Number	Ring Size	Fixed Dimension [A] (mm)	Ring Inner Dimension [B] (mm)	Ring Outer Dimension [C] (mm)
AFR-25	25	25	28	33
AFR-27	27	27	31	36
AFR-29	29	29	34	39
AFR-31	31	31	37	42
AFR-33	33	33	40	44
AFR-35	35	35	41	46
AFR-37	37	37	44	49
AFR-39	39	39	46	51
AFR-41	41	41	49	54
AFR-43	43	43	52	57

ACCESSORIES

Model/Reorder Number	Products	Contents
TAR-505	Tailor Annuloplasty Ring Sizer Set	6 handled sizers, 1 holder handle and 1 extension handle in autoclavable tray
TAR-510R	Tailor and Attune Ring Robotic Sizer Set	10 low-profile robotic sizers in autoclavable tray
HH-05	Replacement Holder Handle	Holder handle for TAR-505
EX-05	Replacement Extension Handle	Extension handle for TAR-505





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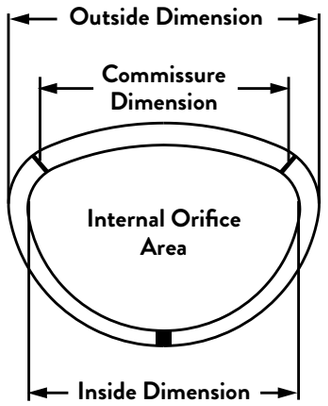
SÉGUIN SEMI-RIGID RING

Ring Model Number	Ring Size	Inside Dimension	Outside Dimension	Commissure Dimension	Internal Orifice Dimension
SARP-24	24 mm	22 mm	29 mm	24 mm	284 mm^2
SARP-26	26 mm	24 mm	31 mm	26 mm	334 mm^2
SARP-28	28 mm	27 mm	34 mm	28 mm	403 mm^2
SARP-30	30 mm	28 mm	35 mm	30 mm	463 mm^2
SARP-32	32 mm	30 mm	37 mm	32 mm	541 mm^2
SARP-34	34 mm	34 mm	41 mm	34 mm	602 mm^2
SARP-36	36 mm	35 mm	43 mm	36 mm	644 mm^2
SARP-38	38 mm	37 mm	45 mm	38 mm	735 mm^2
SARP-40	40 mm	39 mm	46 mm	40 mm	815 mm^2

ACCESSORIES

Model/Reorder Number	Contents
SAR-501	Séguin Annuloplasty Ring Sizer Set One (1) malleable holder handle One (1) extension handle Nine (9) mitral sizers (24, 26, 28, 30, 32, 34, 36, 38, 40) One (1) autoclavable tray for storage of components One (1) autoclavable tray cover
HH-05	Replacement Holder Handle
EX-05	Replacement Extension Handle



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Pericardial Patch
WITH ENCAP™ AC TECHNOLOGY

ENHANCED BIOCOMPATIBILITY FOR LASTING PERFORMANCE

The Pericardial Patch with EnCap AC Technology* combines strong, durable bovine pericardium with a proprietary anti-calcification treatment, making it suitable for a variety of cardiac repairs while offering improved handling and enhanced biocompatibility.

IMPROVED HANDLING AND SUTURABILITY SUPPORT CARDIOVASCULAR REPAIR

- Ready-to-use, rinseless preparation saves time during procedures.
- Bovine pericardium provides improved handling and suturability compared with synthetic patches.[1]
- The strength of glutaraldehyde-fixed tissue enhances durability and helps resist undesirable changes such as patch shrinkage and aneurysm formation, even in high-stress repairs.[2–6]
- Soft, pliable tissue conforms to anatomy and sutures into place with minimal leaking along suture line.

ANTI-CALCIFICATION TREATMENT ENHANCES BIOCOMPATIBILITY AND DURABILITY

- Proprietary EnCap AC Technology caps residual aldehydes to reduce antigenicity and cytotoxicity.[5,7,8]
- Resists calcification and promotes rapid binds, thorough healing with endothelial cell covering.[7–10]
- Improved endothelialization strengthens the reconstruction or repair, helping reduce calcification and other degeneration.[7–9]

APPROPRIATE FOR A WIDE RANGE OF CARDIAC AND VASCULAR REPAIRS[8]

- Annular reconstruction[3]
- Endocarditis leaflet repairs
- Septal defect repairs
- Aortic root enlargement
- Other vascular repairs.

* There is no clinical data currently available which evaluates the long-term impact of anticalcification tissue treatment in humans.

Abbott

ORDERING INFORMATION

Pericardial Patch

Model Number	Patch Size (cm)	Nominal Thickness (mm)
C0205	2 x 5	0.20 – 0.40
C0405	4 x 5	0.15 – 0.25
C0510	5 x 10	0.20 – 0.40
C0914	9 x 14	0.20 – 0.40

All sizes not currently available in all markets.

References:

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NAVITOR™ TAVI SYSTEM

Smart Sealing.
Exceptional Stability.
Uncompromised Access.

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Always check the regulatory status for the device in your region.

OVERVIEW

Navitor™ TAVI System

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NAVITOR™ TAVI SYSTEM

SMART SEALING. EXCEPTIONAL STABILITY. UNCOMPROMISED ACCESS.

Navitor™ TAVI system offers intelligent design advantages, including smart PVL-sealing NaviSeal™ Cuff, stable and accurate placement, exceptional single-digit gradients,[1] and uncompromised small vessel access and coronary access to consistently achieve excellent outcomes across a spectrum of routine to challenging anatomies.

1. Abbott data on file CL1014440.

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NAVITOR™ TAVI SYSTEM

NAVITOR™ VALVE

INTELLIGENT DESIGN.

- Smart PVL-sealing NaviSeal™ Cuff
- Exceptional single-digit gradients[1]
- Uncompromised coronary access

FLEXNAV™ DELIVERY SYSTEM

STABILITY AND ACCURACY.

- Low 5.0 mm minimum vessel diameter for uncompromised small vessel access
- Enhanced flexibility for excellent deliverability
- Stable deployment and accurate valve placement

EXCELLENT OUTCOMES.

30-DAY[1]

0%	0%	0.8%	0.8%	7.4mmHg
SEVERE TO MODERATE PVL	ALL CAUSE MORTALITY	DISABLING STROKE	MAJOR VASCULAR COMPLICATIONS	MEAN GRADIENT

1. Abbott data on file CL1014440.

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NAVITOR™ TAVI SYSTEM

Navitor™ Valve Design Features

Curved Aortic Cells
Reduces risk of injury to native structures

Inner NaviSeal™ Cuff
Fabric material maintains low profile

Outer NaviSeal Cuff
Actively synchronizes to the cardiac cycle to seal and mitigate PVL

Large Cell Design
Minimizes coronary obstruction and improves coronary access and flow

Optimized Radial Force
For expansion, anchoring, stability and sealing

Increased Sealing Zone
Mitigates PVL

Annulus Treatment Range
Treats 19 mm to 27 mm Annulus Diameters

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NAVITOR™ TAVI SYSTEM

FlexNav™ Delivery System Design Features

1 STABILITY LAYER

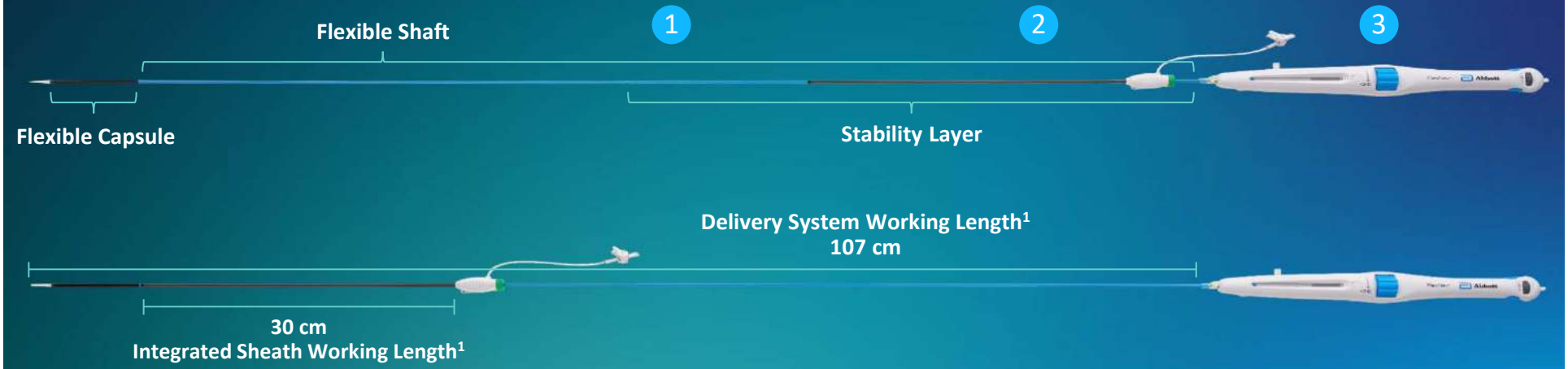
Flexible catheter shaft with improved trackability and an added stability layer maintains implant position during deployment for accurate valve placement

2 INTEGRATED SHEATH

Sheathless approach with integrated sheath and hydrophilic coating for reduced insertion profile and insertion force

3 ERGONOMIC HANDLE

Improved handle ergonomics with simplified use steps including redesigned lockout mechanism for ease of use



1. Navitor™ TAVI System IFU.

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Always check the regulatory status for the device in your region.

NAVITOR™ TAVI SYSTEM

Navitor™ TAVI System Components & Specifications[1]

Catalog Numbers		
Navitor™ Valve	**FlexNav™ Delivery System**	**Navitor™ Loading System**
NVTR-23 (23mm) or NVTR-25 (25mm)	FNAV-DS-SM	NVTR-LS-SM
NVTR-27 (27mm) or NVTR-29 (29mm)	FNAV-DS-LG	NVTR-LS-LG

Valve Catalog Number	Annulus Diameter	Ascending Aorta Diameter	Area	Perimeter
NVTR-23	19 – 21 mm	26 - 36 mm	277 - 346 mm^2	60 - 66 mm
NVTR-25	21 – 23 mm	28 - 38 mm	338 - 415 mm^2	66 - 73 mm
NVTR-27	23 – 25 mm	30 - 40 mm	405 - 491 mm^2	72 - 79 mm
NVTR-29	25 – 27 mm	32 - 42 mm	479 - 573 mm^2	79 - 85 mm

Delivery System Catalog Numbers	Equivalent Integrated Sheath Diameter	Valve Capsule Outer Diameter	Integrated Sheath Working Length	Delivery System Length	Minimum Vessel Diameter Requirement	Compatible Guidewire
FNAV-DS-SM	14 F	6.0 mm	30 cm	107 cm	≥ 5.0 mm	0.035” (0.89 mm)
FNAV-DS-LG	15 F	6.3 mm	30 cm	107 cm	≥ 5.5 mm	0.035” (0.89 mm)

1. Navitor™ TAVI System IFU.

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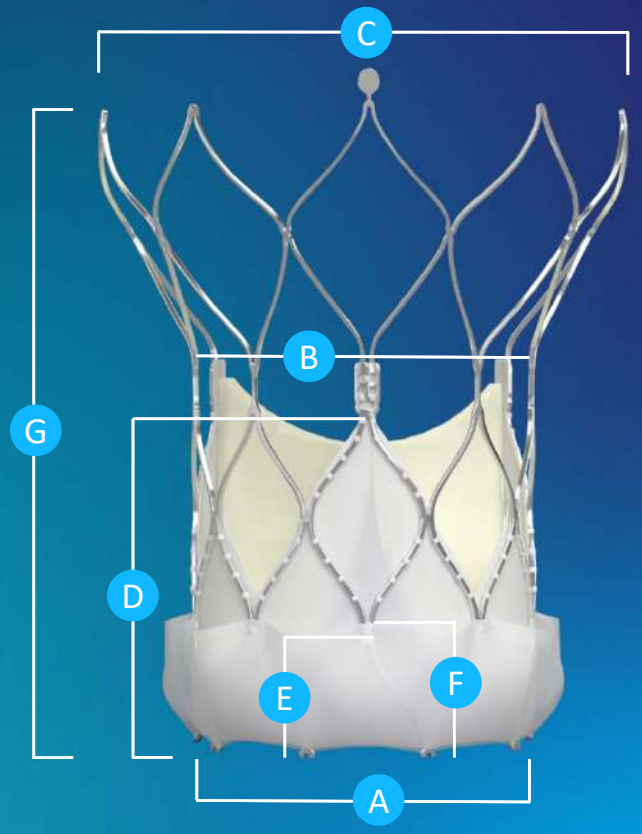
Always check the regulatory status for the device in your region.

NAVITOR™ TAVI SYSTEM

Navitor™ Valve Dimensions[1]

DIMENSION DESCRIPTION (mm)		VALVE SIZE			
		23 mm	25 mm	27 mm	29 mm
A	Valve Inflow Diameter*	23	25	27	29
B	Valve Outflow Diameter*	23	25	27	29
C	Aortic Stent Diameter*	41	43	44	46
D	Commissure Height*	21	23	24	25
E	Half Cell Height*	7	7	8	8
F	NaviSeal™ Cuff Height*†	9	9	10	10
G	Stent Height*	47	48	48	48

* Dimensions at fully expanded and unconstrained stent.
† Outer cuff portion.



1. Abbott data on file 90734545.

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IN-DEPTH REVIEW

Navitor™ Valve

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NAVITOR™ TAVI SYSTEM

Smart Sealing | Exceptional Hemodynamics | Uncompromised Coronary Access

INTELLIGENT DESIGN.

Advancing the forefront of innovative design, the Navitor™ valve brings together smart PVL-sealing technology, exceptional single-digit gradients,[1] and uncompromised coronary access to achieve excellent clinical outcomes.

1. Abbott data on file CL1014440.

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NAVITOR™ TAVI SYSTEM

Smart Sealing

NaviSeal™ Cuff actively synchronizes to the cardiac cycle, seals, and mitigates PVL[1] by expanding to fill calcification-related gaps between the annulus and the valve. By combining an outer cuff with increased sealing zone height and optimized radial force, the NaviSeal Cuff improves sealing and mitigates PVL.

SMART SEALING MITIGATES PVL

30-DAY ECHO CORE LAB DATA[1]

NONE/TRACE	MILD	MODERATE	SEVERE
80%	20%	0%	0%

1. Abbott data on file CL1014440.

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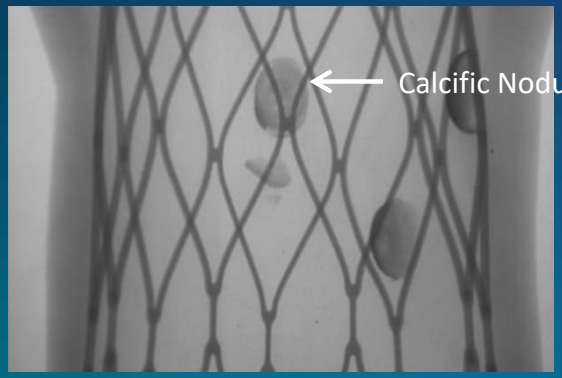
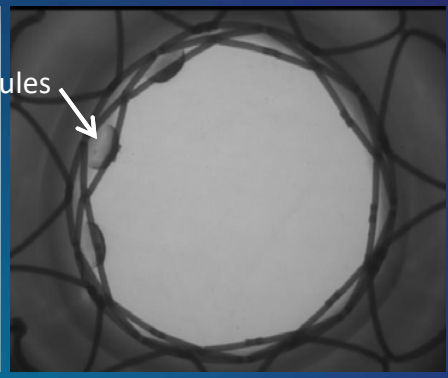
NAVITOR™ TAVI SYSTEM

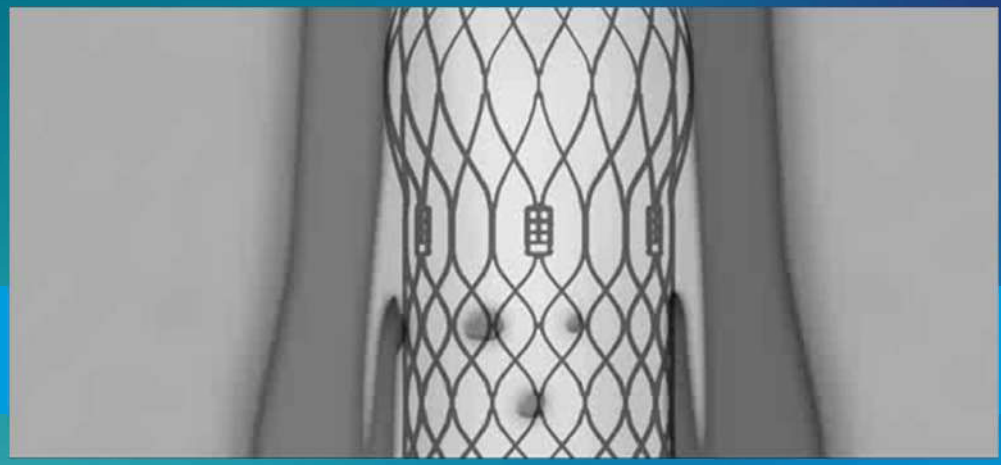
Smart Sealing

Large cells and NaviSeal™ cuff conformability, high fabric to stent ratio, and optimized radial force designed to conform around calcific nodules.





Click video to play



Calcific Nodule Conformability Simulation

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NAVITOR™ TAVI SYSTEM

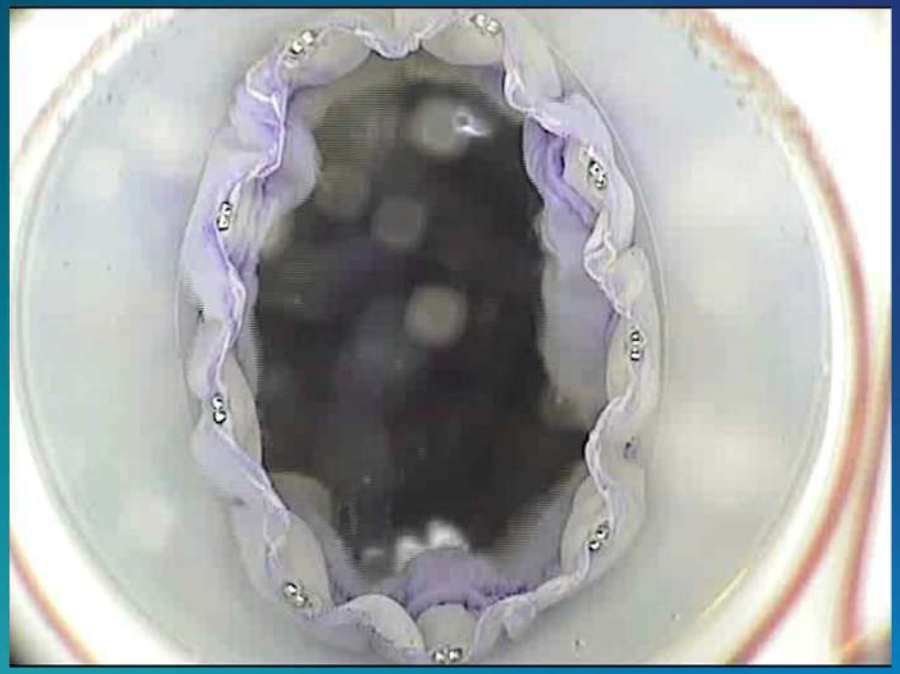
Smart Sealing

Conformable stent frame optimizes leaflet coaptation[1]* designed to function in circular and elliptical configurations.

Durability, coaptation and hemodynamics assessed in both round and elliptical configurations.

In-vitro testing meets durability requirements after > 200 million cycles in round and elliptical annuli.[1]

Click video to play



*Compared to less-conformable self-expanding valve platforms
1. Abbott data on file 90440160.

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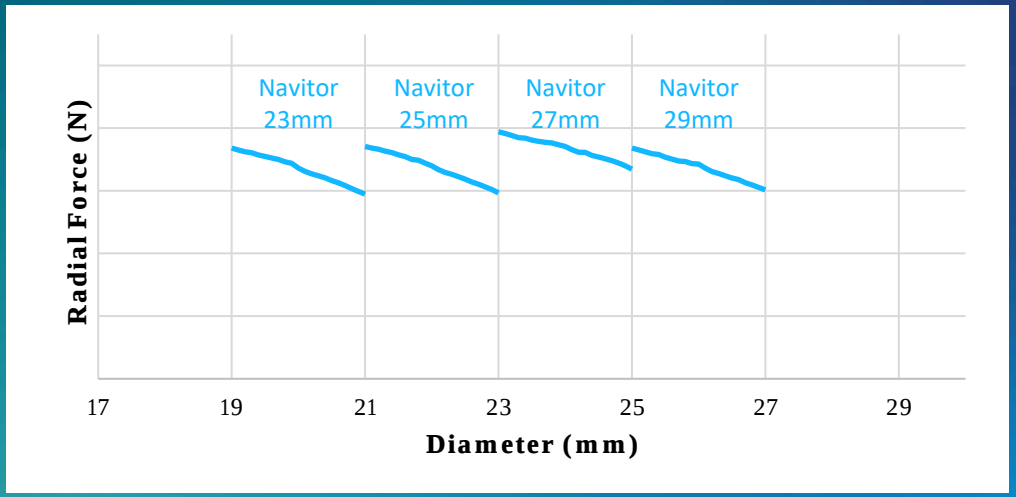
NAVITOR™ TAVI SYSTEM

Smart Sealing

Optimized radial force offers consistent and predictable anchoring and sealing across valve sizes and corresponding use ranges.[1]



1. Abbott data on file CL1007744.

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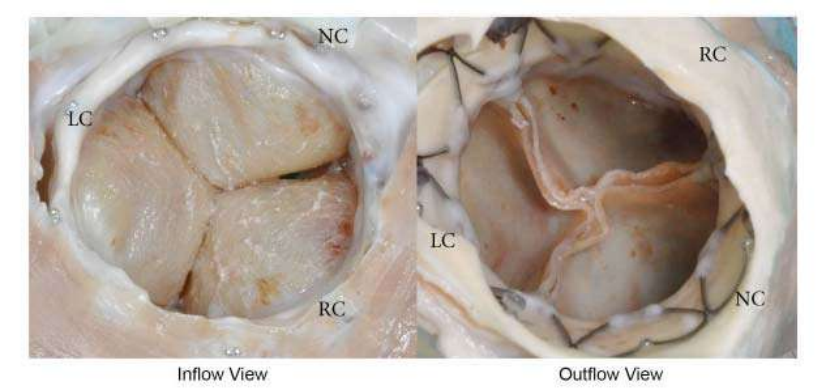
NAVITOR™ TAVI SYSTEM

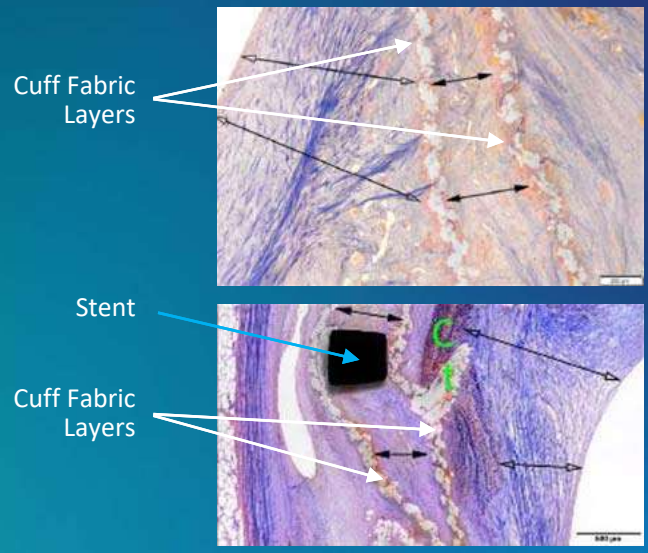
Smart Sealing

90-day GLP preclinical pathology and histopathology study:

- Optimal healing and no adverse calcification or thrombosis altering cusp motion.
- No excessive neointima growth, ischemic changes or emboli in the brain.
- Valve cusps were flexible with optimal conformation and coaptation and without degradation (no tears or fenestrations).



MICROSCOPIC FABRIC ANALYSIS



Magnified short axis valve section shows mature fibrocellular neointima (solid black arrows) between valve cuff fabric layers (white arrows)

1. Abbott data on file 90459999, 90368700.

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NAVITOR™ TAVI SYSTEM

Smart Sealing

PVL 30-DAY ECHO CORE LAB DATA	NAVITOR™[1] N=118	EVOLUT‡ PRO[2] N=58	ACURATE NEO2‡[3] N=100	SAPIEN‡ 3[4] N=113*
None/Trace	**79.7%**	72.4%	35.0%	74.3%
Mild	**20.3%**	27.6%	62.0%	22.1%
Moderate	**0.0%**	0.0%	3.0%	3.5%
Severe	**0.0%**	0.0%	0.0%	0.0%

PVL IMPACT.

Moderate or greater PVL increases 1-year mortality and rehospitalization

2.4x-2.7x

following TAVI[5]

Based on number of subjects with data evaluable by the echo core lab.
NOTE: Data not from head-to-head studies. Data differences depicted between these trials may not be directly comparable, statistically significant, or clinically meaningful due to differences in trial protocols, endpoints, and/or patient populations. Data provided for informational purposes only.
NOTE: Referenced data reflect results from prospective, multicenter clinical studies with contemporary valves in high and extreme risk surgical patients conducted to support CE Mark approval.
* Includes data on subjects implanted via transapical and transaortic access

1. Abbott data on file CL1014440.
2. Forrest JK, et al. Outcomes with the Evolut PRO repositionable self-expanding transcatheter aortic valve with pericardial wrap. J Am Coll Cardiol Intv. 2018;11:160-168.
3. Möllmann H. Transcatheter aortic valve implantation for severe aortic stenosis with the Acurate neo2 valve system: 30-day safety and performance outcomes. Abstract presented at: PCR London Valves; September 10, 2018; London, UK.
4. Webb J, et al. Multicenter evaluation of a next-generation balloon-expandable transcatheter aortic valve. J Am Coll Cardiol. 2014;64:2235-43.
5. Pibarot P, et al. Assessment of paravalvular regurgitation following TAVR: a proposal of unifying grading scheme. JACC Cardiovasc Imaging. 2015;8(3):340-360. doi: 10.1016/j.jcmg.2015.01.008. PMID: 25772838.

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NAVITOR™ TAVI SYSTEM

Exceptional Hemodynamics

Large effective orifice areas, single digit gradients[1] single-digit gradients.[1]

30-DAY ECHO CORE LAB DATA[1]

2.0 cm^2
EOA

7.4 mmHg
MEAN GRADIENT

HEMODYNAMIC IMPACT.

Non-tapered stent and large EOAs resulting in single-digit gradients are associated with improved cardiac function, long-term durability, and minimal prosthesis-patient mismatch.[1]

1. Abbott data on file CL1014440.

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NAVITOR™ TAVI SYSTEM

Exceptional Hemodynamics

30-DAY ECHO CORE LAB DATA	NAVITOR™[1]	EVOLUT‡ PRO[2]	ACURATE NEO2‡[3]	SAPIEN‡ 3[4]
Mean Gradient (mmHg)	**7.4** (N=118)	6.4 (N=55)	7.9 (N=104)	10.6 (N=119*)
EOA (cm^2)	**2.0** (N=101)	2.0 (N=47)	1.7 (N=99)	1.5 (N=97*)

Based on number of subjects with data evaluable by the echo core lab.

NOTE: Data not from head-to-head studies. Data differences depicted between these trials may not be directly comparable, statistically significant, or clinically meaningful due to differences in trial protocols, endpoints, and/or patient populations. Data provided for informational purposes only.

NOTE: Referenced data reflect results from prospective, multicenter clinical studies with contemporary valves in high and extreme risk surgical patients conducted to support CE Mark approval.

* Includes data on subjects implanted via transapical and transaortic access

1. Abbott data on file CL1014440.
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3. Möllmann H. Transcatheter aortic valve implantation for severe aortic stenosis with the Acurate neo2 valve system: 30-day safety and performance outcomes. Abstract presented at: PCR London Valves; September 10, 2018; London, UK.
4. Webb J, et al. Multicenter evaluation of a next-generation balloon-expandable transcatheter aortic valve. J Am Coll Cardiol. 2014;64:2235-43.

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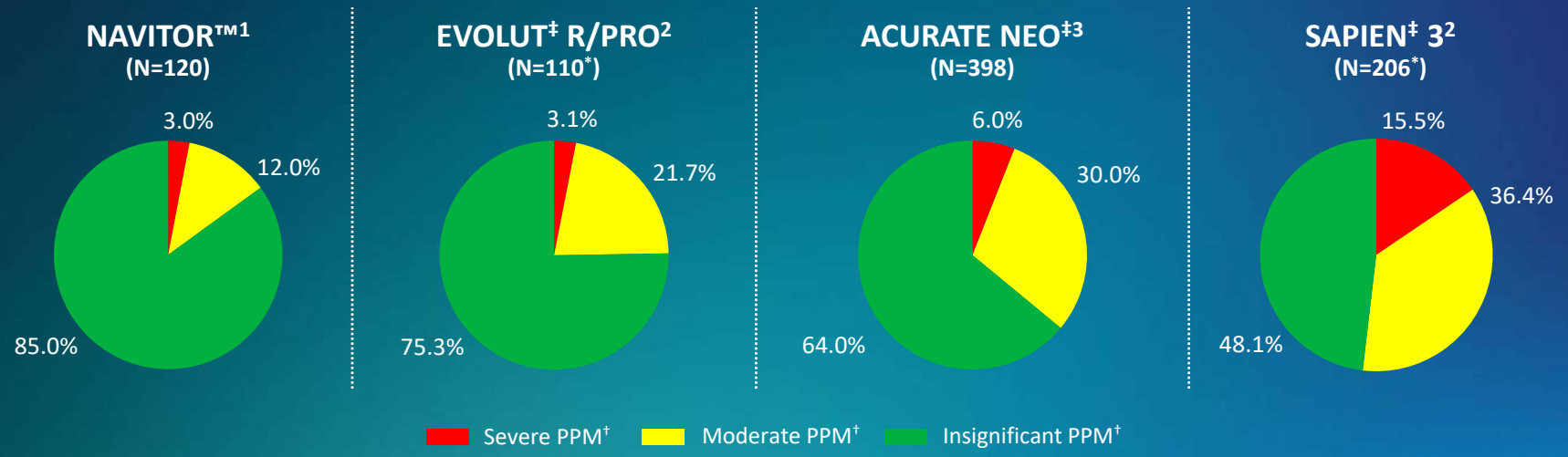
NAVITOR™ TAVI SYSTEM

Exceptional Hemodynamics

Low Incidence of Prosthesis-Patient Mismatch (PPM) – 30 Day[1]



NOTE: Data not from head-to-head studies. Data differences depicted between these trials may not be directly comparable, statistically significant, or clinically meaningful due to differences in trial protocols, endpoints, and/or patient populations. Data provided for informational purposes only. †Prosthesis-patient mismatch (PPM) classified according to VARC 2 criteria and adjusted for BMI.

* Data represent a subset of high- or extreme-risk patients that received an Evolut‡ R, Evolut‡ PRO or Sapien‡ 3 valve implant via a transfemoral or alternative access approach between May 2014 and October 2017. Patients were enrolled as part of a separate pivotal randomized study arm of the PORTICO IDE trial.

1. Abbott data on file for n=100 Navitor subjects. 2. Fontana GP. Safety outcomes from the Portico IDE FlexNav Delivery System study of 100 high and extreme risks patients. Presented at London Valves Meeting, November 18, 2019. 3. Tamburino C, et al. Comparison of self-expanding bioprostheses for transcatheter aortic valve replacement in patients with symptomatic severe aortic stenosis: SCOPE 2 Randomized Clinical Trial. Supplemental Table XIV. Circulation. 2020 Dec 22;142(25):2431-2442.

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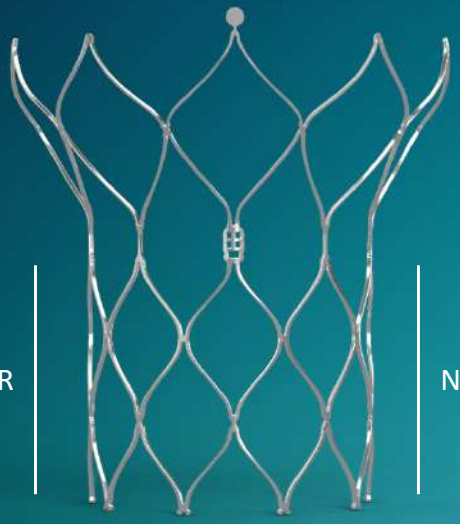
NAVITOR™ TAVI SYSTEM

Exceptional Hemodynamics by Design

Non-Tapered Stent

NAVITOR™ VALVE



NON-TAPER

NON-TAPER

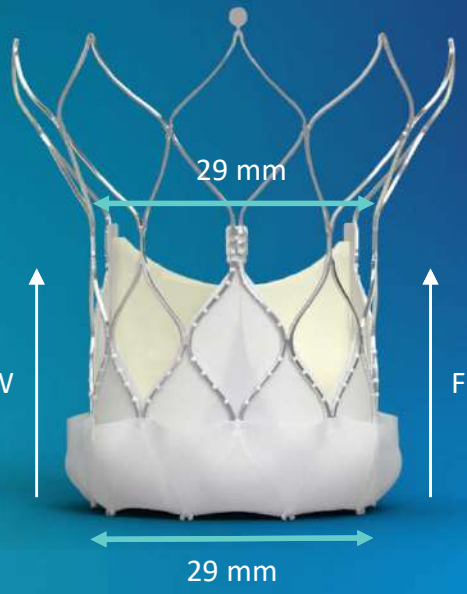
Inflow Diameter*

=

Outflow Diameter*

1:1 Inflow/Outflow Diameter Ratio IN ALL SIZES[1]

NAVITOR™ VALVE (29 mm shown)



FLOW

FLOW

1. Abbott data on file 90734545. * Dimensions at fully expanded and unconstrained stent

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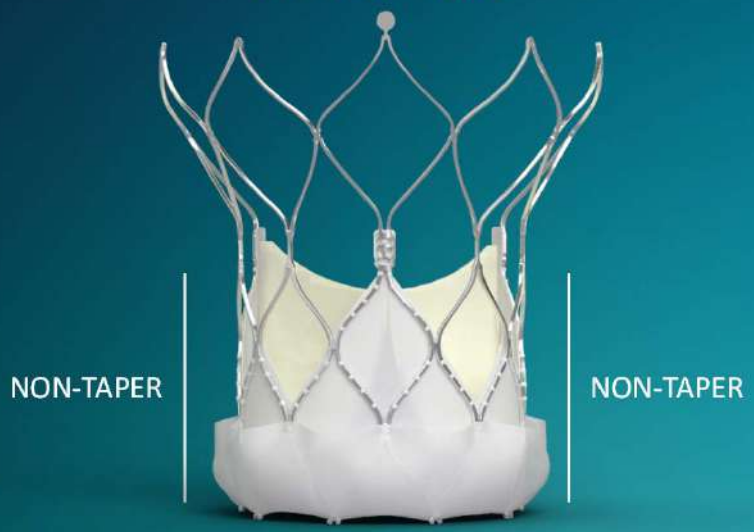
NAVITOR™ TAVI SYSTEM

Comparative Designs

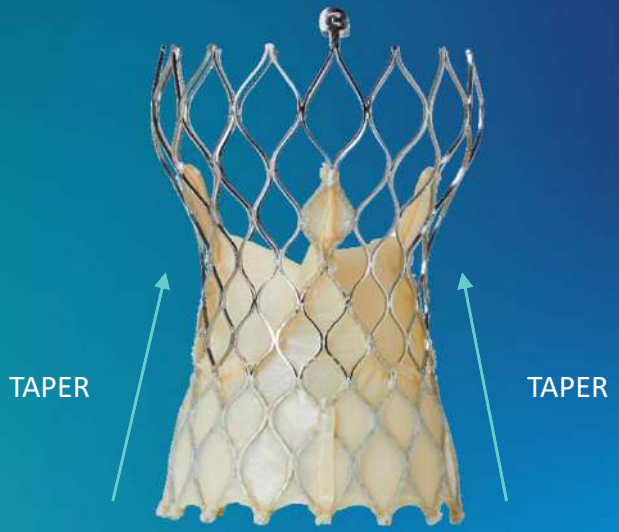
Non-Tapered Stent

NAVITOR™ VALVE



Tapered Stent

EVOLUT‡ PRO VALVE



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NAVITOR™ TAVI SYSTEM

Comparative Designs

1:1 Inflow/Outflow Diameter Ratio IN ALL SIZES.[1]

NAVITOR™ VALVE

Navitor™ Valve	23 mm	25 mm	27 mm	29 mm
Outflow Diameter	23 mm	25 mm	27 mm	29 mm
Inflow Diameter	23 mm	25 mm	27 mm	29 mm
Ratio	1 to 1	1 to 1	1 to 1	1 to 1

< 1:1 Inflow/Outflow* Diameter Ratio IN ALL SIZES.[2]

EVOLUT‡ PRO VALVE

Evolut‡ PRO Valve	23 mm	26 mm	29 mm
Outflow (Waist) Diameter	20 mm	22 mm	23 mm
Inflow Diameter	23 mm	26 mm	29 mm
Ratio	1 to 0.87	1 to 0.85	1 to 0.79

1. Abbott data on file 90734545. 2. Arshi A, et al. Overcoming the transcatheter aortic valve replacement Achilles heel: coronary re-access. Ann Cardiothorac Surg. 2020 Nov;9(6):468-477.

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NAVITOR™ TAVI SYSTEM

Exceptional Hemodynamics

Designed for Immediate Functionality And Durability.

CONTINUOUS STABILITY. NO RAPID PACING.

The only self-expanding valve with intra-annular leaflets that immediately function and a non-tapered stent, providing hemodynamic stability throughout the procedure for a calm and controlled deployment.

DESIGNED FOR DURABILITY.

Exclusive Linx™ anticalcification (AC) technology resists calcification in four distinct ways to improve long-term valve performance.[1-4]

1. Frater RWM, et al. Advances in anticalcific and antidegenerative treatment of heart valve bioprostheses. Silent Partners Inc. 1997;8:105-13.
2. Kelly SJ, et al. Biocompatibility and calcification of bioprosthetic heart valves. Society for biomaterials. Sixth World Biomaterials Congress Transaction. 2000;13534.
3. Vyavahare N, et al. Prevention of bioprosthetic heart valve calcification by ethanol preincubation: efficacy and mechanisms. Circulation. 1997;95(2):479-88.
4. Vyavahare N, et al. Prevention of calcification of glutaraldehyde-crosslinked porcine aortic cusps by ethanol preincubation: mechanistic studies of protein structure and water-biomaterial relationships. J Biomed Mater Res. 1998;40(4):577-85..

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NAVITOR™ TAVI SYSTEM

Designed for Durability

	ABBOTT LINX™ AC*[1-4]	MEDTRONIC AOA‡*[5]	BOSTON SCIENTIFIC BIOFIX‡*	EDWARDS THERMAFIX‡*[6]
PRODUCTS	**NAVITOR™**	**EVOLUT‡ PRO**	**ACURATE NEO2‡**	**SAPIEN‡ 3**
Reduces free aldehydes[1,2]	✓	✓	Not Publicly Available	✓
Extracts lipids[3]	✓		Not Publicly Available	✓
Minimizes uptake of cholesterol[4]	✓		Not Publicly Available	
Stabilizes leaflet collagen[4]	✓		Not Publicly Available	

*There is no clinical data currently available that evaluates the long-term impact of anticalcification tissue treatment in humans.

1. Frater RWM, et al. Advances in anticalcific and antidegenerative treatment of heart valve bioprostheses. Silent Partners Inc. 1997;8:105-13.
2. Kelly SJ, et al. Biocompatibility and calcification of bioprosthetic heart valves. Society for biomaterials. Sixth World Biomaterials Congress Transaction. 2000;13534.
3. Vyavahare N, et al. Prevention of bioprosthetic heart valve calcification by ethanol preincubation: efficacy and mechanisms. Circulation. 1997;95(2):479-88.
4. Vyavahare N, et al. Prevention of calcification of glutaraldehyde-crosslinked porcine aortic cusps by ethanol preincubation: mechanistic studies of protein structure and water-biomaterial relationships. J Biomed Mater Res. 1998;40(4):577-85.
5. Gross J. Calcification of bioprosthetic heart valves and its assessment. J Thorac Cardiovasc Surg. 2003;125:6-8.
6. Edwards website, http://www.webcitation.org/667ClPuMH. This WebCitation captured Edwards' site on 12MAR2012.

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NAVITOR™ TAVI SYSTEM

Uncompromised Coronary Access

UNCOMPROMISED CORONARY ACCESS.

Large-cell geometry and intra-annular valve design preserve coronary access for future intervention.

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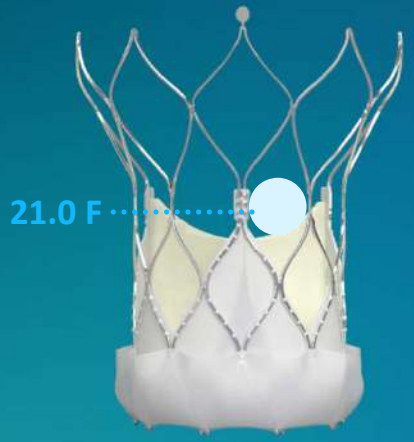
NAVITOR™ TAVI SYSTEM

Uncompromised Coronary Access

VALVE SIZE	NAVITOR™*1	EVOLUT‡ PRO*1
23 mm	14.6 F	12.1 F
25 mm	16.3 F	n/a
26 mm	n/a	11.8 F
27 mm	18.7 F	n/a
29 mm	21.0 F	11.9F

29 mm NAVITOR™ VALVE*1



36 CELLS TOTAL

9 CELLS IN THE ANNULUS SECTION OF THE STENT

29 mm EVOLUT‡ PRO VALVE*1

135 CELLS TOTAL

15 CELLS IN THE ANNULUS SECTION OF THE STENT

* Based on Abbott coronary access testing.
1. Abbott data on file 90664679.

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Abbott