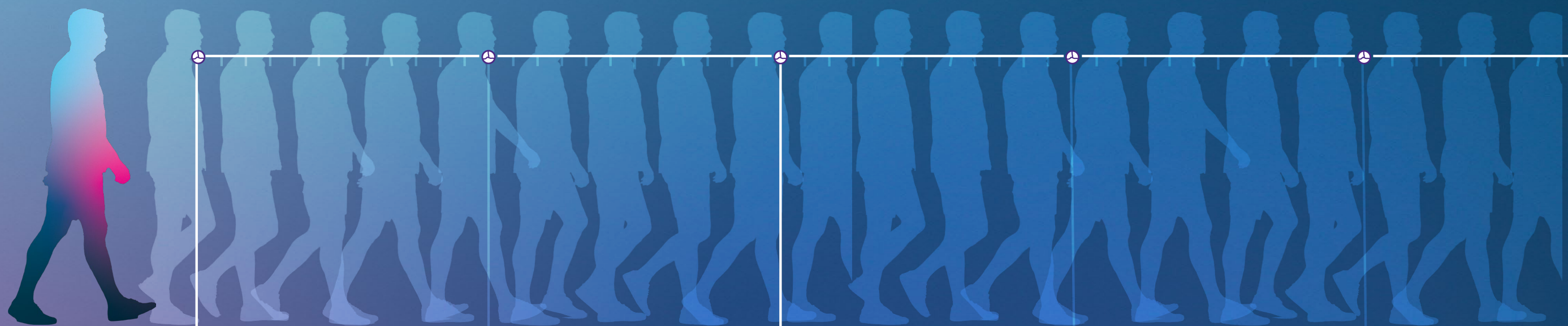
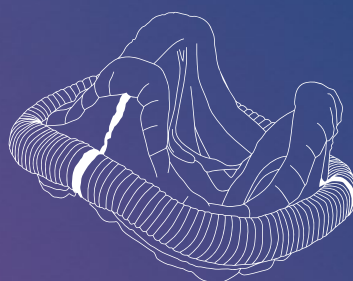




Epic™ Aortic and Mitral
Stented Tissue Valves



BUILT FOR TODAY,
INSPIRED BY TOMORROW.



Epic. By Design.

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Check the regulatory status of the device in areas where CE marking is not the regulation in force.



LET'S SEE WHAT'S AHEAD.

At Abbott, the future is exactly what we design for. It's what inspires us to keep improving Epic™ Stented Tissue Valves—the surgical valve platform that surgeons and patients have trusted for over three decades.

This generation of the Epic Platform has been built on the Biocor™ legacy of excellent **durability**, proven **performance** and unparalleled **implantability**—and reimagined with the **future** of transcatheter interventions in mind.

It's the surgical valve platform that gives you and your patients more choices when it comes to preserving long-term treatment paths.

Reliable therapy for today, possibilities for tomorrow.
Now that's Epic. By Design.



Epic™ Supra
Aortic Stented Tissue Valve



Epic™ Mitral
Stented Tissue Valve

TREATING TODAY, PRESERVING TOMORROW.

The Epic Platform has been proven over time and defined by strong hemodynamics, intuitive implantability, a future-forward design and more.



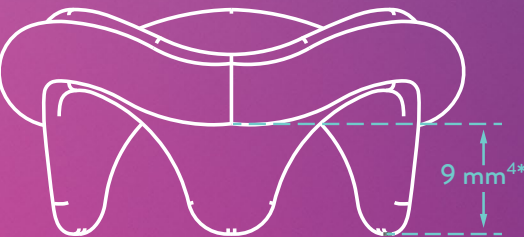
FLEXIBLE DESIGN FOR NOW AND LATER

AORTIC

- Withstands up to approximately 8 atm pressure during balloon valvuloplasty procedures¹
- Internally mounted leaflets and low overall stent post height reduce coronary obstruction²

MITRAL

- Low overall stent post height is less likely to obstruct LVOT³
- Epic[™] leaflets are not prone to forming a curtain between stent posts when opened, which can result in less LVOT obstruction



STREAMLINED, CUSTOMIZABLE IMPLANTATION

- Stent symmetry eliminates the need for specific orientation
- Flexible polymer stent offers more forgiving insertion and seating
- Short rinse time of 2 x 10 seconds⁴
- Epic[™] Mitral's ratcheting holder reduces risk of suture looping
- Epic Platform cuff options allow for secure suture placement while limiting suture drag and parachuting



PROVEN, OUTSTANDING PERFORMANCE

- The platform's optimal leaflet design mitigates regurgitation, while the flexible cuff is designed to minimize risk of paravalvular leak (PVL) and easily fit patient anatomy
- After 5 years, incidence of paravalvular leak is:

<0.1%

One incident of paravalvular leak out of a 1,300+ patient study⁵



EXCEPTIONAL DURABILITY ACROSS PATIENT POPULATIONS

- Linx[™] anticalcification (AC) treatment may improve long-term performance and durability^{**}

AT 10 YEARS



freedom from SVD; all patient ages (Epic[™] Mitral)⁶



freedom from SVD; all patient ages (Epic[™] Aortic)⁷

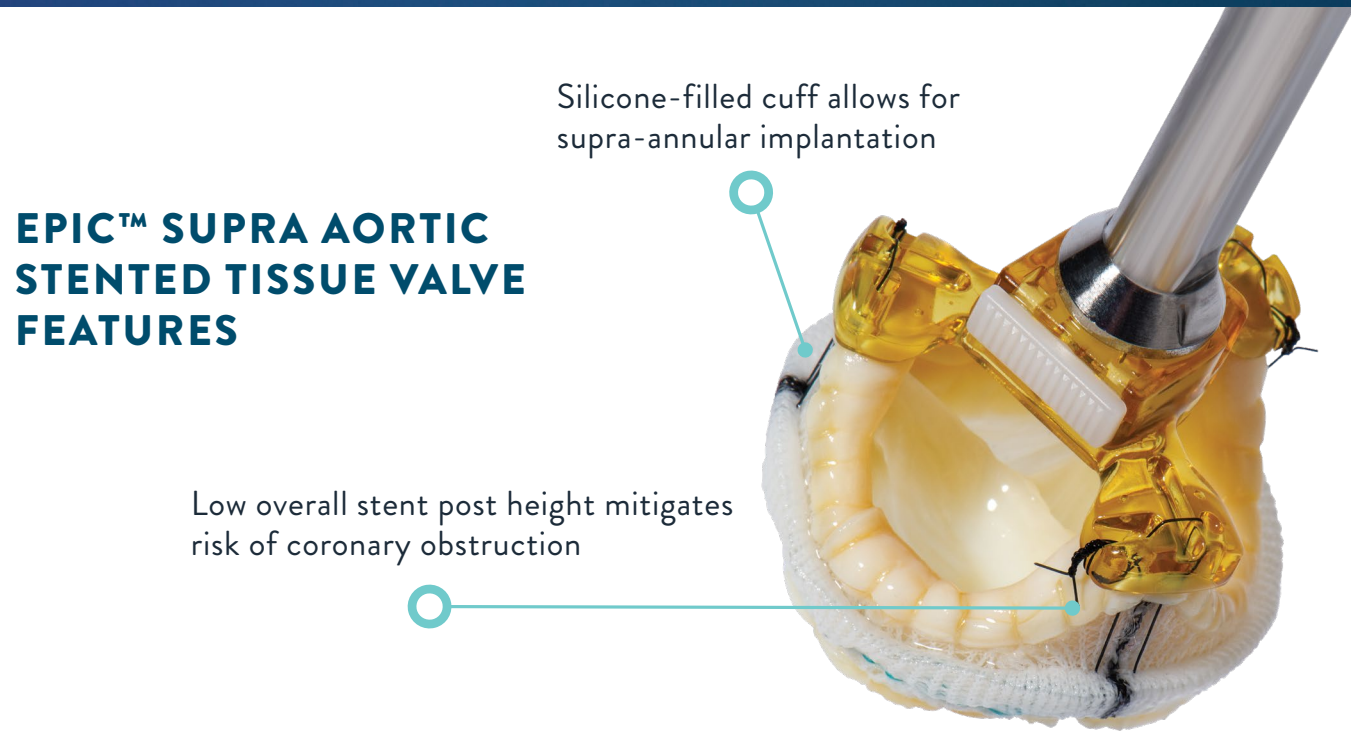
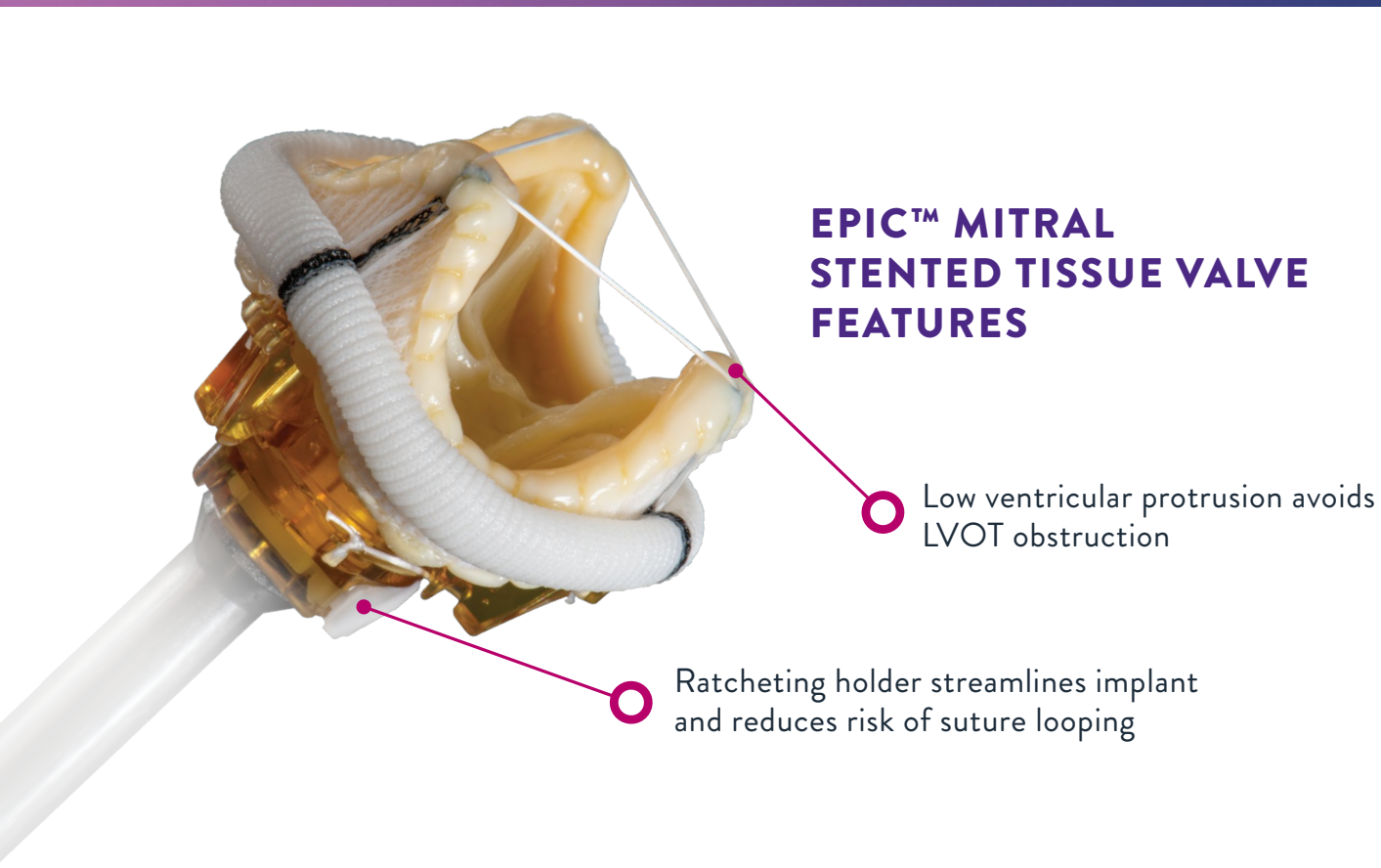
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*For 27 mm valve size, measured from the farthest point of the cuff.
**There is no clinical data currently available that evaluates the long-term impact of anticalcification tissue treatment in humans.
***From stand-alone aortic or mitral valve replacements.

THE PLATFORM FOR POSSIBILITY.

Epic Platform Core Features

FEATURES	Optimal leaflet design and matching	Epic™ leaflets	Flexible cuff	FlexFit™ polymer stent	Unique pericardial shield	Low, symmetrical stent posts	Linx™ AC treatment
BENEFITS	<ul style="list-style-type: none">• Reduces regurgitation risk	<ul style="list-style-type: none">• Lessens risk of LVOT obstruction	<ul style="list-style-type: none">• Mitigates PVL• Easily fits patient anatomy	<ul style="list-style-type: none">• Withstands up to approximately 8 atm pressure during balloon valvuloplasty procedures¹• Eases implant• Accommodates MIS mitral and aortic procedures	<ul style="list-style-type: none">• Provides a tissue-to-tissue interface to help prevent the risk of abrasion	<ul style="list-style-type: none">• Eliminates need for specific orientation at implant	<ul style="list-style-type: none">• Resists calcification*• Improves durability*

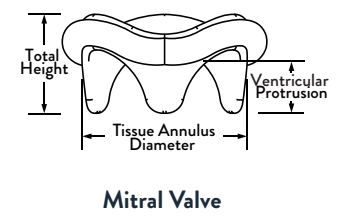


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*There is no clinical data currently available that evaluates the long-term impact of anticalcification tissue treatment in humans.

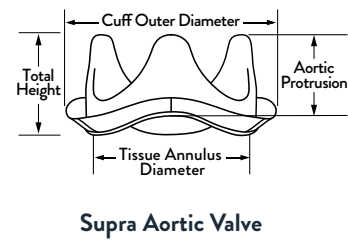
EPIC™ MITRAL VALVE

Model Number	Valve Size (mm)	Tissue Annulus Diameter (mm)	Ventricular Protrusion (mm)	Total Height (mm)	Cuff Outer Diameter (mm)
E100-25M	25	25	9	16	33
E100-27M	27	27	9	17	35
E100-29M	29	29	10	19	37
E100-31M	31	31	10	20	39
E100-33M	33	33	11	20	41



EPIC™ SUPRA AORTIC VALVE

Model Number	Valve Size (mm)	Tissue Annulus Diameter (mm)	Internal Diameter (Stent ID mm)	Aortic Protrusion (mm)	Total Height (mm)	Cuff Outer Diameter (mm)
ESP100-19	19	19	19	11	14	25
ESP100-21	21	21	21	11	15	28
ESP100-23	23	23	23	13	16	29
ESP100-25	25	25	25	13	17	31
ESP100-27	27	27	27	14	19	33



ACCESSORIES

Model Number	Description
B1000	Bioprosthetic Heart Valve Sizer Set One (1) click-in holder handle Six (6) double-ended aortic/Supra sizers (19, 21, 23, 25, 27, 29) Five (5) mitral sizers (25, 27, 29, 31, 33) One (1) autoclavable tray for storage of components One (1) autoclavable tray cover
B1000-H	Replacement handle One (1) click-in holder handle

Recommended Storage Temperature: 5°–25° C (41°–77° F)

Storage Solution: 0.5% formaldehyde solution

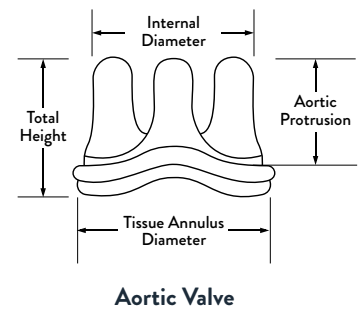
Resterilization: Epic valves must not be resterilized

Shelf Life: Four years

Radiopaque Marker for X-ray: A stainless steel wire located under the sewing cuff allows the valve to be seen under X-ray

EPIC™ AORTIC VALVE

Model Number	Valve Size (mm)	Tissue Annulus Diamter (mm)	Internal Diameter (Stent ID mm)	Aortic Protrusion (mm)	Total Height (mm)
E100-21A	21	21	19	9	14
E100-23A	23	23	21	9	15
E100-25A	25	25	23	10	16
E100-27A	27	27	25	11	17
E100-29A	29	29	27	12	19



References

1. Allen K, et al. Bioprosthetic valve fracture to facilitate transcatheter valve-in-valve implantation. *Ann Thorac Surg.* 2017;104:1501-1508. **2.** Edelman JJ, et al. Valve-in-valve TAVR: state-of-the-art review. *Innovations.* Philadelphia, PA. 2019;14(4):299. **3.** Guler N, Ozkara C, Akyol A. Left ventricular outflow tract obstruction after bioprosthetic mitral valve replacement with posterior mitral leaflet preservation. *Texas Heart Institute Journal.* 2006;33:399-401. **4.** Epic™ Instructions for Use. **5.** Lehmann S, et al. Mid-term results after Epic™ Xenograft implantation for aortic, mitral, and double valve replacement. *Journal of Heart Valve Disease.* 2007;16:641-648. **6.** Lehmann S, et al. Long-term follow-up after porcine xenograft mitral valve replacement. Presented at: 2017 American Association For Thoracic Surgery Mitral Conclave. April 27-28, 2017; New York, NY USA. **7.** Lehmann S, et al. Porcine xenograft for aortic, mitral and double valve replacement: long-term results of 2544 consecutive patients. *Eur J Cardiothorac Surg.* 2016;49:1150–1156.

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CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at manuals.sjm.com for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Abbott

Park Lane, Culliganlaan 2b, 1831 Diegem, Belgium

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