Epic™ Max
Aortic Stented Tissue Valve

OPTIMIZE OUTCOMES.
REDEFINE POSSIBILITIES.

See Important Safety Information referenced within.

Abbott

TODAY

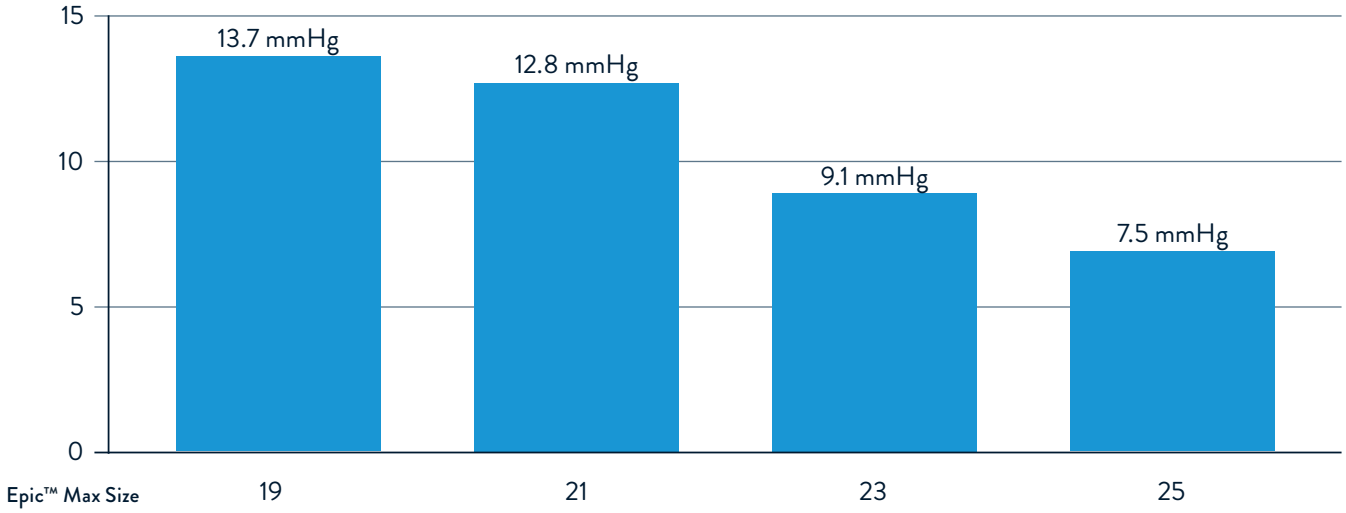
BENEFITS EXPERIENCED BY BOTH PATIENTS AND SURGEONS.

UNPARALLELED HEMODYNAMICS*

Maximizing the internal orifice provides large effective orifice areas (EOAs) and low gradients to reduce the burden on the heart and contribute to better patient outcomes.

Estimated Epic™ Max Mean Pressure Gradients at 1 year (mmHg)[1]

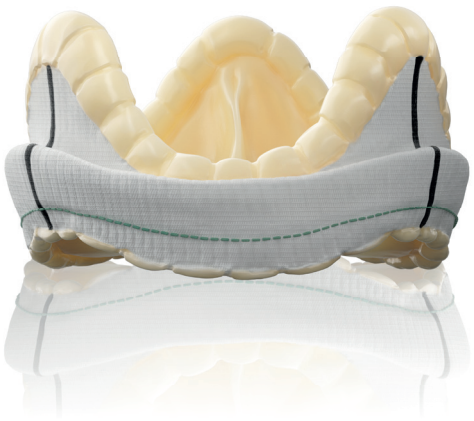
Mean pressure gradient predicted based on matched stent ID for Biocor/Epic™ valves



IMPLANT WITH EASE

The Epic™ Max design was engineered to allow maximum flexibility and easy passage through all anatomies.

The adaptive cuff is designed to prevent paravalvular leaks by sealing in all planes and minimizes parachuting resistance when delivering the valve onto the annulus.



*Compared to previous Epic Platform iterations.

See Important Safety Information referenced within.

TOMORROW

BUILT ON THE EPIC™ PLATFORM THAT HAS STOOD THE TEST OF TIME.

PROVEN LONG-TERM DURABILITY

The Epic™ platform has demonstrated proven outcomes across large patient populations and maximum durability by design.

STABLE GRADIENTS

The Epic valve family has demonstrated stable gradients through all intermediate time points in its multi-center FDA Post Approval study data.[4] This leaflet behavior is advantaged because increasing gradients are a known indicator for Structural Valve Deterioration (SVD) in tissue heart valves.

REDUCED STROKE RISK

- Porcine leaflets have less leaflet calcification at the time of reintervention.[4]
- At the time of reintervention, porcine valves have reduced intra-operative stroke and greater 30-day freedom from stroke compared to bovine pericardial valves.[5]

10-YEAR DURABILITY

Epic™ Supra Valve
Freedom From All-Cause Reintervention[2]

Epic™ Supra Valve
Freedom from SVD (Structural Valve Degeneration) All patient age[3]

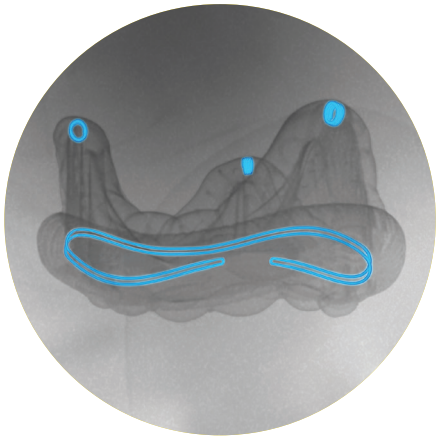
THE ROAD AHEAD

LAY THE FOUNDATION FOR THE NEXT INTERVENTION.

DESIGNED TO REDEFINE POSSIBILITIES

A larger stent internal diameter expands future treatment options for patients by facilitating ViV* procedures with a wide range of Transcatheter Aortic Valve Impantation prostheses.

For illustrative purposes only. TAVI frame used is not meant to depict any specific valve.



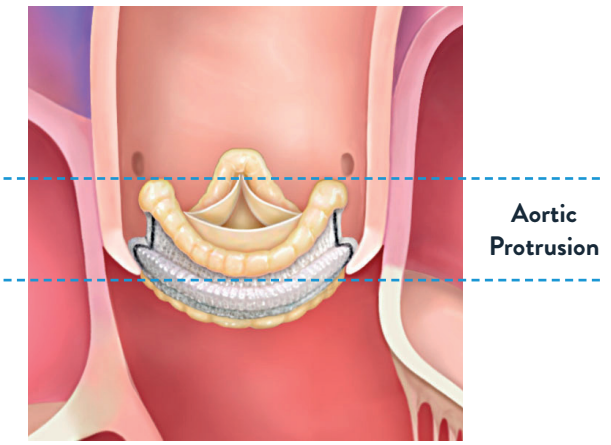
FUTURE-READY VALVE-IN-VALVE* FEATURES

The Epic™ Platform was engineered for future ViV:

- Non-curtaining leaflets
- Low profile
- Internally mounted leaflets
- Radiopacity at the stent posts and annulus
- Fractures at 8 atm of pressure[7]

MITIGATE OBSTRUCTION RISK

Low aortic protrusion and non-curtaining Epic™ leaflets mitigate the risk of coronary obstruction and sinus jailing.

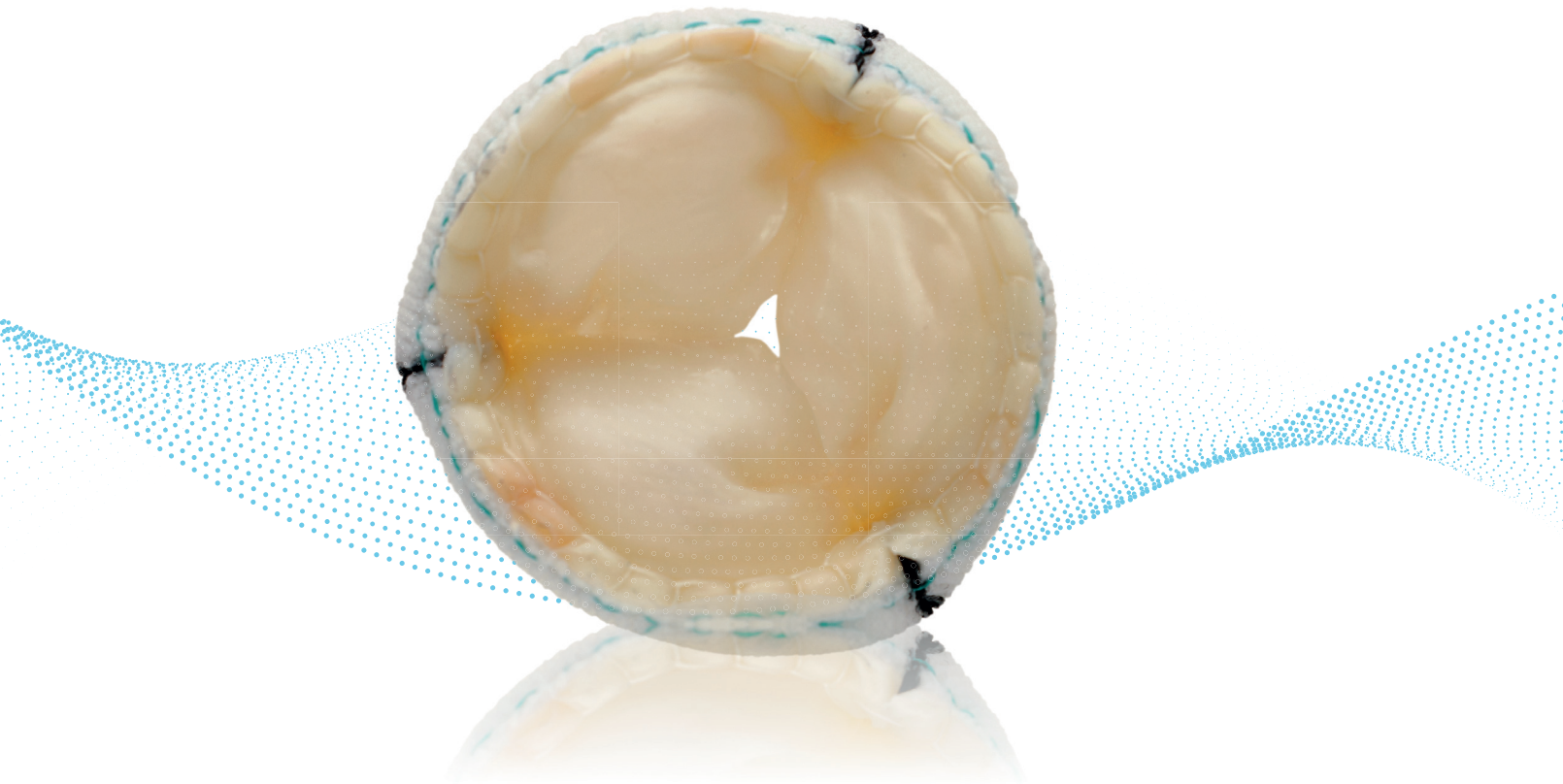


*The safety and effectiveness of valve-in-valve procedures in an Epic™ Max valve has not been established.

MAXIMIZE TODAY, TOMORROW AND **THE ROAD AHEAD.**

INTRODUCING THE EPIC™ MAX, OUR LATEST SOLUTION FOR OPTIMIZING KEY CLINICAL OUTCOMES AND THE POSSIBILITIES FOR PATIENT LIFETIME MANAGEMENT.

Epic™ Max is designed to redefine the future of aortic valve lifetime management by providing unparalleled hemodynamics* while maintaining the Epic Platform's ease of implant, proven durability, and features designed for future intervention.



*Compared to previous Epic Platform iterations.

See Important Safety Information referenced within.

Rx ONLY IMPORTANT SAFETY INFORMATION
EPIC™ MAX AORTIC STENTED TISSUE VALVE

INDICATION FOR USE
The Epic™ Max valve is indicated for patients requiring replacement of a diseased, damaged, or malfunctioning native aortic heart valve. It may also be used as a replacement for a previously implanted aortic prosthetic heart valve.

CONTRAINDICATIONS
None known.

POTENTIAL ADVERSE EVENTS
Adverse events potentially associated with the use of bioprosthetic heart valves (in alphabetical order) include: angina; cardiac arrhythmias; endocarditis; heart failure; hemolysis; hemolytic anemia; hemorrhage, anticoagulant/antiplatelet-related; leak, transvalvular or paravalvular; myocardial infarction; nonstructural dysfunction (entrapment by pannus or suture, inappropriate sizing or positioning, or other); prosthesis regurgitation; stroke; structural deterioration (calcification, leaflet tear, or other); thromboembolism; valve thrombosis. It is possible that these complications could lead to: reoperation; explantation; permanent disability; death.

REFERENCES

1. [a] Biocor IFU [b] Maitland, Andrew, Gregory M. Hirsch, and Edward A. Pascoe. "Hemodynamic Performance of the St. Jude Medical Epic™ Supra Aortic Stented Valve." Journal of Heart Valve disease 20.3 (2011): 327. [c] Epic Plus IFU
2. Wiechmann, RJ. et. al. Ten-year Outcomes of Surgical Aortic Valve Replacement with a Contemporary Supra Annular Porcine Valve in a Medicare Population. JTCVS Open. 2022, https://doi.org/10.1016/j.xjon.2022.08.002.
3. Jawad, Khalil, Sven Lehmann, Alex Koziarz, Maja Dieterlen, Stefan Feder, Martin Misfeld, Jens Garbade, Vivek Rao, and Michael Borger. "Midterm results after St Jude Medical Epic porcine xenograft for aortic, mitral, and double valve replacement." Journal of Cardiac Surgery 35, no. 8 (2020): 1769-1777.
4. Biocor IFU
5. Keshishi, Melanie, et al. "Comparison of Modes of Failure and Clinical Outcomes Between Explanted Porcine and Bovine Pericardial Bioprosthetic Valves." Cardiovascular Pathology (2023): 107516.
6. Bernard, J. et al. (2023, May). Mechanisms of Failure of a Mitral Valve Porcine Xenograft Prosthesis and Comparison of Outcomes According to Reintervention Approach. Poster presented at the AATS Mitral Conclave, New York.
7. Allen, KB., Adnan, CK., Cohen, DJ., et al. Bioprosthetic valve fracture to facilitate transcatheter valve-in-valve implantation. Ann Thorac Surg. 2017;104:1501-1508.

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