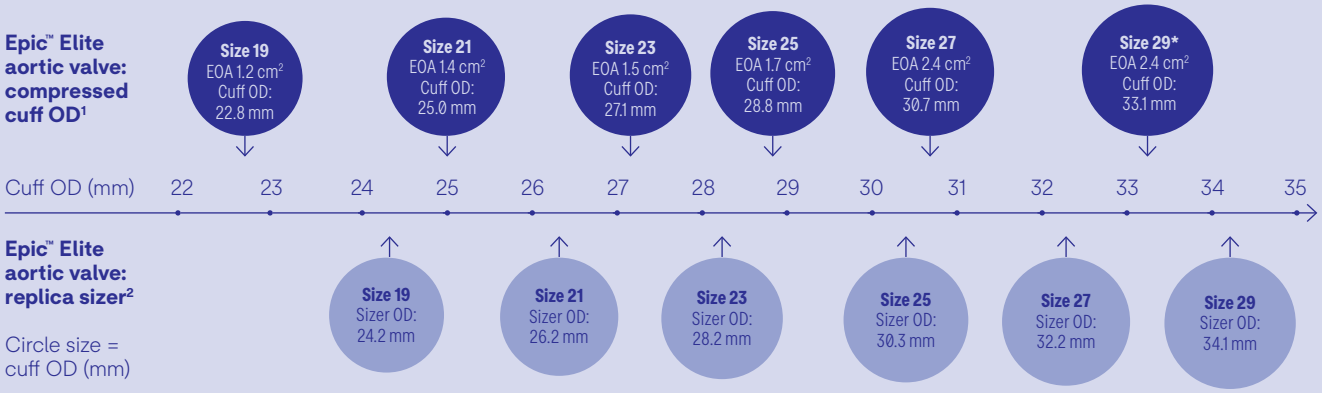
Epic™ Elite
Aortic Valve

ABBOTT

The power of the adaptive cuff, *sizing made simple*

Epic™ Elite aortic valve
1 mm of cuff compression

With the Epic™ Elite aortic valve, you can trust that if the replica sizer fits, the valve will fit. To better accommodate smaller patients, we engineered the valve with a compressible cuff. The fabric-only, compressible cuff reduces parachuting forces during implant and forms an adaptive seal that helps prevent paravalvular leak.



Adaptive cuff provides

1 mm

of compression

Implant an Epic™ Elite aortic valve for a potentially larger valve size

If the replica sizer fits, the valve will fit.

Epic™ Elite aortic valve imposed on replica sizer

For U.S. audience, see Important Safety Information referenced within. For audiences outside of the U.S., always check the regulatory status of the device in your region.

Effective orifice area index (EOAI) calculator[3,4]: EOAI by annular diameter

Labeled Valve Size (mm)	19	21	23	25	27	29*
Valve type	Epic™ Elite valve	Epic™ Elite valve	Epic™ Elite valve	Epic™ Elite valve	Epic™ Elite valve	Epic™ Elite valve
Average EOA (cm²)	**1.20**	**1.40**	**1.50**	**1.70**	**2.40**	**2.40**
Body surface area (BSA) (m²) 1.0	1.20	1.40	1.50	1.70	2.40	2.40
1.1	1.09	1.27	1.36	1.55	2.18	2.18
1.2	1.00	1.17	1.25	1.42	2.00	2.00
1.3	0.92	1.08	1.15	1.31	1.85	1.85
1.4	0.86	1.00	1.07	1.21	1.71	1.71
1.5	0.80	0.93	1.00	1.13	1.60	1.60
1.6	0.75	0.88	0.94	1.06	1.50	1.50
1.7	0.71	0.82	0.88	1.00	1.41	1.41
1.8	0.67	0.78	0.83	0.94	1.33	1.33
1.9	0.63	0.74	0.79	0.89	1.26	1.26
2.0	0.60	0.70	0.75	0.85	1.20	1.20
2.1	0.57	0.67	0.71	0.81	1.14	1.14
2.2	0.55	0.64	0.68	0.77	1.09	1.09
2.3	0.52	0.61	0.65	0.74	1.04	1.04
2.4	0.50	0.58	0.63	0.71	1.00	1.00
2.5	0.48	0.56	0.60	0.68	0.96	0.96

EOAI² = EOA/BSA EOAI > 0.85 cm²/m² EOAI > 0.65 cm²/m² to EOAI ≤ 0.85 cm²/m² EOAI ≤ 0.65 cm²/m²

*Valve size not available in all geographies
Note: All Epic™ Elite average EOA values computed off stent equivalency.

1. Epic™ Elite Instructions for Use.
2. Testing performed by and data on file at Abbott.
3. Data on file at Abbott [a] Epic™ Elite Instructions for Use [b] Maitland A, Hirsch G, Pascoe E. "Hemodynamic Performance of the St. Jude Medical Epic™ Supra Aortic Stented Valve." Journal of Heart Valve disease 20.3 (2011): 327.
4. Pibarot P, Dumesnil JG. Prosthetic heart valves: selection of the optimal prosthesis and long-term management. Circulation 2009;119:1034-48.

For U.S. audience only

Rx Only
Important Safety Information

Epic™ Elite and Epic™ Supra G3 valves

Indications for Use
The Epic™ Elite valve is indicated for patients requiring replacement of a diseased, damaged, or malfunctioning native aortic and/or mitral heart valve. It may also be used as a replacement for a previously implanted aortic and/or mitral prosthetic heart valve.

The Epic™ Supra G3 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
There are no known contraindications.

Potential Adverse Events
Adverse events potentially associated with the use of bioprosthetic heart valves (in alphabetical order) include: angina; annular/aortic injury; cardiac arrhythmias/conduction disturbances; coronary obstruction; endocarditis; heart failure; hemolysis; hemolytic anemia; hemorrhage, 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.

Caution: Product(s) 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 www.eifu.abbott for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Illustrations are artists' representations only and should not be considered as engineering drawings or photographs. Photos on file at Abbott.

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