

No-React® Versaflex Aortic Valve

Combines best aspects of Stented and Stentless Valves

Benefits

- Significant increase in EOA and reduction in left ventricular mass
- Even if distorted wider by 2 -3 sizes the valve can still coapt
- Clinical applicability of a stented valve but with better EOA
- Easy to implant



The BioIntegral Surgical No-React ® treated Versaflex™ valve was designed for ultimate versatility. Its wide clinical applicability is equal to a stented valve, while it delivers the hemodynamics of a stentless valve. The Versaflex does not require special techniques or instruments, and no pre-operative rinsing is required.

The Versaflex has a “skeletonised” plastic stent. The advantage of the skeleton is that the valve is ultra-flexible, easy to implant, and most importantly, the ring of the skeleton assures the cusps are on the same level and any pathological aorta cannot disturb the intended coaptation. For that reason, in 12-years and 20,000 implants, central regurgitation has never been reported.

- Designed for ultimate versatility.
- No special techniques or instruments, no pre-operative rinsing
- Pledged commissures distribute stresses of valve closure
- Flexible stent delivers good haemodynamics, but avoids distortion common to stentless valves
- Over 20,000 implants over 12 years

Super flexible stent allows for less reliance on the shape of the annulus for proper fit. Even if distorted wider by 2 -3 sizes the valve can still coapt

Aortic Root asymmetry has no influence on result. The Versaflex gives very good haemodynamics and favourable outcomes, including significant increase in EOA.

Valves have tested positive for endothelial coverage and have been used to avoid reinfection in cases of infective endocarditis.

Materials	Porcine Pericardium Sleeve Porcine Valve Medical Grade Plastic Stent
Eligible Patients	Suitable for any patient in need of aortic valve replacement
No-React® Treated Tissue	<ul style="list-style-type: none"> • Reduced toxicity • Enhanced biocompatibility • Lower rates of infection, adhesion, and calcification • Promotion of endothelial lining
Indications	<ul style="list-style-type: none"> • Replacement for damaged or diseased aortic heart valves
Design Features	<ul style="list-style-type: none"> • Clinical applicability of a stented valve • Haemodynamics of a stentless valves while avoiding distortion of cusp coaptation • Special techniques and instruments are not required • Pledged commissures distribute stresses of valve closure • Flexibility allows for less reliance on the shape of the annulus • Valve can be oversized to obtain best haemodynamics • Clinical records of significant increase in EOA and reduction in left ventricular mass

Table of EOA . Max BSA and EOAI for No-React® Versaflex

Valve Size (mm)	EOA (cm ²)	Max BSA (m ²)	EOAI (cm ² /m ²)
21	1.61	1.8	0.89
23	1.80	2.0	0.90
25	2.13	2.2	0.97
27	2.30	2.4	0.96

Contact

For customer services and for any further information on the Versaflex or any of the other products in the BioIntegral Surgical No-React® range please contact:

Pierson Surgical Ltd

01225 766632 or sales@piersonsurgical.com

CAUTION: Refer to the Instructions For Use provided with each device for complete information regarding indications for use, contraindications, warnings, precautions and potential complications.

Clinical Papers

Gerding A, et al. "Patient-prosthesis mismatch and left ventricular remodelling after implantation of Shelhigh SuperStentless [Versaflex] aortic valve prostheses." *Cardiovasc Surg (Torino)*. 2008 Aug;49(4):539-43.

Cattaneo et al., 2007, *European Journal of Cardio-thoracic Surgery*, "Early haemodynamic results of the Shelhigh SuperStentless [Versaflex] aortic bioprosthesis". *J Card Surg* 2007;22:379-384.

Siniawski, H. et al. "Factors Influencing the Results of Double-Valve Surgery in Patients with Fulminant Endocarditis: The Importance of Valve Selection." *The Heart Surgery Forum* #2004-1080, 7(5):1-6.