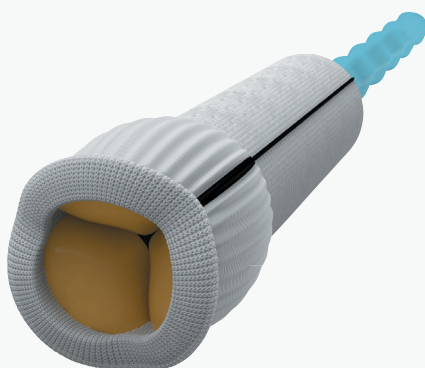


KONECT RESILIA

Aortic Valved Conduit



For

Replacement of the aortic heart valve and the ascending aorta

When

You need a valved conduit, procedural steps can be eliminated and may reduce procedure time. Ask if a KONECT RESILIA is right for you.

Why

RESILIA tissue* offers enhanced anti-calcification technology that will potentially allow the valve to last longer†

RESILIA tissue

- Significant improvement of anti-calcification properties in test compared to control valves†¹
- Sustained hemodynamic performance across 5 years²

Ready-to-implant‡

- Pre-assembly intuitively eliminates procedural steps as compared to self-assembled tissue valved conduits
- Stored dry and ready-to-use‡

Proven technology

- Built on the proven performance of the Carpentier-Edwards PERIMOUNT valve design – a valve design with published clinical durability of over 20 years³⁻⁵
- Gelweave Valsalva graft – the world's first anatomically designed aortic root graft with over 15 years of aortic root surgery clinical experience⁶⁻⁷

* No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.

† RESILIA tissue tested against tissue from commercially-available bovine pericardial valves from Edwards in a juvenile sheep model. Flameng, et al. *J Thorac Cardiovasc Surg* 2015;149:340-5.

‡ Consult **Instructions for Use** for device preparation instructions.



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* KONECT RESILIA aortic valved conduit size 19 mm not available.

Important Safety Information: KONECT RESILIA Aortic Valved Conduit

Indications: For use in replacement of native or prosthetic aortic heart valves and the associated repair or replacement of a damaged or diseased ascending aorta.

Contraindications: There are no known contraindications with the use of the KONECT RESILIA aortic valved conduit. **Complications and Side Effects:** Thromboembolism, valve thrombosis, hemorrhage, hemolysis, regurgitation, endocarditis, structural valve deterioration, nonstructural dysfunction, stenosis, arrhythmia, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, any of which could lead to reoperation, explantation, permanent disability, and death. Adverse events potentially associated with the use of polyester vascular grafts include hemorrhage, thrombosis, graft infection, embolism, aneurysm, pseudoaneurysm, seroma, occlusion (anastomotic intimal hyperplasia), immunological reaction to collagen (shown to be a weak immunogen; infrequent, mild, localized and self-limiting), intimal peel formation, and conduit dilatation, any of which could lead to re-operation, explantation, permanent disability, and death.

CAUTION: For professional use only. The Edwards KONECT RESILIA Aortic Valved Conduit is a Class III medical device and indicated for use in patients with a dysfunctional Aortic Valve and the associated replacement of a damaged or diseased Aorta.

See Instructions for Use for full prescribing information, including indications, contraindications, warnings, precautions, and adverse events.

References

1. Flameng W, et al. A randomized assessment of an advanced tissue preservation technology in the juvenile sheep model. *J Thorac Cardiovasc Surg.* 2015;149:340-5.
2. Bavaria JE, et al. Five-year Outcomes of Aortic Valve Replacement with a Bioprosthetic Valve with a Novel Tissue. The Society of Thoracic Surgeons, 2021 Annual Meeting.
3. Bourguignon T, et al. Very long-term outcomes of the Carpentier-Edwards PERIMOUNT valve in aortic position. *Ann Thorac Surg.* 2015;99:831–7.
4. Johnston DR, et al. Long-term durability of bioprosthetic aortic valves: implications from 12,569 implants. *Ann Thorac Surg.* 2015;99:1239–47.
5. Forcillo J, et al. Carpentier-Edwards pericardial valve in the aortic position: 25-years experience. *Ann Thorac Surg.* 2013;96:486–93.
6. De Paulis R, et al. A new aortic Dacron conduit for surgical treatment of aortic root pathology. *Ital Heart J.* 2000;1(7):457-63.
7. De Paulis R, et al. Long-term results of the valve reimplantation technique using a graft with sinuses. *J Thorac Cardiovasc Surg.* 2016;151:112-9.

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