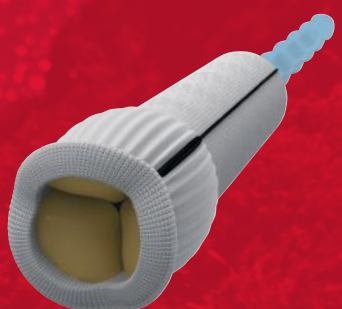
KONECT

RESILIA Aortic Valved Conduit

Resilient tissue.
Ready to go.



The first pre-assembled, ready-to-implant valved conduit with **RESILIA** tissue.

Edwards

KONECT RESILIA Aortic Valved Conduit: Developed specifically for bio-Bentall procedures.

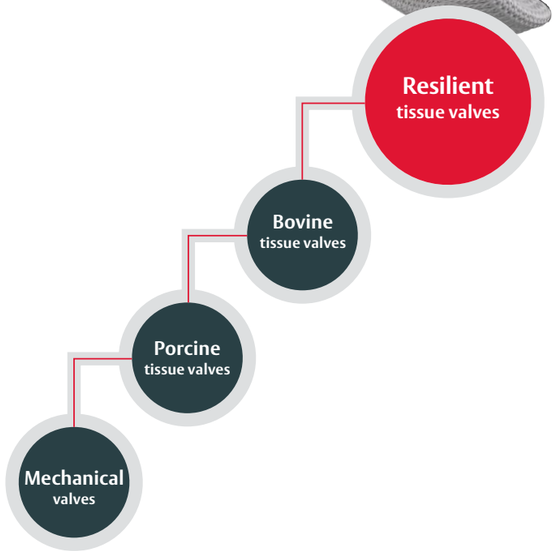
As the next offering in Edwards Lifesciences' class of resilient bovine pericardial valves, ready-to-implant KONECT RESILIA aortic valved conduit helps patients maintain their active lifestyles and streamlines bio-Bentall procedures*.

RESILIA tissue

Edwards Lifesciences' integrity preservation technology transforms bovine pericardial tissue into RESILIA tissue, effectively eliminating free aldehydes, while protecting and preserving the tissue.

RESILIA tissue is the first to deliver the combination of:

- **Improved anti-calcification properties†**
- **Improved sustained hemodynamic performance†**
- **Stored dry and ready to use‡**



A proven heritage

KONECT RESILIA aortic valved conduit is built on the proven performance of both the Carpentier–Edwards PERIMOUNT valve platform and the Gelweave Valsalva graft.

Valve platform
Proven performance of the PERIMOUNT valve design—a design with published clinical durability of over 20 years[2–4]

Gelweave Valsalva graft
The world's first anatomically designed aortic root graft with over 15 years of aortic root surgery clinical experience[5,6]

Ready to implant‡

The pre-assembled KONECT RESILIA aortic valved conduit intuitively eliminates procedural steps§, which is especially important in emergency cases.

Edwards' quality-controlled pre-assembly of valve and Gelweave Valsalva graft provides a consistent and reliable hemostatic connection

Pre-mounted to an easy-access, single-cut release holder

* By eliminating procedure steps.
† RESILIA tissue tested against commercially available bovine pericardial tissue from Edwards in a juvenile sheep model.[1] No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.
‡ Consult instructions for use for device preparation instructions.
§ As compared to self-assembled tissue valved conduits.

KONECT RESILIA Aortic Valved Conduit

Model	Valve size
11060A	21 mm – 29 mm 21, 23, 25, 27 & 29 mm

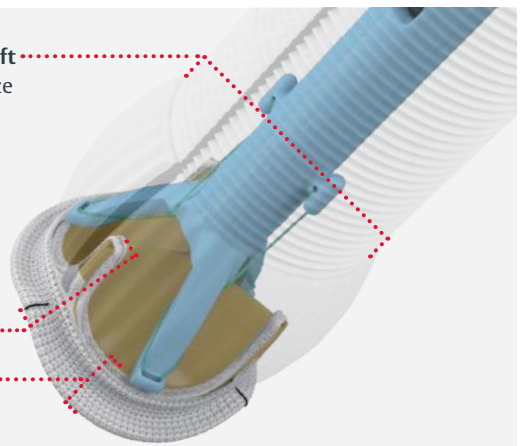
Model	Accessories
TRAY1190	Accessory tray
1190	Individual sizers 19 mm* – 29 mm
1190SET	Sizer set 19 mm* – 29 mm

Electronic Instructions for Use (eIFU)
eifu.edwards.com
+ 1 888 570 4016

Pre-sized Gelweave Valsalva graft
+3 mm from valve size to graft size

Commissure markers
Sewing ring and graft commissure markers facilitate device orientation and coronary reattachment

DualFit sewing ring
Allows for both intra-annular and supra-annular implantation



For use only with the dedicated sizers that replicate the DualFit sewing ring (Model 1190 Sizers and Tray)

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

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. Bourguignon T, et al. Very long-term outcomes of the Carpentier-Edwards PERIMOUNT valve in aortic position. Ann Thorac Surg. 2015;99:831-7.
3. Johnston DR, et al. Long-term durability of bioprosthetic aortic valves: implications from 12,569 implants. Ann Thorac Surg. 2015;99:1239-47.
4. Forcillo J, et al. Carpentier-Edwards pericardial valve in the aortic position: 25-years experience. Ann Thorac Surg. 2013;96:486-93.
5. 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.
6. 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.

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.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information.

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