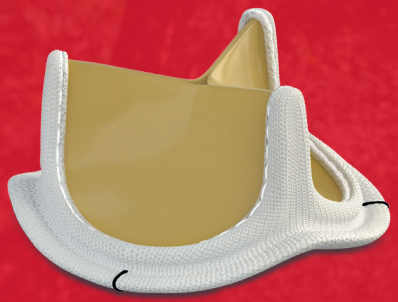
INSPIRIS
RESILIA Aortic Valve

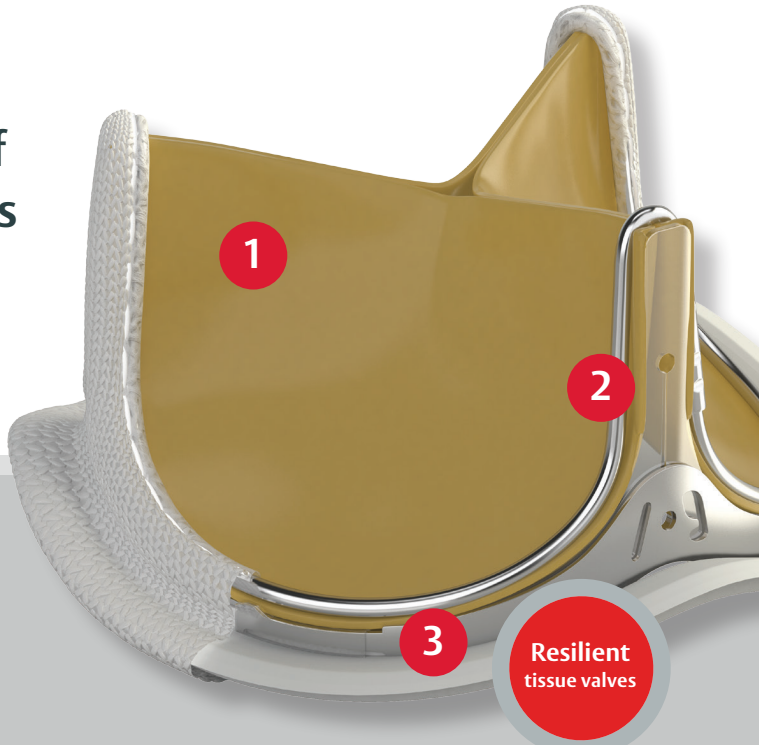
An ideal foundation
for your patient's future



The first product offering in a new class of
resilient heart valves enabled by **RESILIA** tissue

Edwards

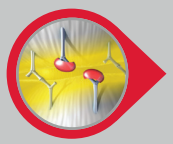
Introducing the INSPIRIS valve:
The first offering in a new class of resilient bovine pericardial valves



1 RESILIA tissue

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

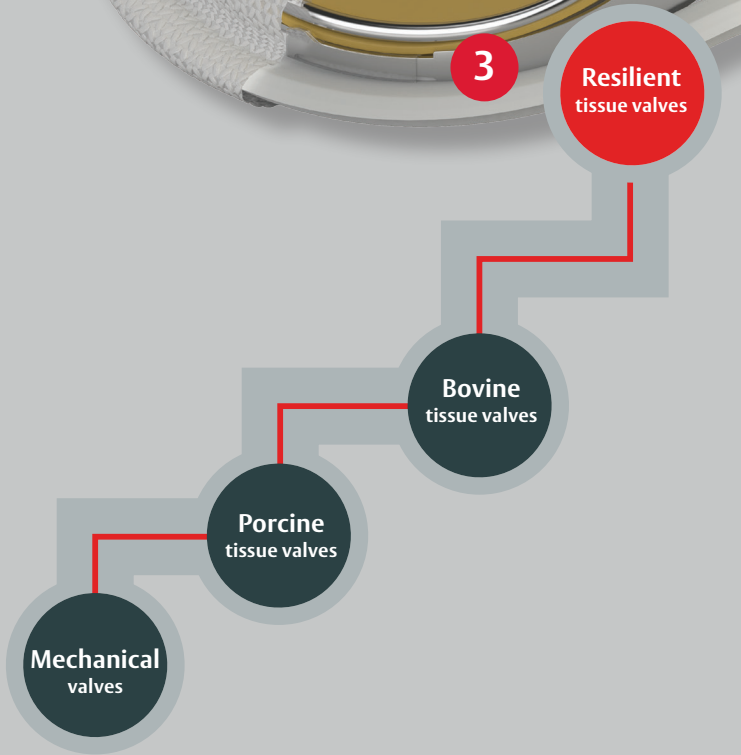
RESILIA tissue is the first to deliver the combination of:



Improved anti-calcification properties*

Improved sustained hemodynamic performance*

Stored dry and ready to use¶



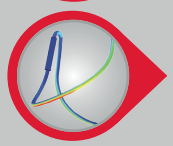
*RESILIA tissue tested against commercially available bovine pericardial tissue from Edwards in a juvenile sheep model.[1] No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.
¶No rinse required.

An ideal foundation for your patient's future:
RESILIA tissue, trusted design and features, and VFit technology

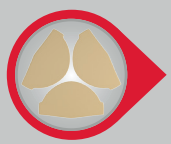
2 Trusted design and features

The INSPIRIS valve leverages features of the trusted Carpentier-Edwards PERIMOUNT Magna Ease valve and is built on the proven performance of the Carpentier-Edwards PERIMOUNT valve design:

Published clinical durability of over 20 years (PERIMOUNT valve)[2,3,4]



Mathematically modeled, bioengineered design



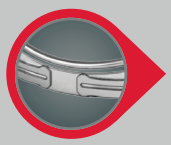
Three independent leaflets matched for thickness and elasticity

Flexible, radiopaque cobalt chromium alloy wireform

3 VFit technology*

VFit technology incorporates two novel features designed for potential future valve-in-valve procedures:

Fluoroscopically visible size markers



Expansion zone*

*Refer to device instructions for use for important warnings related to VFit technology. These features have not been observed in clinical studies to establish the safety and effectiveness of the model 11500A for use in valve-in-valve procedures. VFit technology is available on sizes 19–25 mm.

INSPIRIS RESILIA aortic valve

Model	Size
11500A19	**19 mm**
11500A21	**21 mm**
11500A23	**23 mm**
11500A25	**25 mm**
11500A27	**27 mm**
11500A29	**29 mm**

Model	Accessories
1133SET	**Sizers – Complete Set**
1133	**Sizers – Individual**
TRAY1133	**Accessory Tray**
1111	**Reusable Handle**
1126	**Longer Single-Use Handle**

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.

Important Safety Information: INSPIRIS RESILIA Aortic Valve
Indications: For use in replacement of native or prosthetic aortic heart valves. **Contraindications:** There are no known contraindications with the use of the INSPIRIS RESILIA aortic valve. **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. **Warnings:** DO NOT ADJUST THE VALVE DIAMETER BY EXPANDING THE BAND PRIOR TO/OR DURING IMPLANTATION OF THE SURGICAL VALVE. The expandable band is not designed to allow for compression or expansion during implantation of the surgical valve. This will cause damage to the valve and may result in aortic incompetence. DO NOT PERFORM STAND-ALONE BALLOON AORTIC VALVULOPLASTY PROCEDURES ON THIS VALVE FOR THE SIZES 19 – 25 mm as this may expand the valve causing aortic incompetence, coronary embolism or annular rupture. Valve-in-Valve procedures in an INSPIRIS valve should be performed according to the combinations in the SAPIEN XT IFU. Other combinations have not been evaluated and may result in the embolization of transcatheter devices anchored within or result in annular rupture.

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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