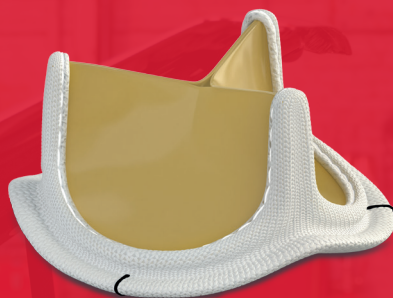


INSPIRIS

RESILIA Aortic Valve

An ideal foundation
for your patient's future

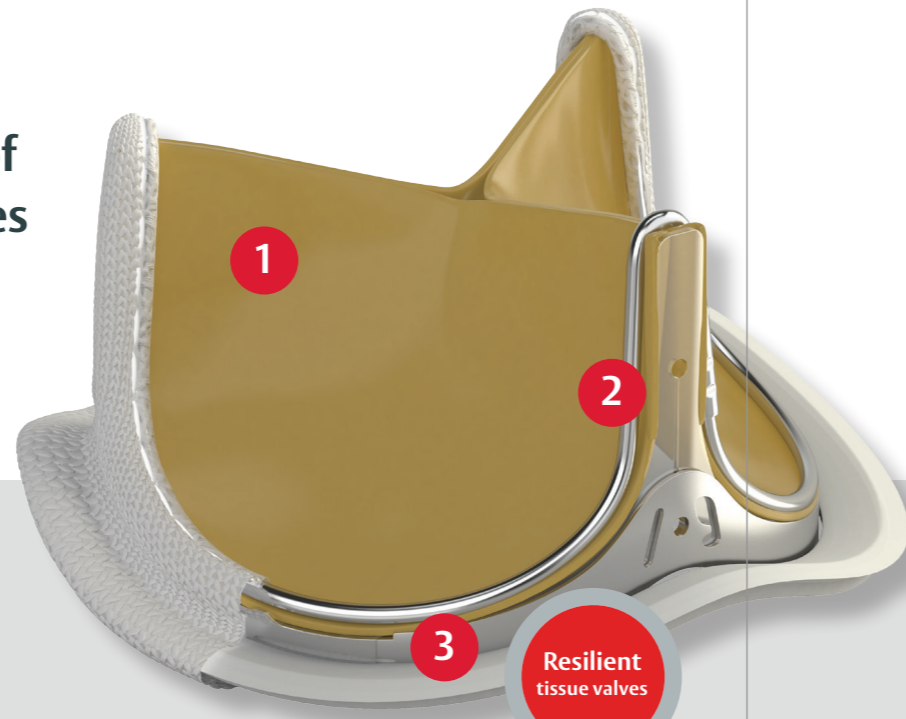


The first product offering in a new class of
resilient heart valves enabled by **RESILIA** tissue



Edwards




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

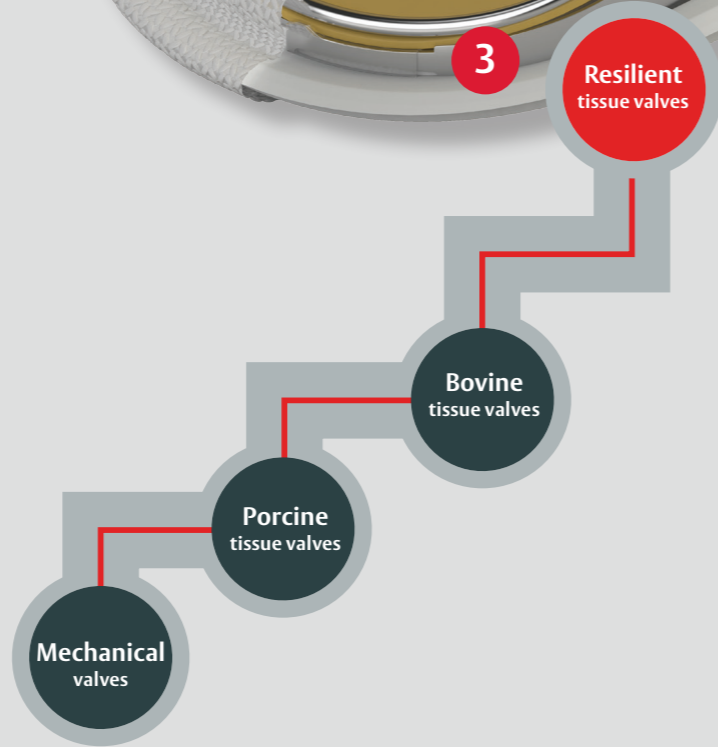


1 RESILIA tissue

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

The result – RESILIA tissue is the first to deliver the combination of:

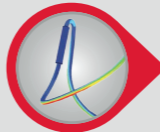


-  Improved anti-calcification properties*
-  Improved sustained hemodynamic performance*
-  Stored dry and ready to use[†]



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 design of the Carpentier-Edwards PERIMOUNT valve:

-  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 (ViV) procedures:

-  Fluoroscopically visible size markers
-  Expansion zone*

* 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.

*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.

Order information for the INSPIRIS RESILIA aortic valve

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

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

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.

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions, and adverse events.

Edwards Lifesciences devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

Material for distribution only in countries with applicable health authority product registrations. Material not intended for distribution in USA or Japan. Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device.

Edwards, Edwards Lifesciences, the stylized E logo, Carpentier-Edwards, INSPIRIS, INSPIRIS RESILIA, Magna, Magna Ease, PERIMOUNT, PERIMOUNT Magna, RESILIA, and VFit are trademarks of Edwards Lifesciences Corporation. All other trademarks are property of their respective owners.

© 2017 Edwards Lifesciences Corporation. All rights reserved. E6689/01-17/HVT PP--EU-0026 v2.0

Edwards Lifesciences • Route de l'Etraz 70, 1260 Nyon, Switzerland • edwards.com



Edwards