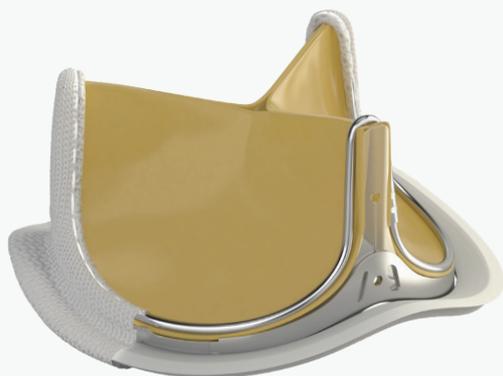


INSPIRIS RESILIA

Aortic Valve



For

Aortic valve replacement

When

Patients want the freedom of an active lifestyle with options for the future

Why

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

RESILIA tissue

- Significant improvement of anti-calcification properties in test valves compared to control†
- Sustained hemodynamic performance across 5 years¹

VFit technology^{†††}

- Expansion zone for future potential valve-in-valve procedures
- Expansion feature available on valve sizes 19–25 mm
- Fluoroscopically visible size markers

Proven valve platform

- Built on the Carpentier-Edwards PERIMOUNT valve platform
- Incorporates features of the trusted PERIMOUNT valve platform to enhance ease of implant

* No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients. Additional clinical data for up to 10 years of follow-up are being collected to monitor the long-term safety and performance of RESILIA tissue.

** Refer to device instruction for use for important warnings related to the VFit technology. This feature has not been observed in clinical studies to establish the safety and effectiveness of the model 11500A for use in valve-in-valve procedure. VFit technology is available in 19-25mm.

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

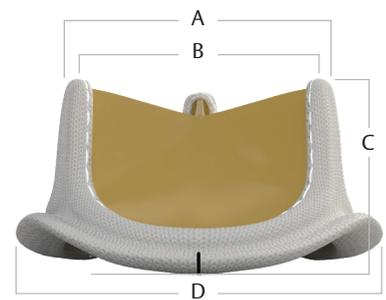
‡ Based on bench data. Refer to device Instructions for Use for important warnings related to VFit technology. These features have not been observed in clinical studies to establish the safety and effectiveness of the model 11500A for use in valve-in-valve procedures.



Edwards

Model 11500A

Size (mm)	19	21	23	25	27	29
A. Tissue Annulus Diameter (Stent Diameter, mm)	19	21	23	25	27	29
B. Internal Diameter (Stent ID, mm)	18	20	22	24	26	28
C. Profile Height (mm)	13	14	15	16	17	18
D. External Sewing Ring Diameter (mm)	25	27	29	32	34	36



Sizers/trays

1133 Sizers
(one barrel/replica set
per valve size, 19–29 mm)

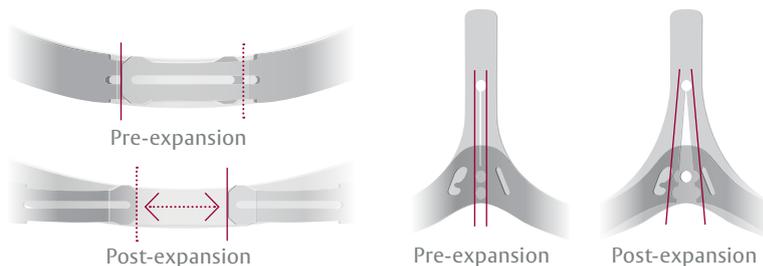
TRAY1133



Handles

Reusable handle 1111

Single-Use handle (extended length) 1126



References:

1. 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.
2. 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.

* No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients. Additional clinical data for up to 10 years of follow-up are being collected to monitor the long-term safety and performance of RESILIA tissue.

** Refer to device instruction for use for important warnings related to the VFit technology. This feature has not been observed in clinical studies to establish the safety and effectiveness of the model 11500A for use in valve-in-valve procedure. VFit technology is available in 19-25mm.

Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

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