Spotlight: VFit technology for valve expansion



The INSPIRIS RESILIA valve with VFit technology helps patients meet the future confidently, with enhanced options for subsequent valve intervention.

Proprietary VFit technology is designed to enable valve-in-valve procedures in the future, at a time when patients are older and potentially at a higher risk for complications.¹



> VFit technology delivers predictable, controlled valve expansion, increasing future intervention options for treatment.

For patients with surgically implanted aortic valves smaller than 25 mm, future transcatheter aortic valve replacement (TAVR) presents a challenge. The small annulus size can impede post-TAVR blood flow, increasing pressure gradients and potentially impacting patient outcomes. A way of increasing the valve's effective orifice area is needed.

Achieving area expansion with most surgically implanted valve designs requires the annulus to be mechanically "cracked" prior to TAVR deployment.² When cracking a valve in this way it is not possible to predict the amount of expansion, or control exactly how and where the fracture will occur.¹

Innovation that fosters confidence

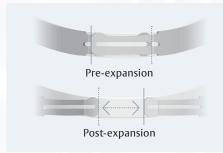
Unlike other valves, the INSPIRIS RESILIA valve with VFit technology is specifically designed to deliver a controlled and predictable expansion during valve-in-valve deployment.*1

With the INSPIRIS RESILIA valve, to achieve area expansion, there is no need for a high-pressure bioprosthetic valve fracture (BVF) to expand the valve. BVF is associated with risk of stroke and other complications in valve-in-valve patients when used to crack a valve.²



^{*}Based on bench data. Refer to device **Instructions for Use** for important warnings related to VFit technology. These features have not been evaluated 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.

How VFit technology enables a controlled expansion



— The expansion is activated by the radial force applied by the expansion of the new transcatheter valve within the existing INSPIRIS RESILIA valve, resulting in a **uniform and controlled expansion** around the INSPIRIS RESILIA valve's perimeter.

— The perforated polyester band is designed to expand at each of the three commissures during deployment of the new transcatheter valve, delivering predictable expansion of the valve's internal orifice.





Pre-expansion

Post-expansion



— The valve's cobalt-chromium alloy band enables a controlled expansion to fit a new transcatheter valve within the existing INSPIRIS RESILIA valve. The expansion feature is **available on sizes 19–25 mm** for a broad range of patients with varying annulus size.

There's more to explore

> To learn more about how the INSPIRIS RESILIA valve can benefit you and your patients, speak with your Edwards Lifesciences representative or visit www.edwards.com/inspiris.

References

- 1. Saxon JT, et al. Bioprosthetic Valve Fracture During Valve-in-valve TAVR: Bench to Bedside. Interv Cardiol. 2018;13(1):20–26.
- 2. Saxon |T, et al. Complications of Bioprosthetic Valve Fracture as an Adjunct to Valve-in-Valve TAVR, Structural Heart, 2019;3:2, 92–99.

Important Safety Information: For Indications, contraindications and general warnings related to use of INSPIRIS RESILIA Aortic Valve, please refer to the detailed Instructions for Use

CAUTION: See instructions for use for full prescribing information.

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

© 2022 Edwards Lifesciences Corporation. All rights reserved. PP_IND_SSH_05 V1.0

Edwards Lifesciences (India) Pvt Ltd • 4th Floor, Commerz II, International Business Park, Oberoi Garden City, Off Western Express Highway, Goregaon (East), Mumbai - 400063 • edwards.com

