

INSPIRIS RESILIA Aortic Valve
Right for today. Ready for tomorrow.

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.

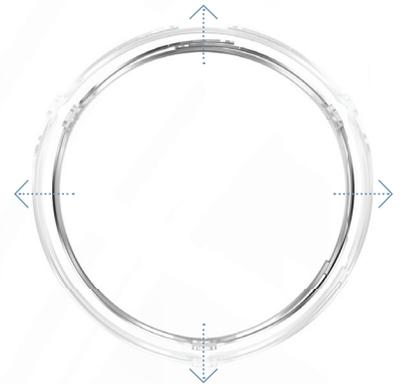
Proprietary VFit technology is designed to enable valve-in-valve procedures in the future, at a time when patients are older and potentially at a higher risk for complications.¹



> 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

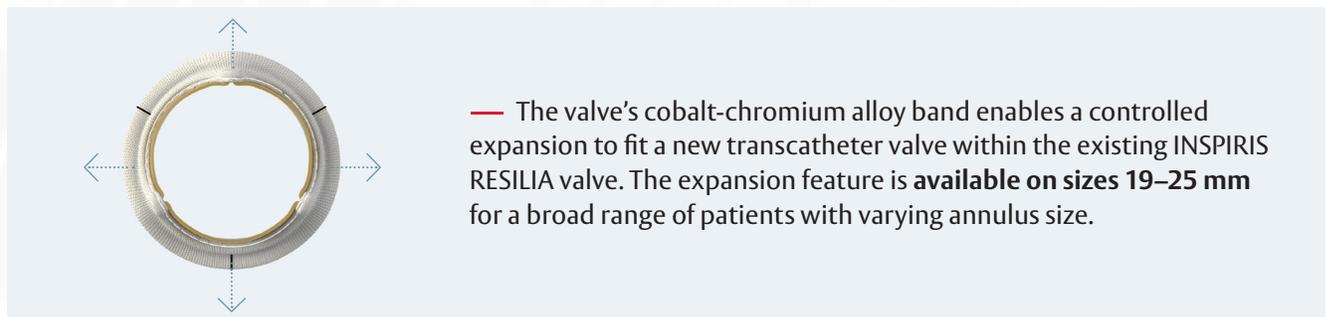
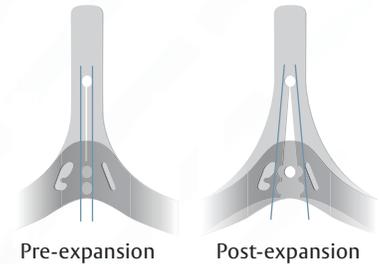
With the INSPIRIS RESILIA valve, to achieve area expansion, there is no need for a high-pressure bioprosthetic valve fracture (BVF) to expand the valve. BVF is associated with risk of stroke and other complications in valve-in-valve patients when used to crack a valve.²

*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 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.



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 JT, 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: 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 sizing in the INSPIRIS valve has only been tested with specific Edwards transcatheter heart valves. Use of other transcatheter valves may result in 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.

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.

© 2020 Edwards Lifesciences Corporation. All rights reserved. PP--US-5486 v1.0

Edwards Lifesciences • One Edwards Way, Irvine CA 92614 USA • edwards.com

