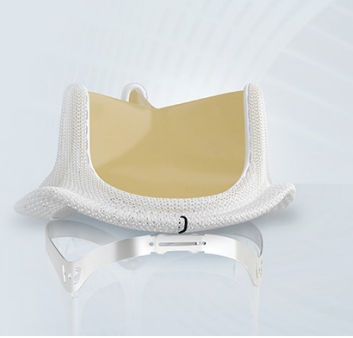
INSPIRIS RESILIA Aortic Valve VFit Technology
Right for today. Ready for tomorrow.

VFit technology: Designed to enable potential future valve-in-valve procedures

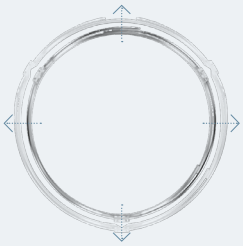


The INSPIRIS RESILIA valve incorporates novel VFit technology, designed to enable valve-in-valve procedures in the future, at a time when patients are older and potentially at a higher risk for complications.

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

> 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.[1]

How VFit technology achieves 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.

WARNING: Size marker corresponds to the labeled valve size of the INSPIRIS valve and is not a replacement for current size identification techniques recommended for use in transcatheter procedures.

Pre-expansion

Post-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.

*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. VFit technology is available on sizes 19–25 mm.

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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.

References:

1. Saxon JT, et al. Complications of Bioprosthetic Valve Fracture as an Adjunct to Valve-in-Valve TAVR. Structural Heart 2019;3:92-9.

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