RESILIA Tissue Valves Seven-Year Outcomes*

A summary of the results, patient demographics, study methods, and key points

*No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.

Study Introduction & Key Points

The COMMENCE aortic trial is a FDA pivotal trial designed to evaluate the safety and effectiveness of a bioprosthetic valve with RESILIA tissue. As the follow up time in this study advances beyond the mid-term period, direct and indirect measures of durability of valves with RESILIA tissue will be highlighted.

Key Points

Younger patients

- **Tissue durability**
  As bioprosthetic aortic valve replacement (AVR) extends to younger patients, tissue durability is becoming of paramount importance
- **65.1 mean age**
  Data demonstrate excellent outcomes in a study of younger patients

Outcomes

- **Clinically stable gradients**
- **Data show high rates of freedom for a variety of events through 7 years**
  - Freedom from all-cause mortality
  - Freedom from reintervention
  - Freedom from structural valve deterioration (SVD)

Safety and effectiveness

- **Favorable safety profile**
- **Strong hemodynamic performance**

Study Methods & Patient Demographics

Methods

Trial methodology

- **A prospective, international IDE trial**
- **27 clinical sites**
  Study subjects enrolled in U.S., Canada, and Europe
- **Patient re-consent at 5 years**
  Performed for extended (years 6-10) follow-up
- **Extended follow-up**
  10 sites participating

Safety endpoints

- **All potential safety endpoints**
  Adjudicated by an Independent Clinical Events Committee
- **SVD and other safety outcomes**
  Defined per "Guidelines for reporting mortality and mortality after cardiac valve interventions" (Akins et al. 2008)

Effectiveness endpoints

- **Independent echocardiographic core laboratory**
  Evaluated hemodynamic performance
- **New York Heart Association (NYHA) functional class**

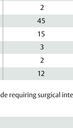
Patient Demographics

225 patients
Reconsented for extended follow-up

2.1 ± 2.1%
STS risk score

65.1 ± 10.9
years mean age

43%
NYHA class II, and



19%
NYHA class III

Results

Safety endpoints, probability event-free at 7 years

Endpoint	Early (≥30 POD) events (%)	Cumulative events @ 7 years	Probability event-free @ 7 years (%) (95% CI)
All-cause mortality	8 (1.2%)	78	85.4 (82.2 – 88.7)
Stroke	11 (1.6%)	37	94.0 (92.1 – 95.9)
Valve thrombosis	0 (0%)	2	99.4 (98.6 – 100.0)
Major bleeding	5 (0.7 %)	45	90.9 (88.1 – 93.8)
Endocarditis	0 (0%)	15	97.3 (95.8 – 98.7)
Major PVL[1]	1 (0.1%)	3	99.5 (99.0 – 100.0)
SVD	0 (0%)	2	99.3 (98.3 – 100.0)
Reoperation	1 (0.1%)	12	97.2 (95.5 – 99.0)

[1]Major paravalvular leak is paravalvular leak of any grade requiring surgical intervention or considered an SAE

Outcomes @ 7 years (Kaplan-Meier analyses)

85.4%
Freedom from all-cause mortality

97.2%
Freedom from reoperation

99.3%
Freedom from SVD

99.4%
Freedom from valve thrombosis

Hemodynamics @ 7 years

Clinically stable hemodynamics

1.82 ± 0.57 cm²
Effective orifice area

9.4 ± 4.5 mmHg
Mean gradient

Hemodynamic performance: Echo-derived mean gradients (mmHg)

Conclusions

Longest follow-up

- **7-year data from the COMMENCE aortic trial represents the longest follow-up after AVR with RESILIA tissue in a large IDE trial utilizing an independent clinical events committee and an echocardiography core laboratory**

Excellent outcomes through 7 years

- **With excellent outcomes through 7 years, the COMMENCE trial demonstrates encouraging results for bioprostheses with RESILIA tissue**

10-year follow-up

- **Ongoing follow up out to 10 years will continue to evaluate the long-term safety and effectiveness of this bioprosthetic valve with RESILIA tissue**

Important Safety Information: RESILIA Tissue Devices

Indications: INSPIRIS RESILIA Aortic Valve - For use in replacement of native or prosthetic aortic heart valves. **KONECT RESILIA Aortic Valved Conduit** - For use in replacement of native or prosthetic aortic heart valves and the associated repair or replacement of a damaged or diseased ascending aorta. **MITRIS RESILIA Mitral Valve** - For use in replacement of native or prosthetic mitral heart valves.

Contraindications: There are no known contraindications with the use of these RESILIA tissue heart valve devices.

Complications and Side Effects: INSPIRIS RESILIA Aortic Valve - 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. Additional adverse events potentially associated with the use of polyester vascular grafts in the **KONECT RESILIA AVC** include hemorrhage, thrombosis, graft infection, embolism, aneurysm, pseudoaneurysm, seroma, occlusion (anastomotic intimal hyperplasia), immunological reaction to collagen (shown to be a weak immunogen; infrequent, mild, localized and self-limiting), intimal peel formation, and conduit dilatation. **MITRIS RESILIA Mitral Valve** - Thromboembolism, valve thrombosis, hemorrhage, hemolysis, regurgitation, endocarditis, structural valve deterioration, nonstructural dysfunction, stenosis, arrhythmia, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, ventricular perforation by stent posts, any of which could lead to reoperation, explantation, permanent disability, and death.

Warnings: INSPIRIS RESILIA Aortic Valve - 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 these devices to sale by or on the order of a physician.
See instructions for use for full prescribing information.

Reference:
1. Bavaria JE, Brindis RG, Grover FL, et al. Seven-year outcomes following aortic valve replacement with a novel tissue bioprosthesis. Presented at the 103rd Annual Meeting of the American Association for Thoracic Surgery, May 2023