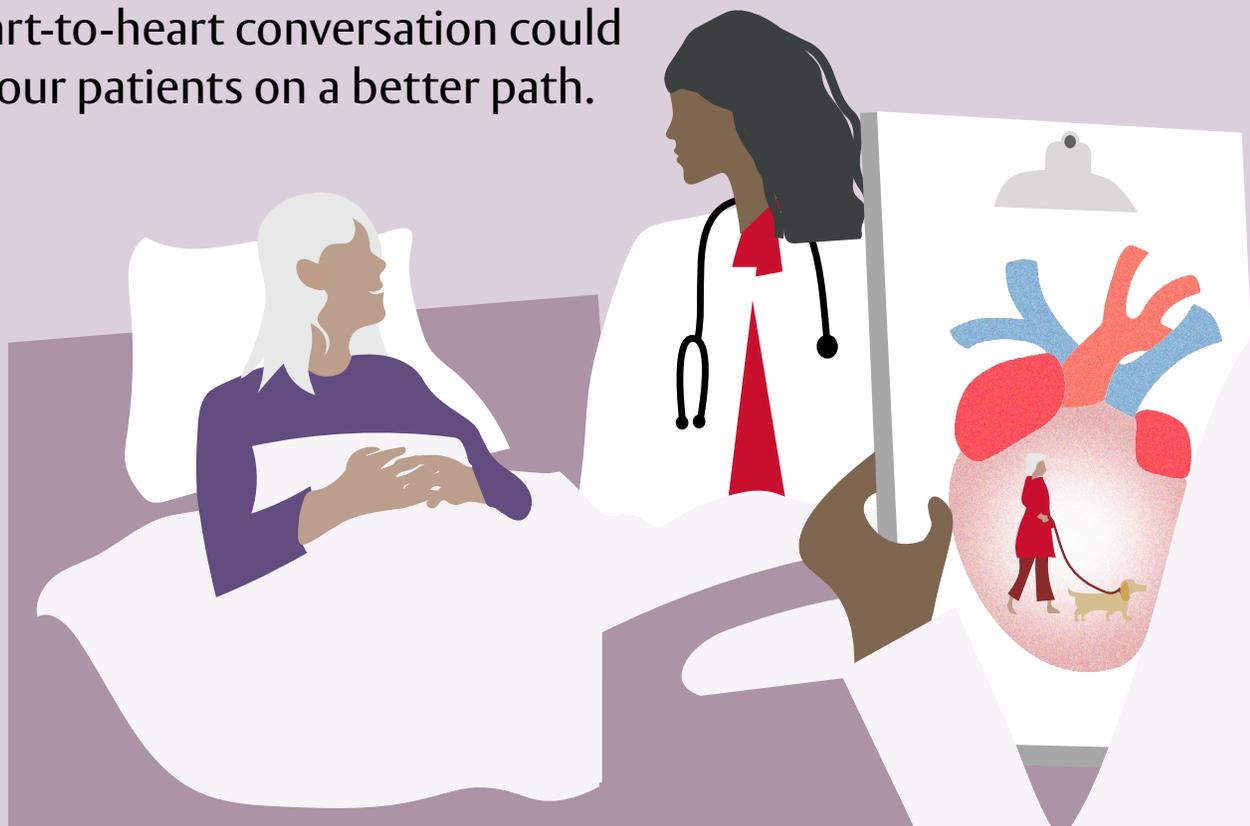


# What does the right surgical valve mean to your patients?

A heart-to-heart conversation could put your patients on a better path.



Edwards

# A shared decision with a trusted partner

As your patients' cardiologist, you are in a position to offer valuable insights and guidance during the shared decision making process on which valve will meet their needs and expectations.

Tissue and mechanical valves each have certain advantages and disadvantages that you should consider with your patients. The chart below outlines the key recommendations from the 2020 ACC/AHA valvular heart disease guidelines that can be used during the discussion.<sup>1</sup>

## Mechanical or tissue valves: What to consider<sup>1</sup>

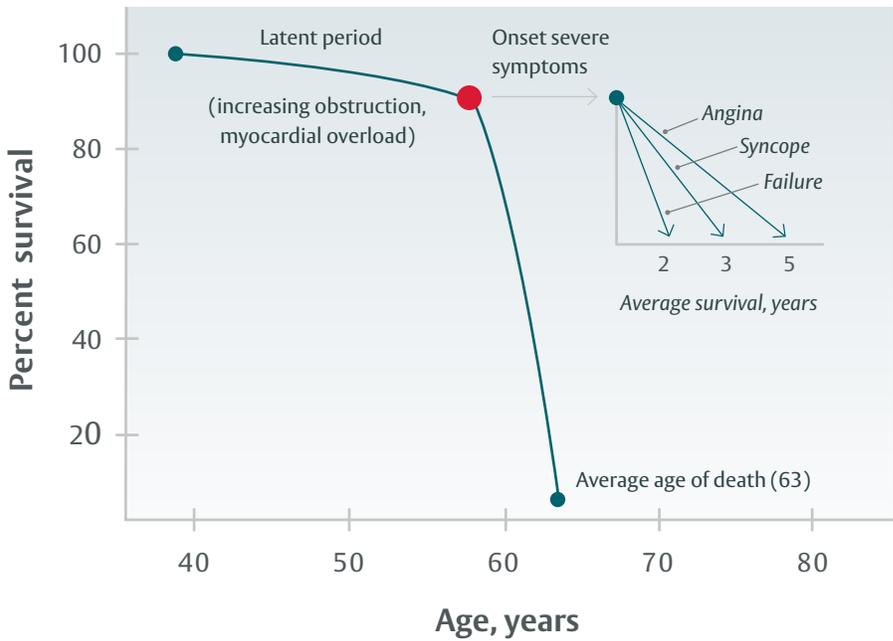
	 <b>A mechanical valve</b> may be a better choice if the patient..	 <b>A tissue valve</b> may be a better choice if the patient..	
US Recommendations Based on Age Only	is younger than <b>50 years</b>	is between the ages of <b>50 and 65 years</b> ; either valve may be appropriate	is older than <b>65 years</b>
Anticoagulation Considerations	<ul style="list-style-type: none"> <li>is <b>already</b> on vitamin K antagonist (VKA) therapy for another reason</li> <li>is <b>able</b> to take VKAs as prescribed</li> </ul>	<ul style="list-style-type: none"> <li>does not want to take VKAs, <b>regardless of age</b></li> <li>is <b>unable</b> to take VKAs as prescribed</li> <li>is at a <b>high risk of complications</b> from taking VKAs</li> </ul>	
Medical Concerns	<ul style="list-style-type: none"> <li>has a <b>medical history</b> that increases the risk associated with potential reintervention</li> <li>has anatomy that may preclude a <b>valve-in-valve</b> procedure in the future</li> </ul>	may wish to become <b>pregnant</b> in the future and avoid the risk of anticoagulation-related maternal and fetal complications	
Other Considerations	prefers to decrease the risk of <b>needing another procedure</b>	<ul style="list-style-type: none"> <li>has an <b>active lifestyle</b> with a high risk of <b>injury</b></li> <li>has limited access to <b>routine medical care</b> to help manage blood thinners</li> </ul>	

For patients with severe aortic valve disease, the need for timely replacement is undeniable, but today's valve choices leave much more to discuss.

# Time is of the essence

Aortic valve disease symptoms may not appear until the condition is severe, and waiting for symptoms before treatment could lead to more serious complications and even death.<sup>2</sup>

## Aortic Stenosis



The onset of serious symptoms is associated with a steep drop-off in the survival curve<sup>3</sup>

Adapted from Braunwald 2018

## Help patients hold on to their quality of life longer

Guidelines suggest that postoperative outcomes are better when surgery is performed early or before the onset of symptoms.<sup>1</sup>



## A critical decision to make – together

Help your patients evaluate their valve options by discussing their values and preferences as part of the shared decision making process.

# Choosing tissue? Consider RESILIA tissue valves

Include RESILIA tissue and its unique benefits in the valve selection discussion with your patients.



## Tissue with a difference. Designed to last.<sup>4,5</sup>

- The primary cause of tissue valve failure is calcification
- The INSPIRIS RESILIA aortic valve is made with bovine heart tissue that has been preserved with a special Edwards Lifesciences technology to reduce calcium build-up
- Less calcium build-up could potentially allow the valve to last longer\*

RESILIA tissue offers enhanced anti-calcification technology that will potentially allow the valve to last longer than conventional bioprosthetic valves.<sup>4,6\*</sup>

The RESILIA tissue portfolio represents the culmination of years of careful, deliberate development.

Valves with RESILIA tissue continue to show strong performance and durability in the aortic position.<sup>5,6</sup>

## Built on a proven valve platform

The foundation of the INSPIRIS RESILIA valve is the PERIMOUNT valve platform, whose performance is backed by 30 years of durability data, including the largest long-term study of a bioprosthetic valve.

### PERIMOUNT valve platform

~30

years of  
published clinical  
durability

40+

years of  
real-world  
experience

### INSPIRIS RESILIA aortic valve

200k

Over 200,000  
implants worldwide

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

# Help your patients meet the future more confidently

Surgical heart valves with RESILIA tissue offer patients a way to think differently about life after surgery.

**RESILIA tissue is building a track record of study data<sup>4,5,7,8</sup>**

Patient Demographics				
225 patients*	1.7 ± 1.5% STS risk score	65.1 ± 10.9% years mean age	43% NYHA class II	19% NYHA class III

\*Reconsented for extended follow-up



**Excellent outcomes at 7 years**

This demonstrates encouraging results for bioprostheses with RESILIA tissue.



**Freedom from SVD at 7 years**

99.3% of patients were free from structural valve deterioration (SVD) at 7 years.



**Longest follow-up**

7-year data from the COMMENCE aortic trial represents the longest follow-up after aortic valve replacement with RESILIA tissue.

The latest COMMENCE aortic trial data show strong clinical outcomes and excellent durability for valves with RESILIA tissue at 7 years<sup>5\*</sup>

## Protecting their future, preserving options

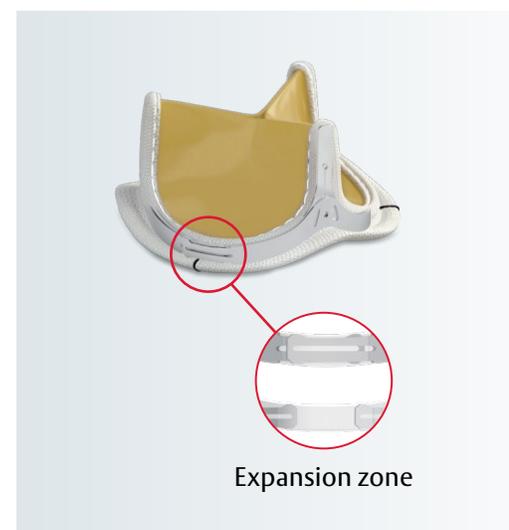
Patients under 60 at the time of aortic valve replacement are more likely to outlive their valves and require subsequent intervention.



The INSPIRIS RESILIA valve incorporates novel VFit technology, designed to enable potential future valve-in-valve procedures.



For patients, a valve with RESILIA tissue means a life with the potential to avoid future open-heart surgery.



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

- > Performing surgery early improves postoperative outcomes<sup>1</sup>
- > Include RESILIA tissue and its unique benefits in the valve selection discussion with your patients
- > Help your patients meet the future more confidently
  - Valves made with RESILIA tissue have the potential to last longer than conventional bioprosthetic valves.<sup>4\*</sup>
  - For patients, a valve with RESILIA tissue means a life with the potential to avoid future open-heart surgery.



Help your patients understand all their options – get resources to support your guidance and learn more about RESILIA tissue products at [edwards.com/heart2heart](https://edwards.com/heart2heart)

\*No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients; RESILIA tissue tested against tissue from commercially-available bovine pericardial valves from Edwards in a juvenile sheep model. Flameng, et al. J Thorac Cardiovasc Surg 2015;149:340-5.

**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** - or 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.**

**References:**

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7. Bartus K, Litwinowicz R, Bilewska A, et al. Final 5-year outcomes following aortic valve replacement with a RESILIA™ tissue bioprosthesis. Eur J Cardiothorac Surg. 2021 Jan 29;59(2):434-441.
8. Heimansohn DA, Baker C, Rodriguez E, et al. Mid-term outcomes of the COMMENCE trial investigating mitral valve replacement using a bioprosthesis with a novel tissue. JTCVS Open. 2023 Jun 2;15:151-163.

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