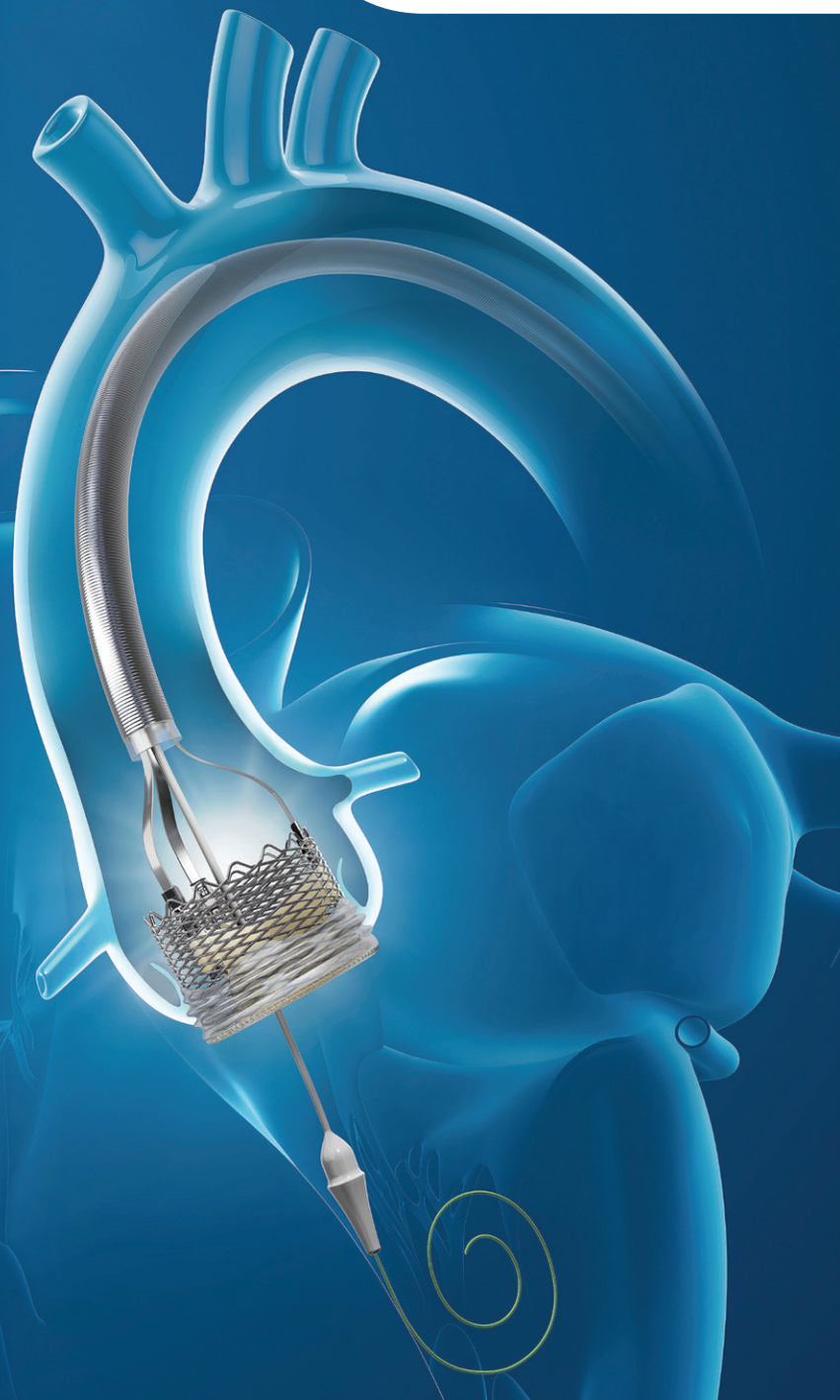
Boston Scientific

Advancing science for life™

LOTUS *Edge*™
Aortic Valve System

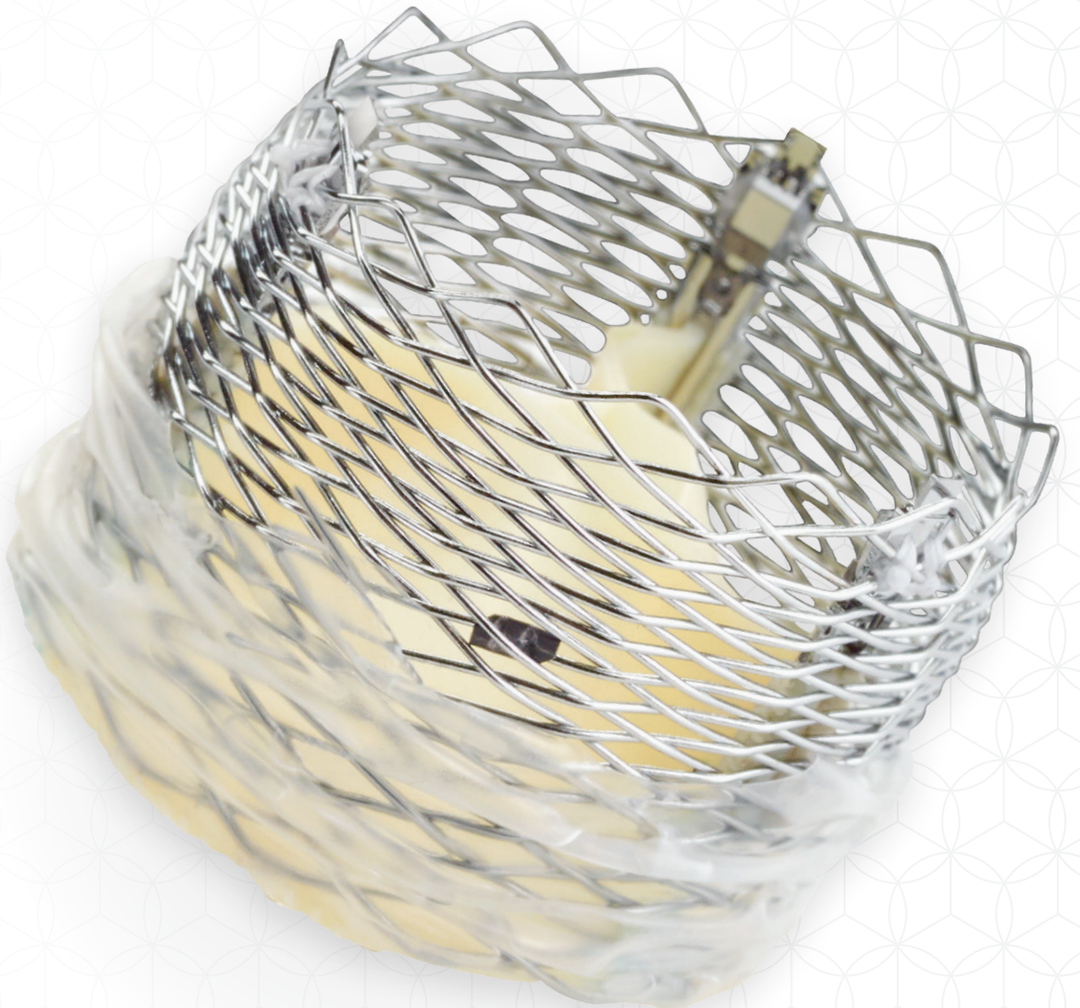
Complete CONTROL

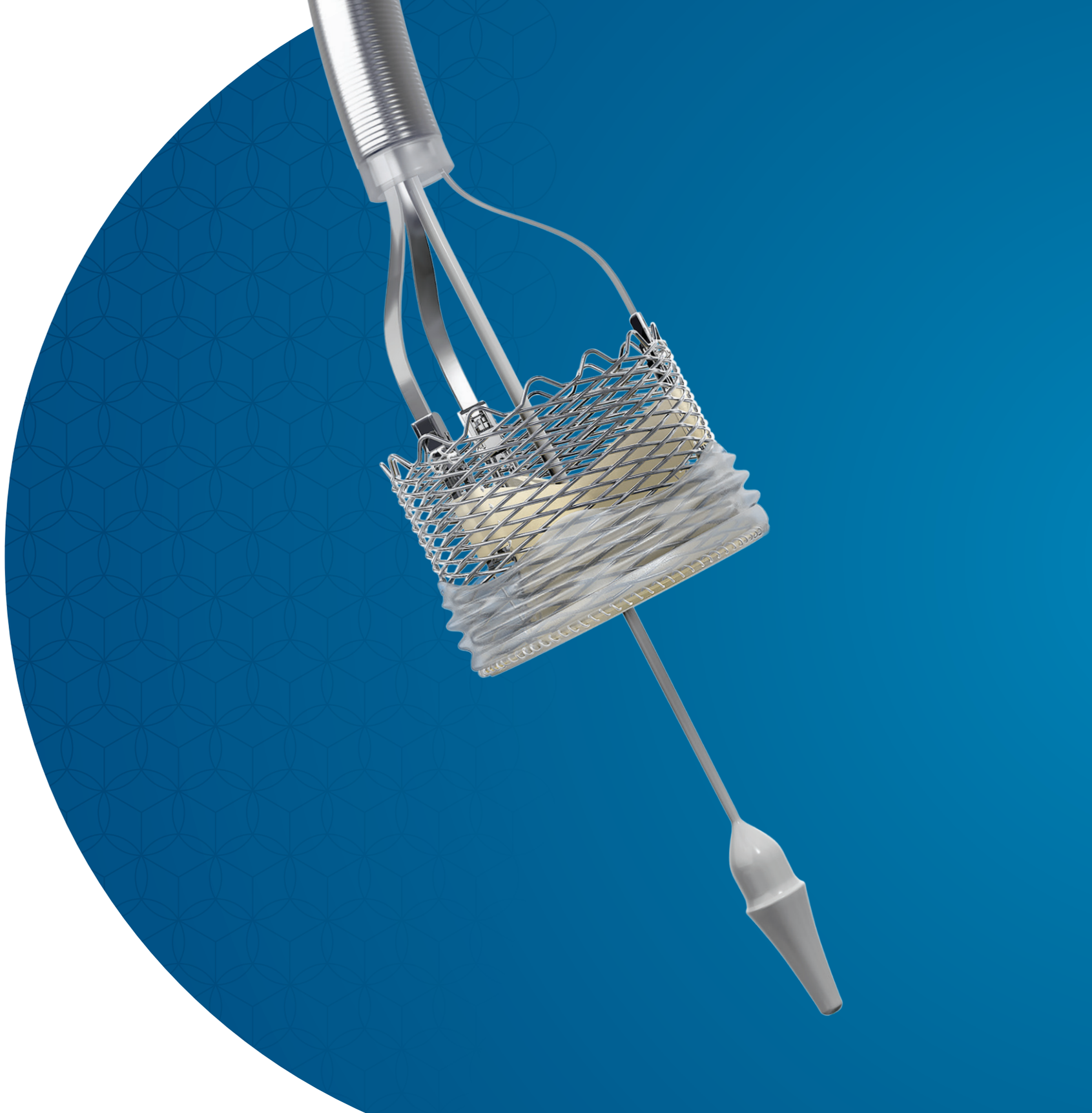
PREDICTABLE Results



When Complete
CONTROL
Matters

LOTUS *Edge*™
DELIVERS





SURGICAL-LIKE PVL

CONSISTENT, STABLE DELIVERY

REPOSITIONABLE
AFTER 100% DEPLOYMENT

LOTUS *Edge*™
Aortic Valve System

Surgical-Like PVL

LOTUS™ demonstrates best-in-class PVL rates across clinical studies:

1 YEAR

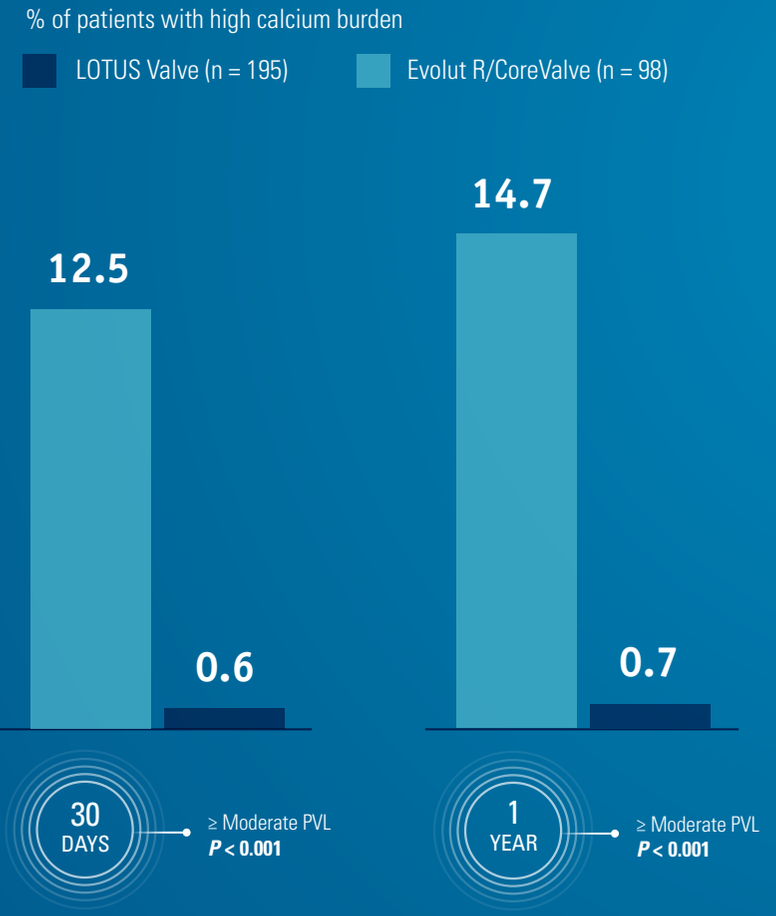
REPRISE III TRIAL RESULTS[1]

0.9%	11.5%	87.6%
Moderate or Greater PVL	Mild PVL	None/ Trace PVL

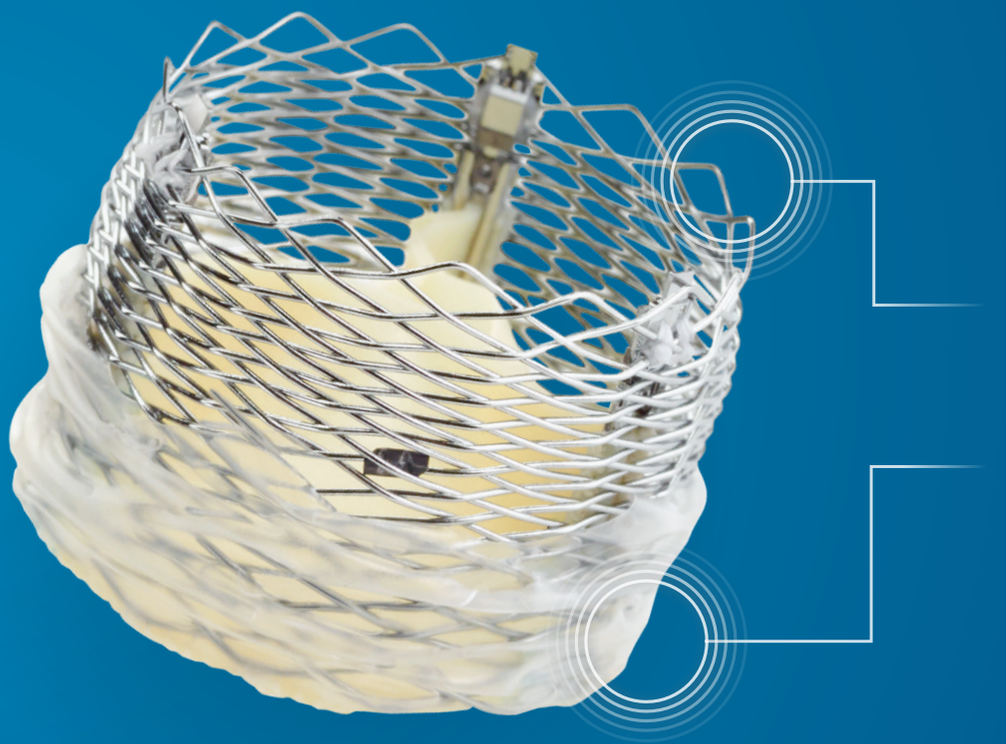
30 DAYS

LOTUS showed a **4x LOWER rate** of mild or greater PVL vs. Evolut™ R/CoreValve™

REPRISE III: HIGH CALCIUM COHORT[2]



1. Feldman T. MD. A Prospective, Randomised Investigation of a Novel Transcatheter Aortic Valve Implantation System: The REPRISE III Trial; EuroPCR 2017; Paris, France.
2. Makkar R., MD. The impact of calcium burden on clinical outcomes and paravalvular regurgitation in the REPRISE III randomised controlled clinical trial; PCRLV 2017; London, United Kingdom.



The unique Adaptive Seal™ and braided valve frame conform to patient anatomies, virtually eliminating PVL.*

BRAIDED NITINOL FRAME

Conforms to irregular anatomy

ADAPTIVE SEAL

Unique polyurethane material folds to create a seal designed to conform to irregular anatomies and minimize PVL

LOTUS *Edge*™ COMBINED COHORT TRIAL[3]

97.1% | None/Trace PVL (N = 34)

*Moderate or greater PVL.

3. Götberg M., MD. One-year outcomes with the transcatheter LOTUS Edge Aortic Valve System; PCRLV 2018; London, United Kingdom. Includes high-surgical-risk patients with symptomatic calcific aortic stenosis from the LOTUS Edge Feasibility Study (N = 21) and the REPRISE EDGE Study (N = 15).

Consistent, STABLE DELIVERY

The exclusive deployment technology is designed to provide complete control and stability for precise placement and reduced procedural complications.

CONTROLLED DEPLOYMENT AND PRECISE PLACEMENT WITHOUT VALVE MIGRATION

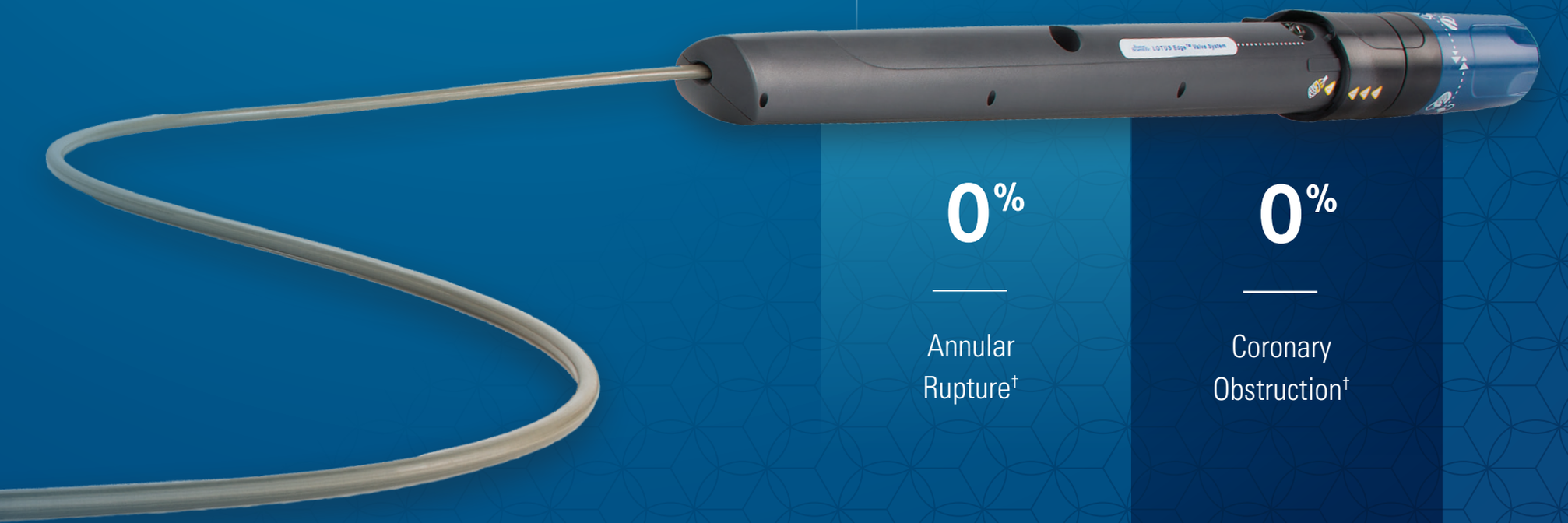
0%	0%
TAV-in-TAV†	Valve Migration†

† As shown in REPRISE III, 1 year.

Repositionable After 100% DEPLOYMENT

The only 100% repositionable TAVR technology that allows you to evaluate your final result prior to release to help ensure optimal outcomes every time.

ASSESS FINAL VALVE POSITION AND FUNCTION AFTER DEPLOYMENT WITH THE OPTION TO RECAPTURE AND REPOSITION



0%

Annular Rupture†

0%

Coronary Obstruction†

EFFECTIVENESS and SAFETY DATA

In the REPRISE III trial, the **LOTUS™ valve showed superiority** to the Evolut™ R/CoreValve™ Platform in the primary effectiveness endpoint at 1 year and non-inferiority in the primary safety endpoint at 30 days.

PRIMARY EFFECTIVENESS ENDPOINT‡

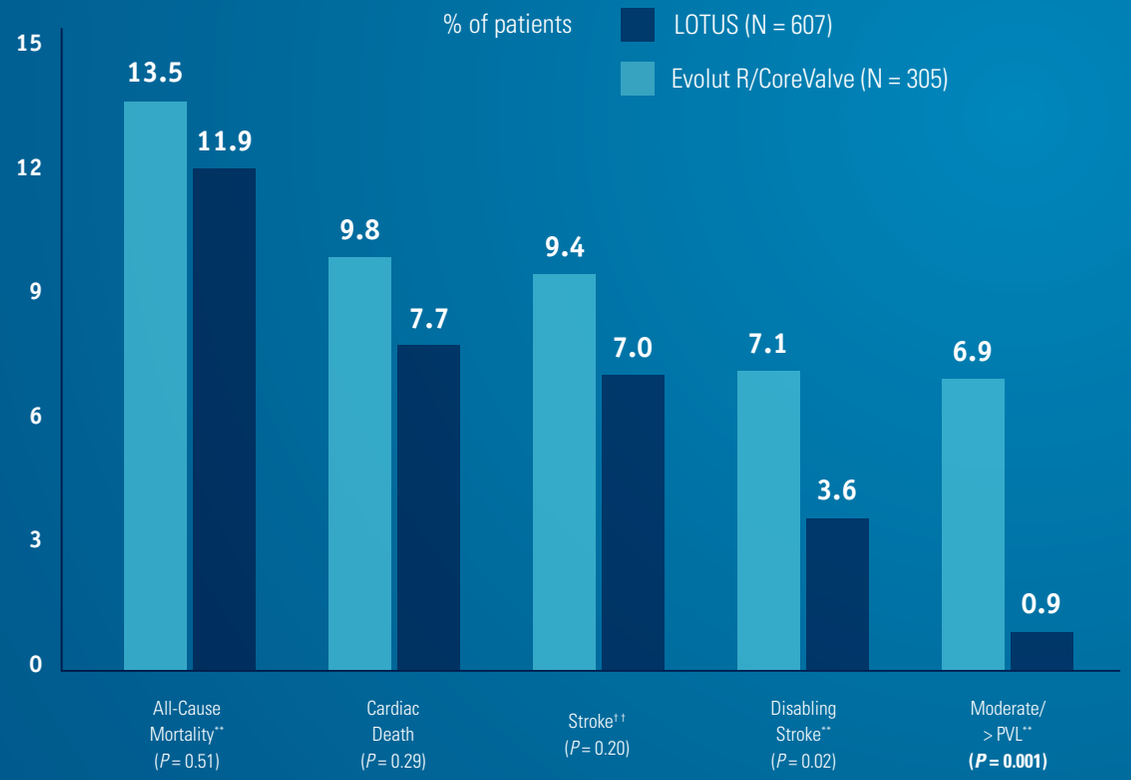
15.8% **LOTUS Valve**

VS. → Superiority ($P < 0.001$)

26.0% **Evolut R/CoreValve§**

1 YEAR

PRIMARY EFFECTIVENESS ENDPOINT COMPONENTS



LOTUS VALVE SUPERIOR TO EVOLUT R / COREVALVE Primary effectiveness endpoint (1 year): Composite of all-cause mortality, disabling stroke, moderate or greater PVL. LOTUS Valve = 15.8% vs. Evolut R / CoreValve Platform = 26.0%. Superiority $P < 0.001$.

‡ Composite of moderate/severe PVL, disabling stroke and all death. N = 912; § CoreValve platform is approximately ½ CoreValve and ½ Evolut R.

** Component of Primary Effectiveness Endpoint.

†† Neurologic exam conducted by a neurology professional was required at baseline, discharge, 1 year, and after any suspected stroke. NIHSS was required at discharge and 1 year and mRS at baseline and all f/u time points.

Event rates for Primary Effectiveness endpoint based on intent to treat. Event rates for Primary Safety endpoint based on implanted valves.

PRIMARY SAFETY ENDPOINT

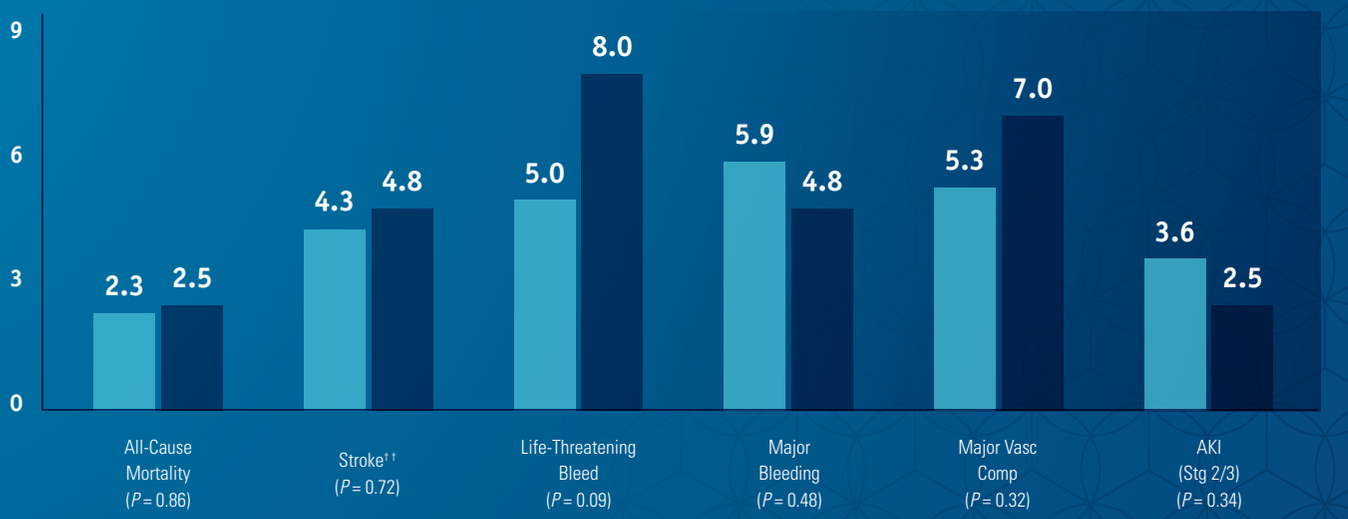
30 DAYS

20.3% **LOTUS Valve**

vs. — Non-inferiority (*P* = 0.003)

17.2% **Evolut R/CoreValve**

PRIMARY SAFETY ENDPOINT COMPONENTS



LOTUS VALVE NON-INFERIOR TO EVOLUT R / COREVALVE Primary safety endpoint (30 days): Composite of all-cause mortality, stroke, life-threatening and major bleeding events, stage 2/3 kidney injury, major vascular complications. LOTUS Valve = 20.3% vs. Evolut R / CoreValve Platform = 17.2%. Non-inferiority *P* = 0.003.

Committed to TAVR

As part of our commitment to the structural heart community, Boston Scientific focuses on providing innovative solutions that advance safety in TAVR procedures, help optimize patient outcomes and improve procedural efficiency.

Our differentiated portfolio of TAVR devices – including valves, accessories and a proven cerebral embolic protection device – delivers enhanced control and precision backed by strong clinical evidence and program support.

JOIN US AT
bostonscientific.com/LOTUSEdge

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LOTUS Edge™ Valve System
INTENDED USE/INDICATIONS FOR USE: The LOTUS Edge Valve System is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis (aortic valve area [AVA] of ≤ 1.0 cm^2 or index of ≤ 0.6 cm^2/m^2) who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicated risk of surgical mortality ≥8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator). **CONTRAINDICATIONS:** • Non-calcified aortic annulus. • Active systemic infection, sepsis or endocarditis. • Known hypersensitivity to contrast agents that cannot be adequately pre-medicated, or has known hypersensitivity or contraindication to aspirin, thienopyridines, heparin, nickel, titanium, tantalum, bovine-derived materials or polyurethanes. • Severe arterial tortuosity or calcification that would prevent safe placement of the introducer sheath. **WARNINGS:** • Valve implantation should only be performed in a facility where emergency aortic valve surgery is available. • Do not attempt to place the valve if patient's annulus is outside of the dimensions specified in Table I of the DFU. Patient prosthesis mismatch, valve migration or embolization may lead to severe patient compromise, additional procedures or death. **PRECAUTIONS:** • Device implantation should only be performed by physicians who have completed training with the LOTUS Edge Valve System. • Administer periprocedural antiplatelet and/or anticoagulant therapy at the discretion of the physician consistent with the local standard-of-care. • Safety, effectiveness, and durability have not been established for valve-in-valve procedures. The safety and efficacy of the LOTUS Edge Valve System has not been established in patients with the following characteristics/comorbidities: • Congenital unicuspid or congenital bicuspid aortic valve • Severe ventricular dysfunction with left ventricular ejection fraction <20% • Hypertrophic obstructive cardiomyopathy • Echocardiographic evidence of intracardiac mass, thrombus, or vegetation • Blood dyscrasias defined as: leukopenia (WBC<1000 cells/mm^3, acute anemia (Hgb<9g/dL), thrombocytopenia (platelet count <50,000 cells/mm^3), history of bleeding diathesis or coagulopathy • Pre-existing prosthetic heart valve or prosthetic ring in any position • Any considerations for coronary artery obstruction • End-stage renal disease or has GFR<20 (based on Cockcroft-Gault formula) • Severe (4+) aortic, tricuspid, or mitral regurgitation • Mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation >3+). • Perform balloon aortic valvuloplasty (BAV) with an appropriately sized balloon prior to delivery of the valve to the aortic annulus at the discretion of the implanting physician. • Partial resheathing (and subsequent unsheathing) can be performed an unlimited number of times during any phase of the procedure prior to valve release. Valve may be completely resheathed (past the post markers) once during the procedure at any phase prior to valve release. If a second full resheathing becomes necessary, exchange the device. **POTENTIAL ADVERSE EVENTS:** Adverse events (in alphabetical order) potentially associated with transcatheter aortic valve implantation (including standard cardiac catheterization, BAV and the use of anesthesia) as well as additional risks related to the use of the LOTUS Edge Valve System: • Abnormal lab values (including electrolyte imbalance) • Access site complications (including arteriovenous (AV) fistula, hematoma or lymphatic problems) • Allergic reaction (including to medications, anesthesia, contrast, or device materials, including nickel, titanium, tantalum, bovine-derived materials or polyurethanes) • Anemia • Angina • Arrhythmia or new conduction system injury (including need for pacemaker insertion) • Bleeding or hemorrhage (possibly requiring transfusion or additional procedure) • Cardiac arrest • Cardiac failure/low cardiac output • Cerebrovascular accident, stroke, transient ischemic attack or cerebral infarction including asymptomatic neuroimaging findings • Coronary obstruction • Death • Device misplacement, migration or embolization • Emboli (including air, tissue, thrombus or device materials) • Endocarditis • Fever or inflammation • Heart failure • Hemodynamic instability or shock • Hemolysis and/or hemolytic anemia • Hypertension/hypotension • Infection (local and/or systemic) • Mitral valve insufficiency • Myocardial infarction • Myocardial or valvular injury (including perforation or rupture) • Nerve injury or neurologic deficits (including encephalopathy) • Pain • Pericardial effusion or tamponade • Peripheral ischemia or infarction • Permanent disability • Pleural effusion • Pulmonary edema • Renal insufficiency or failure • Respiratory insufficiency or failure • Restenosis (including pannus formation) • Valve dysfunction, deterioration or failure • Valve or device thrombosis • Valvular stenosis or regurgitation (central or paravalvular) • Vessel injury (including spasm, trauma, dissection, perforation, rupture, pseudoaneurysm or arteriovenous fistula). As a result of these adverse events, the subject may require medical, percutaneous or surgical intervention, including re-operation and replacement of the valve. These events may lead to fatal outcomes. **CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.
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