Boston Scientific
Advancing science for life™

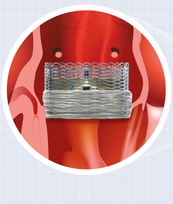
Lotus™ Valve System
What is Severe Aortic Stenosis

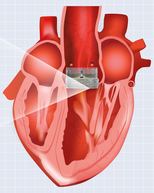
Aortic Valve Stenosis (AS) is the process of thickening and stiffening in the valve, which can result in an abnormal narrowing of the aortic valve opening and reduction in blood flow.[1]

AS affects **2-7 %** of the population > 65 years old in Europe and North America[2]

Approximately **1.2 million** patients suffer from AS[3,4]

Approximate **30 %** of patients with AS are not suitable for Surgical Aortic Valve Replacement (SAVR)[5,6]





Replacement options include Surgical Aortic Valve Replacement (SAVR) or Transcatheter Aortic Valve Implantation (TAVI).

» What Is Transcatheter Aortic Valve Implantation (TAVI)

TAVI is a minimally invasive procedure that replaces the stenotic or diseased valve with a prostetic tissue valve and is implanted by means of a catheter. It is therefore an alternative treatment to SAVR without open-heart surgery.[5]

Approximately 30 % of patients with Aortic Stenosis (AS) are contra-indicated for SAVR due to age, comorbidities, and other complications.[5,6]

Moderate and severe PVL has been associated with an increase in mortality rate after TAVI procedures.[9]

» Limitations with early TAVI devices

The most common limition with TAVI is paravalvular leakage (PVL). Moderate and severe PVL has been associated with an increase in mortality rate after TAVI procedures.[7,9]

It refers to blood flowing through a channel between the structure of the implanted valve and cardiac tissue as a result of a lack of appropriate sealing.[8]

Non-Circular Annulus with calcification + Prosthetix Valve=PVL

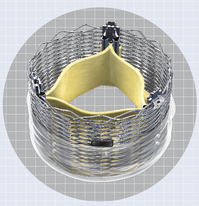
Lotus™ Valve System

The Lotus™ Valve System is a next-generation TAVI device, which consists of a pre-attached valve prosthesis and catheter delivery system. The valve is deployed transfemorally through a controlled mechanical expansion. The valve is designed to treat patients with severe symptomatic aortic valve stenosis.[10]

The Power of Control

Transform your TAVI Experience with the Lotus™ Valve System

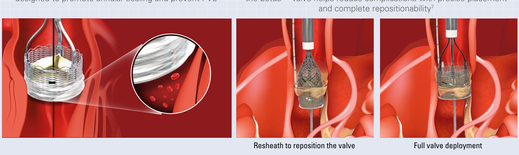
- Confidence knowing your procedural result before valve release
- Help reduce complications with precise placement and complete repositionability
- Minimize paravalvular leak with the innovative Adaptive Seal™[10]



Innovative Technologies

Adaptive Seal™ Technology
designed to promote annular sealing and prevent PVL

Complete repositionability at 100 % deployment
the Lotus™ Valve helps reduce complications with precise placement and complete repositionability[7]



REPRISE II Clinical Study[7]

OBJECTIVE

REPRISE II is a prospective, single-arm, multicentre study designed to evaluate safety and performance of the Lotus™ Valve System for symptomatic patients with severe calcific aortic stenosis who are considered high risk for surgical valve replacement.

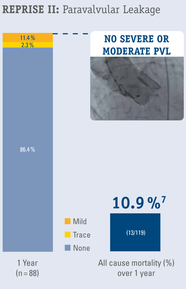
PRIMARY ENDPOINTS

PERFORMANCE: Mean aortic valve pressure gradient at 30 days
SAFETY: All-cause mortality at 30 days 4.2 % (5/119)

Lotus™ Valve System= 100 % Implantation Success[7]

REPRISE II results at one year n=120 presented at TCT 2014, Ian T. Meredith, AM, MBBS, PhD

REPRISE II: Paravalvular Leakage



STRONG AND SAFETY PROFILE
First 120 patients

Parameter	Patients %
Aortic valve malpositioning	0
Valve migration	0
Valve embolization	0
Ectopic valve deployment	0
TAV-in-TAV deployment	0
Aortic valve endocarditis	0
Aortic valve thrombosis	0
Aborted procedure	0
Aortic dissection	0
Cardiopulmonary bypass*	0
Non-Study valve implantation	0
Repeat procedures for valve dysfunction	0

PRIMARY ENDPOINT Safety: 30-day all-cause mortality

The Lotus™ Valve System, a true differentiated TAVI device, has demonstrated strong and sustainable safety performance in REPRISE II.[7]

REFERENCES

*Boston Scientific Data on file.

1. Kurtz CE, Otto CM. Aortic stenosis: clinical aspects of diagnosis and management, with 10 illustrative case reports from a 25-year experience. Medicine (Baltimore) 2010;89(6):349-79.
2. Vahanian, A, et al. Guidelines on the management of valvular heart disease (version 2012) European Heart Journal (2012) 33, 2451–2496doi:10.1093/eurheartj/ehs109
3. Bordoni B, Sala E, Cuca C, Marmzzino C, Santoro M, Dall'ara G, et al. Prevalence of degenerative aortic valve stenosis in the elderly: results of a large community-based epidemiological study. G Ital Cardiol (Rome) 2013;14(4):282-8.
4. Lung B, Baron G, Tornos P, Gohlke-Barwolf C, Butchart EG, Vahanian A. Valvular heart disease in the community: a European experience. Curr Probl Cardiol 2007;32(11):609-61.
5. Charlson E. J Heart Valve Dis 2006;15:312-321.
6. Lung B. Eur Heart J 2002;24:1231-1243
7. Meredith, I. One-Year Outcomes With the Fully Repositionable and Retrievable Lotus™ Transcatheter Aortic Replacement Valve in 120 High-Risk Surgical Patients With Severe Aortic Stenosis: Results From the REPRISE II CE-Mark Study. Presented at the Transcatheter Cardiovascular Therapeutics (TCT) meeting 2014 in Washington, USA.
8. Smolka G, et al. Paravalvular leak – important complication after implantation of prosthetic valve. ESC Nov 2010
9. Kodali SK et al. Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement. NEJM 2012;366:1686, http://www.nejm.org/doi/full/10.1056/NEJMoa1200384 (Accessed: December 19, 2014).
10. Lotus Valve System DFU