Lotus™
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™

Learn more about the clinical data of the REPRISE II Clinical Study and the Lotus™ Valve System on www.lotus-valve-system.eu
Indications For Use

The Lotus™ Valve System is intended to improve the aortic valve function for symptomatic patients with severe calcific aortic stenosis (aortic valve area [AVA] of <1.0 cm² or index of <0.6 cm² / m²) who are at high risk for standard surgical valve replacement.

Access Route

Transfemoral

Expansion Design

Controlled Mechanical Expansion

Tissue Material

Bovine Pericardium

Frame Material

Braided Nitinol Frame

Valve Sizes

23 mm, 25 mm and 27 mm

Treatment Range

23 mm: ≥20 mm to ≤23 mm
25 mm: ≥23 mm to ≤25 mm
27 mm: ≥25 mm to ≤27 mm

Frame Height

19 mm

Delivery System

Lotus™ Valve System

Delivery System Minimum Length

23 mm: 103 cm
25 mm: 113 cm
27 mm: 113 cm

Sheath

23 mm: Lotus™ Introducer Set Small (LIS-S)
25 mm: Lotus™ Introducer Set Large (LIS-L)
27 mm: Lotus™ Introducer Set Large (LIS-L)

Guidewire Compatibility

23 mm: 0.035 in (0.89 mm) x 260 cm Super / Extra Stiff Guidewire
25 mm: 0.035 in (0.89 mm) x 300 cm Super / Extra Stiff Guidewire
27 mm: 0.035 in (0.89 mm) x 300 cm Super / Extra Stiff Guidewire

Retrievable / Repositionable / Redeployable

Yes, up to 100 % after deployment and before release

Seal Technology

Adaptive Seal™ – polycarbonate - based urethane material

Markers To Aid Positioning

Radiopaque Marker

Use

Single Use

Anti-Calcification Process

T-Guard™

The Lotus™ Valve is Magnetic Resonance Imaging (MRI) Conditional:

Field strengths of 1.5 and 3 Tesla
Static magnetic field gradient of 2500 Gauss / cm or less
Normal operational mode (maximum whole-body-averaged specific absorption rate (SAR) of lower than 2.0 W / kg) for a total active MR scan time (with RF exposure) of 15 minutes or less

Delivery System Sterilization

Radiation Process

Valve Sterilization

Chemical Solution

Product Code | Product Description
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H749LTV230 | Lotus™ Valve System 23 mm Transcatheter aortic valve prosthesis premounted on delivery system
H749LTV250 | Lotus™ Valve System 25 mm Transcatheter aortic valve prosthesis premounted on delivery system
H749LTV270 | Lotus™ Valve System 27 mm Transcatheter aortic valve prosthesis premounted on delivery system
H749NTR180 | Lotus™ Introducer Set Small (LIS-S) Introducer sheath
H749NTR200 | Lotus™ Introducer Set Large (LIS-L) Introducer sheath
Z65LOTUSKIT23 | Lotus™ Valve Kit 23 mm Lotus™ Kit including Lotus™ 23 mm Valve System and Lotus™ Introducer Set Small
Z65LOTUSKIT25 | Lotus™ Valve Kit 25 mm Lotus™ Kit including Lotus™ 25 mm Valve System and Lotus™ Introducer Set Large
Z65LOTUSKIT27 | Lotus™ Valve Kit 27 mm Lotus™ Kit including Lotus™ 27 mm Valve System and Lotus™ Introducer Set Large

* Meredith, IT. REPRISE II one year results, presented at TCT 2014

The Lotus™ Introducer Set is manufactured by Creganna-Tactx Medical and distributed by Boston Scientific Corporation.

Illustrations for information purposes – not indicative of actual size or clinical outcome.

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Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations. Not intended for use or distribution in France, Japan and the USA.

www.bostonscientific.eu

www.lotus-valve-system.eu

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DINSH0052EA