

REPRISE II Clinical Study¹

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.

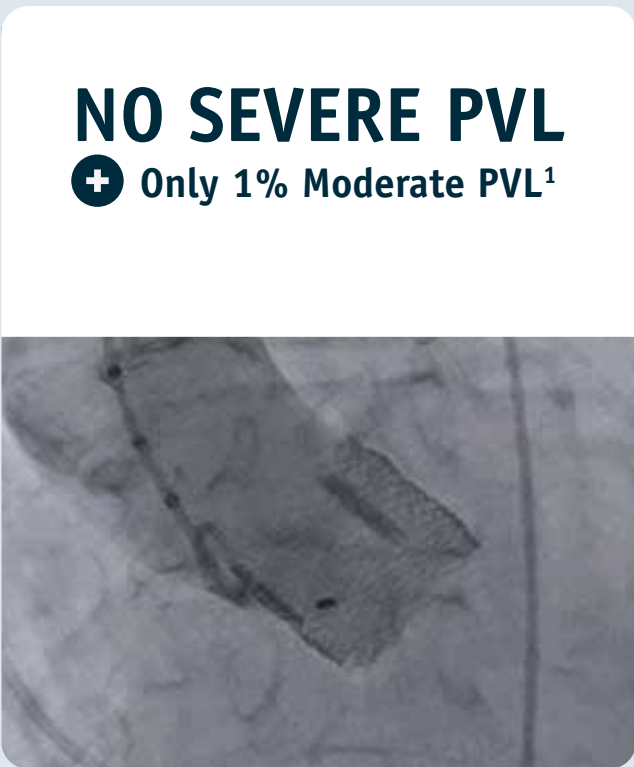
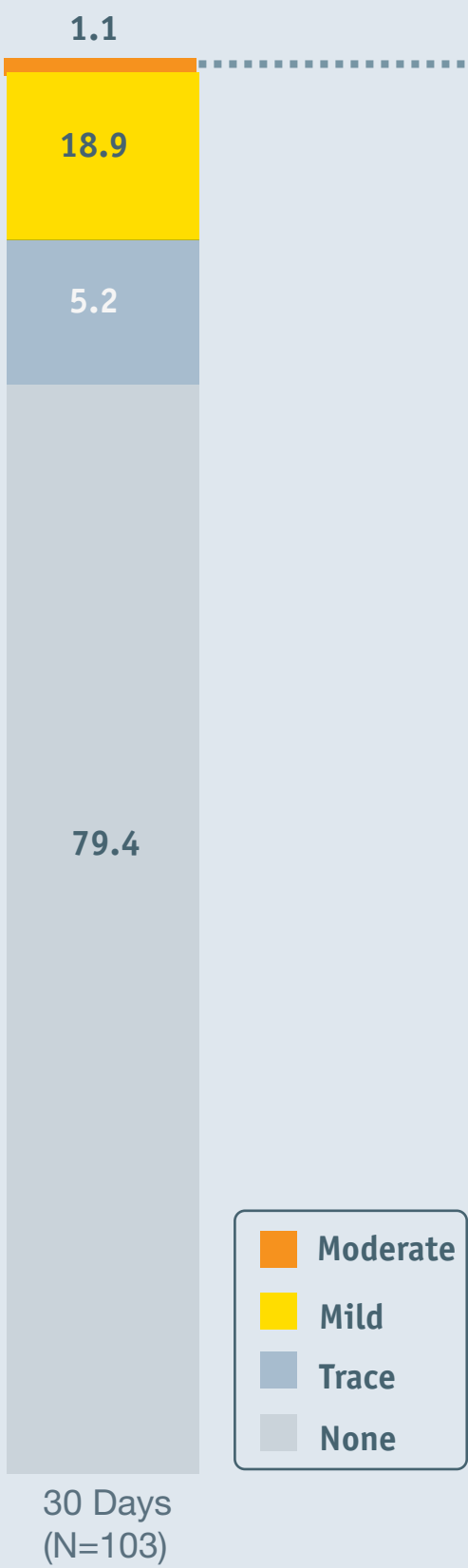
PRIMARY ENDPOINTS

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 Success¹

REPRISE II Results at 6 months n=120 presented at EuroPCR 2014, Ian T. Meredith, AM, MBBS, PhD.

REPRISE II: Paravalvular Leakage



PRIMARY ENDPOINT
Safety: 30-day all-cause mortality

8.4%¹

(10/119)

All-cause mortality(%) over 6 months

STRONG SAFETY PROFILE

6-month outcomes - first 120 patients

Successful device implantation	100%
Procedural complications (%)	
≥2 valves implanted (TAV-in-TAV)	0
Aborted procedure	0
Aortic rupture	0
Aortic dissection	0
Cardiopulmonary bypass	0
Valve embolisation	0
Ectopic valve placement	0
Valve migration	0
Non-study valve implantation	0
Repeat procedures for valve dysfunction	0

The Lotus Valve System, a true differentiated TAVI device, has demonstrated strong and sustainable safety performance in REPRISE II.¹

References

1. Meredith, I. Six-month outcomes with a fully repositionable and retrievable transcatheter aortic replacement valve in 120 high-risk surgical patients with severe aortic stenosis: results from the REPRISE II CE-Mark study. Presented at EuroPCR 2014.

All cited trademarks are the property of their respective owners. CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information contained herein for distribution outside the USA, France and Japan only and only in countries with applicable health authority product registrations.

© 2014 Boston Scientific Corporation or its affiliates. All rights reserved.