

LOTUS *Edge*™

Aortic Valve System

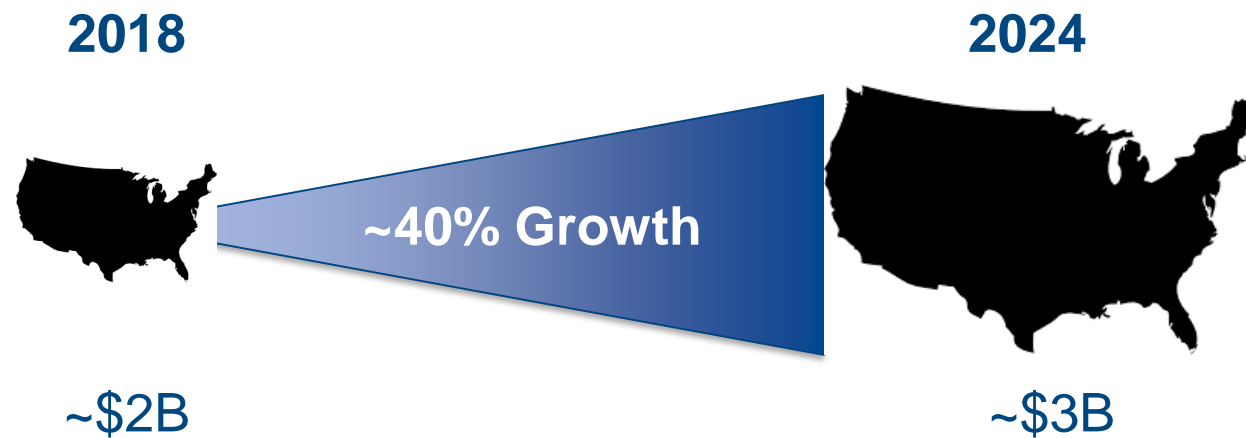
Product Overview for the Hospital Administrator



**Complete
CONTROL**
**PREDICTABLE
Results**

Transcatheter Aortic Valve Market Steadily Growing

TAVR Market Growth Projection¹



~ 600 TAVR Centers Today
Nearly 300% Growth Since 2012²

Growth Drivers

- Aging US population
- Increased awareness of minimally invasive options
- Expanding indications to lower risk populations

1. Edwards Lifesciences 2018 Investor Conference, 12/5/18

2. Holmes, D, et. al., Annual Outcomes with Transcatheter Valve Therapy: From the STS/ACC TVT Registry, JACC, 29 December, 2015.

Opportunities Remain to Evolve your TAVR Program

PATIENT OUTCOMES

COMPLICATION RATES

LENGTH OF STAY

COST VARIATION

PROCEDURAL EFFICIENCY

PATIENT SATISFACTION



Improve
Financial
Health



Enhance
Patient
Experience

Boston
Scientific



Strengthen
Quality
Outcomes



Increase
Operational
Efficiencies

Complications Impact Cost, Mortality & Quality of Life

TAVR Complications Associated with Mortality & Quality of Life¹

~6x

Risk of death in one year if stroke occurs,
driving a 33% increase in TAVR hospitalization
costs²

~2x

Risk of death in one year
with moderate/severe PVL³

TAVR Complications Increase Cost*

\$12,475

Per patient cost attributed to complications⁴

2.4

Additional days of hospitalization
due to complications⁴

25%

Of non-implant related hospital costs
are driven by complications³

*Complications Associated with Increased Cost: Death, major stroke,
major bleeding, renal failure, arrhythmia, repeat TAVR, surgical AVR

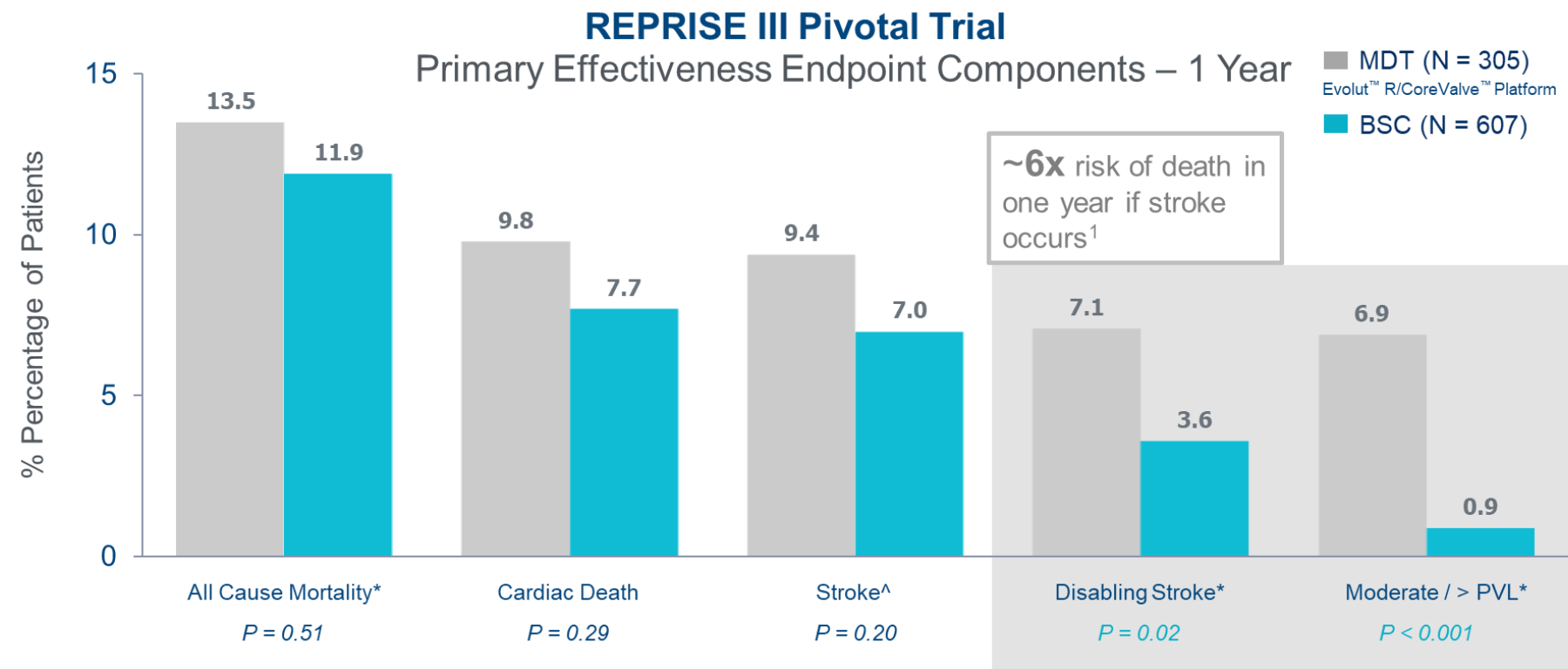
1. PARTNER 2 and S3 data (Edwards valves) used to examine the impact of peri-procedural complications on mortality and quality of life at 1 year after TAVR – 3763 patients of high/intermediate risk

2. Alqahtani, F. et. al. Clinical and Economic Burden of Acute Ischemic Stroke Following Transcatheter Aortic Valve Repair, The Journal of the Heart Team, November 16, 2018

3. Arnold S, Zhang Y, Baron S, et al. Impact of Peri-Procedural Complications on Mortality and Quality of Life after TAVR. *Circ Cardiovasc Interv.* 2014;7:829-836

4. Arnold SV et al, *Circ Cardiovascular Interv* 2014; 829-36

LOTUS Edge™ is the Only Valve that Demonstrated Head-to-Head Superiority in Reduction of Disabling Stroke & Moderate/Severe PVL



Primary Effectiveness Endpoint

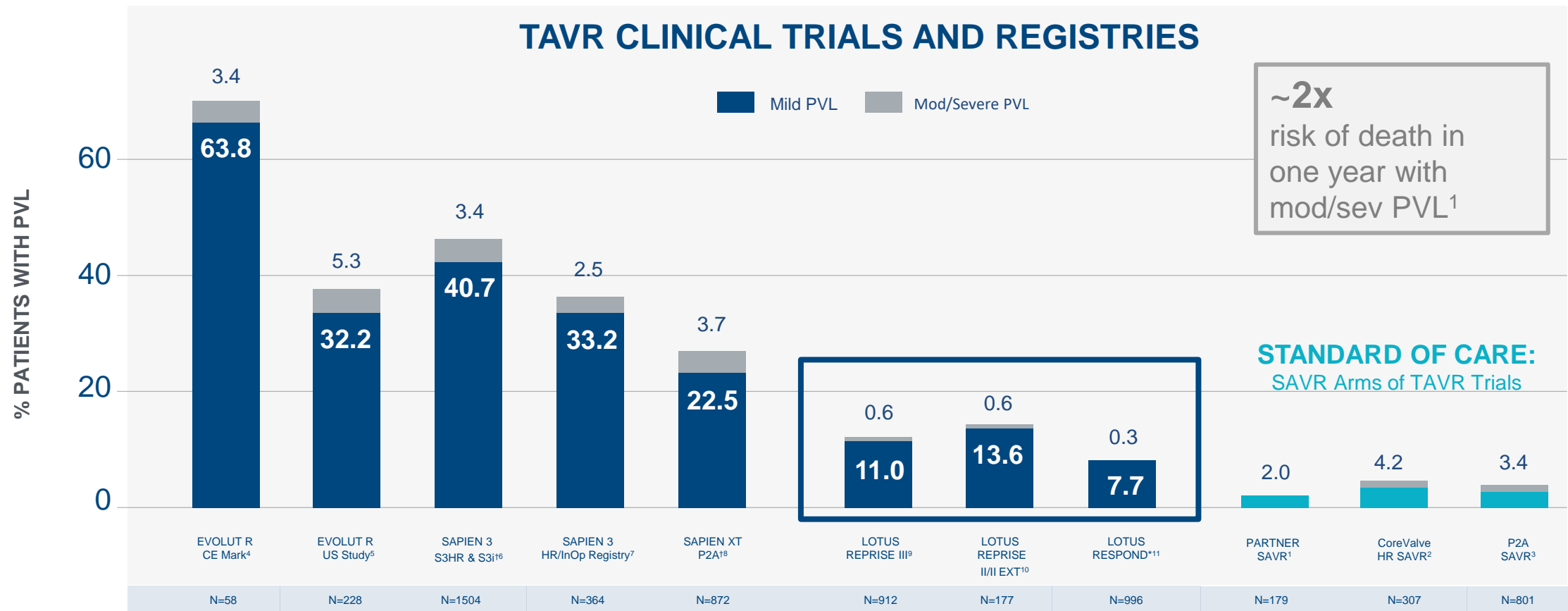
LOTUS Valve = 15.8% v. Evolut R / CoreValve Platform = 26.0%
Superiority $P < 0.001$

Primary Safety Endpoint

LOTUS Valve = 20.3% v. Evolut R / CoreValve Platform = 17.2%
Non-inferiority $P = 0.003$

1. Feldman TE, et al. JAMA 2018;319:27-37

LOTUS Edge™ PVL Rates in Perspective



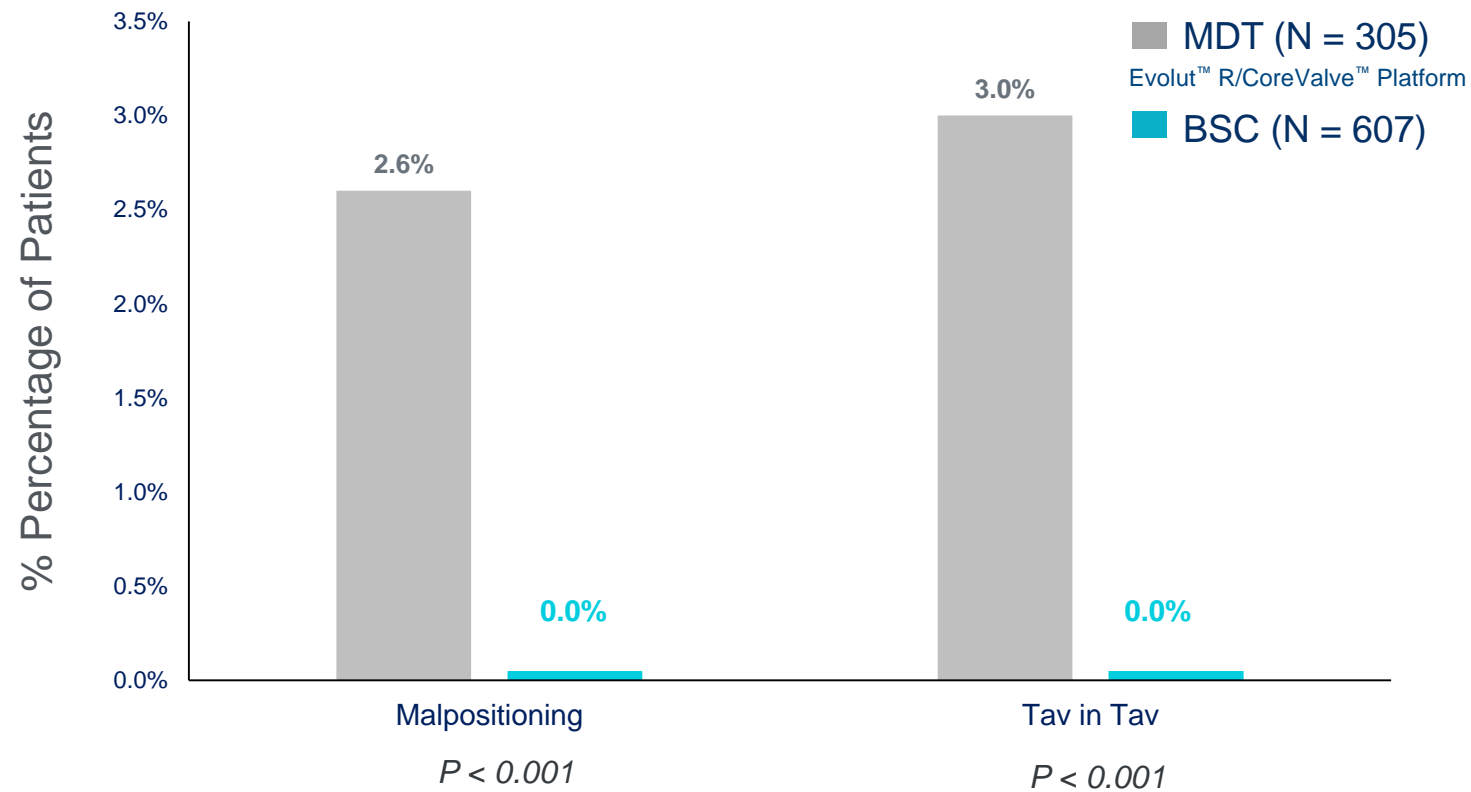
Lower PVL rates may delay the onset of heart failure and reduce readmissions

1. Arnold S, Zhang Y, Baron S, et al. Impact of Peri-Procedural Complications on Mortality and Quality of Life after TAVR. *Circ Cardiovasc Interv.* 2014;7:829-836

*7d/Discharge; 30d angiography not mandated per protocol. †Intermediate risk patient population. Results from different studies are not directly comparable. Information provided for educational purpose only. ¹Leon, NEJM 2012 Suppl. Appendix. ²Adams, NEJM 2014 Suppl. Appendix. ³Thourani, Lancet 2016 Suppl. Appendix. ⁴Manoharan, JACC 2015. ⁵Popma JACC 2017. ⁶Kodali, EHJ 2016. ⁷Hermann, Circulation 2016. ⁸Leon NEJM 2016. ⁹Feldman, PCR 2017. ¹⁰Meredith, PCR LV 2014. ¹¹Falk V, PCR 2016.

LOTUS Edge™ Showed Superior Procedural Outcomes in REPRISE III

REPRISE III: 30-Day Procedural Outcomes¹



LOTUS Edge™ is:

100%
REPOSITIONABLE at

100%
DEPLOYMENT with

0%
MALPOSITIONING IN

**REPRISE
CLINICAL TRIALS^{1,2*}**

1. Feldman TE, et al. JAMA 2018;319:27-37
2. Meredith IT, et al. EuroIntervention 2017;13:788-954;

LOTUS Edge™ Design Goals

Repositionable after 100% Deployed

Know your final result before
release

Adaptive Seal™

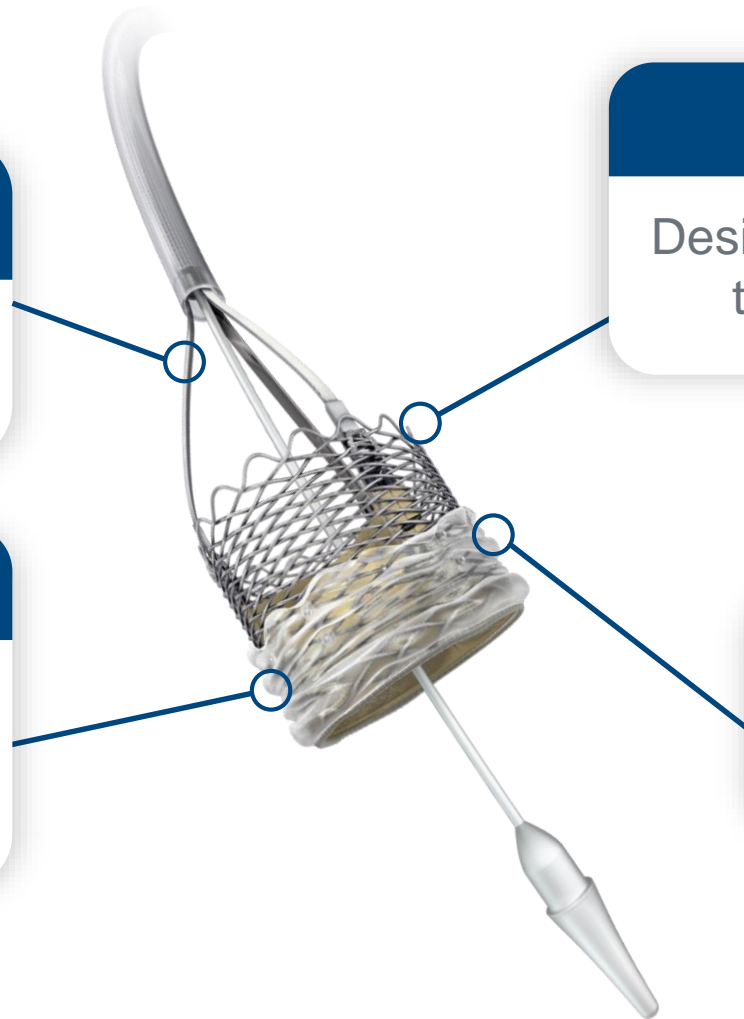
Minimize paravalvular leak by
conforming to irregular
anatomical surfaces

Braided Nitinol Frame

Designed for strength, flexibility, and ability
to retrieve, reposition, and redeploy

Bovine Pericardium

Proven Long-Term Material

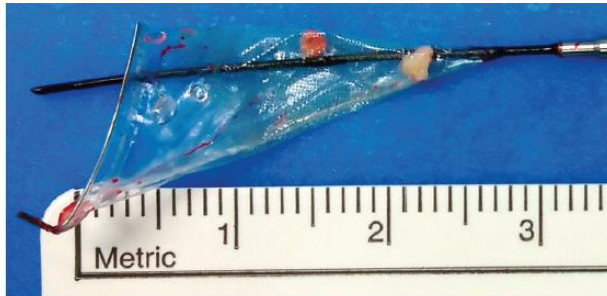


Sentinel Embolic Protection System Provides Additional Stroke Protection for your Most Vulnerable Patients



In SENTINEL IDE Trial, captured and removed embolic debris in

- 99%¹ of TAVR patients, regardless of valve type



Protected TAVR patients had

- 63% fewer strokes when compared to unprotected TAVR patients, a 3-4% absolute stroke rate reduction^{1,2,3}

Peri-procedural strokes drive

- 67% increase in LOS⁴
- 37% increase in hospital charges⁴
- 31% increase in 30-day readmissions⁴

Available NTAP for additional reimbursement (\$0 - \$1,400)

CMS will pay 50% of the excess between estimated hospital costs and payments for the claim⁵

1. Kapadia SR. *et al.* Protection Against Cerebral Embolism During Transcatheter Aortic Valve Replacement. *J Am Coll Cardiol.* 2017 Jan 31;69(4):367-377.

2. Seeger J *et al.* 2017. *JACC Cardiovasc Interv.* 10(22):2297-2303;

3. Van Mieghem N. presented at TVT 2018; Chakravarty T. presented at TVT 2018

4. Alkhouli M, Alqahtani F, *et al.* Outcomes of Acute Ischemic Stroke After TAVR: Potential Impact of Embolic Protection ACC 2018.

5. CMS IPPS Final Rule (2019), <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2019-IPPS-Final-Rule-Home-Page-Items/FY2019-IPPS-Final-Rule-Regulations.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending>, August 2, 2018

Differentiated Patient Outcomes

- Highly calcified annuli: Adaptive Seal™ supports improved outcomes
- Low EF patients: No rapid pacing required & improved hemodynamic stability



Enhance
Patient
Experience

Low Complication Rates in REPRISE III Clinical Trial

- 3.6% disabling stroke rate vs. 7.2% with CoreValve™ at 12 months, $p=0.02$
- 0.9% moderate to severe PVL rate vs. CoreValve's™ rate of 6.9% at 12 months, $p<0.001$



Strengthen
Quality
Outcomes



Improve
Financial
Health

Predictability and Control

- 0% malpositioning in REPRISE trials
- Valve functionality can be assessed prior to release



Increase
Operational
Efficiencies

LOTUS *Edge*™

Aortic Valve System

Product Overview

for the Hospital Administrator



**Complete
CONTROL**

**PREDICTABLE
Results**

APPENDIX

Over 2,500 Patients Studied

T LOTUS Edge™ Valve

T LOTUS Valve

Intermediate
Risk/(Bicuspid)

IDE Trial for
FDA Approval

Post Market

CE Mark

Feasibility

REPRISE I
(N = 11)

REPRISE Edge
and Feasibility
(N = 36)

REPRISE II /
Extension
(N = 250)

RESPOND
(N = 1014)

REPRISE III
(N = 912)

REPRISE Japan
(N = 50)

REPRISE IV
(Enrolling)