LOTUS Edge™
Aortic Valve System

Product Overview
for the Hospital Administrator
Transcatheter Aortic Valve Market Steadily Growing

TAVR Market Growth Projection

2018

~$2B

2024

~$3B

~40% Growth

Growth Drivers

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

~ 600 TAVR Centers Today
Nearly 300% Growth Since 2012

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
- Strengthen Quality Outcomes
- Increase Operational Efficiencies
Complications Impact Cost, Mortality & Quality of Life

**TAVR Complications Associated with Mortality & Quality of Life**

- **~6x**
  Risk of death in one year if stroke occurs, driving a 33% increase in TAVR hospitalization costs

- **~2x**
  Risk of death in one year with moderate/severe PVL

**TAVR Complications Increase Cost**

- **$12,475**
  Per patient cost attributed to complications

- **2.4**
  Additional days of hospitalization due to complications

- **25%**
  Of non-implant related hospital costs are driven by complications

*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
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 $P = 0.003$
## TAVR CLINICAL TRIALS AND REGISTRIES

<table>
<thead>
<tr>
<th>Study/Registries</th>
<th>Mild PVL (%)</th>
<th>Mod/Severe PVL (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVOLUT R CE Mark</td>
<td>63.8</td>
<td>3.4</td>
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<tr>
<td>EVOLUT R US Study</td>
<td>5.3</td>
<td>40.7</td>
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<tr>
<td>SAPIEN 3 S3HR &amp; S3i</td>
<td>2.5</td>
<td>33.2</td>
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<td>SAPIEN XT P2A***</td>
<td>0.6</td>
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<tr>
<td>LOTUS REPRSE III*</td>
<td>11.0</td>
<td>0.3</td>
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<tr>
<td>LOTUS REPRSE III EXT**</td>
<td>13.6</td>
<td>7.7</td>
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<tr>
<td>LOTUS RESPOND***</td>
<td>2.0</td>
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<tr>
<td>PARTNER SAVR1</td>
<td>3.4</td>
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<tr>
<td>CoreValve HR SAVR1</td>
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</tr>
<tr>
<td>P2A SAVR1</td>
<td>3.4</td>
<td></td>
</tr>
</tbody>
</table>

N=58  N=228  N=1504  N=384  N=872  N=912  N=364  N=801  N=177  N=996

**STANDARD OF CARE:**
SAVR Arms of TAVR Trials

~2x risk of death in one year with mod/sev PVL

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


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 TRIALS¹,²*


% Percentage of Patients

- Malpositioning
  - MDT (N = 305): 2.6%
  - BSC (N = 607): 3.0%
  - *P < 0.001
- Tav in Tav
  - MDT (N = 305): 0.0%
  - BSC (N = 607): 0.0%
  - *P < 0.001
LOTUS Edge™ is Designed for Complete Control & Predictable Results

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
In SENTINEL IDE Trial, captured and removed embolic debris in

- 99% 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

Peri-procedural strokes drive

- 67% increase in LOS
- 37% increase in hospital charges
- 31% increase in 30-day readmissions

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

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

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2. Seeger J et al. 2017. JACC Cardiovasc Interv. 10(22)2297-2303;
3. Van Mieghem N. presented at TVT 2018; Chakarvarty T. presented at TVT 2018

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LOTUS Edge™ and Your TAVR Program Goals

Differentiated Patient Outcomes

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

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

Predictability and Control

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

Enhance Patient Experience

Strengthen Quality Outcomes

Improve Financial Health

Increase Operational Efficiencies
LOTUS Edge™
Aortic Valve System

Product Overview
for the Hospital Administrator
LOTUS Edge™ Research Pathway

Over 2,500 Patients Studied

- **Feasibility**
  - REPRISE I (N = 11)
  - REPRISE Edge and Feasibility (N = 36)

- **CE Mark**
  - REPRISE II / Extension (N = 250)

- **Post Market**
  - RESPOND (N = 1014)

- **IDE Trial for FDA Approval**
  - REPRISE III (N = 912)
  - REPRISE Japan (N = 50)

- **Intermediate Risk/(Bicuspid)**
  - REPRISE IV (Enrolling)

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