LOTUS Edge™
Aortic Valve System
for the Hospital Purchasing Committee
WHAT IS TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)?

Transcatheter aortic valve replacement (TAVR) is a minimally invasive procedure that repairs the aortic valve without removing the old or diseased valve. Instead, it provides ‘valve-in-valve’ placement of a new, artificial valve. The delivery of the fully collapsible replacement valve is performed through a transcatheter mechanism and once deployed, the tissue in the replacement valve takes over the role of regulating blood flow.

WHAT MAKES THIS PRODUCT UNIQUE?

The LOTUS Edge™ Aortic Valve System is an intra-annular valve made up of a nitinol wire frame that uses controlled expansion during deployment. It is the only aortic replacement valve on the market that is 100% repositionable, and does not require rapid pacing during delivery and placement. LOTUS Edge has a dynamic Adaptive Seal™ around the outside of the valve frame to conform to patients’ anatomy and eliminate paravalvular leak (PVL).
The LOTUS Edge™ Aortic Valve System is a next-generation controlled expansion TAVR technology, designed to provide surgical-like PVL, precise delivery and deployment, and predictable results.

**TECHNOLOGY OVERVIEW**

**Repositionable After 100% Deployed**
Know your final result before release

**Adaptive Seal™**
Minimizes 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

**TECHNOLOGY SPECIFICATIONS**

<table>
<thead>
<tr>
<th>LOTUS Edge Aortic Valve System</th>
<th>Transcatheter Aortic Valve Prosthesis Premounted on a Delivery System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access Route</td>
<td>Transfemoral and Transaortic</td>
</tr>
<tr>
<td>Deployment Procedure</td>
<td>Controlled Expansion with Depth Guard™</td>
</tr>
<tr>
<td>Guidewire Compatibility</td>
<td>0.035” (0.89 mm) Super/Extra Stiff Guidewire</td>
</tr>
<tr>
<td>Delivery System Nominal Length</td>
<td>114 cm (23 mm, 25 mm); 115 cm (27 mm)</td>
</tr>
<tr>
<td>Valve Frame Material</td>
<td>Braided nitinol</td>
</tr>
<tr>
<td>Valve Leaflet Material</td>
<td>Bovine pericardium</td>
</tr>
<tr>
<td>Valve Leaflet Treatment</td>
<td>TGuard™, Proprietary Technology to Reduce Calcification</td>
</tr>
<tr>
<td>Valve Seal Technology</td>
<td>Adaptive Seal, Polycarbonate-based Urethane</td>
</tr>
<tr>
<td>Use</td>
<td>Single Use</td>
</tr>
<tr>
<td>Repositionability</td>
<td>100%. Repositionable after full deployment, prior to valve release</td>
</tr>
<tr>
<td>Retrievability</td>
<td>100%. Retrievable after full deployment, prior to valve release</td>
</tr>
<tr>
<td>Valve Sterilization</td>
<td>Chemically Sterilized</td>
</tr>
</tbody>
</table>

**Native Annulus Diameter**
- ≥ 20 mm & ≤ 23 mm
- ≥ 23 mm & ≤ 25 mm
- ≥ 25 mm & ≤ 27 mm

**Deployed LOTUS Edge Valve OD**
- 23 mm
- 25 mm
- 27 mm

**Deployed Valve Height**
- 19 mm

Illustrations for information purposes—not indicative of actual size or clinical outcome.
**TECHNOLOGY SPECIFICATIONS**

The **LOTUS™ Introducer Set (Large)** offers an atraumatic design, maximized trackability* and kink resistance† for an enhanced user experience.

**TECHNOLOGY SPECIFICATIONS**

- **Hydrophilic Coating**
  - Enhances tracking through challenging anatomy
  - Facilitates smooth sheath entry and removal

- **Coil-Reinforced Pebax™ Shaft**
  - Provides resistance to kinking while maximizing trackability*

- **Tapered Soft Tip**
  - Allows for atraumatic delivery

- **Silicone Coating**
  - Minimizes resistance during dilator insertion

**Silicone Strain Relief**

**Hemostasis Valve**

**Recommended Guidewire**
0.035" (0.89 mm)

**Introducer Profile**
21F

**Sheath Working Length**
30.5 cm

**Dilator Length**
47.5 cm

**Valve Compatibility**
For use with all LOTUS Edge™ Aortic Valve Systems

**Use**
Single Use

**Sterilization**
Ethylene Oxide Gas

---

**REGULATORY INFORMATION**

**REGULATORY SUMMARY**

<table>
<thead>
<tr>
<th>Regulation Medical Specialty</th>
<th>Cardiovascular</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation Description</td>
<td>Transcatheter Aortic Valve Prosthesis</td>
</tr>
<tr>
<td>Device Classification Name</td>
<td>Aortic Valve, Prosthesis, Percutaneously Delivered</td>
</tr>
<tr>
<td>Trade/Device Name</td>
<td>LOTUS Edge™ Valve System</td>
</tr>
<tr>
<td>Intended Use</td>
<td>The LOTUS Edge Valve System is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis (aortic valve area [AVA] of ≤ 1.0 cm² or index of ≤ 0.6 cm²/m²) who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator).</td>
</tr>
<tr>
<td>PMA Number</td>
<td>P180029</td>
</tr>
<tr>
<td>FDA Classification</td>
<td>Class III (PMA)</td>
</tr>
<tr>
<td>Approval Date</td>
<td>April 23, 2019</td>
</tr>
</tbody>
</table>

---

**REGULATORY SUMMARY**

<table>
<thead>
<tr>
<th>Regulation Medical Specialty</th>
<th>Cardiovascular</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation Description</td>
<td>Introducer, Catheter</td>
</tr>
<tr>
<td>Device Classification Name</td>
<td>Introducer, Catheter</td>
</tr>
<tr>
<td>Trade/Device Name</td>
<td>LOTUS Introducer Set</td>
</tr>
<tr>
<td>Intended Use</td>
<td>The LOTUS Introducer Set is intended to provide femoral access to the vascular system.</td>
</tr>
<tr>
<td>510(k) Number</td>
<td>K140338</td>
</tr>
<tr>
<td>Regulation Number</td>
<td>21 CFR 870.1340</td>
</tr>
<tr>
<td>FDA Classification</td>
<td>Class II</td>
</tr>
<tr>
<td>Approval Date</td>
<td>August 22, 2014</td>
</tr>
</tbody>
</table>

---

* Coil reinforced Pebax™ shaft and silicone strain relief provides resistance to kinking while maximizing trackability.
† Data on file with Creganna Medical, TR140806, n=10.

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

The LOTUS Introducer Set is manufactured by Creganna Medical and distributed by Boston Scientific Corporation.
Dear Ms. Eyers:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the LOTUS Edge™ Valve System. This device is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis (aortic valve area [AVA] of ≤ 1.0 cm² or index of ≤ 0.6 cm²/m²) who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy.

This device is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis (aortic valve area [AVA] of ≤ 1.0 cm² or index of ≤ 0.6 cm²/m²) who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy.

You have agreed to work with the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (TVT) Registry to ensure Surveillance of the LOTUS Edge™ Valve System for the “High Risk and above” Indication

You must conduct one post-approval study (PAS) and participate in an active surveillance plan as described below:

1. **Continued Follow-Up of the REPRISE III Trial Premarket Cohorts:** This study should be conducted in accordance with protocol version AK dated October 6, 2017. The study will consist of all living subjects who were enrolled in the REPRISE III randomized, roll-in, continued access, and nested registry cohorts under the IDE. Subject follow-up will continue for all cohorts based on the timelines and assessments stipulated in the IDE protocol.

   The objective of this PAS is to characterize the clinical outcomes annually through 5 years post-procedure. Data will be collected per the study protocol, including, but not limited to, the following key safety and effectiveness endpoints: all-cause mortality, all-cause and disabling stroke, life-threatening and major bleeding events, stage 2 or 3 acute kidney injury, major vascular complications, paravalvular aortic regurgitation, valve performance and durability, myocardial infarction, re-operation for valve-related dysfunction, rehospitalization for valve-related symptoms or worsening congestive heart failure, new permanent pacemaker implantation, new-onset atrial fibrillation, functional status as evaluated by New York Heart Association (NYHA) Class 5-meter gait speed test at 1 year, and health status as evaluated by Kansas City Cardiomyopathy Questionnaire (KCCQ) and SF-12 Quality of Life questionnaire at 1, 3, and 5 years. Data will be collected per the study protocol, including, but not limited to, the following key safety and effectiveness endpoints: all-cause mortality, all-cause and disabling stroke, life-threatening and major bleeding events, stage 2 or 3 acute kidney injury, major vascular complications, paravalvular aortic regurgitation, valve performance and durability, myocardial infarction, re-operation for valve-related dysfunction, rehospitalization for valve-related symptoms or worsening congestive heart failure, new permanent pacemaker implantation, new-onset atrial fibrillation, functional status as evaluated by New York Heart Association (NYHA) Class 5-meter gait speed test at 1 year, and health status as evaluated by Kansas City Cardiomyopathy Questionnaire (KCCQ) and SF-12 Quality of Life questionnaire at 1, 3, and 5 years.

2. **Registry-Based Real-World Use Surveillance of the LOTUS Edge™ Valve System for the “High Risk and above” Indication:** You have agreed to work with the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (TVT) Registry to ensure Surveillance of the LOTUS Edge™ Valve System for the “High Risk and above” Indication. You have agreed to work with the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (TVT) Registry to ensure Surveillance of the LOTUS Edge™ Valve System for the “High Risk and above” Indication. You have agreed to work with the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (TVT) Registry to ensure Surveillance of the LOTUS Edge™ Valve System for the “High Risk and above” Indication.

The objective of this PAS is to characterize the clinical outcomes annually through 5 years post-procedure. Data will be collected per the study protocol, including, but not limited to, the following key safety and effectiveness endpoints: all-cause mortality, all-cause and disabling stroke, life-threatening and major bleeding events, stage 2 or 3 acute kidney injury, major vascular complications, paravalvular aortic regurgitation, valve performance and durability, myocardial infarction, re-operation for valve-related dysfunction, rehospitalization for valve-related symptoms or worsening congestive heart failure, new permanent pacemaker implantation, new-onset atrial fibrillation, functional status as evaluated by New York Heart Association (NYHA) Class 5-meter gait speed test at 1 year, and health status as evaluated by Kansas City Cardiomyopathy Questionnaire (KCCQ) and SF-12 Quality of Life questionnaire at 1, 3, and 5 years.

You must conduct one post-approval study (PAS) and participate in an active surveillance plan as described below:

1. **Continued Follow-Up of the REPRISE III Trial Premarket Cohorts:** This study should be conducted in accordance with protocol version AK dated October 6, 2017. The study will consist of all living subjects who were enrolled in the REPRISE III randomized, roll-in, continued access, and nested registry cohorts under the IDE. Subject follow-up will continue for all cohorts based on the timelines and assessments stipulated in the IDE protocol.

   The objective of this PAS is to characterize the clinical outcomes annually through 5 years post-procedure. Data will be collected per the study protocol, including, but not limited to, the following key safety and effectiveness endpoints: all-cause mortality, all-cause and disabling stroke, life-threatening and major bleeding events, stage 2 or 3 acute kidney injury, major vascular complications, paravalvular aortic regurgitation, valve performance and durability, myocardial infarction, re-operation for valve-related dysfunction, rehospitalization for valve-related symptoms or worsening congestive heart failure, new permanent pacemaker implantation, new-onset atrial fibrillation, functional status as evaluated by New York Heart Association (NYHA) Class 5-meter gait speed test at 1 year, and health status as evaluated by Kansas City Cardiomyopathy Questionnaire (KCCQ) and SF-12 Quality of Life questionnaire at 1, 3, and 5 years.

2. **Registry-Based Real-World Use Surveillance of the LOTUS Edge™ Valve System for the “High Risk and above” Indication:** You have agreed to work with the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (TVT) Registry to ensure Surveillance of the LOTUS Edge™ Valve System for the “High Risk and above” Indication. You have agreed to work with the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (TVT) Registry to ensure Surveillance of the LOTUS Edge™ Valve System for the “High Risk and above” Indication. You have agreed to work with the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (TVT) Registry to ensure Surveillance of the LOTUS Edge™ Valve System for the “High Risk and above” Indication.
patients through 5 years post implantation (follow-up period). This surveillance will monitor the following: (1) device success (intra-procedure); (2) all-cause mortality, all stroke, life-threatening/major bleeding, new requirement for dialysis, peri-procedural myocardial infarction, and repeat procedure for valve-related dysfunction (surgical or interventional therapy) at 30 days and 12 months; (3) neurological (non-stroke), vascular complications, and quality of life (KCCQ) outcomes at 30 days and 12 months; and (4) all-cause mortality, all stroke, and repeat procedure for valve-related dysfunction (surgical or interventional therapy) at 2-5 year post implantation.

You are required to submit a progress report every six months for this surveillance during the first two years of the study, and annually thereafter.

Note: Remaining standard FDA regulatory language truncated for brevity. For full approved order, see https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180029A.pdf.

Sincerely,
Nicole G. Ibrahim-S
for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health
WITHDRAWN

Sincerely yours,

[Signature]

for

[Name]

[Title]

[Division]

[Department]

[Address]

[City, State, Zip]

[Phone]

[Email]

Enclosure

Page 2 - Niall Fox

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807), labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1090.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesYouIndustry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Parts 800-898), please go to http://www.fda.gov/MedicalDevices/Safety/ReportProblems/default.htm for the CDER’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesYouIndustry/default.htm.

Sincerely yours,

[Signature]

for

[Name]

[Title]

[Division]

[Department]

[Address]

[City, State, Zip]

[Phone]

[Email]

Enclosure

Page 2 - Niall Fox

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807), labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1090.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesYouIndustry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Parts 800-898), please go to http://www.fda.gov/MedicalDevices/Safety/ReportProblems/default.htm for the CDER’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesYouIndustry/default.htm.

Sincerely yours,

[Signature]

for

[Name]

[Title]

[Division]

[Department]

[Address]

[City, State, Zip]

[Phone]

[Email]

Enclosure

PRESCRIPTIVE INFORMATION

LOTUS™ Valve System

Intended use/Indications for use: The LOTUS Edge Valve System is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis (aortic valve area [AVA] of ≤ 1.0 cm² or index of ≤ 0.6 cm²/m²) who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality >38% at 30 days, based on the Society of Thoracic Surgeons [STS] risk score and other clinical comorbidities unmeasured by the STS risk calculator).

Contraindications: • Non-calcified aortic annulus. • Active systemic infection, sepsis or endocarditis. • Known hypersensitivity to contrast agents that cannot be adequately pre-medicated, or has known hypersensitivity or contraindication to aspirin, thienopyridines, heparin, nickel, titanium, tantalum, bovine-derived materials or polyurethanes. • Severe aortic valvular insufficiency or failure. • Severe calcification of ostia, coronary arteries or aorta. • Hypertrophic obstructive cardiomyopathy. • Hypertrophic obstructive cardiomyopathy. • Echocardiographic evidence of intracardiac mass, thrombus, or vegetation. • Blood dyscrasias defined as: leukopenia (WBC<4000 cells/mm³), acute anemia (Hgb<8g/dL), thrombocytopenia (platelet count <50,000 cells/mm³), history of bleeding diathesis or coagulopathy. • Pre-existing prosthetic heart valve or prosthetic ring in any position. • Key considerations for coronary artery obstruction. • End-stage renal disease or has GFR<20 based on Cockcroft-Gault formula. • Severe (≥4+), aortic, tricuspid, or mitral regurgitation. • Mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation >3+). • Perform balloon aortic valvuloplasty (BAV) with an appropriately sized balloon prior to delivery of the valve to the aortic annulus at the discretion of the implanting physician. • Partial reshaping (and subsequent unshaping) can be performed an unlimited number of times during any phase of the procedure prior to valve release. Valve may be completely reshatched (past the post markers) once during the procedure at any phase prior to valve release. If a second full resheathing becomes necessary, exchange the device. • Potential Adverse Events: Adverse events (in alphabetical order) potentially associated with transcatheter aortic valve implantation (including standard cardiac catheterization, BAV) and the use of anesthesia as well as additional risks related to the use of the LOTUS Edge Valve System: • Abnormal lab values (including electrolyte imbalance) • Access site complications (including arteriovenous [AV] fistula, hematoma or lymphatic problems) • Allergic reaction (including to medications, anesthesia, contrast, or device materials, including nickel; stannum, tantalum, bovine-derived materials or polyurethanes) • Anemia • Angina • Atrial fibrillation or new conduction system injury (including need for pacemaker insertion) • Bleeding or hemodynamic (possibly requiring transfusion or additional procedures) • Cardiac arrest • Cardiac failure (including left ventricular failure, cardiovascular accident, stroke, transient ischemic attack or cerebral infarction including asymptomatic neuroimaging findings) • Coronary obstruction • Death • Device embolization, migration or malposition • Embolization (including air, tissue, thrombus, device materials or drug elution) • Emboli (including air, tissue, thrombus, device materials or drug elution) • Endocarditis • Fever or inflammation • Heart failure • Hypertension or other complications • Hypotension or hypotension • Hypothermia • Intravascular catheterization • Iodinated contrast • Ischemia or infarction • Kidney failure • Liver failure • Mitral valve insufficiency • Myocardial infarction • Myocardial ischemia or infarction or other complications • Nerve injury or neurologic deficits (including encephalopathy) • Pain • Pericardial effusion or tamponade • Peripher al ischemia or infarction • Permanent pacemaker insertion • Pulmonary edema • Renal insufficiency or failure or respiratory insufficiency or failure • Restenosis (including pseudoaneurysm) • Type B dissection • Valve dysfunction • Valve or device thrombosis • Valvular stenosis or regurgitation (central or paravalvular) • Vessel injury (including spasm, trauma, dissection, perforation, rupture, pseudoaneurysm or arteriovenous fistula). As a result of these adverse events, the subject may require medical, percutaneous or surgical intervention, including re-operation and replacement of the valve. These events may lead to fatal outcomes.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

92366617-AA
LOTUS Introducer Set

Intended use/Indications for use: The LOTUS Introducer Set is intended to provide percutaneous femoral access to the vascular system.

Contraindications: Severe iliofemoral tortuosity or calcification that would prevent safe placement of the introducer sheath.

Warnings: • Only those physicians who are trained in intravascular percutaneous procedures should use this device.  
• After use, dispose of product and packaging in accordance with hospital administrative and/or local government policy.

Precautions: Before using this device please note the following: 1. The sterile package of the LOTUS Introducer Set should be inspected prior to use. If sterility or integrity of the package is suspect or compromised, the product should not be used. 2. All patients should receive antiplatelet and/or anticoagulant therapy appropriate to their condition at the discretion of their physician. 3. Do not use if labeling is incomplete or illegible. 4. No component of the LOTUS Introducer Set should be resterilized. 5. Do not insert or remove device if resistance is noted. 6. Do not attempt advancement without a guidewire. Severe vascular damage and/or injury may occur. 7. When puncturing, suturing or incising the tissue near the LOTUS Introducer Set, use caution to avoid damaging the Lotus Introducer Set.

Potential Adverse Events: Potential adverse events include but are not limited to: • air embolism • hemorrhage • infection • injury to the vascular introduction site • procedural discomfort • thromboembolism • thrombosis • tissue trauma • vessel perforation or dissection

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete “Directions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

National Coverage Determination (NCD)
The Centers for Medicare & Medicaid Services (CMS) covers transcatheter aortic valve replacement (TAVR) under Coverage with Evidence Development (CED) for the treatment of symptomatic aortic valve stenosis furnished according to a Food and Drug Administration (FDA)-approved indication and when all of the conditions outlined in the NCD are met. Most TAVR patients are Medicare beneficiaries. Below are highlights of the National Coverage Determination (NCD) that CMS implemented in 2013 for TAVR procedures. Note, this NCD is under revision and will be updated in 2019. For private payers, coverage varies by payer policy. Check with local payers for specifics.

Highlights of the current Medicare NCD include:

• All Medicare beneficiaries are covered, but coverage varies for Medicare Advantage plans
• There are procedure volume requirements for hospitals and physicians to meet in order to gain/maintain Medicare coverage and start/continue to offer a TAVR program
• Participation in the TVT and NCDR registries is mandatory
• The heart team must be involved in all cases. It includes at least two physicians, an interventional cardiologist and a cardiovascular surgeon as well as other members

Hospital Coding and Payment
Based on CMS billing instructions and the NCD, physician and hospital claims must include a number of items in order to be processed appropriately. Please refer to the Boston Scientific 2019 Billing and Coding Guide for TAVR Procedures or check with your local Medicare Contractor for more details.

2019 Most Common MS–DRG Assignments for TAVR Procedures

<table>
<thead>
<tr>
<th>MS–DRG</th>
<th>Definition</th>
<th>MS–DRG National Base Rate Payment Amounts</th>
</tr>
</thead>
<tbody>
<tr>
<td>MS–DRG 266</td>
<td>Endovascular cardiac valve replacement with Major Complication or Comorbidity (MCC)</td>
<td>$43,935</td>
</tr>
<tr>
<td>MS–DRG 267</td>
<td>Endovascular cardiac valve replacement without Major Complication or Comorbidity (MCC)</td>
<td>$35,727</td>
</tr>
</tbody>
</table>

2019 Most Common ICD–10 PCS Codes

<table>
<thead>
<tr>
<th>ICD-10-PCS</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>02RF38Z</td>
<td></td>
</tr>
</tbody>
</table>

2. Estimate based on AHDI HCOP data www.QICnet.ahrq.gov
## Physician Coding and Payment

### Common CPT® Codes for TAVR Procedures, 2019 Payment Rates

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>CPT® Code Description</th>
<th>Physician In-Hospital Payment</th>
<th>Work RVU</th>
<th>Total RVU</th>
</tr>
</thead>
<tbody>
<tr>
<td>33861 Aortic</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach</td>
<td>$1,423</td>
<td>26.13</td>
<td>39.48</td>
</tr>
<tr>
<td>33862 Aortic</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach</td>
<td>$1,553</td>
<td>27.52</td>
<td>43.10</td>
</tr>
<tr>
<td>33863 Aortic</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach</td>
<td>$1,609</td>
<td>28.50</td>
<td>44.64</td>
</tr>
<tr>
<td>33864 Aortic</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach</td>
<td>$1,663</td>
<td>30.00</td>
<td>46.14</td>
</tr>
<tr>
<td>33865 Aortic</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach</td>
<td>$1,886</td>
<td>33.12</td>
<td>51.83</td>
</tr>
<tr>
<td>33866 Aortic</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical approach (e.g., median sternotomy, mediastinotomy)</td>
<td>$2,019</td>
<td>35.88</td>
<td>56.03</td>
</tr>
<tr>
<td>+33867 Aortic</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (e.g., femoral vessels) (list separately in addition to code for primary procedure)</td>
<td>$659</td>
<td>11.68</td>
<td>18.29</td>
</tr>
<tr>
<td>+33868 Aortic</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (e.g., femoral, iliac, axillary vessels) (list separately in addition to code for primary procedure)</td>
<td>$783</td>
<td>14.39</td>
<td>21.72</td>
</tr>
<tr>
<td>+33869 Aortic</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (e.g., aorta, right atrium, pulmonary artery) (list separately in addition to code for primary procedure)</td>
<td>$1,033</td>
<td>19.00</td>
<td>26.67</td>
</tr>
<tr>
<td>33477 Pulmonary Valve</td>
<td>Transcatheter pulmonary valve implantation, percutaneous approach, including pre-atenting of the valve delivery site, when performed</td>
<td>Carrier priced</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>33999</td>
<td>Unlisted procedure, cardiac surgery</td>
<td>Carrier priced</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>33418</td>
<td>Transcatheter mitral valve repair; percutaneous approach, including transseptal puncture when performed; initial prosthesis</td>
<td>$1,888</td>
<td>32.25</td>
<td>52.39</td>
</tr>
<tr>
<td>+33419</td>
<td>Transcatheter mitral valve repair; percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure)</td>
<td>$446</td>
<td>7.99</td>
<td>12.37</td>
</tr>
</tbody>
</table>

### Paravalvular Leak Repair

<table>
<thead>
<tr>
<th>CPT® Code</th>
<th>Physician In-Hospital Payment</th>
<th>Work RVU</th>
<th>Total RVU</th>
</tr>
</thead>
<tbody>
<tr>
<td>93590</td>
<td>Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve</td>
<td>$1,124</td>
<td>21.70</td>
</tr>
<tr>
<td>93591</td>
<td>Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, aortic valve</td>
<td>$926</td>
<td>17.97</td>
</tr>
<tr>
<td>93592</td>
<td>Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (List separately in addition to code for primary procedure)</td>
<td>$410</td>
<td>8.00</td>
</tr>
</tbody>
</table>

*Note: The Medicare reimbursement amounts shown are currently published national base rate payment amounts. Actual reimbursement will vary for each provider and institution for a variety of reasons including geographic differences in labor and non-labor costs, hospital teaching status, proportion of low-income patients, coverage, and/or payment rules.

### Coding & Reimbursement Support

Boston Scientific is dedicated to providing physicians, allied health professionals, and hospitals with world-class programs and services to help advance the standard of patient care and appropriate access to life-enhancing technologies. For questions regarding TAVR procedure reimbursement, please contact:

- **Email:** IC.Reimbursement@bsci.com
- **Vicemail:** 1 IRDI CARDIAC, and request extension 24114 to leave a message.

**IMPORTANT**—Note: The Medicare reimbursement amounts shown are currently published national base rate payment amounts. Actual reimbursement will vary for each provider and institution for a variety of reasons including geographic differences in labor and non-labor costs, hospital teaching status, proportion of low-income patients, coverage, and/or payment rules.

**Disclaimer**

Note: This coding information may include codes for procedures for which Boston Scientific currently offers no cleared or approved products. In those instances, such codes have been included solely in the interest of providing users with comprehensive coding information and are not intended to promote the use of any Boston Scientific products for which they are not cleared or approved.

Health economic and reimbursement information provided by Boston Scientific Corporation is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules and policies. This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice. Boston Scientific encourages providers to submit accurate and appropriate claims for services. It is always the provider’s responsibility to determine medical necessity, the proper site for delivery of any services and to submit appropriate codes, charges, and modifiers for services that are rendered. Boston Scientific recommends that you consult with your payers, reimbursement specialists, and/or legal counsel regarding coding, coverage, and reimbursement matters. It is always the provider’s responsibility to understand and comply with national coverage determinations (NCD), local coverage determinations (LCD) and any other coverage requirements established by relevant payers which can be updated frequently.

**CPT® Copyright 2018 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DIFARS Restrictions Apply to Government Use. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.**
Boston Scientific has a very comprehensive TAVR clinical program, including multiple studies that follow more than 2,000 patients. Through this clinical program, we are focused on demonstrating that the LOTUS valve platform offers outstanding clinical data.

**LOTUS™ Valve showed superiority** to Evolut™ R / CoreValve™ Platform in the primary effectiveness endpoint at 1 year and non-inferiority in the primary safety endpoint at 30 days.

**PVL**

The LOTUS Valve showed *Superior PVL Performance* with significantly lower Moderate PVL than the Evolut R / CoreValve Platform. 0.9% vs 6.9% (*P* < 0.001 at 1 year).

**STROKE**

The LOTUS Valve showed *Superior Disabling Stroke Outcomes* with a significantly lower disabling stroke rate than the Evolut R / CoreValve Platform. 3.6% vs 7.1% (*P* = 0.02 at 1 year).

**TAV in TAV**

The LOTUS Valve showed *Superior Procedural Outcomes* with significantly lower rates than the Evolut R / CoreValve Platform. 0% vs 2.6% Malpositioning (*P* < 0.001) 0% vs. 3.0% TAV in TAV (*P* < 0.001)

LOTUS has consistently demonstrated surgical-like PVL rates in clinical studies. The latest data presented on LOTUS Edge shows a 97.1% rate of None / Trace PVL, as presented at PCR London Valves 2018.

- Mild PVL was associated with increased all-cause and cardiovascular mortality after TAVR
- Lower PVL rates may delay the onset of heart failure and reduce readmissions

In the REPRISE III High Calcium Cohort, the LOTUS Valve platform had significantly lower PVL than Evolut R / CoreValve in patients with high calcium burden. This data is consistent with the superior PVL performance of LOTUS in the broader REPRISE III Trial.
**ECONOMIC VALUE**

**Low Complication Rates in REPRISE III Clinical Trial**
- Highly calcified annuli: Adaptive Seal™ supports improved outcomes
- Low EF patients: No rapid pacing required and improved hemodynamic stability

**Predictability and Control**
- 0% malpositioning in REPRISE trials
- Valve functionality can be assessed prior to release

**Differentiated Patient Outcomes**

**Enabling TAVR programs to...**
- Improve Financial Health
- Enhance Patient Experience
- Strengthen Quality Outcomes
- Increase Operational Efficiencies

**ORDERING INFORMATION**

<table>
<thead>
<tr>
<th>Products (sold together)</th>
<th>LOTUS Edge™ Aortic Valve System</th>
<th>LOTUS™ Introducer Set</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Boston Scientific</td>
<td>Boston Scientific</td>
</tr>
<tr>
<td>Manufacturer federal tax ID</td>
<td>04 069 5240</td>
<td>04 069 5240</td>
</tr>
<tr>
<td>Will this product replace or supplement a current Boston Scientific product?</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Is this item/technology on contract with GPOs and/or IDNs?</td>
<td>Please speak to your Boston Scientific sales representative for the contract status of specific GPOs and IDNs.</td>
<td></td>
</tr>
<tr>
<td>Order units (sold together)</td>
<td>1 valve and 1 delivery system</td>
<td>1 sheath</td>
</tr>
<tr>
<td>Mode of transportation</td>
<td>FedEx for standard inventory shipments; CH Robinson to facilitate inventory transfers (managed entirely by BSC sales team).</td>
<td></td>
</tr>
<tr>
<td>Minimum order quantity</td>
<td>Will be available on consignment. Please speak to your Boston Scientific sales representative for consignment quantities.</td>
<td></td>
</tr>
<tr>
<td>Lead shipping time in working days</td>
<td>2-day shipping will be standard; overnight shipping available as needed.</td>
<td></td>
</tr>
<tr>
<td>Shipping carton dimensions</td>
<td>PTG Thermo Shipping Box: 56lbs, 38.25” × 24” × 11”</td>
<td>NA</td>
</tr>
<tr>
<td>Product packaging dimensions</td>
<td>34” × 19” × 9.5”</td>
<td>23.5” × 7” × 1”</td>
</tr>
<tr>
<td>Last price (sold together)</td>
<td>Please speak to your Boston Scientific sales representative for the price per each unit.</td>
<td></td>
</tr>
<tr>
<td>Workstation storage considerations</td>
<td>Store at 25°C (77°F); excursions permitted from 15°C – 30°C (59°F – 86°F). Device shipping conditions must be maintained between 2°C – 40°C (35.6°F – 104°F). Use products prior to the ‘Use By’ date on package label.</td>
<td>Store in a cool, dry, dark place.</td>
</tr>
<tr>
<td>Shelf life</td>
<td>9 months</td>
<td>2 years</td>
</tr>
<tr>
<td>What department(s) will use and/or be affected by this product?</td>
<td>Operating Room, Cardiology Suite, and Purchasing</td>
<td></td>
</tr>
<tr>
<td>Will there be additional implementation costs, such as installation, cost of education, impact on equipment or additional space?</td>
<td>No additional costs will be incurred by customers; however Boston Scientific is required to provide product training and proctoring to implanters and procedure teams prior to independent use.</td>
<td></td>
</tr>
<tr>
<td>Will this product require evaluation by any of the following departments?</td>
<td>Epidemiology/Infection Control? No</td>
<td>Safety and Security? No</td>
</tr>
<tr>
<td>Does this item and its packaging contain latex?</td>
<td>There is no detectable latex in this product.</td>
<td></td>
</tr>
</tbody>
</table>
More Paths Forward

Empowering physicians with a portfolio of transcatheter Structural Heart valvular therapies, offering more paths to predictable procedures and optimized outcomes.

TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

CEREBRAL EMBOLIC PROTECTION

TRANSCATHETER MITRAL VALVE REPAIR

LOTUS Edge™

ACURATE neo™

SENTINEL™

MILLIPEDE

All trademarks are property of their respective owners.
All photographs taken by Boston Scientific.

CAUTION: The Millipede device is for educational purposes only. Not available for sale. The ACURATE neo Aortic Valve System is not available for sale or use in the U.S.

© 2019 Boston Scientific Corporation or its affiliates. All rights reserved.