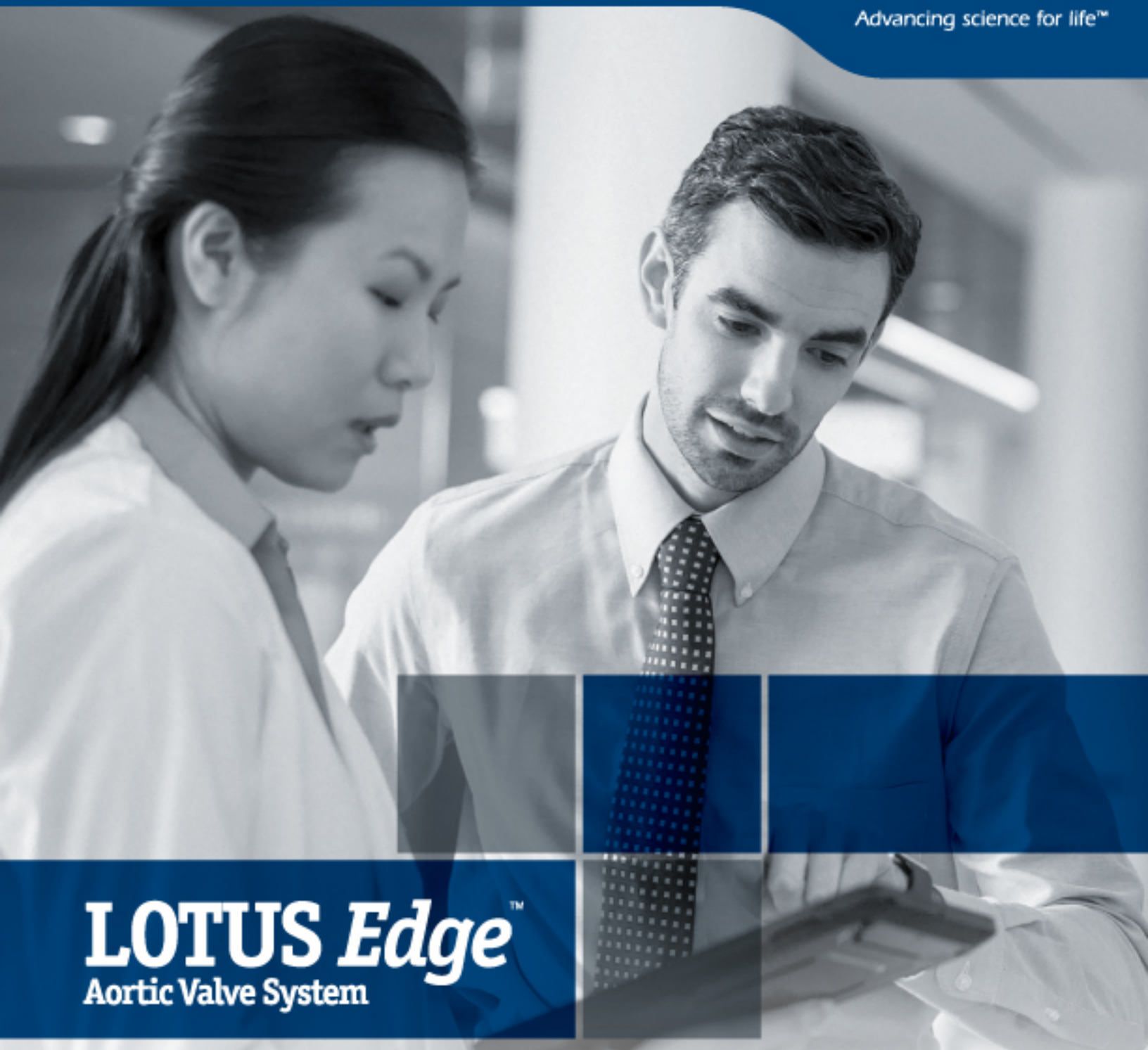
Boston Scientific
Advancing science for life™



LOTUS *Edge*™
Aortic Valve System

for the Hospital Purchasing Committee

CONTENTS

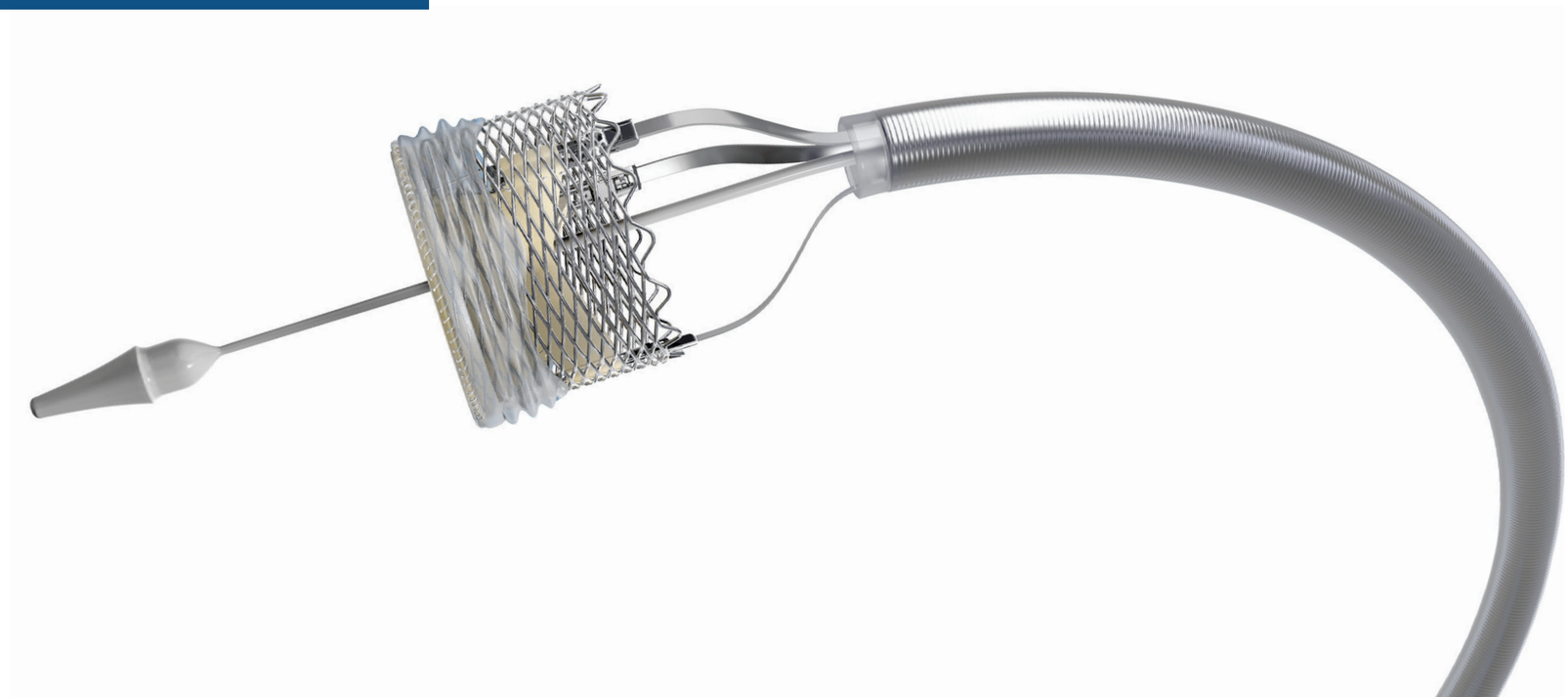
PRODUCT OVERVIEW

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?

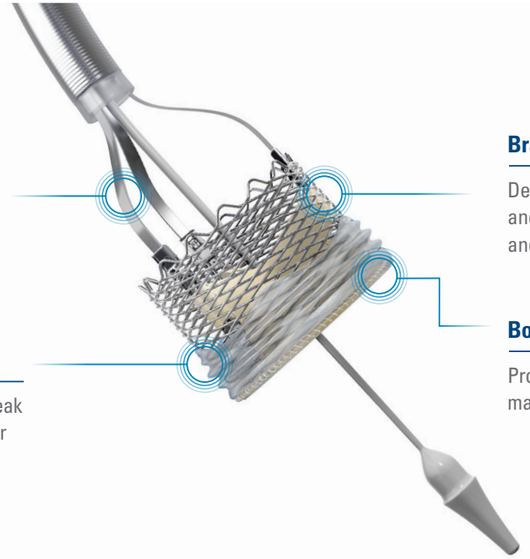
The LOTUS *Edge*™ Aortic Valve System is an intra-annular valve made up of a nitinol wire frame that uses controlled expansion during deployment. It is the only aortic replacement valve on the market that is 100% repositionable, and does not require rapid pacing during delivery and placement. LOTUS *Edge*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



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

TECHNOLOGY OVERVIEW

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.



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

LOTUS *Edge* Aortic Valve System

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

23 mm

25 mm

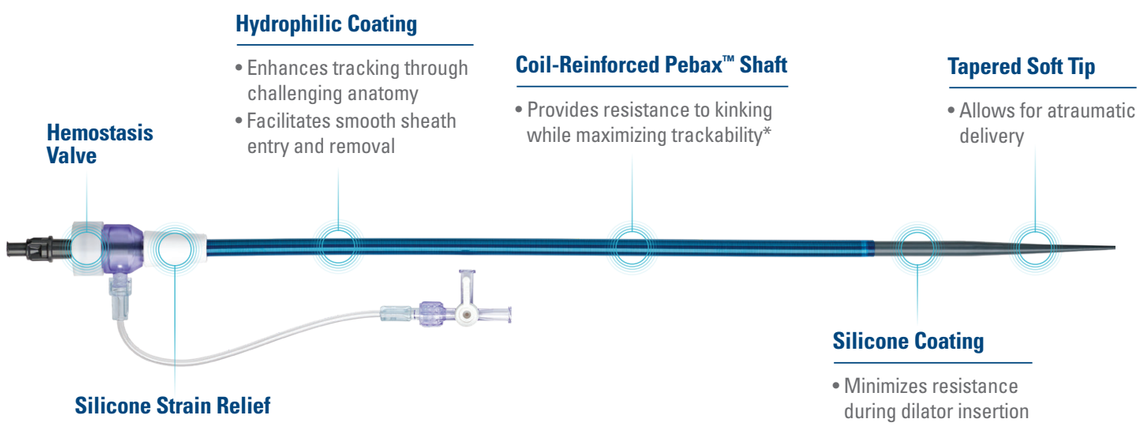
27 mm

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	19 mm	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.



LOTUS Introducer Set (Large)

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

* 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.

REGULATORY INFORMATION

REGULATORY SUMMARY

Regulation Medical Specialty	Cardiovascular
Regulation Description	Transcatheter Aortic Valve Prosthesis
Device Classification Name	Aortic Valve, Prosthesis, Percutaneously Delivered
Trade/Device Name	LOTUS *Edge*™ Valve System
Intended 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 cm^2 or index of ≤ 0.6 cm^2/m^2) 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).
PMA Number	P180029
FDA Classification	Class III (PMA)
Approval Date	April 23, 2019

REGULATORY SUMMARY

Regulation Medical Specialty	Cardiovascular
Regulation Description	Introducer, Catheter
Device Classification Name	Introducer, Catheter
Trade/Device Name	LOTUS Introducer Set
Intended Use	The LOTUS Introducer Set is intended to provide femoral access to the vascular system.
510(K) Number	K140338
Regulation Number	21 CFR 870.1340
FDA Classification	Class II
Approval Date	August 27, 2014

U.S. FOOD & DRUG ADMINISTRATION

April 23, 2019

Boston Scientific Corporation
c/o Julie Eyers
Boston Scientific Limited
Regulatory Affairs Manager
Ballybrit Business Park
Ballybrit, Galway, Ireland

Re: P180029
Trade/Device Name: LOTUS Edge™ Valve System
Product Code: NPT
Filed: August 14, 2018
Amended: October 4, 2018; February 8, 2019

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 cm^2 or index of ≤ 0.6 cm^2/m^2) 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). We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 9 months.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. This report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

In addition to the Annual Report requirements, you must provide the following data in post-approval study (PAS) reports for each PAS listed below. The PAS Progress Reports must be submitted for each study annually, unless otherwise specified by FDA. Each report, identified as a "PMA Post-Approval Study Report" in accordance with how the study is identified below and bearing the applicable PMA reference number, should be submitted to the address below.

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 that FDA surveillance occurs for the LOTUS Edge™ Valve System used for the "high risk and above" indication over the next 2 years (enrollment period). You have also agreed to link the data to Centers for Medicare and Medicaid Services (CMS) database for long-term surveillance of these

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

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 27, 2014

Creganna-Tactx Medical
% Niall Fox
Sr. Regulatory Affairs Specialist
Parkmore West
Galway, Ireland

Re: K140338
Trade/Device Name: Creganna-Tactx Lotus Introducer Set (small), Creganna-Tactx Lotus Introducer Set (large)
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer Catheter
Regulatory Class: Class II
Product Code: DYB
Dated: July 18, 2014
Received: July 23, 2014

Dear Niall Fox,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

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 1000-1050.

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/ResourcesforYou/Industry/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 Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH'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/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

PRESCRIPTIVE INFORMATION

LOTUS *Edge*™ 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 cm^2 or index of ≤ 0.6 cm^2/m^2) who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicated risk of surgical mortality ≥8% at 30 days, based on the Society of ThorWacic 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 arterial tortuosity or calcification that would prevent safe placement of the introducer sheath.

Warnings: • Valve implantation should only be performed in a facility where emergency aortic valve surgery is available. • Do not attempt to place the valve if patient's annulus is outside of the dimensions specified in Table I of the DFU. Patient prosthesis mismatch, valve migration or embolization may lead to severe patient compromise, additional procedures or death.

Precautions: • Device implantation should only be performed by physicians who have completed training with the LOTUS Edge Valve System. • Administer periprocedural antiplatelet and/or anticoagulant therapy at the discretion of the physician consistent with the local standard-of-care. • Safety, effectiveness, and durability have not been established for valve-in-valve procedures. The safety and efficacy of the LOTUS Edge Valve System has not been established in patients with the following characteristics/comorbidities: • Congenital unicuspid or congenital bicuspid aortic valve • Severe ventricular dysfunction with left ventricular ejection fraction <20% • Hypertrophic obstructive cardiomyopathy • Echocardiographic evidence of intracardiac mass, thrombus, or vegetation • Blood dyscrasias defined as: leukopenia (WBC<1000 cells/mm^3, acute anemia (Hgb<9g/dL), thrombocytopenia (platelet count <50,000 cells/mm^3), history of bleeding diathesis or coagulopathy • Pre-existing prosthetic heart valve or prosthetic ring in any position • Any 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 resheathing (and subsequent unsheathing) can be performed an unlimited number of times during any phase of the procedure prior to valve release. Valve may be completely resheathed (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, titanium, tantalum, bovine-derived materials or polyurethanes) • Anemia • Angina • Arrhythmia or new conduction system injury (including need for pacemaker insertion) • Bleeding or hemorrhage (possibly requiring transfusion or additional procedure) • Cardiac arrest • Cardiac failure/low cardiac output • Cerebrovascular accident, stroke, transient ischemic attack or cerebral infarction including asymptomatic neuroimaging findings • Coronary obstruction • Death • Device misplacement, migration or embolization • Emboli (including air, tissue, thrombus or device materials) • Endocarditis • Fever or inflammation • Heart failure • Hemodynamic instability or shock • Hemolysis and/or hemolytic anemia • Hypertension/hypotension • Infection (local and/or systemic) • Mitral valve insufficiency • Myocardial infarction • Myocardial or valvular injury (including perforation or rupture) • Nerve injury or neurologic deficits (including encephalopathy) • Pain • Pericardial effusion or tamponade • Peripheral ischemia or infarction • Permanent disability • Pleural effusion • Pulmonary edema • Renal insufficiency or failure • Respiratory insufficiency or failure • Restenosis (including pannus formation) • Valve dysfunction, deterioration or failure • 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

PRESCRIPTIVE INFORMATION

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 guide-wire. 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.

REIMBURSEMENT INFORMATION

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.[1] Most TAVR patients are Medicare beneficiaries.[2] 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

MS–DRG	Definition	MS–DRG National Base Rate Payment Amounts
MS–DRG 266	Endovascular cardiac valve replacement with Major Complication or Comorbidity (MCC)	$43,935
MS–DRG 267	Endovascular cardiac valve replacement without Major Complication or Comorbidity (MCC)	$35,727

2019 Most Common ICD–10 PCS Codes

ICD–10–PCS	02RF38Z

1. Source: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=355&NCAId=257&NcaName=Transcatheter+Aortic+Valve+Replacement+(TAVR).
2. Estimate based on AHRQ HCUP data www.hcupnet.ahrq.gov.

REIMBURSEMENT INFORMATION

Physician Coding and Payment

Common CPT(R) Codes for TAVR Procedures, 2019 Payment Rates

CPT® Codes	CPT® Code Description	Physician In-Hospital Payment*	*Work* RVU Total RVU
Endovascular or Transthoracic Valves			
33361 *Aortic*	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach	$1,423	*25.13* 39.48
33362 *Aortic*	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach	$1,553	*27.52* 43.10
33363 *Aortic*	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach	$1,609	*28.50* 44.64
33364 *Aortic*	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach	$1,663	*30.00* 46.14
33365 *Aortic*	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (e.g., median sternotomy, mediastinotomy)	$1,868	*33.12* 51.83
33366 *Aortic*	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy)	$2,019	*35.88* 56.03
+33367 *Aortic*	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)	$659	*11.88* 18.29
+33368 *Aortic*	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)	$783	*14.39* 21.72
+33369 *Aortic*	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)	$1,033	*19.00* 28.67
33477 *Pulmonary*	Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed	*Carrier priced*	*0.00* 0.00
33999	Unlisted procedure, cardiac surgery	*Carrier priced*	*0.00* 0.00
33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis	$1,888	*32.25* 52.39
+33419	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)	$446	*7.93* 12.37
Paravalvular Leak Repair			
93590	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve	$1,124	*21.70* 31.20
93591	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, aortic valve	$926	*17.97* 25.70
93592	Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (List separately in addition to code for primary procedure)	$410	*8.00* 11.39

*Inpatient information effective through September 30, 2019 | Physician fee information effective through December 31, 2019.
National base rate Medicare physician payment rates calculated using the 2019 conversion factor of $36.0391.

REIMBURSEMENT INFORMATION

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
Voicemail: 1 (800) CARDIAC, and request extension 24114 to leave a message.
Messages are monitored M–F, 8am–4pm CT. Responses are often on the same or following business day.

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.

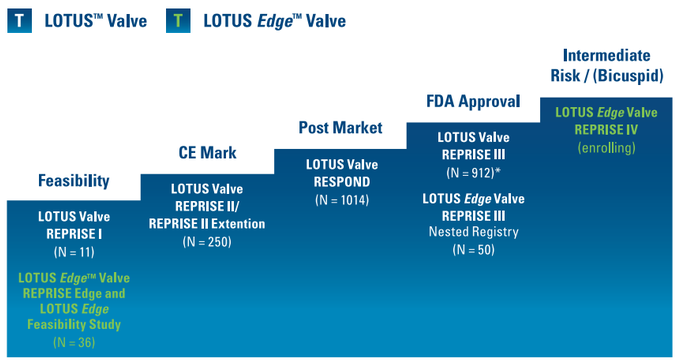
Disclaimer

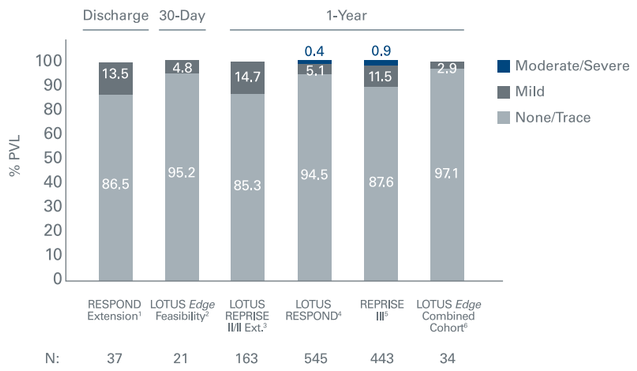
Note: This coding information may include codes for procedures for which Boston Scientific currently offers no cleared or approved products. In those instances, such codes have been included solely in the interest of providing users with comprehensive coding information and are not intended to promote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

CLINICAL SUMMARY

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.





REPRISE III TRIAL RESULTS[5] – 1 YEAR

0.9%	11.5%	87.6%
Moderate or Greater PVL	Mild PVL	None/ Trace PVL

* LOTUS N = 607; CoreValveTM N = 305. 1. Blackman, D., MD. Thirty-day outcomes in patients treated with a repositionable and fully retrievable aortic valve designed to reduce the incidence of conduction disturbances (RESPOND Extension study); EuroPCR 2017; Paris, France. 2. Walters D., MD. First Report of Clinical Outcomes with the Next-Generation LOTUS Edge Valve System: Results from the LOTUS Edge Feasibility Trial; ACC 2017; Washington, DC. 3. Meredith I., MD. Two-year outcomes with a fully repositionable and retrievable percutaneous aortic valve in 250 high surgical risk patients: Results from the REPRISE II trial extended cohort; PCRLV 2016; London, United Kingdom. 4. Van Meighem, N., MD. The RESPOND Study at One-Year: Primary Endpoint Outcomes with a Repositionable and Fully Retrievable Aortic Valve in Routine Clinical Practice; EuroPCR 2017; Paris, France. 5. Feldman TE, et al. Effect of mechanically expanded vs self-expanding transcatheter aortic valve replacement on mortality and major adverse clinical events in high-risk patients with aortic stenosis: the REPRISE III randomized clinical trial. JAMA 2018;319:27-37.

CLINICAL SUMMARY

REPRISE III Trial Overview

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

Differentiated Patient Outcomes

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

Low Complication Rates in REPRISE III Clinical Trial

- 3.6% disabling stroke rate vs. 7.1% with Evolut™ R / CoreValve™ at 12 months, $P = 0.02$
- 0.9% moderate to severe PVL rate vs. Evolut R / 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

Enabling TAVR programs to…

Improve
Financial Health

Enhance
Patient Experience

Strengthen
Quality Outcomes

Increase
Operational Efficiencies

ORDERING INFORMATION

Products (sold together)	LOTUS *Edge*™ Aortic Valve System	LOTUS™ Introducer Set
Manufacturer	Boston Scientific	Boston Scientific
Manufacturer federal tax ID	04 069 5240	04 069 5240
Will this product replace or supplement a current Boston Scientific product?	No	No
Is this item/technology on contract with GPOs and/or IDNs?	Please speak to your Boston Scientific sales representative for the contract status of specific GPSs and IDNs.	
Order units (sold together)	1 valve and 1 delivery system	1 sheath
Mode of transportation	FedEx for standard inventory shipments; CH Robinson to facilitate inventory transfers (managed entirely by BSC sales team).	
Minimum order quantity	Will be available on consignment. Please speak to your Boston Scientific sales representative for consignment quantities.	
Lead shipping time in working days	2-day shipping will be standard; overnight shipping available as needed.	
Shipping carton dimensions	PTG Thermo Shipping Box: 58lbs, 38.25" × 24" × 11"	NA
Product packaging dimensions	34" × 19" × 3.5"	23.5" × 7" × 1"
List price (sold together)	Please speak to your Boston Scientific sales representative for the price per each unit.	
Workstation storage considerations	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.	Store in a cool, dry, dark place.
Shelf life	9 months	2 years
What department(s) will use and/or be affected by this product?	Operating Room, Cardiology Suite, and Purchasing	
Will there be additional implementation costs, such as installation, cost of education, impact on equipment or additional space?	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.	
Will this product require evaluation by any of the following departments?	Epidemiology/Infection Control? No Safety and Security? No	
Does this item and its packaging contain latex?	There is no detectable latex in this product.	

NOTES

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)

LOTUS *Edge*™

ACURATE *neo*™

CEREBRAL EMBOLIC PROTECTION

SENTINEL™

TRANSCATHETER MITRAL VALVE REPAIR

MILLIPEDE

Boston Scientific
Advancing science for life™

Interventional Cardiology
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

To order product or for more information contact customer service at 1.888.272.1001.

SH-632609-AA

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.