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LOTUS Edge™
Aortic Valve System

	CT Measurements for Patient Screening	 23 mm	 25 mm	 27 mm
Valve	Diameter (mm)	23	25	27
	Perimeter (mm)	72.3	78.5	84.8
	Area (mm^2)	415.5	490.9	572.6
Annulus	Diameter (mm)	20 ≤ ideal ≤ 23	23 ≤ ideal ≤ 25	25 ≤ ideal ≤ 27
	Perimeter (mm)	62.8 ≤ ideal ≤ 72.3	72.3 ≤ ideal ≤ 78.5	78.5 ≤ ideal ≤ 84.8
	Area (mm^2)	314.0 ≤ ideal ≤ 415.5	415.5 ≤ ideal ≤ 490.9	490.9 ≤ ideal ≤ 572.6
LVOT	Diameter (mm)	20 ≤ ideal ≤ 23	23 ≤ ideal ≤ 25	25 ≤ ideal ≤ 27
	Perimeter (mm)	62.8 ≤ ideal ≤ 72.3	72.3 ≤ ideal ≤ 78.5	78.5 ≤ ideal ≤ 84.8
	Area (mm^2)	314.0 ≤ ideal ≤ 415.5	415.5 ≤ ideal ≤ 490.9	490.9 ≤ ideal ≤ 572.6
	Unsuitable area (mm^2)	< 280	< 330	< 390
SOV	Area too small (mm^2)	< 540	< 595	< 650
	Ideal area (mm^2)	> 600	> 700	> 800
	Area too large (mm^2)	> 1100	> 1200	> 1300
Coronary Height	Height (mm)	Caution if < 10 mm; need to also consider sinus area		

Prior to use, review full DFU for operating instructions.

The LOTUS™ Introducer Set is manufactured by Creganna Medical and distributed by Boston Scientific.
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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 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 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.

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