Boston Scientific
Advancing science for life™

SENTINEL™
Cerebral Protection System

HOSPITAL REIMBURSEMENT GUIDELINES

The SENTINEL Cerebral Protection System (CPS) is a percutaneously delivered embolic protection device, designed to protect the brain from injury caused by embolic debris dislodged while performing TAVR (transcatheter aortic valve replacement) procedures.

This guide has been developed as a resource for individuals seeking a better understanding of hospital reimbursement for services rendered to patients who receive SENTINEL CPS in conjunction with a transcatheter aortic valve replacement (TAVR). We strongly suggest that you consult your payer organizations with regard to local coverage, coding and reimbursement policies.

The Centers for Medicare & Medicaid Services (CMS) has approved the SENTINEL CPS for a new technology add-on payment (NTAP) as part of the FY 2019 Inpatient Prospective Payment System (IPPS) final rule. The NTAP payment will become effective for discharges on or after October 1, 2018. Hospitals must use the existing SENTINEL CPS ICD-10-PCS code below (X2A5312) when SENTINEL CPS is used in TAVR procedures in order to be eligible for the NTAP payment.

There is not a new CPT-code for the use of SENTINEL CPS. HCPCS code C1884 (Embolization Protective System) may be used when appropriate.

HCPCS CODE	
C1884	Embolization Protective System

To comply with Medicare and third-party payer requirements, all hospital claim forms must indicate the International Classification of Diseases, 10th Revision (ICD-10) codes that identify diagnoses, symptoms, conditions, problems, complaints, or other reason(s) for the encounter/visit. Partial list of common diagnoses for patients who may require a TAVR include:

ICD-10-CM DIAGNOSIS CODES	
I35.0	Nonrheumatic aortic (valve) stenosis
I06.0	Rheumatic aortic stenosis

ICD-10 codes that may be used to describe TAVR and the use of SENTINEL CPS procedures:

ICD-10-PCS PROCEDURE CODES	
X2A5312	Cerebral Embolic Filtration, Dual Filter in Innominate Artery and Left Common Carotid Artery, Percutaneous Approach, New Technology Group 2
02RF38H	Replacement of Aortic Valve with Zooplastic Tissue, Transapical, Percutaneous Approach
02RF38Z	Replacement of Aortic Valve with Zooplastic Tissue, Percutaneous Approach
02RF3KH	Replacement of Aortic Valve with Nonautologous Tissue Substitute, Transapical, Percutaneous Approach
02RF3KZ	Replacement of Aortic Valve with Nonautologous Tissue Substitute, Percutaneous Approach

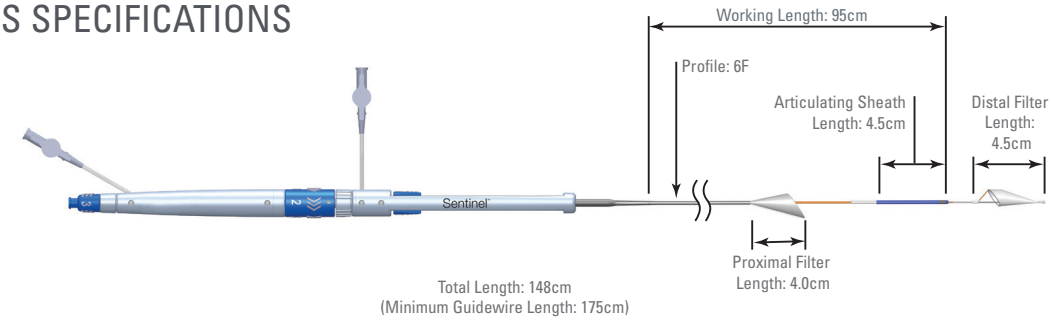
Below are typical MS-DRGs assuming TAVR with the SENTINEL CPS are the only procedures. If the patient receives additional procedures the DRG assignment may be different.

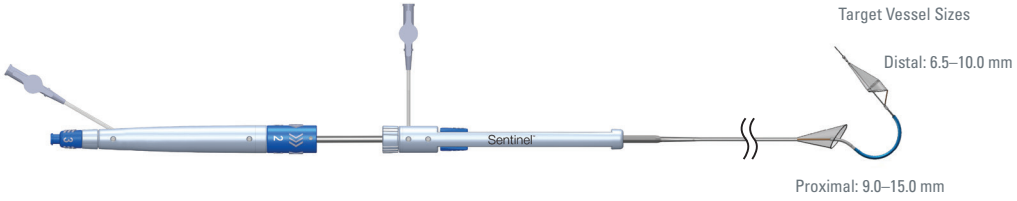
MS-DRG	MS-DRG Description*
266	Endovascular Cardiac Valve Replacement w MCC
267	Endovascular Cardiac Valve Replacement w/o MCC

*MCC = Major complication or co-morbidity

See page 2 for important information about the uses and limitations of this document.

SENTINEL™ CPS SPECIFICATIONS





INDICATIONS FOR USE

The SENTINEL Cerebral Protection System is indicated for use as an embolic protection device to capture and remove thrombus/debris while performing transcatheter aortic valve replacement procedures. The diameters of the arteries at the site of filter placement should be between 9–15 mm for the brachiocephalic and 6.5–10 mm in the left common carotid.

ORDERING INFORMATION

REF (Model) Number for Ordering	Proximal Filter Size (mm)	Target Proximal Vessel Size (mm)	Distal Filter Size (mm)	Target Distal Vessel Size (mm)
CMS15-10C-US	15	9–15	10	6.5–10

HCPCS code C1884 (Embolization protective system) may be used when appropriate.
ICD-10-PCS Procedure code X2A5312 (Cerebral Embolic Filtration, Dual Filter in Innominate Artery and Left Common Carotid Artery, Percutaneous Approach, New Technology Group 2) may be used to describe TAVR and the use of SENTINEL Cerebral Protection System procedures.

Important Information

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. Boston Scientific does not promote the use of its products outside their FDA-approved label.

Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

SENTINEL Cerebral Protection System (CPS)
INDICATIONS FOR USE: The Sentinel Cerebral Protection System is indicated for use as an embolic protection device to capture and remove thrombus/debris while performing transcatheter aortic valve replacement procedures. The diameters of the arteries at the site of filter placement should be between 9 – 15 mm for the brachiocephalic and 6.5 – 10 mm in the left common carotid. CONTRAINDICATIONS • Do not use in patients for whom anticoagulant and antiplatelet therapy is contraindicated. • Do not use in patients with a known hypersensitivity to nickel-titanium. • Do not use in vessels with excessive tortuosity. • Do not use in patients with uncorrected bleeding disorders. • Do not use in patients with compromised blood flow to the right upper extremity. • Do not use in patients who have arterial stenosis >70% in either the left common carotid artery or the brachiocephalic artery. • Do not use in patients whose brachiocephalic or left carotid artery reveals significant stenosis, ectasia, dissection, or aneurysm at the aortic ostium or within 3cm of the aortic ostium. WARNINGS • Carefully read all instructions and labeling prior to use. Observe all warnings, cautions, and precautions noted throughout these instructions. Failure to do so may result in complications. • Refer to the instructions for use supplied with any interventional devices to be used in conjunction with the Sentinel System for their intended uses, sizing, warnings, and precautions. • The safety and effectiveness of the Sentinel System have not been demonstrated with transcatheter aortic valves other than the SAPIEN XT, SAPIEN 3, CoreValve® , and CoreValve® Evolut R® . • The appropriate antiplatelet/anticoagulation therapy should be administered pre- and post-procedure in accordance with standard medical practice. • Prior to use, the packaging and product should be inspected for signs of damage. Never use a damaged product or product from a damaged package. • Never advance or withdraw the Sentinel System without proper fluoroscopic guidance or against resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage. • It is recommended that the patency of the right radial or brachial artery be assessed prior to the introduction of the Sentinel System. • It is recommended that the patient be tested for occlusion of the radial or brachial artery prior to device introduction. • Do not use the device in left radial or left brachial access. • Do not use the Sentinel System to deliver any type of fluid to the patient e.g. contrast media, heparinized saline, etc. due to risk of air embolization and comprise to device performance. • Minimize movement of the Sentinel System after initial placement and stabilize the patient's right arm by their side. Excessive movement of filters may lead to embolization of debris, vessel and/or device damage. • Do not deploy the filters within a previously repaired artery, an artery that has been used for dialysis purposes, or AV fistula. • Observe the Sentinel System under fluoroscopy and monitor the patient to verify the filters have not become occluded with debris resulting in slow or no flow. The filters should be recovered if they become occluded or if flow is compromised (See Procedural Use – Retrieval). • Indwell time of the Sentinel System is not to exceed 90 minutes as occlusion could occur, resulting in slow or no flow. • Failure to adequately close off the Flush Ports (Front Handle, Rear Handle) may result in air embolism. • Do not undersize or oversize the filters in relation to the selected vessel diameter. This may result in inadequate vessel wall apposition or incomplete deployment of the filters. (Refer to Sizing Guide, Table 1 in IFU). • Do not apply excessive force to the Sentinel System. This may lead to distal embolization of debris, and vessel and/or device damage. PRECAUTIONS • Do not forcefully bend or reshape the Articulating Sheath of the Sentinel System. This may cause device damage. • A guidewire with excessive stiffness may alter the shape of the Articulating Sheath curve and make cannulation of the left common carotid difficult. • Use of a guidewire with an intermediate coil may result in compromised guidewire movement. • Improper bending of the Sentinel System may damage the catheter. • Do not re-sterilize or reuse on another vessel or patient. ADVERSE EVENTS Possible adverse events associated with Sentinel System use and application procedure include, but are not limited to, the following:
• Access site complications • Angina • Aortic dissection • Arrhythmia • Arteriovenous fistula • Atelectasis • Bleeding, operative or post-operative • Cardiac Tamponade • Cardiogenic Shock • Conduction system injury • Congestive Heart Failure (CHF) • Death • Endocarditis • Embolism, including air • Gastrointestinal (GI) bleed • Hematoma • Ischemia (coronary, limb, carotid) • Infection (local or systemic) • Myocardial Infarction (MI) • Nerve injury • Pericardial effusion • Pneumonia • Pulmonary edema • Pulmonary embolism • Respiratory failure • Respiratory insufficiency • Stroke • Vessel injury (e.g., dissection, rupture, perforation, pseudoaneurysm) Adverse events experienced during clinical studies are presented in the Clinical Study Overview section of the Instructions For Use (IFU). Rx Only, CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Boston Scientific
Advancing science for life™

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

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

SH-583808-AA