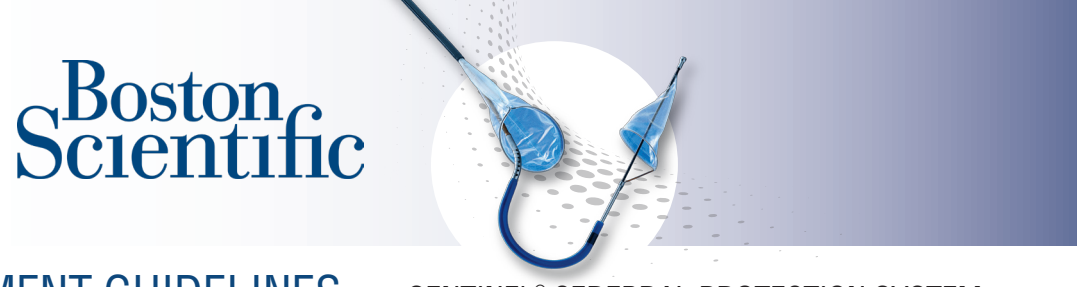


HOSPITAL REIMBURSEMENT GUIDELINES

SENTINEL® CEREBRAL PROTECTION SYSTEM

The Sentinel Cerebral Protection System is a percutaneously delivered embolic protection device, designed to protect the brain from injury caused by embolic debris dislodged during endovascular procedures.

This guide has been developed to assist you in obtaining the appropriate hospital reimbursement for services rendered to patients who receive the Sentinel System 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 Cerebral Protection System 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 ICD-10-PCS code below (X2A5312) when Sentinel 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. 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 Cerebral Protection System procedures:

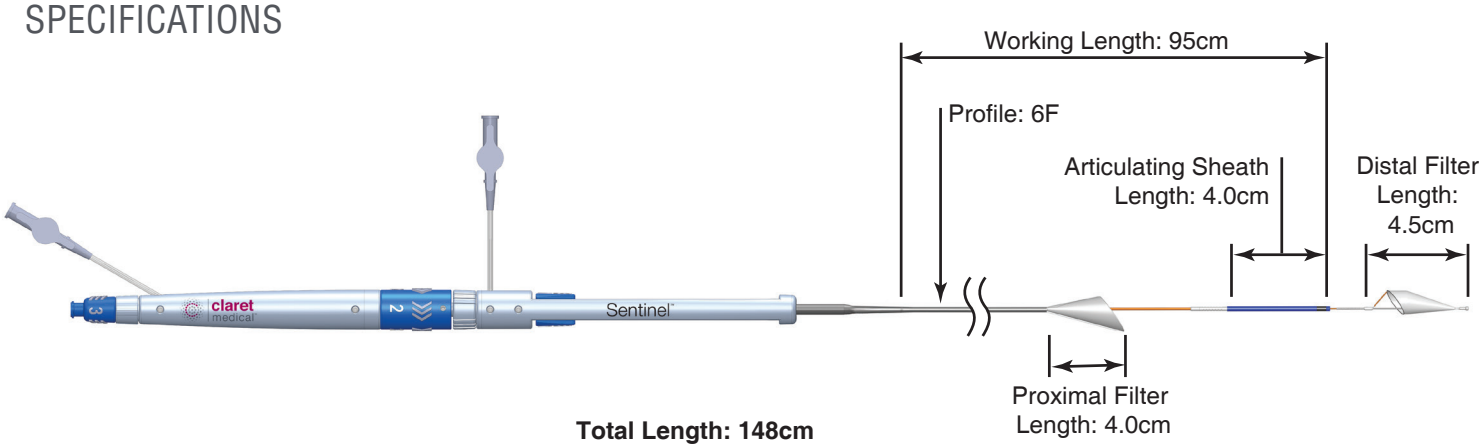
ICD-10-PCS PROCEDURE CODES	
X2A5312	**Cerebral Embolic Filtration, Dual Filter in Innominate Artery and Left Common Carotid Artery, Percutaneous Approach, New Technology Group 2**
02RF38H	Replacement of Aortic Valve with Zooplastic Tissue, Transapical, Percutaneous Approach
02RF38Z	Replacement of Aortic 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 and the Sentinel System are the only procedures. If the patient receives additional procedures the DRG assignment may be different.

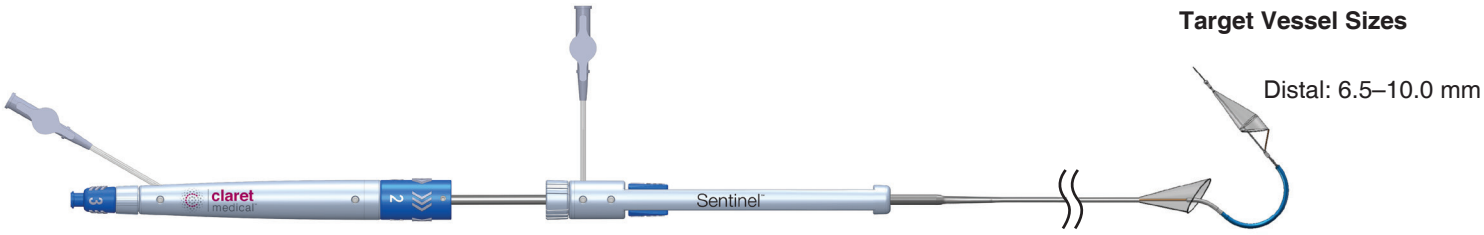
MS-DRG	MS-DRG Description*
266	Endovascular Cardiac Valve Replacement w MCC
267	Endovascular Cardiac Valve Replacement w/o MCC

*MCC = Major complication or co-morbidity

SPECIFICATIONS



Total Length: 148cm
(Minimum Guidewire Length: 175cm)



As Deployed

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

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