SENTINEL™
Cerebral Protection System

Boston Scientific
Advancing science for life™

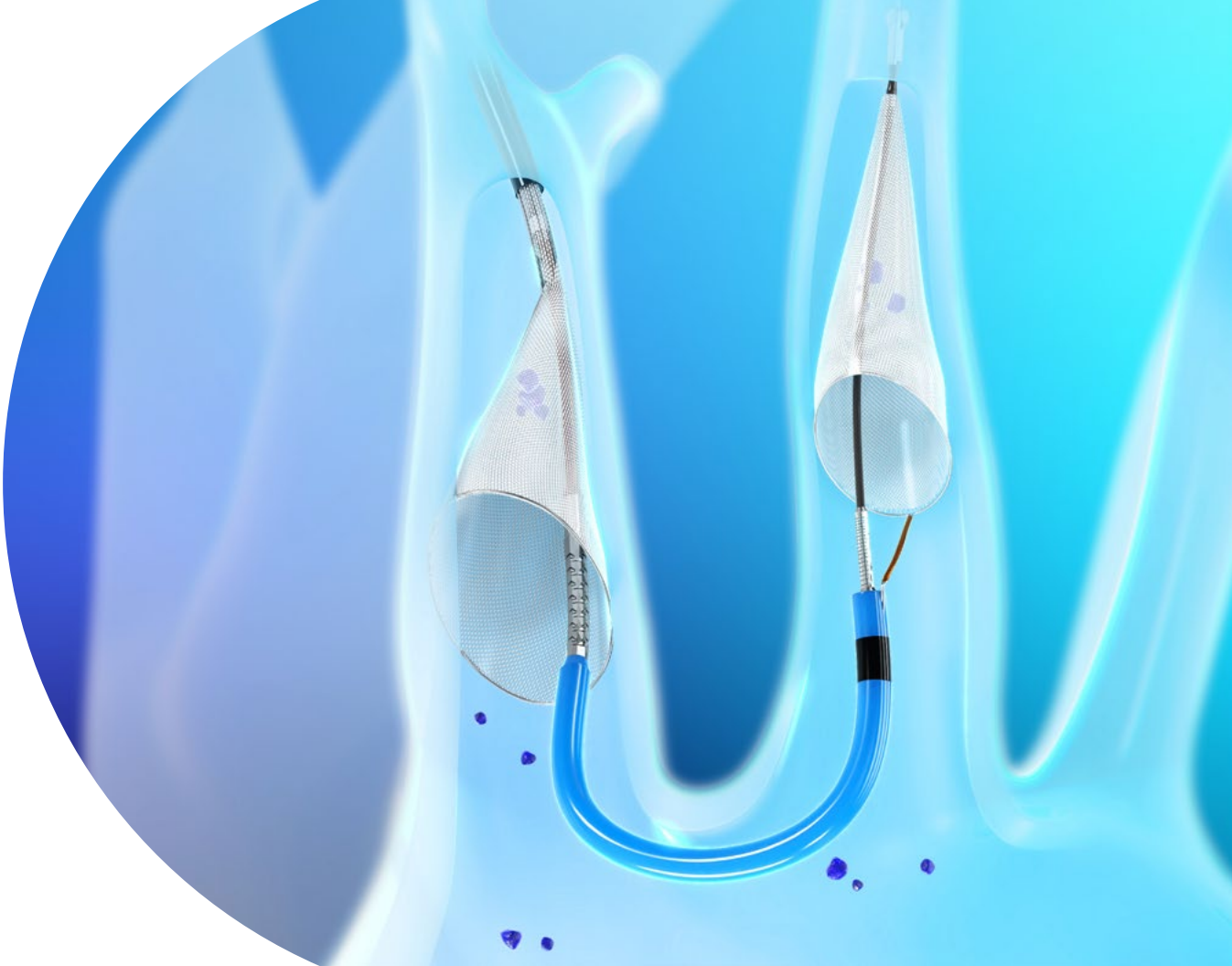
Stroke happens. **Protection works.**

Capture. Remove. **Protect.**

Designed to capture and remove embolic debris, SENTINEL™ Cerebral Protection System reduces the risk of stroke during TAVR procedures, ensuring enhanced patient safety and outcomes.

Protect your TAVR patients against stroke:

- Designed for Protection
- Backed by Data
- Easy to Use

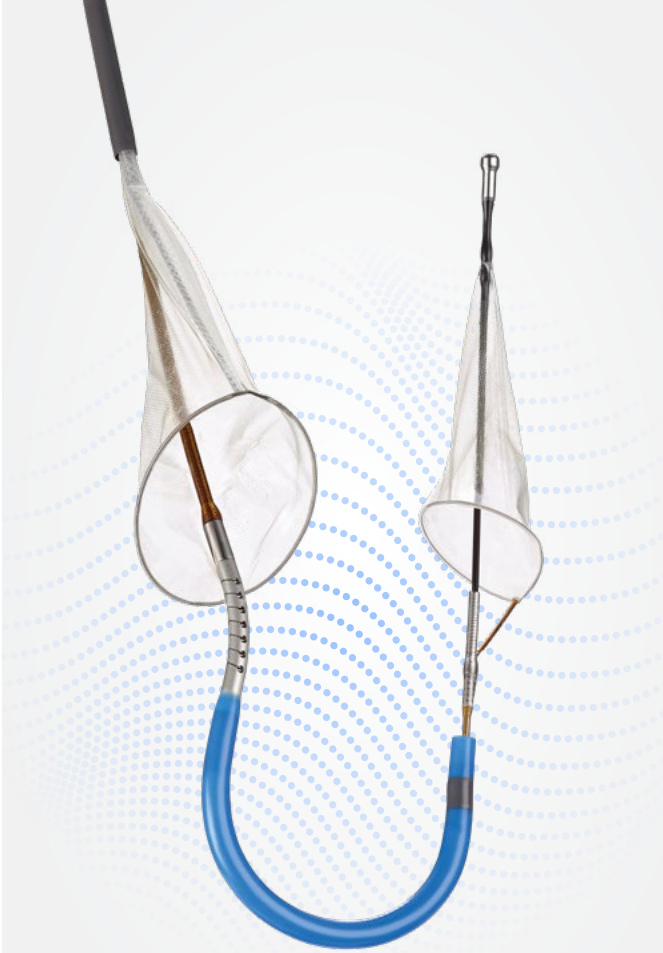


Designed for Protection

>90% Filters >90% of the blood flow to the brain[1]

99% Deflecting stroke-causing embolic debris isn't enough. SENTINEL is designed to capture and remove this debris, which was found in 99% of patients treated with SENTINEL[2–5]

90% Designed to fit 90% of patient anatomies[6]



1. Zhao M, et al. Regional cerebral blood flow using quantitative MR angiography. *AJNR Am. J. Neuroradiol*. 2007;28:1470–1473.
2. Kapadia SR, et al. Protection against cerebral embolism during transcatheter aortic valve replacement. *J Am Coll Cardiol*. 2017;69:367-377.
3. Kawakami R, et al. Characterization of cerebral embolic capture using the SENTINEL device during transcatheter aortic valve implantation in low to intermediate-risk patients: The SENTINEL-LIR Study. *Circ Cardiovasc Interv*. 2022;15: e011358. CIRCINTERVENTIONS.121.011358.
4. Schmidt T, et al. Debris heterogeneity across different valve types captured by a cerebral protection system during transcatheter aortic valve replacement. *JACC Cardiovasc Intv*. 2018;11:1262–1273.
5. Seeger J, et al. Significant differences in debris captured by the SENTINEL dual-filter cerebral embolic protection during transcatheter aortic valve replacement among different valve types. *JACC Cardiovascular Interv*. 2018;11:1683-1693.
6. SENTINEL US IDE trial data presented at the SENTINEL CPS FDA Advisory Panel, February 23, 2017.

Easy to Use

Simple for you. Vital for patients. Stroke protection that fits your workflow.

Reduce patient risk without complicating your workflow.

4 minutes deployment time[6]

Right radial access

Protect patients without compromising access for other tools.

The deflectable compound-curve catheter facilitates cannulation of the left common carotid artery.

The minimal profile of SENTINEL allows for little interaction with other devices in the aortic arch.[6]

With a low-profile catheter, SENTINEL enables access to small, tortuous anatomies.[7]

6. SENTINEL US IDE trial data presented at the SENTINEL CPS FDA Advisory Panel, February 23, 2017.
7. SENTINEL IDE subanalysis. Jilaihawi H. Anatomical predictors of stroke prevention during catheter aortic valve implantation: The SENTINEL Trial. Presented at EuroPCR 2018.

Easy to Use

Reduce overall costs of patient care by lowering the risk of stroke in TAVR patients – and the likelihood of hospitalization and readmission.

Stroke leads to an average of:

23% higher hospitalization cost[8]

4.2 day longer hospital stay index[8]

31% higher readmission rate[8]

8. Alkhouli M, et al. Cost of procedural stroke in TAVR in a US Medicare population. Valve20A-POS01; PCR London Valves 2020.

Backed by Data

Don’t TAVR without it

Choose with confidence, knowing SENTINEL is the most-studied cerebral embolic protection for TAVR. The first and only FDA-cleared product on the market, it has protected more than 120,000 patients from stroke worldwide.

97.3%
safety composite endpoint with death from any cause or stroke[9]

98.2%
safe and successful delivery and retrieval[9]

0.1%
access site-related vascular complication rate[9]

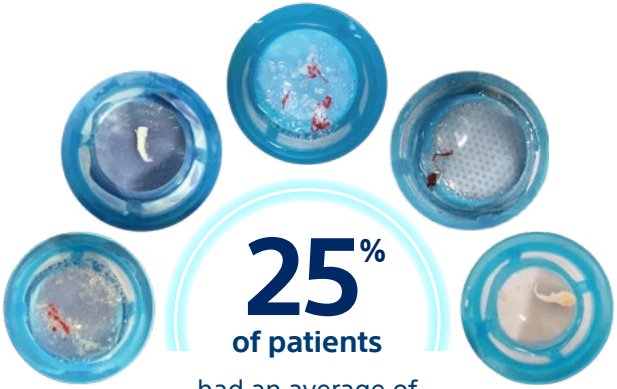
62%
reduced risk of disabling stroke through 72-hours[9]

9. Kapadia SR, et al. Cerebral embolic protection during trans catheter aortic-valve replacement. *N Engl J Med*. 2022;387:1253–1263.

Backed by Data

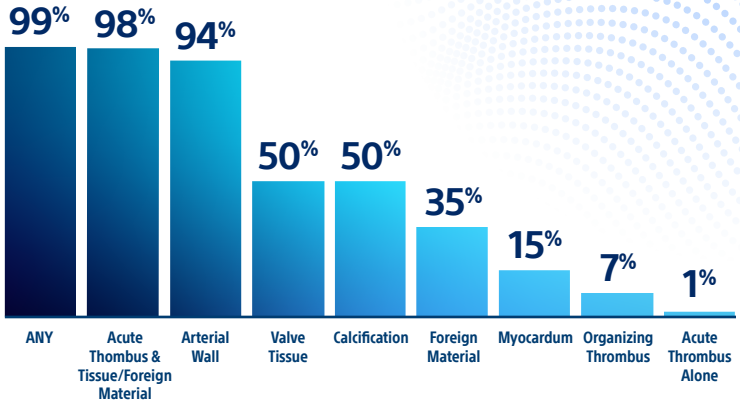
Don't TAVR without it

In 99% of procedures, SENTINEL was shown to capture and remove stroke-causing embolic debris such as arterial wall pieces, valve tissue, calcified and foreign material.[10, 11]



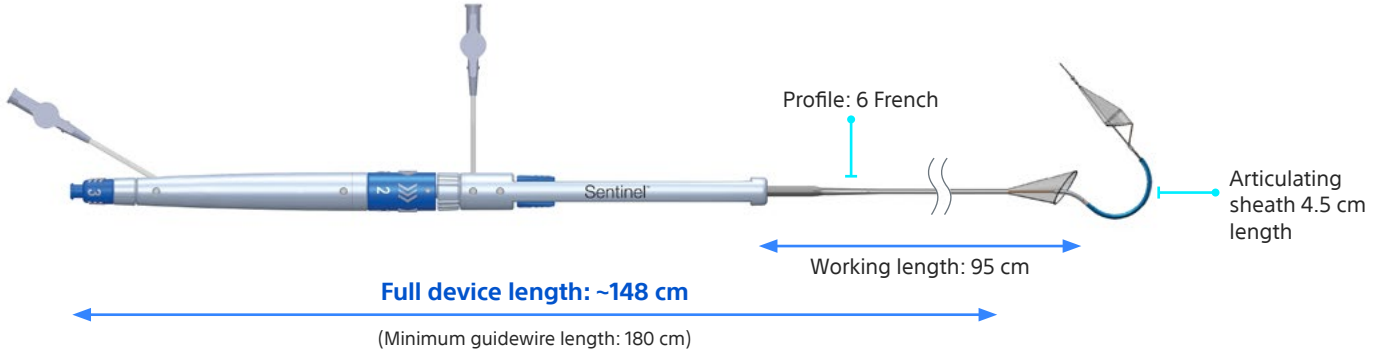
had an average of
25 particles ≥ 0.5 mm
in size captured and removed[11]

Type of debris captured:



10. Virmani R, et al. CVPath. SENTINEL IDE Trial. Data presented at Sentinel FDA Advisory Panel February 23, 2017.
11. All photographs taken by Boston Scientific. Illustrations for informational purposes only – not indicative of actual size or clinical outcome.

SENTINEL CPS – Device overview



Filter - Vessel Sizing Guide

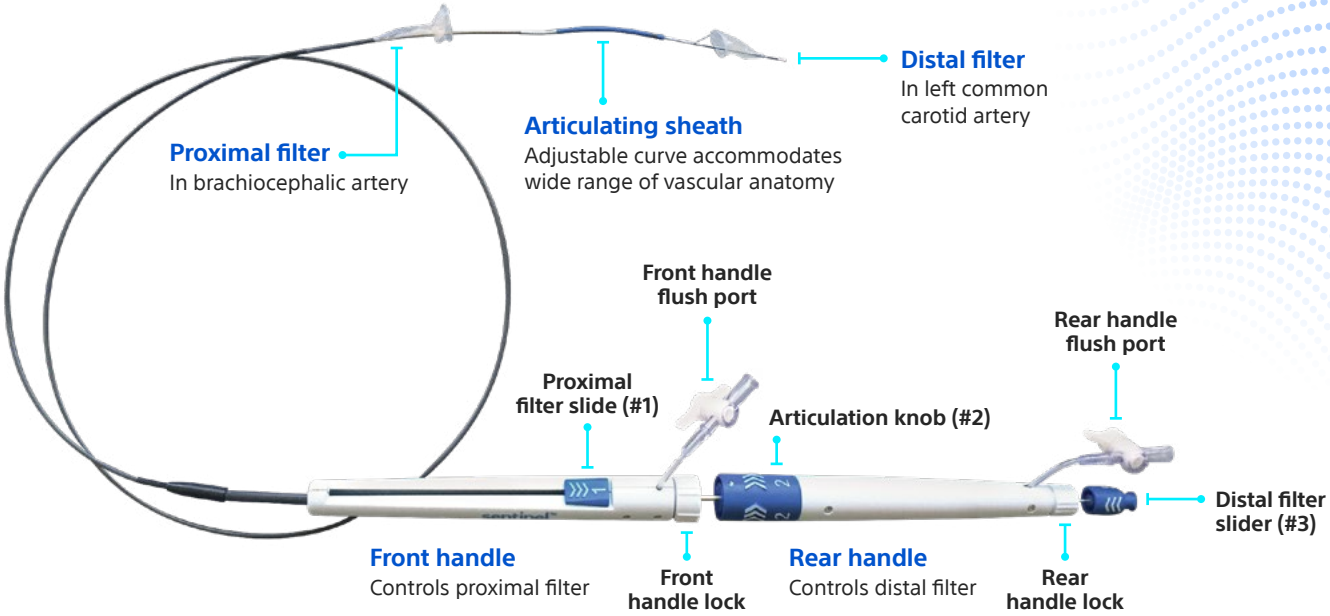
Proximal filter size (mm)	15
Target proximal vessel size (mm)	9 – 15
Distal filter size (mm)	10
Target distal vessel size (mm)	6.5 – 10

System Specifications

Delivery profile	6F
Working length	95 cm
Articulating sheath length	4.5 cm
Guidewire compatibility	0.014" (0.36 mm) diameter floppy tip coronary guidewire, 180 cm length minimum

SENTINEL CPS – Device components

Device has two coaxial filters housed within sheaths integrated into a catheter



Ordering Information

SENTINEL™ CPS System

Ref/Catalog #	Order Number (GTIN)	Proximal Filter Size (mm)	Target Proximal Vessel Size (mm)	Distal Filter Size (mm)	Target Distal Vessel Size (mm)	Quantity
CMS15-10C-US	00863229000004	15.0	9.0-15.0	10.0	6.5 – 10.0	1

SENTINEL Cerebral Protection System
Intended Use/Indications for Use: The SENTINEL 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 9.0 mm – 15.0 mm for the brachiocephalic and 6.5 mm – 10.0 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 3 cm 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 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 administered an Allen Test should the radial artery be used for 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 salin due to risk of air embolization and compromise 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 advance the device through an artery that has been used for dialysis purposes or an AV fistula. • Do not deploy the filters within a previously repaired artery. • 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 filter apposition against the vessel wall, incomplete deployment of the filters, or vessel damage. (Refer to Sizing Guide, Table 1 in the 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. • Use of Transcatheter Aortic Valve Replacement (TAVR) delivery systems other than those designed to cross the aortic arch with a valve frame in a sheathed or crimped configuration may result in device interference or entanglement. • 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. • Device should be used with caution in patients with known allergy to nickel. **ADVERSE EVENTS** This device is an adjunct to a TAVR procedure, that has its own risks/adverse events. Refer to the specific IFU of the devices used for a complete list of potential adverse events. Possible adverse events associated with SENTINEL System use and application procedure include, but are not limited to, the following: • Access site complications • Allergic Reaction • Angina • Aortic Dissection • Arrhythmia • Arteriovenous fistula • Bleeding, operative or post-operative • Cardiac failure leading to low cardiac output (cardiogenic shock) or pulmonary edema • Cardiac Tamponade • Death • Embolism, including air • Emergent Surgery • Hematoma • Hypertension/hypotension • Ischemia (coronary, limb, carotid) • Infection (local or systemic) • Nerve injury or neurologic deficits (including encephalopathy) • Pain or inflammation • Radiation Injury • Renal Insufficiency • Respiratory insufficiency or failure • Stroke/Transient Ischemic Attack • Vessel injury (e.g., dissection, rupture, perforation, pseudoaneurysm) As a result of these adverse events, the subject may require medical, percutaneous or surgical intervention. **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 "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. 92329606 E

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Interventional Cardiology
300 Boston Scientific Way
Marlborough, MA 01752-1234
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