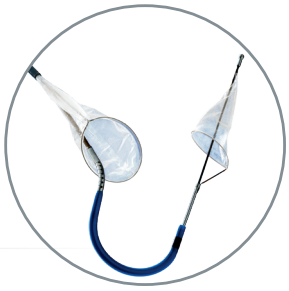
Boston Scientific
Advancing science for life™

SENTINEL™
Cerebral Protection System

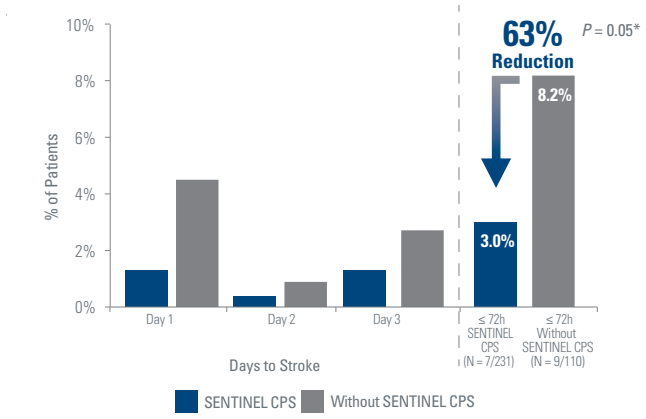
Protected TAVR™ with SENTINEL CPS gives you the power to reduce stroke.



Clinical Highlights

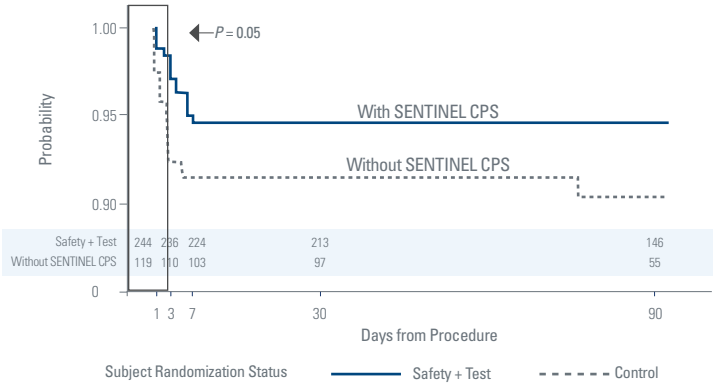
The SENTINEL Pivotal US IDE demonstrated a significant 63% reduction in neurologist-adjudicated peri-procedural (≤ 72 hours) stroke when SENTINEL CPS was used

SENTINEL US IDE[1]



SENTINEL CPS provided a significant treatment effect during the critical peri-procedural (≤ 72 hours) period, and the treatment effect was preserved through 90 days post-procedure

SENTINEL US IDE - Freedom From Stroke[2]



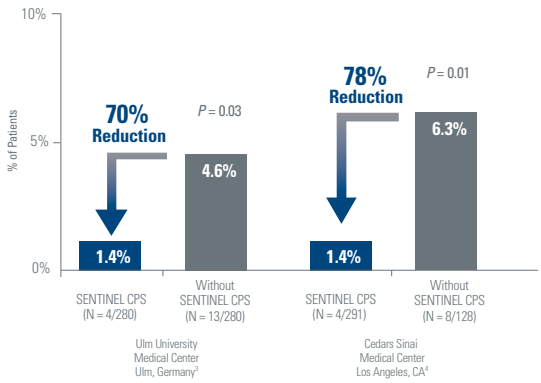
1. SENTINEL US IDE trial data presented at the SENTINEL CPS FDA Advisory Panel, February 23, 2017
* Fisher Exact Test

2. Kaplan-Meier Curve data on file from the SENTINEL US IDE

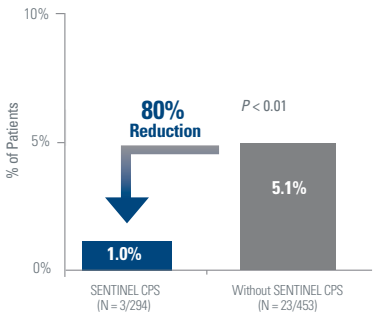
Several independent centers demonstrated a consistent reduction in clinically assessed peri-procedural neurological events with SENTINEL CPS[3,4]

Independent Single Center Experiences

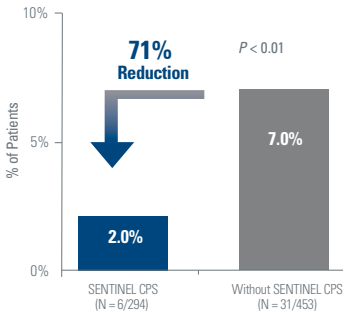
All-Stroke at 7 Days



Neurological Events at 72 Hours



Composite of Mortality and Neurological Events at 72 Hours

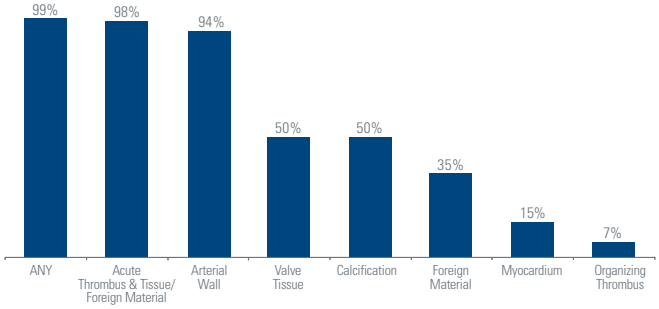


Erasmus Medical Center, Rotterdam, Netherlands[5]

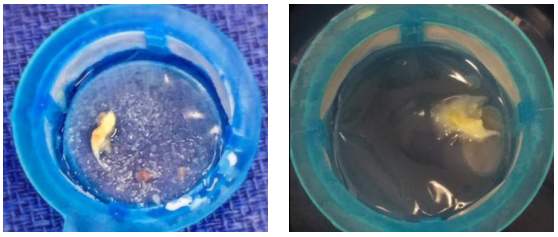
3. Seeger J, et al. *JACC Interv.* 2017 Nov 27;10(22):2297-2303
4. Makkar R, presented at *CRT* 2018
5. Van Mieghem N, et al. presented at *JIM* 2018 and *CRT* 2018

Debris Matters

The SENTINEL Cerebral Protection System was able to capture and remove embolic debris in 99% of TAVR patients, regardless of valve type and patient risk profile[1]

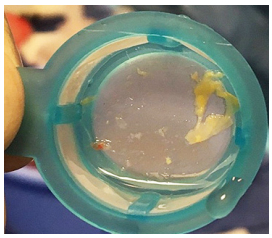


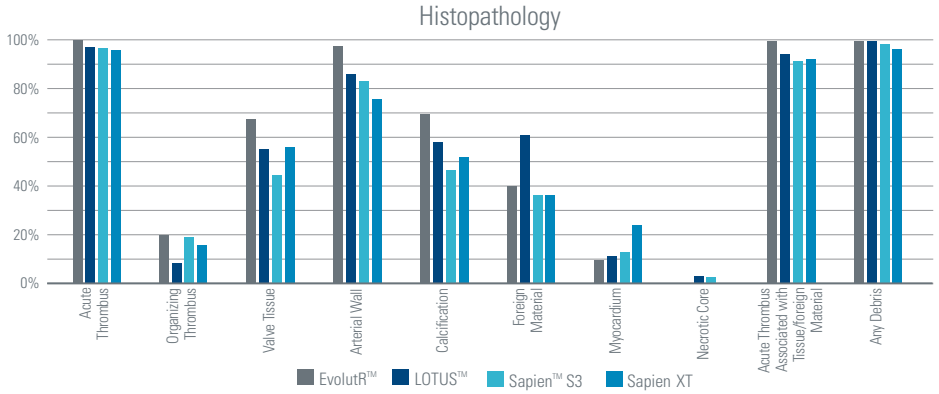
1 in 4 Patients had an average of 25 particles ≥ 0.5 mm[1]



1. SENTINEL US IDE

Capture of embolic debris is universal regardless of transcatheter heart valve type[6]

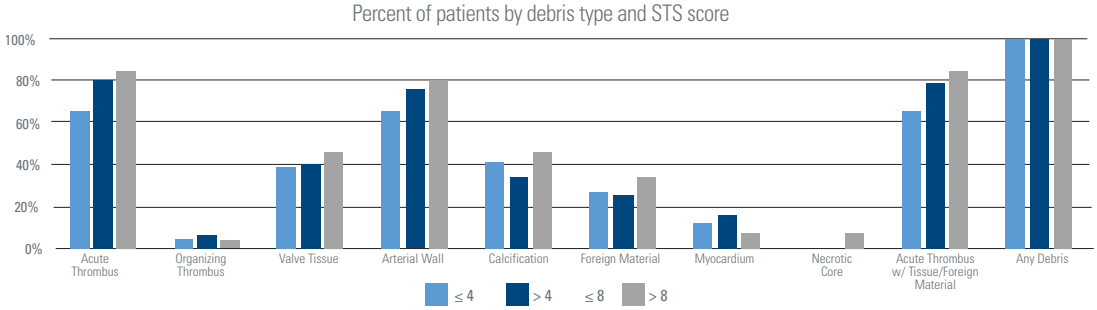




- Pooled treatment data from the SENTINEL US IDE and SENTINEL H Trials demonstrate ubiquitous capture of embolic debris[6]
- A total of 53% of patients had debris particles larger than 1 mm[6]
- Histopathology and histomorphometry measured particle size, count and area of debris captured in 492 filters from 246 patients[6]

6. Schmidt T. et al. 2018. *JACC Cardiovasc Intv.* 11(13):1262-1273

Embolic debris was captured with SENTINEL CPS regardless of surgical risk score[7]



Patients from the SENTINEL and SENTINEL H studies with STS score and debris collected, n = 129
The data above did not reach statistical significance, per Fisher's Exact Test.
7. Data on file for the SENTINEL US IDE and SENTINEL H trials

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.

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