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Advancing science for life™

Stroke Happens PROTECTION Works

A growing body of clinical evidence provides a strong foundation for the benefits of Cerebral Embolic Protection and the SENTINEL™ Cerebral Protection System

Stroke is a Devastating Event

All-Stroke occurs on average 4% of the time
across contemporary studies, independent of center experience, operator volume, or patient risk score. [1-5]

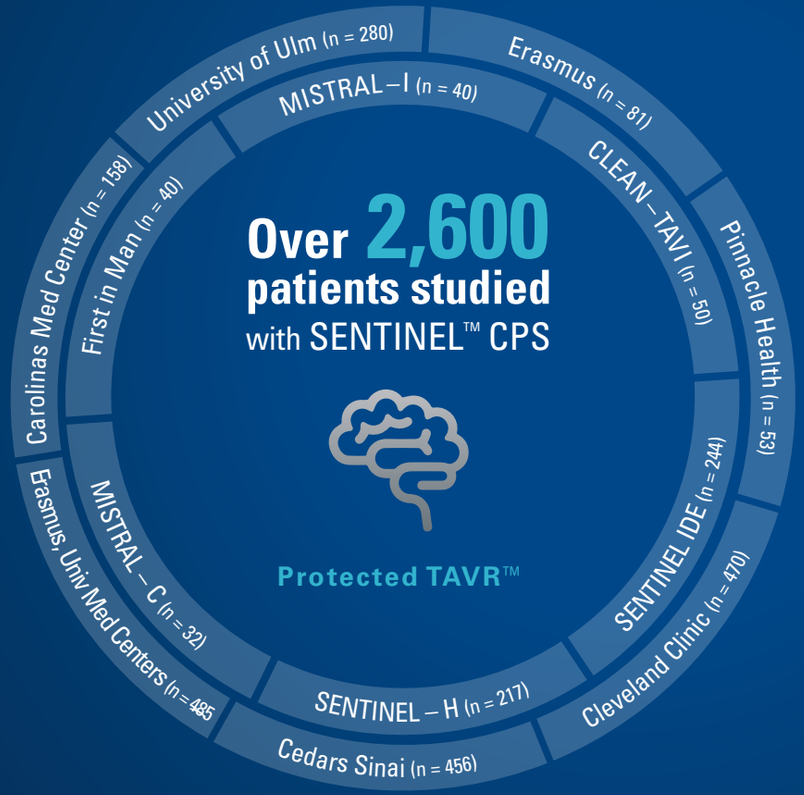
1/10

Post-procedure TAVR patients show overt signs of ischemic brain injury [6]

6×

Increase in stroke-related 30-day mortality, post TAVR [7]

1. Manoharan G, et al., *J Am Coll Cardiol Intv* 2015; 8:1359-67. **2.** Wendler O, et al., *Circulation* 2017; 135: 1123–1132. **3.** Seeger J, et al., *Eur Heart J.* 2018 Dec 24. doi: 10.1093/eurheartj/ehy847. **4.** Haussig S et al., *JAMA* 2016; 316:592–601. **5.** Kapadia S, Kodali S, Makkar R, et al., Protection against cerebral embolism during transcatheter aortic valve replacement. *JACC.* 2017; 69(4): 367–377. **6.** SENTINEL IDE Trial. Data presented at SENTINEL Advisory Panel, February 23, 2017. **7.** The CENTER Collaboration. N = 10982 Patients undergoing TF-TAVR with Edwards™ balloon-expandable valves or Medtronic™ self-expanding valves between 2007-2018 from 3 national registries and 7 local registries or prospective clinical trials.



SENTINEL Cerebral Protection System is Investigated

SENTINEL CPS leads the way in clinical evidence for Cerebral Embolic Protection for **over 2,600 patients** across a randomized trial and multiple registries.

SENTINEL™ Cerebral Protection System Performs

University of Ulm

The largest propensity matched meta-analysis comparison of All-Stroke and mortality. [8]

66% REDUCTION in All-cause Mortality and Stroke *

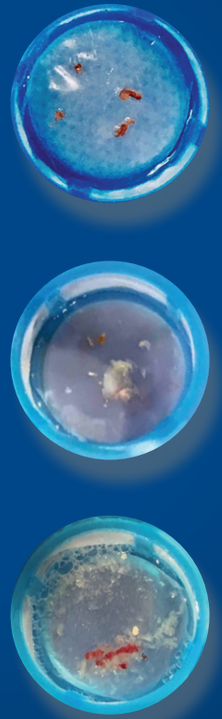
65% REDUCTION in All-procedural Stroke †

84% REDUCTION in Disabling Stroke ‡

* $P = 0.0013$; with SENTINEL CPS (n = 11/533), without SENTINEL CPS (n = 32/533). † $P = 0.0028$; with SENTINEL CPS (n = 10/533), without SENTINEL CPS (n = 29/533). ‡ $P = 0.0045$; with SENTINEL CPS (n = 11/533), without SENTINEL CPS (n = 32/533). **8.** Seeger J., Snapshots from Real World High Volume Single Center Experiences with Sentinel Cerebral Embolic Protection During TAVR, University of Ulm, presented at TVT 2018.

In the SENTINEL IDE Trial

SENTINEL Captured Debris in 99% of Procedures[6]



See the data
bostonscientific.com/SENTINEL

6. SENTINEL IDE Trial. Data presented at SENTINEL Advisory Panel, February 23, 2017.

Illustrations for information purposes – not indicative of actual size or clinical outcome. All photographs taken by Boston Scientific.

SENTINEL™ Cerebral Protection System

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 3 cm of the aortic ostium. **WARNINGS:** • The appropriate antiplatelet/anticoagulation therapy should be administered pre- and post-procedure in accordance with standard medical practice. • 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. 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 an AV fistula. • Indwell time of the Sentinel System is not to exceed 90 minutes as occlusion could occur, resulting in slow or no flow. • 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 the DFU). **PRECAUTIONS:** • Do not forcefully bend or reshape the Articulating Sheath of the Sentinel System. • Use of 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. **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) **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.**

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