Boston Scientific

Advancing science for life™

SENTINEL™

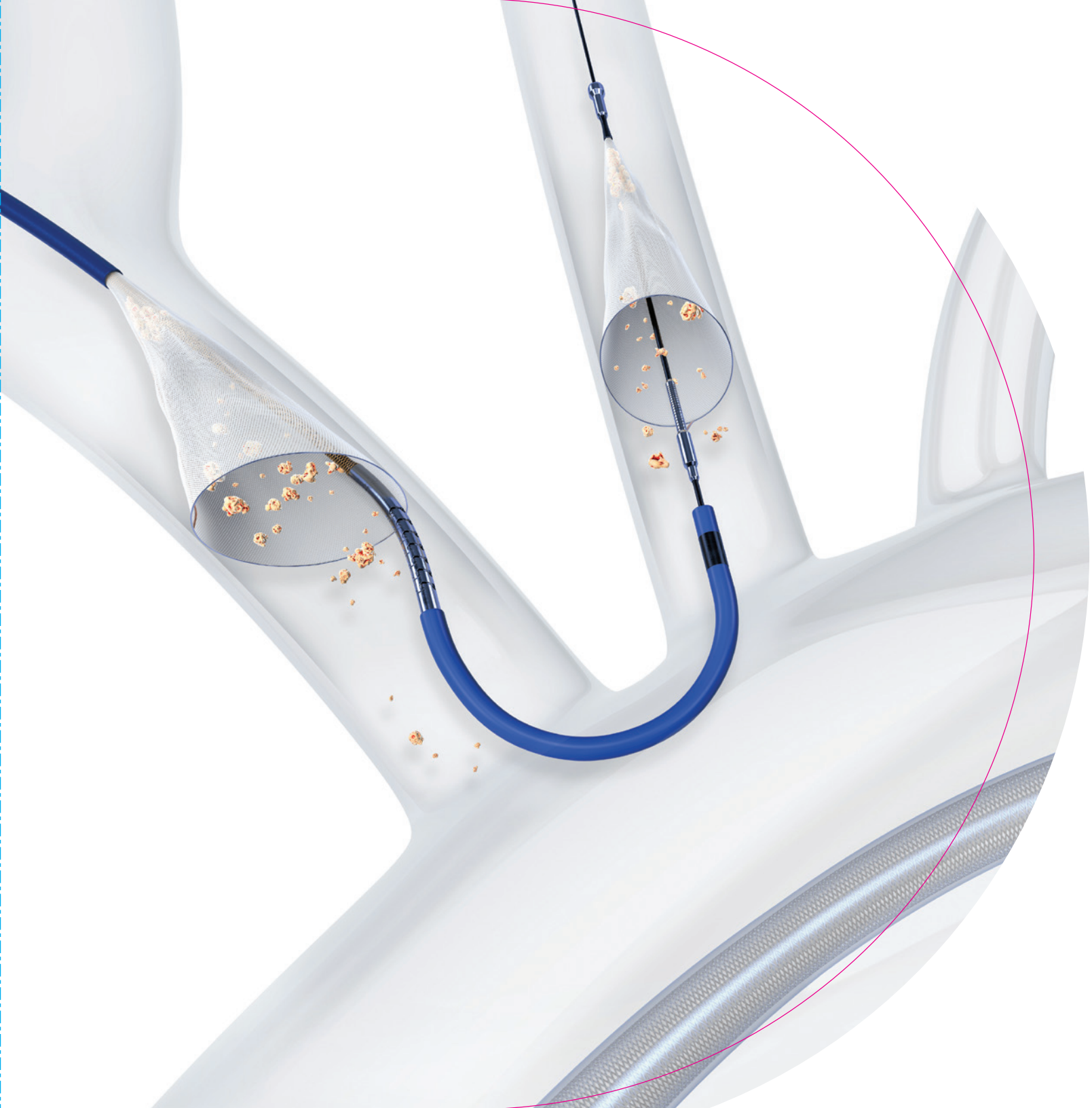
Cerebral Protection System

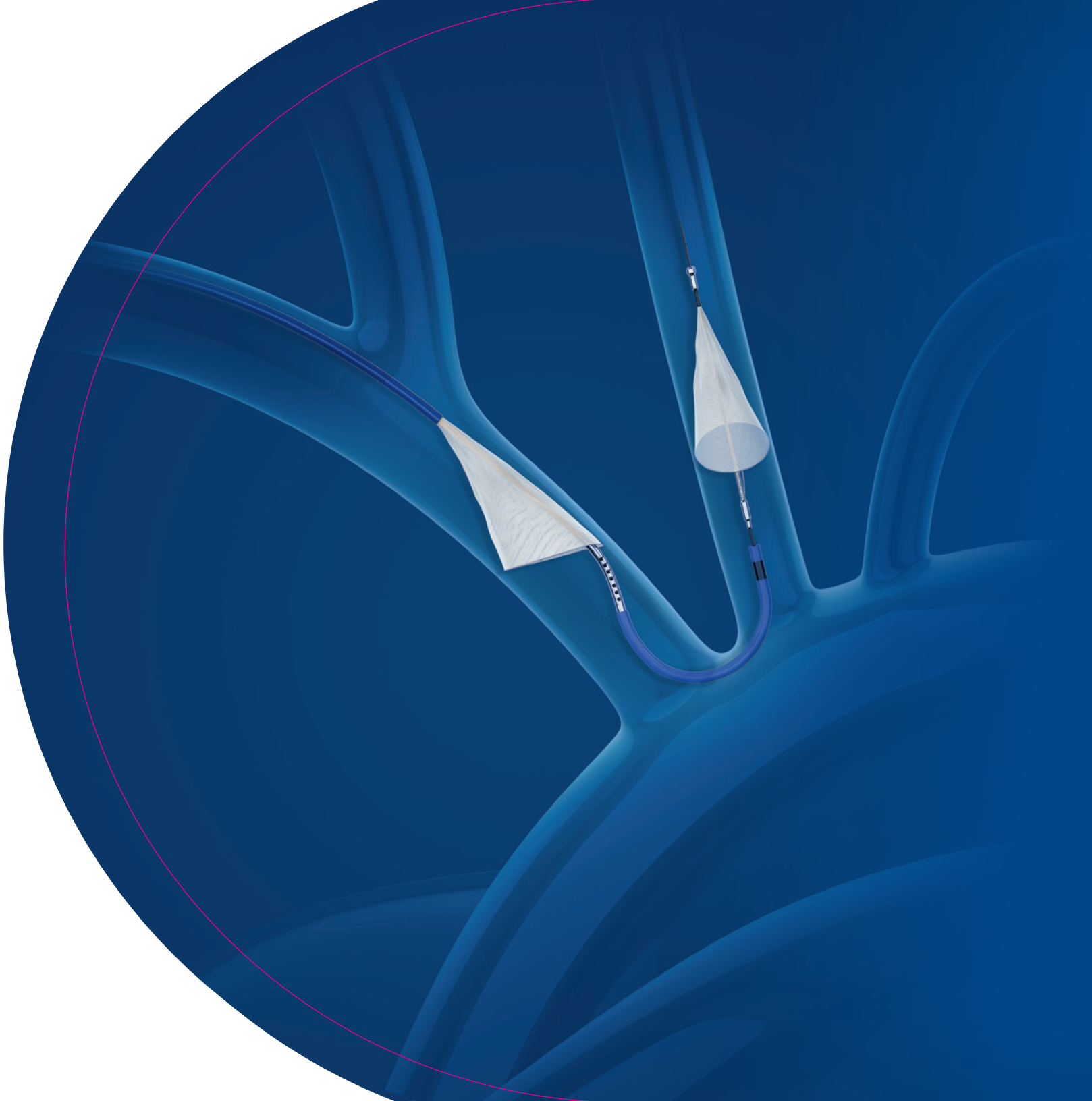
Stroke Happens

PROTECTION Works

Protected TAVR

with SENTINEL™ Cerebral Protection System Gives You the Power to Reduce Stroke





An Unpredictable, Underreported, AND DEVASTATING EVENT

THE EFFECT OF STROKE IS OFTEN UNDERREPORTED AND UNDERDIAGNOSED[1–5]

4% Weighted-average All-Stroke rate across contemporary studies, independent of center experience, operator volume, or patient risk score

>9% Stroke rates in studies that include a mandated neurological assessment[6]

DEBRIS MATTERS

Stroke and neurological impairment can be a serious and potentially devastating event.

During the TAVR procedure, embolic debris may be dislodged. Pieces of arterial wall, valve tissue, calcified and foreign material, and both acute and organizing thrombus can lead to periprocedural (≤ 72 hours) stroke.

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. Messé SR, et al., *Circulation* 2014; 129:2253-61.

SENTINEL™
Cerebral Protection System

Stroke Impacts
HOSPITALS and PATIENTS

HOSPITAL IMPACT

Stroke and stroke-related incidents can account for increased hospital costs, increased length of stay, and higher readmission rates.[7]

HOSPITALIZATION COSTS ARE

33% HIGHER

for TAVR procedures with stroke

HOSPITAL LENGTH OF STAY IS

6 DAYS LONGER

(on average) for TAVR procedures with stroke

30-DAY READMISSIONS ARE

31% HIGHER

for TAVR procedures with stroke

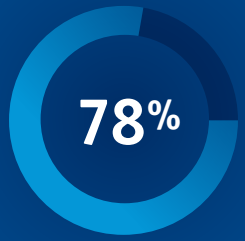
The Centers for Medicare & Medicaid Services (CMS) has approved the SENTINEL CPS for a new technology add-on payment (NTAP).

7. Alqahtani F, Sengupta P, Badhwar V, et al., Clinical and economic burden of acute ischemic stroke following transcatheter aortic valve replacement. *Structural Heart Journal* online, 16 Nov 2018.

PATIENT IMPACT

Physicians report that the biggest concern among their patients undergoing TAVR is suffering a stroke or some other loss of cognitive or mental acuity.[8]

MANY PATIENTS FAVOR QUALITY OF LIFE OVER SURVIVAL



of patients identify maintaining independence and being able to perform daily activities as their primary goals following a TAVR procedure[9]

121%

Increase in **long-term costs** as a result of nursing home and intermediate care facility utilization[7]

8. Leon M. Future considerations: The role of shared decision making and adoption of CEP in practice. TCT 2018, San Diego, CA. **9.** Coylewright M, Palmer R, O'Neil E, et al., Patient-defined goals for the treatment of severe aortic stenosis: A qualitative analysis. *Health Expect.* Oct 2016:19(5): 1-36-1043.

PROVEN TO REDUCE Stroke Risk

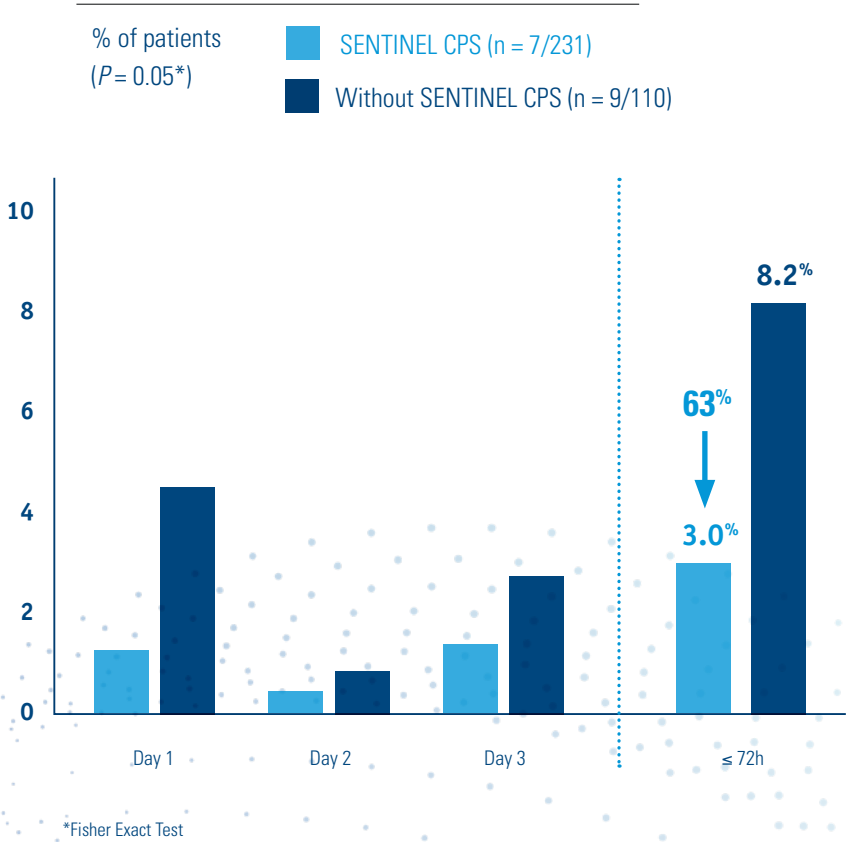
Cerebral embolic protection has emerged as a solution to decrease cerebral embolization and its associated neurological effects.

THE SENTINEL IDE TRIAL SHOWED:

SENTINEL™ Cerebral Protection System (CPS) captured and removed embolic debris in 99% of TAVR patients, regardless of valve type and patient risk profile[10]

The neurologist-adjudicated periprocedural (≤ 72 hours) **stroke rate was reduced by 63%** when SENTINEL CPS was used[10]

SENTINEL IDE TRIAL: ALL STROKE AT ≤ 72 HOURS POST-TAVR[10]



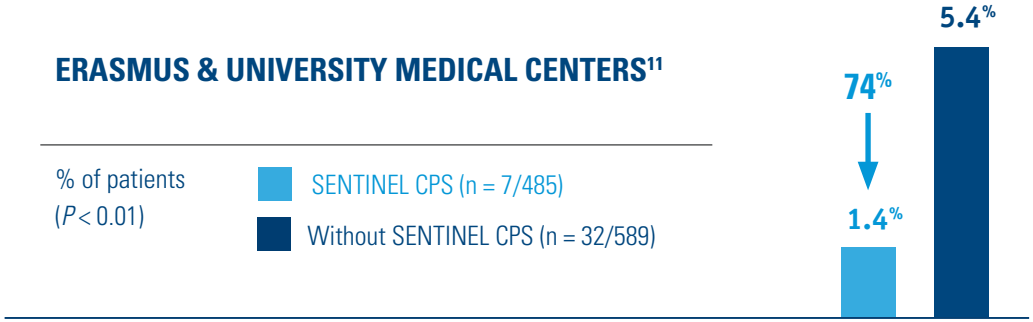
*Fisher Exact Test

10. SENTINEL US IDE trial data presented at the SENTINEL CPS FDA Advisory Panel, February 23, 2017.

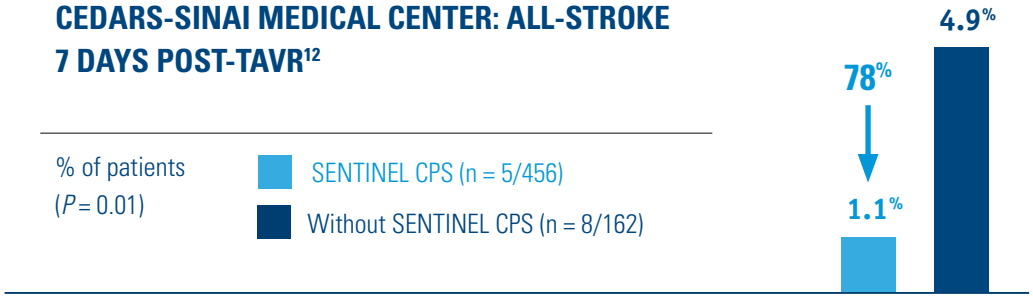
INDEPENDENT REAL-WORLD STUDIES HAVE CONSISTENTLY CONFIRMED REDUCTIONS IN TAVR-RELATED STROKE

A 60–80% periprocedural (≤ 72 hours to 7 days) **relative reduction** in neurologist-adjudicated TAVR All-Stroke with an **average absolute reduction of 3–4%**.

ERASMUS & UNIVERSITY MEDICAL CENTERS[11]



CEDARS-SINAI MEDICAL CENTER: ALL-STROKE 7 DAYS POST-TAVR[12]



DEBRIS CAPTURED BY SENTINEL CPS

11. Van Mieghem N, presented at TVT 2018. **12.** Chakravarty T, Makkar R. Snapshots from "real-world" high-volume single-center experiences with SENTINEL cerebral embolic protection during TAVR. TVT 2018.

Safe, Fast, and EFFECTIVE[10]

SENTINEL™ CPS demonstrated safety superiority in the IDE Trial and works as part of the minimalist approach to TAVR.

30-DAY MACCE RATE LOWER THAN CONTROL
SENTINEL IDE trial

NO SIGNIFICANT DIFFERENCE
in contrast agent volumes used

MINIMAL INTERFERENCE
with advancement of the TAVR valve

COVERS 90% OF ANATOMIES WITH ONE SIZE

99.4% Safe and successful delivery and retrieval

4 mins Median deployment time

0.4% Access site–related vascular complication rate

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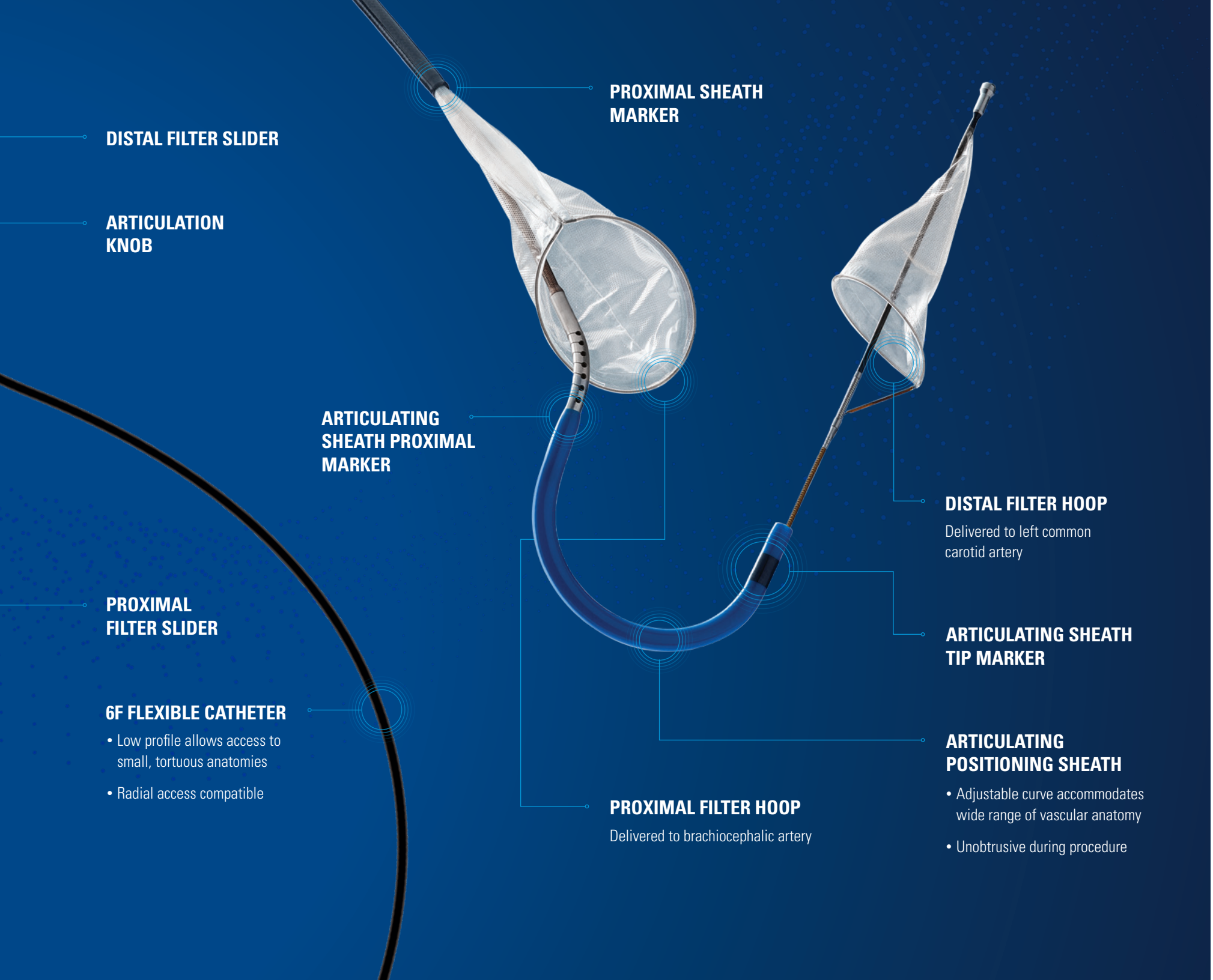
DISTAL FILTER SLIDER
ARTICULATION KNOB
PROXIMAL SHEATH MARKER
ARTICULATING SHEATH PROXIMAL MARKER
PROXIMAL FILTER SLIDER
6F FLEXIBLE CATHETER
• Low profile allows access to small, tortuous anatomies
• Radial access compatible
PROXIMAL FILTER HOOP
Delivered to brachiocephalic artery
DISTAL FILTER HOOP
Delivered to left common carotid artery
ARTICULATING SHEATH TIP MARKER
ARTICULATING POSITIONING SHEATH
• Adjustable curve accommodates wide range of vascular anatomy
• Unobtrusive during procedure

Committed to TAVR

As part of our commitment to the structural heart community, Boston Scientific focuses on providing innovative solutions that advance safety in TAVR procedures, help optimize patient outcomes, and improve procedural efficiency.

Our differentiated portfolio of TAVR devices – including valves, accessories, and a proven cerebral embolic protection device – delivers enhanced control and precision backed by strong clinical evidence and program support.

JOIN US AT
bostonscientific.com/SENTINEL

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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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