

**SENTINEL™**  
Cerebral Protection System

**Stroke Happens**  
**PROTECTION**  
**Works**



# Protected TAVI™

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<sup>1-5</sup>

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<sup>6</sup>

## DEBRIS MATTERS

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

During the TAVI 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 peri-procedural ( $\leq$  72 hours) stroke.

1. Manoharan G, et al., *J Am Coll Cardiol Interv* 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.

# 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.<sup>7</sup>

HOSPITALIZATION COSTS ARE

**33%  
HIGHER**

for TAVI procedures with stroke

HOSPITAL LENGTH OF STAY IS

**6 DAYS  
LONGER**

(on average) for TAVI procedures with stroke

30-DAY READMISSIONS ARE

**31%  
HIGHER**

for TAVI procedures with stroke



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



## PATIENT IMPACT

Physicians report that the biggest concern among their patients undergoing TAVI is suffering a stroke or some other loss of cognitive or mental acuity.<sup>8</sup>

### 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 TAVI procedure<sup>9</sup>

**121%**

Increase in nursing home and intermediate care facility utilization.<sup>7</sup>


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.


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

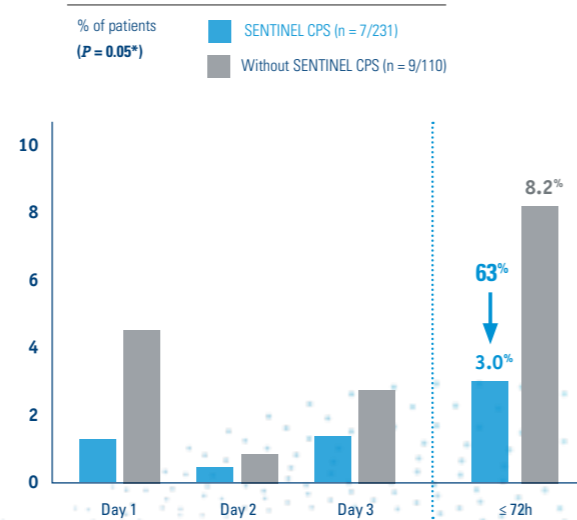
Cerebral embolic protection has emerged as a solution to decrease cerebral embolization and its associated neurological effects.

## THE SENTINEL IDE TRIAL SHOWED:

 **SENTINEL™ Cerebral Protection System (CPS) captured and removed embolic debris in 99% of TAVI patients**, regardless of valve type and patient risk profile<sup>10</sup>

 The neurologist-adjudicated peri-procedural (≤ 72 hours) **stroke rate was reduced by 63%** when SENTINEL CPS was used<sup>10</sup>

**SENTINEL IDE TRIAL: ALL STROKE AT ≤ 72 HOURS POST-TAVI<sup>10</sup>**



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

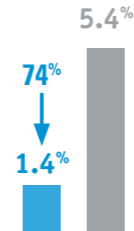


**A 60 - 80% peri-procedural (≤ 72 hours to 7 days) relative reduction in neurologist-adjudicated TAVI All-Stroke with an average absolute reduction of 3 - 4%.**

### ERASMUS & UNIVERSITY MEDICAL CENTERS<sup>11</sup>

% of patients ( $P < 0.01$ )

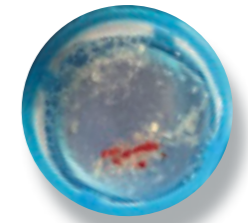
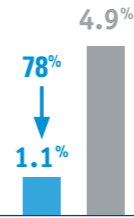
- SENTINEL CPS (n = 7/485)
- Without SENTINEL CPS (n = 32/589)



### CEDARS-SINAI MEDICAL CENTER: ALL-STROKE 7 DAYS POST-TAVI<sup>12</sup>

% of patients ( $P = 0.01$ )

- SENTINEL CPS (n = 5/456)
- Without SENTINEL CPS (n = 8/162)



**DEBRIS CAPTURED BY SENTINEL CPS**

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

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 TAVI. TVT 2018.

# Safe, Fast and EFFECTIVE<sup>10</sup>

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



## 30-DAY MACCE RATE LOWER THAN CONTROL

SENTINEL IDE trial

**99.6%**

Safe and successful delivery and retrieval



## NO SIGNIFICANT DIFFERENCE in contrast agent volumes used

**4 mins**

Median deployment time



## MINIMAL INTERFERENCE with advancement of the TAVI valve

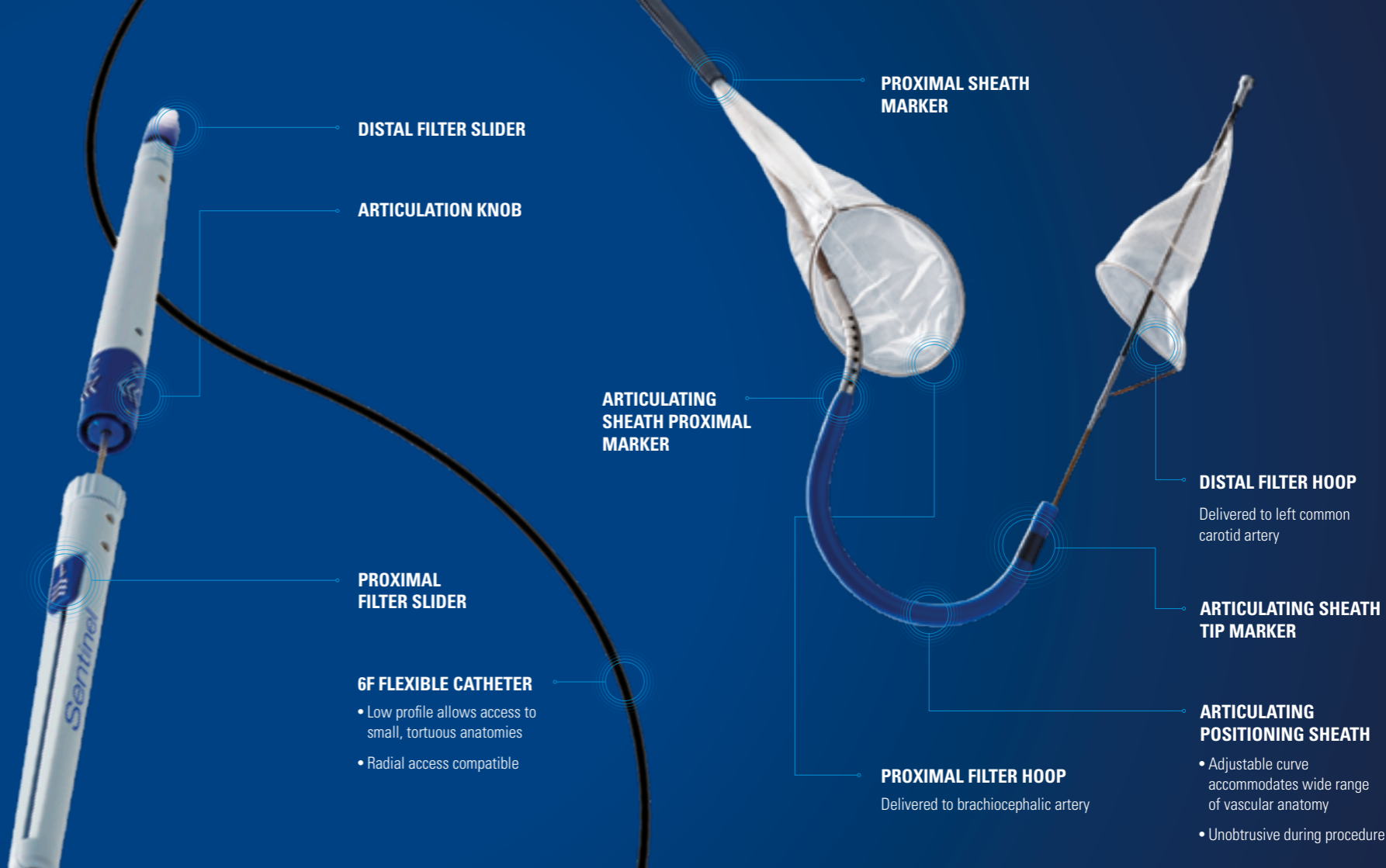
**0.4%**

Access site-related vascular complication rate



## COVERS 90% OF ANATOMIES WITH ONE SIZE

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



# Committed to TAVI

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

Our differentiated portfolio of TAVI 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.eu/SENTINEL](https://bostonscientific.eu/SENTINEL)

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

All cited trademarks are the property of their respective owners. **CAUTION:** The SENTINEL Cerebral Protection System may only be used in countries where it is approved for use. The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device. Information for use only in countries with applicable health authority product registrations. Information not for use or distribution in France.

SH-567406-AD Printed in Germany by medicalvision.

**Boston  
Scientific**  
Advancing science for life™

[bostonscientific.eu](https://bostonscientific.eu)

© 2019 Boston Scientific Corporation  
or its affiliates. All rights reserved.  
DINSH0180EF