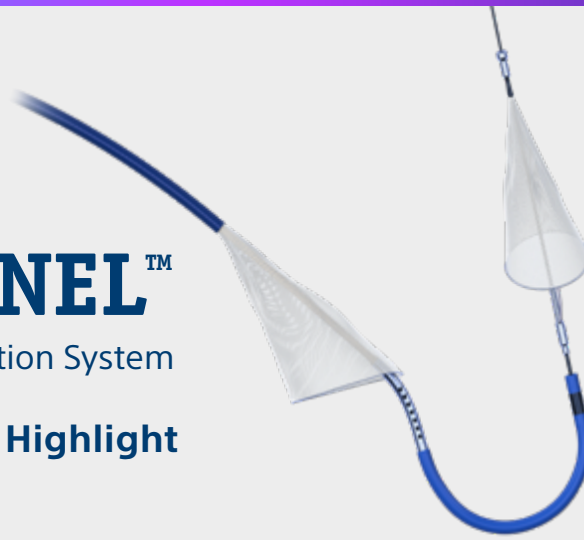




SENTINEL™

Cerebral Protection System

Clinical Data Highlight



SENTINEL leads the way in clinical evidence for Cerebral Embolic Protection (CEP).

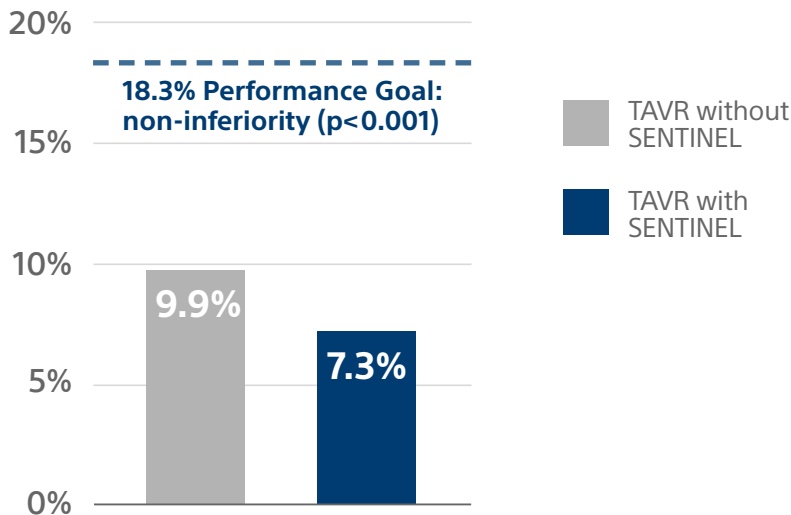


SENTINEL IDE

Study: Randomized Controlled Trial to evaluate the safety and efficacy of the SENTINEL device during Transcatheter Aortic Valve Replacement (TAVR).

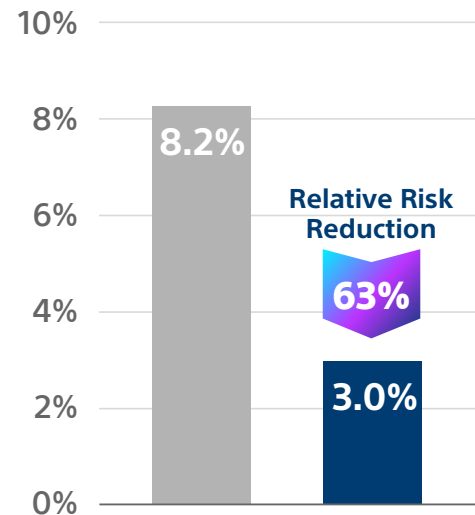
30-days MACCE rates

Primary Endpoint



All stroke

≤ 72h post TAVI, p = 0.05



99% patients with captured debris

SENTINEL demonstrated to be safe and effective in capturing debris such as thrombus, calcification, valve tissue, artery wall, and foreign material.

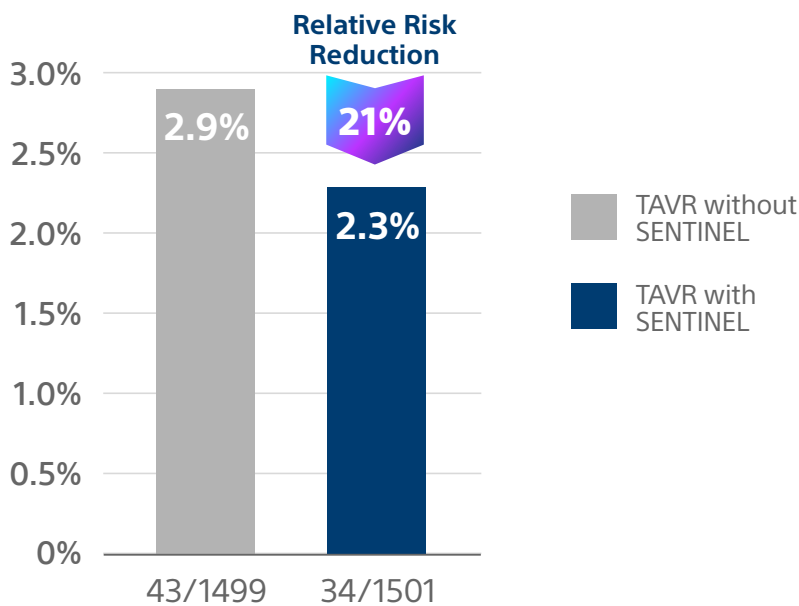


Protected TAVR

Study: The largest randomized TAVR trial to date with 3,000 patients enrolled at >50 global sites who were randomized 1:1 – patients protected with SENTINEL vs. no use of SENTINEL during TAVR.

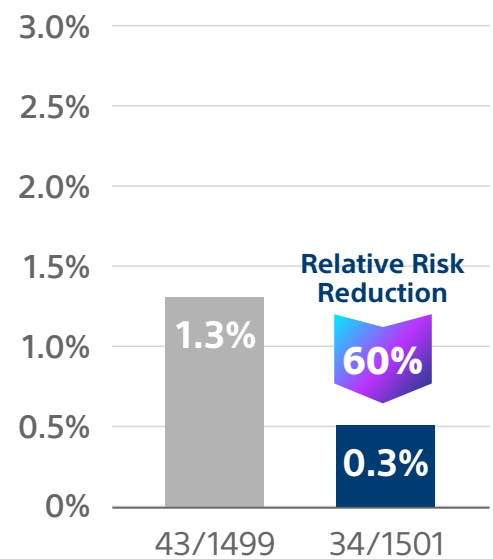
All stroke

Primary endpoint
p = 0.30



Disabling stroke

Secondary analysis
p = 0.02



94%
safe and effective device
delivery & retrieval

0.1%
complication rates at
vascular access site

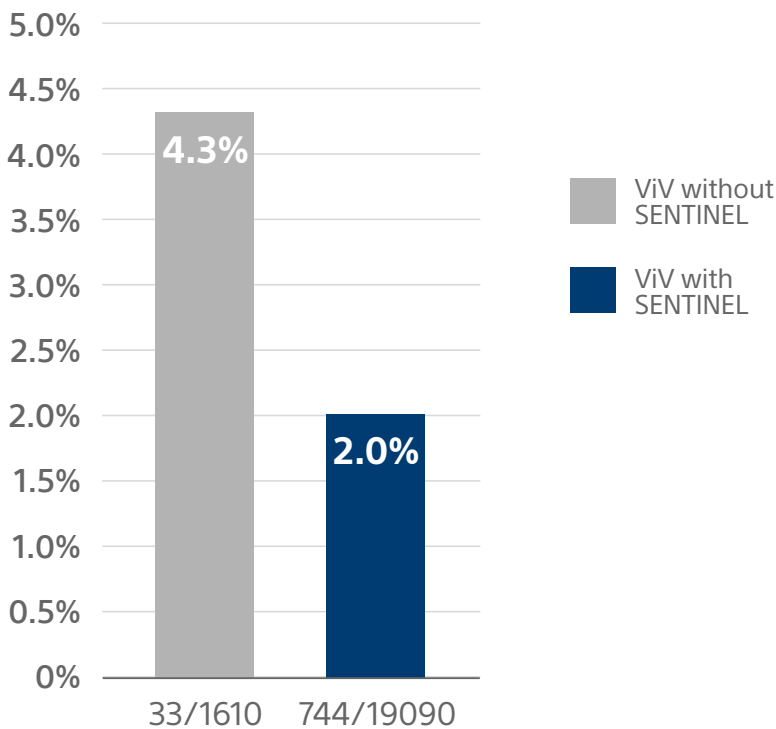
The use of SENTINEL demonstrated a 21 % relative risk reduction in all stroke and a 60 % significant relative risk reduction in disabling stroke through 72-hours after TAVR.



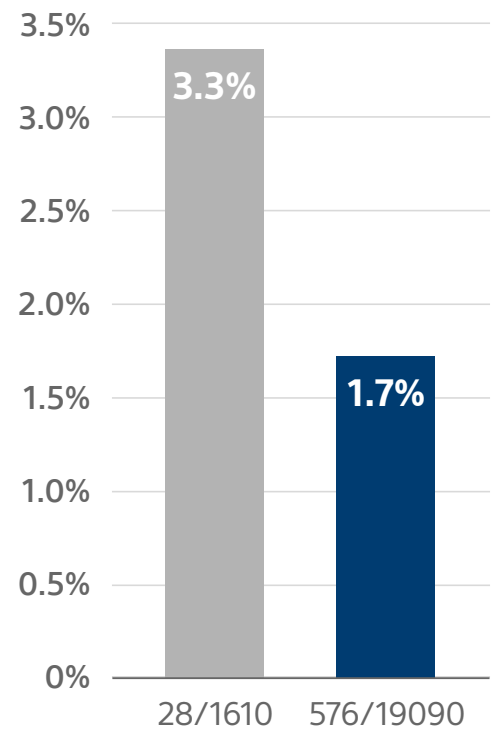
CEP in Valve-in-Valve TAVR

Study: Retrospective analysis on the impact of CEP on outcomes in patients who underwent ViV-TAVR from a national, all-comers database (the Nationwide Readmissions Database, or NRD).

Overall stroke
p < 0.001



Major stroke
p < 0.001



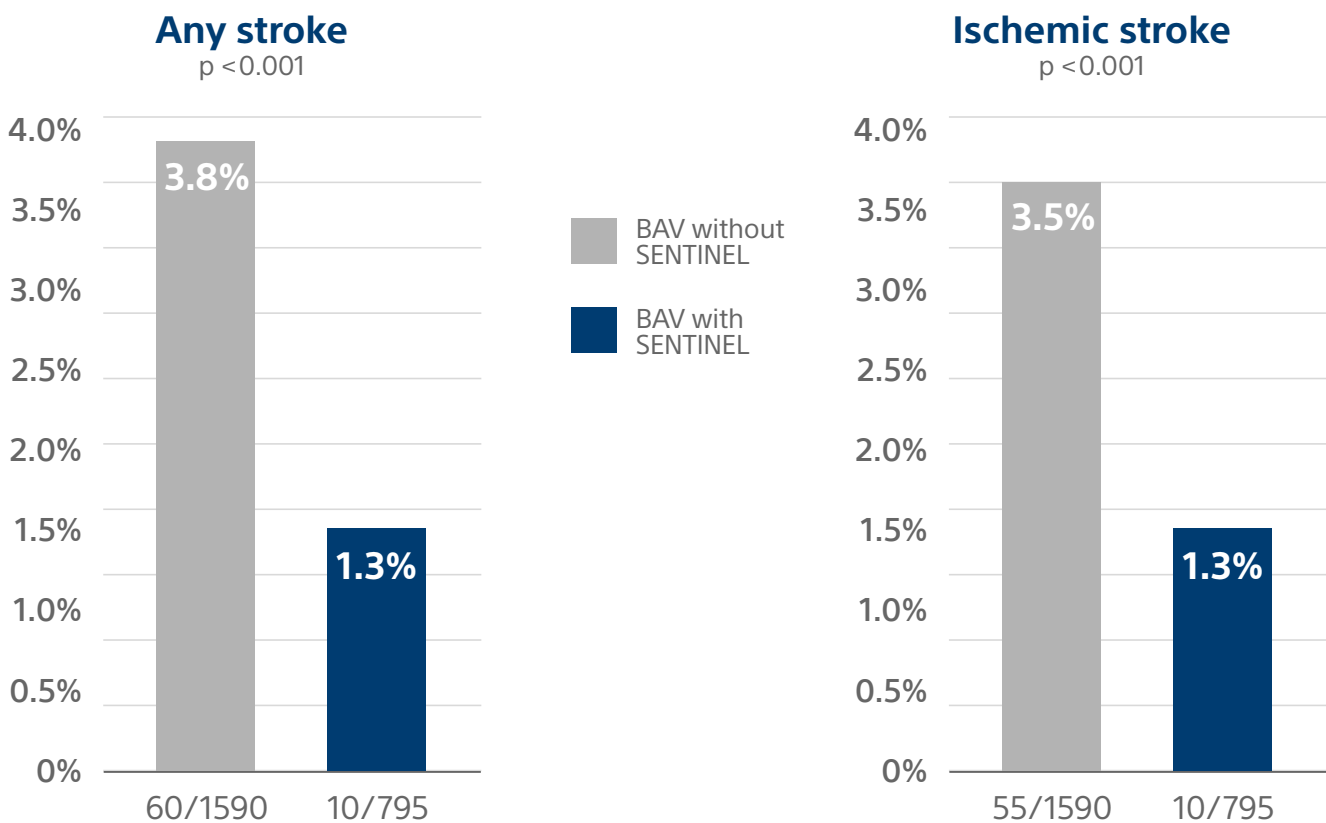
Shorter hospital stay with SENTINEL
(2 vs. 3 days, p < 0.001)

CEP with SENTINEL in patients undergoing ViV-TAVR is associated with a reduction of overall stroke, major stroke, duration of median hospital stay, and 30-day readmission rates.



CEP in TAVR for Bicuspid Aortic Valve Stenosis

Study: Retrospective analysis on the impact of CEP on outcomes in patients with Bicuspid Aortic Valve (BAV) stenosis who underwent TAVR from the National Inpatient Sample (NIS) database. Data comparing outcomes with or without SENTINEL are obtained after a propensity-score matching.



Shorter hospital stay with SENTINEL
(1 vs. 2 days, $p < 0.001$)

This analysis supported CEP use for BAV stenosis, which was independently associated with less in-hospital stroke and a shorter hospital stay length.