

## Notes from my Heart Team

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As with any medical device, there are risks associated with use of the SENTINEL Cerebral Protection System. These risks include but are not limited to:

- Infection
- Blood Vessel Injury
- Stroke
- Death

Issues specific to the use of the SENTINEL have been reported in a small number of patients and typically went away in 30 days. The use of SENTINEL during your procedure is solely at the discretion of your doctor.

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1. Seeger J et al., Eur Heart J. 2018 Dec 24. doi: 10.1093/eurheartj/ehy847 Haussig S et al., JAMA. 2016;316:592-601. Kapadia S et al., JACC. 2017;69(4): 367-377. SENTINEL IDE Trial. Data presented at SENTINEL FDA Advisory Panel, February 23, 2017. Van Mieghem N, et al. EuroIntervention. 2016;12:499-507. Van Mieghem N, presented at TVT 2018. Chakravarty T, presented at TCT 2018. Seeger J et al. 2017. JACC Cardiovasc Interv. 10(22):2297-2303.
2. Zhao M, et al. Regional Cerebral Blood Flow Using Quantitative MR Angiography. AJNR 2007;28:1470-1473.

CAUTION: 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 labelling supplied with each device. Products shown for information purposes only and may not be approved or for sale in certain countries. This material is not intended for use in France.

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## Cerebral Embolic Protection

with the  
**SENTINEL™**  
Cerebral Protection System



**A Guide for Patients  
and their Families**



Your heart team has recommended transcatheter aortic valve implantation (TAVI) to treat your severe aortic stenosis.

This guide is meant to help you understand more about the SENTINEL™ Cerebral Protection System that may be used during your TAVI procedure to minimize the risk of stroke.

After reviewing this information, be sure to talk with your heart team about any questions you have.

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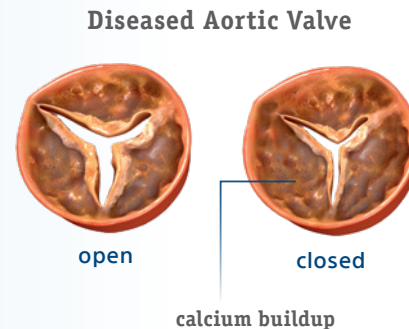


## Severe Aortic Stenosis

Severe aortic stenosis occurs when the aortic valve leaflets become stiff, reducing their flexibility and ability to fully open and close properly. This results in a narrowing (stenosis) of the valve opening. This narrowing reduces and restricts blood flow, requiring your heart to work harder.

Severe aortic stenosis is an age-related, progressive disease, most commonly caused by a gradual buildup of calcium (mineral deposits) on the leaflets of the aortic valve.

Transcatheter Aortic Valve Implantation (TAVI) is a less invasive procedure that replaces the diseased aortic valve *without* opening your chest to reach your heart. TAVI can save lives and significantly improve quality of life, but like all medical procedures, it may involve risk.



## Risk of Stroke with TAVI

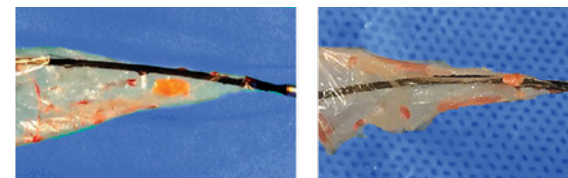
Blood carries essential nutrients and oxygen to the brain. A stroke occurs when the blood supply to part of the brain is interrupted. During the TAVI procedure, pieces of the calcified heart valve, or other debris, can break loose and travel through the arteries toward the brain. This material is called embolic debris and may block blood flow to the brain which can cause long-term damage. Unfortunately, the damage is difficult to predict.



## Stroke Risk Reduction

The SENTINEL™ Cerebral Protection System (CPS) is the first and only device in the U.S. to offer you protection from the risk of stroke during TAVI. It works by capturing embolic debris dislodged during TAVI before it can reach the brain.

Clinical trials involving more than 3,500 patients have demonstrated that the SENTINEL device is safe and effective. The SENTINEL cerebral protection technology has been used to protect thousands of patients worldwide and is the most-studied embolic protection device in its field.



Embolic debris captured by the SENTINEL Device

SENTINEL CPS captured visible embolic debris headed toward the brain in

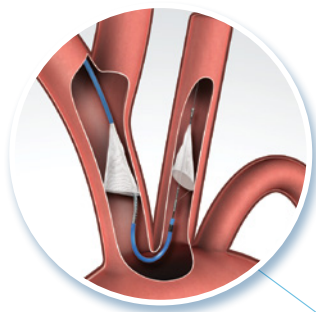
**99%**  
of TAVI cases.<sup>1</sup>

Studies show more than a

**60%**

reduction in TAVI-related strokes when SENTINEL Cerebral Protection was used.<sup>1</sup>

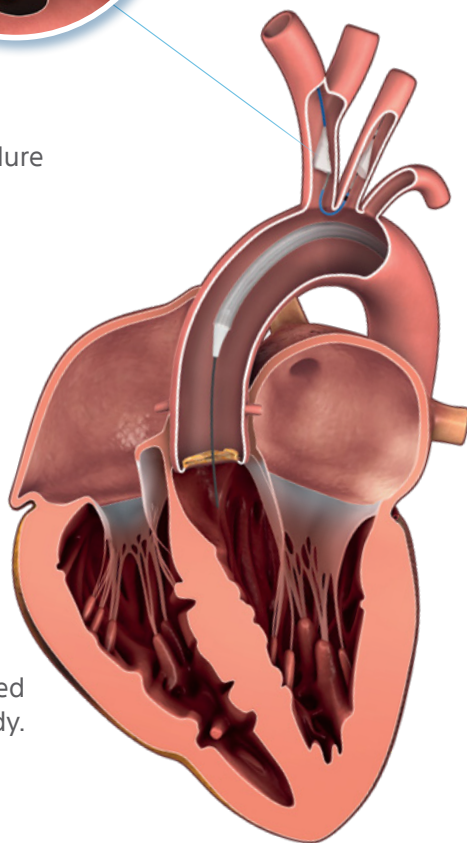
# How the SENTINEL™ Cerebral Protection System Works



**1** The SENTINEL device is placed at the beginning of the TAVI procedure through a small puncture in the right wrist.

**2** Two tiny filters are placed in the main arteries that carry 90% of the blood to the brain. These filters collect any dislodged debris, preventing it from traveling to the brain.<sup>2</sup>

**3** At the completion of the TAVI procedure, the filters and collected debris are removed from the body.



“Any occurrence of stroke is one too many. By both capturing and removing embolic debris, the SENTINEL CPS device may offer a unique neurologic-protective benefit.”

– Dr. Samir Kapadia, Cleveland Clinic

“We are now able to universally remove debris that otherwise had the potential to travel to patients' brains. This is a meaningful step in enhancing the safety of TAVI.”

– Dr. Raj Makkar, Cedars-Sinai Medical Center

**Protected TAVI™** with the SENTINEL Cerebral Protection System provides peace of mind for you and your loved ones.

Talk with your heart team about how to reduce your risk of stroke, prior to the TAVI procedure.

For more information about cerebral embolic protection and treatment options for severe aortic stenosis, visit

**TreatTheHeart.com**