

# Restore the heart, protect the brain.

The ProtEmbo® Cerebral Protection System

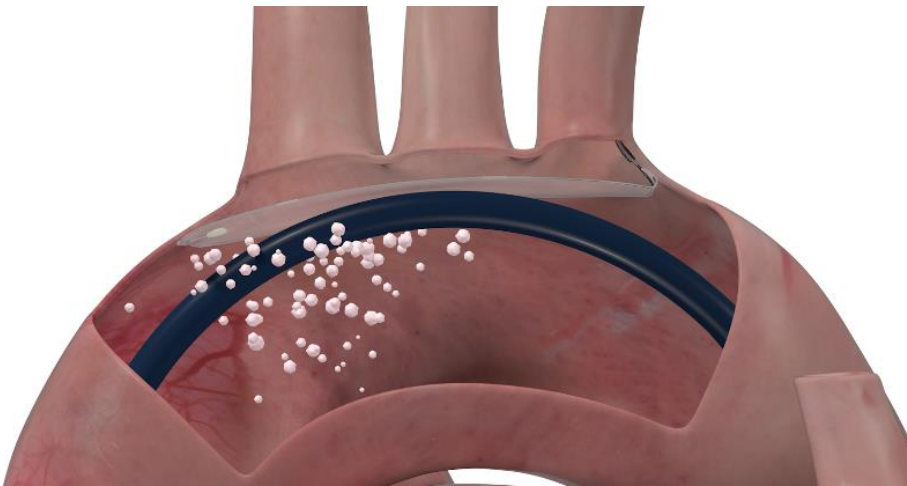


## Cerebrovascular Events during TAVR

Cerebrovascular events occur in nearly all transcatheter aortic valve replacements (TAVR); These are associated with cognitive decline, 2-4-fold risk of future stroke, >3-fold risk of mortality and >2-fold risk of dementia; Clinical cerebrovascular event rates as high as 9.1% have been reported following TAVR.

## ProtEmbo® Deflects Embolic Material Away from the Brain

ProtEmbo® is the best in class system providing a simple, timely and reliable solution to reduce the risk of cerebrovascular events during TAVR:

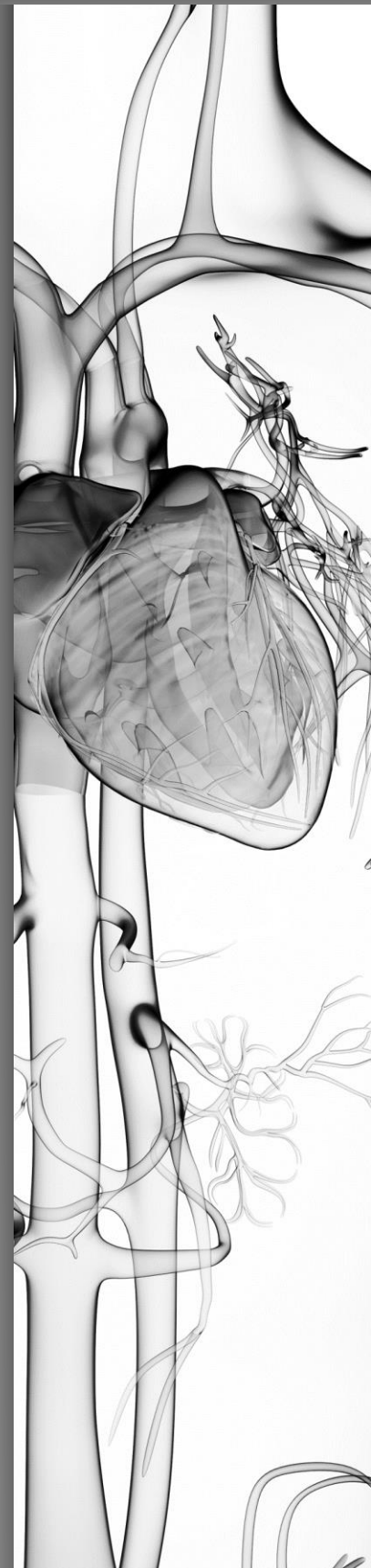


## Facts To Know About ProtEmbo®

- Low-profile access via left radial artery (6-Fr. guiding sheath)
- Simple, quick and reliable deployment
- Complete coverage of all 3 aortic side branches
- Deflection of micro-particles as tiny as 60 microns to descending aorta
- Suitable for a wide variety of aortic arch anatomies
- Heparin coating for optimal biocompatibility
- Best access route: no interference with TAVR catheter or accessories

## Improve Patient Care and Reduce Cost for Health Care Systems

Cost of clinical cerebrovascular events are as high as € 100,000 (average lifetime cost per patient), cerebral protection devices are currently priced at € 3,000 (average competitive price); i.e. it is less costly to use ProtEmbo® in every TAVR patient if only 3% of patients had a clinical cerebrovascular event.



## What the Experts are Saying About Protecting the Brain While Treating the Heart...

*“The low-profile access of the ProtEmbo® via the left radial artery is an ideal access route. This device combines what is needed for TAVR: a simple, fast and smooth way to protect the brain, while not interfering with the valve implantation.”*

Ulrich Schäfer, M.D. – University Heart Center Hamburg

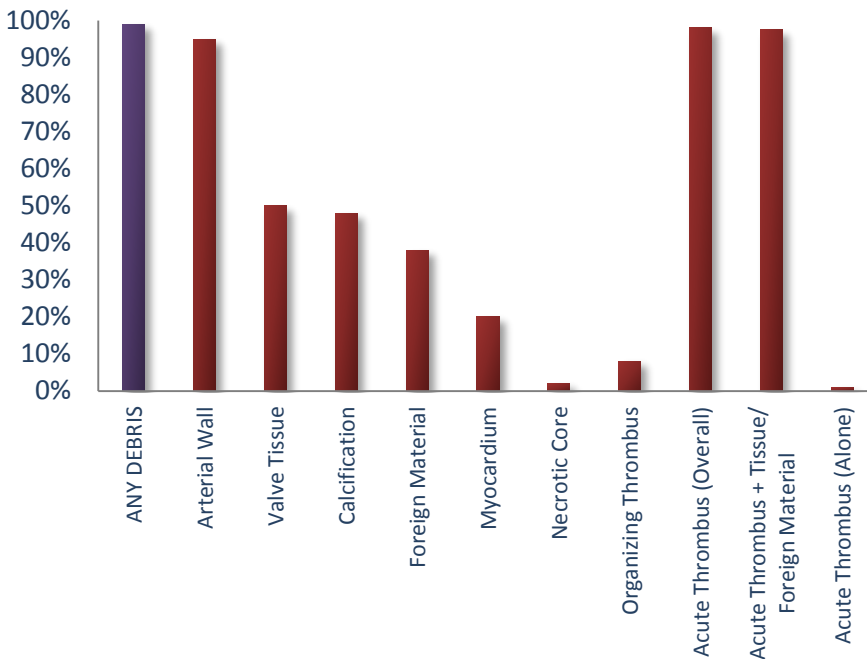
*“Clinically detectable strokes are only a small fraction of embolic events that occur in TAVR and may have adverse long-term effects on brain function. No doubt, we need a simple yet effective way to protect the brain during TAVR.”*

Nikos Werner, M.D. – University Hospital Bonn

*“Over the next 10 years, TAVR procedures are expected to increase fourfold. It is therefore critically important that we have an embolic protection device that will reduce the high frequency of embolic events.”*

Darren Mylotte, M.D. – University Hospital Galway

### Dire Clinical Need: Embolic Debris Evident in Up to 99% of Patients



### Most Clinical Cerebrovascular Events Are Periprocedural

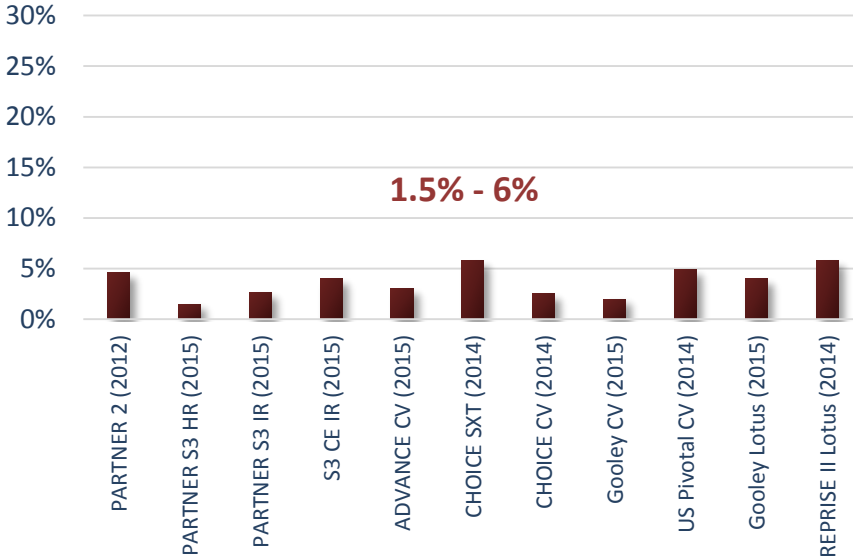
Most of the clinical cerebrovascular events occur during the TAVR procedure ( $\geq 50\%$ ) or on the day of the procedure; Most of these events are ischemic ( $>95\%$ ); No anti-coagulation therapy can resolve this issue completely.

Sources: Kodali, S. SENTINEL – A Prospective, Randomized Trial Evaluating Cerebral Protection in Patients with Severe AS Undergoing TAVR. TCT 2016; Nombela-Franco et al., Circulation 2012;126:3041-53.



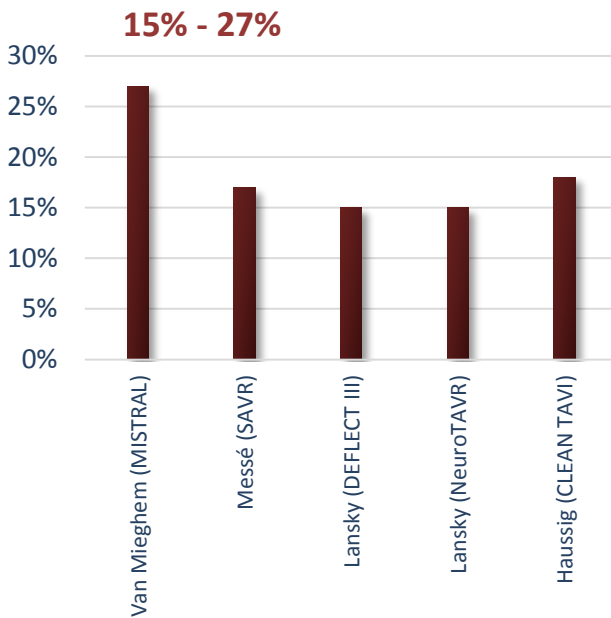
# Stroke Rates May be Underreported in Recent Clinical Trials

## 30-day stroke rates in recent TAVR randomized controlled trials



**Stroke rates Under-Reported?**

**Stroke rate is 15-27% after TAVR by current AHA/ASA definitions**



## TAVR Shifting to Younger and Lower Risk Patients

Cerebral protection becomes even more important with TAVR shifting towards younger and lower risk patients; Recent clinical data from intermediate risk patients undergoing TAVR suggest 30-day stroke risk up to 5.5%.

Sources: Thourani, et al, presented at ACC 2016; Lansky et al., presented at PCR LV 2015.

