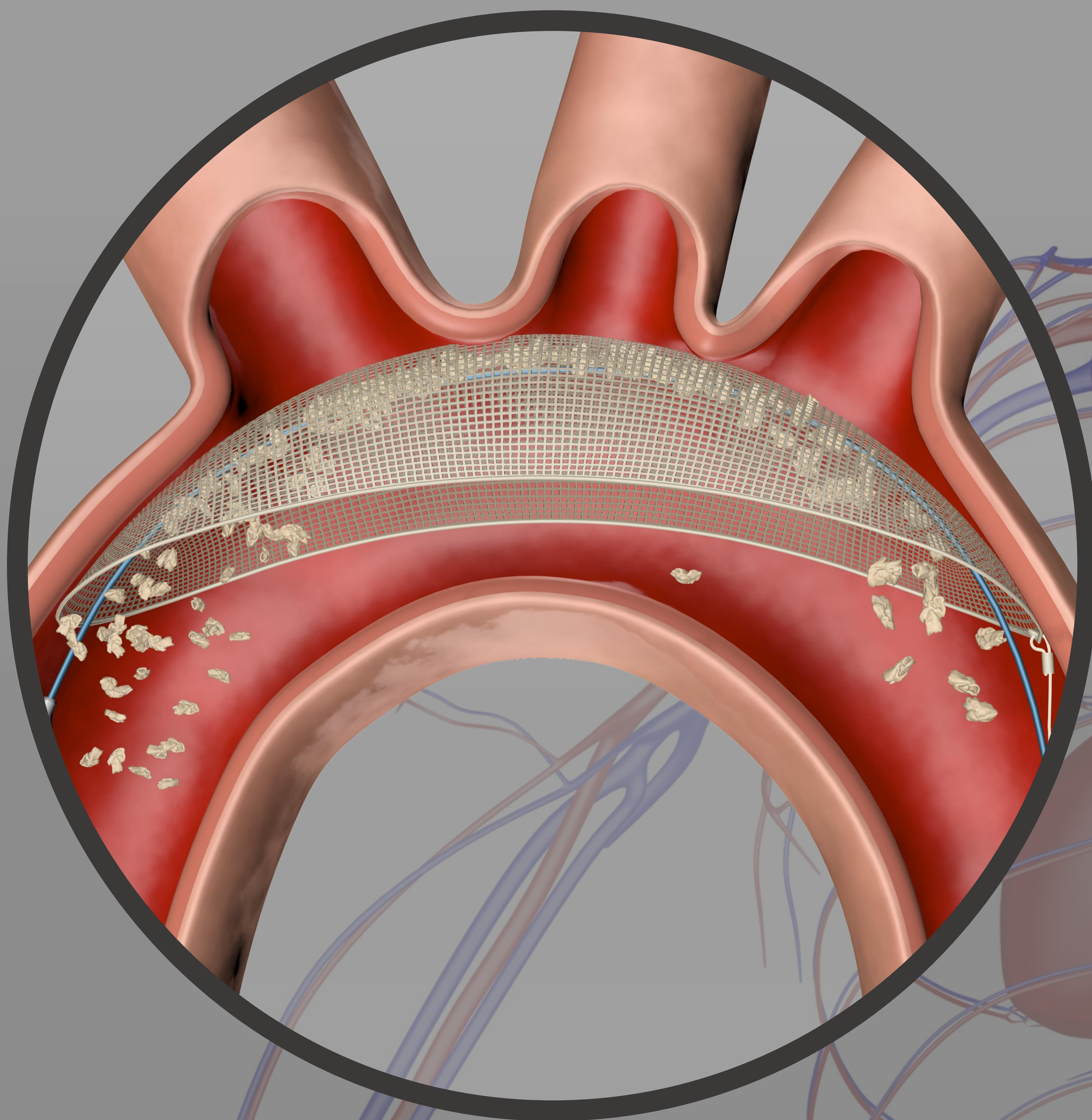


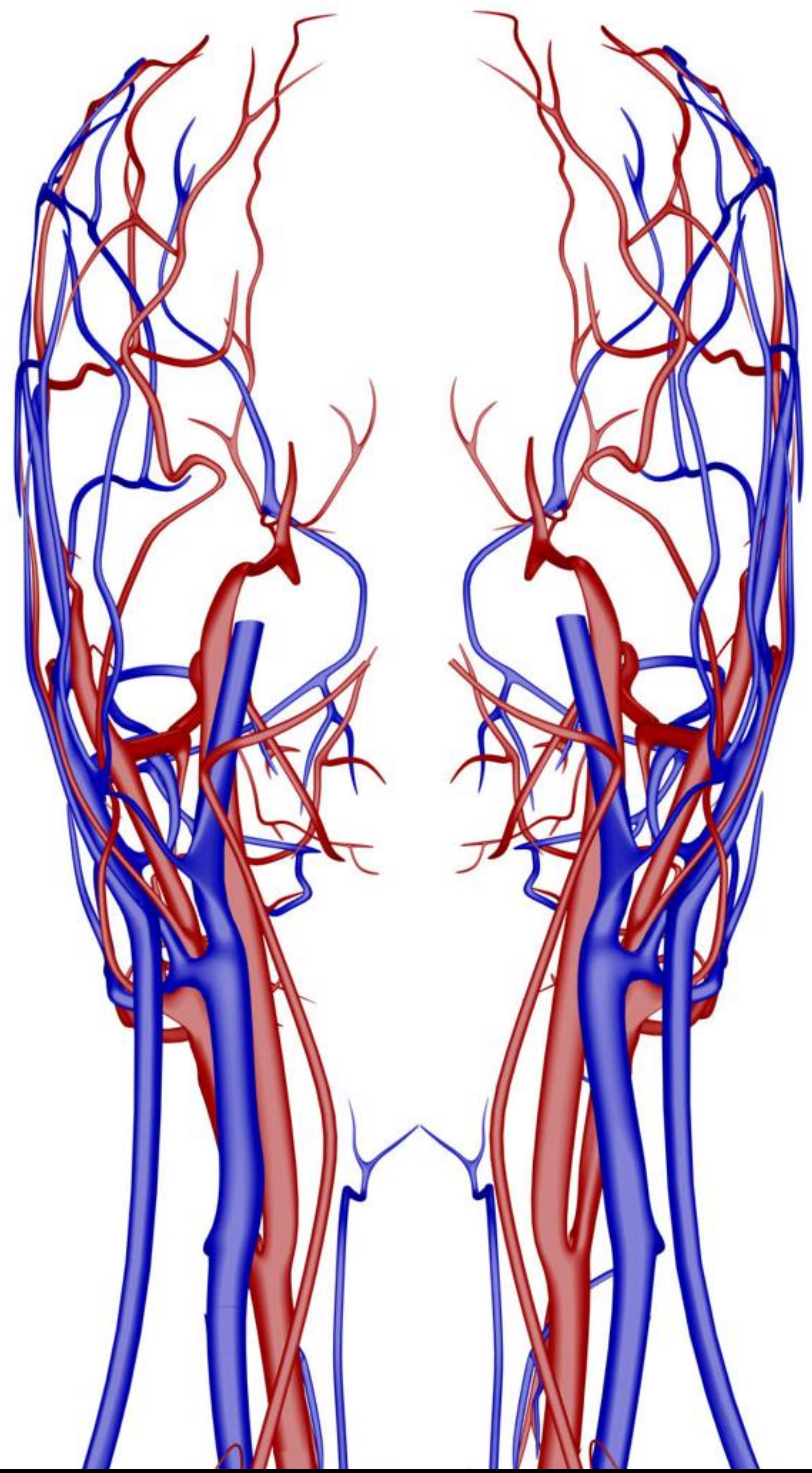
TriGUARD³

CEREBRAL EMBOLIC PROTECTION DEVICE

Complete Coverage by Design



ENTER



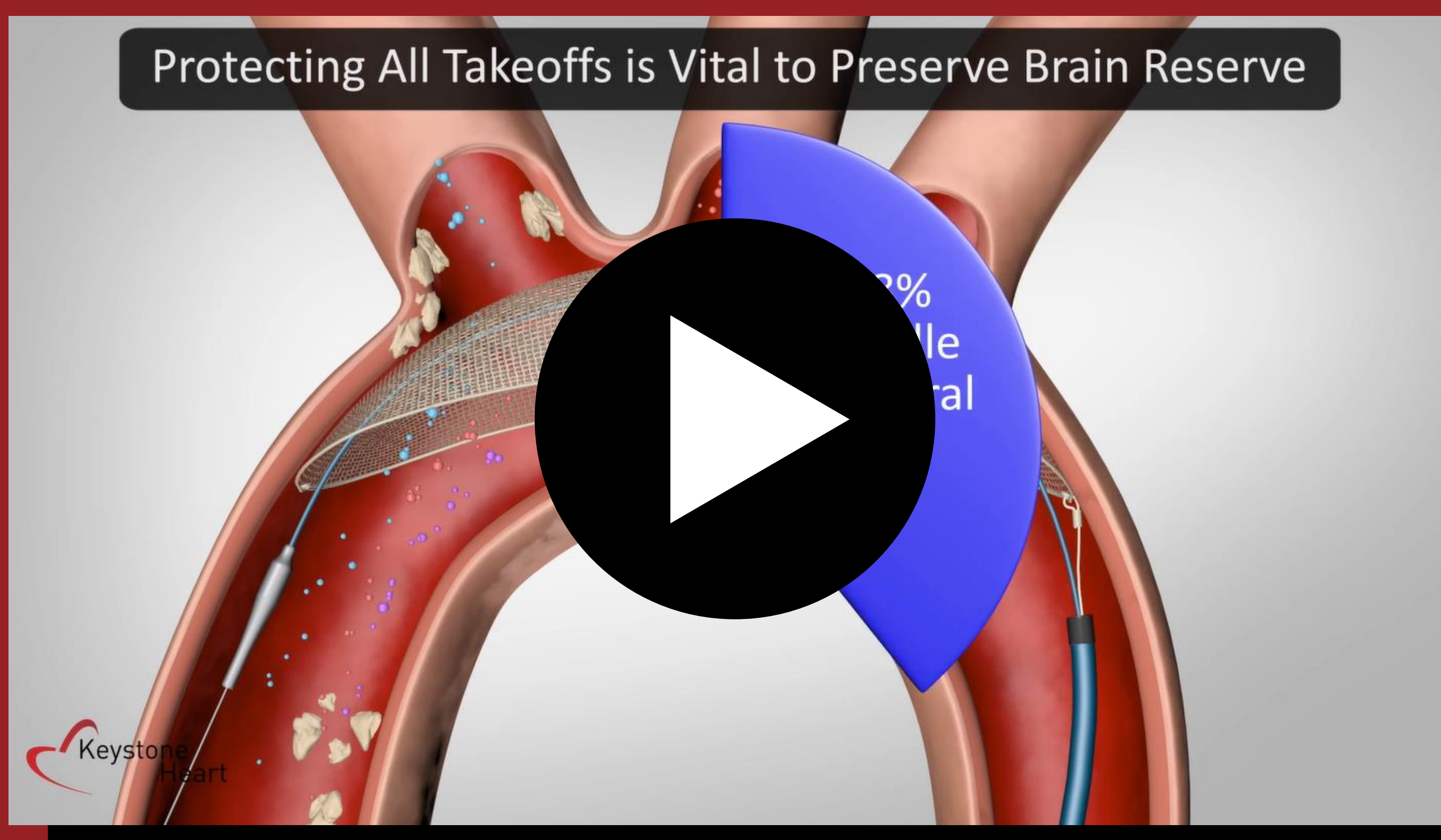
Why is Cerebral Embolic Protection Important?

- Cerebral emboli detected on DWI MRI increases the risk of clinically overt stroke 2-4 times, and can lead to; cognitive dysfunction, depression, impaired mobility, dementia and increased mortality.^{1,2}
- The greater the volume of DWI lesions seen on MRI, the greater the long-term risk of cognitive dysfunction and long-term dementia.^{1,2}
- Cerebral microembolization can occur during each step of a TAVI procedure, notably during manipulation of the calcified aortic valve while the stent prostheses is positioned and implanted.³
- Cerebral embolization demonstrated by DWI MRI is common with TAVR, occurring in 68-98% of cases.^{4,5}
- Peri procedural stroke in patients during TAVI increases thirty-day mortality by four times compared to patients undergoing TAVI without stroke.⁶

Complete 3 Vessel Coverage by Design

Designed to cover and protect **ALL 3** cerebral aortic arch vessels delivered transfemorally exclusive of anatomical restrictions or cerebral vessel manipulation.

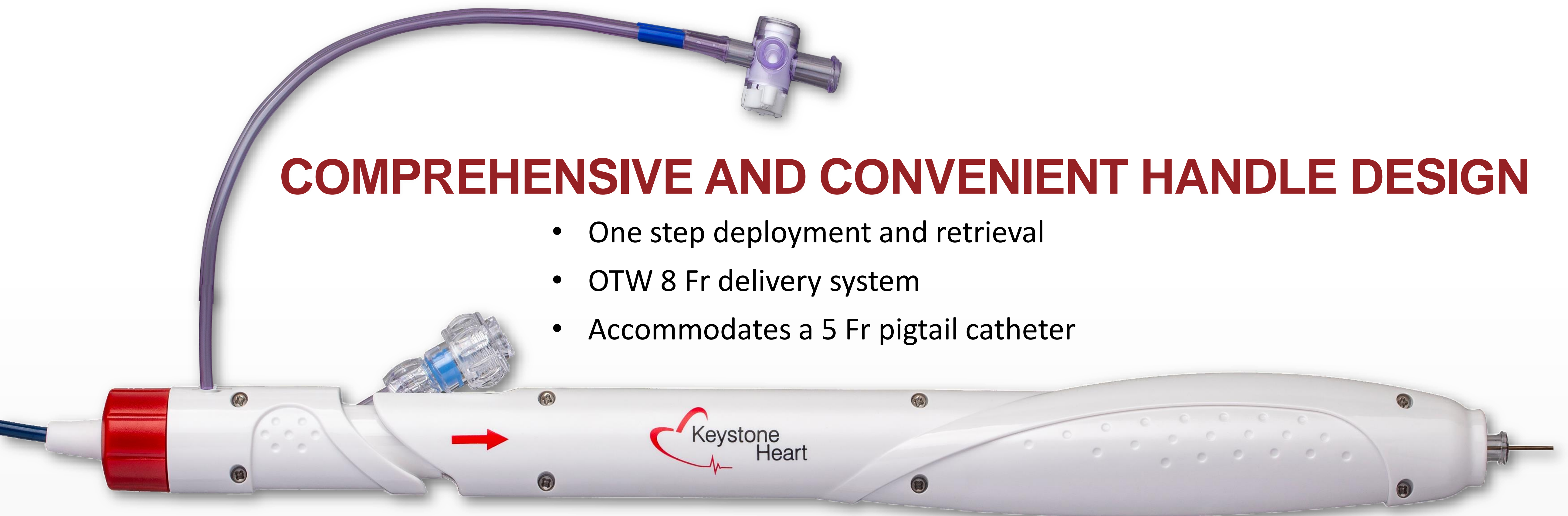
- Rapid deployment in the aortic arch covering ALL 3 vessels
- Self-positioning in the aortic arch
- Stability throughout valve deployment



Designed for Complete Protection and Confidence

COMPREHENSIVE AND CONVENIENT HANDLE DESIGN

- One step deployment and retrieval
- OTW 8 Fr delivery system
- Accommodates a 5 Fr pigtail catheter



NO ADDITIONAL ACCESS SITE REQUIRED

SELF POSITIONS FOR COMPLETE COVERAGE

- Designed to self-position in the aortic arch for complete 3 vessel coverage
- Allows adequate blood flow to brain while diverting emboli downstream
- Nitinol frame conforms to the majority of aortic arch anatomies while providing stability
- Hydrophilic/Heparin coated to reduce risk of thrombogenicity and increase lubricity
- Highly radiopaque for visual confirmation via fluoroscopy
- Minimizes device/TAVI accessories interference



TriGUARD 3™

CEREBRAL EMBOLIC PROTECTION DEVICE

TriGUARD 3™ Cerebral Embolic Protection Device Model Number: FG00005



Technical Specifications

Deflection Filter	Frame Width	74mm
	Frame Length	98mm
Delivery Shaft	Inner Diameter	Accommodates 0.035" Guide-wire
	Total Length	127.5cm
8Fr Sheath	Inner Diameter	8Fr
	Effective Length	76cm
Delivery Effective Length	Strain relief to atraumatic tip (during over the wire advancement)	78cm

References:

1. Sacco RL, Stroke. 2013;44:00
2. Vermeer SE, Lancet Neurol 2007;6:611
3. Kahlert, Circulation. 2012;216:1245
4. Arnold S, J Am Coll Cardiol Intv. 2010;3:1126
5. Lansky AJ, Eur Heart J. 2015;36:2070
6. Muralidharan et al. Am J Cardiol 2016

[CLICK HERE for Important Safety Information](#)

Keystone Heart, LTD

3000 Bayport Drive, Suite 980
Tampa, FL 33607
813-530-8200

website: www.keystoneheart.com
email: info@keystoneheart.com

