Practical Considerations and Design Requirements for Clinically Relevant CEP: The Keystone TriGUARD *3* Device

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Disclosure Statement of Financial Interest

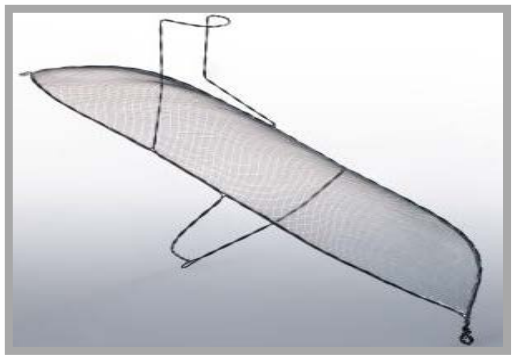
I, Tamim Nazif DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

Designs Goals for CEPD for TAVR

- **The Challenge: To provide safe and efficacious cerebral embolic protection during the TAVR procedure**
- **Specific Goals as an accessory device**
  - **Safety – minimal additional risk**
  - **Efficacy – protect all regions of the brain from emboli**
  - **Ease of use – minimal disruption of TAVR procedure**
  - **Generalizability – suitable for most pts**

Cerebral Embolic Protection For TAVR
Surveying the Device Landscape

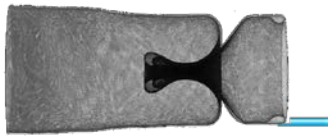
Sentinel
FDA approved 2017



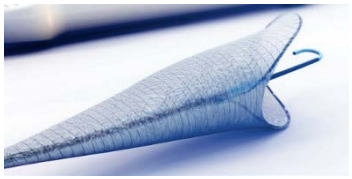
TriGuard HDH
REFLECT Trial

Embrella
Inactive

Point-Guard



Emboliner

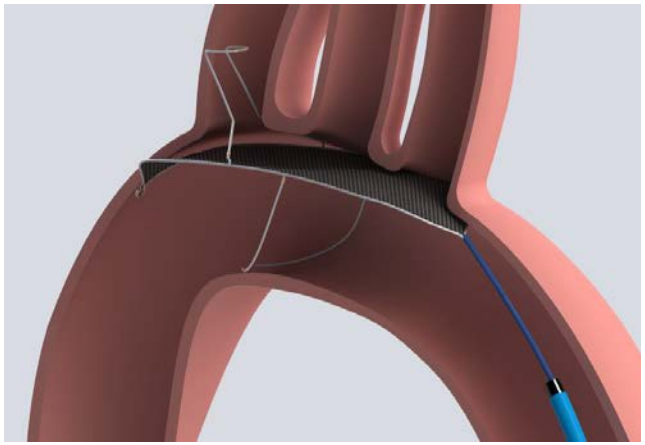


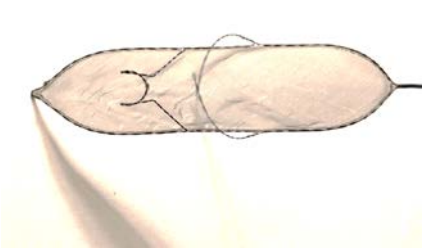
Emblok

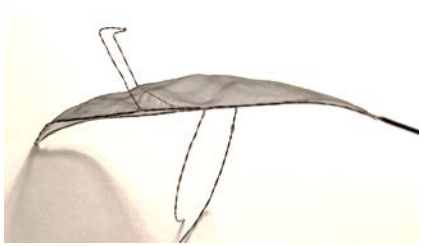
ProtEmbo

FIH/EFS

The Keystone Heart TriGuard Device



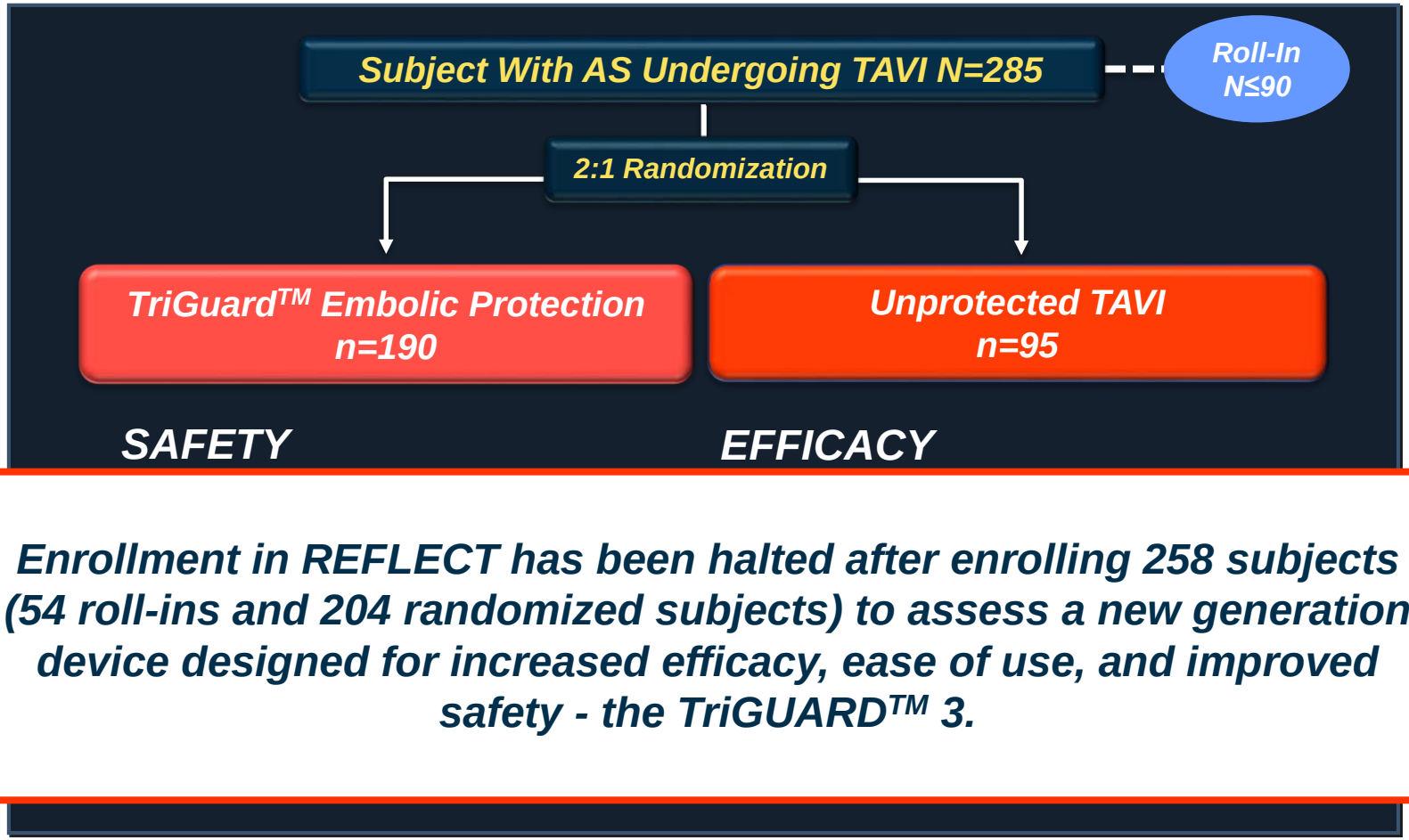




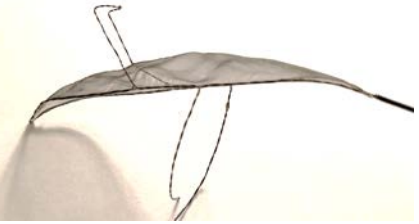
- ***Femoral arterial access: 9 Fr sheath also accommodates pigtail***
- ***Designed for complete 3-vessel cerebral coverage: deflects embolic debris, allows cerebral perfusion***
- ***Self-expanding nitinol frame and mesh filter with pore size of 130 x 250 µm***
- ***Maintained in position by stabilizers in the innominate and aortic arch***

REFLECT US IDE Trial

Chair Jeffrey Moses, CO PIs A Lansky, R Makkar (US) and J Schofer, A Baumbach (EU)



Enrollment in REFLECT has been halted after enrolling 258 subjects (54 roll-ins and 204 randomized subjects) to assess a new generation device designed for increased efficacy, ease of use, and improved safety - the TriGUARD™ 3.

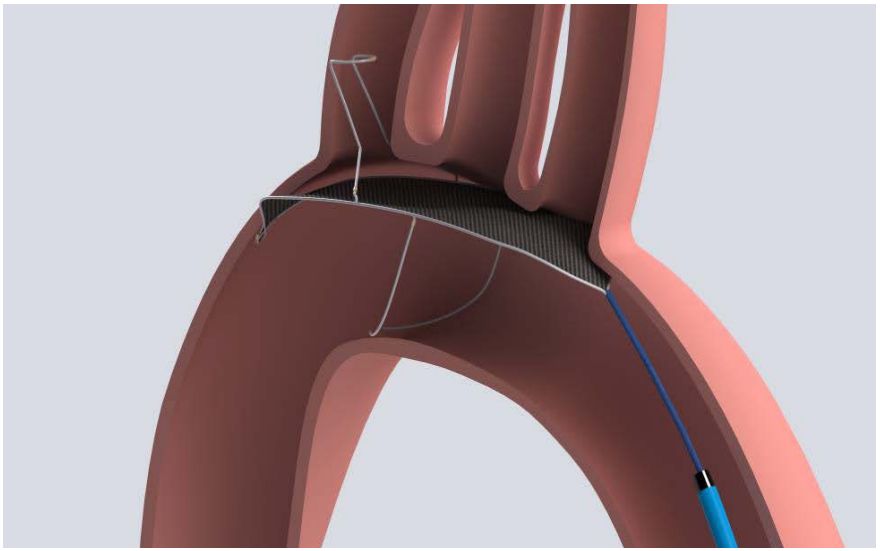


TriGuard HDH Lessons Learned: Successes and Challenges

- **Safety and Efficacy**:
  - Complete 3 vessel cerebral embolic protection.
  - Flexible, atraumatic nitinol filter unit shown safe, effective in DEFLECT III. REFLECT results remain blinded.
- **Ease of Use**:
  - Contralateral femoral access and accommodation of pigtail catheter fits well into procedure flow.
  - Positioning, ensuring guidewires stay below, and avoiding interaction with TAVR devices sometimes challenging
- **Generalizability**:
  - Approximately 1/3 of patients screen out due to anatomic criteria (innominate size, calcification, angulation)

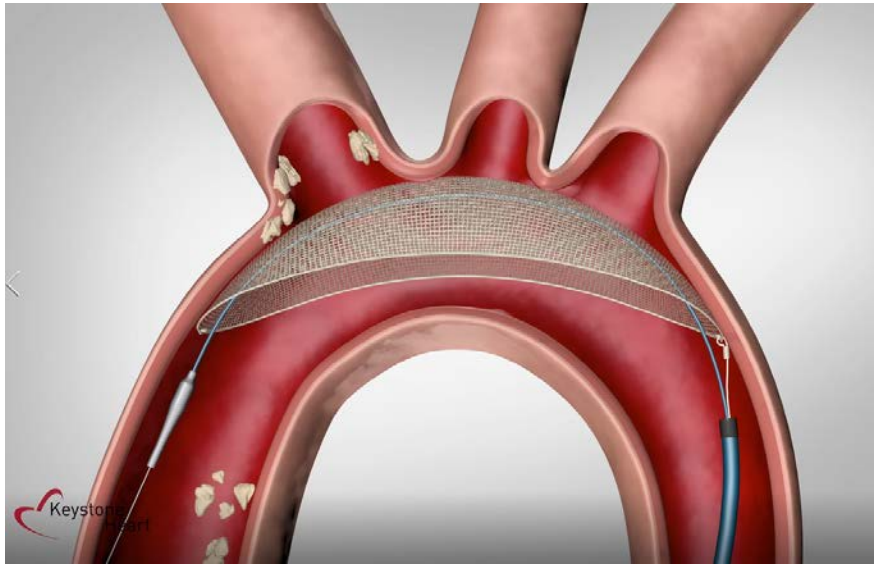
TriGuard HDH vs. TriGUARD *3*

TriGuard HDH



- *Nitinol frame with upper and lower stabilizers*
- *Nitinol mesh (pore size 130 x 250 µm)*
- *Filter area = 20.9 cm²*
- *9 Fr RX delivery*

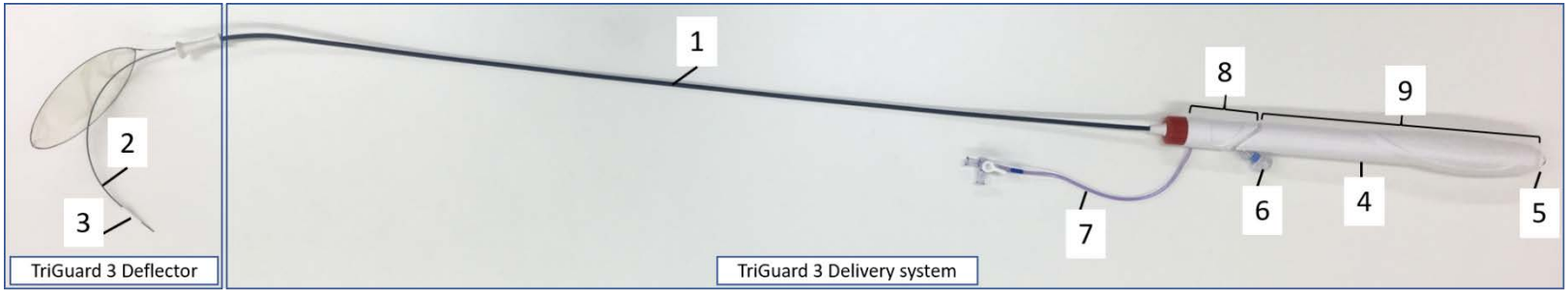
TriGUARD *3*



- *Self-positioning, nitinol frame without stabilizers*
- *PEEK mesh (pore size 115 x 145 µm)*
- *Filter area = 68.3 cm²*
- *8 Fr OTW delivery*

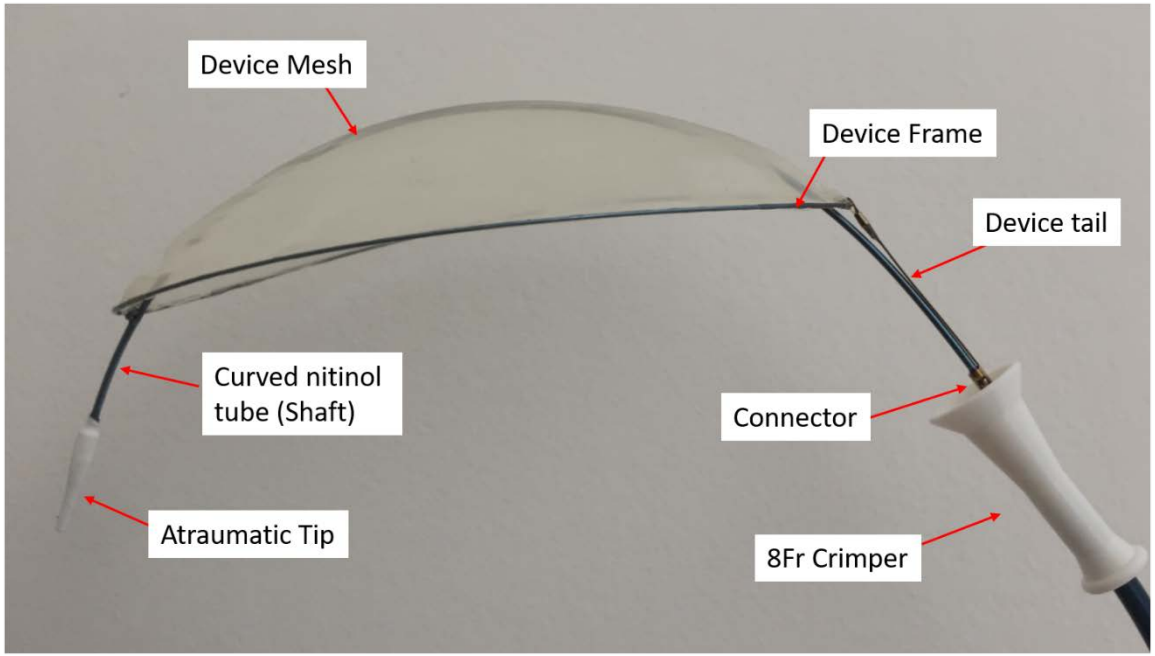
Identical principle of operation and intended use

TriGUARD™ *3* System



1. 8 Fr commercial delivery sheath (included)
2. Nitinol shaft
3. Atraumatic tip accommodates guidewire
4. Control handle: pulling (8) against (9) unsheaths filter unit
5. Shaft end, Luer lock, 0.035” guidewire entry port
6. Y-connector, pigtail entry port
7. Flushing port
8. Handle front (connected to the delivery sheath)
9. Handle back (connected to the nitinol shaft)

TriGUARD *3* Filter



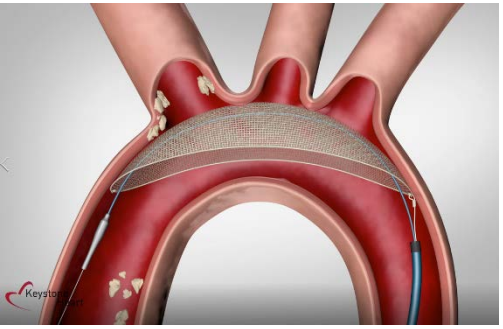
- ***Dome-shaped PEEK mesh (pore size 115 x 145 µm); 60% open area***
- ***Heparinized coating (identical to TriGuard HDH)***
- ***Self-positioning, self-stabilizing, radiopaque nitinol frame***
- ***Over-the-wire nitinol delivery shaft (length = 1275 mm)***
- ***Atraumatic distal tip***

TriGuard *3* Animation

- **Video here**

TriGuard 3 Specific Advantages

- **Safety**:
  - Smaller sheath (8 Fr), OTW delivery, atraumatic tip, elimination of innominate/arch stabilizers.
- **Efficacy**:
  - Improved apposition, increased mesh area, decreased pore size
- **Ease of Use**:
  - Ergonomic handle, OTW delivery, simplified deployment, improved visualization. Positioning and apposition minimize interactions
- **Generalizability**:
  - Relative anatomy independence, no exclusions related to innominate / arch anatomy



Conclusion

- The Keystone Heart TriGUARD 3 is a next generation cerebral embolic protection device for TAVR
- Features the same complete, 3-vessel cerebral protection from femoral arterial access as the original
- Specific design features are expected to improve both safety and efficacy
- There has also been an increased focus on ease of use and generalizability to ensure real world utility