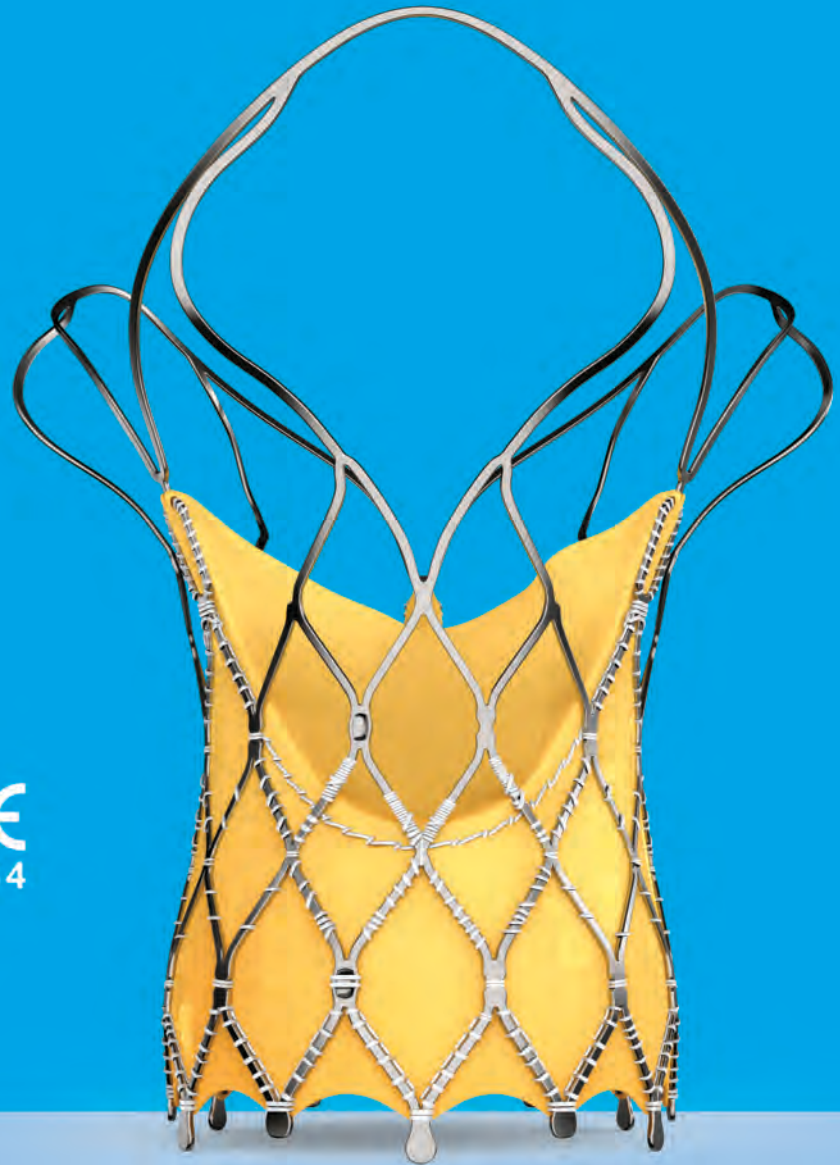


hydra

CE
1434

Transcatheter Aortic Valve



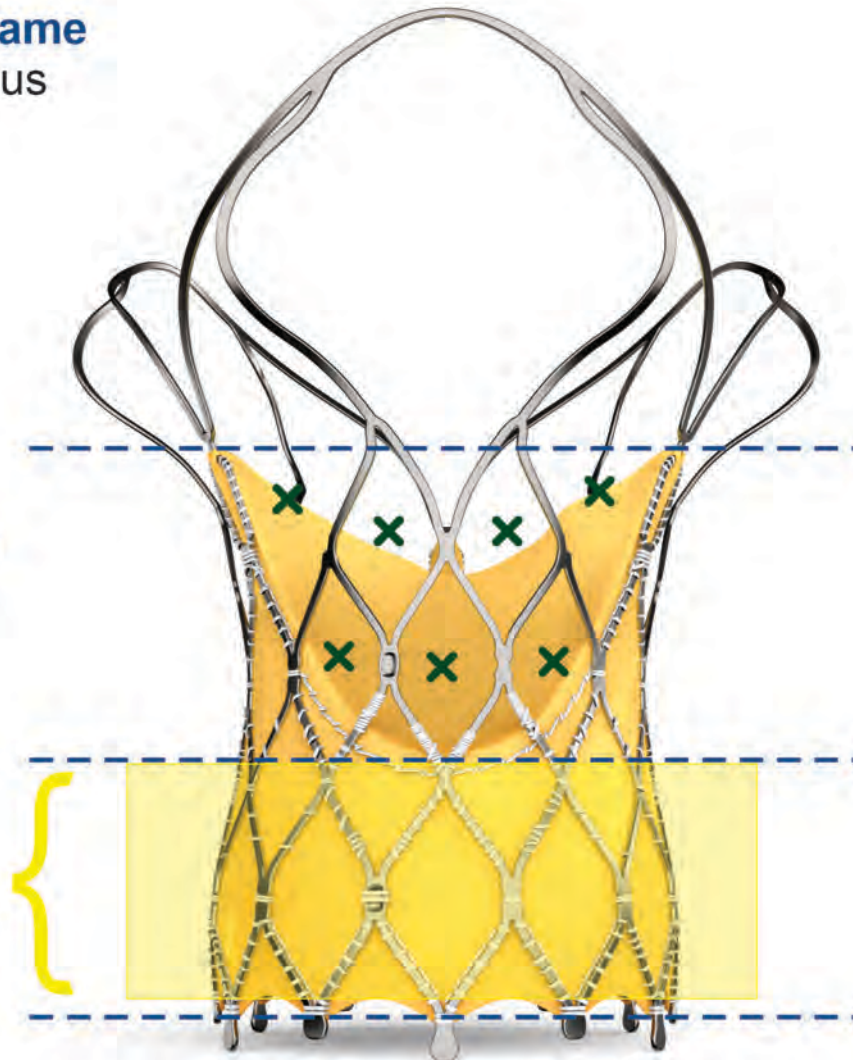
Self-Expandable Nitinol Frame
Conformable to native annulus

Three Tentacle Design
Less metal at outflow

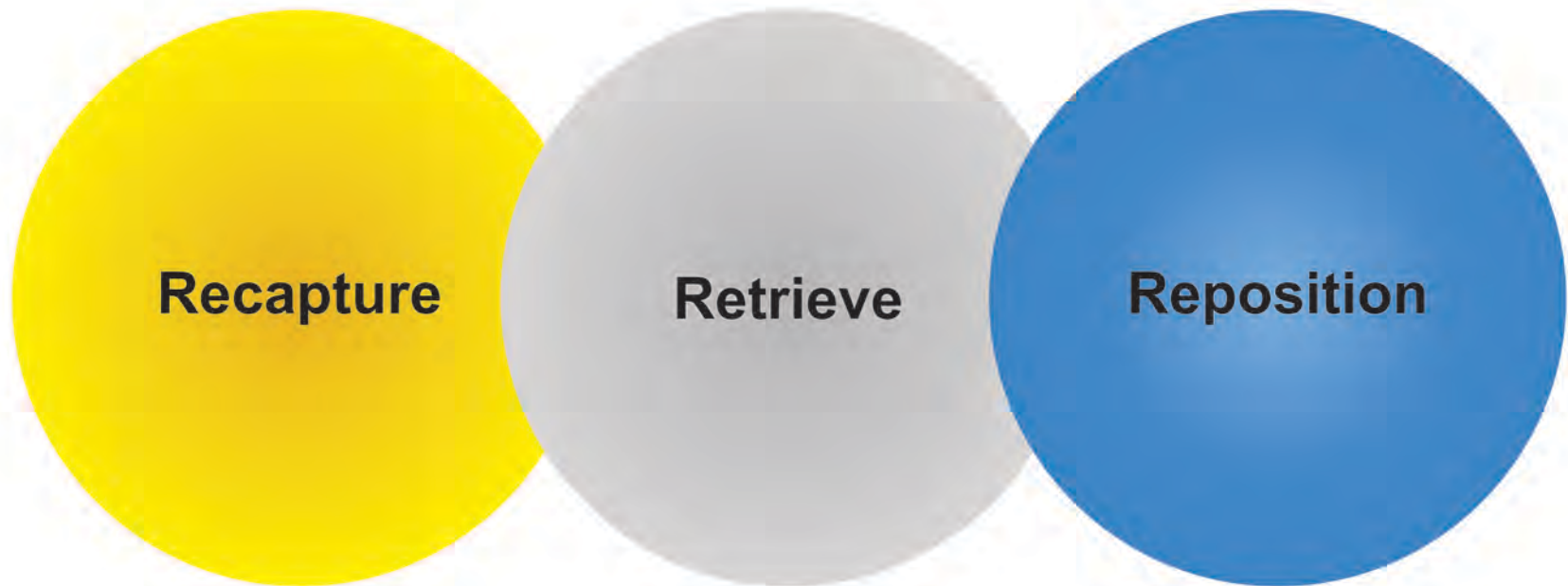
Large Frame Cells ($\geq 15F$)
Facilitates easy access to the coronary arteries

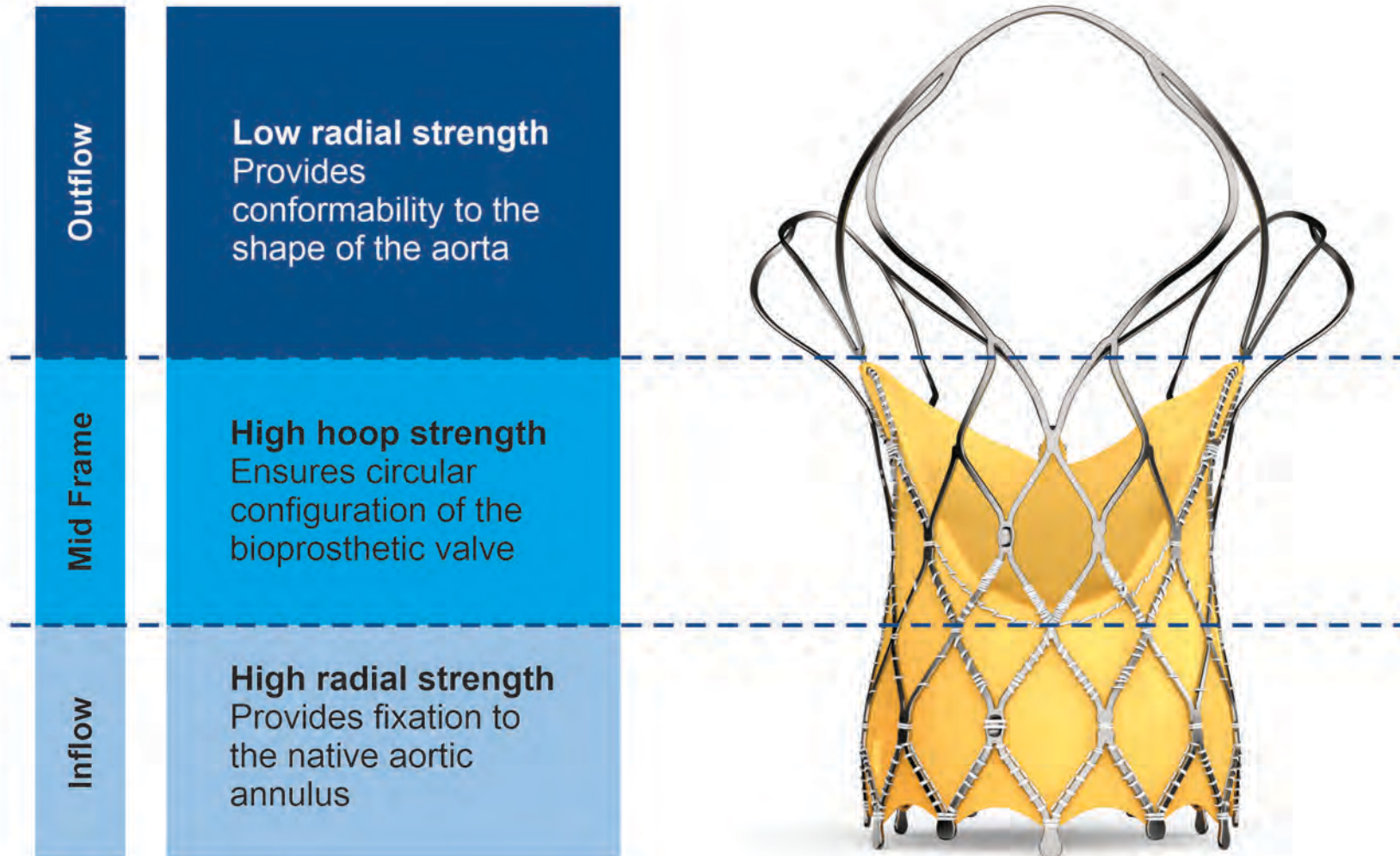
Extended Sealing Skirt
Mitigates paravalvular leak

Non-Flared Inflow Part
Reduces conduction abnormality



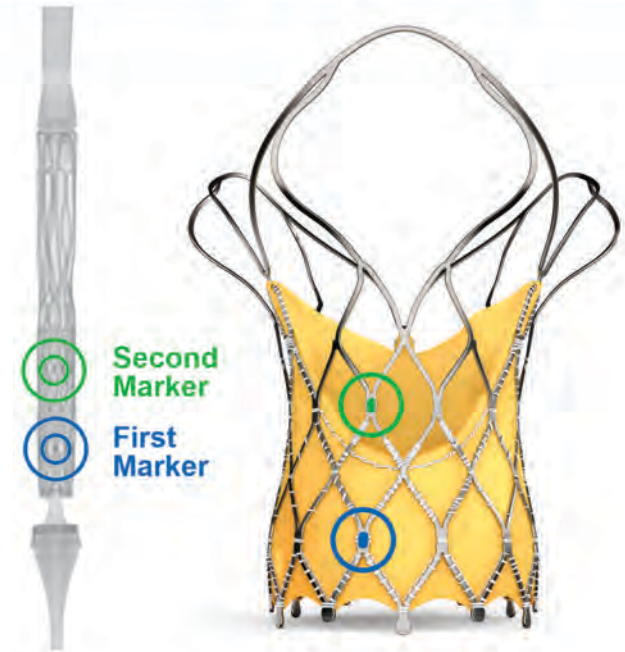
Each 'x' represents a single large cell





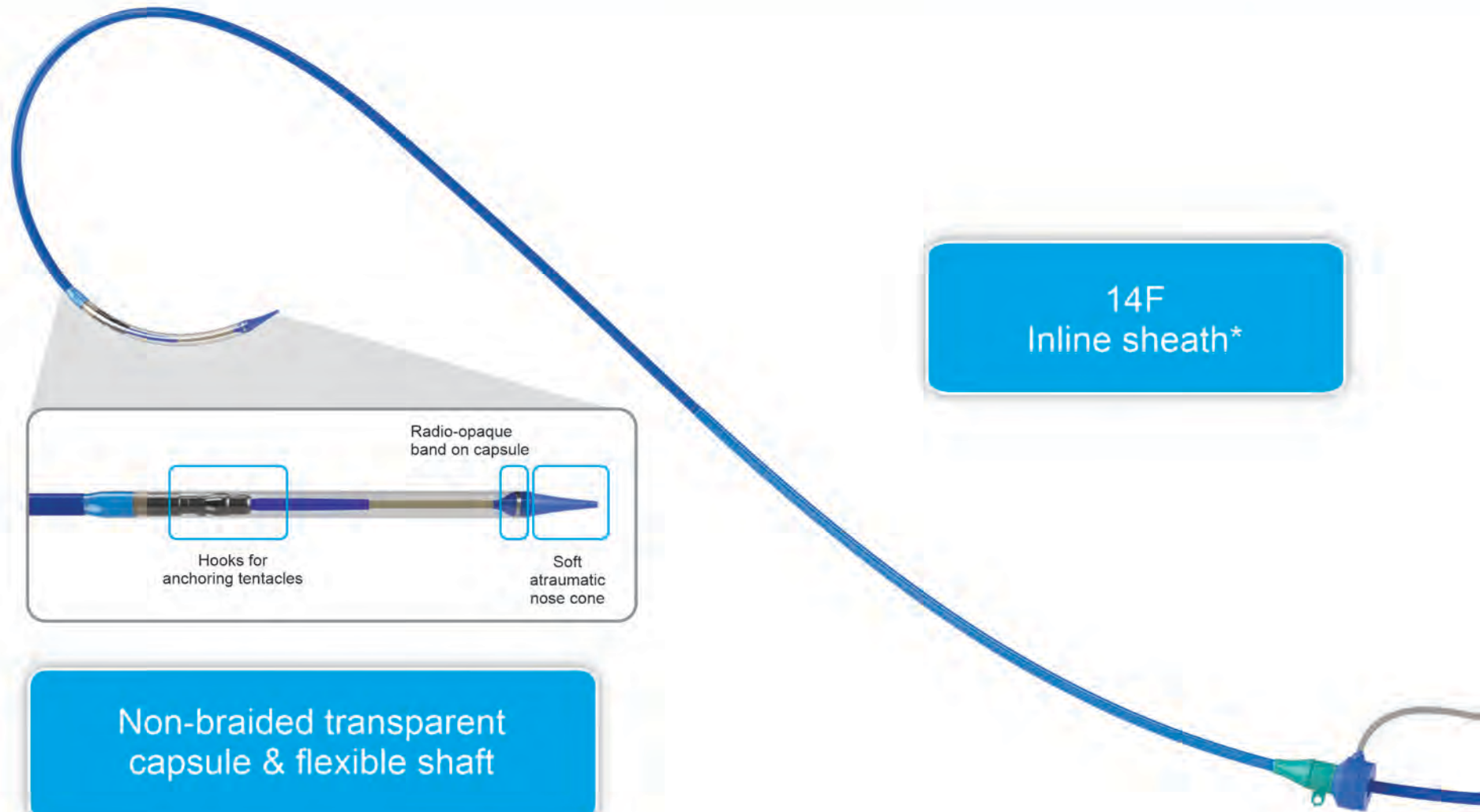
Marker Location and Significance

- First self-expanding TAVI device to have 2 rows of marker
 - **First markers** are located at **Node 1**
 - **Second markers** are located at **Node 3**
- **First markers** help
 - In precise implantation of the valve at the targeted implantation zone
 - To ascertain the depth of implant
- **Second markers** indicate
 - When the THV leaflets are going to get deployed

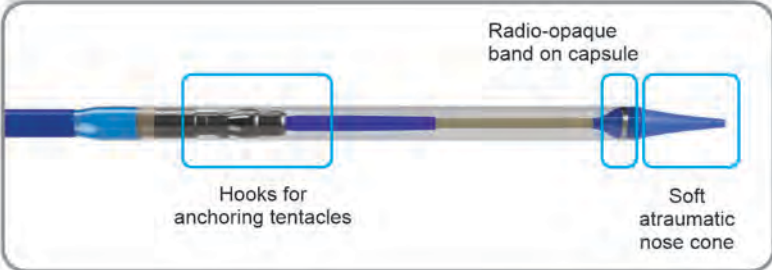


Case Example

Hydra AVDC (Aortic Valve Delivery Catheter)



14F
Inline sheath*



Non-braided transparent capsule & flexible shaft

Ease of navigation through tortuous anatomy and coplanar implantation in horizontal aorta

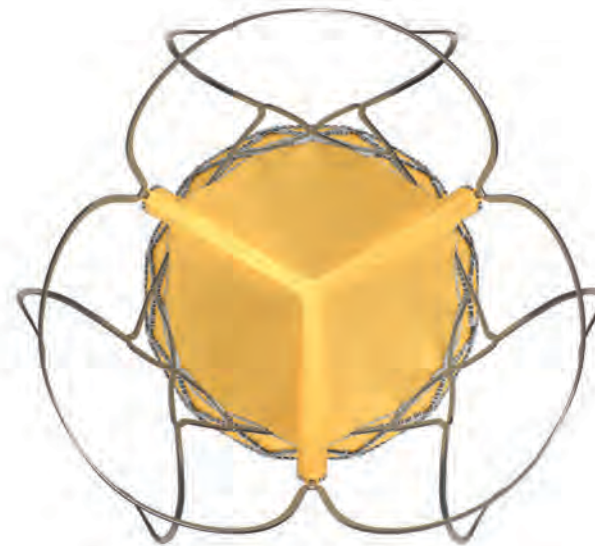
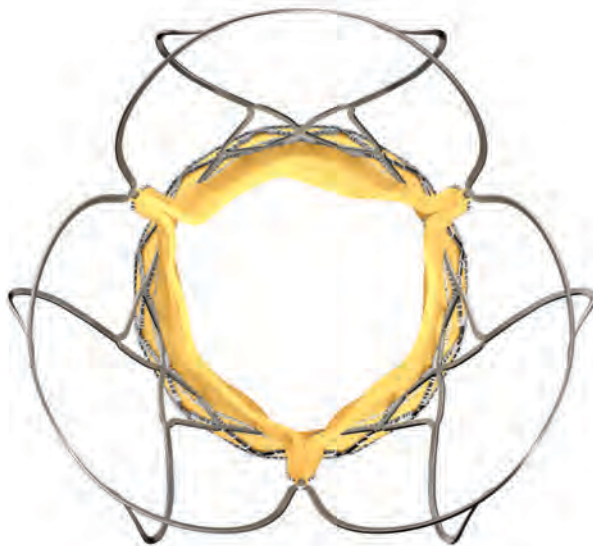
Improved control handle along with Active Release

Provides overall stability and control during valve implantation to achieve the desired implant depth



* 14F equivalent integrated sheath diameter for patients requiring 22 mm or 26 mm Hydra valve.

- Made from **single bovine pericardium**
- Bioprosthetic valve leaflets are **supra-annular** in position, provide superior hemodynamics by providing larger effective orifice area and lower pressure gradient
- **Supra-annular** valve position helps to maintain circular shape of the bioprosthetic valve even if the native annulus shape is elliptical
- Proprietary **anti-calcification** treatment

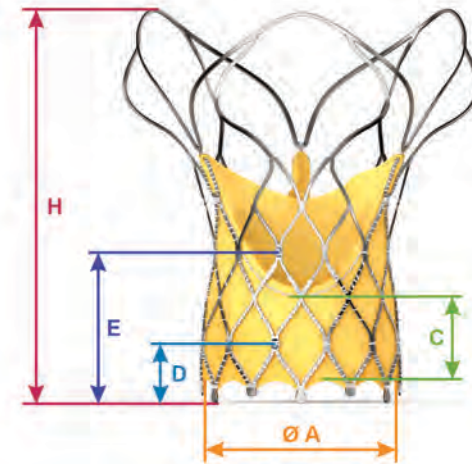
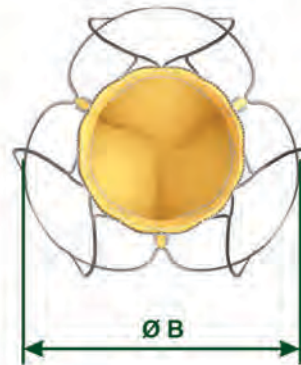


Size Matrix



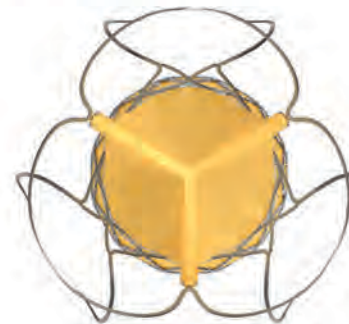
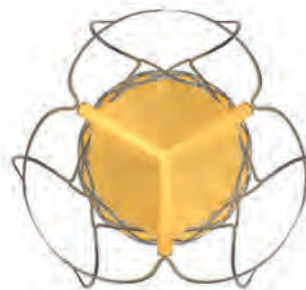
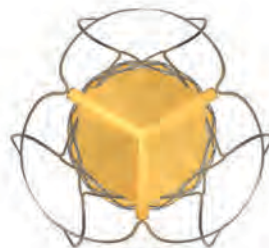
| | | Hydra 22 | Hydra 26 | Hydra 30 |
|----------------------|---|----------|----------|----------|
| Diameter at Bottom | A | 22 | 26 | 30 |
| Diameter at Top | B | 39 | 43 | 47 |
| Sealing Skirt Height | C | 12 | 13 | 14 |
| First Marker Crimped | X | 8 | 9 | 10 |
| First Marker | D | 5 | 6 | 7 |
| Second Marker | E | 15 | 18 | 21 |
| Height | H | 55 | 53 | 51 |

Sizes mentioned in "mm"



Crimped

Intended Annular Treatment Range



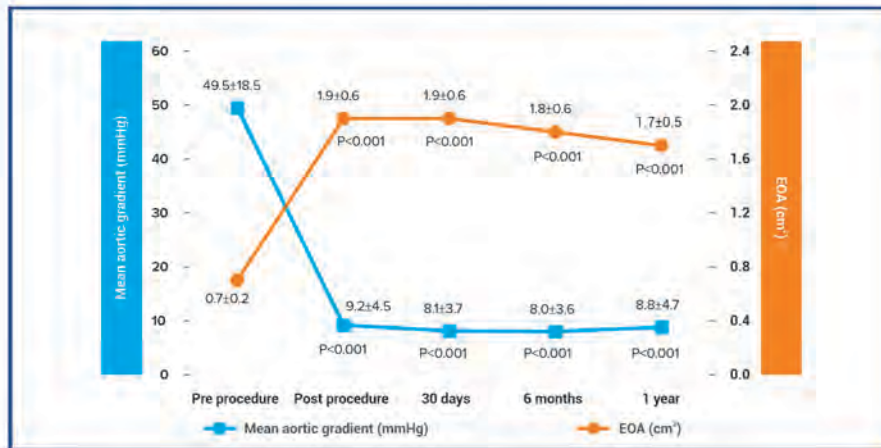
17 18 19 20 21 22 23 23.5 25 26 27

Annulus Size (mm)

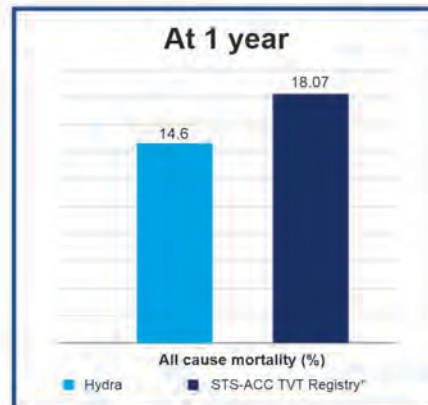
Transesophageal Echocardiogram (TEE) Derived Annular Treatment Range

Excellent Hemodynamics¹

- Single digit valve gradient up to 1-year follow-up.
- Larger effective orifice area (EOA) up to 1-year follow-up.



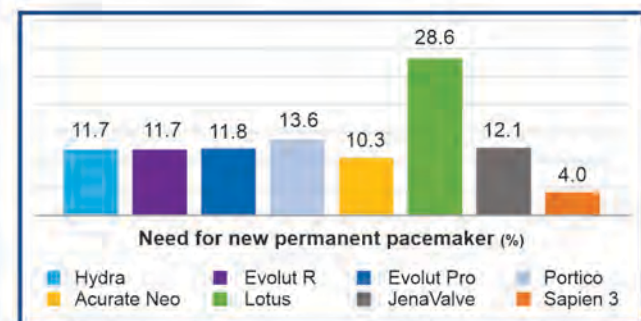
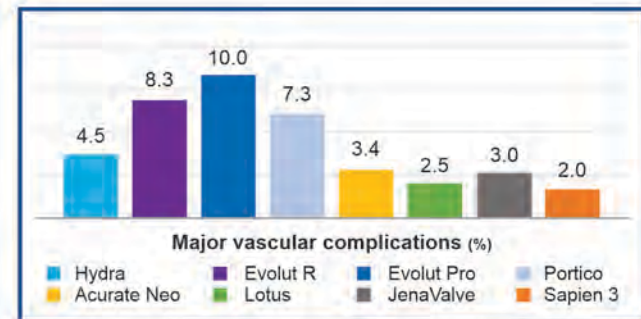
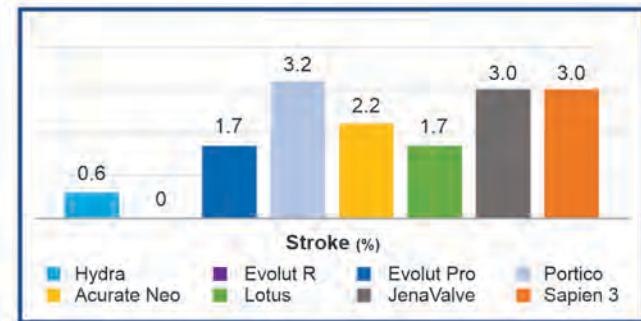
Comparison of Hydra CE study with STS-ACC TVT Registry of TAVR^{1,2}



*2015 data

Comparison of CE-mark studies for major TAVR devices¹

At 30 days



TAVR - Transcatheter Aortic Valve Replacement

| Frame | Valve | Hydra AVDC | Safety features |
|--|---|---|---|
| <ul style="list-style-type: none">▶ Varying radial force▶ Two set of markers on the frame for precise positioning▶ Highly flexible design and easy navigation due to less metal▶ Extended sealing skirt▶ Large open cells for future coronary access | <ul style="list-style-type: none">▶ Supra-annular design▶ Bovine pericardial tissue▶ Anti-calcification treatment | <ul style="list-style-type: none">▶ Flexible non-braided capsule▶ Radio-opaque band on capsule▶ 14F equivalent *▶ Active release mechanism | <ul style="list-style-type: none">▶ Recapturable▶ Repositionable▶ Retrievable |

AVDC - Aortic Valve Delivery Catheter * 14F equivalent integrated sheath diameter for patients requiring 22 mm or 26 mm Hydra valve.

Ordering Information

| Reference Number | Size |
|------------------|-------|
| HYDRA22 | 22 mm |
| HYDRA26 | 26 mm |
| HYDRA30 | 30 mm |

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HYDRA/BRO/EN01 REV.03

