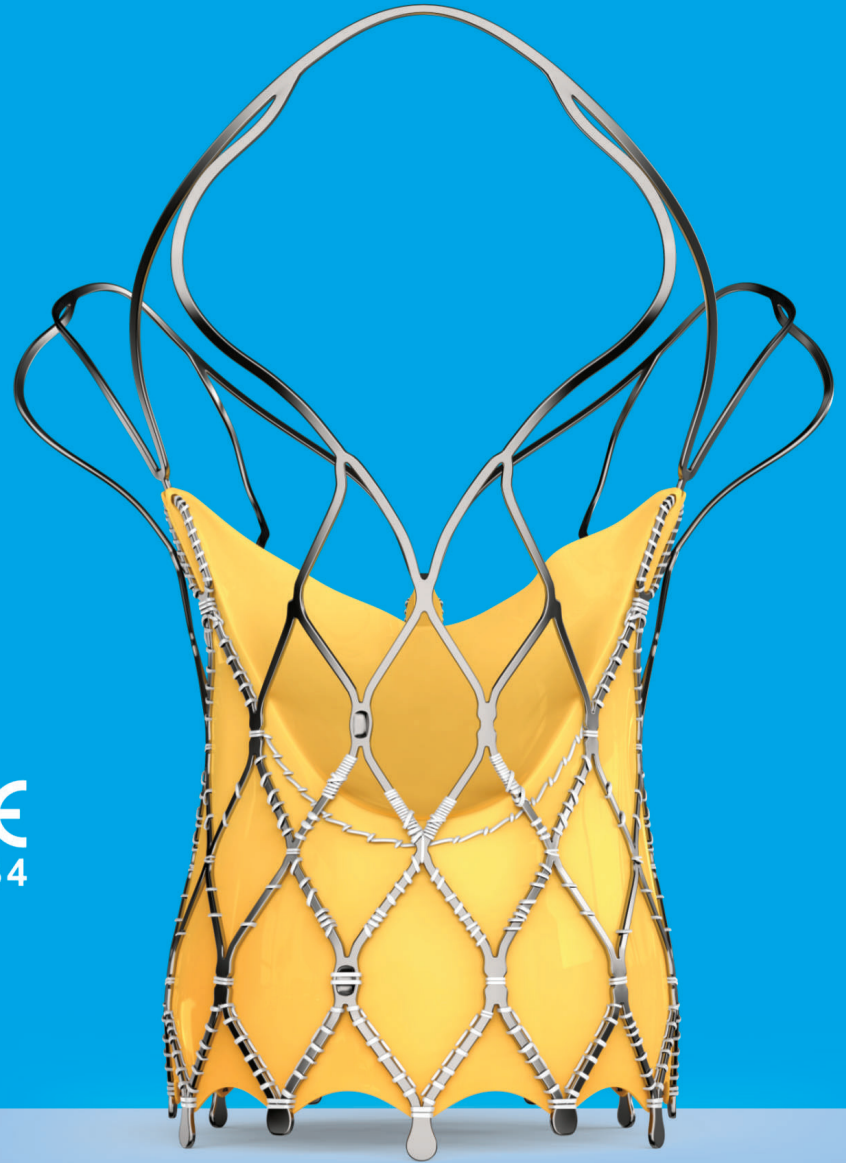


hydra

CE  
1434

Transcatheter Aortic Valve



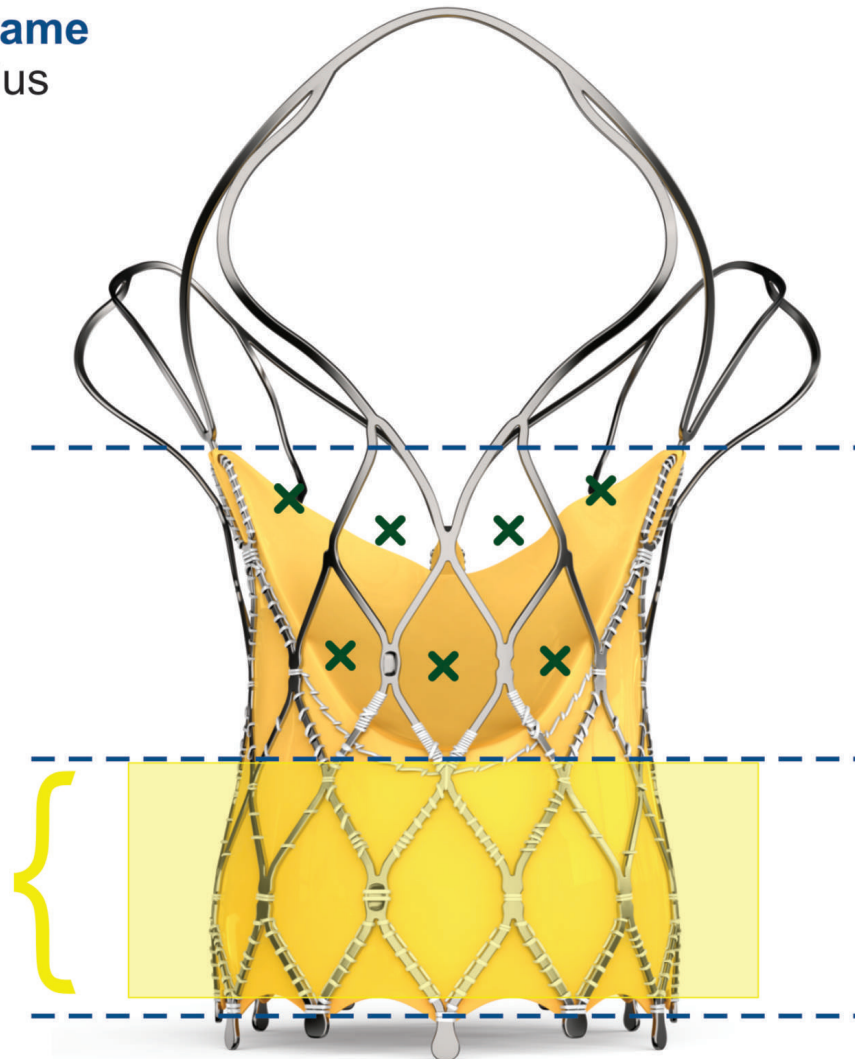
**Self-Expandable Nitinol Frame**  
Conformable to native annulus

**Three Tentacle Design**  
Less metal at outflow

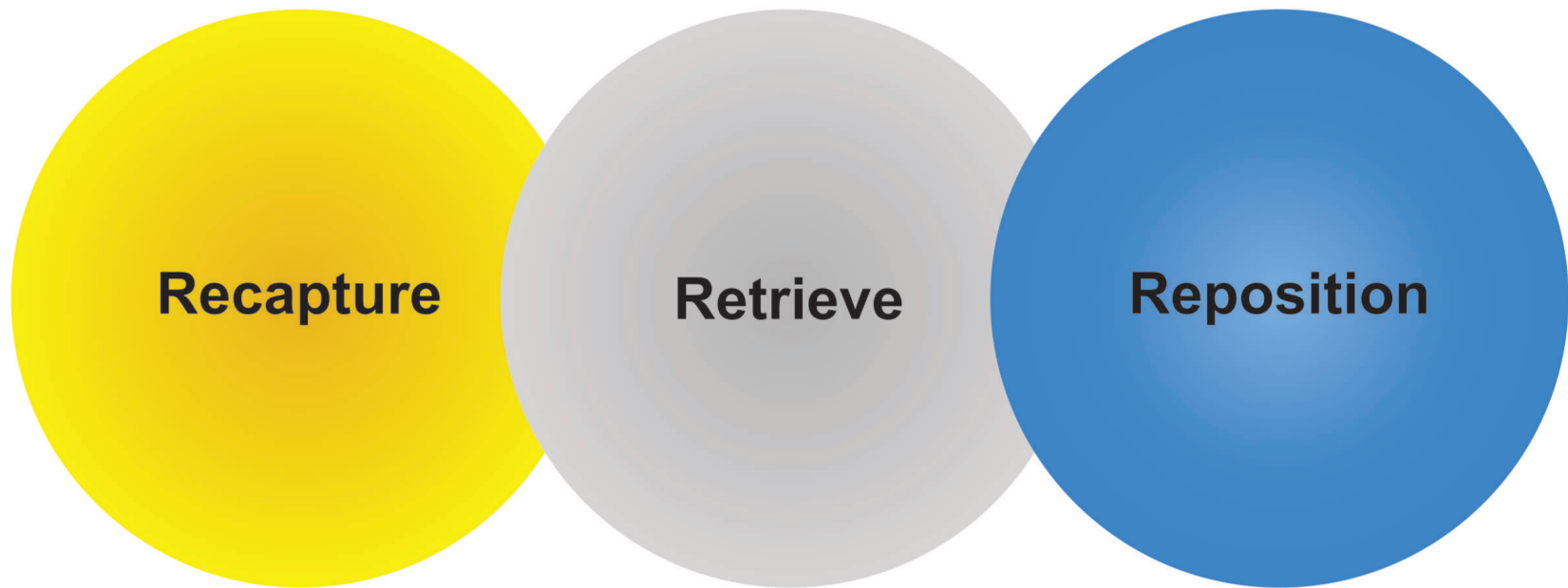
**Large Frame Cells ( $\geq 15F$ )**  
Facilitates easy access to the coronary arteries

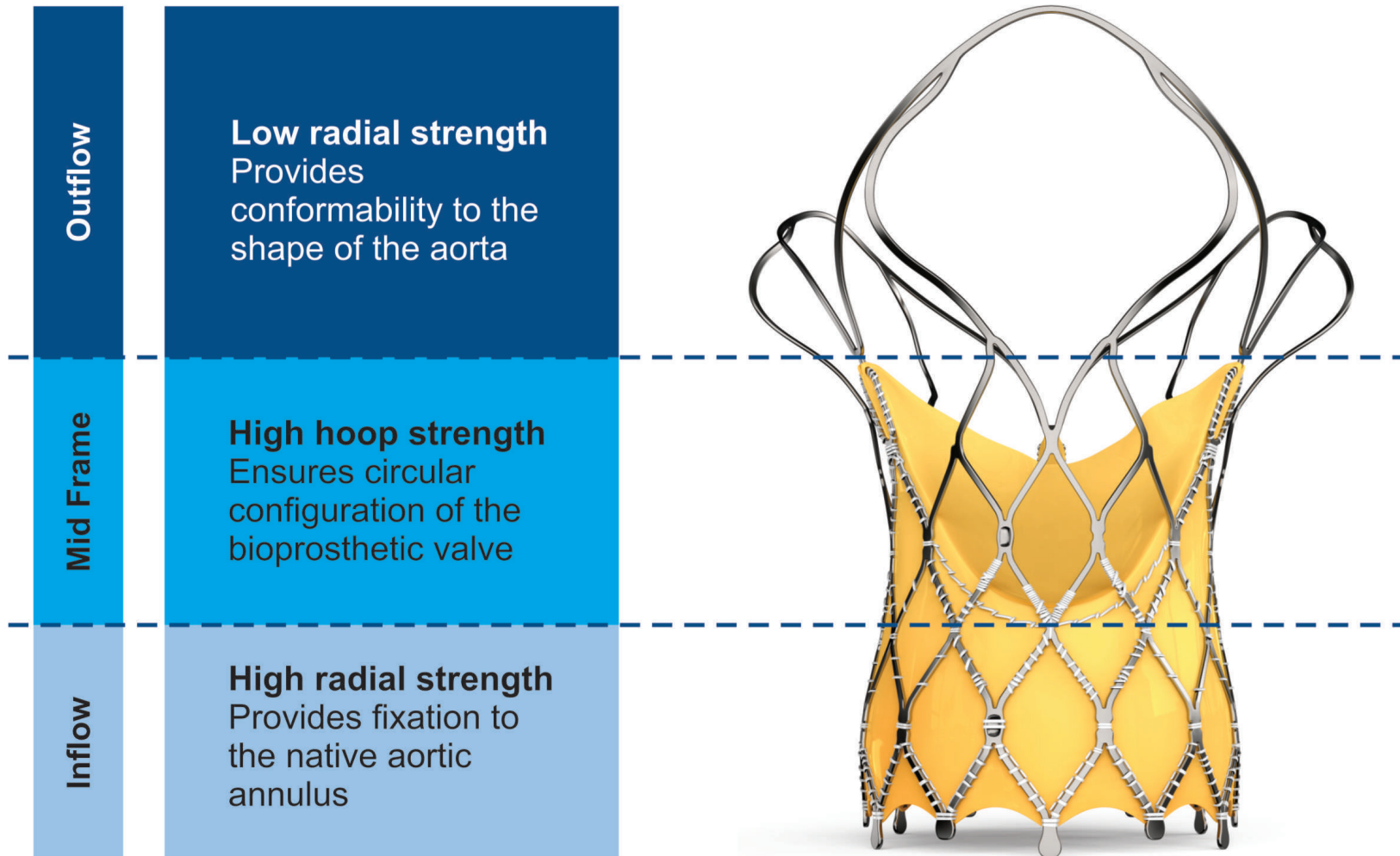
**Extended Sealing Skirt**  
Mitigates paravalvular leak

**Non-Flared Inflow Part**  
Reduces conduction abnormality

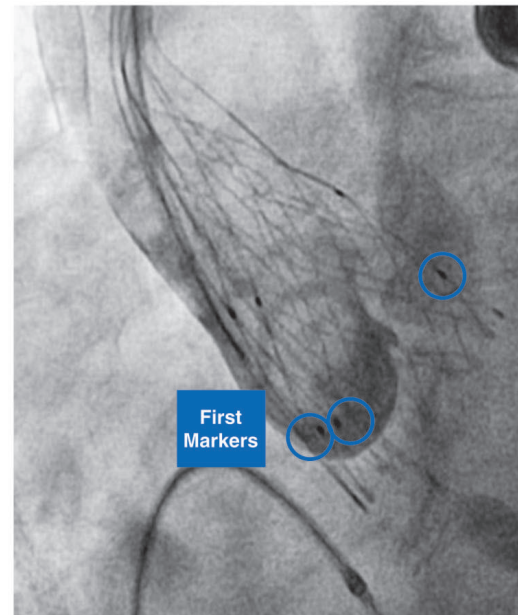
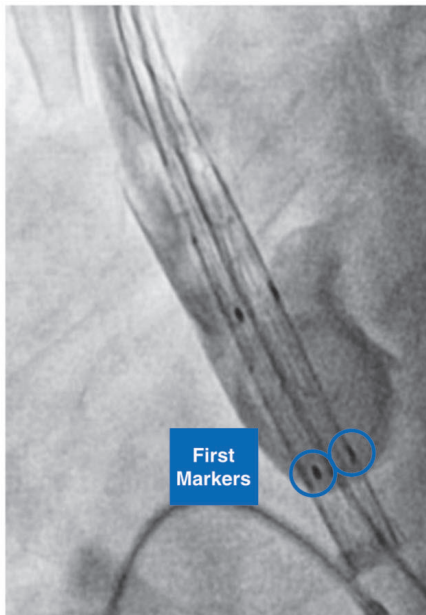
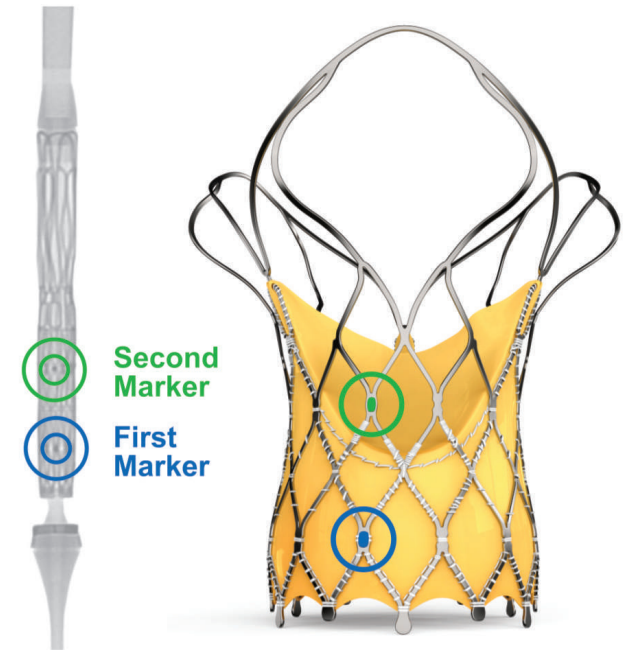


Each 'X' represents a single large cell



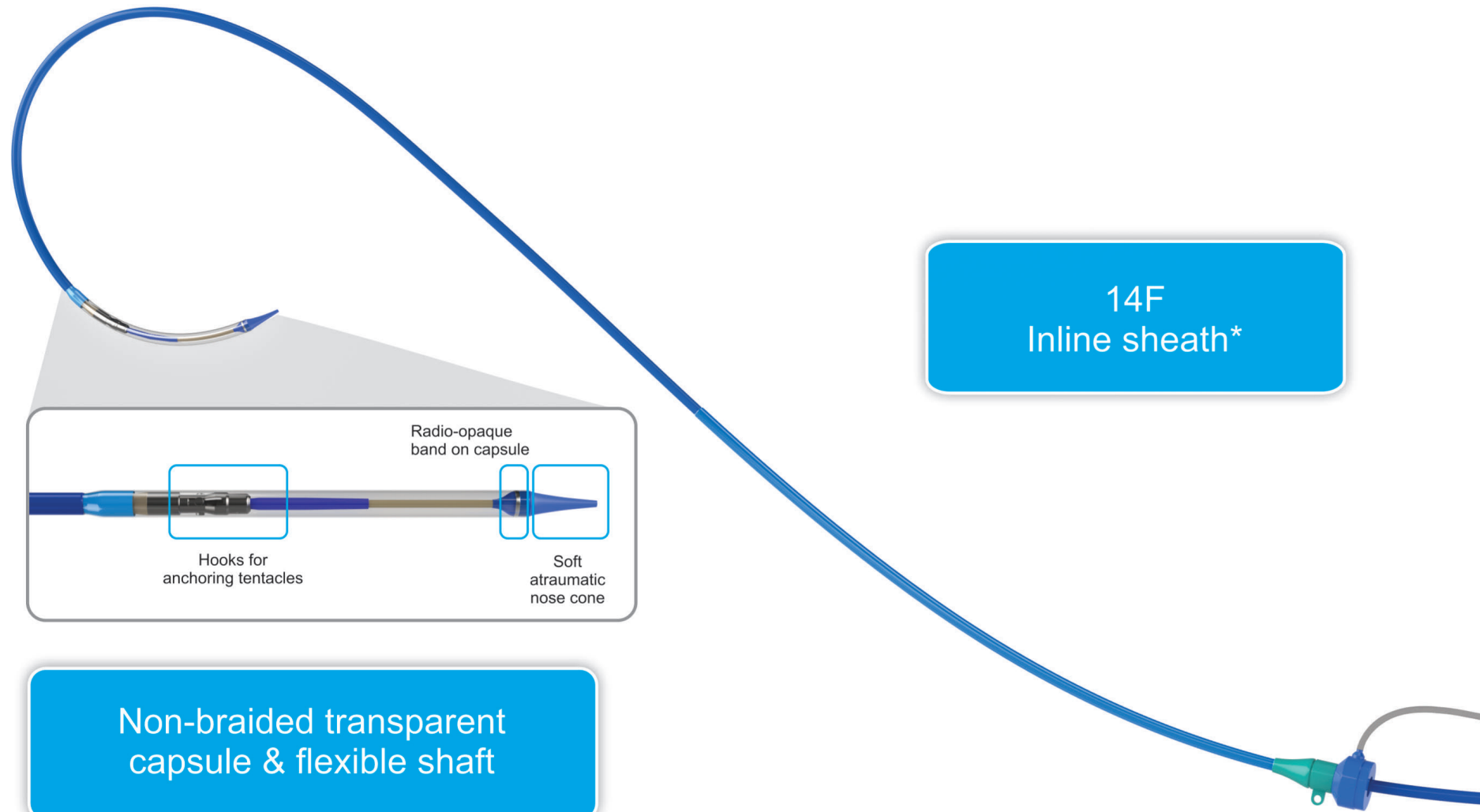


- First self-expanding TAVI device to have 2 rows of marker
  - **First markers** are located at **Node 1**
  - **Second markers** are located at **Node 3**
- **First markers** help
  - In precise implantation of the valve at the targeted implantation zone
  - To ascertain the depth of implant
- **Second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

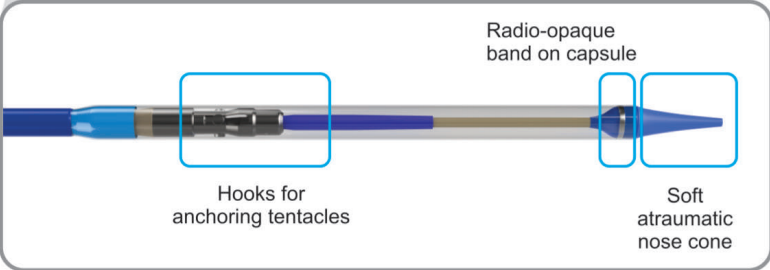


Case Example





14F  
Inline sheath\*

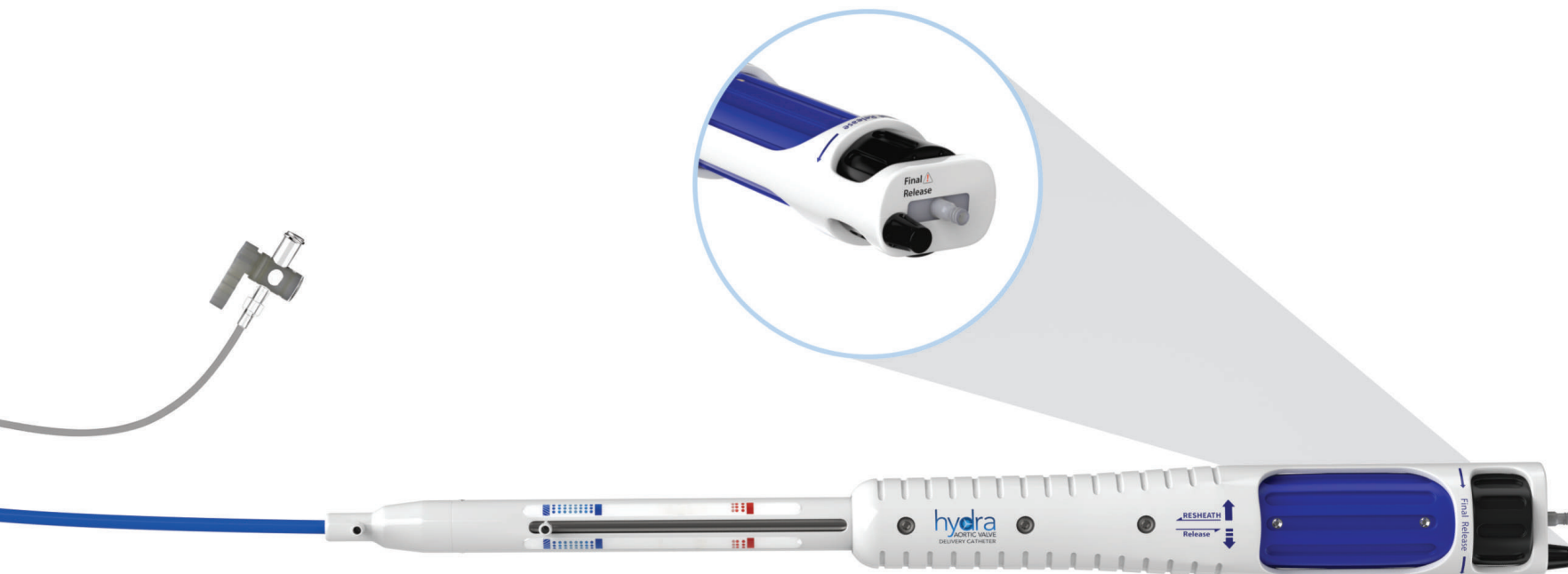


Non-braided transparent  
capsule & flexible shaft

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

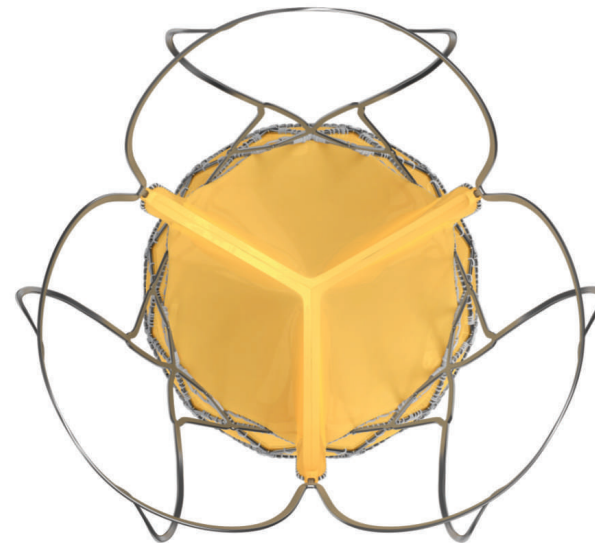
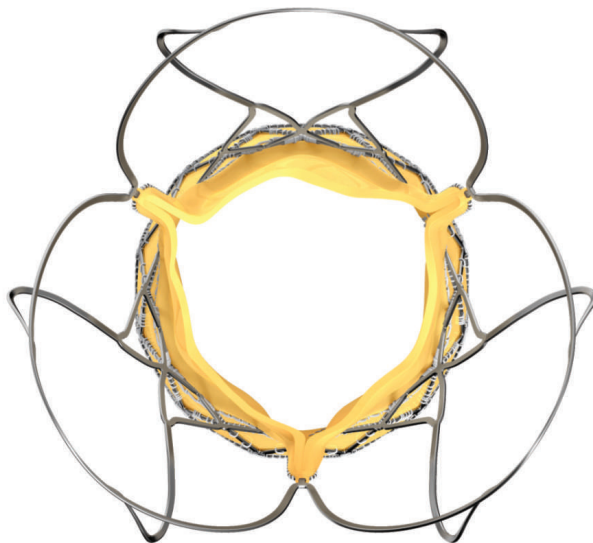
## Improved control handle along with Active Release

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



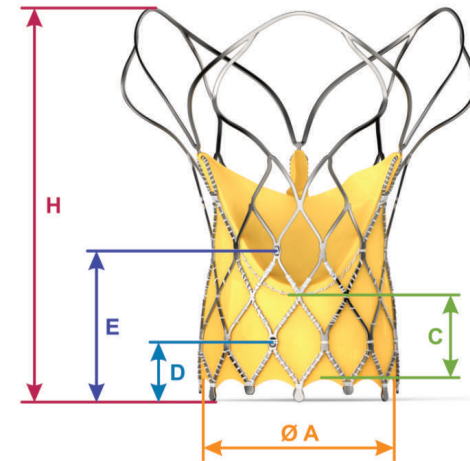
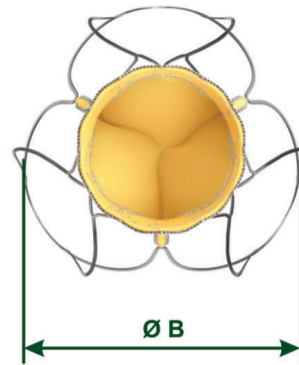


# Size Matrix



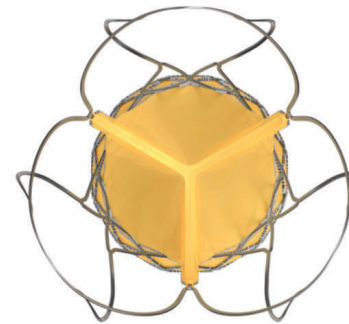
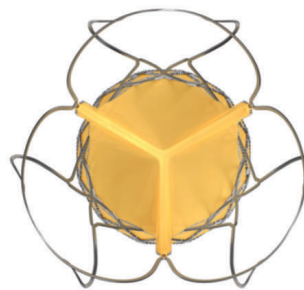
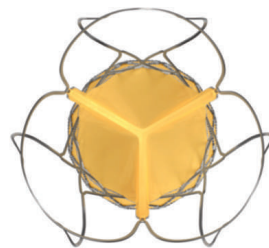
|                      |   | Hydra 22 | Hydra 26 | Hydra 30 |
|----------------------|---|----------|----------|----------|
| Diameter at Bottom   | A | 22       | 26       | 30       |
| Diameter at Top      | B | 39       | 43       | 47       |
| Sealing Skirt Height | C | 12       | 13       | 14       |
| 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

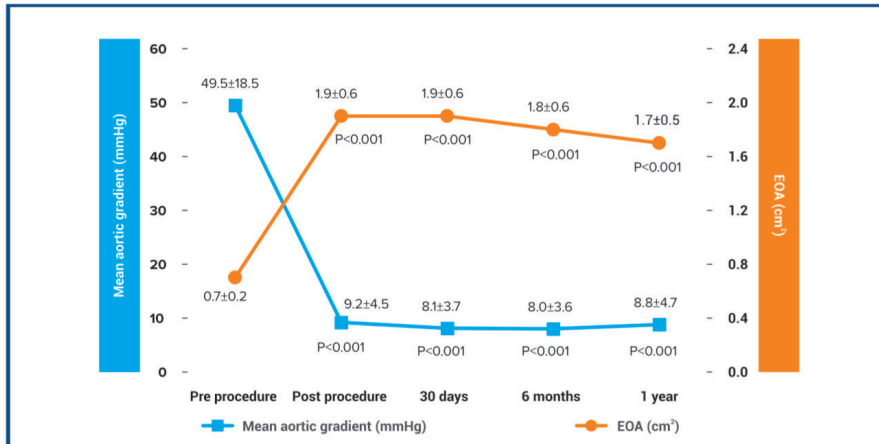


**Annulus Size (mm)**

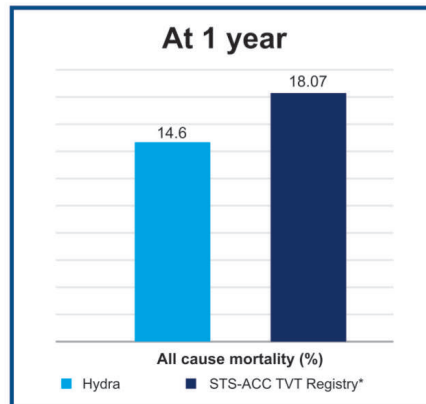
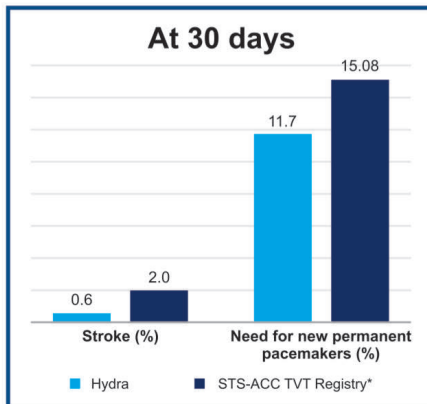
*Transesophageal Echocardiogram (TEE) Derived Annular Treatment Range*

## Excellent Hemodynamics<sup>1</sup>

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

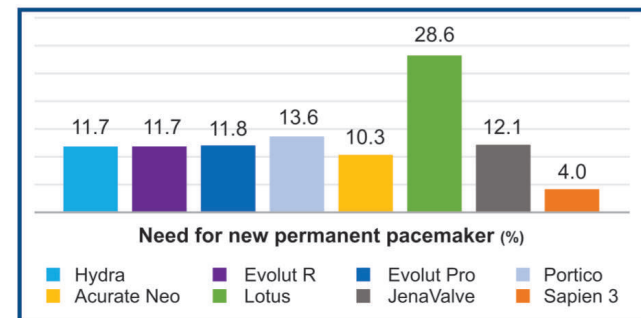
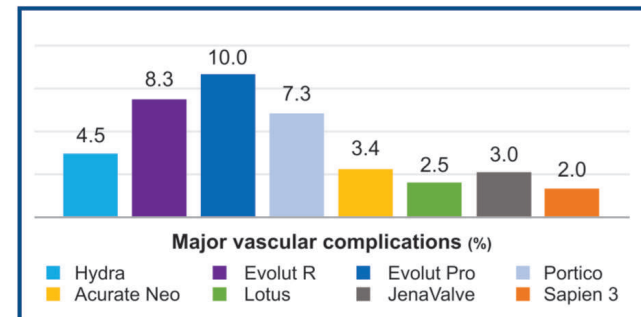
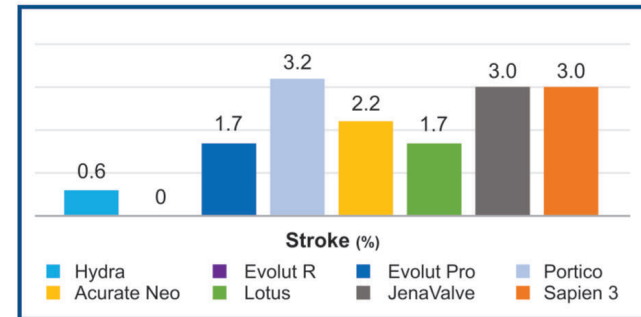


## Comparison of Hydra CE study with STS-ACC TVT Registry of TAVR<sup>1,2</sup>



\*2015 data

## Comparison of CE-mark studies for major TAVR devices<sup>1</sup> At 30 days



TAVR - Transcatheter Aortic Valve Replacement

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

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 |

## www.smtpl.com

### Head office – Surat

Sahajanand Medical Technologies Limited  
Sahajanand Estate, Wakhariawadi,  
Near Dabholi, Ved Road, Surat - 395 004,  
GJ, India.  
Tel: +91 261 6112800  
Fax: +91 261 6112801  
E-mail: contact@sahmed.com

### Spain

SMT Iberia  
Leonardo Da Vinci, 22,  
46980 Paterna Valencia SPAIN,  
Tel: +34 96 293 4934  
Fax: +34 96 293 4933  
E-mail: info.iberia@smtpl.com

### Russia

SMT CIS  
Building 1, 89 Krasnobogatyrskaya str.  
Moscow 107076,  
Russian Federation.  
Mrs. Maria Bokova Tel: +7 906 7368113  
E-mail: smtcis@smtpl.com

### References:

1. Hydra CE study- DOI:10.1016/j.JCIN.2021.09.004 2.STS/ACC TVT registry- DOI:10.1016/j.JACC.2020.09.595

**Disclaimers:** This product is intended for use by or under the directions of a physician. Prior to use, refer to the "Instructions for use" supplied with the product for indications, contraindications, side effects, suggested procedure warnings and precautions. As part of our continuous product development policy we reserve the right to change product specifications without prior notification.

The Hydra CE study data included here is based on the data published in JACC: Cardiovascular Interventions. JACC: Cardiovascular Interventions is a specialty journal of Journal of the American College of Cardiology (JACC) and is a copyright of ©2022 American College of Cardiology Foundation. JACC: Cardiovascular Interventions encompasses the entire field of interventional cardiovascular medicine, including coronary, structural, peripheral and cerebrovascular interventions.

STS/ACC TVT Registry data is owned and operated by the American College of Cardiology Foundation ("ACCF"), 2400 N Street, NW, Washington, DC 20037. STS/ACC TVT registry related content is the property of ACCF, ACC, affiliates or licensors, and is protected by copyright and other intellectual property laws.

Caution: Check the regulatory status of the device before distribution in area where CE marking is not the regulation in force. Illustrations are artist's representation only and should not be considered as engineering drawings or photographs. This document does not replace medical advice from the doctor / physician.

Hydra is manufactured by Vascular Innovations Co., Ltd, Thailand, an SMT group company. Hydra is a trademark of Vascular Innovations Co., Ltd.

©2022 Sahajanand Medical Technologies Limited - All Rights Reserved. www.smtpl.com

### Corporate office – Mumbai

Sahajanand Medical Technologies Limited  
221, C – Wing, Kankia Atrium, Andheri - Kurla Road  
AAI Colony, J B Nagar, Andheri East,  
Mumbai, Maharashtra 400059, MH, India.  
Tel: +91 22 62844000  
Fax: +91 22 62844019  
E-mail: contact@sahmed.com

### Switzerland

SMT Switzerland AG  
Rue des Vignerons lb / 1110 Morges  
Tel: +41 (0) 41 71000 82  
Fax: +41 (0) 41 71000 84  
E-mail: customercare.dach@smtpl.com

### SMT Importadora e Distribuidora de Produtos Hospitalares Ltda.

Av Nonoai, No 360- Bairro Nonoai,  
Porto Alegre - RS  
ZIP Code: 91720-000 - Brazil  
Phone: +55 51 3315 5000  
E-mail: brasil@smtpl.com, diego@smtpl.com

### Europe Headquarter

SMT Germany GmbH  
Weiseler Strasse 16,  
35510 Butzbach, Germany  
Tel: +496033.97 24 53-0  
Fax: +496033.97 24 53-9  
E-mail: customercare.dach@smtpl.com

### Poland

SMT Polonia sp. z o.o.  
Al. Grunwaldzka 411,  
80-309 Gdansk,  
Aurum, 5 piętro.  
Tel: +48 603 095 223  
E-mail: smtpolonia@smtpl.com

### Thailand

Vascular Innovations Co., Ltd.,  
(SMT Group of Company )  
88/38 Moo 1, 345 Rd.,  
Bangtanai Pakkret Nonthaburi 11120  
Tel. (662) 598-2361  
Fax. (662) 598-2360

### SMT France SAS

Centre d'Affaires Alta Rocca / Bat A  
1120 Route de Gémenos 13 400 Aubagne  
Bureau: +33 484 489 770  
Fax: +33 484 489 656  
Service Clients : adv.smtfrance@smtpl.com

### Ireland

Sahajanand Medical Technologies Ireland Ltd.  
Ground Floor, Block 5, Galway Technology Park,  
Parkmore, Galway, H91 R9YR,  
Ireland.  
Tel: +353 9139 7472  
E-mail: smtireland@smtpl.com

HYDRA/BRO/EN01 REV.03

