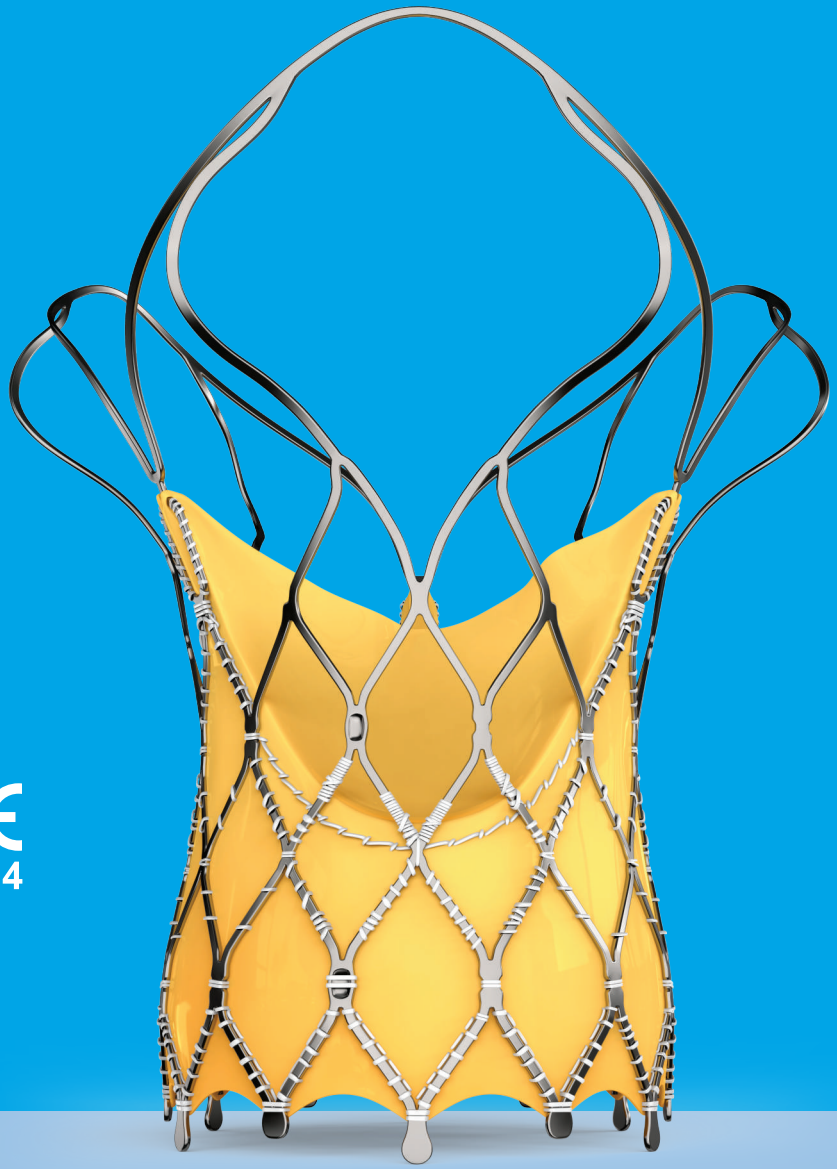
hydra

CE 1434

Transcatheter Aortic Valve



SMT | VASCULAR INNOVATIONS

Hydra Aortic Valve

hydra

Outflow

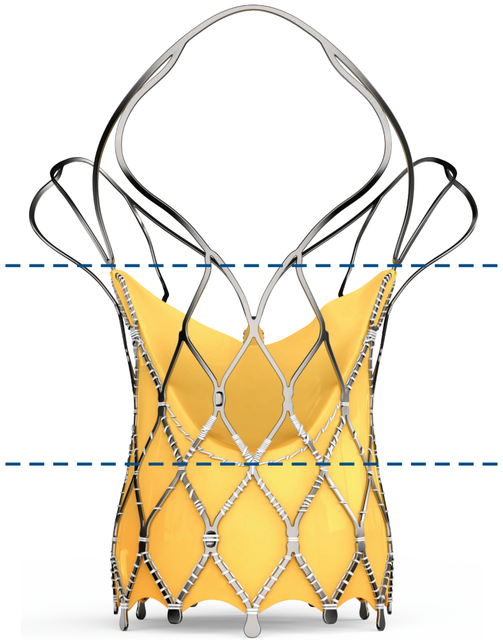
Low radial strength
Provides conformability to the shape of the aorta

Mid Frame

High hoop strength
Ensures circular configuration of the bioprosthetic valve

Inflow

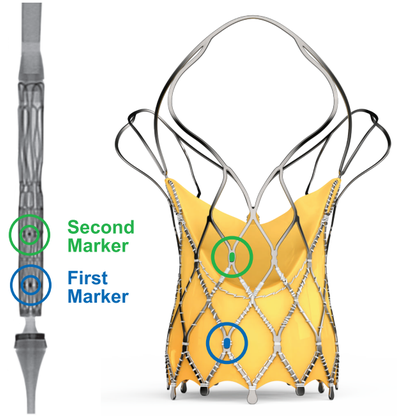
High radial strength
Provides fixation to the native aortic annulus

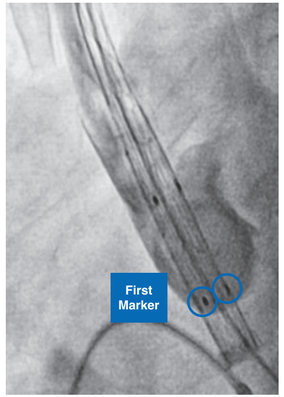


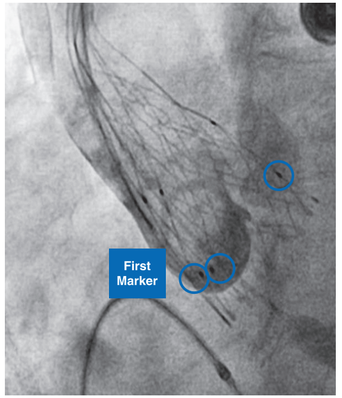
Marker location and significance

hydra

- 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 marker** helps
  - In precise implantation of the valve at the targeted implantation zone
  - To ascertain the depth of implant
- **Second marker** indicates
  - When the THV leaflets are going to get deployed







Case Example

Key Features

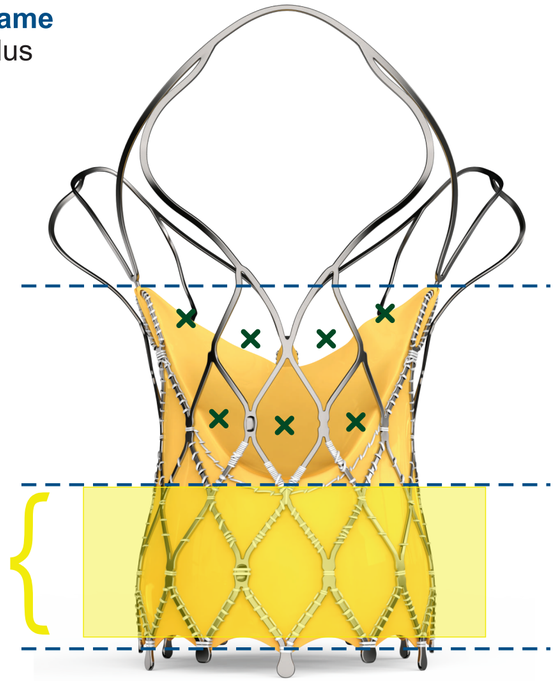
Self expandable Nitinol Frame
Conformable to native annulus

Three-tentacle design
Less metal at outflow

Large Frame cells (≥15 Fr)
Facilitates easy access to the coronary arteries

Extended Sealing skirt
Mitigates paravalvular leak

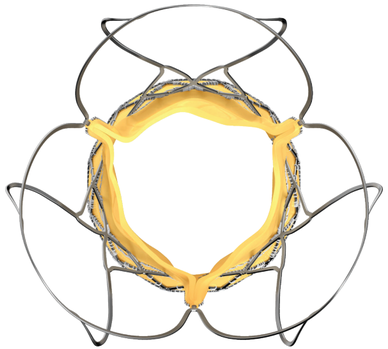
Non-flared inflow part
Reduces conduction abnormality

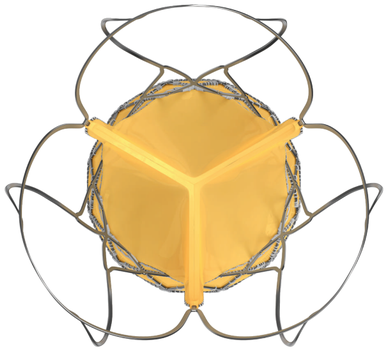


Each '✕' represents a single large cell

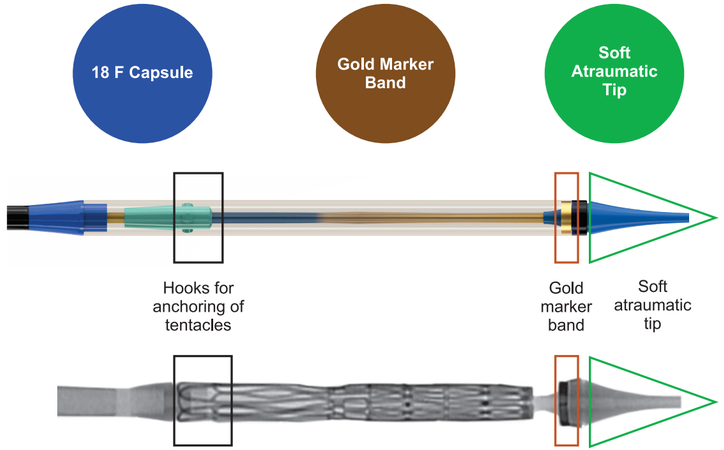
Bovine Pericardium

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





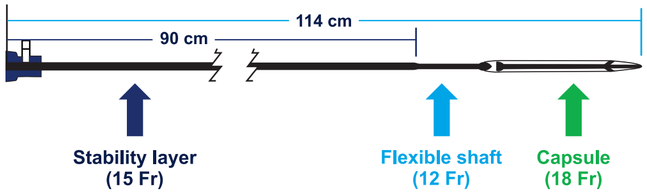
Capsule



- Radiopaque soft atraumatic tip
- Gold marker band on the capsule helps in determining the location of sheath while release/recapture

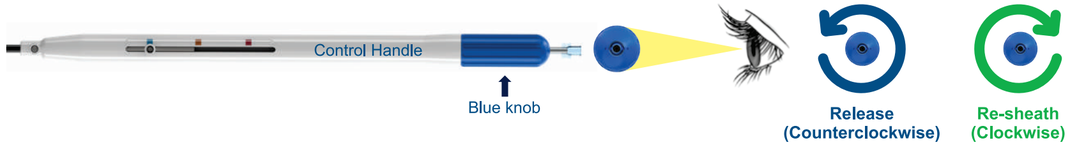
Flexible Shaft and Stability layer

- **Flexible shaft** ensures flexibility of the overall system while navigating through the arch of aorta
- **Stability layer** enables stable catheter position during the deployment and aids in accurate valve implantation



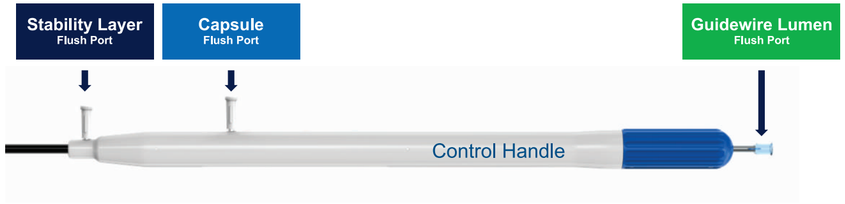
Control Handle

- Three unique color-coded indicators to determine the deployment stage
  - **Blue** signifies fully encapsulated valve
  - **Yellow** signifies release of second marker
  - **Orange** signifies release of tentacles
- **Blue Knob:** Counterclockwise to Un-sheath (Release), Clockwise to Re-sheath (Capture)



Flush Port

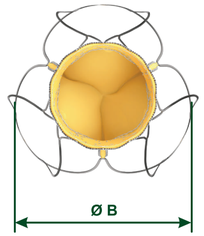
- 3 Dedicated Flush ports on the Control Handle

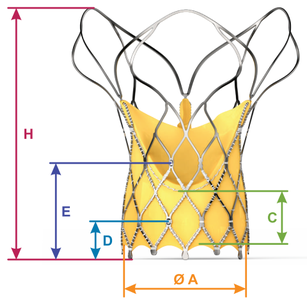


Size Matrix

		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

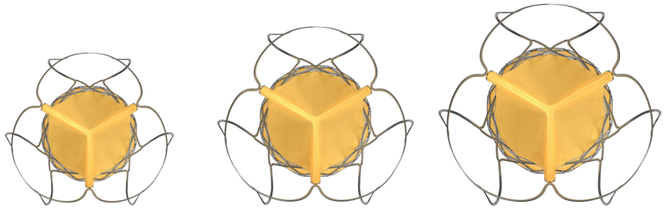
Sizes mentioned in "mm"





Crimped

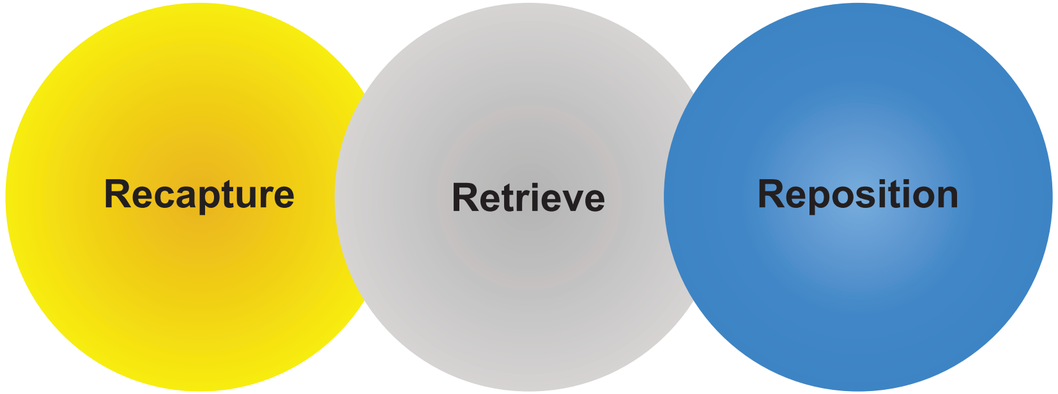
Intended Annular Treatment Range



Annulus Size (mm)

TEE Derived Annular Treatment Range

Recapturable up to 80% deployment



Hydra THV* can be **Re-captured up to 80%** deployment

*Transcatheter Heart Valve

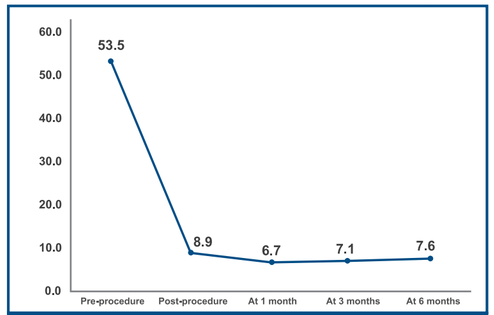
Clinical experience

Excellent Hemodynamics

Genesis study (n=40)*

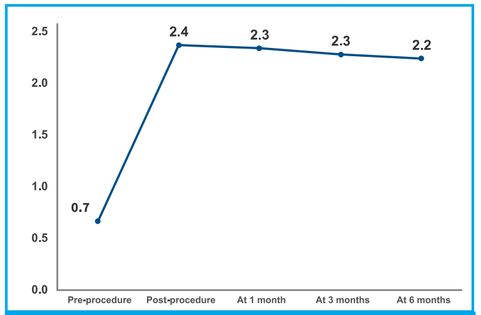
0% moderate-to-severe paravalvular leakage

Mean aortic valve gradient, mmHg



Valve gradient was in single digit and remained consistent at 6-month follow up.

Mean aortic valve area, cm^2



Effective orifice area was consistently above 2 cm^2 up to 6-month follow up.

*11 Centres across India; Mean age: 74.5 years; Mean STS score: 5.05% *Data on file

Ordering information

Reference Number	Size	Delivery Catheter System	Valve Loading system
HYDRA22	22 mm	HYDRA18F	HYDRA18VLS
HYDRA26	26 mm	HYDRA18F	HYDRA18VLS
HYDRA30	30 mm	HYDRA18F	HYDRA18VLS

Summary

Frame	Valve	Hydra AVDC	Safety features
• 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	• Supra-annular design • Bovine pericardial tissue • Anti-calcification treatment	• 3 Unique color-coded indicators for deployment guidance • Ease of release of the valve • One delivery system for three THV sizes • 18 Fr compatible	• Recapturable • Repositionable • Retrievable

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