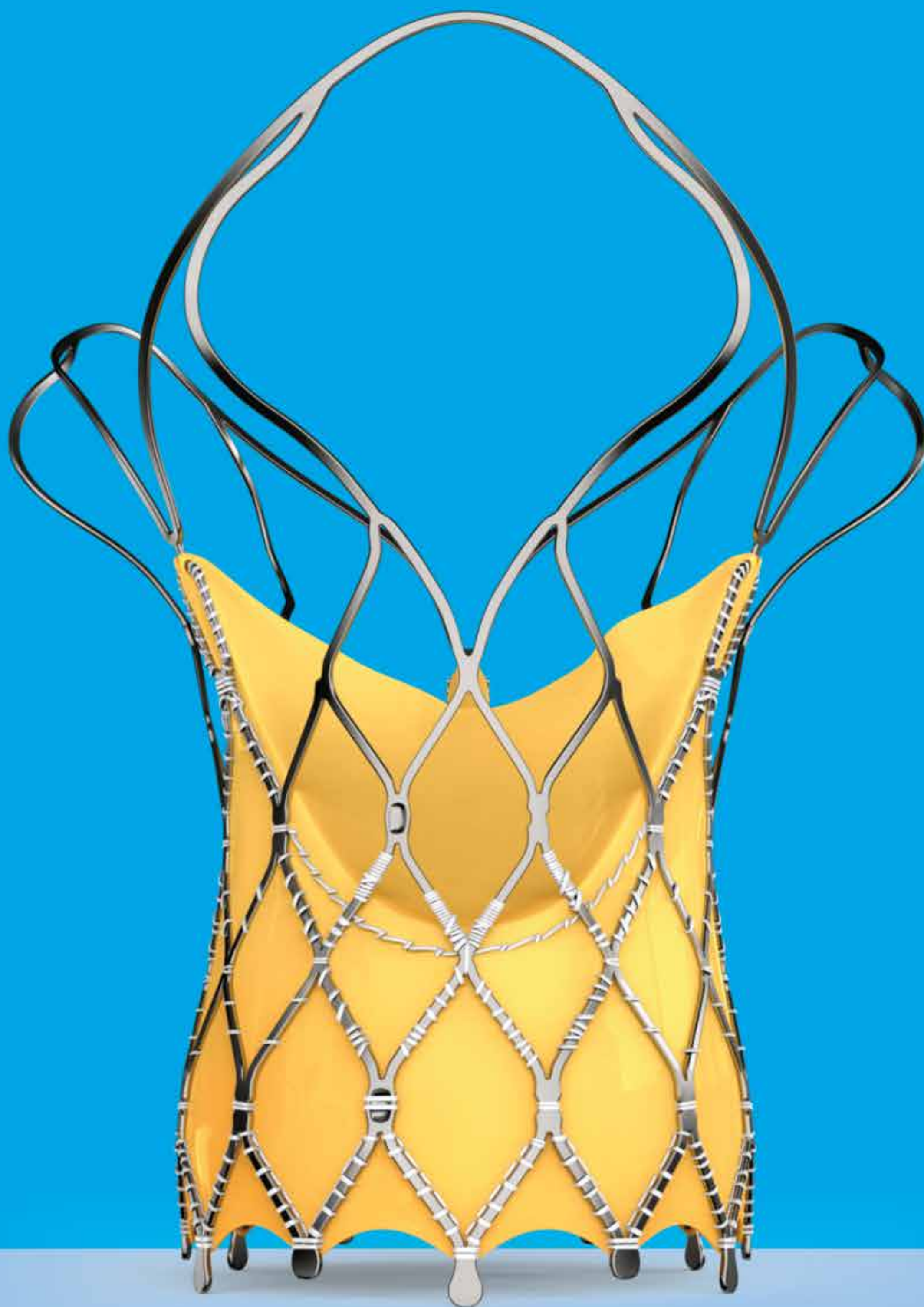


# hydra

CE  
1434

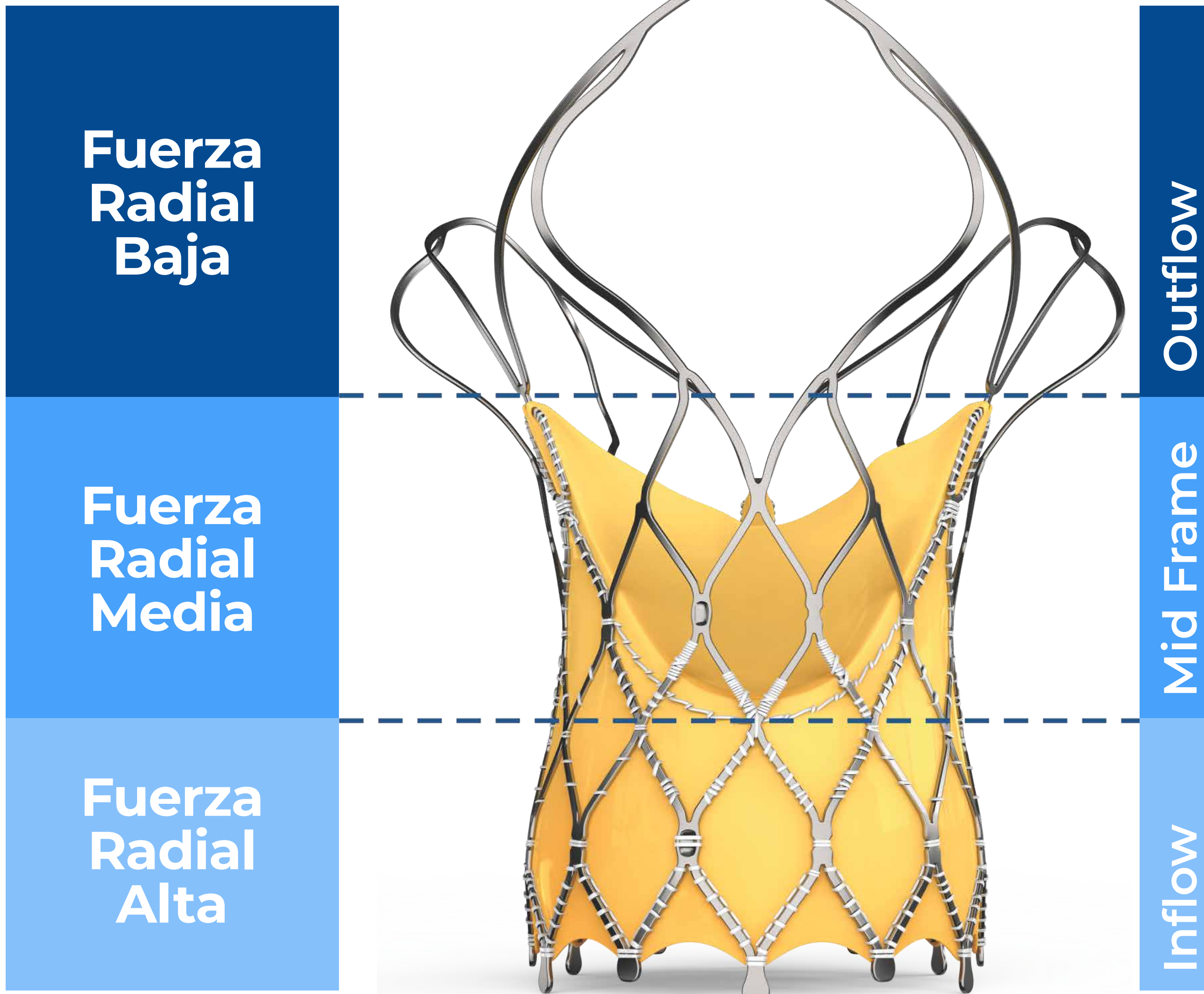
Transcatheter Aortic Valve



## Frame material: Nitinol

- Proporciona fuerza continua hacia el exterior
- Anatomía comfortable al anillo. (Anillos circular y no circular)
- Mantiene su forma aun en anatomías con alto índice de calcio
- Resistente a la corrosión, bio-compatible y poco trombo génico
- MR\*

## Hydra Frame Diseño: Fuerza radial variable.



\* Static magnetic field of 1.5-Tesla and 3-Tesla, only · Maximum spatial gradient magnetic field of 8,000-Gauss/cm (extrapolated) or less · Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Level Controlled Operating Mode of operation for the MR system

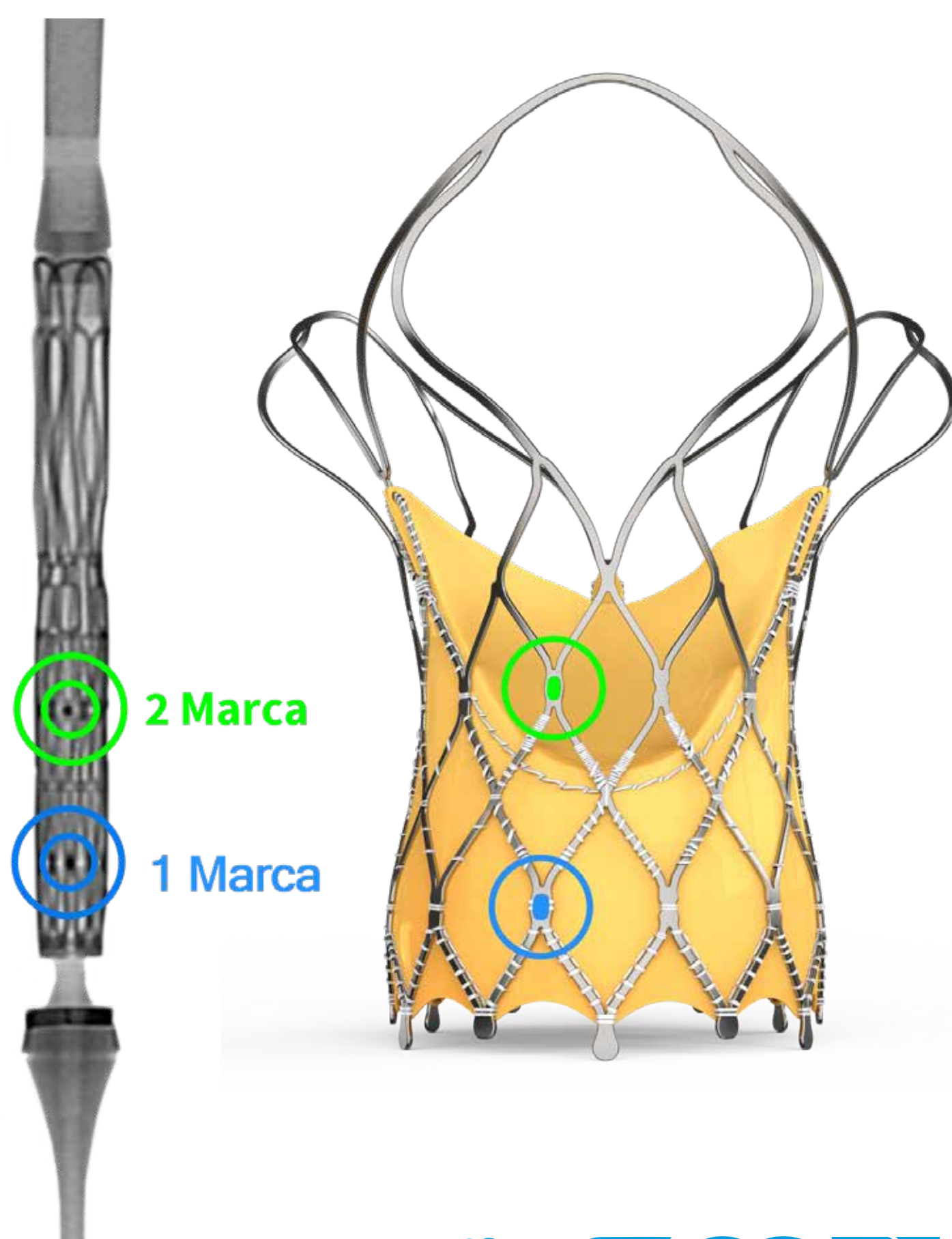
## Hydra Frame Diseño: **Struts**, **Cells** y **Nodos**



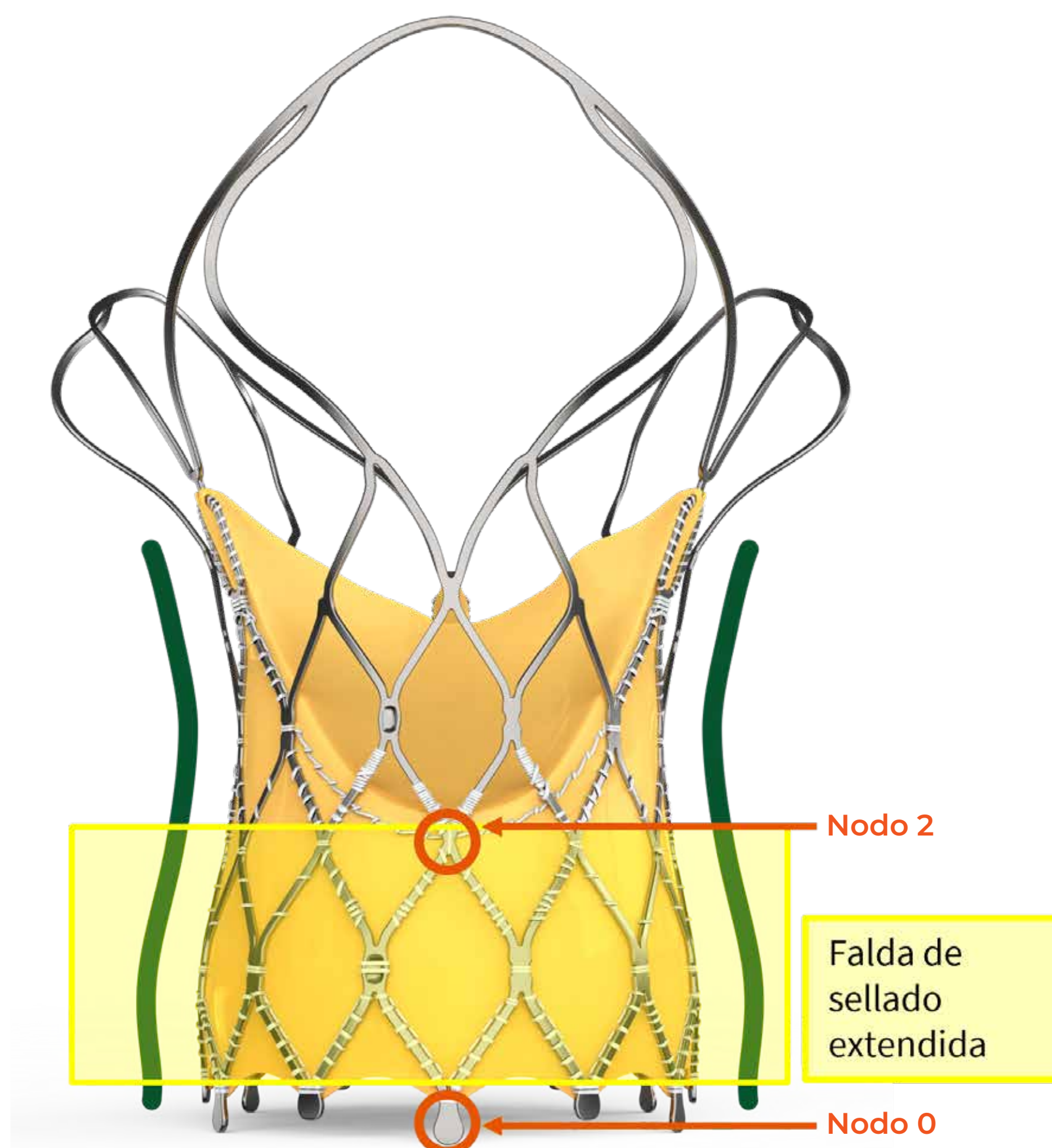
**Nodos.** Aparecen como bandas cuando se comprimen en el sistema de liberación.

## Marcas

- Primer dispositivo TAVI en tener 2 marcadores.
  - Marca 1 - Nodo 1
  - Marca 2 - Nodo 3
- Primera marca
  - Ayuda en la posición de implante.
- Segunda marca
  - Indica donde se liberan los leaflets.



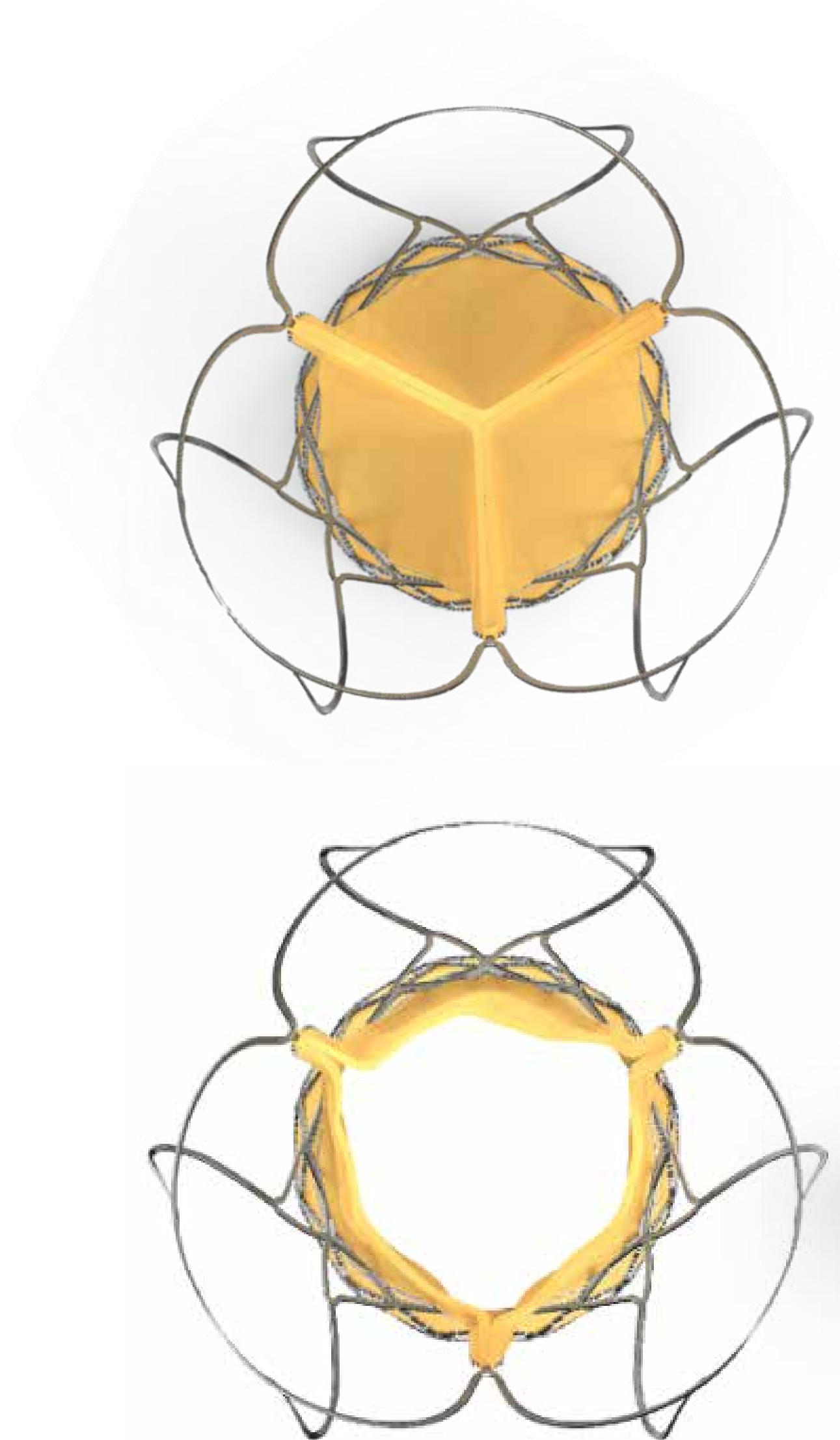
## Características y ventajas: Inflow



- Fuerza radial en la sección de entrada:
  - Ayuda a proporcionar la fijación de HYDRA THV en anillo aórtico nativo.
- Geometría de frame:
  - Adaptable a anatomías complejas
  - Proporciona sellado a múltiples niveles
  - Reduce el leak para valvular.
- Faldón de sellado extendido
  - Pericardio Bovino ubicado entre **Nodo 0** y **Nodo 2**
  - Tejido de alta resistencia.

## Diseño Supra-annular, pericardio bovino

- Mayor performance hemodinámica.
- Mayor superficie de flujo. (orificio efectivo)
- El pericardio bovino es grueso y tiene una alta resistencia a la tracción.
- Tratamiento anti-calcificación.
- Proviene de países GRB1\*
- El material bovino de Hydra supera los mayores estándares de durabilidad en test (ISO 5840S-3;2013)

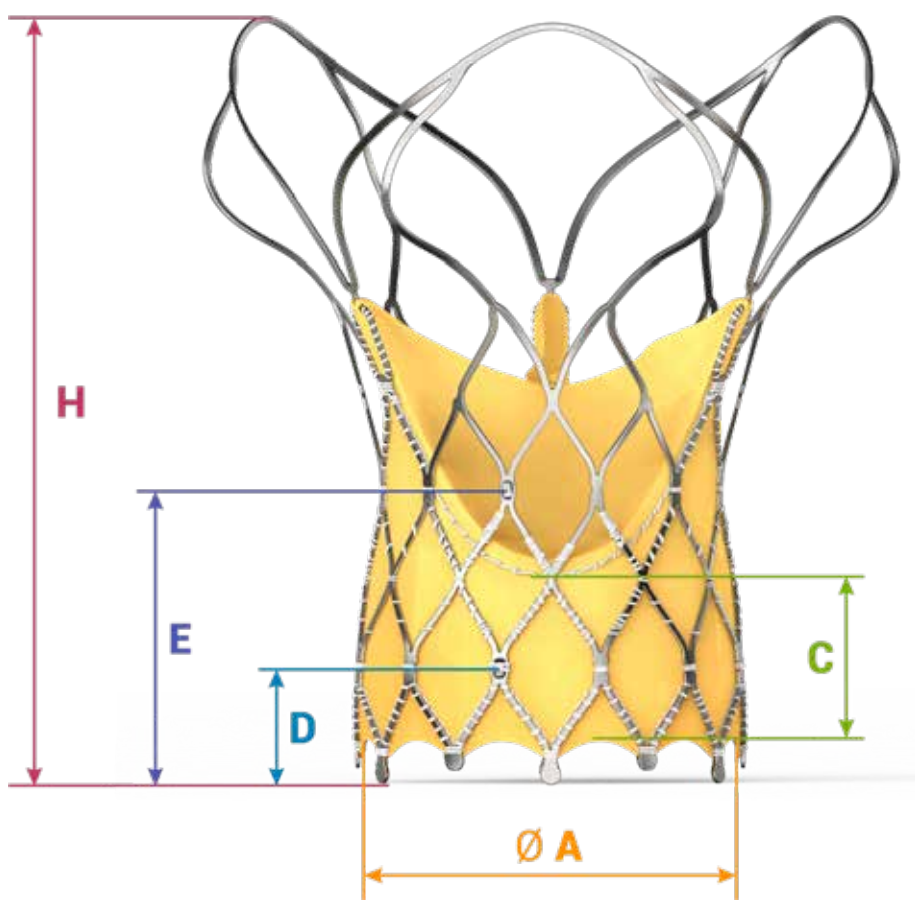
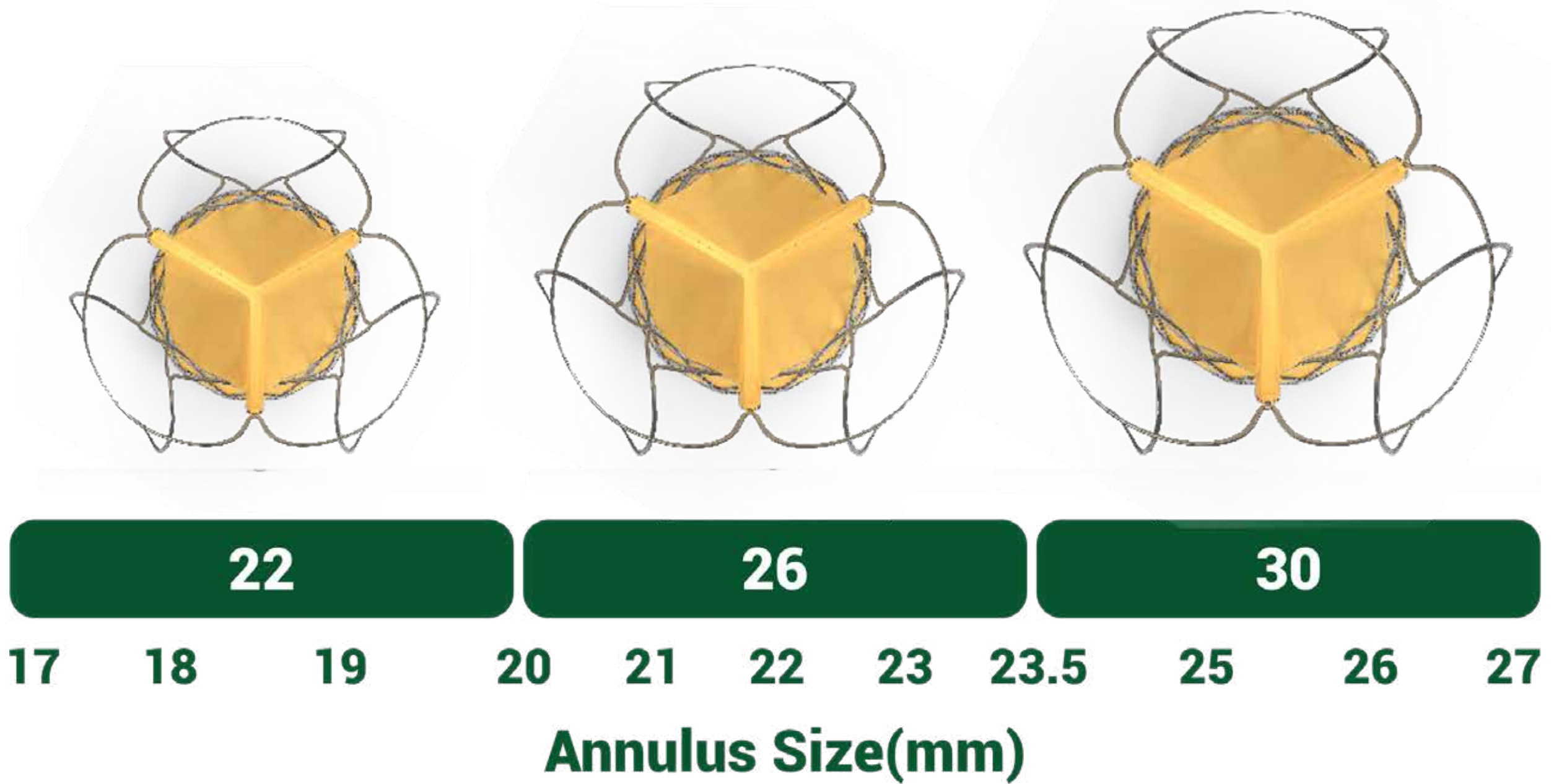


\*GBR1 : Highly unlikely Geographical Risk of Bovine Spongiform Encephalopathy

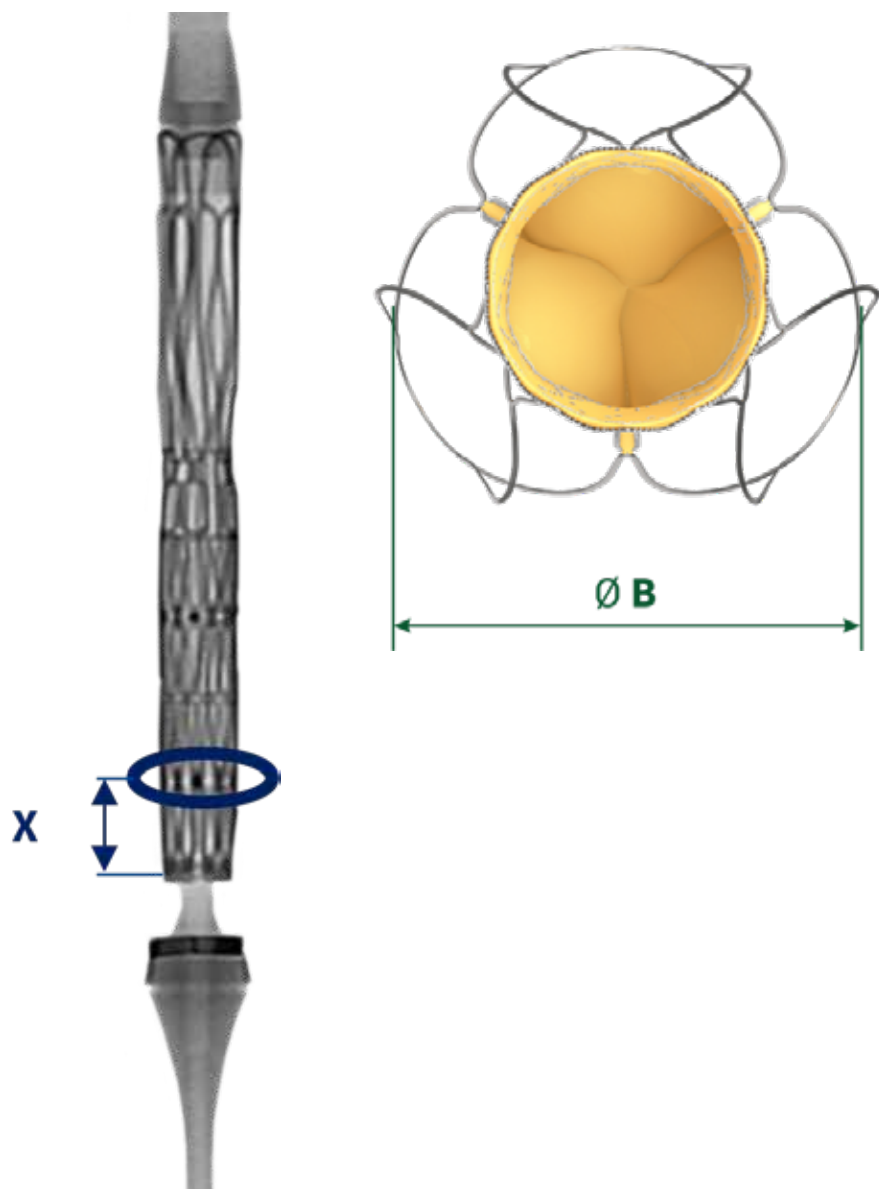
# Tamaños Hydra



Rango de anillos nativos: 17-27 mm



	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



# Hydra Cateter

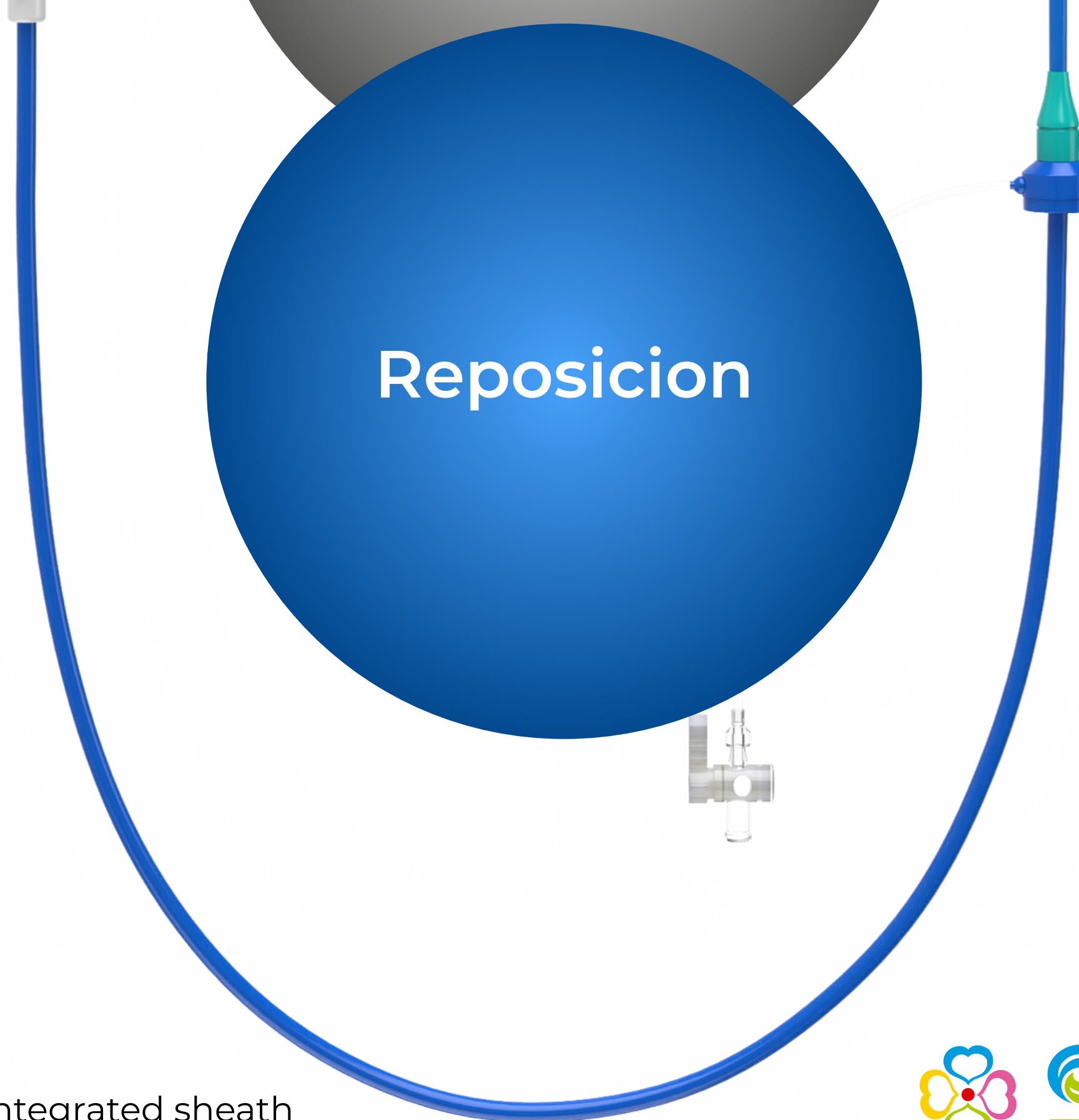
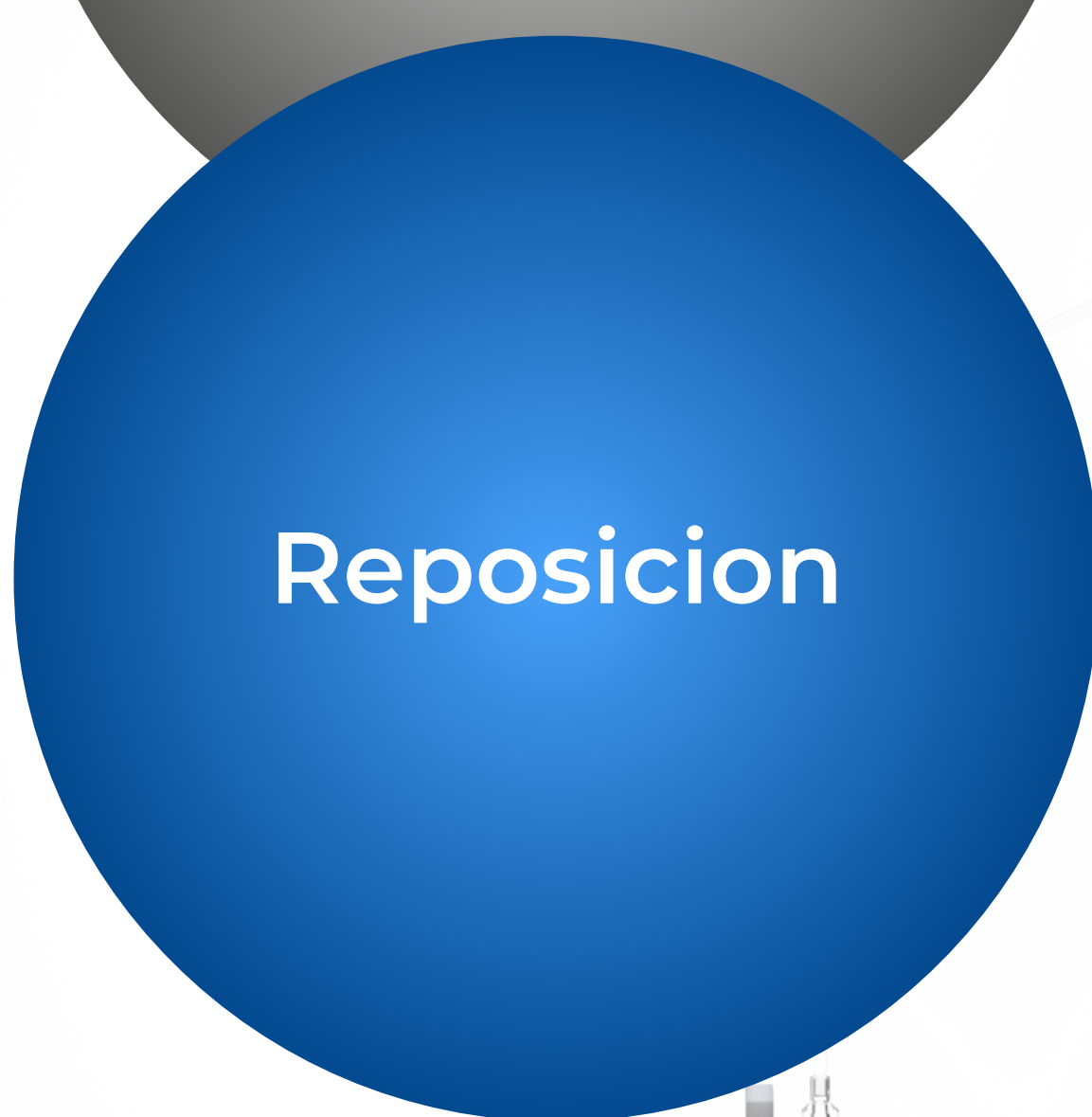
(AVDC)

hydra

## Sistema Flexible 14/15F

Hydra THV se puede  
Re-capturar al 80% del  
despliegue

Seguro de liberación



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



# Hydra Cateter

(AVDC)

hydra

14/15F

Seguro de liberación

Mango de control mejorado con función de liberación activa

Para facilitar la liberación

- Mayor flexibilidad
- Mejor control
- Recapturable 80%

Inline Sheath\*

Para accesos más pequeños

Capsula transparente no trenzada y flexible

Para mayor entrega

Cono  
Banda radio-opaca  
Gancho de fijación

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



First-in-Man study (n=15) <sup>1</sup>	GENESIS study (n=40) <sup>2</sup>	Hydra CE study (n=157) <sup>3</sup>
<ul style="list-style-type: none"> <li>- Published in Asia Intervention</li> <li>- Good hemodynamic performance</li> <li>- EOA increased from 0.68 cm<sup>2</sup> to 1.53 cm<sup>2</sup></li> <li>- Mean Aortic gradient decreased from 49.0 mmHg to 9.4 mmHg</li> </ul>	<ul style="list-style-type: none"> <li>- Published in CCI</li> <li>- 0% Moderate-to-severe-para-valvular leak at 6-month follow up</li> </ul>	<ul style="list-style-type: none"> <li>- Published in JACC : Cardiovascular Interventions</li> <li>- Excellent Haemodynamic</li> <li>- Valve gradient in single digit and remained consistent at 1-year follow up.</li> <li>- Larger effective orifice area up to 1-year follow up.</li> <li>- Low rates of PVL</li> </ul>

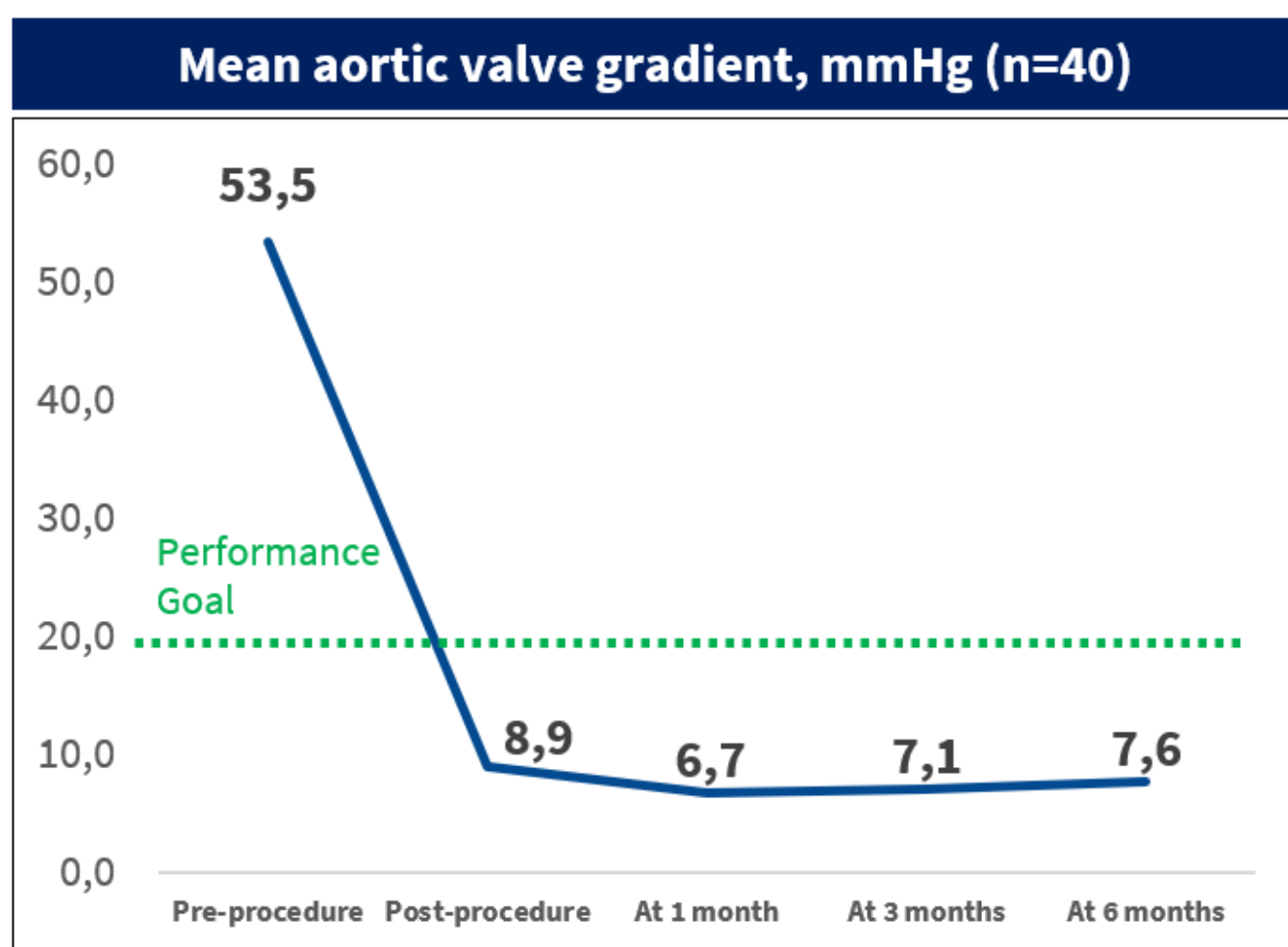
1 month Follow-up

6 month Follow-up

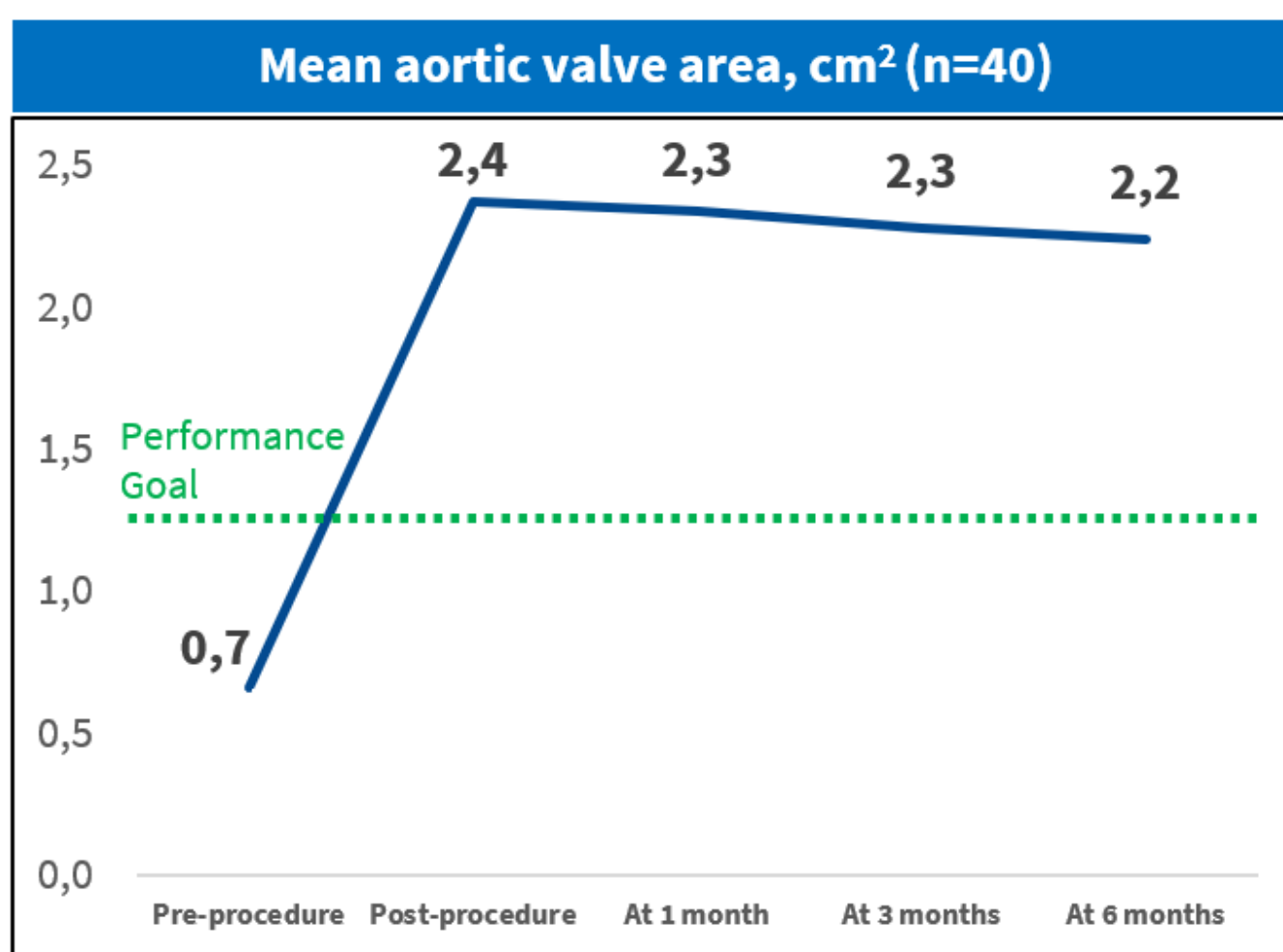
1 year Follow-up

Ref : 1 [https://www.asiaintervention.org/wp-content/uploads/2017/11/web37\\_AIJ-D-17-00007\\_Srimahachota.pdf](https://www.asiaintervention.org/wp-content/uploads/2017/11/web37_AIJ-D-17-00007_Srimahachota.pdf)  
 2. <https://doi.org/10.1002/ccd.29733>  
 3. <https://doi.org/10.1016/j.jcin.2021.09.004>

## Hydra Genesis study: Key Findings



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



Effective orifice area was consistently above 2 cm<sup>2</sup> up to 6-month FUP.

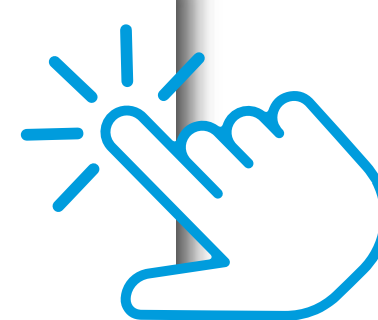


ORIGINAL STUDIES

### Clinical evaluation of the Hydra self-expanding transcatheter aortic valve: 6 month results from the GENESIS trial

Praveen Chandra MD, DM, FACC, FESC, FSCAI, FAPSIC, John Jose MD, DM ✉  
 Shafeeq Mattummal MD, DM, FESC, FSCAI, FACC ... See all authors ▾

First published: 20 April 2021 | <https://doi.org/10.1002/ccd.29733> | Citations: 4



Haga clic para acceder al estudio



## 30-Days and 1-Year Outcomes with HYDRA Self-Expanding Transcatheter Aortic Valve : Hydra CE Study

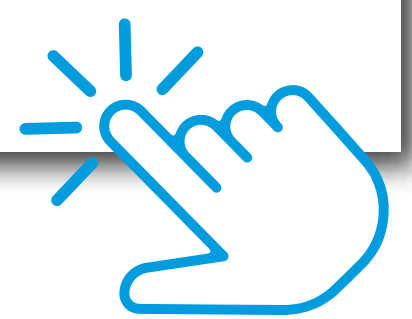
Now Published in

### JACC : Cardiovascular Interventions

Impact Factor : 11.195



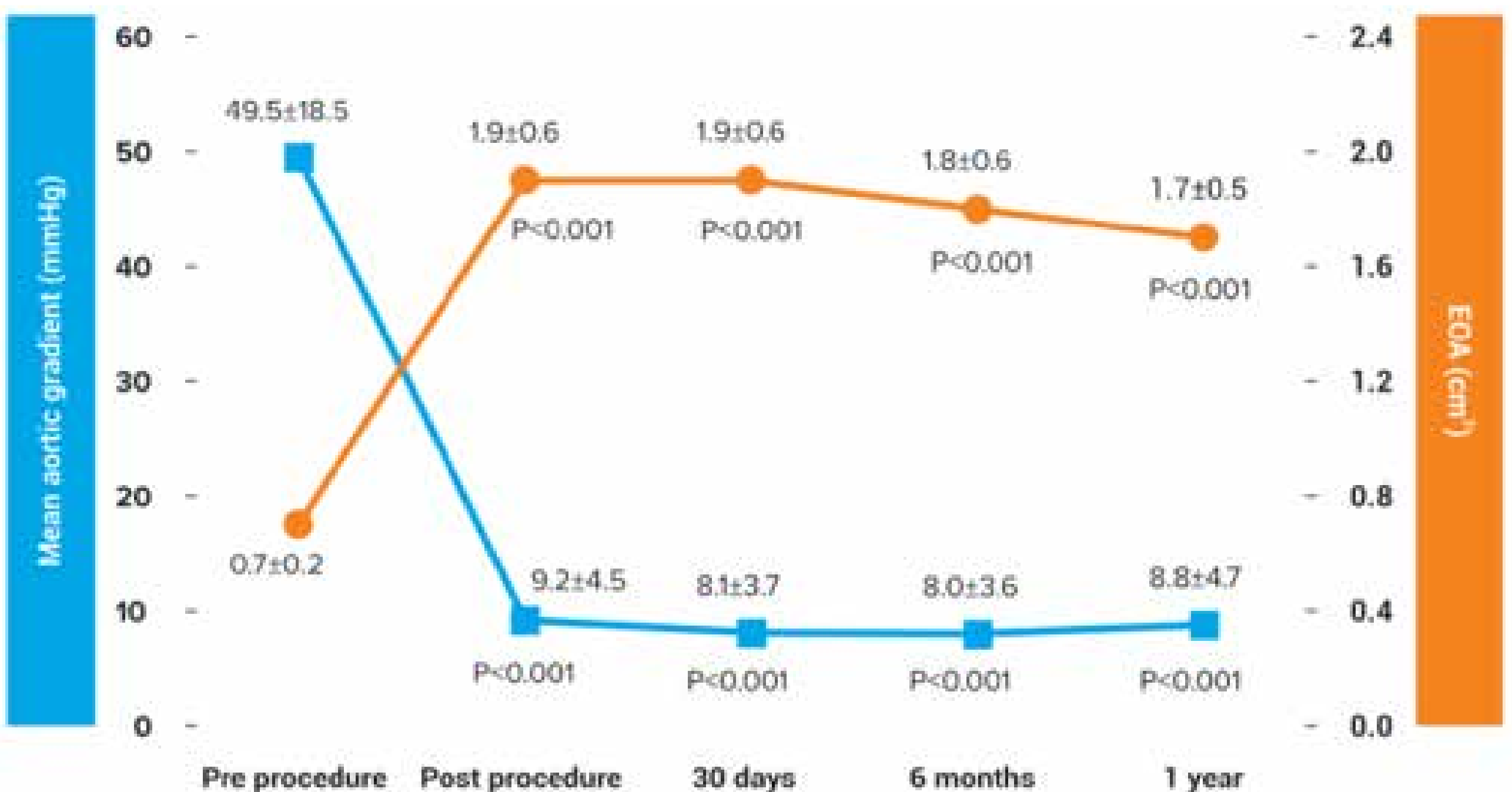
JACC: Cardiovascular Interventions Vol . 15 , No.1 , 2022 Jan 10 , <https://doi.org/10.1016/j.jcin.2021.09.004>



Haga clic para acceder al estudio

## Excellent Hemodynamics

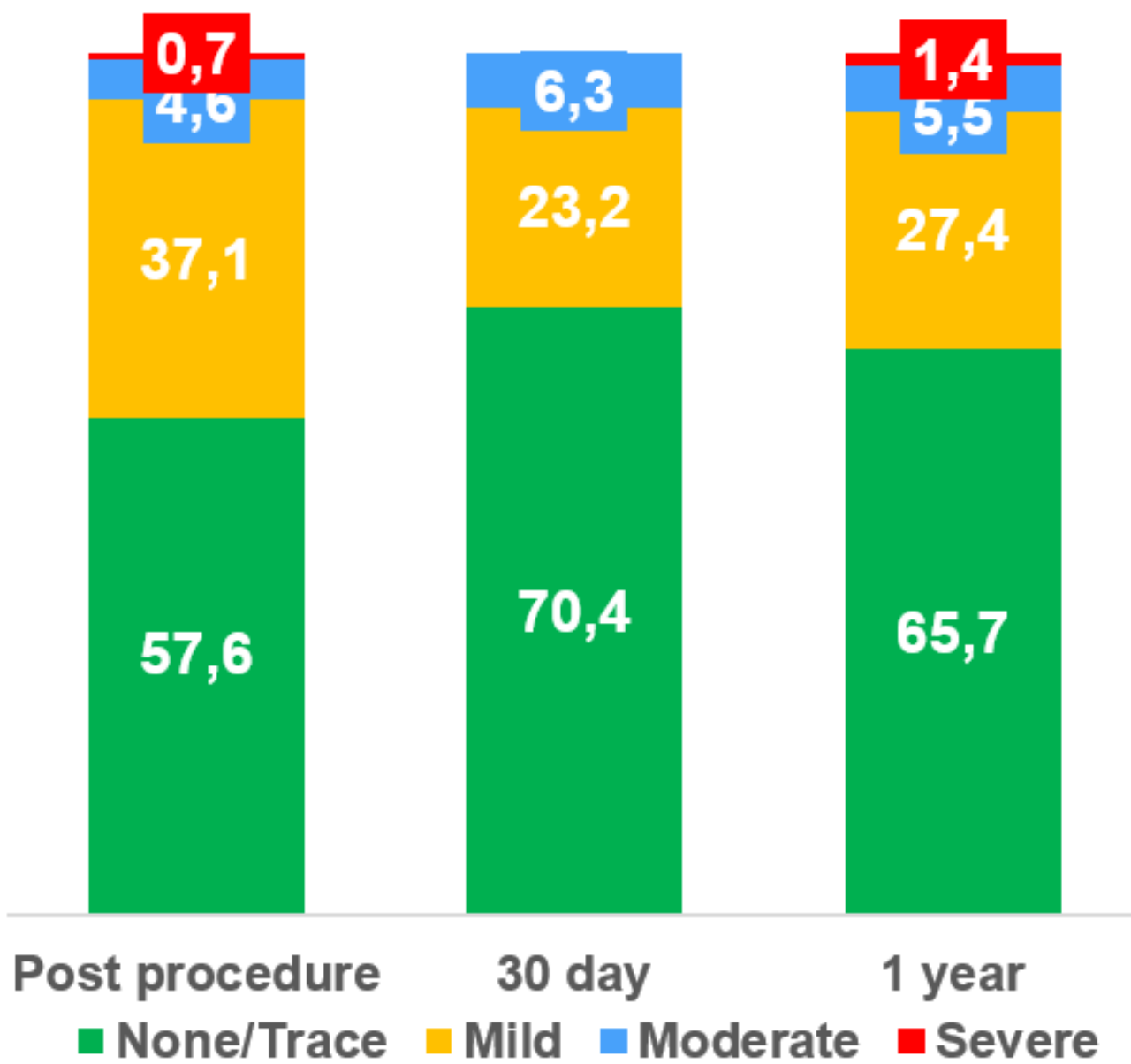
Single digit valve gradient up to 1-year follow up  
Larger effective orifice area (EOA) up to 1-year follow up



## Resultados

### Para-Valvular Leak (%)

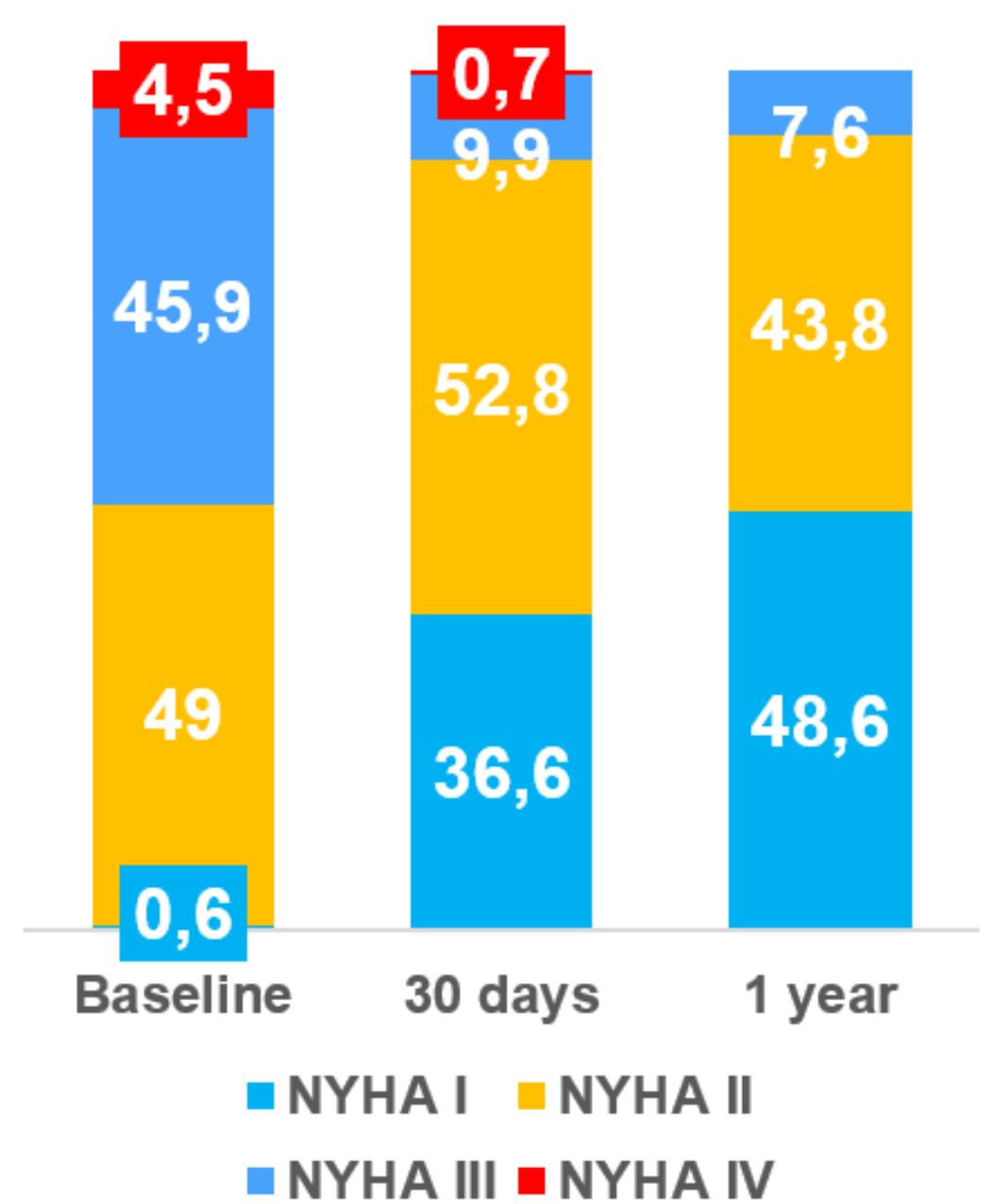
Low rate of moderate to severe para-valvular leak



### NYHA Functional Class (%)

72.4% patients improved by ≥1 Functional class

21.9% patients improved by ≥2 Functional class



JACC: Cardiovascular Interventions Vol . 15 , No. 1 , 2022 Jan 10 , <https://doi.org/10.1016/j.jcin.2021.09.004>  
 NYHA: New York Heart Association

## Conclusiones

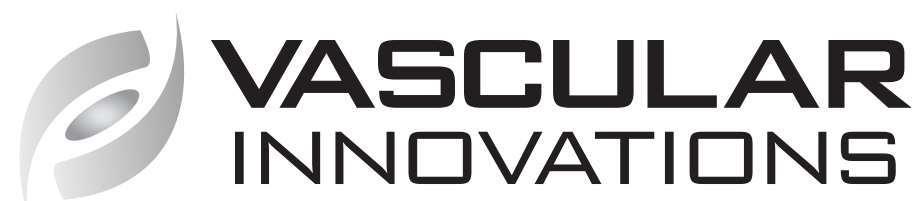
La válvula aortica transcater Hydra esta diseñada para optimizar los resultados de los procedimientos, así como para el tratamiento de por vida de los pacientes con estenosis aortica grave.

El estudio Hydra CE demuestra una eficacia favorable que proporciona una gran área de orificio efectiva y gradientes transvalvulares bajos, así como tasas bajas de complicaciones con respecto a fugas para valvulares y el nuevo marcapasos permanente.

# hydra

CE  
1434

## Transcatheter Aortic Valve



Habla con un representante:  
Colombia, Venezuela, Peru, Ecuador,  
Centroamérica y Caribe.



**North Latam**



Argentina, Chile, Uruguay, Paraguay y Bolivia.



**South Latam**



Siga a SMT en las redes sociales



**smtlatam**



**smtlatam**



**smt-latam**



**LatamSmt**

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