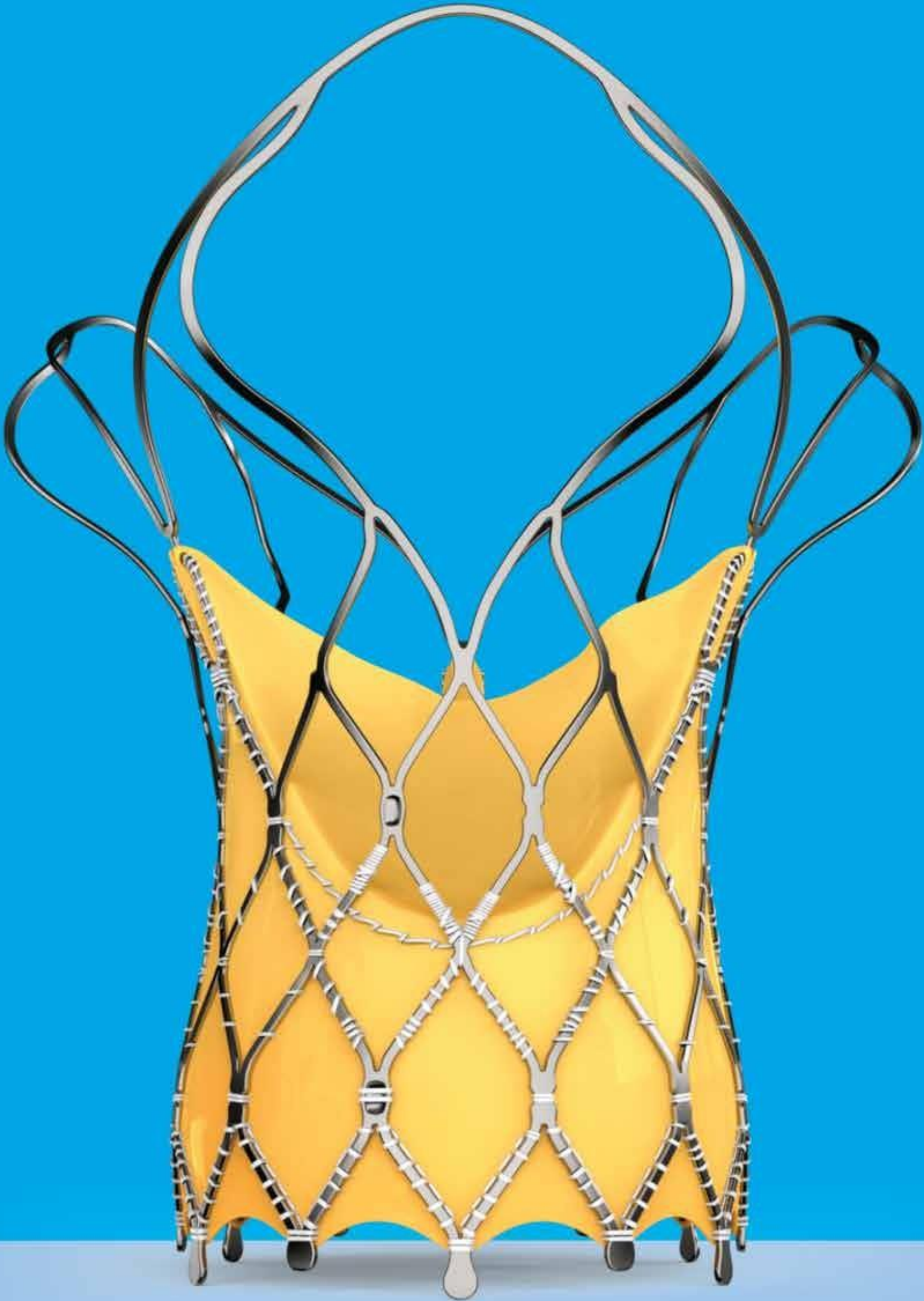


hydra

CE
1434

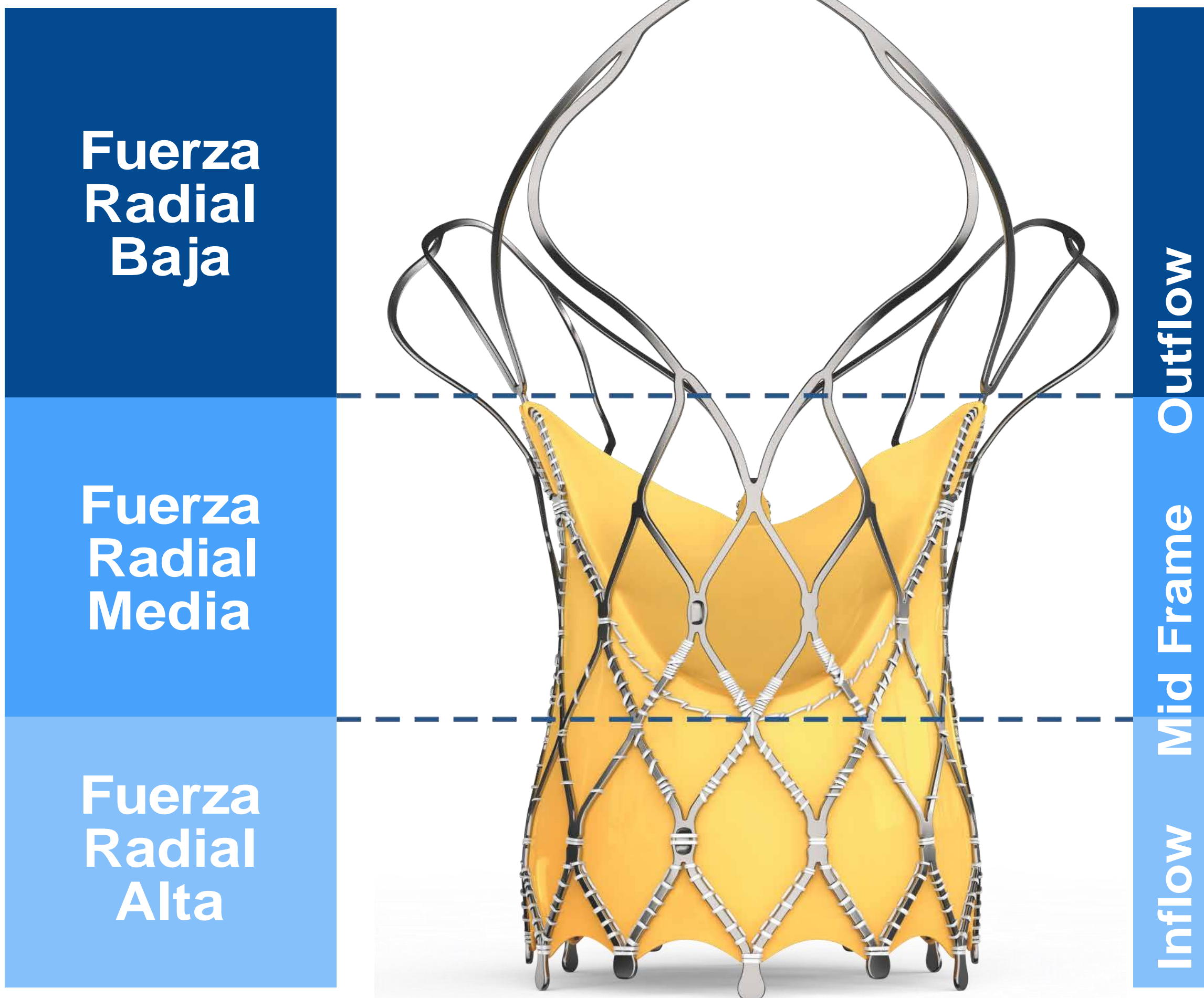
Transcatheter Aortic Valve



Frame material: Nitinol

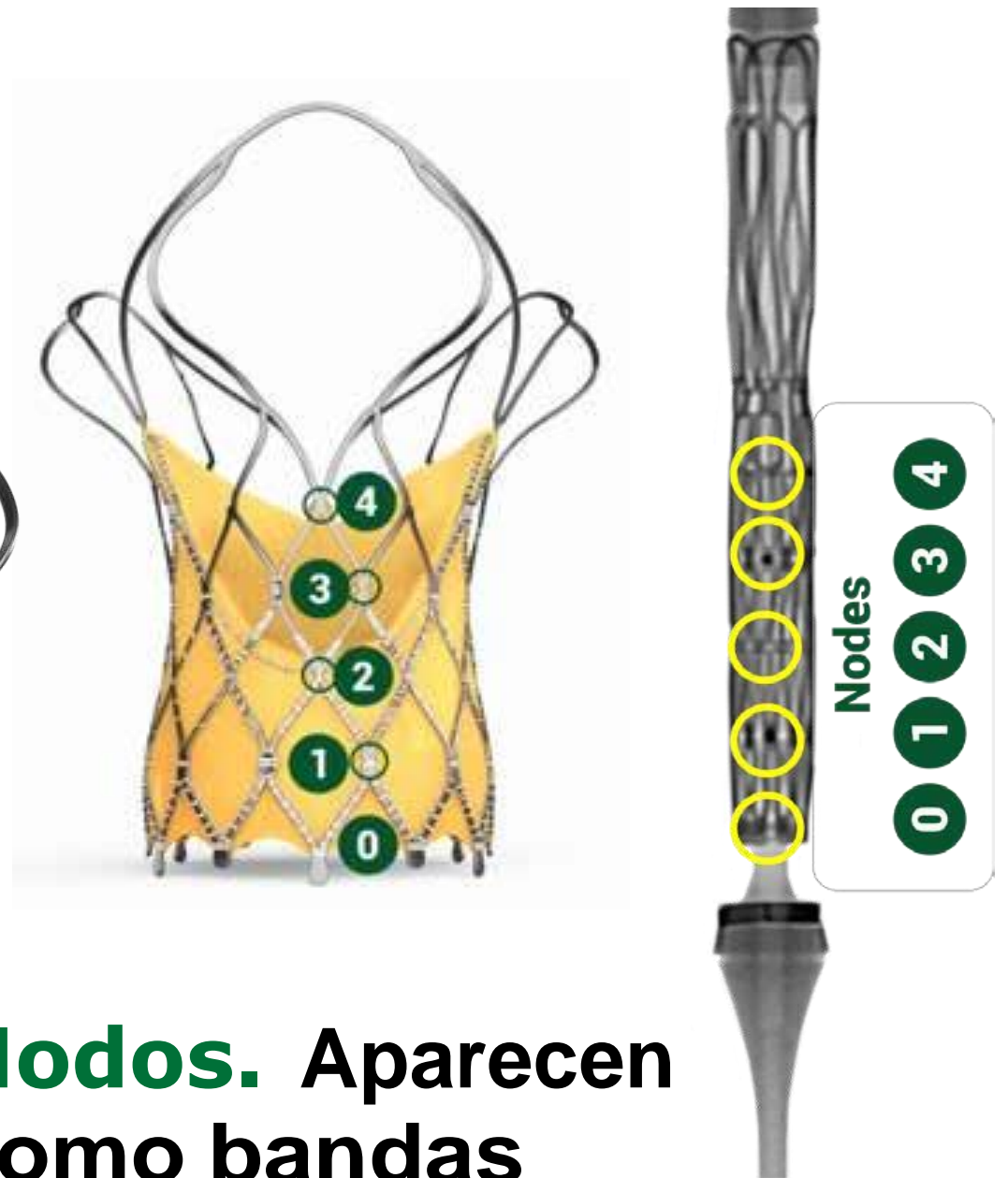
- Proporciona fuerza continua hacia el exterior
- Anatomía comfortable al anillo. (Anillos circular y no circular)
- Mantiene su forma aun en anatomías con alto índice de calcio
- Resistente a la corrosión, bio-compatible y poco trombo génico
- MR*

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

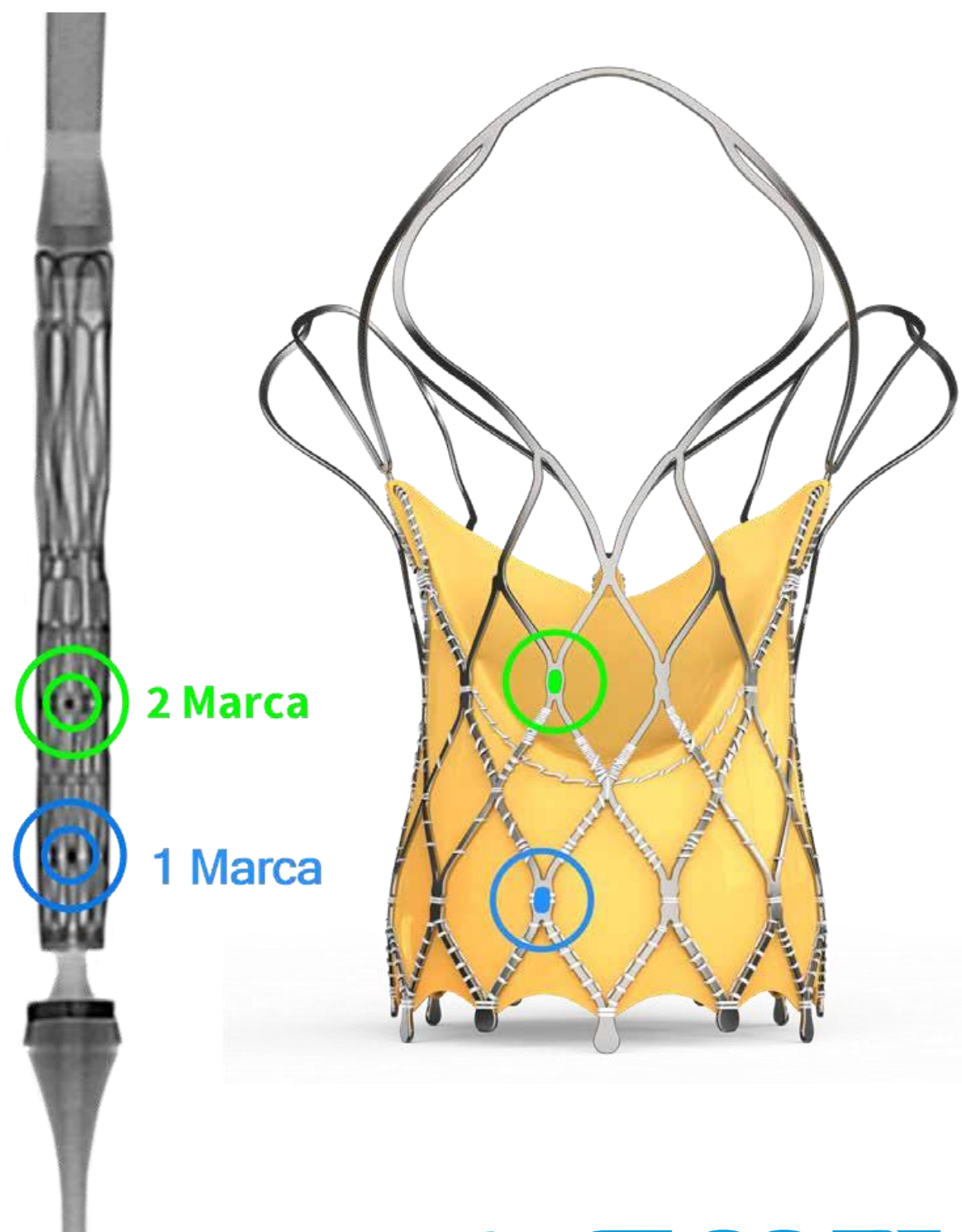
Hydra Frame Diseño: **Struts**, **Cells** y **Nodos**



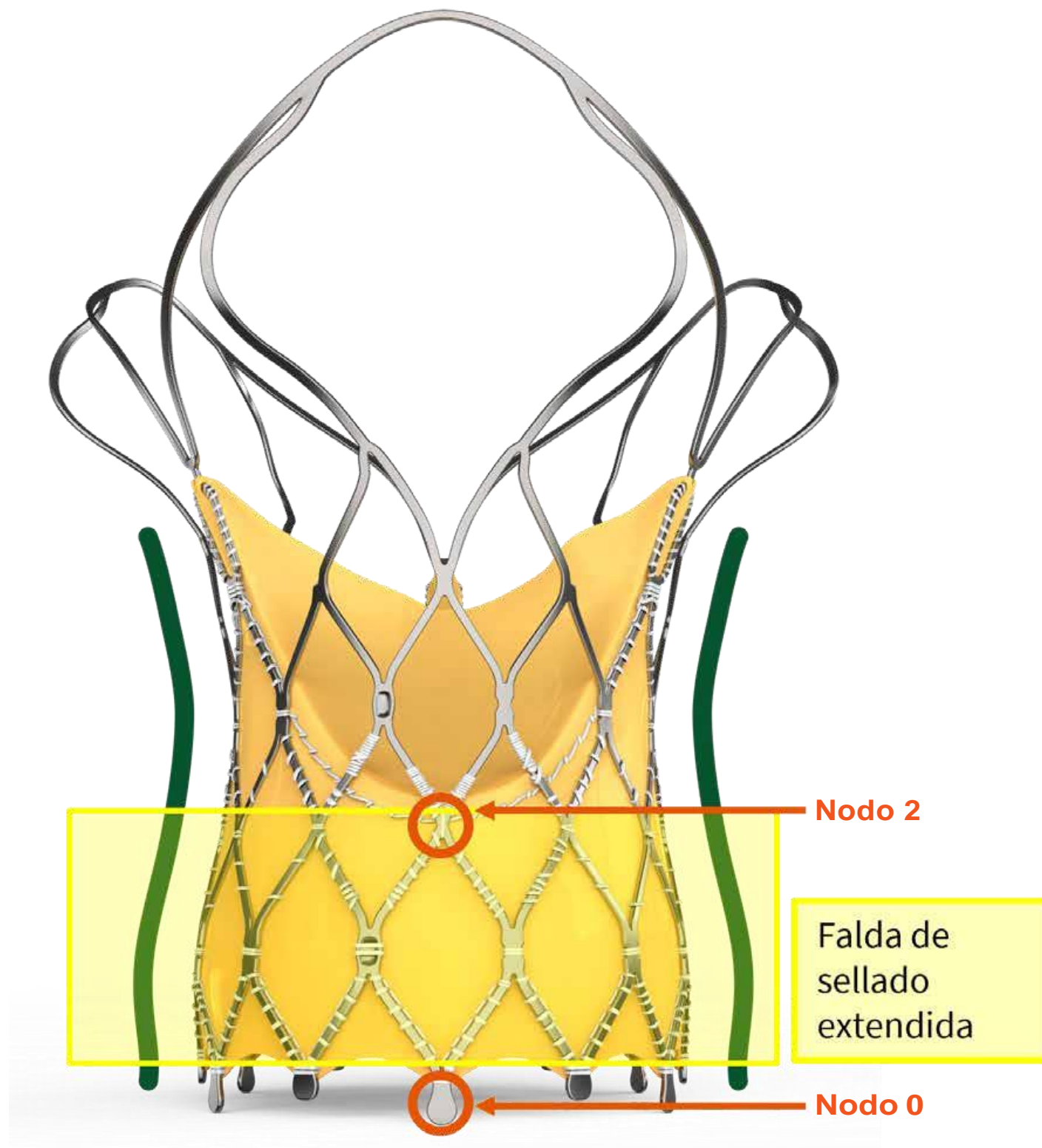
Nodos. Aparecen como bandas cuando se comprimen en el sistema de liberación.

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.



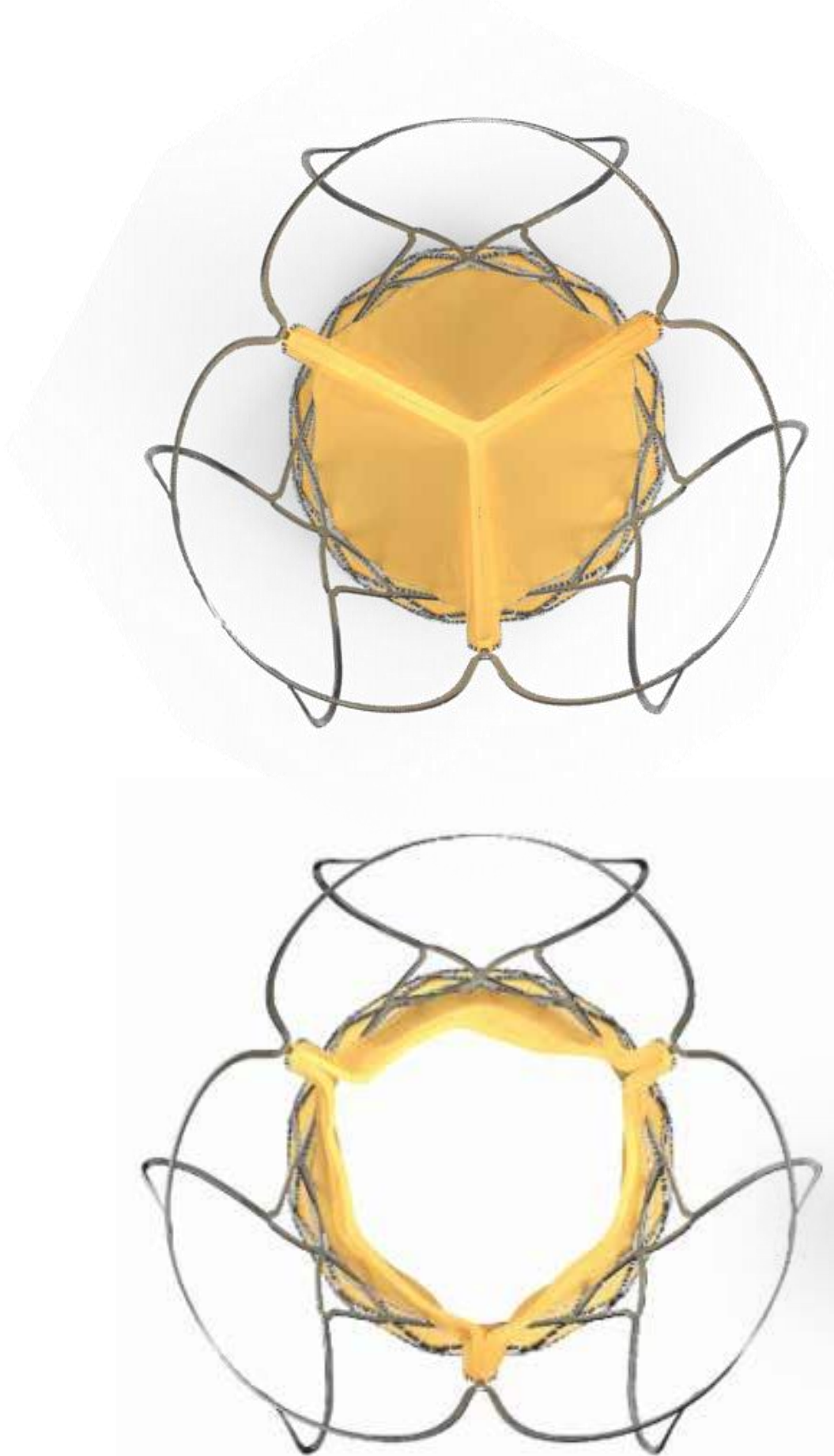
Características y ventajas: Inflow



- **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

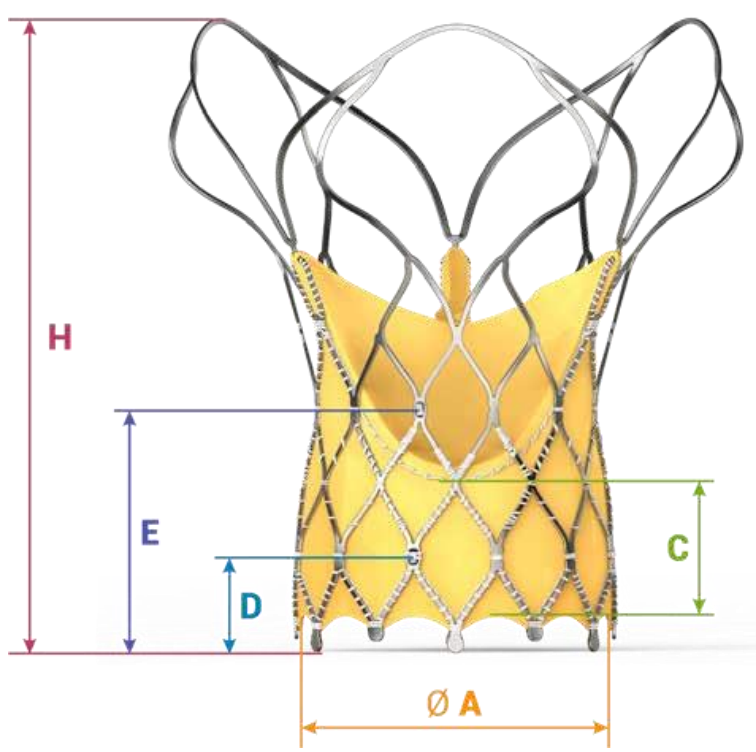
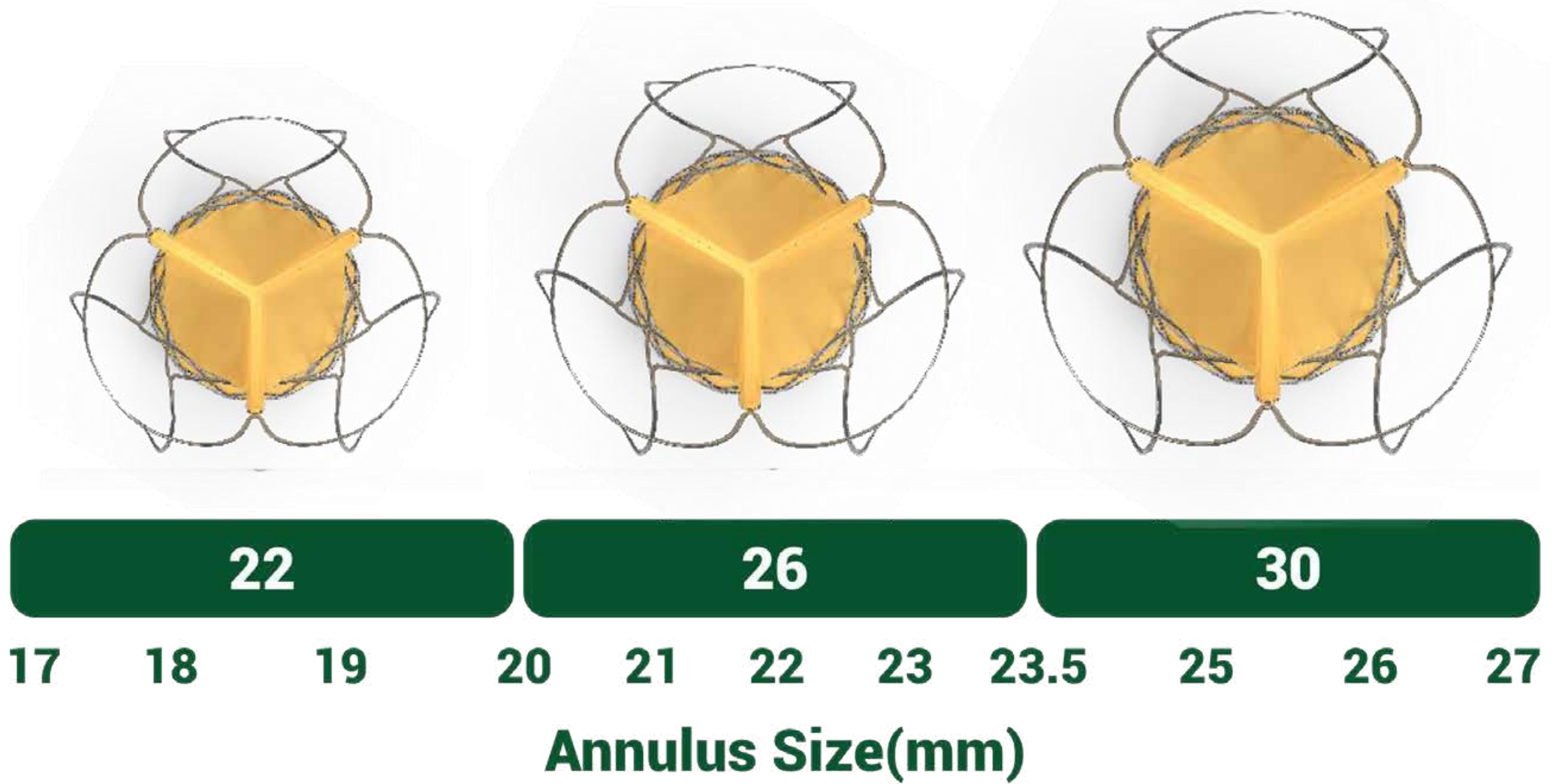
- Mayor performance hemodinámica.
- Mayor superficie de flujo. (orificio efectivo)
- El pericardio bovino es grueso y tiene una alta resistencia a la tracción.
- Tratamiento anti-calcificación.
- Proviene de países GRB1*
- El material bovino de Hydra supera los mayores estándares de durabilidad en test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



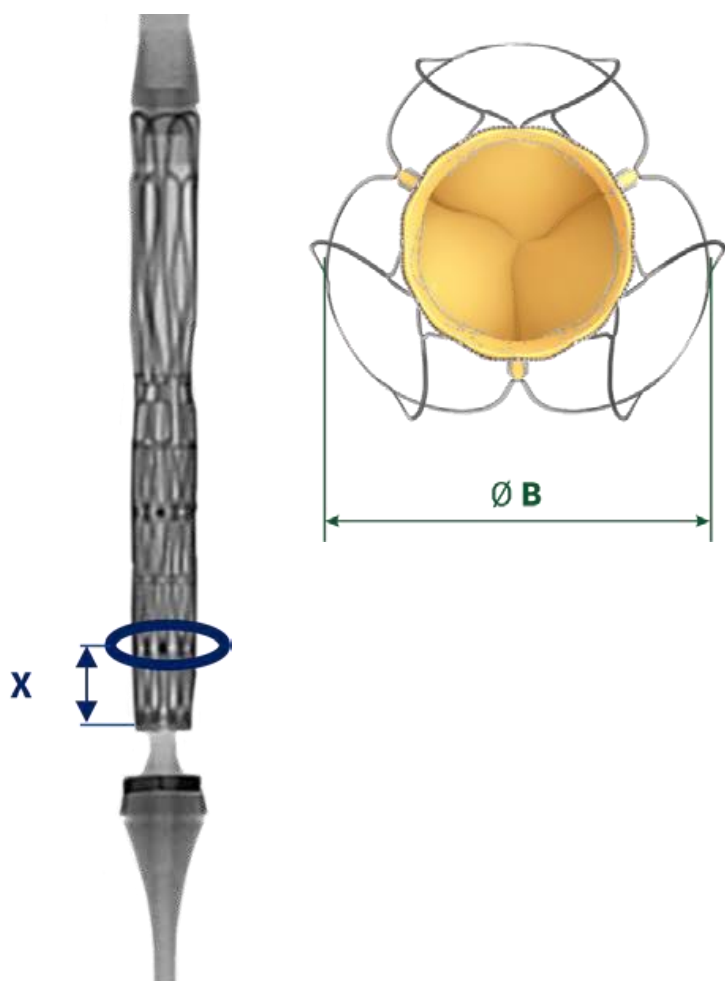
Tamaños Hydra



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



Liberacion

Recuperar

Reposicion



*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 function de liberación activa

Para facilitar la liberación

- Mayor flexibilidad
- Mejor control
- Recapturable 80%

Inline Sheath*

Para accesos más pequeños

Capsula trasparente 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.

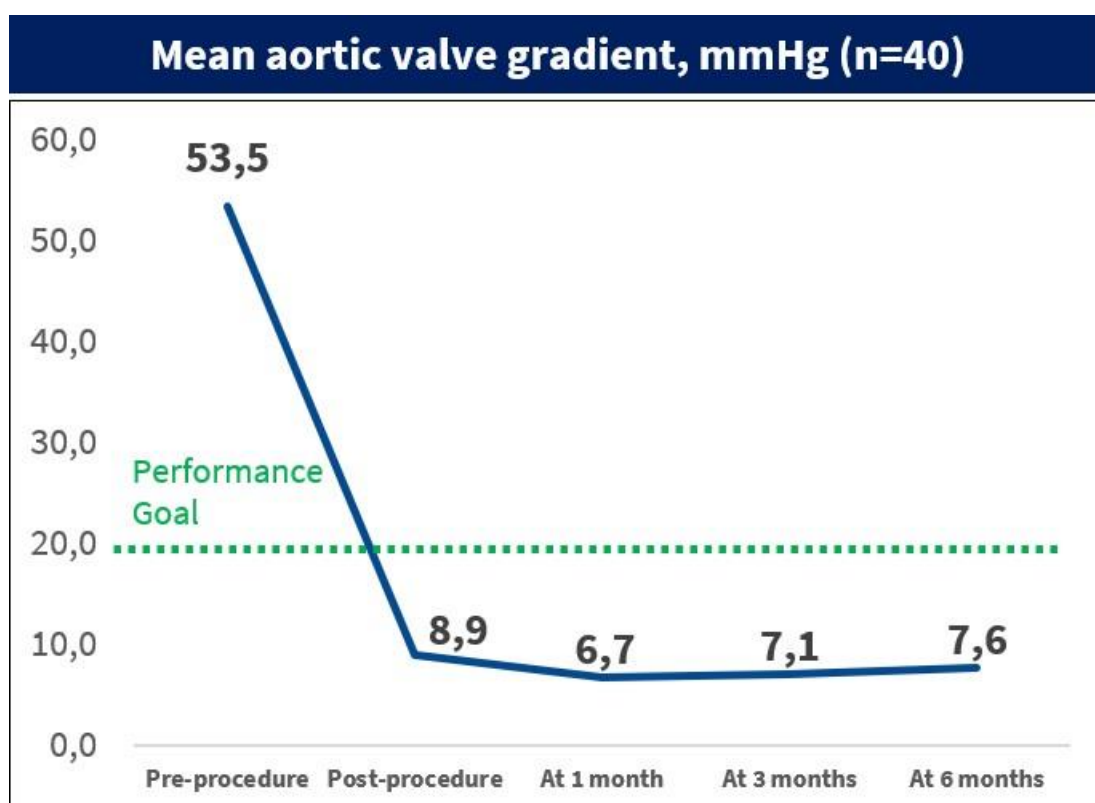
First-in-Man study (n=15) ¹	GENESIS study (n=40) ²	Hydra CE study (n=157) ³
<ul style="list-style-type: none"> - Published in Asia Intervention - Good hemodynamic performance - EOA increased from 0.68 cm² to 1.53 cm² - Mean Aortic gradient decreased from 49.0 mmHg to 9.4 mmHg 	<ul style="list-style-type: none"> - Published in CCI - 0% Moderate-to-severe-para-valvular leak at 6-month follow up 	<ul style="list-style-type: none"> - Published in JACC : Cardiovascular Interventions - Excellent Haemodynamic - Valve gradient in single digit and remained consistent at 1-year follow up. - Larger effective orifice area up to 1-year follow up. - Low rates of PVL
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

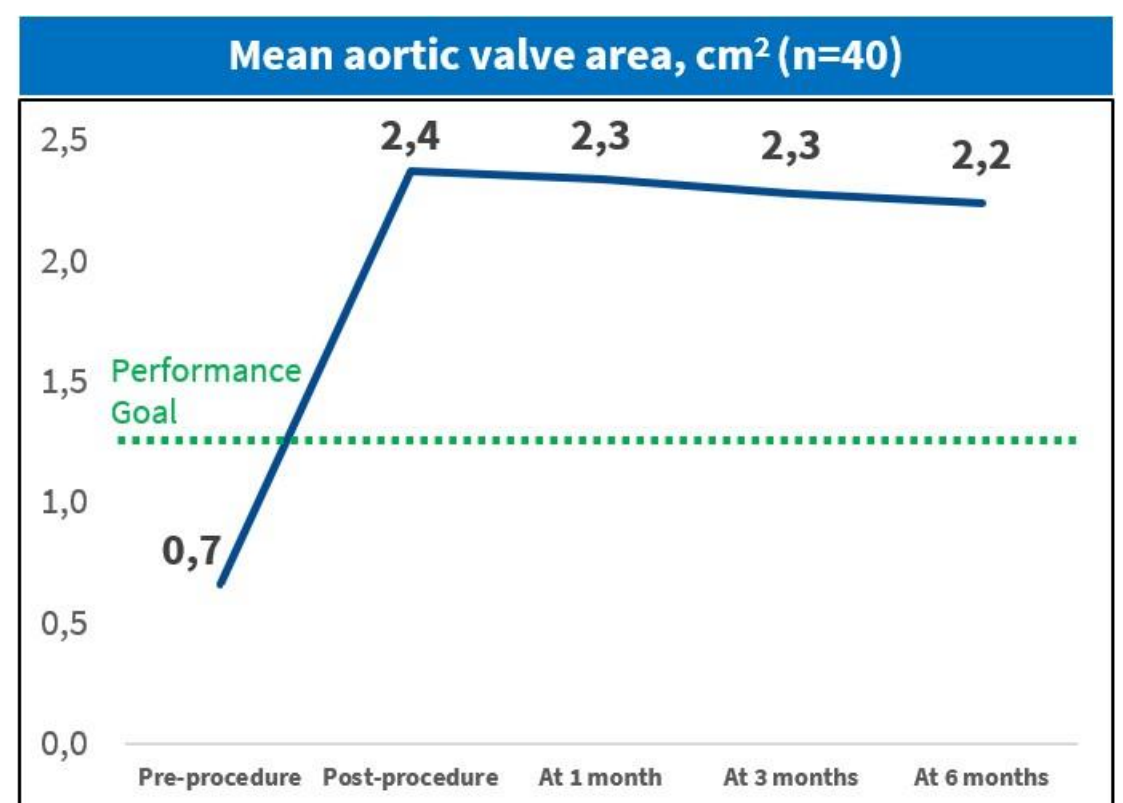
2. <https://doi.org/10.1002/ccd.29733>

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 cm² up to 6-month FUP.

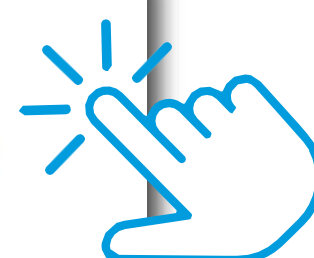


ORIGINAL STUDIES

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 HYDRASelf-Expanding Transcatheter Aortic Valve : Hydra CE Study

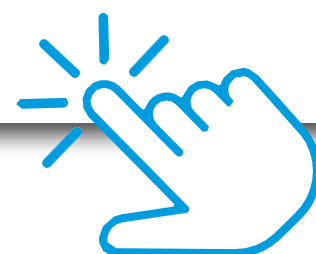
Now Published in

JACC : Cardiovascular Interventions

Impact Factor : 11.195



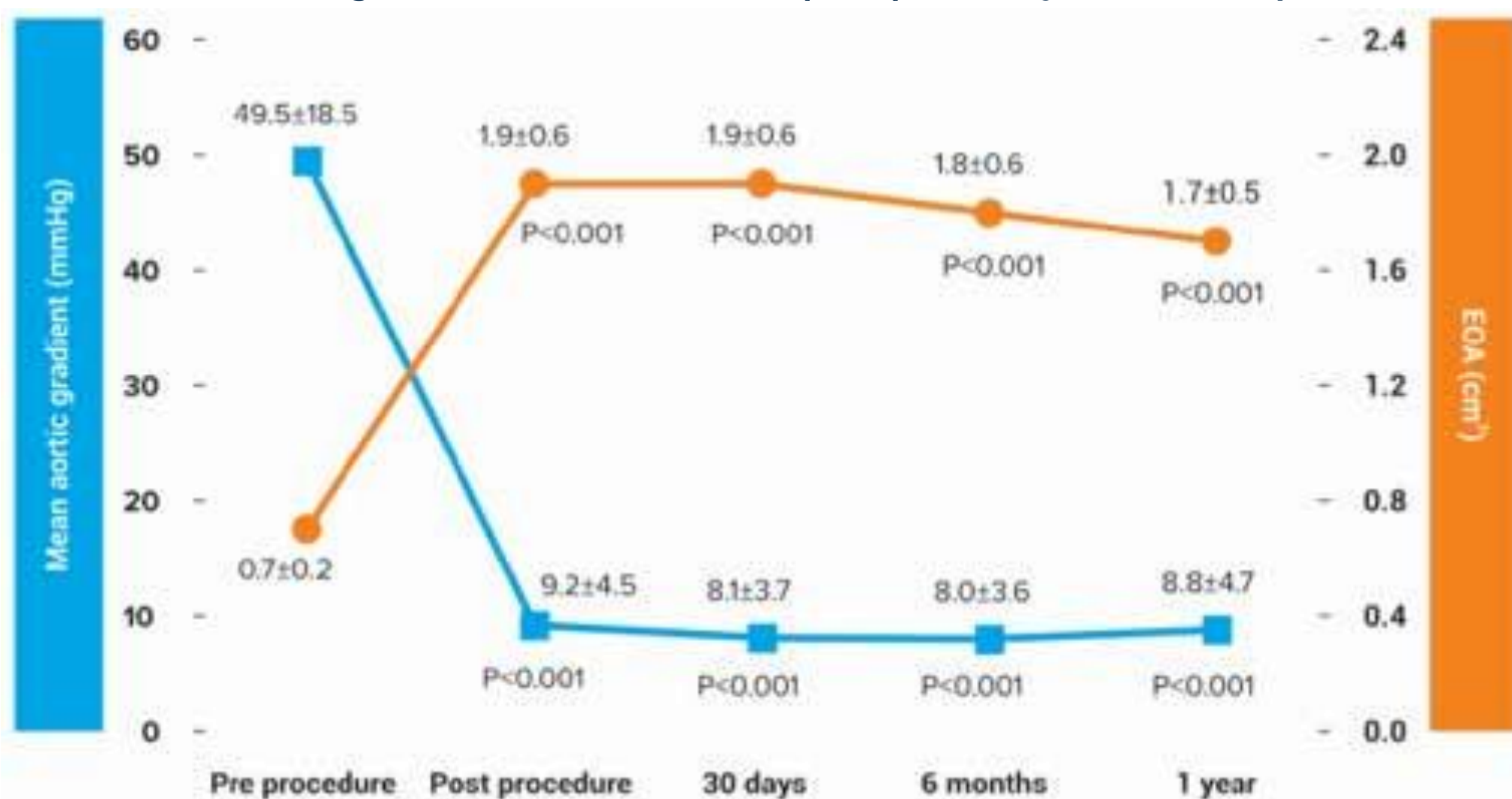
JACC: Cardiovascular Interventions Vol . 1 5 , No. 1 , 2022 Jan 10 , <https://doi.org/10.1016/j.jcin.2021.09.004>



Haga clic para acceder al estudio

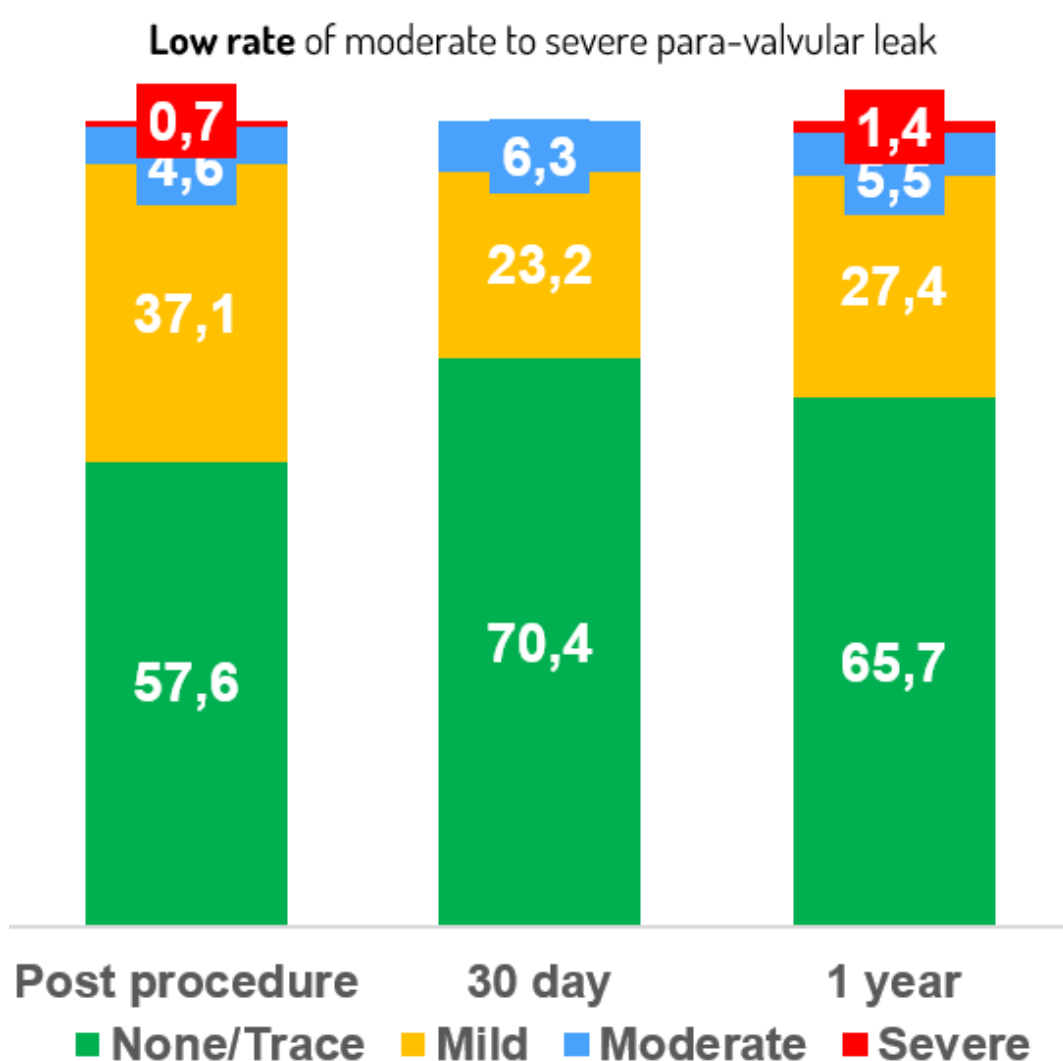
Excellent Hemodynamics

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



Resultados

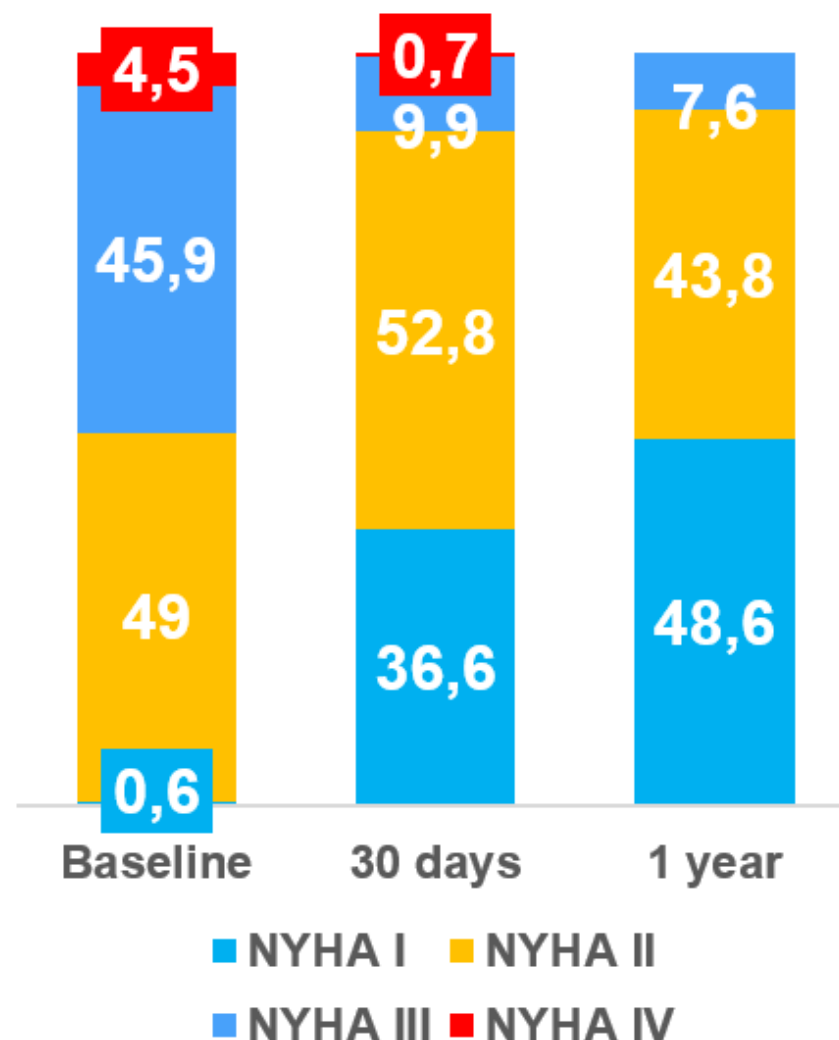
Para-Valvular Leak (%)



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

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.

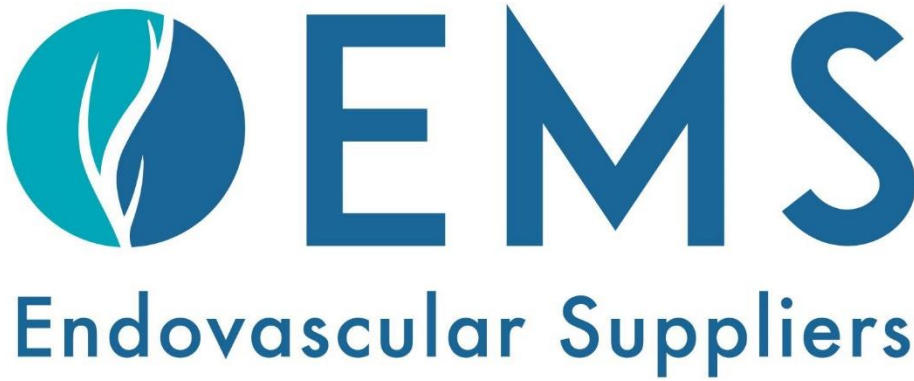


CE
1434

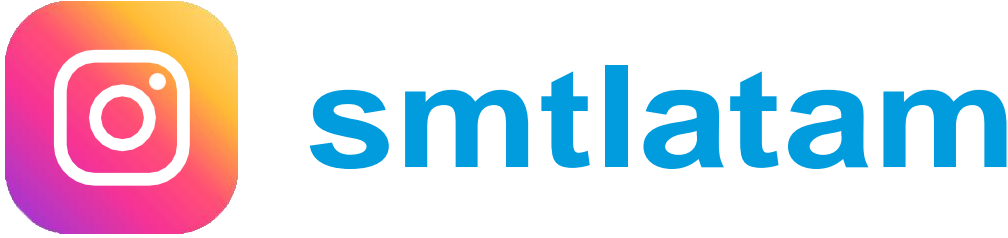
Transcatheter Aortic Valve



Habla con un representante:



Siga a SMT en las redes sociales



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