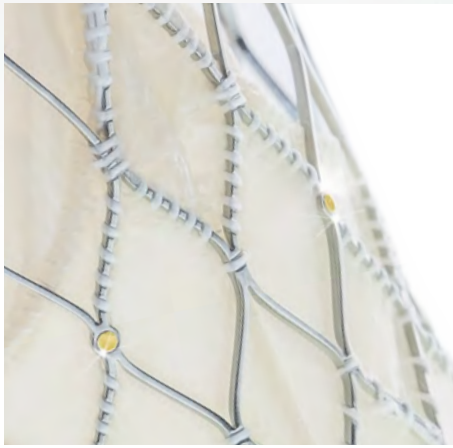
ALLEGRA™



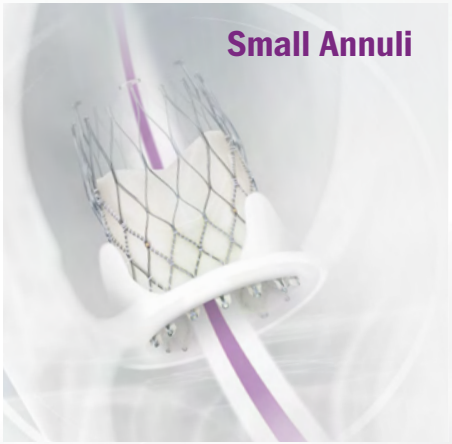
Uncompromised Hemodynamics. By Design.

A collaboration

BIOSENSORS INTERNATIONAL™

NEW VALVE TECHNOLOGY

Overview



ALLEGRA™

Uncompromised Hemodynamics. By Design.

ALLEGRA™ has been designed for uncompromised hemodynamic performance with single digit mean pressure gradients and high effective orifice areas[1-3].

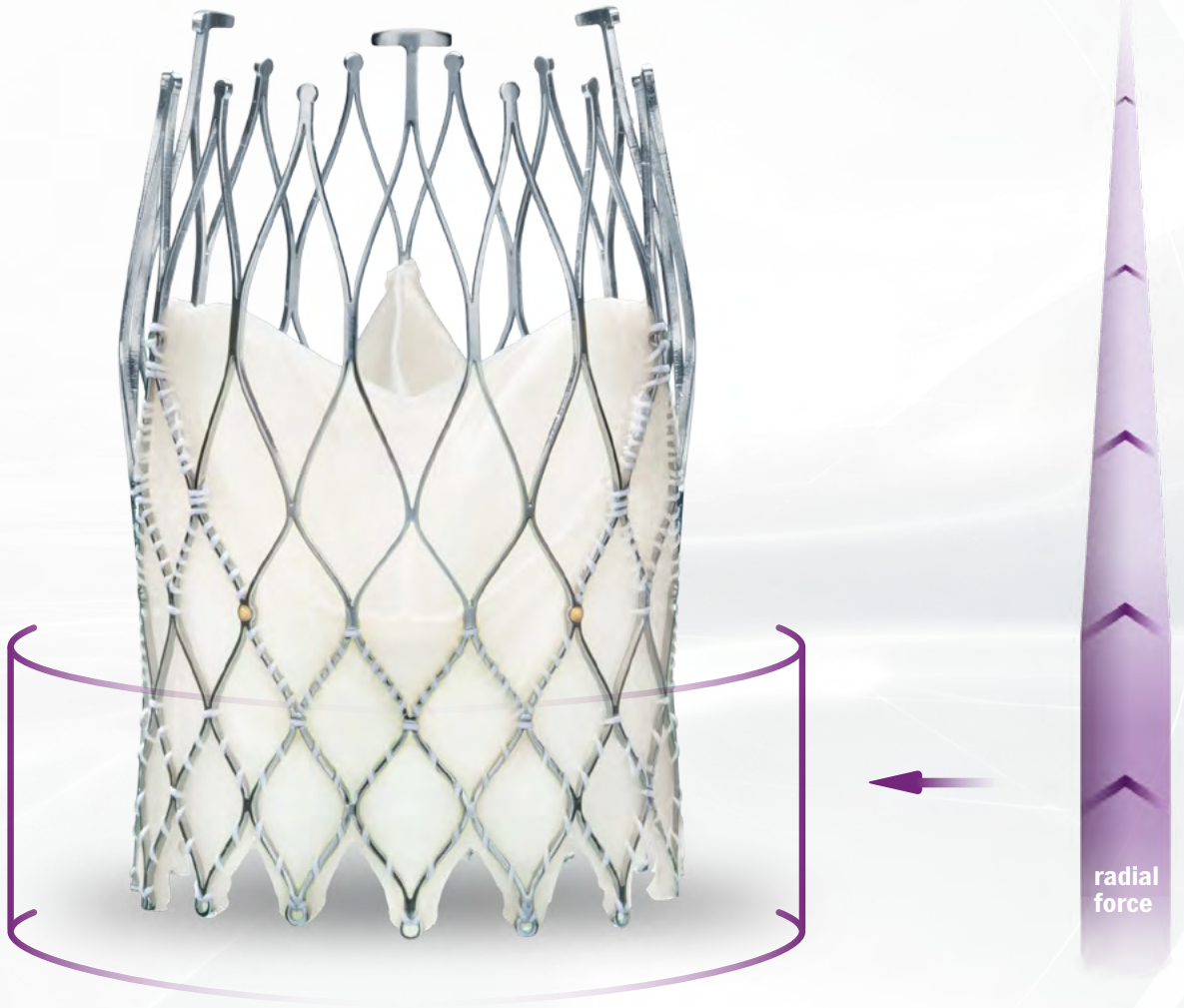
ALLEGRA™

unique self-expanding stent frame

The ALLEGRA™ has a unique self-expanding stent frame with convex and concave areas that provide high EOA (effective orifice areas), even in small annuli[1-3].
This unique stent shape also means that there is no interaction with the ascending aorta.

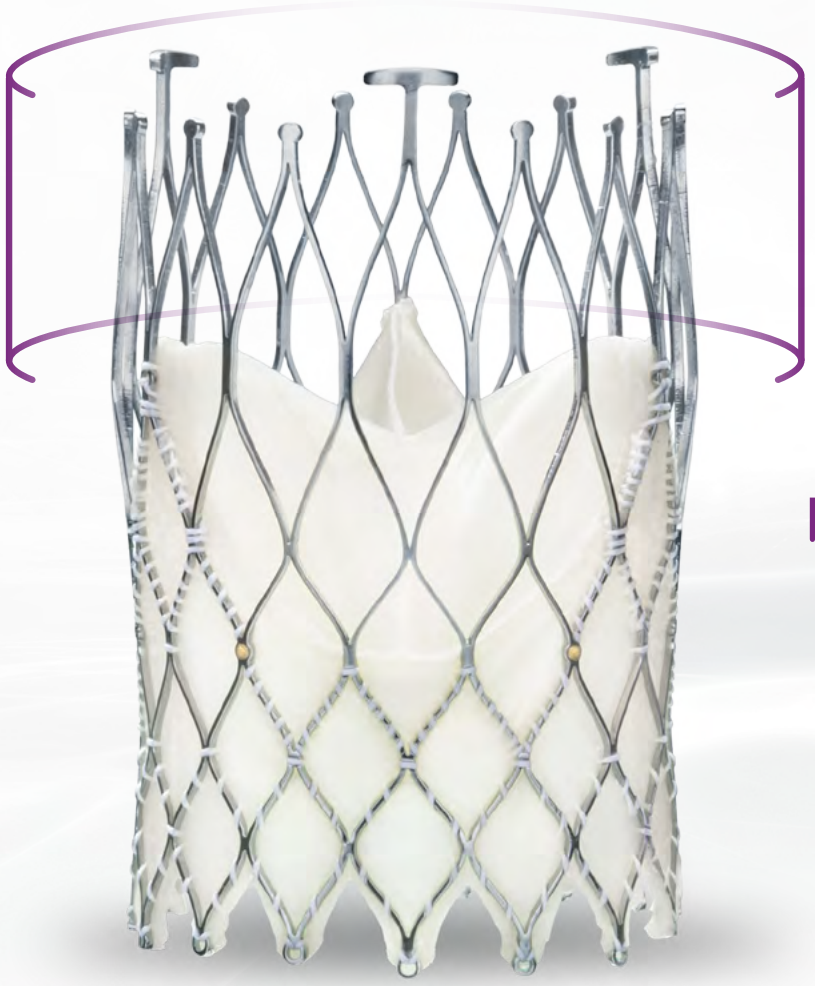
ALLEGRA™

The ALLEGRA™ stent design incorporates tailored radial force distribution with high radial force in the sealing area to achieve secure anchoring and low radial force in the outflow section.



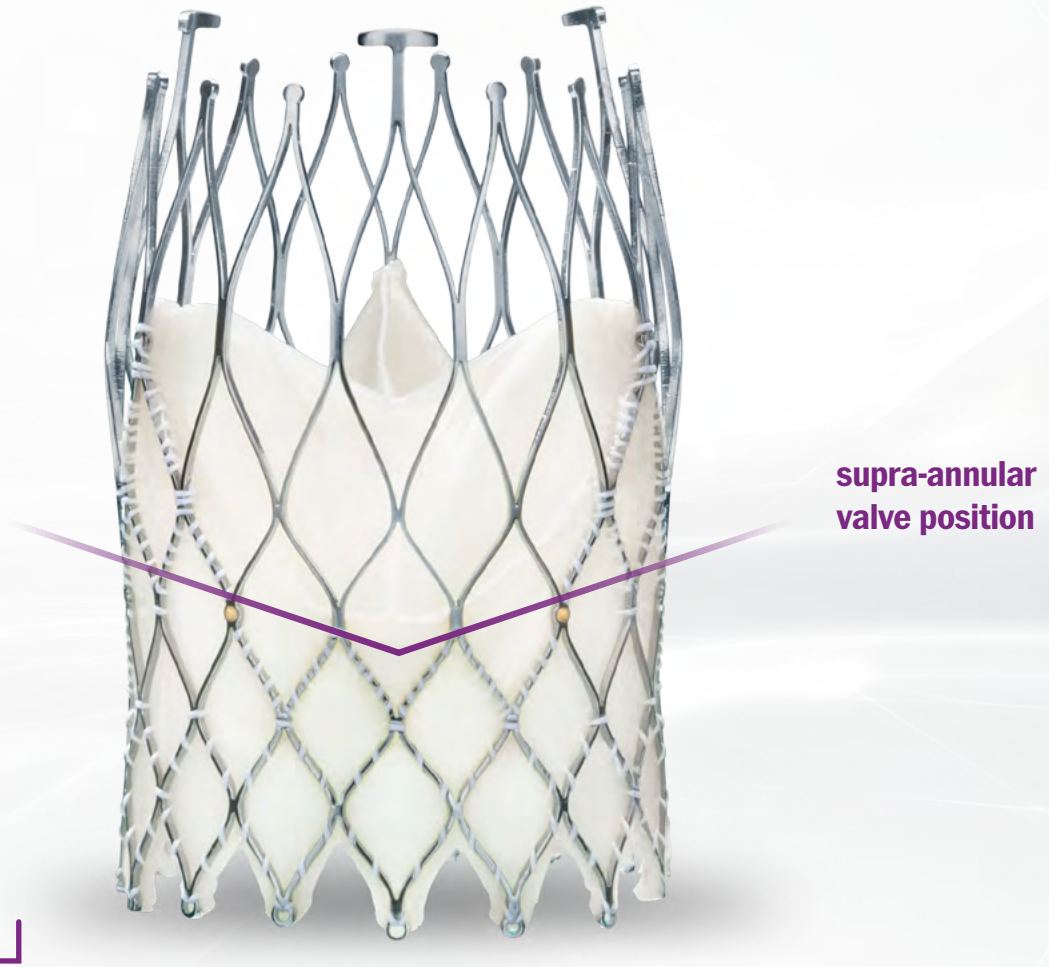
ALLEGRA™

wider valve opening



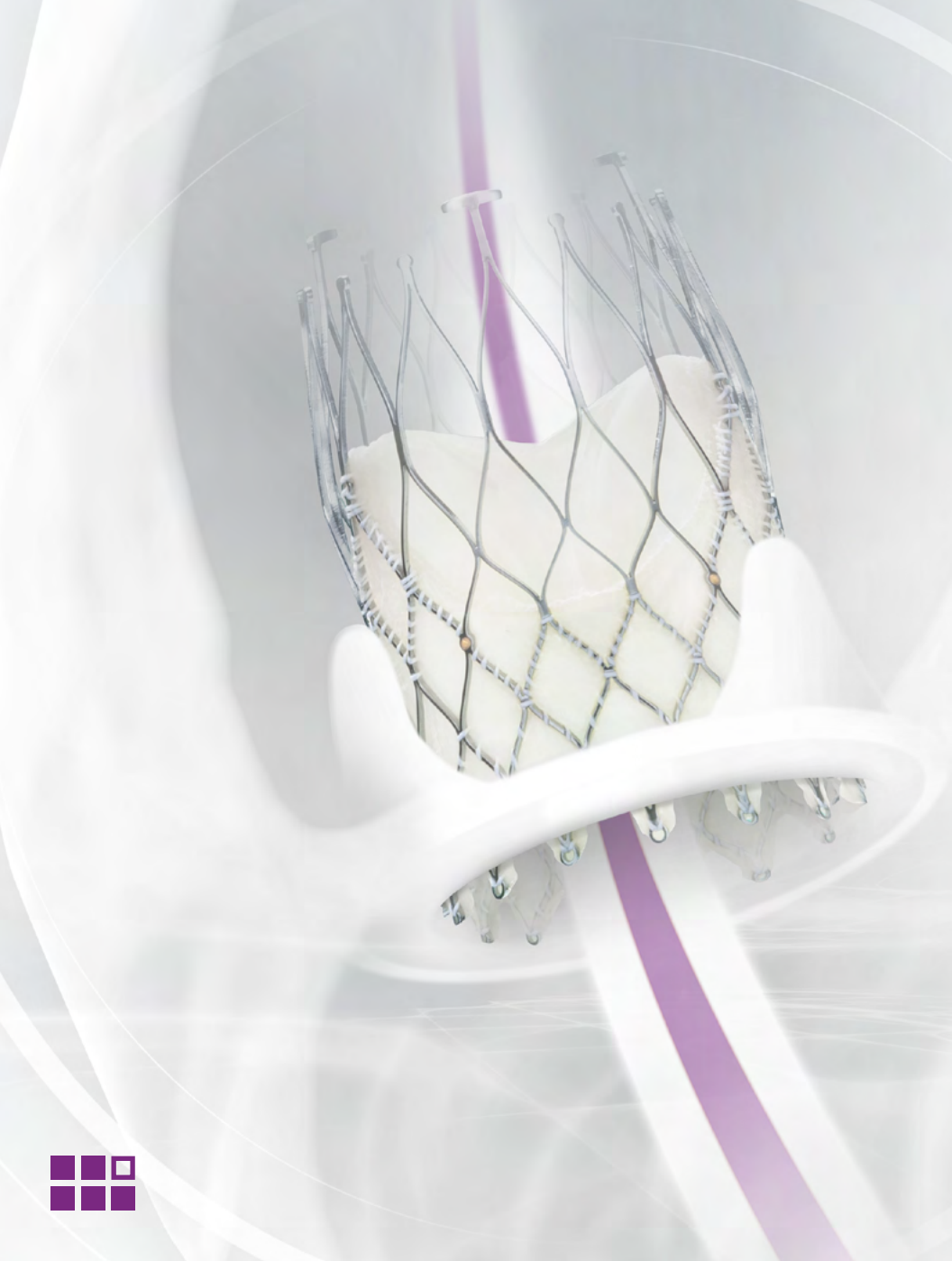
The low radial force in the outflow section supports wider valve opening and contributes to the large EOA and low mean pressure gradient[1-3].

ALLEGRA™



The ALLEGRA™ is a supra-annular valve. The new valve plane sits above the constrained and diseased native valve. This supra-annular valve position also contributes to the large EOA and low mean pressure gradient[1-3].

ALLEGRA™



Maximizing the Effect in Small Annuli.

VALVE-IN-VALVE INDICATION

CE APPROVED

The outstanding hemodynamics of the **ALLEGRA™** are particularly important in small native annuli and surgical valves (ViV).

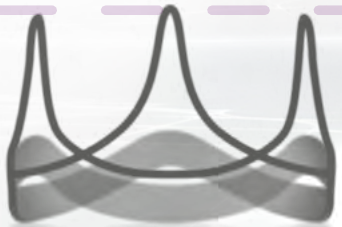
ALLEGRA™

Patients with small annuli derive particular benefit from the use of the ALLEGRA™ valve, due to the combination of wide valve opening and supra-annular valve plane.
The ALLEGRA™ can be used with annular diameters as low as 19 mm in native valves and 16.5 mm in surgical valves. Even in these very small annuli, low single digit mean pressure gradients and high effective orifice areas can be achieved[1,3].

ALLEGRA™ shows better in-vitro hemodynamic performance than other TAVI devices in the Valve-in-Valve setting.
In-vitro comparisons have shown higher EOA compared to other intra-annular and supra-annular valves[4,5].

ALLEGRA™

The design features of the ALLEGRA™ make it an excellent choice for Valve-in-Valve procedures with low frame height and unique visualization of the new valve plane by 6 radiopaque gold markers.

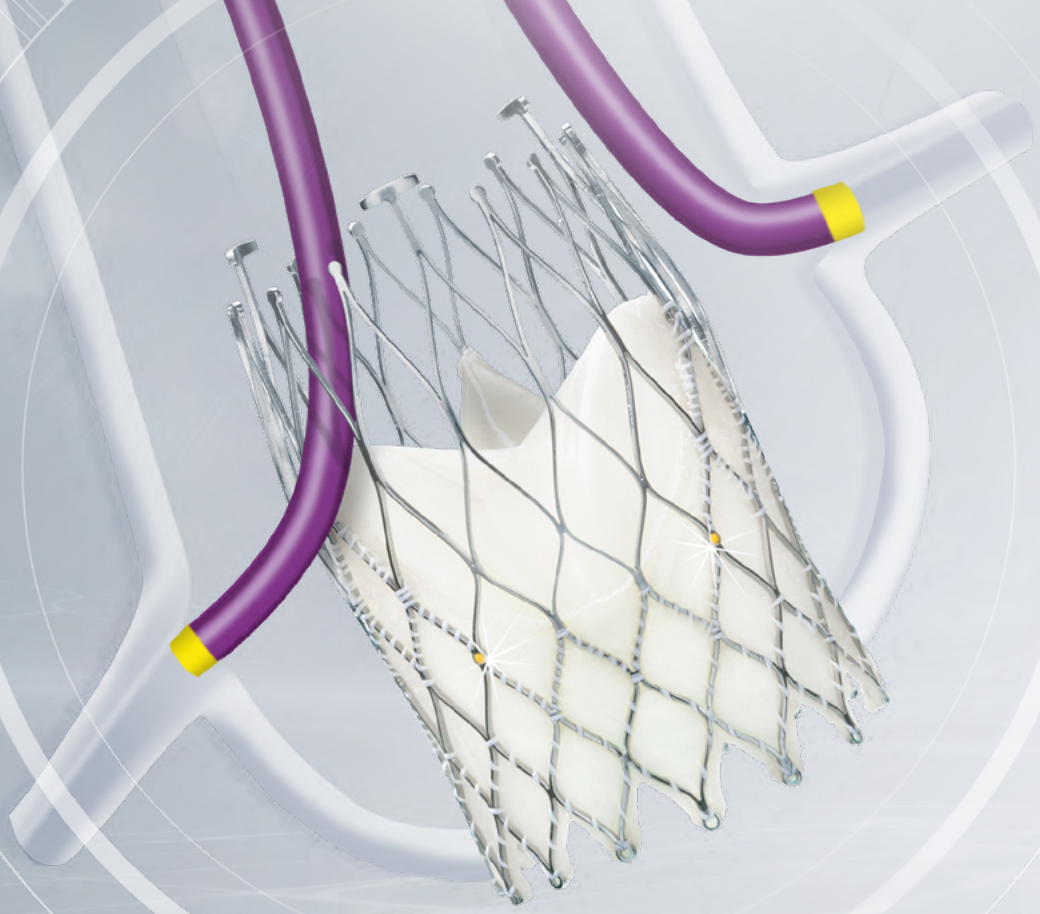


ALLEGRA™

Maintaining Coronary Access.

Whatever the anatomic situation, coronary access should be maintained. In all studies conducted with **ALLEGRA™** so far, there is a 0% incidence of coronary obstruction[1-3].

ALLEGRA™



In patients with wide coronary sinuses, intra-annular fixation of the ALLEGRA™ and the absence of any interaction with the ascending aorta both ensure continued access to the coronary ostia.

In patients with narrower coronary sinuses, the outflow section of the ALLEGRA™ has large stent cells which further facilitate coronary access. The stent frame can be safely crossed with standard interventional catheters including up to 12 Fr [6].

In patients with very low-lying coronary ostia, the 6 easily visualized gold markers which mark both the new valve plane and the top of the 12 mm high sealing skirt allow the operator to accurately position the valve taking into account the coronary heights.

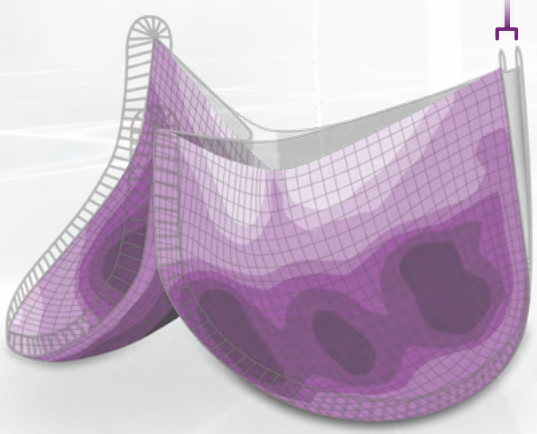
Durability by Design.

Durability of a trans-catheter heart valve is critically important in younger patients.

ALLEGRA™

The stent frame of the ALLEGRA™ allows pole movement which reduces leaflet stress.
Pole movement allows the commissural points of the leaflets to move with every cardiac cycle and reduces stress to the leaflets[7]. In the surgical aortic valve literature reduction of leaflet stress is associated with increased durability[8].

stent tip deflection during the cardiac cycle



stent frame allows pole movement

ALLEGRA™

For the ALLEGRA™ bovine pericardium is used for all tissue components. Bovine pericardium was chosen as it has an excellent performance profile with very good bio-compatibility, outstanding hemodynamic characteristics, low complication rates and extensive data on durability from the surgical literature[9].

The ALLEGRA™ bovine pericardium is treated to reduce calcification potential. The protective treatment is based on proven techniques such as the elimination of the phospholipid layer of the pericardial cells and the reduction of the glutaraldehyde free bonds. Both of these treatments offer anti-calcification characteristics to the pericardium.

ALLEGRA™

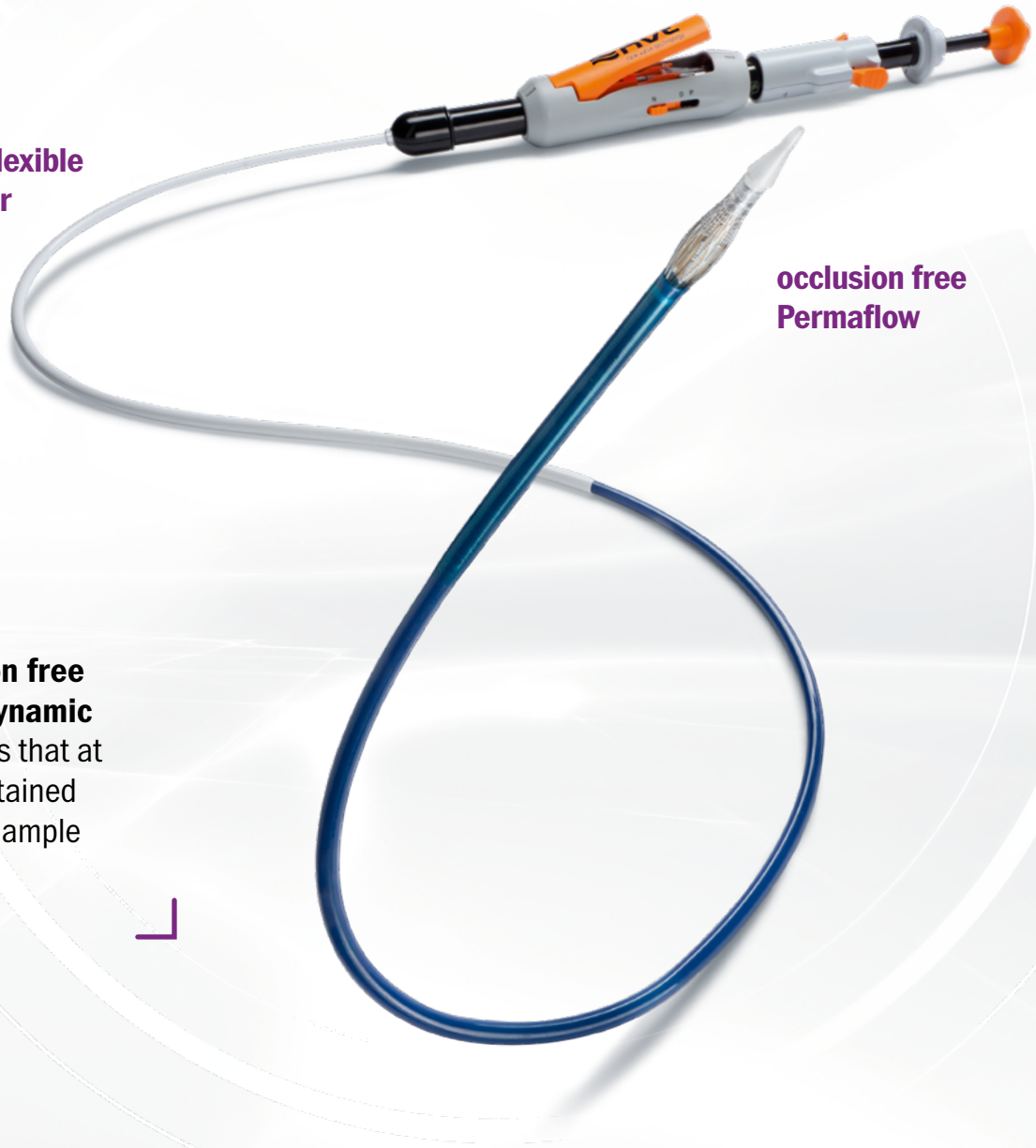
Bespoke Delivery System.

ALLEGRA™ comes with a bespoke delivery system for occlusion free Permaflow implantation technique.

ALLEGRA™

A highly flexible 15 Fr catheter with an 18 Fr valve cartridge allows enhanced cross-ability through the aortic arch.

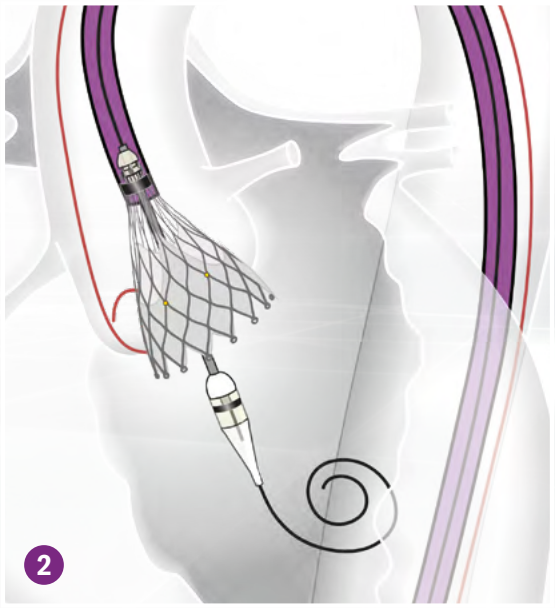
The ALLEGRA™ delivery system offers an occlusion free Permaflow deployment technique with no hemodynamic compromise during implantation. Permaflow means that at all times during delivery and deployment, flow is maintained providing the clinician with stable hemodynamics and ample time to optimize device position.



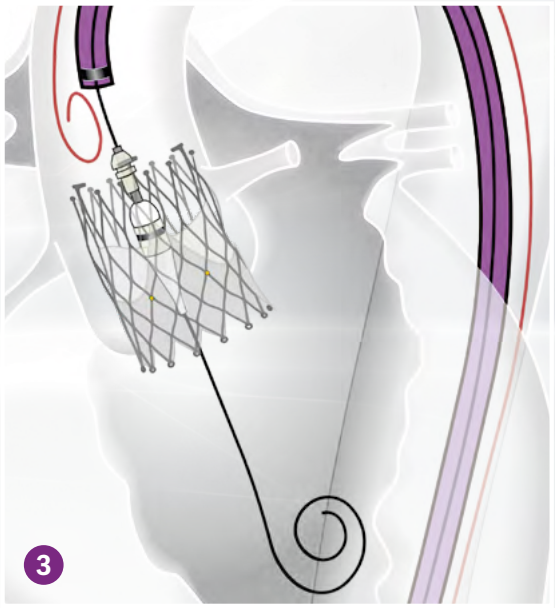
ALLEGRA™

The ALLEGRA™ delivery system incorporates an easy 3-step deployment. Step 1 is Permaflow, step 2 is the inflow release and step 3 is the final detachment of the valve.

Permaflow



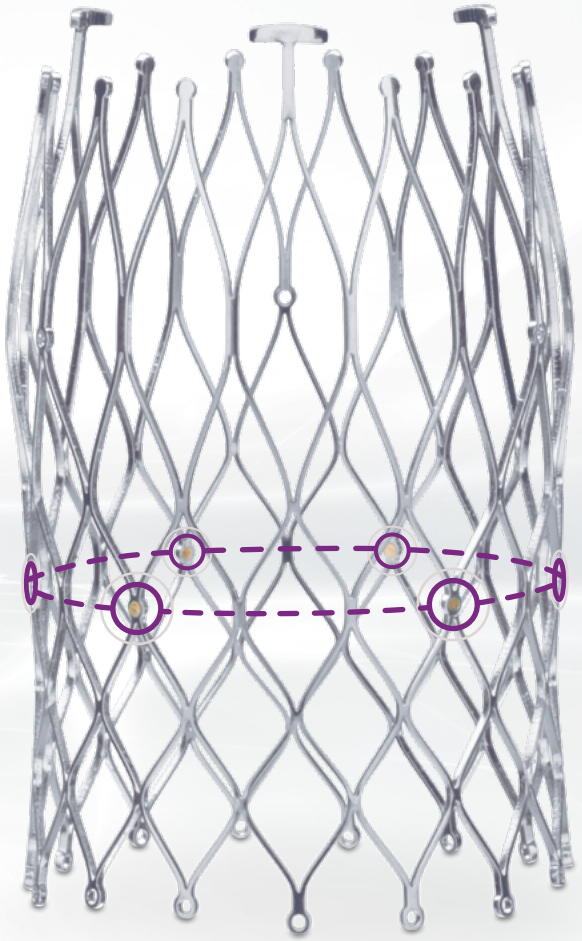
Inflow release



Final detachment of the valve

ALLEGRA™

Visibility for precise implantation is important. The ALLEGRA™ delivery system and the ALLEGRA™ transcatheter heart valve offer unique visibility features which allow precise positioning and implantation of the valve. The delivery system has two ring markers for top and bottom reference and the valve has 6 radiopaque gold markers to indicate the new valve plane and the top of the 12 mm sealing skirt.



ALLEGRA™

ALLEGRA™

(in mm)	ALLEGRA™ 23	ALLEGRA™ 27	ALLEGRA™ 31
Tissue annulus diameter	19 – 22	22 – 25	25 – 28
Annulus perimeter	59.7 – 69.1	69.1 – 78.5	78.5 – 88
Annulus area	280 – 380 mm^2	380 – 490 mm^2	490 – 620 mm^2
Inner diameter aortic valve bioprosthesis	16.5 – 21.5	22 – 24.5	25 – 28

ALLEGRA™ Delivery System TF
15 Fr catheter with an 18 Fr valve cartridge
Compatible with a 0.035 inch (0.889 mm) guide wire
Usable length 115 cm
Hydrophilic coating

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NEW VALVE TECHNOLOGY

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