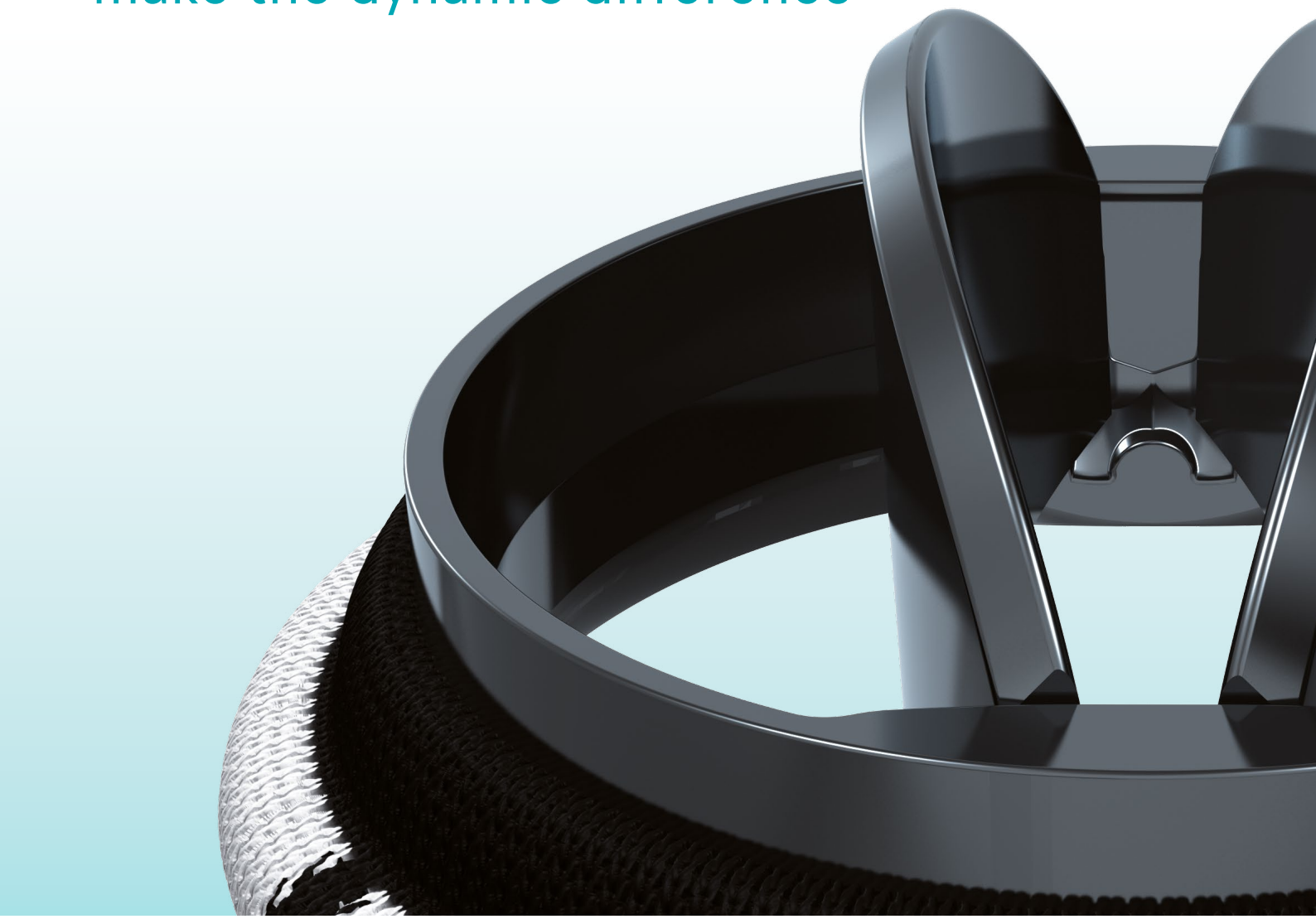
LivaNova

Health innovation that matters

BICARBON FAMILY

Distinguished details make the dynamic difference



Bileaflet mechanical heart valve solutions to meet patient and surgeon needs

Detailed options for detailed benefits

LivaNova Bicarbon mechanical heart valves have been specifically designed to offer an utmost advanced solution to patients undergoing cardiac valve replacement.

Featuring many distinguished details, Bicarbon valves provide top hemodynamic performance combined with proven safety and durability. The benefits of its innovative design are reflected in the excellent clinical outcomes documented in scientific literature across over 25 years of clinical use.

Bicarbon mechanical valves feature the exclusive LivaNova Carbofilm™ coating technology which enhances hemo and biocompatibility.

Innovative design, innovative choice of materials and a long track of proven clinical results make of this valve the best choice looking for an advanced solution backed by compelling long term data.

The Bicarbon range can boast excellent clinical results in over 25 years of clinical use. The outstanding design features offer excellent hemodynamic performance, optimal thromboresistance, ease of implant and proven safety and durability.

Detailed Hemodynamics

Detailed Thromboresistance

Detailed safety and durability

Detailed performance for excellent clinical outcomes

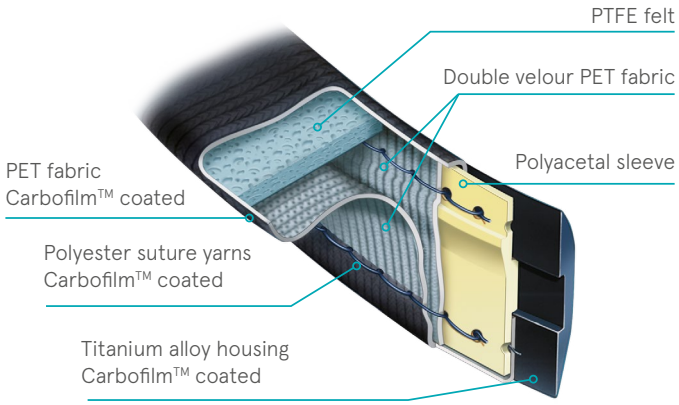
Detailed Hemodynamics

Bicarbon's distinguished details make the difference when it comes to hemodynamic performance

Detailed choice of materials

LivaNova Bicarbon is the only valve in the market featuring a Titanium housing coated with Carbofilm™. Titanium is a highly biocompatible material with twice the structural stability of commonly used Pyrolite Carbon. This allows for a slimmer housing thus maximizing the area available to the blood flow.

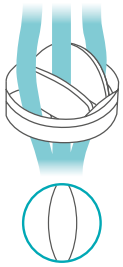
The LivaNova proprietary Carbofilm™ coating applied both to the Titanium housing and the sewing cuff, enhances hemocompatibility minimizing the risk for pannus formation and favoring a gentle tissue ingrowth that prevents perivalvular leaks.[1,2,3]



1. Sovering annuloplasty rings: Experimental pathology in the sheep model. Della Barbera et al.- Cardiovascular Pathology 14 (2005) 96-103
2. Pyrolitic carbon coating enhances Teflon and Dacron fabric compatibility with endothelial cell growth. Sbarbati et al. - Int J Artif Organs 14: 491 -498, 1991
3. Tissue reaction to fabrics coated with turbostratic carbon:subcutaneous versus vascular implants. Aebischer et al. - Biomaterials 9: 80-85, 1988

Detailed Design

BICARBON™ Solution



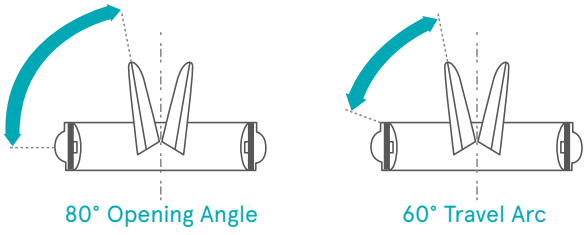
Not only the detailed choice of materials but also the utmost innovative design is key to Bicarbon's top hemodynamic performance.

Unique among mechanical heart valves, Bicarbon features curved leaflets specifically engineered to achieve an even flow distribution downstream. This leads to several major benefits to the patient:[4,5]

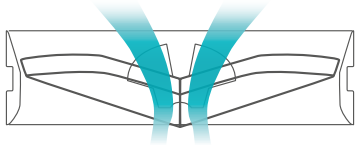
- minimum turbulence which avoids blood stasis and thus the risk for thrombus formation
- low pressure gradients for optimal hemodynamic performance
- reduced energy loss for an efficient functioning with a benefit for cardiac workload

Also the special aerofoil profile of the housing, which gently decreases in width from the inflow towards the outflow side, is intended to optimize the organization of the flow, minimizing blood turbulence and favoring pressure recovery.[4,5]

The 80 degrees opening angle, in combination with curved leaflets has been specifically established to minimize turbulence, while the short travel arc contributes to low regurgitation levels and low energy loss.[4,5]



The unique two open-chimney design ensures an effective passive washing of the hinges even when the valve is closed, avoiding blood stasis and hemolysis at the same time.[4,6]



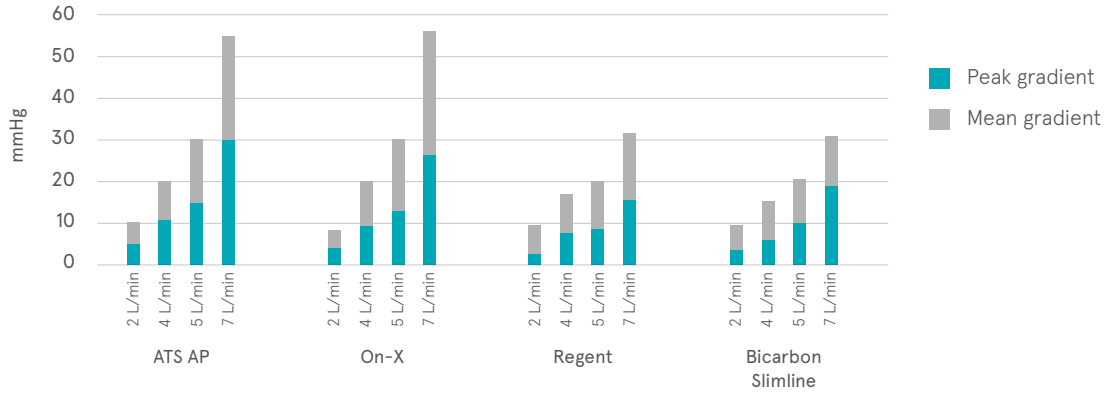
The excellent hemodynamic performance of Bicarbon valves are well proven in the published scientific literature.

In vitro comparisons with other commercially available valves have shown that Bicarbon are among the best performing valves with respect to all the relevant parameters:[5]

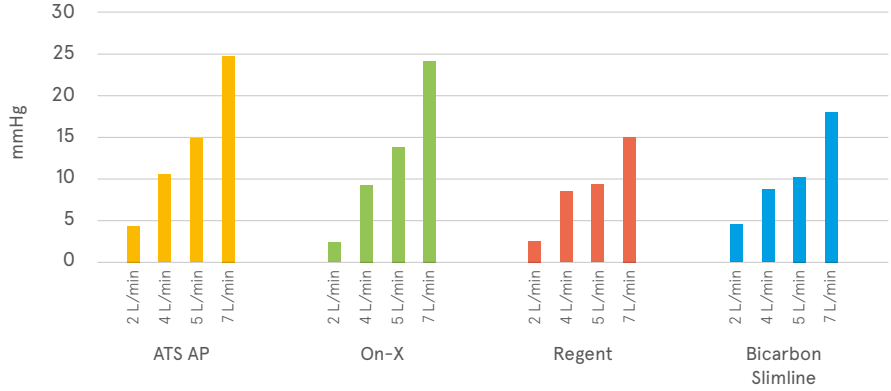
- pressure gradients
- leakage volume
- energy loss
- velocity profiles
- shear stress distribution

This is confirmed in small aortic annuli[7], even when comparing among valves specifically designed for improved hemodynamic performance.[8]

Mean and peak pressure gradients at 70 bpm (mmHg)*[8]



Energy loss at 70 bpm (%)*[8]



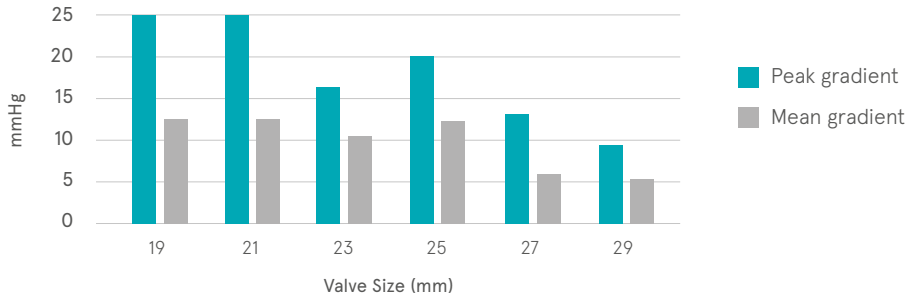
** Test performed with Sheffield pulse duplicator. Valves fitting a 21 mm diameter valve holder.*

4. Pivot design in bileaflet valves. Vallana et al. - Asaio Journal 1992; 38:M600-M606
5. In vitro comparison of bileaflet aortic heart valve prostheses. Reul et al. – J. Thorac and Cardiov Surg 1992; 106 (3): 412-20
6. Leakage flow at mechanical heart valve prostheses: improved washout or increased blood damage. Steegers, Reul, Rau - J Heart Valve Dis 1999; 8: 312-323
7. Comparative study of the hydrodynamic function of six size 19 mm bileaflet heart valves. J. Fisher – Eur J Cardio-thorac Surg (1995)9: 692-96
8. Small aortic annulus: The hydrodynamic performances of 5 commercially available bileaflet mechanical valves. Bottio et al.- J. Thorac and Cardiovasc Surg (3): 457

The hydrodynamic efficiency of Bicarbon valves is reflected by the excellent hemodynamic results reported in the published in-vivo evaluations.

Peak and Mean Pressure Gradients[9]*

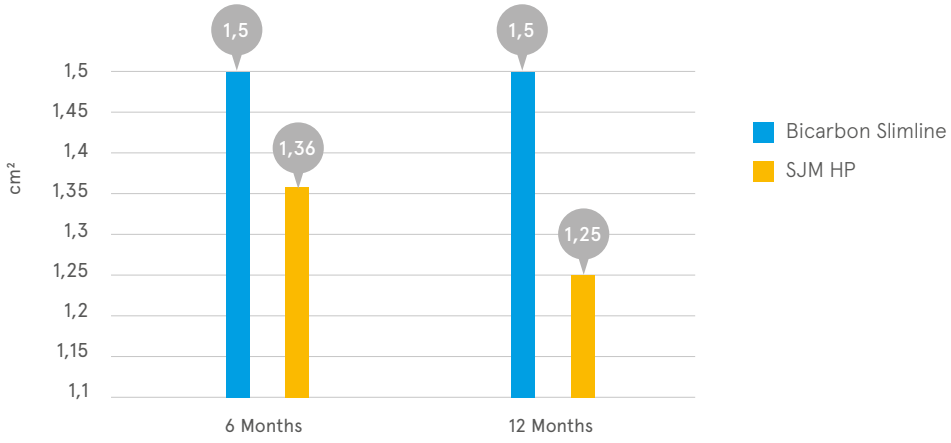
IN VIVO AORTIC POSITION



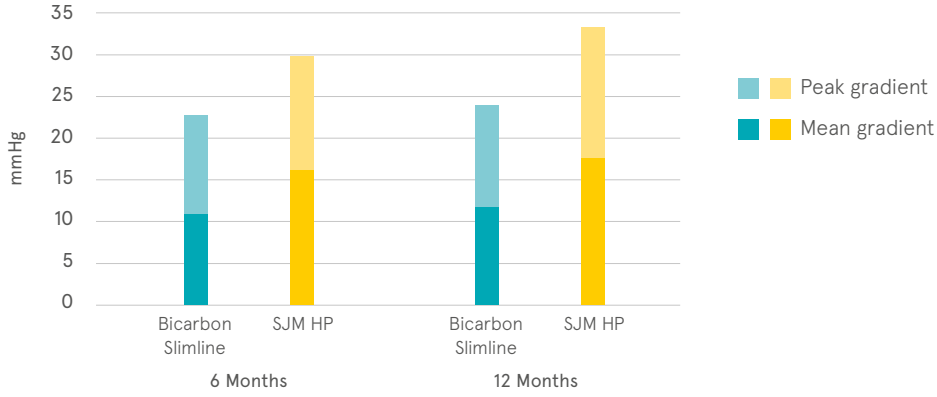
* Bicarbon standard model

Comparative evaluation of small-size LivaNova Bicarbon Slimline and St. Jude HP heart valve prosthesis.[10]

Size 19 Effective Orifice Area (cm²)[10]



Size 19 Mean and Peak pressure gradients (mmHg)[10]

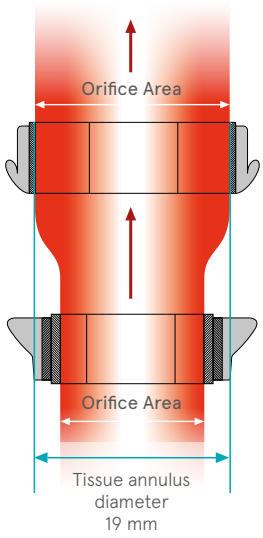


9. Normal echocardiographivc characteristics of the Sorin Bicarbon bileaflet prosthetic heart valve in the mitral and aortic positions. Badano et al. – J Am Soc Echocardiogr 1997; 10: 632- 43
10. Comparative evaluation of small-size Sorin Slimline and St. Jude HP Heart Valve Prostheses. Otero et al. – Ann Thorac Surg 2005; 79: 1284-90

Overline for Top Hemodynamic performance

To further optimize hemodynamics, especially in small aortic annuli, LivaNova features in its Bicarbon portfolio the Overline aortic prosthesis, a truly totally supra-annular model.[11] A totally supra annular positioning can provide an advantage of 1 to 2 sizes over intra-annular valves.[12,13]

100% ORIFICE TO ANNULUS MATCH



Overline improves effective valve orifice area thanks to a 100% orifice to annulus match, thus contributing to reduce the risk of PPM.[14]

" An 18 mm or 20 mm valve was implanted in more than 80% of the present patients.[...] However, no cases of PPM were observed, despite the use of 18 and 20 mm valves."[15]

Hemodynamic function on echocardiography before and at 12 months after surgery, by labeled valve size.[15]

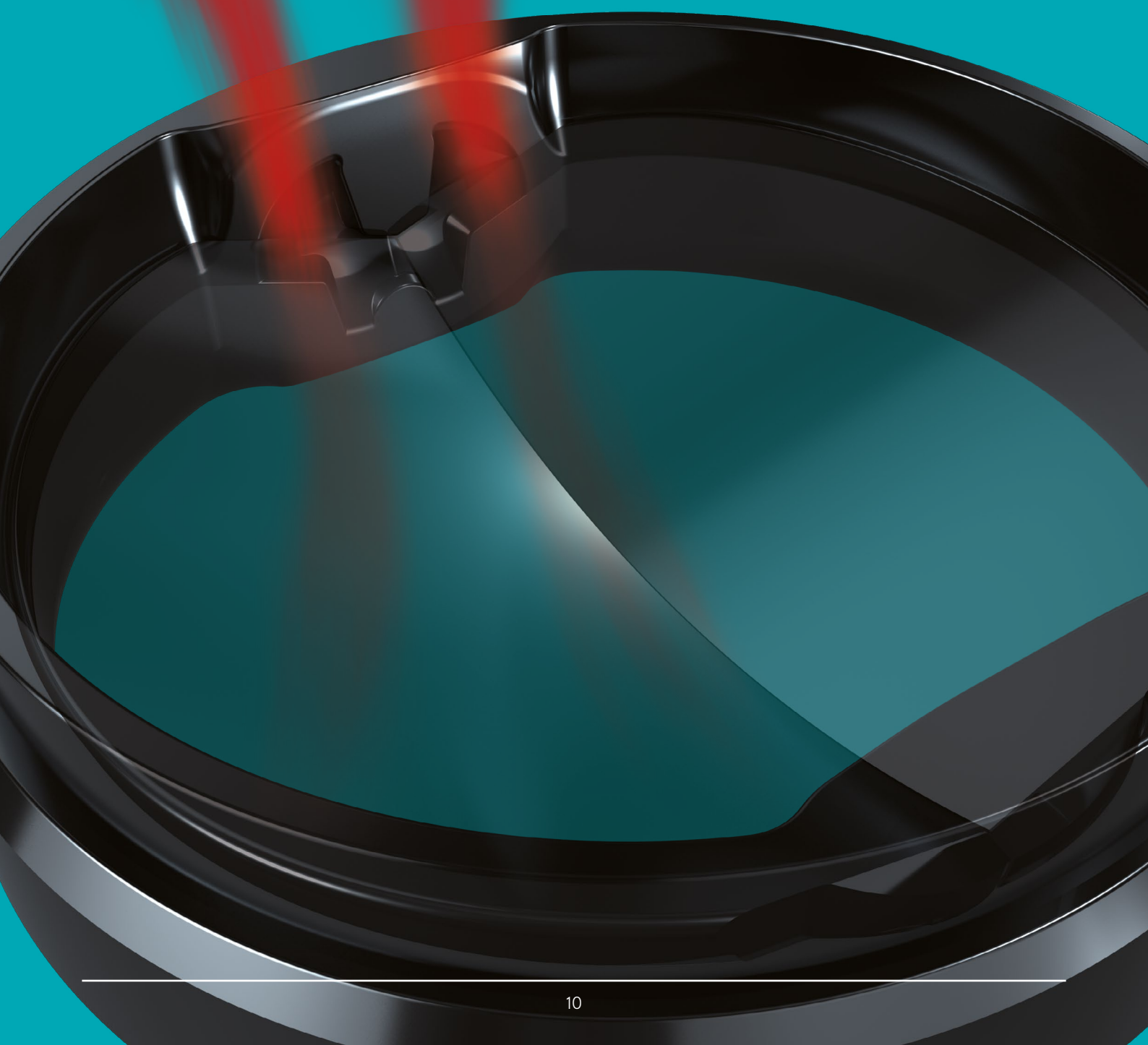
Parameters	Time	Total pts	Valve size (mm)		
		(n=102)	18 (n=27)	20 (n=51)	22 (n=24)
PPG (mmHg)	Preoperative	67 ± 29	78 ± 24	64 ± 21	62 ± 32
	12 months	24 ± 8	26 ± 8	23 ± 8	24 ± 9
MPG (mmHg)	Preoperative	42 ± 19	50 ± 17	37 ± 19	44 ± 19
	12 months	13 ± 5	15 ± 6	12 ± 4	12 ± 5

MPG: Mean pressure gradient; PPG: Peak pressure gradient

"The in vivo data showed excellent hemodynamic results for all valve sizes [..]. In addition, the EOA was significantly increased, from 0.80 ± 0.41 cm² before surgery to 2.01 ± 0.26 cm² after 12 months".[15]

11. Supra annular model as defined by International Standard for Cardiovascular implants - Cardiac valve Prostheses-Part 2. ISO 5840-2:2015(E)
12. The Carbomedics Supraannular Top hat Valve improves prosthesis size in the Aortic Root. Lundblad R et al.- J Heart Valve Dis 2001;10:196-201
13. Maximizing prosthetic valve size with the Top Hat® supraannular aortic valve. Aagard et al.- The Journal of Heart Valve Disease 2007;16:84-90
14. Hemodynamic and Clinical Impact of Prosthesis-Patient Mismatch in the Aortic Valve Position and its Prevention. Pibarot P., Dumesnil JG.- J Am Coll Cardiol 2000;36:1131- 41
15. Results of aortic valve replacement with the supra-annular Sorin Bicarbon Overline prosthesis. Reyes et al.- J Heart Valve Dis 2012; 21 (3): 358-63

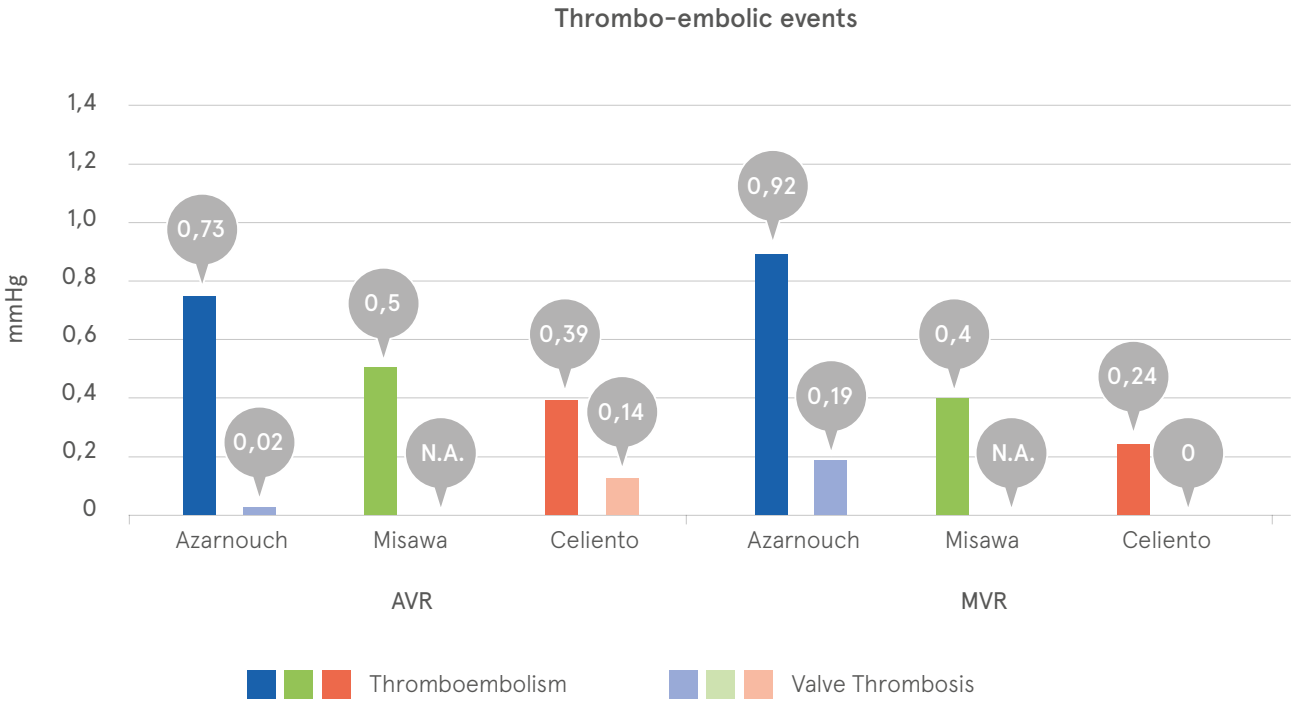
Detailed Thromboresistance



Bicarbon valves are specifically designed to minimize thrombogenicity:

- Carbofilm coating increases hemocompatibility lowering the risk of thrombus formation.[1,2,3]
- Curved leaflets, aerofoil housing profile, optimized leaflets travel arc and opening angle favor a laminar blood flow which reduces shear stress and hemolysis. This results in lower serum levels of lactatedehydrogenase (LDH) [16] as compared to those found for other commercially available valves.[17] A low degree of hemolysis leads to less platelet activation and consequently less risk of clots.[19,20]
- The unique two open-chimney design ensures an effective passive washing of the hinges avoiding blood stasis and hemolysis at the same time.[4,6]

This is why Bicarbon valves have shown a very low incidence of thrombosis and thromboembolic events in up to 17 years of published follow up.[20,21,22]



16. Hemolysis in mechanical bileaflet prostheses: experience with the Bicarbon valve. Josa et al. - Ann Thorac Surg 2006; 81:1291-6
17. Hemolysis parameters of St. Jude Medical: Hemodynamic Plus and Regent valves in aortic position. Suedkamp et al. - Int J Cardio. 2004; 95(1): 89 – 93
18. In vitro pulsatile hemodynamics of five mechanical aortic heart valve prostheses. Walker, Yoganathan – Eur J Cardiothorac Surg 1992; 69 (Suppl1): S113-23
19. Blood rheology after cardiac valve replacement with mechanical prostheses or bioprostheses.. Koppensteiner et al. ; - Am J Cardiolo 1991; 67:79-83
20. The Sorin Bicarbon over 15 years clinical outcomes: multicentre experience in 1704 patients. Azarnoush, Laborde, De Riberolles - Eur J Cardio-thoracic Surg 38 (2010) 759—66
21. Fifteen-year experience with the Bicarbon heart valve prosthesis in a single center. Misawa et al. - J Cardiothorac Surg. 2015; 10: 89.
22. Single center experience with the Sorin Bicarbon prosthesis: A 17-year clinical follow-up. Celiento et al. - J Thorac Cardiovasc Surg 2014;148:2039-44

LOWERing the INtensity of oral anticoaGulant Therapy in patients with bileaflet mechanical aortic valve replacement: Results from the "LOWERING-IT" Trial.

As a further proof of its excellent thromboresistance, Bicarbon is backed by the 'LOWERING-IT' trial,[23] an independent prospective controlled randomized study which has established for the first time that a lower INR target (1.5-2.5) is safe and feasible in low risk patients after aortic valve replacement .

Flow diagram of the LOWERING-IT trial

396 patients included in the analysis

CONVENTIONAL-INR GROUP
PTS assigned to INR 2.0-3.0
199 pts. Included in the Analysis

LOW-INR GROUP
PTS assigned to INR 1.5-2.5
197 pts. Included in the Analysis

3 out of 4 patients in the Low-INR group of the LOWERING-IT Trial had a Bicarbon valve implanted

Outcome events

	LOW-INR (n=197)	CONVENTIONAL-INR (n= 199)	*P*	OR (95% exact CI)
Thromboembolic events	1	3	.62 ns	0.33 (0.006-4.20)
Hemorrhagic events	6	16	.04	0.36 (0.11-0.99)

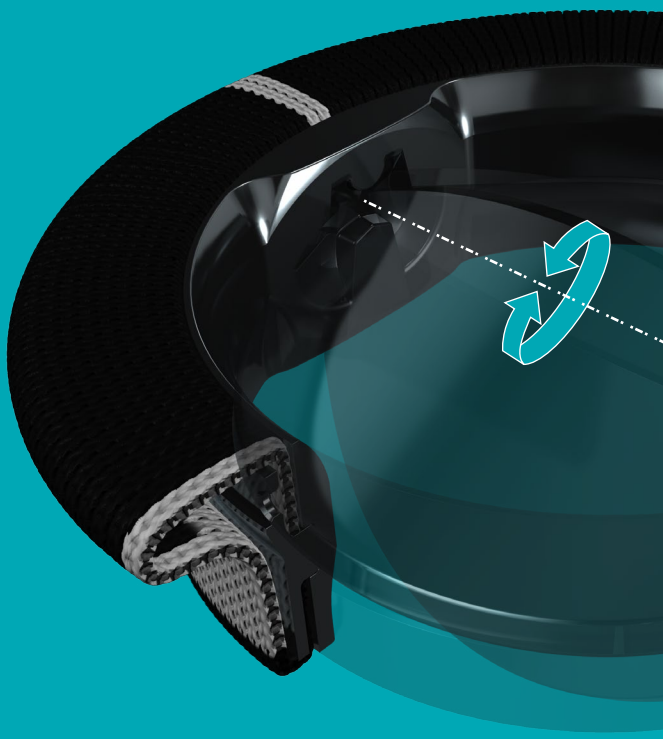
"LOWERING-IT trial established that the proposed LOW-INR target is safe and feasible in low-risk patients after bileaflet aortic mechanical valve replacement. It results in similar thrombotic events and in a significant reduction of bleeding occurrence when compared to the conventional anticoagulation regimen."[23]

23. LOWERing the INtensity of oral anticoaGulant Therapy in patients with bileaflet mechanical aortic valve replacement: Results from the "LOWERING-IT" Trial. Torella et al. - Am Heart J 2010;160:171-8

Detailed safety and durability

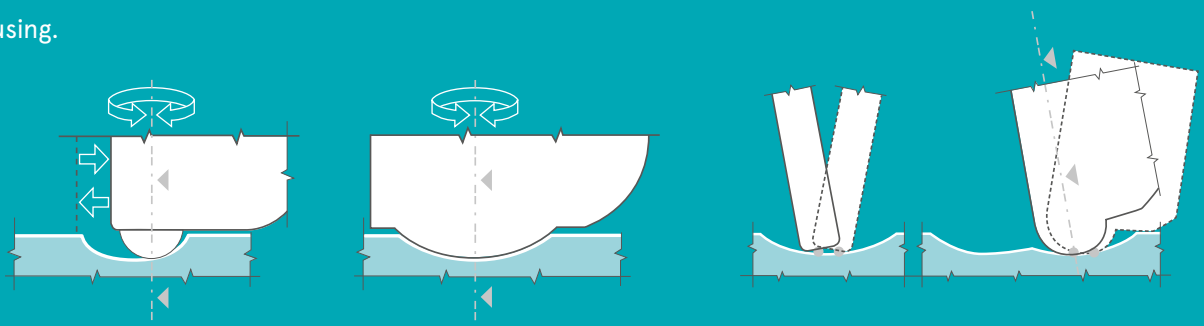
Every single detail of the Bicarbon valve is carefully engineered to offer outstanding performance to last over time.

- The Titanium housing, with twice the structural stability of solid Pyrolytic Carbon housings, ensures correct leaflet retention and functioning.
- The unique two open-chimney design of the hinges avoid blood stasis and hemolysis minimizing the risk of structural valve failure and clinical complications
- The Carbofilm™ coated PET fabric sewing ring provides a safe anchorage favoring a gentle tissue ingrowth that minimizes the risk of perivalvular leaks and pannus formation at the same time.
- The unique, proprietary 'rolling without sliding' hinge mechanism, characterized by a constantly varying single point of contact between the pivot and the housing, minimizes friction and wear and consequently the risk of structural valve deterioration.



The Bicarbon solution versus competitive valves[4]

Friction and wear are minimized by the constantly varying single point of contact between the pivot and the housing.



The Titanium housing ensures correct leaflet retention with twice the structural stability and only half the width of solid Pyrolytic Carbon housings. Biocompatibility is assured by the total Carbofilm™ coating.

Rolling without sliding

One single point of contact
The point continously varying

Motion with sliding

The whole surfaces in contact

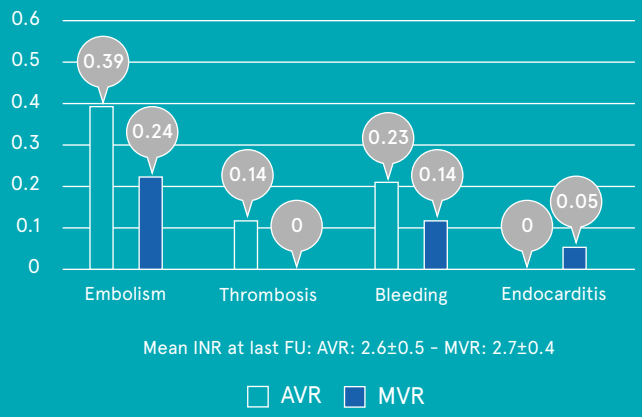
Detailed performance for excellent clinical outcomes

Bicarbon has proven to be a safe, high performing valve with excellent clinical outcomes in the long term follow up.[20,21,22,24]

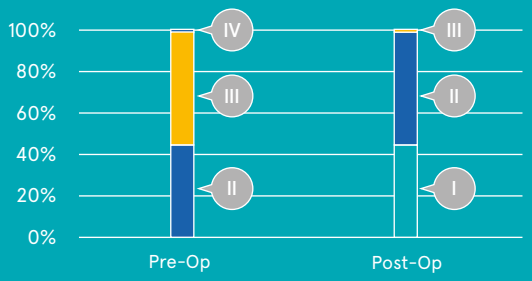
Single center experience with the LivaNova Bicarbon prosthesis: A 17-year clinical follow-up

"The Bicarbon Prosthesis has shown excellent results in terms of clinical improvement and freedom from valve-related complications, even up to 17 years after AVR and MVR."[22]

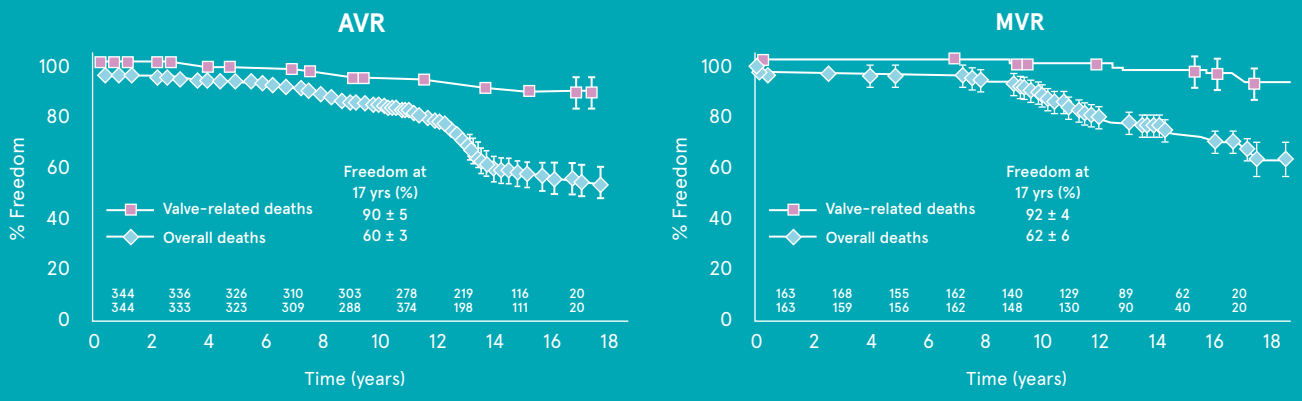
Linearized rate of adverse events (%PT-YR)



NYHA CLASS



Actuarial Survival and Freedom from valve-related deaths



Numbers on the horizontal axis indicate patients at risk at each time interval

20. The Sorin Bicarbon over 15 years clinical outcomes: multicentre experience in 1704 patients. Azarnoush, Laborde, De Riberolles - Eur J Cardio-thoracic Surg 38 (2010) 759–66

21. Fifteen-year experience with the Bicarbon heart valve prosthesis in a single center. Misawa et al. - J Cardiothorac Surg. 2015; 10: 89.

22. Single center experience with the Sorin Bicarbon prosthesis: A 17-year clinical follow-up. Celiento et al. - J Thorac Cardiovasc Surg 2014;148:2039-44

24. Sorin Bicarbon™ bileaflet valve: a 10-year experience. Borman, De Riberolles - Eur J Cardio-thorac Surg 2003; 23: 86-92

The voice of experience

"The Bicarbon Prosthesis continues to perform satisfactorily even in the long term with low incidence of valve-related mortality and morbidity confirming to be an extremely reliable and durable mechanical valve substitute."[20]

"In the present series, a low incidence of embolic events was observed [...] indicating that the innovative changes incorporated into the Bicarbon Prosthesis design, improving transprosthetic flow and reducing turbulence, might positively influence its thrombogenicity".
"We have also found that other major postoperative complications, [...] are extremely uncommon after AVR and MVR with the Bicarbon Prosthesis".
"[...] no cases of structural failure were recorded".[22]

"The present study gives additional evidence of low rates of valve-related complications after Bicarbon valve Implantation. [...] we maintain the INR between 1.8 and 3.0. The rate of thromboembolic events in this study is excellent and the rates of bleeding complications are also acceptable."
"This single-center study of a 15-year follow-up of the Bicarbon prosthetic heart valve shows excellent clinical results associated with a low incidence of valve-related mortality and morbidity".[21]

LivaNova

Health innovation that matters

BICARBON OVERLINE

TOTALLY SUPRA-ANNULAR AORTIC VALVE
Sizes 16-24 mm

BICARBON SLIMLINE

SUPRA-ANNULAR AORTIC VALVE
Sizes 17-27 mm

Application

- Aortic procedures
- Normal sinus area
- Small aortic annulus
- Severely calcified aortic annulus
- Double valve replacement

- Aortic procedures
- Low coronary ostia
- Narrow, rigid aortic annulus
- Small, inflexible aorta (Sinus of Valsalva)

Implantation Consideration

- Totally supra-annular placement
  - allows for largest valve possible
  - increases ease and safety of DVR procedure
- Orientation of the implanted valve facilitated by a Polyacetal sleeve mounted inside the sewing cuff, which maintains torque at a constant level
- Three orientation markers for suture spacing
- Soft, pliable cuff for an easy handling and to better conform to the patient's annulus.
- Special sizers allow surgeon to assess position of valve within sinus area and clearance of coronaries before implantation

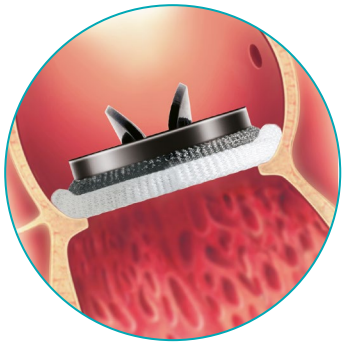
- Indicated in cases in which the external valve dimension needs to be reduced in relation to the available flow area
- Orientation of the implanted valve facilitated by a Polyacetal sleeve mounted inside the sewing cuff, which maintains torque at a constant level
- Three orientation markers for suture spacing
- Soft, pliable cuff for an easy handling and to better conform to the patient's annulus.

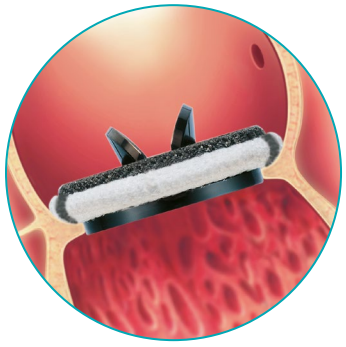
Clinical Considerations

- Advanced design optimized for top hemodynamic performance
- Size upgrades further improve valve hemodynamics
- Allows the largest possible orifice of any mechanical valve
- Alternative to aortic root enlargement
- Advanced design allows to achieve a laminar blood flow that minimizes the risk of thrombus formation
- Excellent clinical record for valve-related events
- Proven safety and durability

- Advanced design optimized for top hemodynamic performance
- Alternative to aortic root enlargement where supra-annular valve will not fit in sinus
- Advanced design allows to achieve a laminar blood flow that minimizes the risk of thrombus formation
- Excellent clinical record for valve-related events
- Proven safety and durability

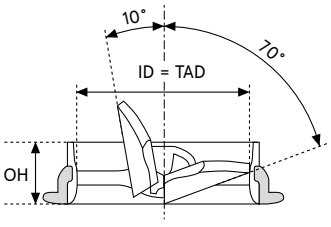
Valve placement *in-situ*





Product specifications

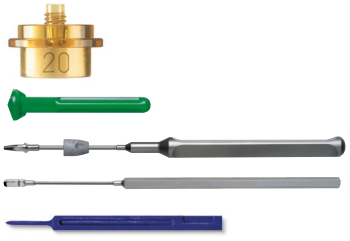
BICARBON OVERLINE



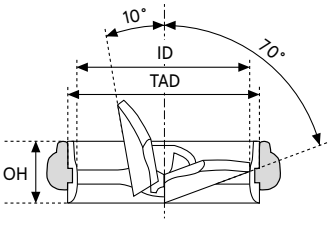
Nominal size	TAD	ID	OH	GOA	EOA[1]*	Catalog N.
16	15.2	15.2	6.0	1.76	0.97	ICV0870
18	17.2	17.2	6.4	2.27	1.54	ICV0871
20	19.2	19.2	6.8	2.83	2.07	ICV0872
22	21.3	21.3	7.2	3.45	2.39	ICV0873
24	23.3	23.3	7.6	4.14	3.06	ICV0874

Accessories

Article	Code	Description
UNI cylindrical sizers set	ICV0867	5 sizers
Aortic rotators set	ICV0868	5 aortic rotators
UNI handle	ICV0664	1 universal bandable handle to be used with all sizers
Valve holder handle	P0593	1 Nitinol bandable handle
Occluder tester	VT-100	10 disposable occluder tester (provided sterile)
Empty tray	ICV0736	1 orange empty tray compatible with BICARBON OVERLINE accessories



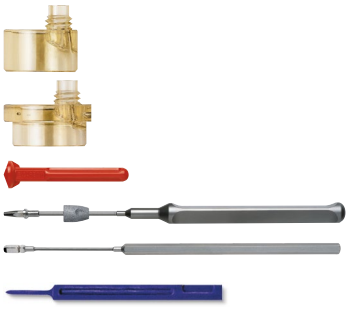
BICARBON SLIMLINE



Nominal size	TAD	ID	OH	GOA	EOA*	Catalog N.
17	17.2	15.2	6.0	1.76	1.01[2]	ICV0934
19	19.2	17.2	6.4	2.27	1.50[2]	ICV0935
21	21.3	19.2	6.8	2.83	1.90[2]	ICV0936
23	23.4	21.3	7.2	3.45	2.39[1]	ICV0937
25	25.6	23.3	7.6	4.14	3.06[1]	ICV0938
27	28.0	25.6	8.0	5.0	3.45[1]	ICV0939

Accessories

Article	Code	Description
UNI cylindrical sizers set	ICV0728	6 universal cylindrical sizers
UNI profile sizers set	ICV0730	6 universal profile sizers
Aortic rotators set	ICV0950	6 aortic rotators
UNI handle	ICV0664	1 universal bandable handle to be used with all sizers
Valve holder handle	P0593	1 Nitinol bandable handle
Occluder tester	VT-100	10 disposable occluder tester (provided sterile)
Empty tray	ICV0736	1 orange empty tray



Legend

TAD = Tissue Annulus Diameter (mm)	OH = Orifice Height (mm)
ID = Internal Diameter (mm)	GOA = Geometric Orifice Area (cm²)
EOA = In vivo Effective Orifice Area (cm²)	

CE 0459

1. Normal echocardiographivc characteristics of the Sorin Bicarbon bileaflet prosthetic heart valve in the mitral and aortic positions. Badano et al. – J Am Soc Echocardiogr 1997; 10: 632- 43
2. Comparative evaluation of small-size Sorin Slimline and St. Jude HP Heart Valve Prostheses. Otero et al. – Ann Thorac Surg 2005; 79: 1284-90

* For Bicarbon Overline reported EOA based on reference 1 are a two sizes up-sized estimate; for Bicarbon Slimline reported EOA based on reference 1 are a one size up-sized estimate

Please always refer to the Instructions For Use (IFU) manual provided with each product for detailed information, warnings, precautions and possible adverse side effects.

LivaNova
Health innovation that matters

BICARBON FITLINE AORTIC

INTRA-ANNULAR AORTIC VALVE
Sizes 19-31 mm

BICARBON FITLINE MITRAL

INTRA-ANNULAR MITRAL VALVE
Sizes 19-33 mm

Application

- Aortic procedures
- Low coronary ostia
- Narrow, rigid aortic sinus
- Large annulus
- Redo AVR

- Mitral valve replacement with or without mitral leaflet preservation
- Double valve replacement

Implantation Consideration

- Orientation of the implanted valve facilitated by a Polyacetal sleeve mounted inside the sewing cuff, which maintains torque at a constant level
- Three orientation markers for suture spacing
- Soft, pliable cuff for an easy handling and to better conform to the patient's annulus

- Orientation of the implanted valve facilitated by a Polyacetal sleeve mounted inside the sewing cuff, which maintains torque at a constant level
- Four orientation markers for suture spacing
- Soft, pliable cuff for an easy handling and to better conform to the patient's annulus, promotes coaptation to annulus

Clinical Considerations

- Advanced design optimized for top hemodynamic performance
- Advanced design allows to achieve a laminar blood flow that minimizes the risk of thrombus formation
- Excellent clinical record for valve-related events
- Proven safety and durability

- Advanced design optimized for top hemodynamic performance
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- Excellent clinical record for valve-related events
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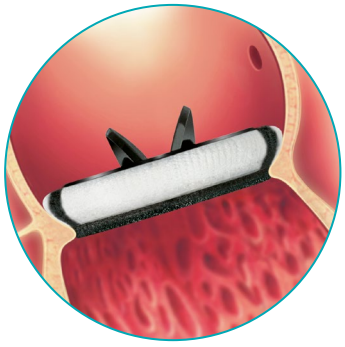
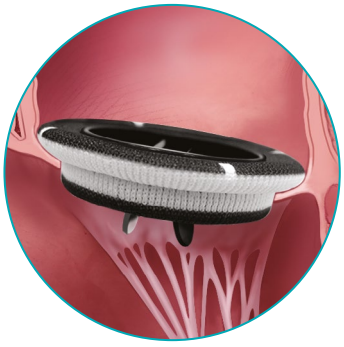
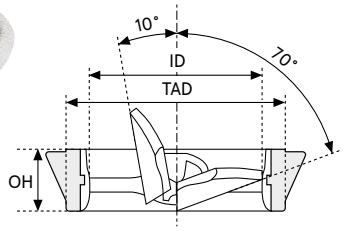
Valve placement *in-situ*





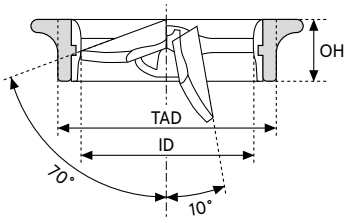
Product specifications

BICARBON FITLINE AORTIC



Nominal size	TAD	ID	OH	GOA	EOA[1]	Catalog N.
19	19.0	15.2	6.0	1.76	0.97	ICV0917
21	21.2	17.2	6.4	2.27	1.54	ICV0918
23	23.4	19.2	6.8	2.83	2.07	ICV0919
25	25.6	21.3	7.2	3.45	2.39	ICV0920
27	27.8	23.3	7.6	4.14	3.06	ICV0921
29	30.0	25.6	8.0	5.00	3.45	ICV0922
31	32.0	25.6	8.0	5.00	3.45	ICV0923

BICARBON FITLINE MITRAL



Nominal size	TAD	ID	OH	GOA	Catalog N.
19	19.0	15.2	6.0	1.76	ICV0924
21	21.2	17.2	6.4	2.27	ICV0925
23	23.4	19.2	6.8	2.83	ICV0926
25	25.6	21.3	7.2	3.45	ICV0927
27	27.8	23.3	7.6	4.14	ICV0928
29	30.0	25.6	8.0	5.00	ICV0929
31	32.0	25.6	8.0	5.00	ICV0930
33	34.0	25.6	8.0	5.00	ICV0931

Accessories

Article	Code	Description
UNI cylindrical sizers set	**ICV0662**	8 universal cylindrical sizers
UNI profile sizers set	**ICV0663**	8 universal profile sizers
Rotators set	**ICV0732**	7 aortic rotators + 8 mitral rotators
UNI handle	**ICV0664**	1 universal bandable handle to be used with all sizers and mitral rotators
Valve holder handle	**P0593**	1 Nitinol bandable handle
Occluder tester	**VT-100**	10 disposable occluder tester (provided sterile)
Empty tray	**ICV0735**	1 gray empty tray

Legend	
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Bicarbon range

Bicarbon Overline

Bicarbon Slimline

Bicarbon Fitline Aortic

Bicarbon Fitline Mitral

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Health innovation that matters

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01/17 IC0870001130/O

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