MECHANICAL
HEART VALVES

BICARBON™ FAMILY

Distinguished details
make the dynamic
difference

CORCYM
WE TAKE LIFE TO HEART

BICARBON™ FAMILY

Many options for many benefits[1,2]

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

Featuring many distinguished details, Bicarbon valves provide favorable hemodynamic performance[3,4] combined with proven safety and durability.* The benefits of its innovative and distinguished design are reflected in the desirable clinical outcomes[2,5]** reported in scientific literature across over 25 years of clinical use.

Bicarbon mechanical valves feature the exclusive CORCYM Carbofilm™ coating technology which favors both hemo and biocompatibility.[6]

Innovative design,[2] innovative choice of materials and a proven track record of positive clinical results make this valve an advanced solution backed by compelling long term data.[2,5]*

*The Bicarbon range boasts trusted clinical results[2,5]** in over 25 years of clinical use. The distinguished design features offer a favorable hemodynamic performance,[3,4] optimal thromboresistance,[7,8] ease of implant and proven safety and durability*.*

* Based on CORCYM post-market surveillance, valve structural failure is expected to occur less than 1 time per 1000000 device population.

** Based on CORCYM post-market surveillance, valve structural failure is expected to occur less than 1 time per 1000000 device population, while valve-related thromboembolic events are expected to occur between 0.1 and 1 times per 100000 device population.

1. *Celiento et al., Single center experience with the Sorin Bicarbon prosthesis: A 17-year clinical follow-up, J Thorac Cardiovasc Surg, 148:2039-44, 2014.*
2. *Azarnoush et al., the Sorin Bicarbon over 15 years clinical outcomes: multicentre experience in 1704 patients, Eur J Cardio-thoracic Surg; 38:759—66, 2010.*
3. *Reyes et al., Results of aortic valve replacement with the supra-annular Sorin Bicarbon Overline prosthesis, J Heart Valve Dis, 21 (3): 358-63, 2012.*
4. *Badano et al., Normal echocardiographivc characteristics of the Sorin Bicarbon bileaflet prosthetic heart valve in the mitral and aortic positions, J Am Soc Echocardiogr 10: 632- 43, 1997.*
5. *Misawa et al., Fifteen-year experience with the Bicarbon heart valve prosthesis in a single center, J Cardiothorac Surg, 10: 89, 2015.*
6. *Vallana et al., Carbofilm: Present and Future Applications in Biomedical Devices, Ceramics International 19 (1993) 169-179.*
7. *Torella et al., LOWERing the INtensity of oral anticoaGulant Therapy in patients with bileaflet mechanical aortic valve replacement: Results from the "LOWERING-IT" Trial, Am Heart J; 160:171-8, 2010.*
8. *Falk et al., 2017 ESC/EACTS Guidelines for the management of valvular heart disease. The Task Force for the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS), European Journal of Cardio-Thoracic Surgery 52 (2017) 616–664.*

Technical claims are supported by CORCYM data on file.

Details make the difference

Hemodynamics

Thromboresistance

Safety and Durability

Clinical outcomes

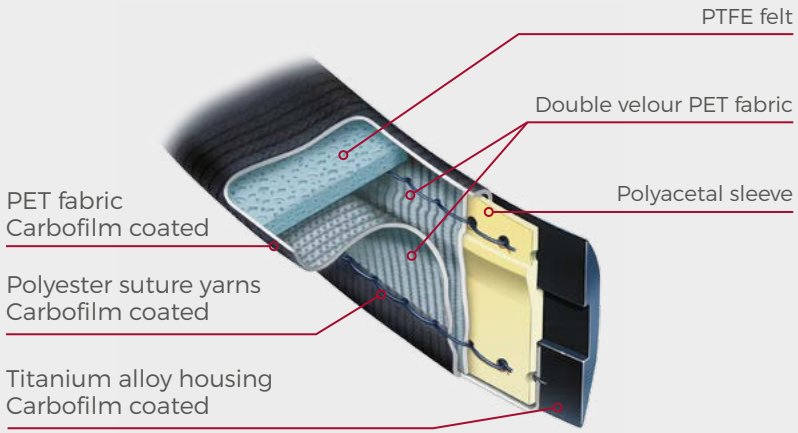
Details make the difference: Hemodynamics[1,2]

Bicarbon’s distinguished details make the difference when it comes to hemodynamic performance[1,2]

Careful choice of materials.

CORCYM Bicarbon is a unique valve featuring a Titanium housing coated with Carbofilm. Titanium is a highly biocompatible material with greater structural stability than the commonly used Pyrolite Carbon. This allows for a slimmer housing, increasing the area available for blood flow.[3]

The CORCYM proprietary Carbofilm coating is applied to both the valve's Titanium housing and the sewing cuff. The coating favors hemocompatibility, minimizing the risk for pannus formation* and favoring a gentle tissue ingrowth.[3,4]



* Based on CORCYM post-market surveillance, valve-related pannus formation is expected to occur between 0.1 and 1 times per 100000 device population.

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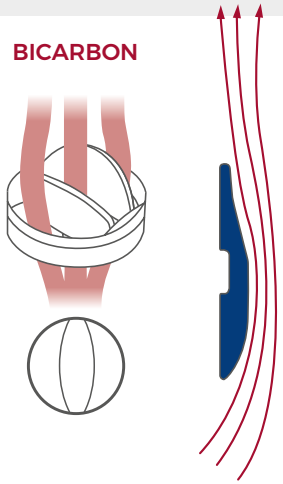
Innovative Design

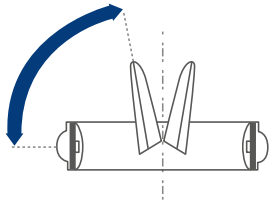
Not only a careful choice of materials but also an innovative design are key to Bicarbon's hemodynamic performance.[1,2]

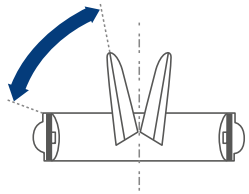


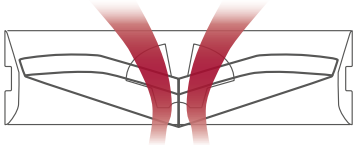
Bicarbon is a unique mechanical heart valve featuring curved leaflets specifically engineered to achieve an even flow distribution downstream.[3] This leads to several benefits to the patien:[1,3]

- low turbulence which prevents blood stasis and thus the risk for thrombus formation
- low pressure gradients for favorable hemodynamic performance
- reduced energy loss for an efficient functioning and beneficial cardiac workload.

The 80-degree 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.[1,3]







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.[3,5]

Technical claims are supported by CORCYM data on file.

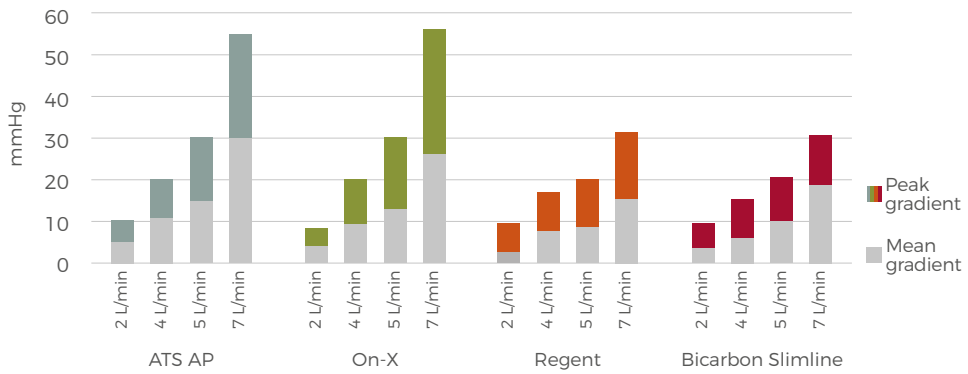
The favorable hemodynamic performance of Bicarbon valves is well proven in the published scientific literature.[1,2]

In vitro comparisons[1] with other commercially available valves have shown that Bicarbon are among the best performing valves with respect to all the relevant parameters:

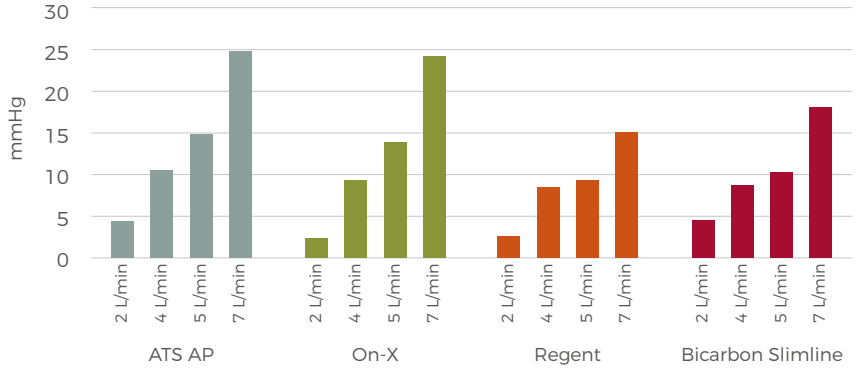
- pressure gradients
- leakage volume
- energy loss
- velocity profiles
- shear stress distribution

This is confirmed in small aortic annuli, even when compared with valves specifically designed to improve hemodynamic performance.[6,7,8]

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



Energy loss at 70 bpm (%)*[6]



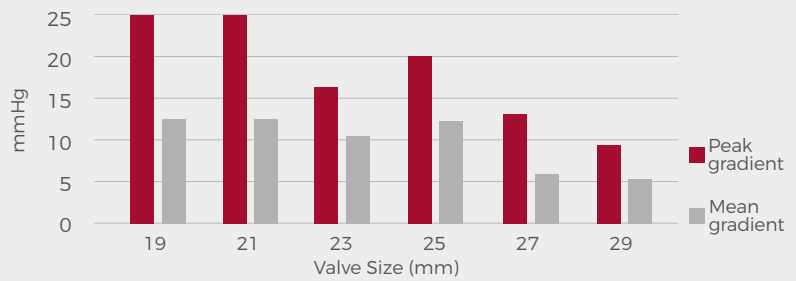
* Test performed with Sheffield pulse duplicator. Valves fitting a 21 mm diameter valve holder.

Technical claims are supported by CORCYM data on file.

The hydrodynamic efficiency of Bicarbon valves is reflected by the favorable hemodynamic results reported in the published in-vivo evaluations.[9]

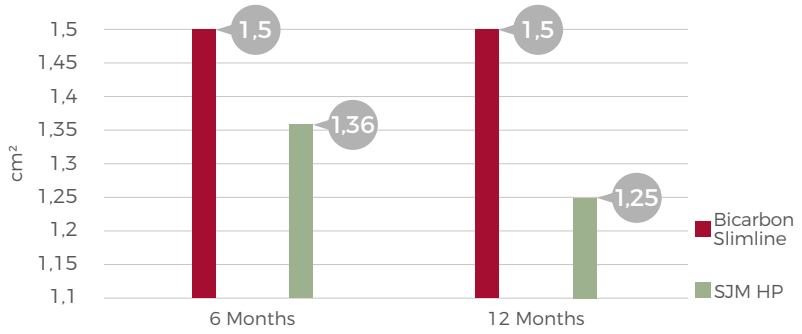
Peak and Mean Pressure Gradients*

IN VIVO AORTIC POSITION

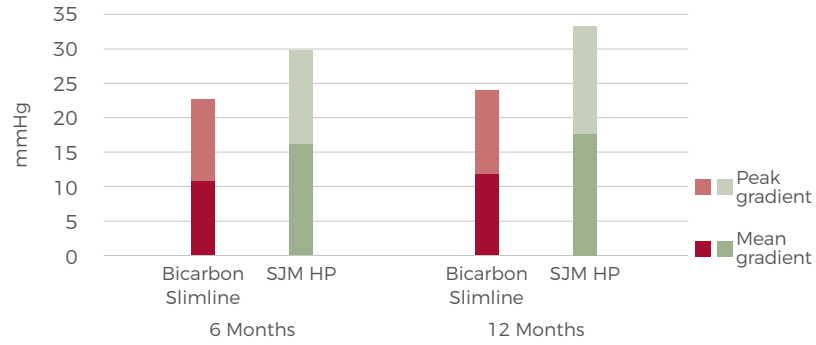


Comparative evaluation of small-size CORCYM Bicarbon Slimline and St. Jude HP heart valve prosthesis.[8]

Size 19 Effective Orifice Area (cm²)



Size 19 Mean and Peak pressure gradients (mmHg)



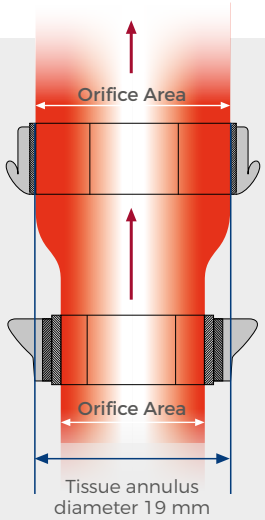
* Bicarbon standard model

Technical claims are supported by CORCYM data on file.

Overline: engineered for hemodynamic performance

To further optimize hemodynamic performances, especially in small aortic annuli, CORCYM features in its Bicarbon portfolio the Overline aortic prosthesis, a truly totally supra-annular model.

A totally supra annular positioning can provide an advantage of 1 to 2 sizes over intra-annular valves.[10]



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.[2,11]

" 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."[2]

Hemodynamic function on echocardiography before and at 12 months after surgery, by labeled valve size.[2]

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

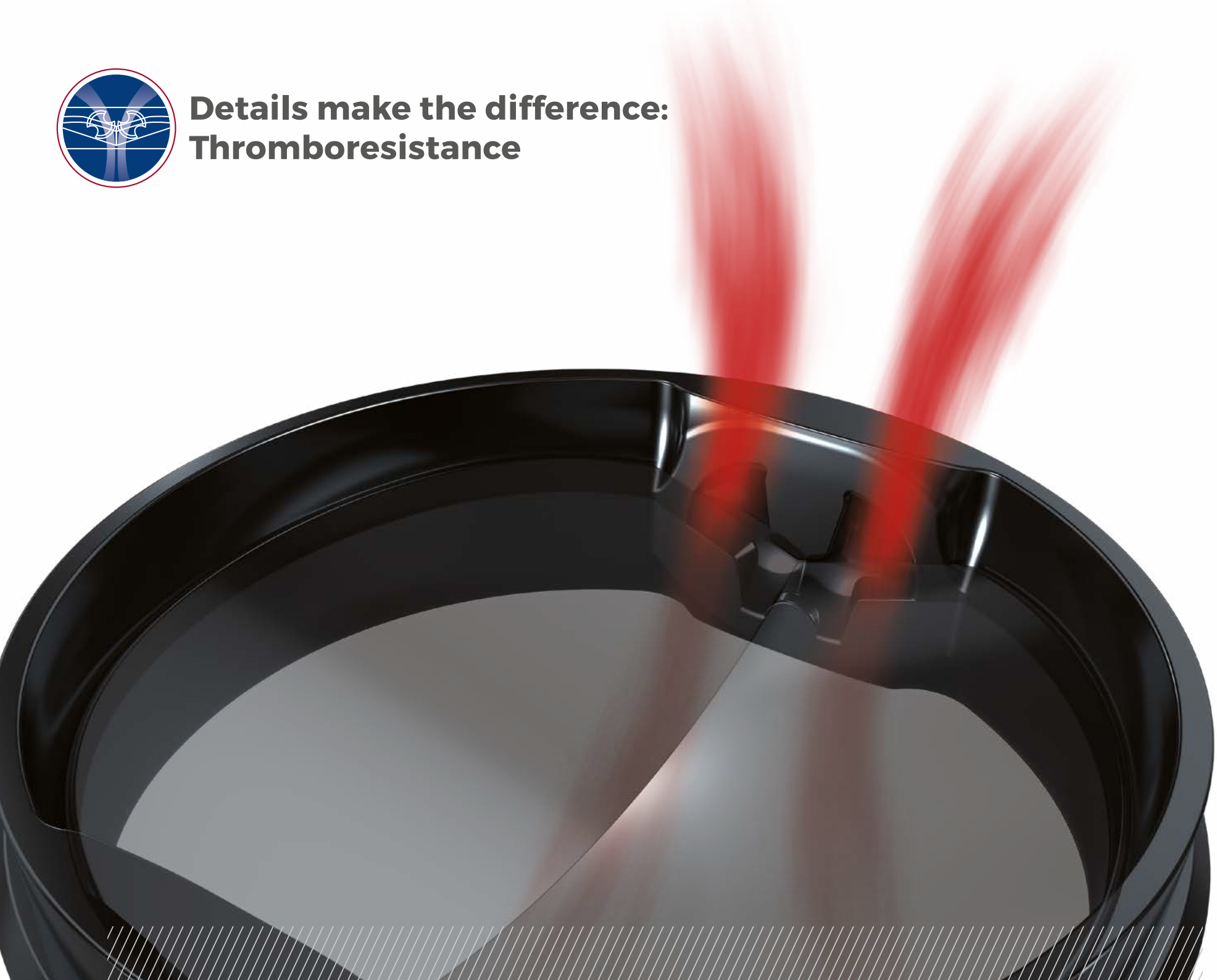
MPG: Mean pressure gradient; PPG: Peak pressure gradient

"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".[2]

1. *Reul et al., In vitro comparison of bileaflet aortic heart valve prostheses, J. Thorac and Cardiov Surg 106 (3): 412-20, 1992.*
2. *Reyes et al., Results of aortic valve replacement with the supra-annular Sorin Bicarbon Overline prosthesis, J Heart Valve Dis, 21 (3): 358-63, 2012.*
3. *Vallana et al., Pivot design in bileaflet valves, Asaio Journal, 38:M600-M606, 1992.*
4. *Della Barbera et al., Sovering annuloplasty rings: Experimental pathology in the sheep model, Cardiovascular Pathology 14 (2005) 96-103.*
5. *Steegers et al., J. Leakage flow at mechanical heart valve prostheses: improved washout or increased blood damage, Heart Valve Dis 8 : 312-323, 1999.*
6. *Bottio et al., Small aortic annulus: The hydrodynamic performances of 5 commercially available bileaflet mechanical valves, J Thorac Cardiovasc Surg 2004;128:457-62.*
7. *Fisher et al., Comparative study of the hydrodynamic function of six size 19 mm bileaflet heart valves, Eur J Cardio-thorac Surg 9: 692-96, 1995.*
8. *Otero et al., Comparative evaluation of small-size Sorin Slimline and St. Jude HP Heart Valve Prostheses., Ann Thorac Surg 79: 1284-90, 2005.*
9. *Badano et al., Normal echocardiographivc characteristics of the Sorin Bicarbon bileaflet prosthetic heart valve in the mitral and aortic positions, J Am Soc Echocardiogr 10: 632- 43, 1997.*
10. *Aagard et al., Maximizing prosthetic valve size with the Top Hat supraannular aortic valve, The Journal of Heart Valve Disease, 16:84-90, 2007.*
11. *Aagard et al., Midterm Evaluation of Hemodynamics of the Top Hat Supraannular Aortic Valve. Asian Cardiovasc Thorac Ann 2010;18:1-5.*

Technical claims are supported by CORCYM data on file.

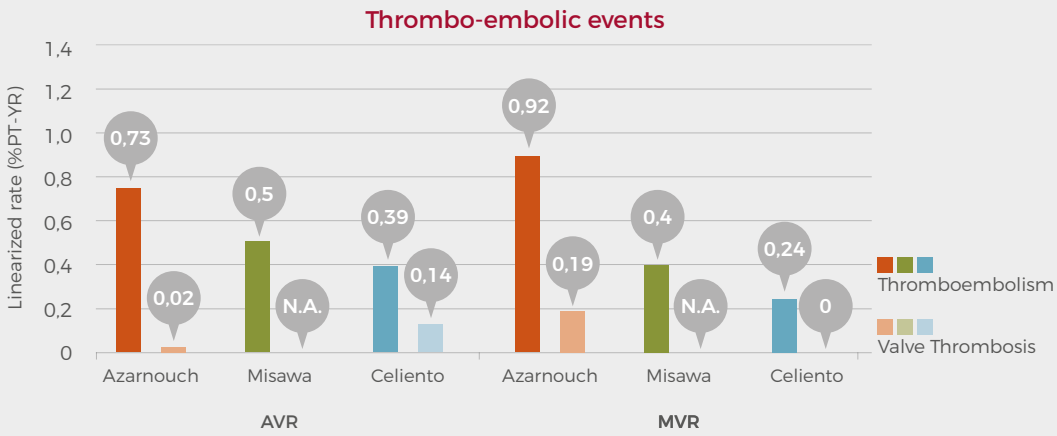
Details make the difference: Thromboresistance



Bicarbon valves are specifically designed to minimize thrombogenicity:[1,2]

- Carbofilm coating increases hemocompatibility lowering the risk of thrombus formation.[3,4*]
- Curved leaflets, aerofoil housing profile, optimized leaflets travel arc and opening angle favor a laminar blood flow which reduces shear stress and hemolysis.[3] A low degree of hemolysis leads to less platelet activation and consequently less risk of clots.[5]
- The unique two-open-chimney design ensures an effective passive washing of the hinges avoiding blood stasis and hemolysis at the same time.[3,6]

Bicarbon valves have shown a very low incidence of thrombosis and thromboembolic events in up to 17 years of published follow up.[7,8,9]



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Technical claims are supported by CORCYM data on file.

LOWERing the INtensity of oral anticoaGulant Therapy in patients with bileaflet mechanical aortic valve replacement: Results from the "LOWERING-IT" Trial.[2]

As a further proof of its excellent thrombo-resistance, Bicarbon is backed by the 'LOWERING-IT' trial, 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.[2]

BICARBON aortic valves are the only mechanical prostheses in the market backed by an independent randomized clinical trial which has demonstrated the safety and feasibility of a lower INR regimen of 1.5 to 2.5 without the addition of aspirin, in low-risk patients undergoing isolated aortic valve implantation.[2]

Flow diagram of the LOWERING-IT trial[2]

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[2]

Outcome events[2]

	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."[2]

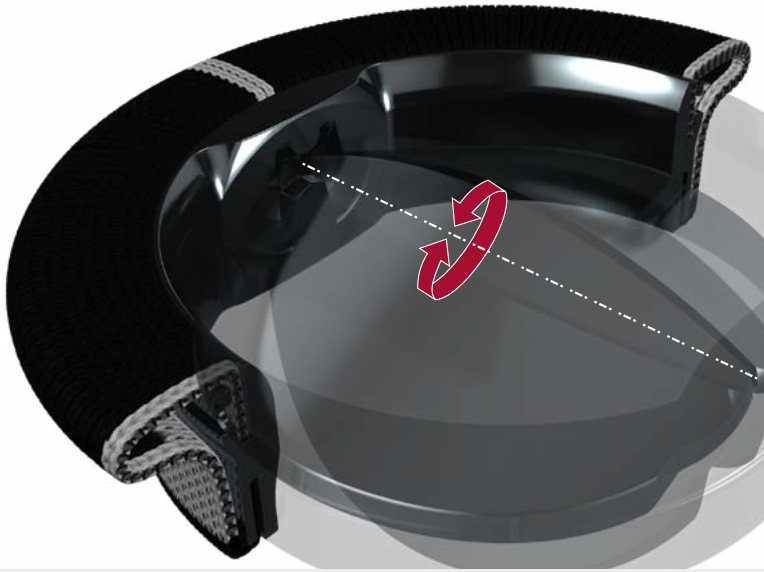
1. Falk et al., European Journal of Cardio-Thoracic Surgery 52 (2017) 616–664.
2. Torella et al., LOWERing the INtensity of oral anticoaGulant Therapy in patients with bileaflet mechanical aortic valve replacement: Results from the "LOWERING-IT" Trial, Am Heart J; 160:171-8, 2010.
3. Vallana et al., Pivot design in bileaflet valves, Asaio Journal, 38:M600-M606, 1992.
4. Della Barbera et al., Sovering annuloplasty rings: Experimental pathology in the sheep model, Cardiovascular Pathology 14 (2005) 96-103.
5. Koppensteiner et al., Blood rheology after cardiac valve replacement with mechanical prostheses or bioprostheses, Am J Cardiolo; 67:79-83, 1991.
6. Steegers et al., J. Leakage flow at mechanical heart valve prostheses: improved washout or increased blood damage, Heart Valve Dis 8 : 312-323, 1999.
7. Azarnoush et al., The Sorin Bicarbon over 15 years clinical outcomes: multicentre experience in 1704 patients, Eur J Cardio-thoracic Surg; 38:759—66, 2010.
8. Misawa et al., Fifteen-year experience with the Bicarbon heart valve prosthesis in a single center, J Cardiothorac Surg, 10: 89, 2015.
9. Celiento et al., Single center experience with the Sorin Bicarbon prosthesis: A 17-year clinical follow-up, J Thorac Cardiovasc Surg, 148:2039-44, 2014.

Technical claims are supported by CORCYM data on file.

Details make the difference: Safety and Durability

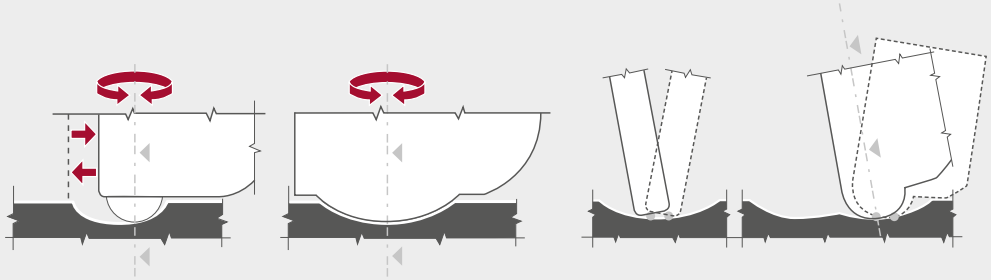
The Bicarbon design was carefully engineered to last over time.*

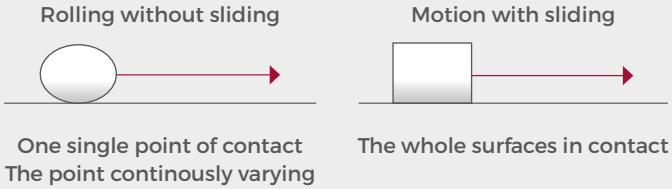
- The Titanium housing, with greater structural stability than solid Pyrolytic Carbon housings, ensures correct leaflet functionality.[1]
- The unique two-open-chimney design of the hinges avoid blood stasis and hemolysis minimizing the risk of structural valve failure and clinical complications.[1,2]
- The Carbofilm coated PET fabric sewing ring provides a safe anchorage favoring a gentle tissue ingrowth that minimizes pannus formation.**
- 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.[1,2]



The innovative Bicarbon solution

Friction and wear are minimized by the constantly varying single point of contact between the pivot and the housing.[1,2]





* According to ISO 5840:2015 requirements, CORCYM post-market surveillance and published experience on long term results (Celiento et al., J Thorac Cardiovasc Surg, 148:2039-44, 2014).
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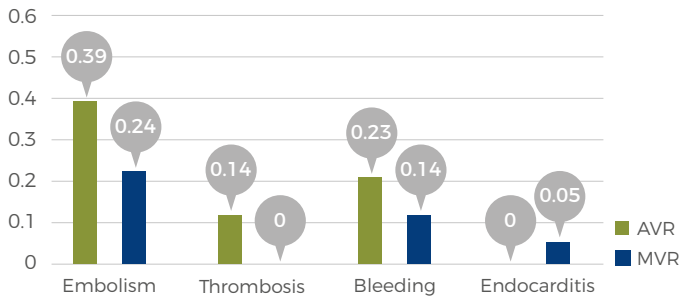
Details make the difference: Clinical outcomes

Bicarbon has proven to be a safe, high performing valve with desirable clinical outcomes in the long term follow up.[1,2]

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

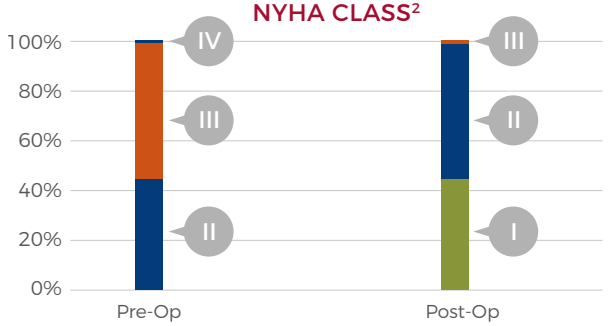
AVR: 344 Patients - MVR: 163 Patients - Cumulative follow-up: 6475 Patient-years

Linearized rate of adverse events (%PT-YR)[2]



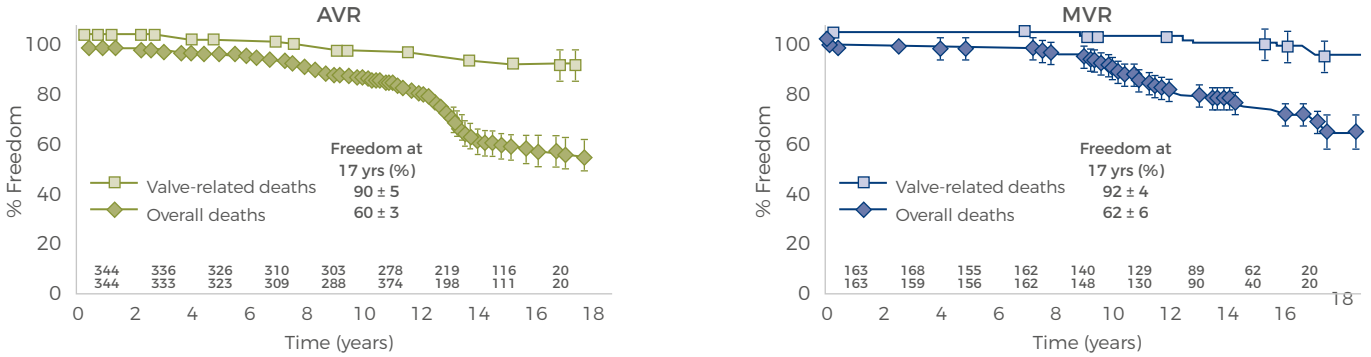
Mean INR at last FU: AVR: 2.6±0.5 - MVR: 2.7±0.4

NYHA CLASS[2]



"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." [2]

Actuarial Survival and Freedom from valve-related deaths[2]



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

1. Azarnoush et al., The Sorin Bicarbon over 15 years clinical outcomes: multicentre experience in 1704 patients, Eur J Cardio-thoracic Surg; 38:759—66, 2010.
2. Celiento et al., Single center experience with the Sorin Bicarbon prosthesis: A 17-year clinical follow-up, J Thorac Cardiovasc Surg, 148:2039-44, 2014.

BICARBON FAMILY

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."[1]*

"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."[2]*

"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."[3]*

* CORCYM post-market surveillance classifies the incidence of valve structural failure *P* as very improbable ($P \leq 10\text{-}6$) and the incidence of valve related thromboembolic events *P*1 as improbable ($10\text{-}6 < P1 \leq 10\text{-}5$).

1. *Azarnoush et al., The Sorin Bicarbon over 15 years clinical outcomes: multicentre experience in 1704 patients, Eur J Cardio-thoracic Surg; 38:759-66, 2010.*
2. *Celiento et al., Single center experience with the Sorin Bicarbon prosthesis: A 17-year clinical follow-up, J Thorac Cardiovasc Surg, 148:2039-44, 2014.*
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BICARBON™ FAMILY MECHANICAL HEART VALVES

BICARBON OVERLINE

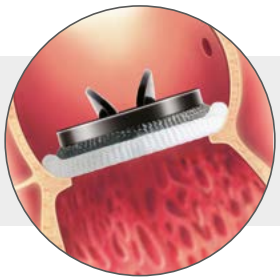
Implantation Consideration

- Totally supra-annular placement
  - provides an advantage of 1 to 2 sizes over intra-annular valves[1]
  - facilitates double valve replacement procedure[2]
- 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 easy handling and better conformity to the patient's annulus
- Special sizers allow surgeon to assess position of valve within sinus area and clearance of coronaries before implantation

Clinical Consideration

- Advanced design optimized for favorable hemodynamic performance[2,5]
- Special sizers allow surgeon to assess position of valve within sinus area and clearance of coronaries before implantation
- Size upgrades provide improved valve hemodynamics[1]*
- Totally supra-annular design allows a 100% orifice to annulus match, maximazing the orifice available to blood flow
- Alternative to aortic root enlargement[2]
- Advanced design allows to achieve a laminar blood flow that minimizes the risk of thrombus formation[4]
- Very low valve-related adverse events[2,5,6]**
- Proven safety and durability[2,5]***

Valve Placement *in-situ*



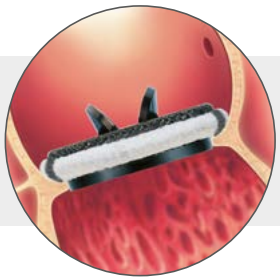
BICARBON SLIMLINE

Implantation Consideration

- A partially supra-annular solution when in need of larger orifice areas compared to intra-annular valves[3]
- 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 easy handling and better conformity to the patient's annulus

Clinical Consideration

- Special sizers allow surgeon to assess position of valve within sinus area and clearance of coronaries before implantation
- Advanced design allows to achieve a laminar blood flow that minimizes the risk of thrombus formation[4]
- Very low valve-related adverse events[2,5]**
- Proven safety and durability[2,5]***



*Compared to non totally supra-annular models.

**Based on CORCYM post-market surveillance, valve structural failure is expected to occur less than 1 time per 1000000 device population, while valve-related thromboembolic events are expected to occur between 0.1 and 1 times per 100000 device population.

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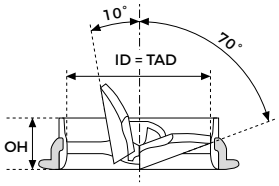
1. *Aagard et al., Maximizing prosthetic valve size with the Top Hat supraannular aortic valve, The Journal of Heart Valve Disease, 16:84-90, 2007.*
2. *Reyes et al., Results of aortic valve replacement with the supra-annular Sorin Bicarbon Overline prosthesis, J Heart Valve Dis, 21 (3): 358-63, 2012.*
3. *Otero et al., Comparative evaluation of small-size Sorin Slimline and St. Jude HP Heart Valve Prostheses, Ann Thorac Surg 79: 1284-90, 2005.*
4. *Vallana et al., Pivot design in bileaflet valves, Asaio Journal, 38:M600-M606, 1992.*
5. *Badano et al., Normal echocardiographivc characteristics of the Sorin Bicarbon bileaflet prosthetic heart valve in the mitral and aortic positions, J Am Soc Echocardiogr 10: 632- 43, 1997.*
6. *Celiento et al., Single center experience with the Sorin Bicarbon prosthesis: A 17-year clinical follow-up, J Thorac Cardiovasc Surg, 148:2039-44, 2014.*

BICARBON OVERLINE

TOTALLY SUPRA-ANNULAR AORTIC VALVE Sizes 16-24 mm

Product specifications



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

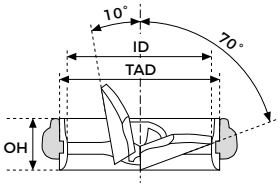
Accessories

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	TR-101	1 empty tray

BICARBON SLIMLINE

PARTIALLY SUPRA-ANNULAR AORTIC VALVE Sizes 17-27 mm

Product specifications



Nominal size	TAD	ID	OH	GOA	EOA[1]	REF	Catalog N.
17	17.2	15.2	6.0	1.76	1.01[2]	ART 17 LSA	ICV0934
19	19.2	17.2	6.4	2.27	1.50[2]	ART 19 LSA	ICV0935
21	21.3	19.2	6.8	2.83	1.90[2]	ART 21 LSA	ICV0936
23	23.4	21.3	7.2	3.45	2.39[1]	ART 23 LSA	ICV0937
25	25.6	23.3	7.6	4.14	3.06[1]	ART 25 LSA	ICV0938
27	28.0	25.6	8.0	5.0	3.45[1]	ART 27 LSA	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	TR-101	1 empty tray

Legend

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

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

BICARBON FITLINE AORTIC

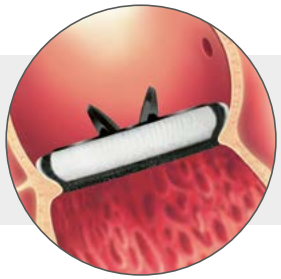
Implantation Consideration

- 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 easy handling and better conformity to the patient's annulus

Clinical Consideration

- Special sizers allow surgeon to assess position of valve within sinus area and clearance of coronaries before implantation
- Advanced design allows to achieve a laminar blood flow that minimizes the risk of thrombus formation[1]
- Very low valve-related adverse events*
- Proven safety and durability**

Valve Placement *in-situ*



BICARBON FITLINE MITRAL

Implantation Consideration

- 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 Consideration

- Special sizers allow surgeon to assess position of valve within sinus area and clearance of coronaries before implantation
- Advanced design allows to achieve a laminar blood flow that minimizes the risk of thrombus formation[1]
- Very low valve-related adverse events*
- Proven safety and durability**

Valve Placement *in-situ*

*CORCYM post-market surveillance classifies the incidence of valve structural failure *P* as very improbable ($P \leq 10\text{-}6$) and the incidence of valve-related thromboembolic events *P*1 as improbable ($10\text{-}6 < P1 \leq 10\text{-}5$).

**CORCYM post-market surveillance classifies the incidence of valve structural failure *P* as very improbable ($P \leq 10\text{-}6$).

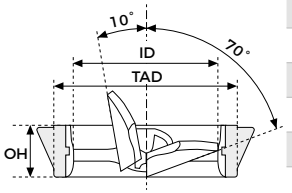
1. *Vallana et al., Pivot design in bileaflet valves, Asaio Journal, 38:M600-M606, 1992.*

Technical claims are supported by CORCYM data on file.

BICARBON FITLINE AORTIC

INTRA-ANNULAR AORTIC VALVE Sizes 19-31 mm

Product specifications

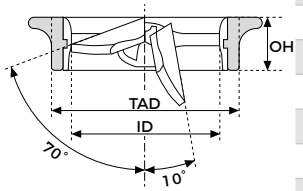


Nominal size	TAD	ID	OH	GOA	EOA[1]	REF	Catalog N.
19	19.0	15.2	6.0	1.76	0.97	ART 19 LFA	ICV0917
21	21.2	17.2	6.4	2.27	1.54	ART 21 LFA	ICV0918
23	23.4	19.2	6.8	2.83	2.07	ART 23 LFA	ICV0919
25	25.6	21.3	7.2	3.45	2.39	ART 25 LFA	ICV0920
27	27.8	23.3	7.6	4.14	3.06	ART 27 LFA	ICV0921
29	30.0	25.6	8.0	5.00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

BICARBON FITLINE MITRAL

Sizes 19-33 mm

Product specifications



Nominal size	TAD	ID	OH	GOA	REF	Catalog N.
19	19.0	15.2	6.0	1.76	MTR 19 LFM	ICV0924
21	21.2	17.2	6.4	2.27	MTR 21 LFM	ICV0925
23	23.4	19.2	6.8	2.83	MTR 23 LFM	ICV0926
25	25.6	21.3	7.2	3.45	MTR 25 LFM	ICV0927
27	27.8	23.3	7.6	4.14	MTR 27 LFM	ICV0928
29	30.0	25.6	8.0	5.00	MTR 29 LFM	ICV0929
31	32.0	25.6	8.0	5.00	MTR 31 LFM	ICV0930
33	34.0	25.6	8.0	5.00	MTR 33 LFM	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	6 aortic rotators + 6 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	TR-101	1 empty tray

Legend

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

1. *Badano et al., Normal echocardiographivc characteristics of the Sorin Bicarbon bileaflet prosthetic heart valve in the mitral and aortic positions, J Am Soc Echocardiogr 1997; 10: 632- 43.*

INTENDED USE/INDICATIONS
The Bicarbon prosthesis is intended for use as a replacement valve in patients with diseased, damaged, or malfunctioning mitral or aortic heart valve. This device may also be used to replace a previously implanted mitral or aortic prosthetic heart valve.
Bicarbon Aortic/Mitral prostheses, respectively, are indicated for use in patients suffering from aortic/mitral valvular heart disease, that is a condition involving obstruction of the aortic/mitral heart valve or stenosis; leakage of the aortic/mitral valve, known as regurgitation, incompetence, or insufficiency; and combinations of the two; or patients with a previously implanted aortic/mitral valve prosthesis that is no longer functioning adequately and requires replacement.

KEY CONTRAINDICATIONS
The Bicarbon prostheses are contraindicated in patients at risk for complications associated with long-term anticoagulant treatment that clinical experience has shown to be indispensable for patients with mechanical heart valves.

KEY WARNINGS
For single use only. The use of the Bicarbon prostheses is not recommended in patients with hypersensitivity to Titanium alloys and to Cobalt Chromium alloys (Stellite). Do not manipulate the Bicarbon prosthesis with instruments other than those supplied by Corcym.

TOP POTENTIAL SIDE EFFECTS
The complications associated with heart valve prosthesis implantation include: hemolysis, infections, thrombosis or thromboembolic events, dehiscence, unacceptable hemodynamic performance, hemorrhagic events due to anticoagulant therapy, prosthesis malfunction, heart failure, myocardial infarction due to coronary obstruction, allergic reaction and death. Any one of these complications may require re-operation or removal of the prosthesis.

MRI conditional

For professional use. Instructions for Use are available upon request through the manufacturer's website. Not approved in all geographies. Consult your labeling.

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WE TAKE LIFE TO HEART

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