BIOSISTEM-MLD S.R.L.
c/f 1010600028048; adresa: str. Albișoara 16/1 of.7, or. Chișinău
tel.+373-22-808517, +373-22-808719, fax +373-22-808519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Date generale despre ofertant

SRL Biosistem mld
Administrator: Poiata Vitalie
Adresa poştală: str. Albișoara 16/1 of.7, or. Chișinău
Tel./Fax: .+373-22-808517, +373-22-808719, fax +373-22-808519 **E-mail:** biosistem.mld@gmail.com; info@biosistem-mld.com
Cod IBAN: MD95ML0000000022514292 43
Banca: BC "Moldindconbank" S.A. fil. Invest
Codul băncii: MOLDMD2X329
Cod fiscal: 1010600028048
Cod TVA: 0607490

Cu respect,

Vitalie Poiata

Administrator

Digitally signed by Poiata Vitalie
Date: 2024.02.29 16:21:43 EET
Reason: MoldSign Signature
Location: Moldova

BC "MOLDINDCONBANK" S.A.
Filiala "Invest"

Republica Moldova, MD-2068
mun. Chişinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 – 19/23

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московей, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDMD2X329

Filiala „Invest" BC „Moldindconbank" SA confirmă existența contului curent in moneda nationala al **"BIOSISTEM MLD" S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML0000000022514292 43**.

Codul băncii MOLDMD2X329.

Director **Nina Țurcan**

Director financiar **Nina Balmuş**

Ex. Diana Brinza
Tel. 43-45-96

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea cu Răspundere Limitată "BIOSISTEM MLD"
ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării **12.08.2010**

Data eliberării **12.08.2010**

Svirepova Ludmila, registrator

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA
CAMERA ÎNREGISTRĂRII DE STAT I.S.
1004600077777
104

MD 0101250

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. **531522** data **15.09.2023**

Denumirea completă: **Societatea cu Răspundere Limitată "BIOSISTEM MLD"**
Denumirea prescurtată: **"BIOSISTEM MLD" S.R.L.**
Forma juridică de organizare: **Societate cu răspundere limitată,**
Numărul de identificare de stat şi codul fiscal (IDNO): **1010600028048**
Data înregistrării de stat: **12.08.2010**
Sediul: **MD-2001, str. Albişoara, 16/1, ap. 7, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1. Activitatea farmaceutică; importul şi (sau) producerea articolelor de parfumerie şi cosmetică
2. Fabricarea, comercializarea, asistenţa tehnică, repararea şi verificarea articolelor de tehnică şi optică medicală
3. Acordarea asistenţei medicale de către instituţiile medico-sanitare private
4. Comerţul cu ridicata al calculatoarelor,echipamentelor periferice şi software-ului
5. Întreţinerea şi repararea maşinilor de birou şi a tehnicii de calcul
6. Consultaţii în domeniul sistemelor de calcul

Capitalul social: **5400** lei.

Administrator: **POIATA VITALIE, IDNP 0983103892591,**

Asociaţii:
1. POIATA VITALIE, IDNP 0983103892591, cota 1803,60 lei, ce constituie 33,4%
Beneficiar efectiv:
1.1. POIATA VITALIE, IDNP 0983103892591,

2. NASEDCHIN ALEXANDR, IDNP 2002001070747, cota 1798,20 lei, ce constituie 33,3%
Beneficiar efectiv:
2.1. NASEDCHIN ALEXANDR, IDNP 2002001070747,

3. KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 1798,20 lei, ce constituie 33,3%
Beneficiar efectiv:
3.1. KOJEVNIKOV DMITRII, IDNP 0972305012362

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: **15.09.2023**.

Registrator în domeniul înregistrării de stat

Digitally signed by Rusu Diana
Date: 2023.09.15 16:44:17 EEST
Reason: MoldSign Signature
Location: Moldova

Rusu Diana

EB 0461494

Date cu caracter personal

BIOSISTEM-MLD S.R.L.
c/f 1010600028048; adresa: or. Chișinău, str. Albișoara 16/1 of.7
tel.+373-22-808-517, +373-22-808719, fax: +373-22-808-519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Lista fondatorilor Biosistem-mld SRL

Nr.	Nume, Prenume	IDNP
1.	Vitalie Poiata	0983103892591
2.	Alexandr Nasedchin	2002001070747
3.	Dmitrii Kojevnikov	0972305012362

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

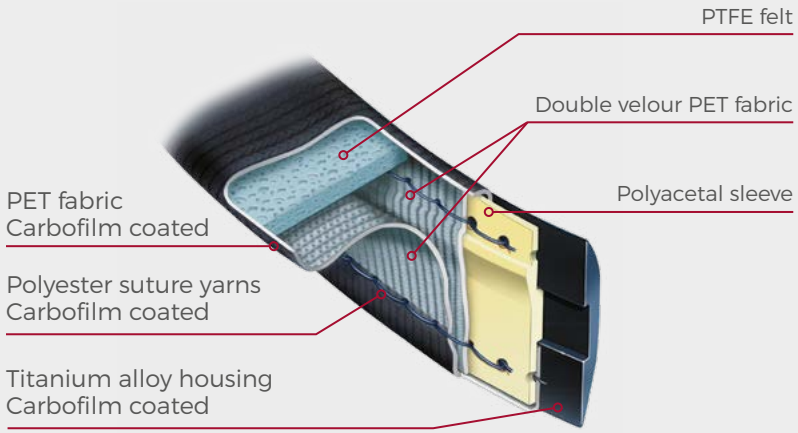
Details make the difference: Hemodynamics[1,2]

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]

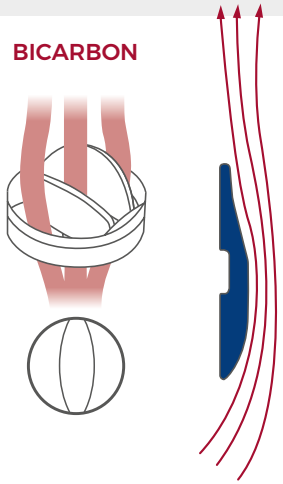


* Based on CORCYM post-market surveillance, valve-related pannus formation is expected to occur between 0.1 and 1 times per 100000 device population.

Technical claims are supported by CORCYM data on file.

Innovative Design

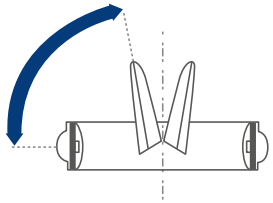
Not only a careful choice of materials but also an innovative design are key to Bicarbon's hemodynamic performance.[1,2]

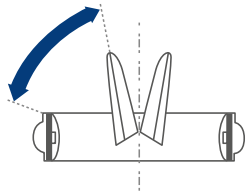


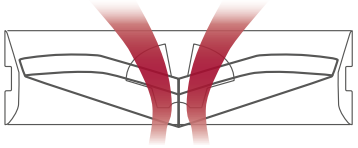
Bicarbon is a unique mechanical heart valve featuring curved leaflets specifically engineered to achieve an even flow distribution downstream.[3] This leads to several benefits to the patien:[1,3]

- 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.

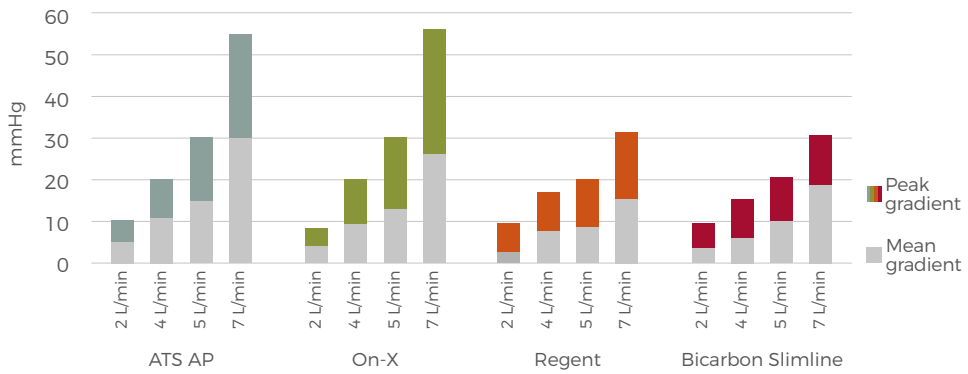
The favorable hemodynamic performance of Bicarbon valves is well proven in the published scientific literature.[1,2]

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:

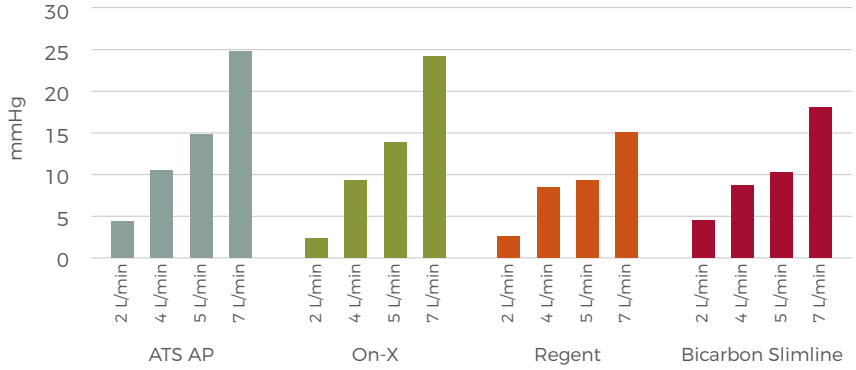
- pressure gradients
- leakage volume
- energy loss
- velocity profiles
- shear stress distribution

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]



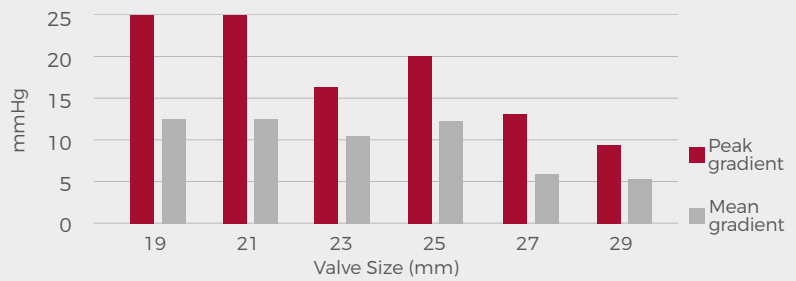
* Test performed with Sheffield pulse duplicator. Valves fitting a 21 mm diameter valve holder.

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]

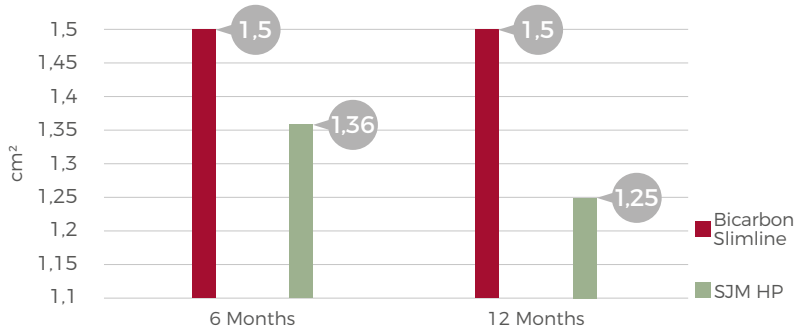
Peak and Mean Pressure Gradients*

IN VIVO AORTIC POSITION

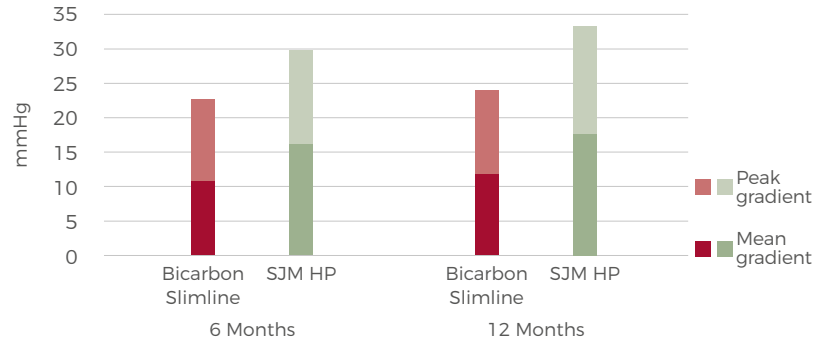


Comparative evaluation of small-size CORCYM Bicarbon Slimline and St. Jude HP heart valve prosthesis.[8]

Size 19 Effective Orifice Area (cm²)



Size 19 Mean and Peak pressure gradients (mmHg)



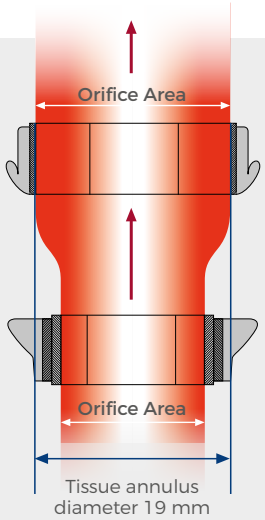
* Bicarbon standard model

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

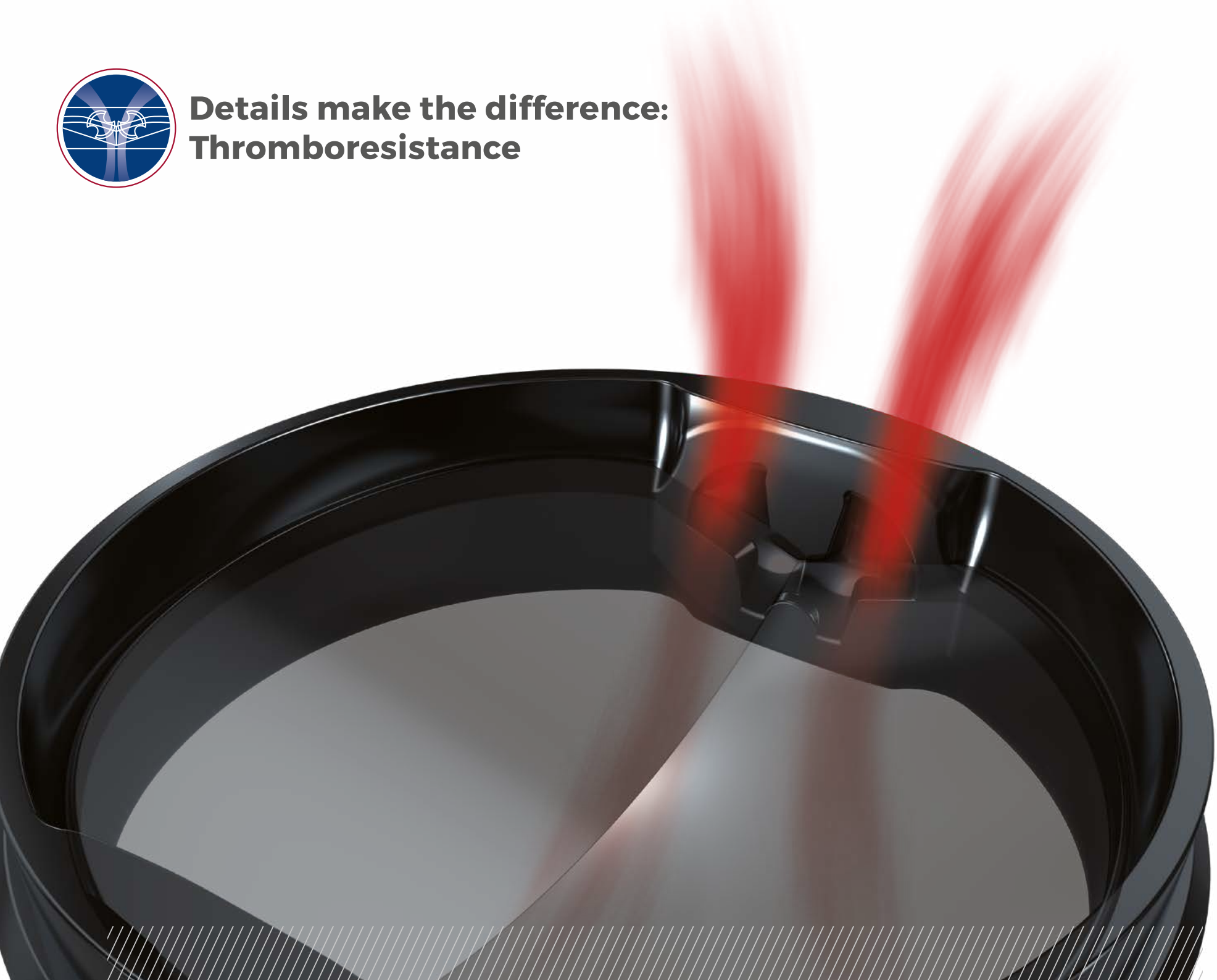
MPG: Mean pressure gradient; PPG: Peak pressure gradient

"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.

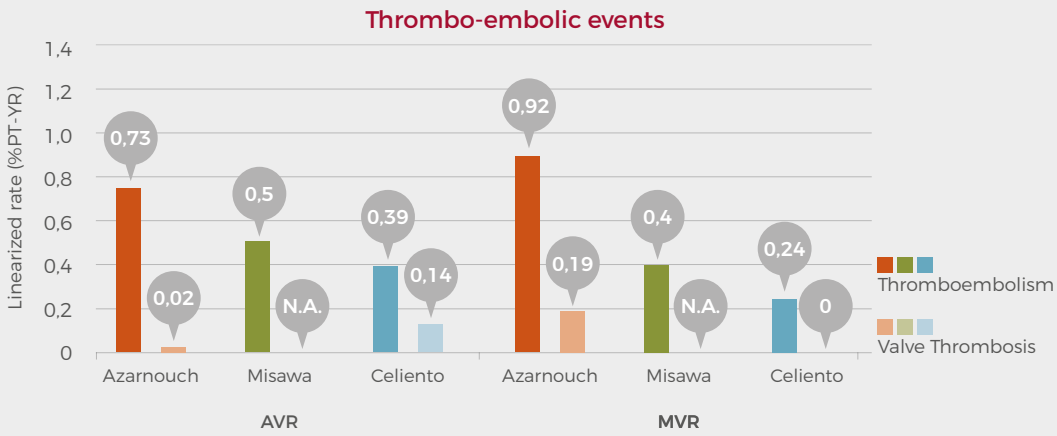
Details make the difference: Thromboresistance



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]



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

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]

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]

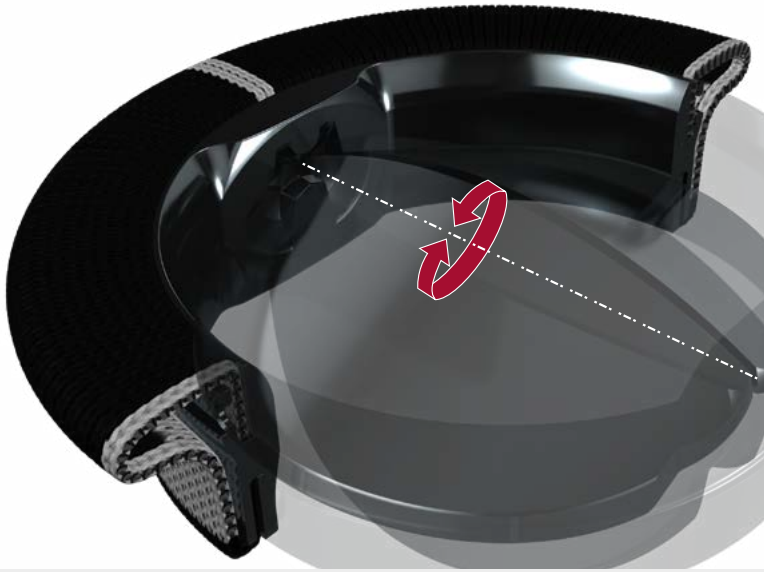
1. Falk et al., European Journal of Cardio-Thoracic Surgery 52 (2017) 616–664.
2. Torella et al., LOWERing the INtensity of oral anticoaGulant Therapy in patients with bileaflet mechanical aortic valve replacement: Results from the "LOWERING-IT" Trial, Am Heart J; 160:171-8, 2010.
3. Vallana et al., 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

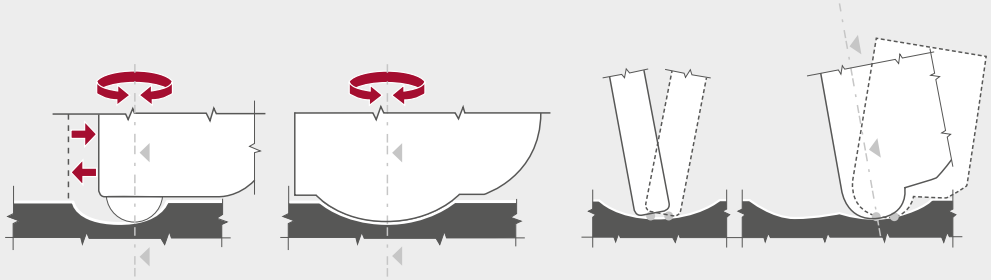
The Bicarbon design was carefully engineered to last over time.*

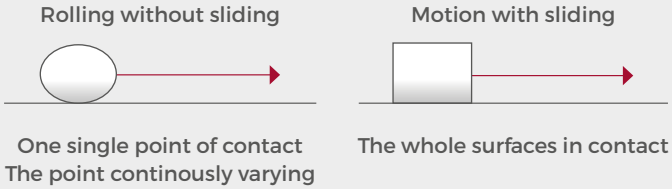
- The Titanium housing, with greater structural stability than solid Pyrolytic Carbon housings, ensures correct leaflet functionality.[1]
- The unique two-open-chimney design of the hinges avoid blood stasis and hemolysis minimizing the risk of structural valve failure and clinical complications.[1,2]
- 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).
** Based on CORCYM post-market surveillance, valve-related pannus formation is expected to occur between 0.1 and 1 times per 100000 device population.

1. Vallana et al., Pivot design in bileaflet valves, Asaio Journal, 38:M600-M606, 1992.
2. Steegers et al., J. Leakage flow at mechanical heart valve prostheses: improved washout or increased blood damage, Heart Valve Dis 8 : 312-323, 1999.

Technical claims are supported by CORCYM data on file.

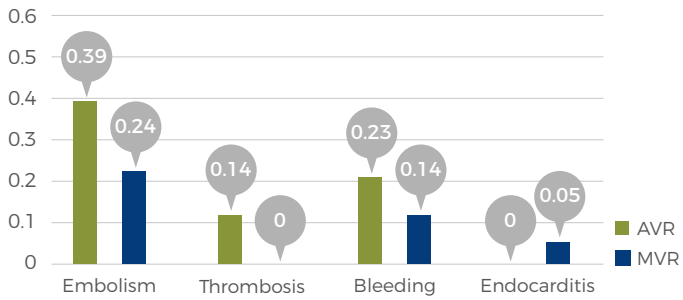
Details make the difference: Clinical outcomes

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

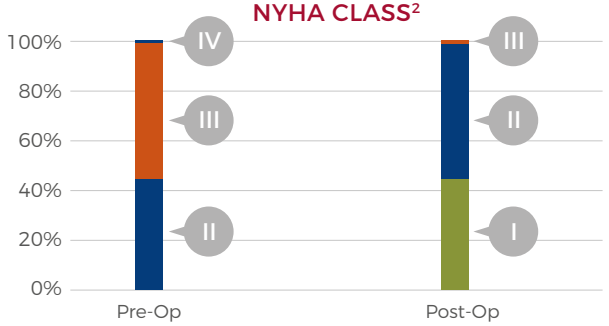
AVR: 344 Patients - MVR: 163 Patients - Cumulative follow-up: 6475 Patient-years

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



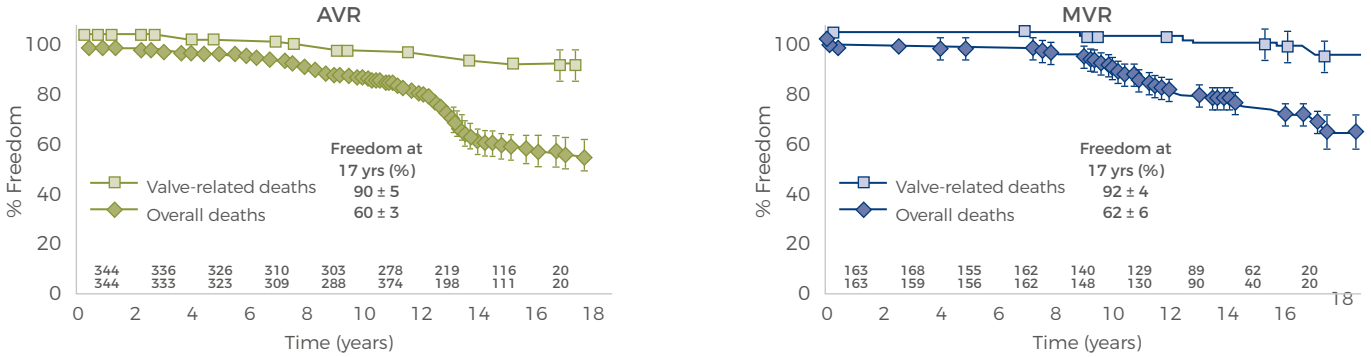
Mean INR at last FU: AVR: 2.6±0.5 - MVR: 2.7±0.4

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

Technical claims are supported by CORCYM data on file.

BICARBON™ FAMILY MECHANICAL HEART VALVES

BICARBON OVERLINE

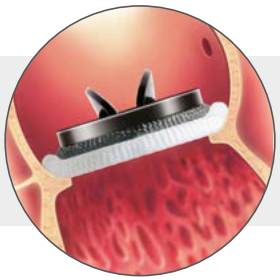
Implantation Consideration

- 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*



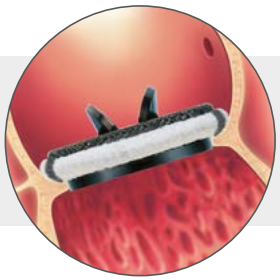
BICARBON SLIMLINE

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.

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

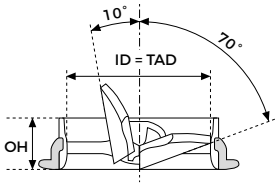
Technical claims are supported by CORCYM data on file.

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]	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

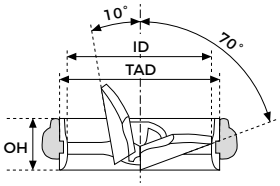
Accessories

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	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]	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	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

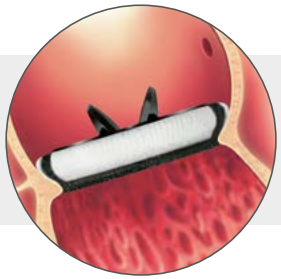
Implantation Consideration

- 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 ($P \leq 10\text{-}6$).

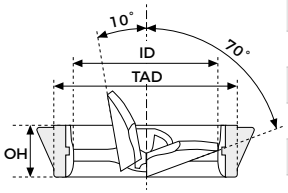
1. *Vallana et al., Pivot design in bileaflet valves, Asaio Journal, 38:M600-M606, 1992.*

Technical claims are supported by CORCYM data on file.

BICARBON FITLINE AORTIC

INTRA-ANNULAR AORTIC VALVE Sizes 19-31 mm

Product specifications

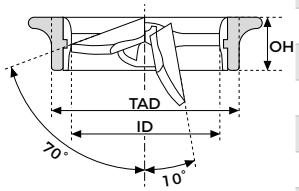


Nominal size	TAD	ID	OH	GOA	EOA[1]	Catalog N.
19	19.0	15.2	6.0	1.76	0.97	ICV0917
21	21.2	17.2	6.4	2.27	1.54	ICV0918
23	23.4	19.2	6.8	2.83	2.07	ICV0919
25	25.6	21.3	7.2	3.45	2.39	ICV0920
27	27.8	23.3	7.6	4.14	3.06	ICV0921
29	30.0	25.6	8.0	5.00	3.45	ICV0922
31	32.0	25.6	8.0	5.00	3.45	ICV0923

BICARBON FITLINE MITRAL

Sizes 19-33 mm

Product specifications



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	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 srl.

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. Please contact us through our website to receive instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events. Not approved in all geographies. Consult your labeling.

CORCYM
WE TAKE LIFE TO HEART

Manufactured by:

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13040 Saluggia (VC) Italy
Tel: +39 0161 487800

CE 0123

corcym
.com

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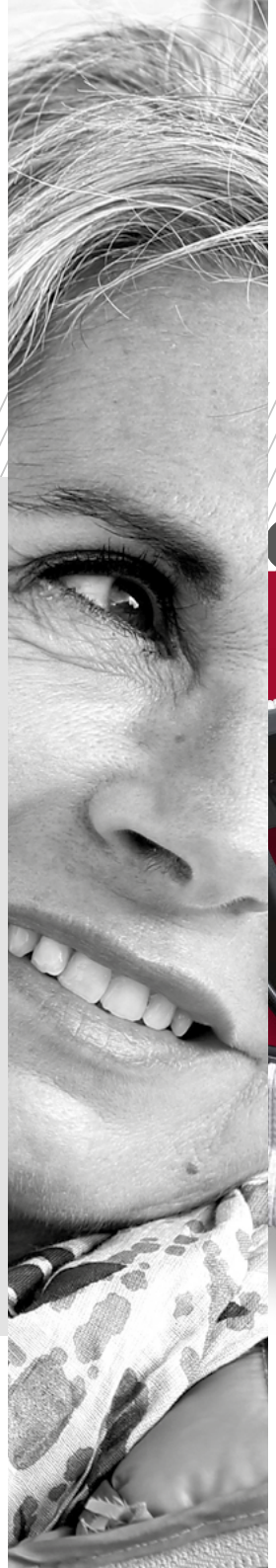


MECHANICAL
HEART VALVES

CARBOMEDICS™ FAMILY

Tailored reliability
for Patients and
Surgeon

CORCYM
WE TAKE LIFE TO HEART

CARBOMEDICS™ FAMILY

Bileaflet mechanical heart valves

With its Carbomedics™ line of products CORCYM offers cardiac Surgeons and Patients a complete set of mechanical heart valve solutions to reliably treat even the challenging cases.[2]

The Carbomedics name is intrinsically linked to the historical development of mechanical heart valves.

Based on the expertise and with the clear mission of providing highly reliable and technologically advanced solutions, in 1986 Carbomedics introduced to the market a mechanical bileaflet valve with a rotatable housing for optimal leaflet positioning.

Since this first step, the Carbomedics portfolio has been enriched over time up to the current, complete set of solutions that offer Surgeons flexibility while treating their Patients.

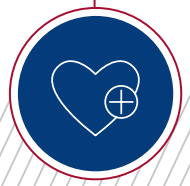
Choosing a Carbomedics mechanical valve today means choosing a reliable solution with proven clinical results in over 20 years of follow up and an extremely low incidence of post-operative structural failures reported in over 1 million implants.*[1]

* CORCYM post-market surveillance classifies the risk of structural valve failure *P* as improbable ($10^{-6} < P \leq 10^{-5}$).

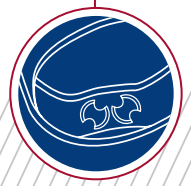
1. *Bouchard et al., Twenty-Year Experience With the CarboMedics Mechanical Valve Prosthesis. Ann Thorac Surg 2014;97:816–23.*
2. *Nishida et al., Single-institution, 22-year follow-up of 786 CarboMedics mechanical valves used for both primary surgery and reoperation. J Thorac Cardiovasc Surg 2014;147:1493-8).*

Tailored options for desirable Patient outcomes[1]

Tailored safety and durability[1]

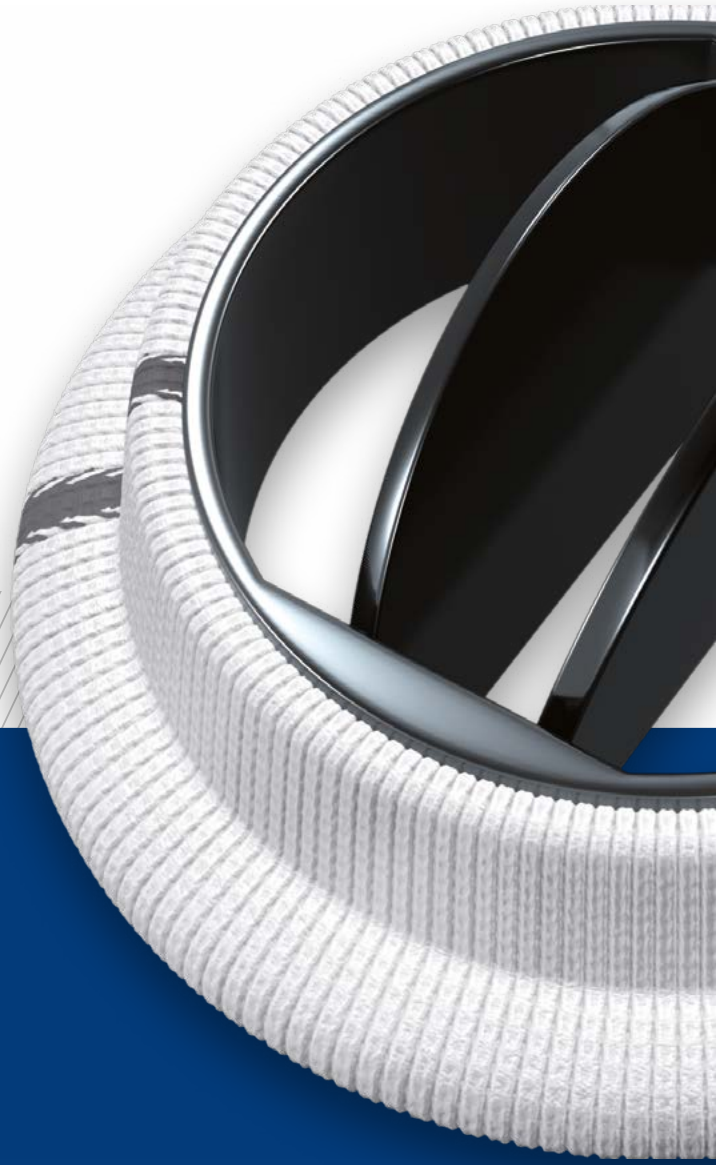


Tailored performance for desirable clinical outcomes



Tailored ease of implant

Tailored solutions for Patients and Surgeons



1. Bouchard et al., Twenty-Year Experience With the CarboMedics Mechanical Valve Prosthesis. Ann Thorac Surg 2014;97:816–23.

Tailored safety and durability[1]

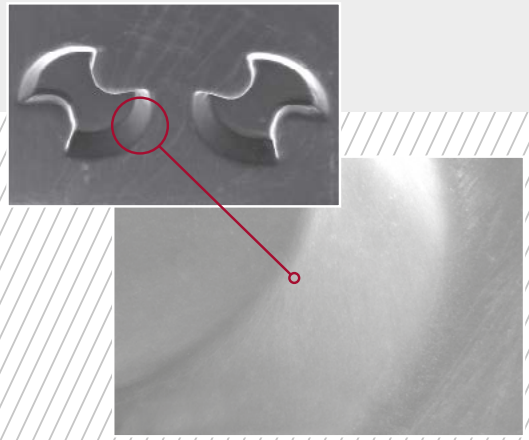
Historically focused on biocompatible materials

Thanks to its robust design, the Carbomedics bileaflet mechanical heart valve has extremely low incidence of post-operative structural failures in over 1 million implants worldwide.*

Carbomedics Pyrolite® Carbon is engineered to provide excellent thromboresistance* and mechanical resistance.[1]

This is achieved by co-depositing a small amount of Silicon during the manufacturing process, because the Silicon acts as a reinforcing element to the crystal structure of Pyrolytic Carbon.[1] The surface is then polished to remove the superficial roughness, thus achieving a mirror like finish.[1,2]

Polished Silicon alloyed varieties of Pyrolytic Carbon exhibit an excellent degree of thromboresistance while improving resistance to wear, offering results proven by over 20 years of clinical follow up.[1,2]



* CORCYM post-market surveillance classifies the risk of structural valve failure *P* as improbable (10-6 < *P* ≤ 10-5).

1. *J.C. Bokros Carbon Biomedical Devices. - Carbon, 1977;15:355-71.*
2. *Goodman et al., Platelet responses to silicon-alloyed pyrolytic carbons. - Wiley Periodicals, Inc. J Biomed Mater Res 83A: 64–69, 2007*

Technical claims are supported by CORCYM data on file.

A robust design* to minimize post-operative structural failures

Pyrolytic carbon coated leaflets

The leaflets of the Carbomedics valves are made of a substrate of tungsten filled graphite coated with Pyrolite® Carbon. The presence of Tungsten provides better radiopacity allowing a non invasive diagnostic observation of the leaflets' motion through fluoroscopy or similar methodologies.

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]

Pyrolytic carbon housing

Differently from other substrate processes, which results in a graphite core coated with pyrolytic carbon, Carbomedics valves employ an advanced mandrel process resulting in a low profile housing made entirely of Pyrolite® Carbon.

The mandrel process allows pivots to be located within the housing, reducing pannus ingrowth and interference with leaflet motion that can occur around the protruding “pivot ear” design.[1,2] Moreover, it permits a more sophisticated design of the pivot, the shape of which grants total washing of its entire surface, minimizing thromboembolic events**.[3]

Structural components

To further enhance structural stability, the housing is reinforced by a titanium stiffening band which makes it stronger than a valve without a stiffening element, minimizing the risk of deformation and, consequently, the risk of leaflet dislodgement or lockup.[3,4]
A lock wire forms a solid mechanical bond between the housing and the titanium reinforcement band while creating a track for rotation.

Secure attachment of the sewing cuff to the housing is ensured by double lock wires.

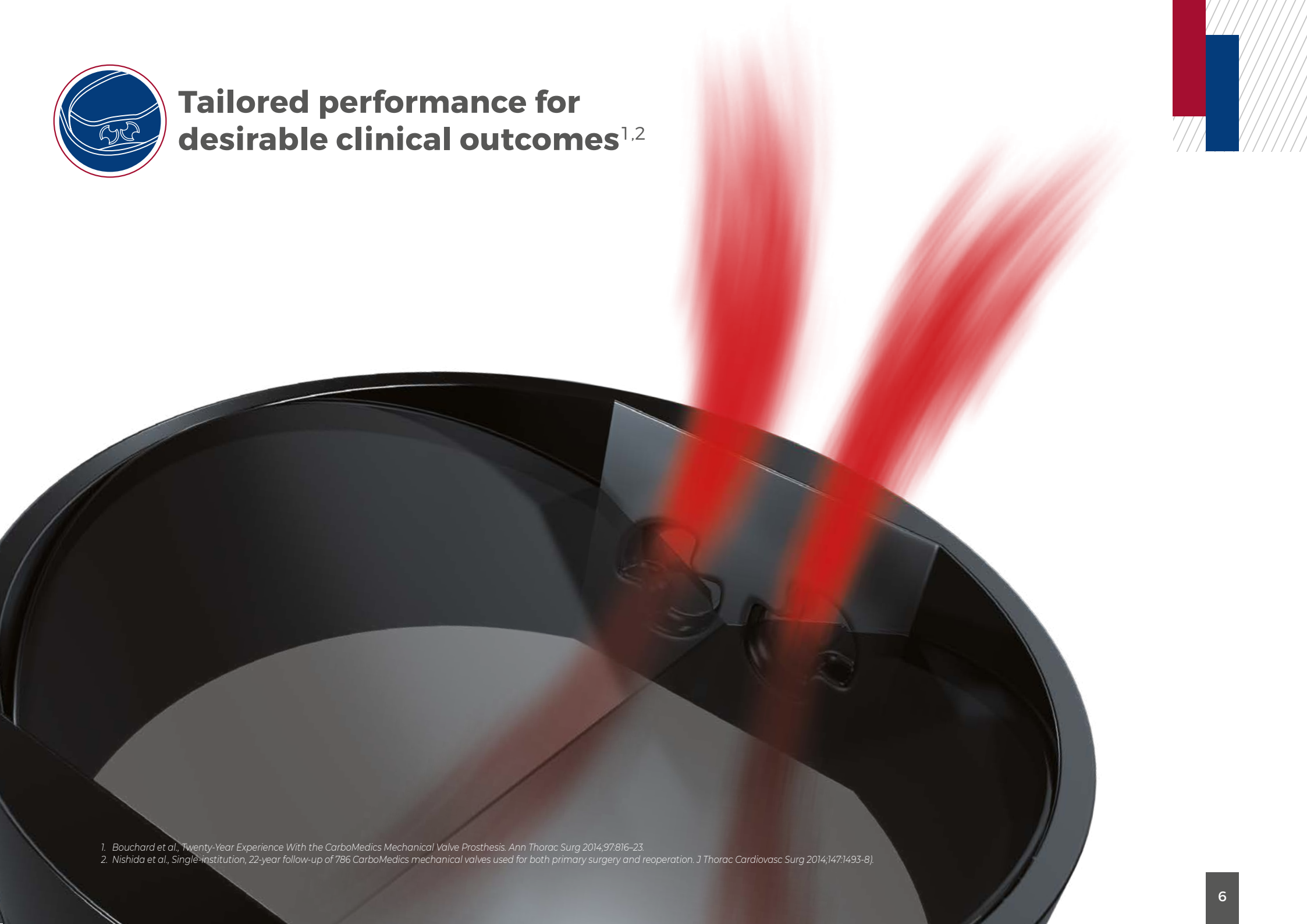
* According to ISO 5840:2015 requirements, CORCYM post-market surveillance and published experience on long term results (Bouchard et al., Ann Thorac Surg 2014;97:816-23).

** Falk et al., European Journal of Cardio-Thoracic Surgery 52 (2017) 616-664.

1. *Aoyagi et al., Obstruction of St Jude medical valves in the aortic position: a consideration for pathogenic mechanism of prosthetic valve obstruction. - Cardiovasc Surg. 2002 Aug;10(4):339-44.*
2. *Dearani et Al., Entrapment of subvalvular mitral tissue causing intermittent failure of a St Jude mitral prosthesis. - J Am Soc Echocardiogr. 2000 Dec;13(12):1121-3.*
3. *Chambers et al., Echocardiographic Description Of The Carbomedics Bileaflet Prosthetic Heart Valve. - J Am Coll Cadiol 1993;21:398-405.*
4. *Bernal et al., The CarboMedics Valve: Experience With 1,049 Implants. - Ann Thorac Surg 1999;67:1299-303*

Technical claims are supported by CORCYM data on file.

Tailored performance for desirable clinical outcomes[1,2]



1. Bouchard et al., Twenty-Year Experience With the CarboMedics Mechanical Valve Prosthesis. Ann Thorac Surg 2014;97:816–23.
2. Nishida et al., Single-institution, 22-year follow-up of 786 CarboMedics mechanical valves used for both primary surgery and reoperation. J Thorac Cardiovasc Surg 2014;147:1493-8).

Carbomedics valves are engineered to achieve proven clinical benefits for Patients throughout their lifetime[1,2]

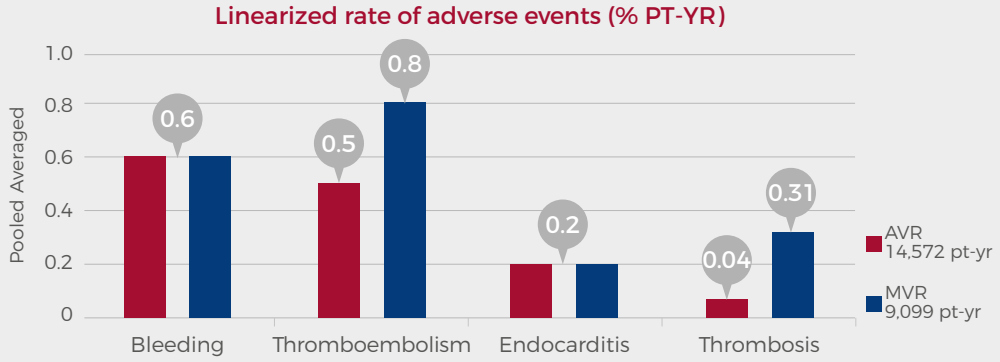
In its long clinical history, Carbomedics valves have demonstrated great levels of safety and reliability, with a considerably low incidence of complications and post-operative structural failures.[1,3]

The enhanced orifice hinge design allows for low thrombogenicity, minimizing pannus overgrowth. The inner surfaces of the pivots are completely open to the flow for washing when the leaflets are closed.[4]

The effectiveness of the Carbomedics design is reflected in the very low linearized rates* (%/pt-yr) of thromboembolic events reported in published scientific literature.

Twenty-Year Experience With the CarboMedics Mechanical Valve Prosthesis[1]

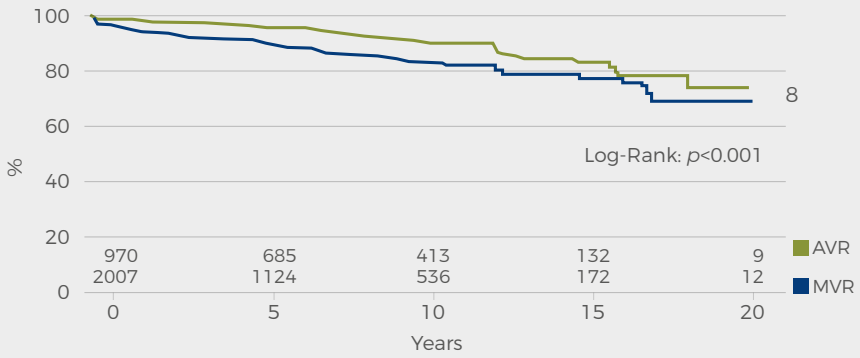
Over **twenty years** of published follow up reports "excellent functional results".[1]



* Objective performance criteria (OPC) as defined in ISO 5840:2012 used for comparison.
CORCYM post-market surveillance classifies the risk of thromboembolic events *P* as improbable (10-6 < *P* ≤ 10-5)[1,3,5]

1. *Bouchard et al., Twenty-Year Experience With the CarboMedics Mechanical Valve Prosthesis. - Ann Thorac Surg 2014;97:816–23.*
2. *CER-00001*
3. *Aagard. Fifteen Years' Clinical Experience with the CarboMedics Prosthetic Heart Valve. - J Heart V Dis 2005 Jan;14(1): 82-8.*
4. *Chambers et al., Echocardiodgraphic Description Of The Carbomedics Bileaflet Prosthetic Heart Valve. - J Am Coll Cadiol 1993;21:398-405.*
5. *Nishida et al., Single-institution, 22-year follow-up of 786 CarboMedics mechanical valves used for both primary surgery and reoperation. J Thorac Cardiovasc Surg 2014;147:1493-8).*

Freedom from valve-related mortality after mitral and aortic valve replacement*.[1,2]



Proven reliability with very low thrombogenicity[3].

Thrombogenicity remains to date one of the major concerns related to the implantation of mechanical heart valves. The safety of the Carbomedics valve with respect to thrombogenicity has been extensively proved in published scientific literature** and is well recognized by the current European guidelines for heart valve disease management which classify Carbomedics as a Low thrombogenic prosthesis.[3]

* All sudden or unknown causes of death were considered valve related in accordance to the Guidelines for reporting morbidity and mortality after cardiac valvular operations.

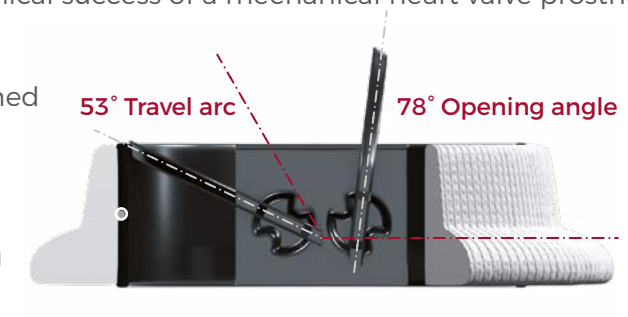
** CORCYM post-market surveillance classifies the risk of structural valve failure *P* as improbable ($10\text{-}6 < P \leq 10\text{-}5$).

1. *Bouchard et al., Twenty-Year Experience With the CarboMedics Mechanical Valve Prosthesis. - Ann Thorac Surg 2014;97:816–23.*
2. *Edmunds et al., Guidelines for reporting morbidity and mortality after cardiac valvular operations. - J Thorac Cardiovasc Surg 1996;112:708–11.*
3. *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*

A unique platform with favorable hemodynamics.[1,2]

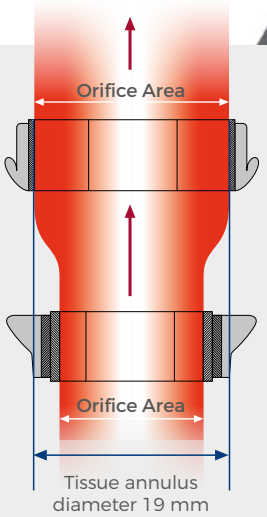
One of the key factors influencing the clinical success of a mechanical heart valve prosthesis is its hemodynamic efficiency.

The opening angle and travel arc of the Carbomedics valves' leaflets are determined by hydrodynamic testing in order to achieve low pressure gradients and an optimal balance between forward flow and regurgitant volume, thus minimizing total energy loss while promoting quiet functioning.



Top Hat, top hemodynamic performance.[1,3]

To further optimize hemodynamics, especially in small aortic annuli, CORCYM features in its Carbomedics portfolio the Top Hat prosthesis, a truly totally supra-annular model which provides an advantage of 1 to 2 sizes over intra-annular valves.[3,4,5] Top Hat improves effective valve orifice area thanks to a 100% orifice to annulus match, thus contributing to reduce the risk of PPM.[1]



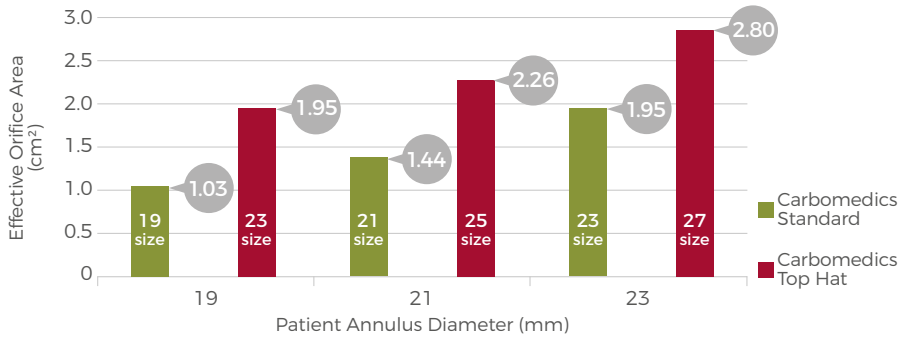
100% ORIFICE TO ANNULUS MATCH

"The Top Hat valve minimizes the risk of patient-prosthesis mismatch, improves hemodynamic performance, and thereby reduces morbidity and mortality".[5]

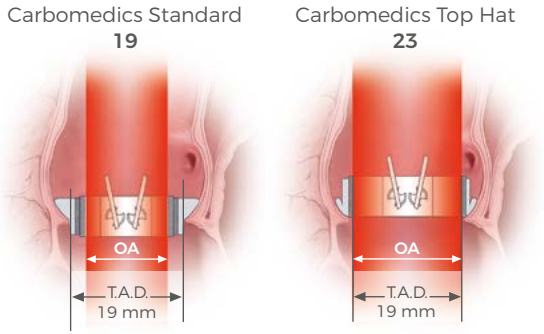
1. *Aagard et al., Midterm Evaluation of Hemodynamics of the Top Hat Supraannular Aortic Valve. - Asian Cardiovasc Thorac Ann 2010;18:1–5.*
2. *Bernal et al., The CarboMedics Valve: Experience With 1,049 Implants. - Ann Thorac Surg 1999;67:1299-303.*
3. *Lundblad R et al., The Carbomedics Supraannular Top hat Valve improves prosthesis size in the Aortic Root. - J Heart Valve Dis 2001;10:196-201.*
4. *Supra annular model as defined by International Standard for Cardiovascular implants - Cardiac valve Prostheses-Part 2. ISO 5840-2:2015(E).*
5. *Aagard et al., Maximizing prosthetic valve size with the Top Hat supraannular aortic valve.- The Journal of Heart Valve Disease 2007;16:84-90.*

Technical claims are supported by CORCYM data on file.

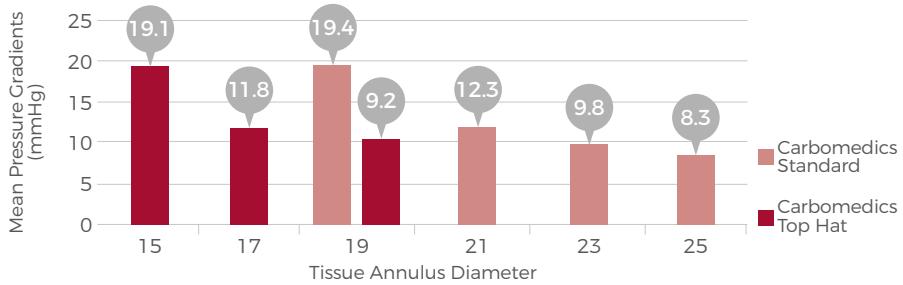
Carbomedics *in vitro* data*

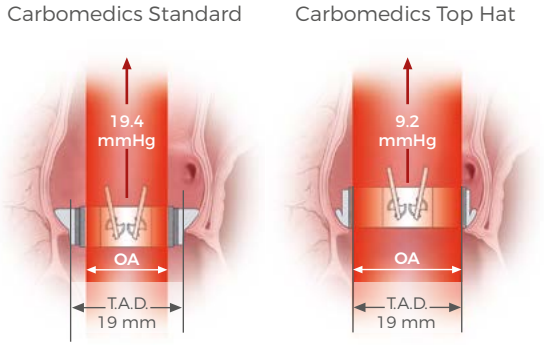


**In vitro test - 5l/min 70 bpm (Data on file at CORCYM)



Carbomedics *in vivo* data[1,2]



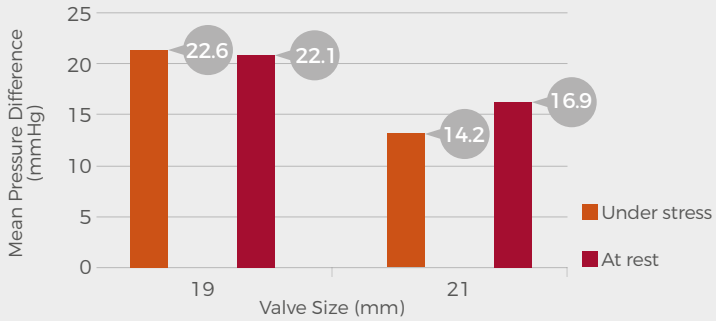


TAD: Tissue Annulus Diameter
OA: Orifice Area

In a published experience on small annuli (sizes 19 and 21), Carbomedics has shown good performance even under stress.[3]

" The result is an optimization of the discharge coefficient with exercise, indicating a good design of the moving part of the valve".[3]

Carbomedics hemodynamics at rest and under stress[3]



1. Chambers et al., Echocardiographic description of the Carbomedics bileaflet prosthetic heart valve, JACC 1993; 21(2); 398-405.
2. Bernal et al., The Carbomedics "Top Hat" Supra-annular prosthesis. - Ann Thorac Surg. 1999;67:1299-303.
3. De Paulis et al., Hemodynamic performance of small diameter Carbomedics and St. Jude valves. - J Heart Valve Dis 1996;5 (Suppl III):S339-43.

Technical claims are supported by CORCYM data on file.

Tailored ease of implant

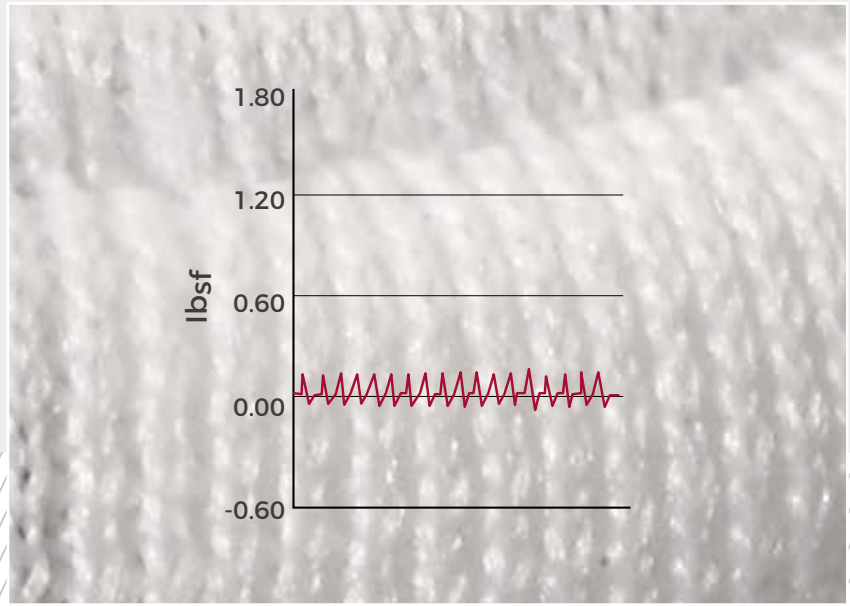
Carbomedics valves are designed for a smooth implant experience

Carbomedics sewing cuffs are optimized for ease of implant and stable seating. The Carbomedics sewing cuff requires a low force for needle penetration facilitating the suturing phase.

Most importantly, the Carbomedics sewing cuff is designed to gently conform to the tissue, thus minimizing the tension on sutures and consequently the risk of dehiscence.[1]

The broad variety of configurations was conceived to provide effective fit in any anatomical configuration.

Carbomedics Sewing Cuff Penetration Force*



* Test performed on Carbomedics Standard Mitral Model. CORCYM data on file.

1. CER-00001.

Technical claims are supported by CORCYM data on file.

Tailored solutions for every Patient and surgeon's need

Different options for your daily practice

CARBOMEDICS TOP HAT

A truly, totally supra-annular aortic prosthesis for improved hemodynamics and reduced risk of PPM*.[1,2]

It is of particular advantage also in double valve replacement, where a total supra-annular seating helps minimise the risk of interference with the mitral prosthesis.[1]

CARBOMEDICS OPTIFORM

A unique mitral prosthesis with versatile positioning to approach even challenging situations.[3]

Thanks to its flexible, generous symmetrical sewing cuff Optiform valve can conform to almost any annulus. Valve placement can be adjusted simply by varying suture entry and exit sites.

Everted Suture Technique

For atrial positioni (supra-annular), needle enters at bottom of cuff and exits at midline

For intra-annular positioning, needle enters at bottom of cuff and exits at top of cuff

For sub-annular positioning, needle enters at midline of cuff and exits at top of cuff

* Compared to non totally supra-annular models.

1. *Lundblad R et al., The Carbomedics Supraannular Top hat Valve improves prosthesis size in the Aortic Root. - J Heart Valve Dis 2001;10:196-201.*
2. *Aagard et al., Midterm Evaluation of Hemodynamics of the Top Hat Supraannular Aortic Valve. - Asian Cardiovasc Thorac Ann 2010;18:1–5.*
3. *Miyairi et al., Redo mitral valve replacement using the valve-on-valve method. - Asian Cardiovascular & Thoracic Annals 2015, Vol. 23(6) 707–709.*

Technical claims are supported by CORCYM data on file.

A complete set of mechanical heart valve solutions

Four different aortic models

Carbomedics Top Hat

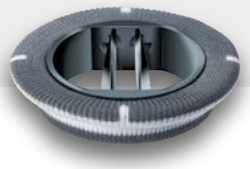
Carbomedics Standard

Carbomedics Reduced

Carbomedics Orbis

Three different mitral models

Carbomedics Standard

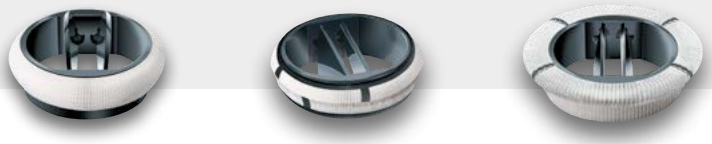


Carbomedics Optiform

Carbomedics Orbis

Small size aortic and mitral valves

Carbomedics Standard small sizes



Two different conduit models

Carbomedics
Carbo-Seal

Carbomedics
Carbo-Seal Valsalva

CARBOMEDICS™ FAMILY

The voice of experience

"We observed that the Carbomedics mechanical prosthesis had excellent durability with no structural failures, good hemodynamics, and a low incidence of TE."[1]*

"Our experience demonstrates excellent functional result of the Carbomedics valve in both mitral and aortic positions. Valve-related events were low and often caused by patient-related factors as opposed to the presence of the prosthesis."[1]*

"In our experience, structural valve failure with this device is inexistent. The Carbomedics mechanical valve is a solid choice for long-term valvular replacement."[1]*

TE: Thromboembolic Events

* CORCYM post-market surveillance classifies the incidence of valve structural failure and thromboembolic events *P*1 as improbable (10 -6 < *P*1 ≤ 10-5).

1. Bouchard et al., Twenty-Year Experience With the CarboMedics Mechanical Valve Prosthesis. - Ann Thorac Surg 2014;97:816–23.

CARBOMEDICS™ FAMILY MECHANICAL HEART VALVES

CARBOMEDICS TOP HAT

Implantation Consideration

- Totally supra-annular placement
  - provides an advantage of 1 to 2 sizes over intra-annular valves[1,2,3]
  - facilitates double valve replacement procedure[4]
- The lock wire, connecting the housing and the Titanium stiffening ring, allows for rotatability in-situ
- Three orientation markers for suture spacing
- Special sizers allow Surgeon to assess position of valve within sinus area and clearance of coronaries before implantation

Clinical Consideration

- Size upgrades provide improved valve hemodynamics*[1,2,3]
- Totally supra-annular design allows a 100% orifice to annulus match, maximazing the orifice available to blood flow[6]
- Alternative to aortic root enlargement[7]
- Low profile housing minimizes interferences with the coronary ostia
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape
- Proven reliable structural stability
- Very low valve-related adverse events[8,9]

CARBOMEDICS REDUCED
CARBOMEDICS ORBIS

Implantation Consideration

- The lock wire, connecting the housing and the Titanium stiffening ring, allows for rotatability in-situ
- Orientation markers provide easy visual suture positioning (except for Orbis)
- Carbomedics Reduced has a smaller and pliable sewing cuff with respect to the Standard model. This design was conceived for improved seating in a smaller annulus or small root.[5]

Clinical Consideration

- Low profile housing minimizes interferences with the coronary ostia
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape
- Proven reliable structural stability
- Very low valve-related adverse events[8,9]

CARBOMEDICS STANDARD

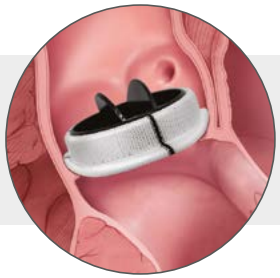
Implantation Consideration

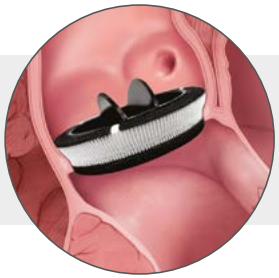
- The lock wire, connecting the housing and the Titanium stiffening ring, allows for rotatability in-situ
- Orientation markers provide easy visual suture positioning
- Generous sewing cuff conforms to annulus, designed to minimize paravalvular leaks

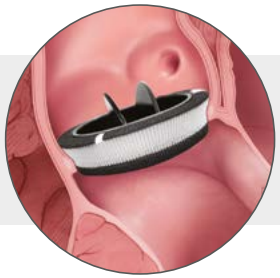
Clinical Consideration

- Low profile housing minimizes interferences with the coronary ostia
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape
- Proven reliable structural stability
- Very low valve-related adverse events[8,9]

Valve Placement *in-situ*







* Compared to non totally supra-annular models.

1. *Supra annular model as defined by International Standard for Cardiovascular implants - Cardiac valve Prostheses-Part 2. ISO 5840-2:2015(E).*
2. *Lundblad R et al., The Carbomedics Supraannular Top hat Valve improves prosthesis size in the Aortic Root. - J Heart Valve Dis 2001;10:196-201.*
3. *Aagard et al., Maximizing prosthetic valve size with the Top Hat supraannular aortic valve. - The Journal of Heart Valve Disease 2007;16:84-90.*
4. *Lundblad R et al., The Carbomedics Supraannular Top hat Valve improves prosthesis size in the Aortic Root. - J Heart Valve Dis 2001;10:196-201.*
5. *CORCYM data on file.*
6. *Aagard et al., Midterm Evaluation of Hemodynamics of the Top Hat Supraannular Aortic Valve. - Asian Cardiovasc Thorac Ann 2010;18:1-5.*
7. *Bernal et al., The Carbomedics "Top Hat" Supra-annular prosthesis. - Ann Thorac Surg. 1999;67:1299-303.*
8. *Aagard. Fifteen Years' Clinical Experience with the CarboMedics Prosthetic Heart Valve. - J Heart V Dis 2005 Jan;14(1): 82-8.*
9. *Bouchard et al., Twenty-Year Experience With the CarboMedics Mechanical Valve Prosthesis. - Ann Thorac Surg 2014;97:816-23.*

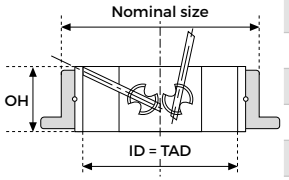
Technical claims are supported by CORCYM data on file.

CARBOMEDICS™ FAMILY

MECHANICAL
HEART VALVES

TOTALLY SUPRA-ANNULAR AORTIC VALVE Sizes 19-27 mm

Product specifications

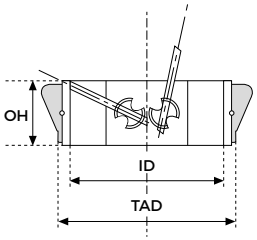


Nominal size	TAD	ID	OH	GOA	EOA	Catalog N.
19	14.7	14.7	6.2	1.59	1.0[1]	S5-019
21	16.7	16.7	6.6	2.07	1.4[2]	S5-021
23	18.5	18.5	7.3	2.56	1.9[2]	S5-023
25	20.5	20.5	7.7	3.16	2.2[2]	S5-025
27	22.5	22.5	8.4	3.84	2.9[2]	S5-027

CARBOMEDICS STANDARD

AORTIC VALVE Sizes 19-29 mm

Product specifications

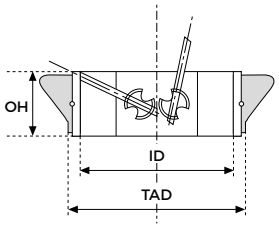


Nominal size	TAD	ID	OH	GOA	EOA[1]	Catalog N.
19	18.8	14.7	6.2	1.59	1.0	R5-019
21	20.8	16.7	6.6	2.07	1.5	R5-021
23	22.6	18.5	7.3	2.56	1.6	R5-023
25	25.0	20.5	7.7	3.16	2.0	R5-025
27	27.0	22.5	8.4	3.84	2.4	R5-027
29	29.0	24.2	8.7	4.44	2.6	R5-029

CARBOMEDICS REDUCED

AORTIC VALVE Sizes 19-29 mm

Product specifications

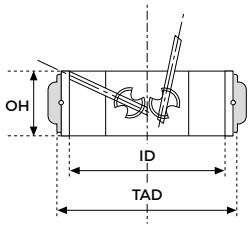


Nominal size	TAD	ID	OH	GOA	EOA[1,2]	Catalog N.
19	19.8	14.7	6.2	1.59	1.0	A5-019
21	21.8	16.7	6.6	2.07	1.5	A5-021
23	23.8	18.5	7.3	2.56	1.6	A5-023
25	25.8	20.5	7.7	3.16	2.0	A5-025
27	27.8	22.5	8.4	3.84	2.4	A5-027
29	29.8	24.2	8.7	4.44	2.6	A5-029
31	31.8	24.2	8.7	4.44	2.6	A5-031

CARBOMEDICS ORBIS

AORTIC VALVE Sizes 19-31 mm

Product specifications



Nominal size	TAD	ID	OH	GOA	EOA[1]	Catalog N.
19	18.8	14.7	6.2	1.59	1.0	A1-019
21	20.8	16.7	6.6	2.07	1.5	A1-021
23	22.6	18.5	7.3	2.56	1.6	A1-023
25	25.0	20.5	7.7	3.16	2.0	A1-025
27	27.0	22.5	8.4	3.84	2.4	A1-027
29	29.0	24.2	8.7	4.44	2.6	A1-029
31	31.0	24.2	8.7	4.44	2.6	A1-031

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. *Chambers et al., Echocardiographic description of the Carbomedics bileaflet prosthetic heart valve. - JACC 1993; 21(2); 398-405.*
2. *Aagard et al., Midterm Evaluation of Hemodynamics of the Top Hat Supraannular Aortic Valve. - Asian Cardiovasc Thorac Ann 2010;18:1-5.*

CARBOMEDICS STANDARD SMALL SIZES

Implantation Consideration

- Sewing cuff assembly reduces cuff size to maximize orifice area by design[1]
- The lock wire, connecting the housing and the Titanium stiffening ring, allows for rotatability in-situ
- Orientation markers provide easy visual suture positioning

Clinical Consideration

- Fits where other Carbomedics valves will not
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape
- Proven reliable structural stability

Valve Placement *in-situ*

CARBOMEDICS STANDARD SMALL SIZES

Implantation Consideration

- Sewing cuff assembly reduces cuff size to maximize orifice area by design[1]
- The lock wire, connecting the housing and the Titanium stiffening ring, allows for rotatability in-situ
- Orientation markers provide easy visual suture positioning

Clinical Consideration

- Fits where other Carbomedics valves will not
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape
- Proven reliable structural stability

Valve Placement *in-situ*

1. CORCYM data on file.

Technical claims are supported by CORCYM data on file.

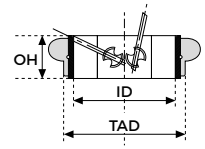

Size 16

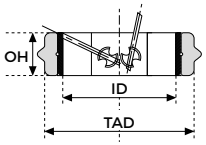

Size 18

CARBOMEDICS STANDARD SMALL SIZES

AORTIC VALVES Sizes 16 and 18 mm

Product specifications





Nominal size	TAD	ID	OH	GOA	EOA[1]	Catalog N.
16	16.2	14.7	6.2	1.59	1	A5-016
18	18.8	14.7	6.2	1.59	1	A5-018


Size 16

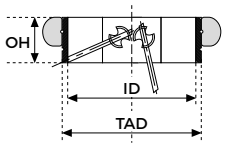

Size 18

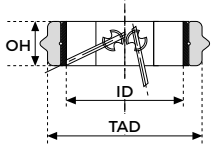

Size 21

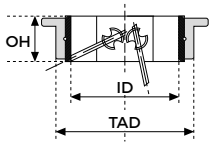
CARBOMEDICS STANDARD SMALL SIZES

MITRAL VALVES Sizes 16, 18 and 21 mm

Product specifications







Nominal size	TAD	ID	OH	GOA	Catalog N.
16	16.2	14.7	6.2	1.59	M7-016
18	18.8	14.7	6.2	1.59	M7-018
21	21.8	16.7	6.6	2.07	M7-021

Legend

TAD = Tissue Annulus Diameter (mm)	EOA = In vivo Effective Orifice Area (cm^2)	GOA = Geometric Orifice Area (cm^2)
ID = Internal Diameter (mm)	OH = Orifice Height (mm)	

1. *Chambers et al., Echocardiographic description of the Carbomedics bileaflet prosthetic heart valve. - JACC 1993; 21(2): 398-405.*

CARBOMEDICS STANDARD

Implantation Consideration

- Generous sewing cuff conforms to annulus, designed to minimize paravalvular leaks
- The lock wire, connecting the housing and the Titanium stiffening ring, allows for rotatability in-situ
- Orientation markers provide easy visual suture positioning

Clinical Consideration

- Low-profile pivot design minimizes protrusion into low-flow atrial area, reducing potential thrombus formation
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape
- Proven reliable structural stability
- Very low valve-related adverse events[3,4]

Valve Placement *in-situ*

CARBOMEDICS OPTIFORM
CARBOMEDICS ORBIS

Implantation Consideration

- Symmetrical cuff design allows valve to be placed in a supraannular, intra-annular or subannular position simply by varying suture entry and exit sites[1,2]
- Flexible, generous cuff easily conforms to difficult Patient annular anatomy[1,2]
- The lock wire, connecting the housing and the Titanium stiffening ring, allows for rotatability in-situ
- Orientation markers provide easy visual suture positioning (Carbomedics Optiform only)

Clinical Consideration

- Variable valve placement allows Surgeon to choose best valve position for each Patient
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape
- Proven reliable structural stability
- Very low valve-related adverse events[3,4]

Valve Placement *in-situ*

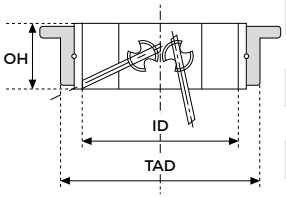
1. *Miyairi et al., Redo mitral valve replacement using the valve-on-valve method. - Asian Cardiovascular & Thoracic Annals 2015, Vol. 23(6) 707–709.*
2. *CORCYM data on file.*
3. *Aagard. Fifteen Years' Clinical Experience with the CarboMedics Prosthetic Heart Valve. - J Heart V Dis 2005 Jan;14(1): 82-8.*
4. *Bouchard et al., Twenty-Year Experience With the CarboMedics Mechanical Valve Prosthesis. - Ann Thorac Surg 2014;97:816–23.*

Technical claims are supported by CORCYM data on file.

CARBOMEDICS STANDARD

MITRAL VALVE Sizes 23-33 mm

Product specifications

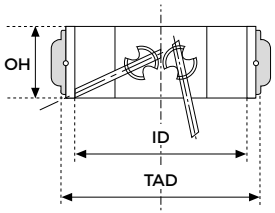


Nominal size	TAD	ID	OH	GOA	Catalog N.
23	23.8	18.5	7.3	2.56	M7-023
25	25.8	20.5	7.7	3.16	M7-025
27	27.8	22.5	8.4	3.84	M7-027
29	29.8	24.2	8.7	4.44	M7-029
31	31.8	24.2	8.7	4.44	M7-031
33	33.8	24.2	8.7	4.44	M7-033

CARBOMEDICS ORBIS

MITRAL VALVE Sizes 21-33 mm

Product specifications

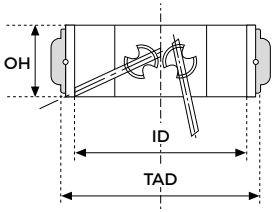


Nominal size	TAD	ID	OH	GOA	Catalog N.
21	20.8	16.7	6.6	2.07	M2-021
23	22.6	18.5	7.3	2.56	M2-023
25	25.0	20.5	7.7	3.16	M2-025
27	27.0	22.5	8.4	3.84	M2-027
29	29.0	24.2	8.7	4.44	M2-029
31	31.0	24.2	8.7	4.44	M2-031
33	33.0	24.2	8.7	4.44	M2-033

CARBOMEDICS OPTIFORM

MITRAL VALVE Sizes 23-33 mm

Product specifications



Nominal size	TAD	ID	OH	GOA	Catalog N.
23	22.6	18.5	7.3	2.56	F7-023
25	25.0	20.5	7.7	3.16	F7-025
27	27.0	22.5	8.4	3.84	F7-027
29	29.0	24.2	8.7	4.44	F7-029
31	31.0	24.2	8.7	4.44	F7-031
33	33.0	24.2	8.7	4.44	F7-033

Legend

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

CARBOMEDICS CARBO-SEAL VALSALVA

Implantation Consideration

- Vertical orientation of sinus pleats facilitates coronary anastomosis[1]
- Graft material resists fraying and quickly seals suture holes, minimizing bleeding[2]
- Easier handling and suturing in comparison to bulkier velour materials[3]
- Ultra-low porosity fabric and gelatin sealing result in less leakage, weeping and blushing[2]
- Pliable, cork-shaped sewing cuff conforms to annulus, designed to minimize potential paravalvular leaks
- Titanium stiffening ring allows valve rotatability in-situ
- Orientation markers provide easy visual suture positioning

Clinical Consideration

- Graft is infused with minimally crosslinked gelatin that does not alter the healing process, encouraging a secure neo-intimal attachment with reduced inflammatory response[4]
- Gelatin hydrolyzes within 14 days[5]
- Sinus of Valsalva reproduces the native sinus, reducing required dissection of and stress on the coronary anastomoses[1]
- Sinus design encourages natural formation of systolic vortex[6]
- Full-sized standard aortic valve provides favorable hemodynamics[7]
- Very low rate of thromboembolic events[8,9]
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape

CARBOMEDICS CARBO-SEAL

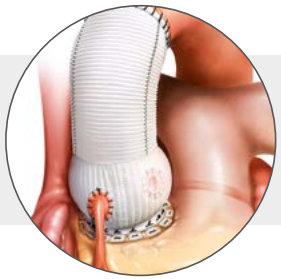
Implantation Consideration

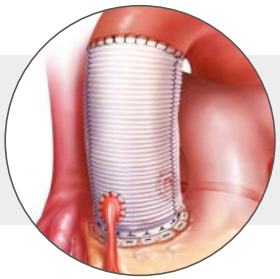
- Pliable, cork-shaped sewing cuff conforms to annulus, designed to minimize potential paravalvular leaks
- Graft material resists fraying and quickly seals suture holes, minimizing bleeding[2]
- Easier handling and suturing in comparison to bulkier velour materials[3]
- Ultra-low porosity fabric and gelatin sealing result in less leakage, weeping and blushing[2]
- Titanium stiffening ring allows rotatability in-situ
- Orientation markers provide easy visual suture positioning

Clinical Consideration

- Graft is infused with minimally crosslinked gelatin that does not alter the healing process, encouraging a secure neo-intimal attachment with reduced inflammatory response[4]
- Collagen gel hydrolyzes within 14 days
- Full-sized standard aortic valve provides favorable hemodynamics[7]
- Very low rate of thromboembolic events[8,9]
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape

Valve Placement *in-situ*



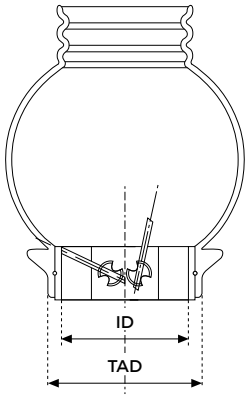


1. *De Paulis, et al., One-year appraisal of a new aortic root conduit with sinuses of Valsalva. - J Thorac Cardiovasc Surg 2002;123:33-9.*
2. *CORCYM data on file.*
3. *Kadoba et al., Experimental comparison of albumin-sealed and gelatin-sealed knitted Dacron conduits. - J Thorac and Cardiovasc Surg 1992;103:1059-67.*
4. *Drury et al., Experimental and Clinical Experience with a Gelatin Impregnated Dacron Prosthesis. - Ann Vasc Surg, 1987, 7, 542-547.*
5. *Cavallaro, A., Sciacca, V., Cisternino, S., Di Marzo, L., Mingoli, A., Abrize, C., Gallo, P., Pollock, J.G., Maini, R., 1986. Pretreatment with gelatin of Dacron Grafts. Experimental Research. Policlinico Sez Chir. Vol. 93 pp. 275-283 [article in italian].*
6. *De Paulis et al., A New Aortic Dacron Conduit for Surgical Treatment of Aortic Root Pathology. - Ital Heart J 2000, 1 (7), 457-463.*
7. *Bouchard et al., Twenty-Year Experience With the CarboMedics Mechanical Valve Prosthesis. - Ann Thorac Surg 2014;97:816–23.*
8. *SM. Langley et al., Replacement of the proximal aorta and aortic valve using a composite bileaflet prosthesis and gelatin-impregnated polyester graft (Carbo-seal): early results in 143 patients. - J Thorac Cardiovasc Surg 1999;118:1014-20*
9. *De Paulis et al., Opening and closing characteristics of the aortic valve after valve-sparing procedure usign a new aortic root conduit. - Ann Thorac Surg 2001;72:487-494.*

Technical claims are supported by CORCYM data on file.

CARBOMEDICS CARBO-SEAL VALSALVA

ASCENDING AORTIC PROSTHESIS (AAP) Sizes 21-29 mm

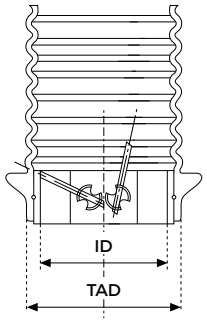


Product specifications

Nominal size	TAD	ID	GOA	Graft ID	Catalog N.
21	21.8	16.7	2.07	24	CP-021
23	23.8	18.5	2.56	26	CP-023
25	25.8	20.5	3.16	28	CP-025
27	27.8	22.5	3.84	30	CP-027
29	29.8	24.2	4.44	32	CP-029

CARBOMEDICS CARBO-SEAL

ASCENDING AORTIC PROSTHESIS (AAP) Sizes 21-33 mm



Product specifications

Nominal size	TAD	ID	GOA	Graft ID	Catalog N.
21	21.8	16.7	2.07	24	AP-021
23	23.8	18.5	2.56	26	AP-023
25	25.8	20.5	3.16	28	AP-025
27	27.8	22.5	3.84	30	AP-027
29	29.8	24.2	4.44	32	AP-029
31	31.8	24.2	4.44	34	AP-031
33	33.8	24.2	4.44	34	AP-033

Legend

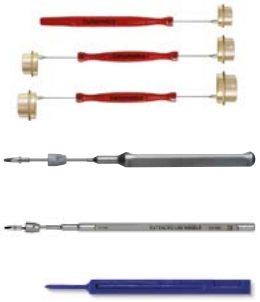
TAD = Tissue Annulus Diameter (mm) ID = Internal Diameter (mm) GOA = Geometric Orifice Area (cm^2)

Aortic mechanical valves ACCESSORIES

CARBOMEDICS TOP HAT

Aortic Mechanical Bileaflet Valve

Article	Code	Description
Empty tray	TR-101	1 empty tray
Sizer set	SAS-200	3 sizers 19mm, 21-23mm, 25-27mm
Uni Handle	ICV0664	1 Universal Bendable Handle
Extended Uni Handle	ICV1342	1 Universal Extended Bendable Handle
Occluder tester	VT-100	10 disposable occluder tester (provided sterile)



CARBOMEDICS REDUCED, ORBIS, STANDARD

Aortic Mechanical Bileaflet Valve

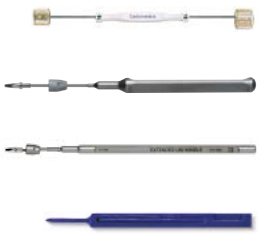
Article	Code	Description
Empty tray	TR-101	1 empty tray
Sizer set	VS-200	4 sizers 19-21mm, 23-25mm 27-29mm, 31-33mm
Uni Handle	ICV0664	1 Universal Bendable Handle
Extended Uni Handle	ICV1342	1 Universal Extended Bendable Handle
Occluder tester	VT-100	10 disposable occluder tester (provided sterile)

Small size Mechanical Valves ACCESSORIES

CARBOMEDICS STANDARD SMALL SIZES

Aortic Mechanical Bileaflet Valve

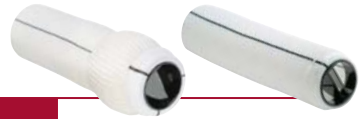
Article	Code	Description
Empty tray	TR-101	1 empty tray
Sizer	VS2-1618	1 sizer (16-18mm)
Uni Handle	ICV0664	1 Universal Bendable Handle
Extended Uni Handle	ICV1342	1 Universal Extended Bendable Handle
Occluder tester	VT-100	10 disposable occluder tester (provided sterile)



Aortic mechanical conduits ACCESSORIES

CARBOMEDICS CARBO-SEAL VALSALVA, CARBO-SEAL

Aortic Mechanical Conduit



Article	Code	Description
Empty tray	TR-101	1 empty tray
Sizer set	VS-200	4 sizers 19-21mm, 23-25mm 27-29mm, 31-33mm
Rotators set	AR-150	6 aortic rotators
Occluder tester	VT-100	10 disposable occluder tester (provided sterile)

Mitral Mechanical Valve ACCESSORIES

CARBOMEDICS OPTIFORM, ORBIS, STANDARD

Mitral Mechanical Bileaflet Valve

Article	Code	Description
Empty tray	TR-101	1 empty tray
Sizer set	VS-200	4 sizers 19-21mm, 23-25mm 27-29mm, 31-33mm
Uni Handle	ICV0664	1 Universal Bendable Handle
Extended Uni Handle	ICV1342	1 Universal Extended Bendable Handle
Occluder tester	VT-100	10 disposable occluder tester (provided sterile)

CARBOMEDICS STANDARD SMALL SIZES

Mitral Mechanical Bileaflet Valve

Article	Code	Description
Empty tray	TR-101	1 empty tray
Sizer	VS2-1618	1 sizer (16-18mm)
Sizer set	VS-200	4 sizers 19-21mm, 23-25mm 27-29mm, 31-33mm
Uni Handle	ICV0664	1 Universal Bendable Handle
Extended Uni Handle	ICV1342	1 Universal Extended Bendable Handle
Occluder tester	VT-100	10 disposable occluder tester (provided sterile)

CARBOMEDICS™ FAMILY

MECHANICAL
HEART VALVES

INTENDED USE/INDICATIONS

Europe, Australia: The Carbomedics Prosthetic Heart Valve is intended for use as a replacement valve in patients with diseased, damaged, or malfunctioning aortic or mitral heart valve.
The Carbomedics Prosthetic Heart Valve Aortic/Mitral models, 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.

US, Canada: The Carbomedics Prosthetic Heart Valves are indicated as a replacement for human cardiac valves that are malfunctioning as a result of acquired or congenital disease, or as a replacement of a previously implanted prosthesis.

KEY CONTRAINDICATIONS

There are no absolute contraindications to the use of the Carbomedics Prosthetic Heart Valve. The mechanical heart valves are contraindicated or difficult to apply in patients unable to tolerate long term anticoagulation therapy or for whom this type of therapy is difficult to carry out.

KEY WARNINGS

For single use only. Safety and effectiveness of the Carbomedics valve has not been demonstrated for valve replacement in the pulmonic and tricuspid positions. Handle the valve only with accessories provided by the manufacturer specifically for the Carbomedics valve. Only use sizers provided by the manufacturer specifically for the Carbomedics valve.

TOP POTENTIAL SIDE EFFECTS

The risks or potential adverse events associated with cardiac valve replacement with a prosthetic mechanical heart valve include: cardiac arrhythmias, death, endocarditis, hemolysis, anti-coagulation related hemorrhage, leaflet entrapment by tissue ingrowth or impingement on anatomic structures, intravalvular and/or paravalvular leak, prosthetis thrombosis, thromboembolism, structural valve deterioration.

MRI conditional

For professional use. Please contact us through our website to receive instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events. Not approved in all geographies. Consult your labeling.

CORCYM
WE TAKE LIFE TO HEART

Manufactured by:

Sorin Group Italia Srl
Via per Crescentino sn
13040 Saluggia (VC) Italy
Tel: +39 0161 487800

CE 0123

corcym
.com

CC-MK-00003 A

CORCYM
WE TAKE LIFE TO HEART

DICHIARAZIONE DI CONFORMITÀ CE
EC DECLARATION OF CONFORMITY

La sottoscritta **Corcym S.r.l.** (Via Crescentino sn, 13040 Saluggia, VC – Italia) dichiara sotto la propria responsabilità di Fabbricante che i prodotti sotto elencati sono conformi alle disposizioni applicabili della Direttiva del Consiglio 93/42/CEE e del Regolamento (UE) della Commissione no. 207/2012.

*We, the undersigned **Corcym S.r.l.** (Via Crescentino sn, 13040 Saluggia, VC – Italy) declare under our sole responsibility as Manufacturer that the products identified below conform to the relevant provisions of Council Directive 93/42/EEC and Commission Regulation (EU) no. 207/2012.*

Identificazione prodotto *Product identification*				
Prodotto *Product*	**Taglia** *Size*	**Codice prodotto (REF)** *Catalogue number (REF)*	**Codice d'ordine** *Ordering code*	**Classe** *Class*
Bicarbon Fitline LFA Aortic	19	ART19LFA	ICV0917	III
	21	ART21LFA	ICV0918	
	23	ART23LFA	ICV0919	
	25	ART25LFA	ICV0920	
	27	ART27LFA	ICV0921	
	29	ART29LFA	ICV0922	
	31	ART31LFA	ICV0923	
Bicarbon Fitline LFM Mitral	19	MTR19LFM	ICV0924	III
	21	MTR21LFM	ICV0925	
	23	MTR23LFM	ICV0926	
	25	MTR25LFM	ICV0927	
	27	MTR27LFM	ICV0928	
	29	MTR29LFM	ICV0929	
	31	MTR31LFM	ICV0930	
	33	MTR33LFM	ICV0931	
Bicarbon Slimline LSA Aortic	17	ART17LSA	ICV0934	III
	19	ART19LSA	ICV0935	
	21	ART21LSA	ICV0936	
	23	ART23LSA	ICV0937	
	25	ART25LSA	ICV0938	
	27	ART27LSA	ICV0939	
Bicarbon Overline Aortic	16	ART16LOV	ICV0870	III
	18	ART18LOV	ICV0871	
	20	ART20LOV	ICV0872	
	22	ART22LOV	ICV0873	
	24	ART24LOV	ICV0874	

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem MLD IDNO 1004600028048 REPUBLICA MOLDOVA

CORCYM SRL
Sede Legale
Via Benigno Crespi 17 – 20159 Milano – Italy

Sede Amministrativa
Via Benigno Crespi 17 – 20159 Milano – Italy
Via per Crescentino sn – 13040 Saluggia (VC) Italy

Stabilimento
Via Crescentino sn – 13040 Saluggia (VC) Italy

PEC: CORCYM@LEGALMAIL.IT

Capitale Sociale: € 2.000.000,00
R.E.A. MILANO 2608814
Registro Imprese di Milano N.11515960968
Cod. Fiscale / Part. IVA 11515960968

ISO Code: IT11515960968
corcym.com

CORCYM
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Informazioni relative alla valutazione della conformità *Conformity assessment information*		
Organismo Notificato *Notified Body*	**Procedura di valutazione conformità** *Conformity assessment procedure*	**Numero certificati CE** *CE Certificates number*
TÜV SÜD Product Service GmbH (0123) Ridlerstr. 65, D-80339 München, GERMANY	Dichiarazione di Conformità CE di cui all' Allegato II, Direttiva 93/42/CEE (Sistema completo di assicurazione di qualità) *EC Declaration of Conformity set out in Annex II, Directive 93/42/EEC (Full Quality Assurance)*	- Annex II section 4: G7 001664 0034 Rev. 01 Valid until: 2024-05-26 - Annex II excluding section 4: G1 001664 0038 Rev.01 Valid until: 2024-05-26

La presente Dichiarazione di Conformità è valida per i dispositivi prodotti presso l'officina sita in Via Crescentino sn, 13040 Saluggia, VC – Italia e descritti nel Technical File TF-08.

This Declaration of Conformity is valid for the medical devices manufactured in the facility of Via Crescentino sn, 13040 Saluggia, VC – Italy and described in the Technical File TF-08.

La presente Dichiarazione di Conformità è valida a partire dalla data di firma e fino alla prima data di scadenza dei certificati sopra indicati.

This Declaration of Conformity is valid from the signature date until the earliest expiry date of the certificates identified above.

Saluggia, June 1st, 2021

Adelina Chiaravalloti
Director, Regulatory Affairs and Clinical Evaluation
Corcym S.r.l.

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem MLD IDNO 1010 REPUBLICA MOLDOVA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 001664 0038 Rev. 01

Manufacturer:

Corcym S.r.l.
Via Crescentino sn
13040 Saluggia (VC)
ITALY

Product Category(ies): **Mechanical Heart Valves**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 001664 0038 Rev. 01

Report No.: ITA1663134

Valid from: 2021-05-25
Valid until: 2024-05-26

Date, 2021-05-10

Christoph Dicks
Head of Certification/Notified Body

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. Biosistem IDNO 1010600028048 REPUBLICA MOLDOVA

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 001664 0034 Rev. 01

Manufacturer: **Corcym S.r.l.**
Via Crescentino sn
13040 Saluggia (VC)
ITALY

Product: **Heart Valves**
Sorin Mechanical Heart Valves

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:G7 001664 0034 Rev. 01

Report no.: 713206835

Valid from: 2021-05-25
Valid until: 2024-05-26

Date, 2021-05-10

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 001664 0034 Rev. 01

Model(s):

Bicarbon Fitline
Bicarbon Slimline
Bicarbon Overline

Parameters:

Model Name	Product codes
Bicarbon Fitline LFA Aortic	ICV0917/ART19LFA
	ICV0918/ART21LFA
	ICV0919/ART23LFA
	ICV0920/ART25LFA
	ICV0921/ART27LFA
	ICV0922/ART29LFA
	ICV0923/ART31LFA
Bicarbon Fitline LFM Mitral	ICV0924/MTR19LFM
	ICV0925/MTR21LFM
	ICV0926/MTR23LFM
	ICV0927/MTR25LFM
	ICV0928/MTR27LFM
	ICV0929/MTR29LFM
	ICV0930/MTR31LFM
	ICV0931/MTR33LFM
Bicarbon Slimline LSA Aortic	ICV0934/ART17LSA
	ICV0935/ART19LSA
	ICV0936/ART21LSA
	ICV0937/ART23LSA
	ICV0938/ART25LSA
	ICV0939/ART27LSA
Bicarbon Overline Aortic	ICV0870/ART16LOV
	ICV0871/ART18LOV
	ICV0872/ART20LOV
	ICV0873/ART22LOV
	ICV0874/ART24LOV

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. Biosistem MLD IDNO 1010600028048 REPUBLICA MOLDOVA

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CORCYM
WE TAKE LIFE TO HEART

DICHIARAZIONE DI CONFORMITÀ CE
EC DECLARATION OF CONFORMITY

La sottoscritta **Corcym S.r.l.** (Via Crescentino sn, 13040 Saluggia, VC - Italia) dichiara sotto la propria responsabilità di Fabbricante che i prodotti sotto elencati sono conformi alle disposizioni applicabili della Direttiva del Consiglio 93/42/CEE e del Regolamento (UE) della Commissione no. 207/2012.

We, the undersigned ***Corcym S.r.l.*** *(Via Crescentino sn, 13040 Saluggia, VC - Italy) declare under our sole responsibility as Manufacturer that the products identified below conform to the relevant provisions of Council Directive 93/42/EEC and Commission Regulation (EU) no. 207/2012.*

Identificazione prodotto *Product identification*			
Prodotto *Product*	**Taglia** *Size*	**Codice prodotto (REF)** *Catalogue number (REF)*	**Classe** *Class*
Carbomedics Standard Aortic	16	A5-016	III
	18	A5-018	
	19	A5-019	
	21	A5-021	
	23	A5-023	
	25	A5-025	
	27	A5-027	
	29	A5-029	
	31	A5-031	
Carbomedics Standard Mitral	16	M7-016	III
	18	M7-018	
	21	M7-021	
	23	M7-023	
	25	M7-025	
	27	M7-027	
	29	M7-029	
	31	M7-031	
	33	M7-033	
Carbomedics Reduced Aortic	19	R5-019	III
	21	R5-021	
	23	R5-023	
	25	R5-025	
	27	R5-027	
	29	R5-029	
Carbomedics Supra-Annular Aortic (Top Hat)	19	S5-019	III
	21	S5-021	
	23	S5-023	
	25	S5-025	
	27	S5-027	

(cont.)

CORCYM SRL
Sede Legale
Via Benigno Crespi 17 - 20159 Milano - Italy

Sede Amministrativa
Via Benigno Crespi 17 - 20159 Milano - Italy
Via per Crescentino sn - 13040 Saluggia (VC) Italy
Tel.+39 0161 487.1 - Fax +39 0161 487.545

Stabilimento
Via Crescentino sn - 13040 Saluggia (VC) Italy

PEC: CORCYM@LEGALMAIL.IT

Capitale Sociale: € 2.000.000,00
R.E.A. MILANO 2608814
Registro Imprese di Milano N.11515960968
Cod. Fiscale / Part. IVA 11515960968

ISO Code: IT11515960968
corcym.com

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Identificazione prodotto ***Product Identification***			
Prodotto *Product*	**Taglia** *Size*	**Codice prodotto (REF)** *Catalogue number (REF)*	**Classe** *Class*
Carbomedics Orbis Aortic	19	A1-019	III
	21	A1-021	
	23	A1-023	
	25	A1-025	
	27	A1-027	
	29	A1-029	
	31	A1-031	
Carbomedics Orbis Mitral	21	M2-021	III
	23	M2-023	
	25	M2-025	
	27	M2-027	
	29	M2-029	
	31	M2-031	
	33	M2-033	
Carbomedics Optiform Mitral	21	F7-021	III
	23	F7-023	
	25	F7-025	
	27	F7-027	
	29	F7-029	
	31	F7-031	
	33	F7-033	

Informazioni relative alla valutazione della conformità ***Conformity assessment information***		
Organismo Notificato *Notified Body*	**Procedura di valutazione conformità** *Conformity assessment procedure*	**Numero certificati CE** *CE Certificates number*
TÜV SÜD Product Service GmbH (0123) Ridlerstr. 65, D-80339 München, GERMANY	Dichiarazione di Conformità CE di cui all' Allegato II, Direttiva 93/42/CEE (Sistema completo di assicurazione di qualità) *EC Declaration of Conformity set out in Annex II, Directive 93/42/EEC (Full Quality Assurance)*	- Annex II section 4: G7 001664 0035 Rev. 01 Valid until: 2024-05-26 - Annex II excluding section 4: G1 001664 0038 Rev.01 Valid until: 2024-05-26

La presente Dichiarazione di Conformità è valida per i dispositivi prodotti presso l'officina sita in Via Crescentino sn, 13040 Saluggia, VC – Italia e descritti nel Technical File TF-03.

This Declaration of Conformity is valid for the medical devices manufactured in the facility of Via Crescentino sn, 13040 Saluggia, VC – Italy and described in the Technical File TF-03.

SOCIETATEA CU RĂSPUNDERE LIMITATĂ
S.R.L.
IDNO 1010800028048
REPUBLICA MOLDOVA

La presente Dichiarazione di Conformità è valida a partire dalla data di firma e fino alla prima data di scadenza dei certificati sopra indicati.

This Declaration of Conformity is valid from the signature date until the earliest expiry date of the certificates identified above.

Saluggia, June 1st, 2021

Adelina Chiaravalloti

Director, Regulatory Affairs and Clinical Evaluation
Corcym S.r.l.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 001664 0038 Rev. 01

Manufacturer:

Corcym S.r.l.
Via Crescentino sn
13040 Saluggia (VC)
ITALY

Product Category(ies): **Mechanical Heart Valves**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II.
This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 001664 0038 Rev. 01

Report No.: ITA1663134

Valid from: 2021-05-25
Valid until: 2024-05-26

Date, 2021-05-10

Christoph Dicks
Head of Certification/Notified Body

SOCIETATEA CU RĂSPUNDERE LIMITATĂ
BioSistem SRL
IDNO 1010600028048
REPUBLICA MOLDOVA

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TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 001664 0035 Rev. 01

Manufacturer: **Corcym S.r.l.**
Via Crescentino sn
13040 Saluggia (VC)
ITALY

Product: **Heart Valves**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:G7 001664 0035 Rev. 01

Report no.: 713206835

Valid from: 2021-05-25
Valid until: 2024-05-26

Date, 2021-05-10

Christoph Dicks
Head of Certification/Notified Body

SOCIETATEA CU RĂSPUNDERE LIMITATĂ
S.R.L.
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TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 001664 0035 Rev. 01

Model(s): Carbomedics Mechanical Bileaflet Heart

Parameters:

Product Name	Size	Product codes
Carbomedics Standard Aortic	16	A5-016
	18	A5-018
	19	A5-019
	21	A5-021
	23	A5-023
	25	A5-025
	27	A5-027
	29	A5-029
	31	A5-031
Carbomedics Standard Mitral	16	M7-016
	18	M7-018
	21	M7-021
	23	M7-023
	25	M7-025
	27	M7-027
	29	M7-029
	31	M7-031
	33	M7-033
Carbomedics Reduced Aortic	19	R5-019
	21	R5-021
	23	R5-023
	25	R5-025
	27	R5-027
	29	R5-029
Carbomedics Supra-Annular Aortic	19	S5-019
	21	S5-021
	23	S5-023
	25	S5-025
	27	S5-027
Carbomedics Orbis Aortic	19	A1-019
	21	A1-021
	23	A1-023

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TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 001664 0035 Rev. 01

	25	A1-025
	27	A1-027
	29	A1-029
	31	A1-031
Carbomedics Orbis Mitral	21	M2-021
	23	M2-023
	25	M2-025
	27	M2-027
	29	M2-029
	31	M2-031
	33	M2-033
Carbomedics Optiform Mitral	21	F7-021
	23	F7-023
	25	F7-025
	27	F7-027
	29	F7-029
	31	F7-031
	33	F7-033

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