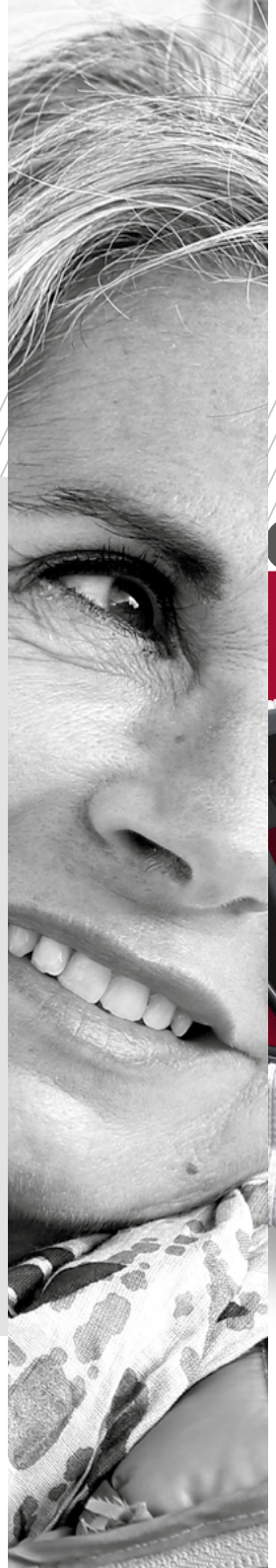


MECHANICAL
HEART VALVES

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.

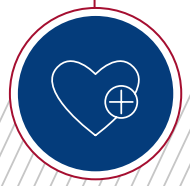
Choosing a Carbomedics mechanical valve today means choosing a reliable solution with proven clinical results in over 20 years of follow up and an extremely low incidence of post-operative structural failures reported in over 1 million implants.*[1]

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

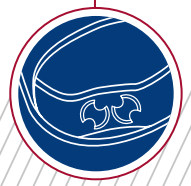
1. *Bouchard et al., Twenty-Year Experience With the CarboMedics Mechanical Valve Prosthesis. Ann Thorac Surg 2014;97:816–23.*
2. *Nishida et al., Single-institution, 22-year follow-up of 786 CarboMedics mechanical valves used for both primary surgery and reoperation. J Thorac Cardiovasc Surg 2014;147:1493-8).*

Tailored options for desirable Patient outcomes[1]

Tailored safety and durability[1]

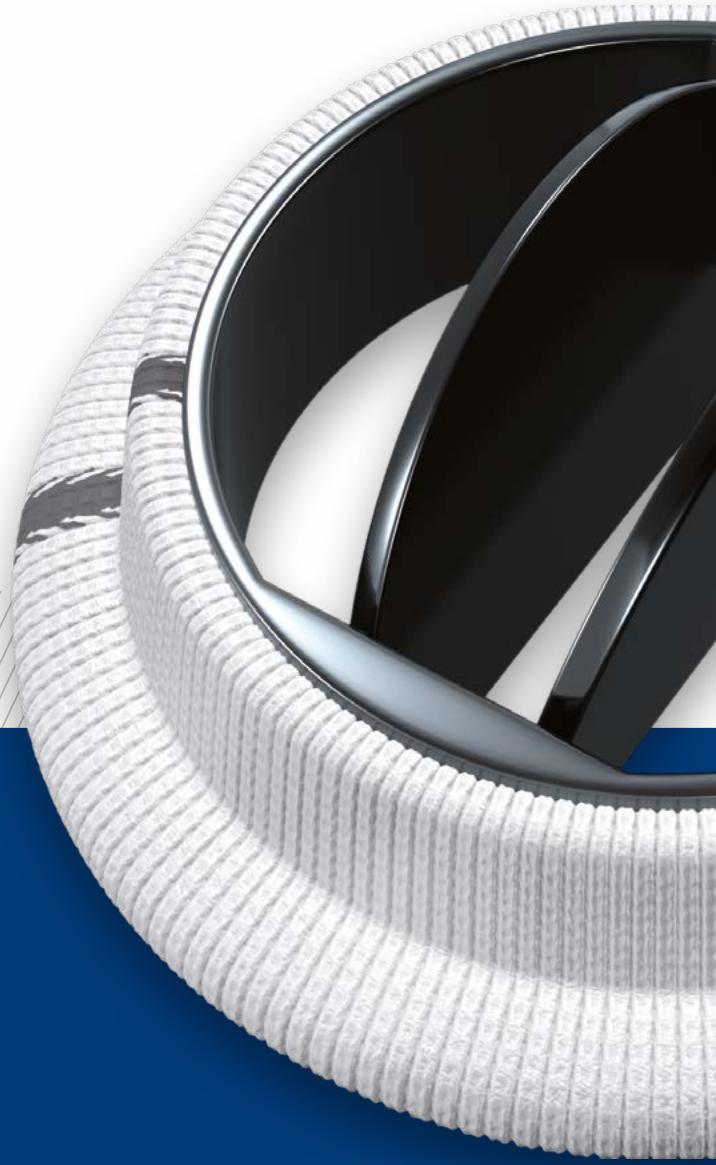


Tailored performance for desirable clinical outcomes



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]

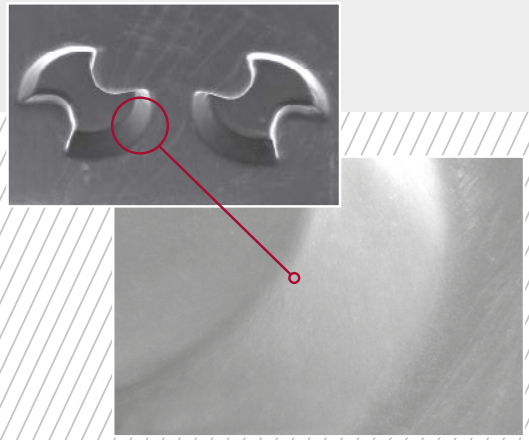
Historically focused on biocompatible materials

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.

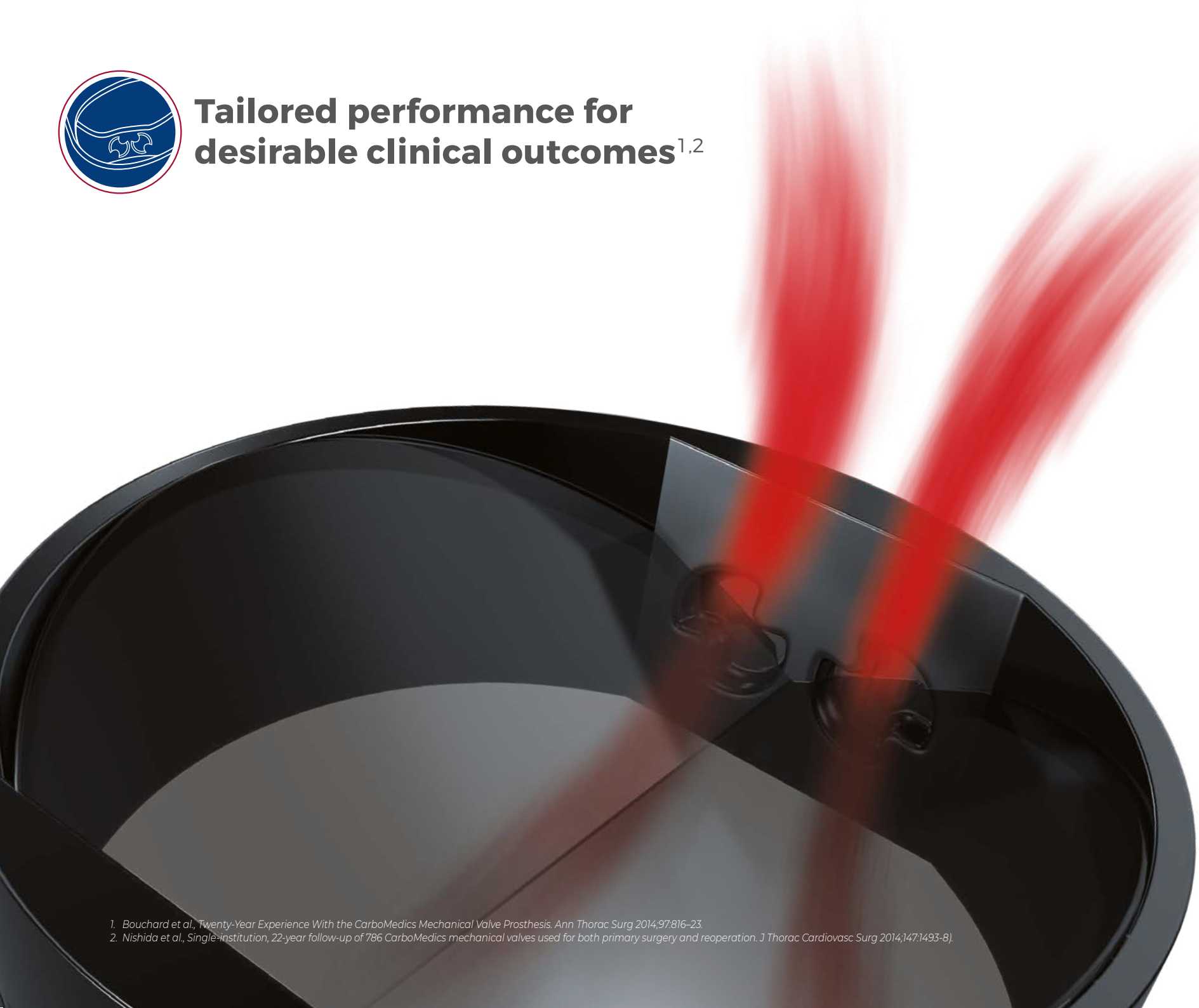
* According to ISO 5840:2015 requirements, CORCYM post-market surveillance and published experience on long term results (Bouchard et al., Ann Thorac Surg 2014;97:816-23).

** 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]

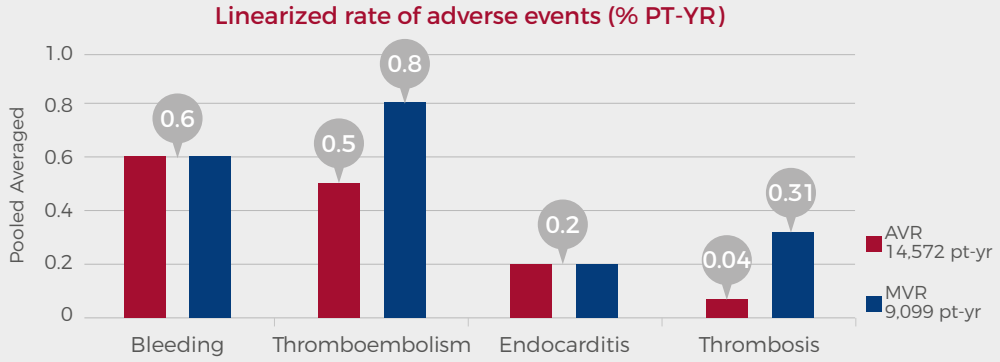
In its long clinical history, Carbomedics valves have demonstrated great levels of safety and reliability, with a considerably low incidence of complications and post-operative structural failures.[1,3]

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]

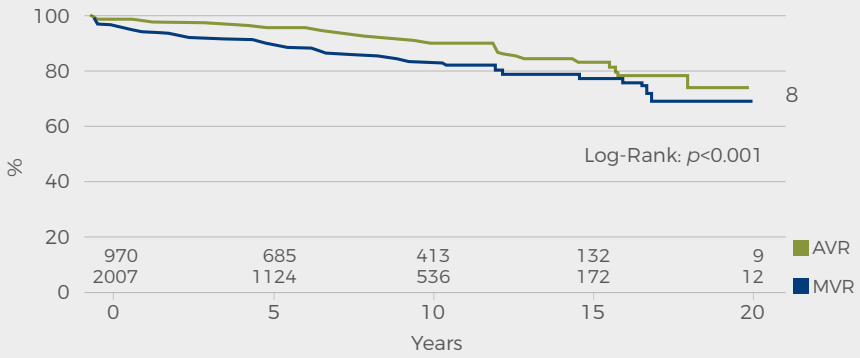
Over **twenty years** of published follow up reports "excellent functional results".[1]



* 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.

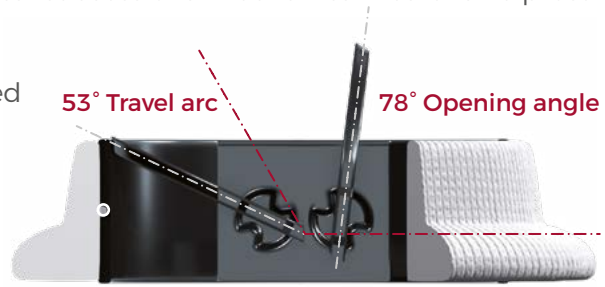
** CORCYM post-market surveillance classifies the risk of structural valve failure *P* as improbable ($10\text{-}6 < P \leq 10\text{-}5$).

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]

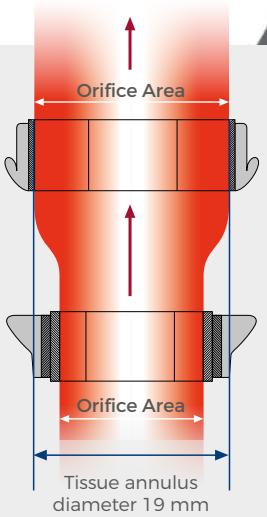
One of the key factors influencing the clinical success of a mechanical heart valve prosthesis is its hemodynamic efficiency.

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]



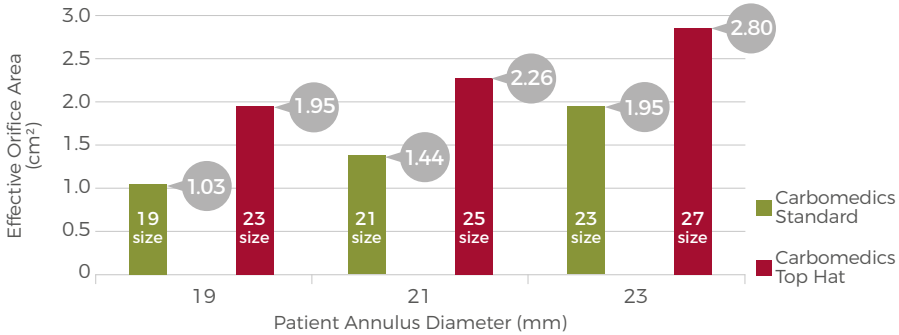
100% ORIFICE TO ANNULUS MATCH

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

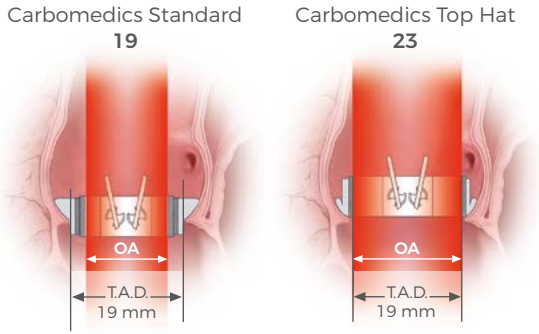
1. *Aagard et al., Midterm Evaluation of Hemodynamics of the Top Hat Supraannular Aortic Valve. - Asian Cardiovasc Thorac Ann 2010;18:1–5.*
2. *Bernal et al., The CarboMedics Valve: Experience With 1,049 Implants. - Ann Thorac Surg 1999;67:1299-303.*
3. *Lundblad R et al., The Carbomedics Supraannular 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.

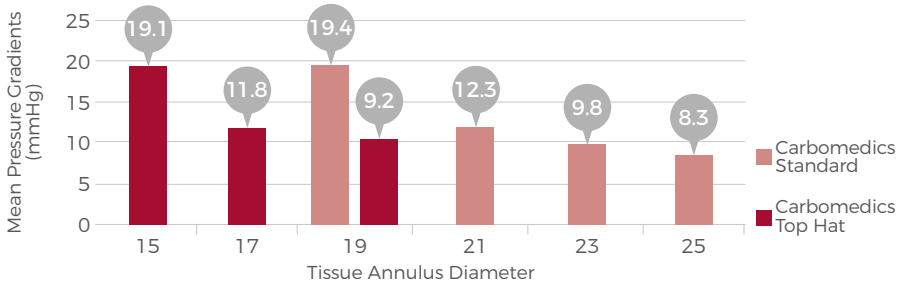
Carbomedics *in vitro* data*

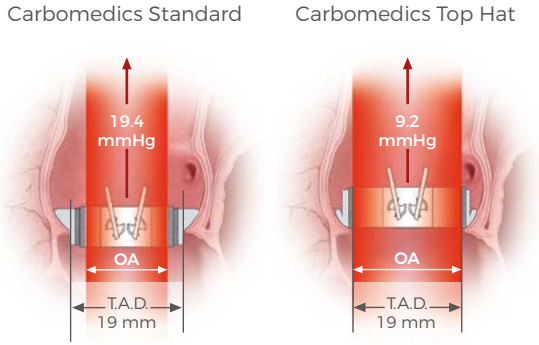


**In vitro test - 5l/min 70 bpm (Data on file at CORCYM)



Carbomedics *in vivo* data[1,2]



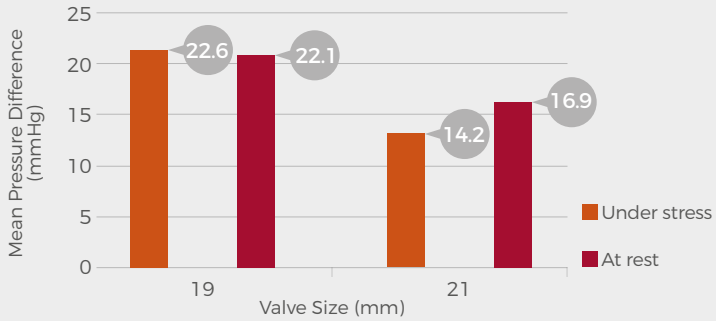


TAD: Tissue Annulus Diameter
OA: Orifice Area

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

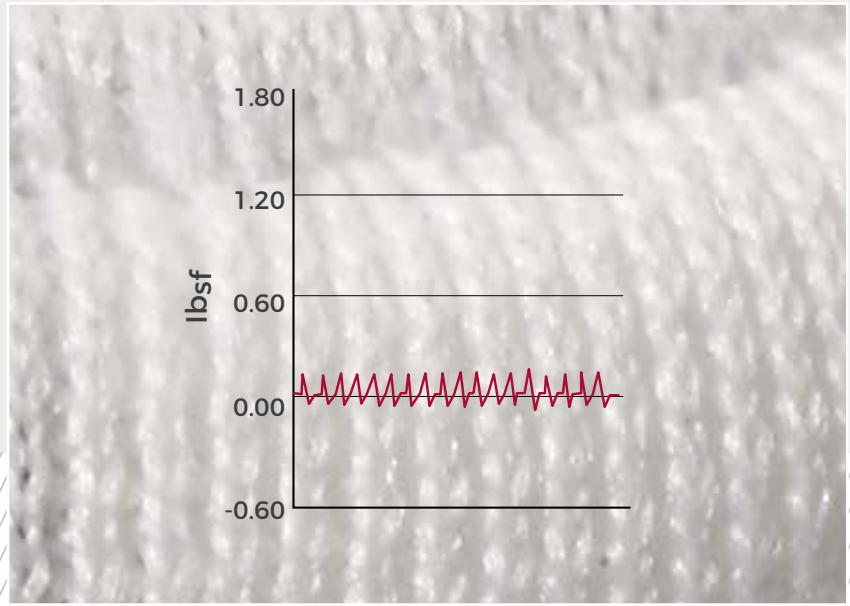
Carbomedics valves are designed for a smooth implant experience

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

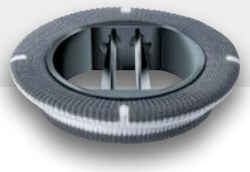
Carbomedics Standard

Carbomedics Reduced

Carbomedics Orbis

Three different mitral models

Carbomedics Standard

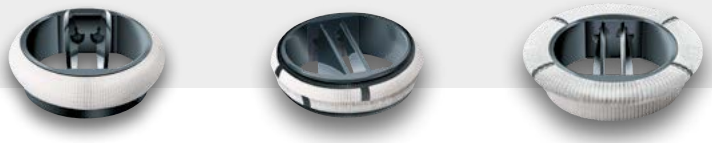


Carbomedics Optiform

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

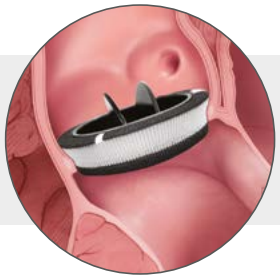
Implantation Consideration

- 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.

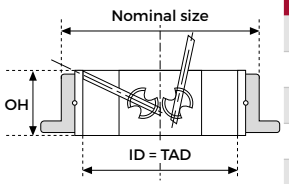
1. *Supra annular model as defined by International Standard for Cardiovascular implants - Cardiac valve Prostheses-Part 2. ISO 5840-2:2015(E).*
2. *Lundblad R et al., The Carbomedics Supraannular Top hat Valve improves prosthesis size in the Aortic Root. - J Heart Valve Dis 2001;10:196-201.*
3. *Aagard 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 TOP HAT

TOTALLY SUPRA-ANNULAR AORTIC VALVE Sizes 19-27 mm

Product specifications

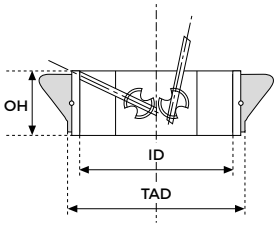


Nominal size	TAD	ID	OH	GOA	EOA	Catalog N.
19	14.7	14.7	6.2	1.59	1.0[1]	S5-019
21	16.7	16.7	6.6	2.07	1.4[2]	S5-021
23	18.5	18.5	7.3	2.56	1.9[2]	S5-023
25	20.5	20.5	7.7	3.16	2.2[2]	S5-025
27	22.5	22.5	8.4	3.84	2.9[2]	S5-027

CARBOMEDICS STANDARD

AORTIC VALVE Sizes 19-31 mm

Product specifications

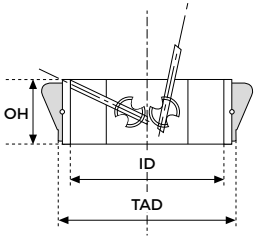


Nominal size	TAD	ID	OH	GOA	EOA[1,2]	Catalog N.
19	19.8	14.7	6.2	1.59	1.0	A5-019
21	21.8	16.7	6.6	2.07	1.5	A5-021
23	23.8	18.5	7.3	2.56	1.6	A5-023
25	25.8	20.5	7.7	3.16	2.0	A5-025
27	27.8	22.5	8.4	3.84	2.4	A5-027
29	29.8	24.2	8.7	4.44	2.6	A5-029
31	31.8	24.2	8.7	4.44	2.6	A5-031

CARBOMEDICS REDUCED

AORTIC VALVE Sizes 19-29 mm

Product specifications

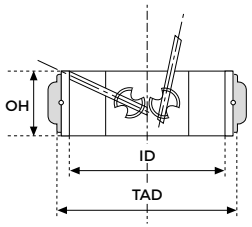


Nominal size	TAD	ID	OH	GOA	EOA[1]	Catalog N.
19	18.8	14.7	6.2	1.59	1.0	R5-019
21	20.8	16.7	6.6	2.07	1.5	R5-021
23	22.6	18.5	7.3	2.56	1.6	R5-023
25	25.0	20.5	7.7	3.16	2.0	R5-025
27	27.0	22.5	8.4	3.84	2.4	R5-027
29	29.0	24.2	8.7	4.44	2.6	R5-029

CARBOMEDICS 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.

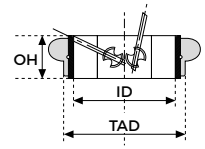
Size 16

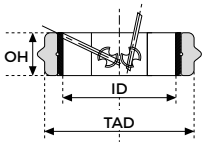
Size 18

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

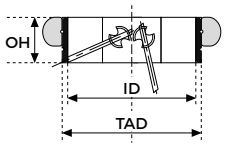
Size 18

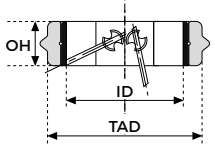
Size 21

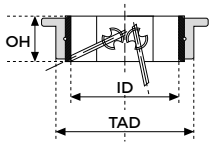
CARBOMEDICS STANDARD SMALL SIZES

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*

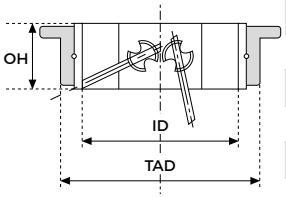
1. *Miyairi et al., Redo mitral valve replacement using the valve-on-valve method. - Asian Cardiovascular & Thoracic Annals 2015, Vol. 23(6) 707–709.*
2. *CORCYM data on file.*
3. *Aagard. Fifteen Years' Clinical Experience with the CarboMedics Prosthetic Heart Valve. - J Heart V Dis 2005 Jan;14(1): 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

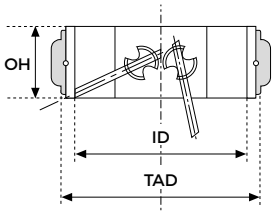


Nominal size	TAD	ID	OH	GOA	Catalog N.
23	23.8	18.5	7.3	2.56	M7-023
25	25.8	20.5	7.7	3.16	M7-025
27	27.8	22.5	8.4	3.84	M7-027
29	29.8	24.2	8.7	4.44	M7-029
31	31.8	24.2	8.7	4.44	M7-031
33	33.8	24.2	8.7	4.44	M7-033

CARBOMEDICS ORBIS

MITRAL VALVE Sizes 21-33 mm

Product specifications

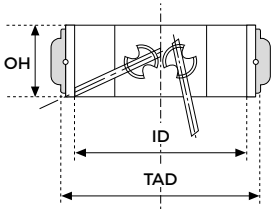


Nominal size	TAD	ID	OH	GOA	Catalog N.
21	20.8	16.7	6.6	2.07	M2-021
23	22.6	18.5	7.3	2.56	M2-023
25	25.0	20.5	7.7	3.16	M2-025
27	27.0	22.5	8.4	3.84	M2-027
29	29.0	24.2	8.7	4.44	M2-029
31	31.0	24.2	8.7	4.44	M2-031
33	33.0	24.2	8.7	4.44	M2-033

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

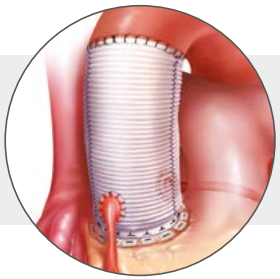
Implantation Consideration

- 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*

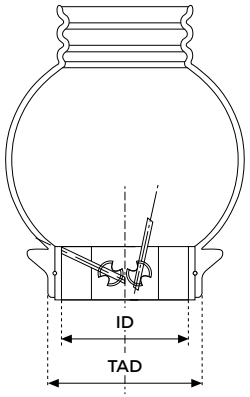


1. *De Paulis, et al., One-year appraisal of a new aortic root conduit with sinuses of Valsalva. - J Thorac Cardiovasc Surg 2002;123:33-9.*
2. *CORCYM data on file.*
3. *Kadoba et al., Experimental comparison of albumin-sealed and gelatin-sealed knitted Dacron conduits. - J Thorac and Cardiovasc Surg 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

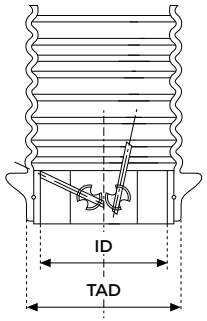


Product specifications

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

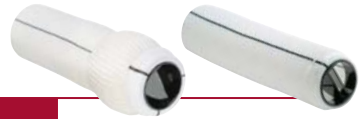
Aortic Mechanical Bileaflet Valve

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, Canada: 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. This device may also be used to replace a previously implanted aortic or mitral prosthetic 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: 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. Do not attempt to clean, resterilize, or reuse any prosthesis. Safety and effectiveness of the Carbomedics valve has not been demonstrated for valve replacement in the pulmonic and tricuspid positions.

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, infection, leaflet entrapment by tissue ingrowth or impingement on anatomic structures, leaflet escape, leaflet fracture, transvalvular or perivalvular leak, non structural dysfunction, prosthesis thrombosis, structural valve deterioration, thromboembolism, valvular insufficiency, valvular stenosis.

MRI conditional

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

CORCYM
WE TAKE LIFE TO HEART

Manufactured by:

Corcym S.r.l.
Via per Crescentino sn
13040 Saluggia (VC) Italy
Tel: +39 0161 487800

Corcym S.r.l. previously Sorin Group Italia S.r.l.

CE 0123

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