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ORDIN DE PLATA NR.: 1180 TIP.DOC. 1 :
DATA EMITERII:22 februarie 2022 :
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PLATITI: 8500-00 LEI: Opt Mii Cinci Sute lei 00 bani :
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PLATITOR: (R) 'BIOSISTEM CONTUL DE PLATI/CODUL IBAN :
MLD" SRL MD95ML000000002251429243 :
CODUL FISCAL :1010600028048 / :
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=====:
PRESTATORUL PLATITOR CODUL BANCII:
BC"Moldindconbank"S.A. fil."Invest" Chisinau :MOLDMD2X329:
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BENEFICIAR (R)Institutul d CONTUL DE PLATI/CODUL IBAN :
e Cardiologie IMSP MD98ML000000002251902161 :
CODUL FISCAL :1003600150613 / :
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=====:
PRESTATORUL BENEFICIAR CODUL BANCII:
BC"Moldindconbank"S.A. :MOLDMD2X :
=====:
DESTINATIA PLATII:Pentru garantia pentru: TIPUL TRANSFERULUI :
oferta la procedura de achizi?ie public: NORMAL/URGENT :N:
a nr. ocds-b3wdpl-MD-1643810304868 din 2: :
2.02.2022 : :
: :
: L.S. :
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CODUL TRANZACTIEI:001: :
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DATA EXECUTARII: : EMITENTULUI :
:-----:
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(semnatura electronica) :
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(semnatura manuala) :
CONTABIL-SEF: :
(semnatura manuala) :
SEMNATURA PRESTATORUL L.S. :
:-----:
MOTIVUL REFUZULUI : L.S. :
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**CERTIFICAT**  
**privind lipsa sau existența restanțelor față de bugetul public național**

Nr.  
№ **A2202726**

din  
от **18.02.2022**

**1. Destinația / Назначение**

Pentru participare la proceduri de achiziții publice

**2. Date despre contribuabil / Информация о налогоплательщике**

Denumirea Наименование	Codul fiscal / Numărul de identificare Фискальный код / Идентификационный номер
<b>BIOSISTEM MLD S.R.L.</b>	<b>1010600028048</b>
Adresa sediului de bază (strada, numărul) Адрес основного месторасположения (улица, номер)	Codul - Denumirea localității Код - Наименование населенного пункта
<b>Albisoara nr.16 bl.1 of.7</b>	<b>0150-SEC.RISCANI</b>

**3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat /**  
Подтверждение отсутствия или наличия недоимки согласно данных Информационной автоматизированной системы

La data emiterii prezentului certificat restanța față de bugetul public național constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет:  
**0,00 lei/лей.**

**4. Valabil până la / Действителен до 05.03.2022**

**5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы**

**Șef DDF Rîșcani**

**a DGDF**  
L.Ș/ M.II.

Executor: **Svetlana Slonovskaia**  
Numele și prenumele/Фамилия и имя  
tel: (022)823102



Semnătura/Подпись

**Petru GRICIUC**

Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 18.02.2022 ora 8:17:43  
cu aplicarea prevederilor pct: 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (3,52)



# BC "MOLDINDCONBANK" S.A.

## Filiala "Invest"

Republica Moldova, MD-2068  
mun. Chișinău, 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. Московской, 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 în moneda națională al **“BIOSISTEM MLD” S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML000000002251429243**.

Codul băncii MOLDMD2X329.

Director

Nina Turcan

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*

*L. Svirepova*  
semnătura

**MD 0101250**







**I.P. "AGENȚIA SERVICII PUBLICE"**

Departamentul înregistrare și licențiere a unităților de drept

**EXTRAS**

**din Registrul de stat al persoanelor juridice**

**nr. 8506 din 28.04.2021**

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 și codul fiscal: **1010600028048.**

Data înregistrării de stat: **12.08.2010.**

Sediul: **MD-2001, str. Albișoara, 16/1, ap.(of.) 7, mun. Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1 Activitatea farmaceutică;**
- 2 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 3 Acordarea asistenței medicale de către instituțiile medico-sanitare private;**
- 4 Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului;**
- 5 Întreținerea și repararea mașinilor de birou și a tehnicii de calcul;**
- 6 Consultații în domeniul sistemelor de calcul.**

Capitalul social: **5400 lei.**

**Administrator: POIATA VITALIE,**

Asociați:

- 1. POIATA VITALIE 33,40 %**
- 2. NASEDCHIN ALEXANDR 33,30 %**
- 3. KOJEVNIKOV DMITRII 33,30 %.**

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 28.04.2021.

Specialist coordonator  
tel. 022-207-840



**Lazari Aliona**



**EB 0358735**



## **Lista fondatorilor Biosistem-mld SRL**

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

# EC DESIGN EXAMINATION CERTIFICATE

This is to certify that Lloyd's Register Quality Assurance, a Notified Body under the terms of:

the Medical Devices Directive 93/42/EEC;

the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618;

did (in accordance with Annex II clause 4 of the Directive) undertake an EC Design Examination on the stated products to ensure their conformity with the requirements of the Directive which apply to them. The products identified below were shown to comply.

This certificate is issued to:

**MANUFACTURER:**

**CryoLife, Inc.**

1655 Roberts Boulevard, NW, Kennesaw, Georgia 30144, United States

**PRODUCT NAME:**

BioGlue© Surgical Adhesive

**PRODUCT DESCRIPTION:**

BioGlue Surgical Adhesive is indicated for use as an adjunct to standard methods of surgical repair (such as sutures, staples, electrocautery, and/or patches) to bond, seal, and/or reinforce soft tissue.

**DESIGN DOSSIER REFERENCE:** document #TF00007.003, revision 003, dated 31 May 2017

This Certificate is not valid for products, the design or characteristics of which have been varied from those examined. The manufacturer shall notify LRQA of any modification or changes to the products in order to maintain a valid certificate.

Certificate No: 0088/094334/00050

Current Certificate: 1 December 2017

Expiry Date: 30 November 2022

Certificate Identity Number: 10039484

LRQA Notified Body Number: 0088

Original Approvals: 25 November 1997

Approval Certificate Number: MDD – 0015237



Chris Koci

Issued By: Lloyd's Register Quality Assurance Ltd



Lloyd's  
Register

# EC DESIGN EXAMINATION CERTIFICATE CERTIFICATE 0949334 SUPPLEMENT

Certificate Identity Number: 10039484

**CryoLife, Inc.**

1655 Roberts Boulevard, NW, Kennesaw, Georgia 30144, United States

LRQA hereby confirms that the change(s) detailed below have been reviewed in conjunction with the approved Design Dossier and the EC Design Examination remains valid.

This supplement is only valid in association with the EC Design Examination certificate detailed above.

Supplement Number:	Supplement Date:	Details of amendment:
0	21 November 2017	Renewal under jobs 1222716 & 1223002

Certificate No: 0088/094334/00050

Current Certificate: 1 December 2017

Expiry Date: 30 November 2022

Certificate Identity Number: 10039484

LRQA Notified Body Number: 0088

Original Approvals: 25 November 1997

Chris Koci

Issued By: Lloyd's Register Quality Assurance Ltd





Product Service

# EC Certificate

## EC Type-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex III  
(Devices in class IIb or III)

No. G5 17 09 01664 011

**Manufacturer:****SORIN GROUP ITALIA 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 type examination has been carried out on the respective device type in accordance with MDD Annex III (4). This representative sample for the envisaged production conforms to the requirements of this Directive. For marketing of class III devices an additional Annex IV or V certificate is mandatory. For marketing of class IIb devices an additional Annex IV, V or VI certificate is mandatory. See also notes overleaf.

**Report no.:**

713114103

**Valid from:**

2017-10-17

**Valid until:**

2021-12-19

**Date,** 2017-10-16

Stefan Preiß

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

Page 1 of 2

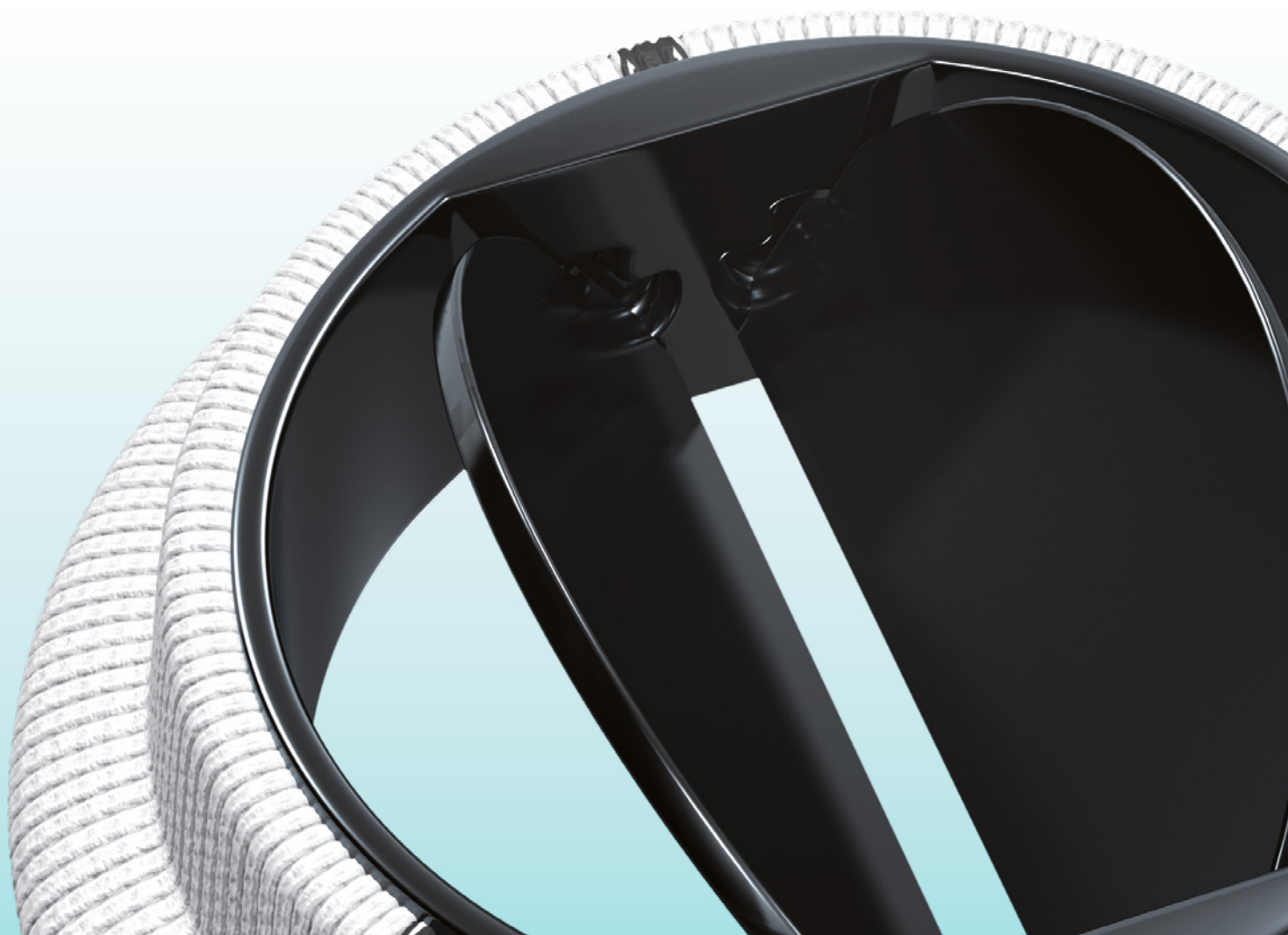


Product Service

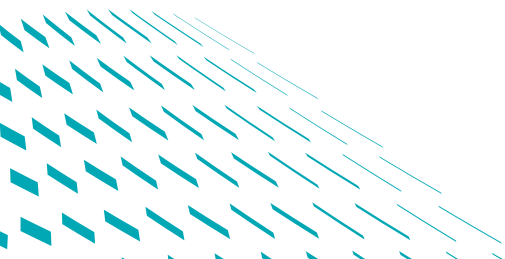
**EC Certificate****EC Type-Examination Certificate**Directive 93/42/EEC on Medical Devices (MDD), Annex III  
(Devices in class IIb or III)**No. G5 17 09 01664 011****Model(s):****Bicarbon Fitline  
Bicarbon Slimline  
Bicarbon Overline****Parameters:****Model Name**  
Bicarbon Fitline  
LFA Aortic**Product codes**ICV0917/ART19LFA  
ICV0918/ART21LFA  
ICV0919/ART23LFA  
ICV0920/ART25LFA  
ICV0921/ART27LFA  
ICV0922/ART29LFA  
ICV0923/ART31LFABicarbon Fitline  
LFM MitralICV0924/MTR19LFM  
ICV0925/MTR21LFM  
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AorticICV0870/ART16LOV  
ICV0871/ART18LOV  
ICV0872/ART20LOV  
ICV0873/ART22LOV  
ICV0874/ART24LOV**Facility(ies):**SORIN GROUP ITALIA S.r.l.  
Via Crescentino sn, 13040 Saluggia (VC), ITALY

# **CARBOMEDICS® FAMILY**

Tailored reliability  
for patients and surgeons



**Adult and Pediatric bileaflet mechanical heart valves**



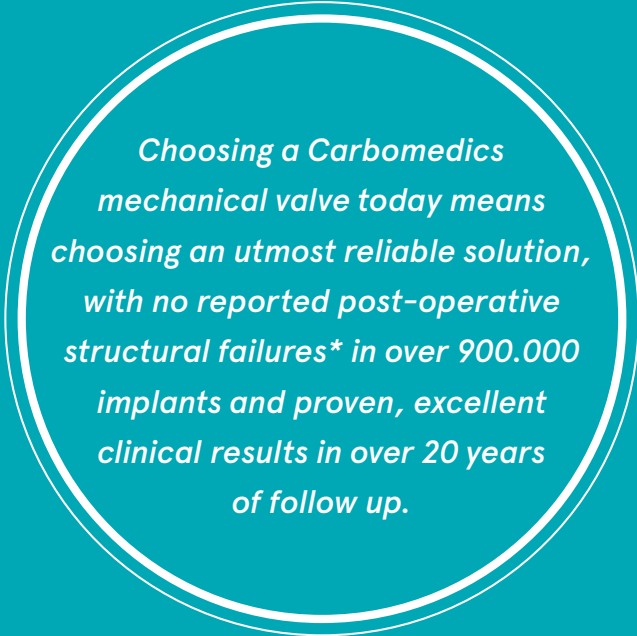


## Tailored options for better patient outcomes

With its Carbomedics line of products LivaNova offers cardiac surgeons and patients a complete set of mechanical heart valve solutions to reliably treat even the most challenging cases.

The Carbomedics name is intrinsically linked to the historical development of mechanical heart valves. Carbomedics is well recognized for having pioneered and mastered pyrolytic Carbon technology for prosthetic devices in the late 1960's, supplying pyrolite components for over 2 million valves manufactured by 14 different companies worldwide. Carbomedics has also contributed to the design and manufacturing of 17 types of valves for a number of companies.

Based on this great expertise and with the clear mission of providing highly reliable and technologically advanced solutions, in 1986 Carbomedics introduced to the market the first 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 and compelling set of solutions that offer surgeons the maximum flexibility while treating their patients.



*Choosing a Carbomedics  
mechanical valve today means  
choosing an utmost reliable solution,  
with no reported post-operative  
structural failures\* in over 900.000  
implants and proven, excellent  
clinical results in over 20 years  
of follow up.*

\* No reported structural valve failure in the published scientific literature. None of the events reported to LivaNova Quality System has been classified as structural valve failure upon completion of the analysis.

Tailored  
safety and durability



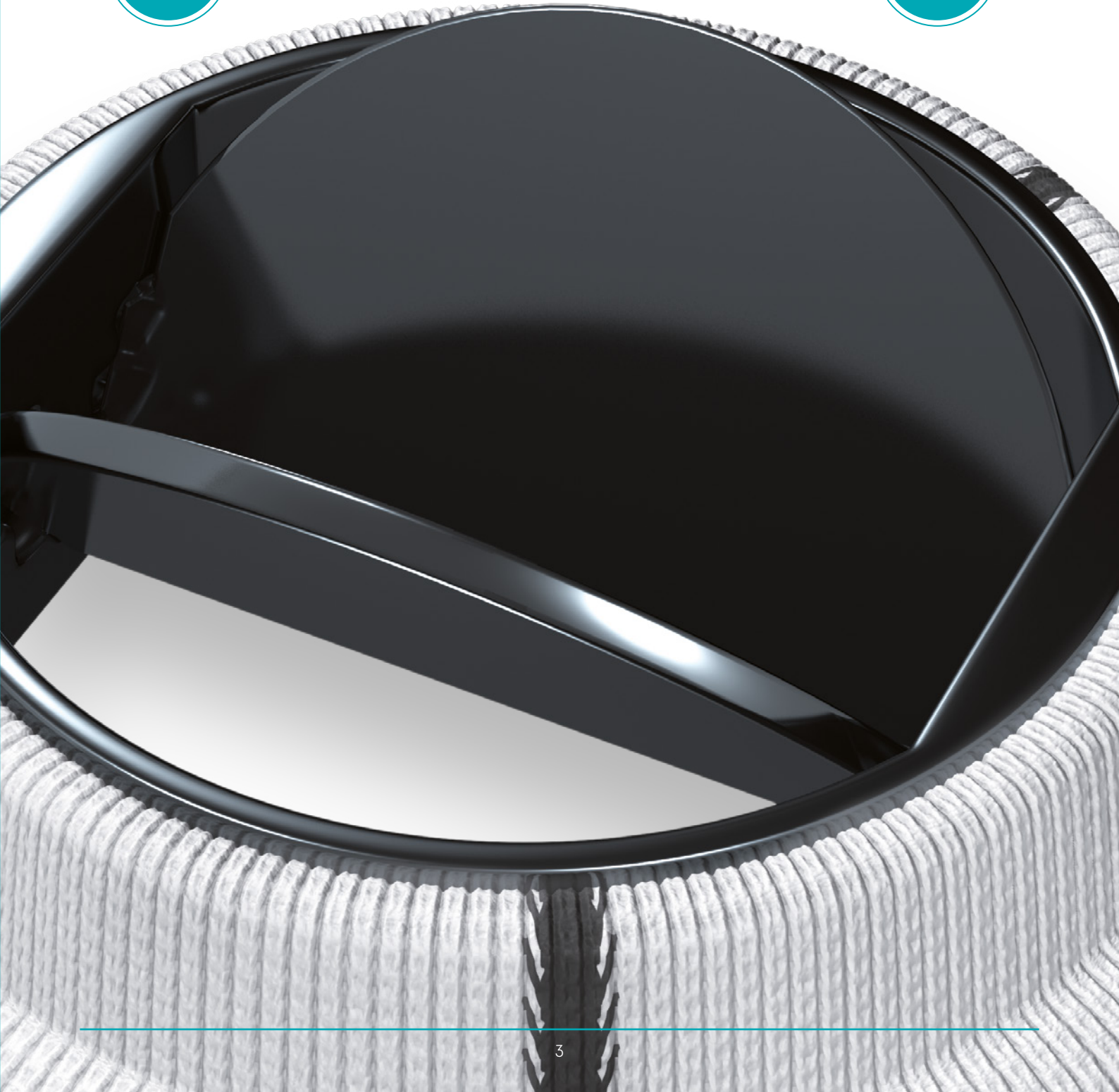
Tailored performance  
for excellent clinical  
outcomes



Tailored  
ease of implant



Tailored solutions  
for patients and surgeons





## Tailored safety and durability

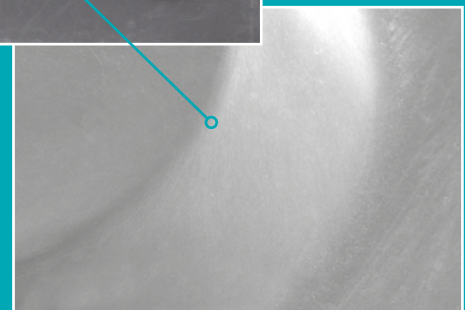
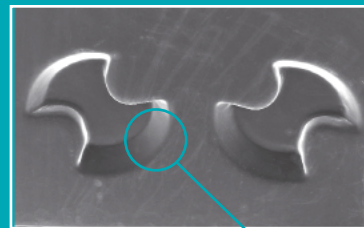
### Leader in biocompatible materials

*Due to its robust design, the Carbomedics bileaflet mechanical heart valve has no reported post-operative structural failures\* in over 900.000 implants worldwide.*

Carbomedics Pyrolite® Carbon is engineered to provide excellent thromboresistance combined with optimal strength.

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.<sup>1</sup> The surface is then polished to remove the superficial roughness, thus achieving a mirror like finish.

Polished Silicon alloyed varieties of Pyrolytic Carbon exhibit an excellent degree of thromboresistance while improving resistance to wear,<sup>1,2</sup> offering excellent and durable clinical results as proven in over 20 years of clinical follow up.



\* No reported structural valve failure in the published scientific literature. None of the events reported to LivaNova Quality System has been classified as structural valve failure upon completion of the analysis.



## A robust design for no structural failure

### 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.

### Pyrolytic carbon housing

Differently from the substrate processes used by other manufacturers, 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, minimizing pannus ingrowth and interference with leaflet motion that can occur around the protruding “pivot ear” design.<sup>3,4,5</sup> Moreover, it permits a more sophisticated design of the pivot, the shape of which grants total washing of its entire surface, minimizing thromboembolic events.<sup>6</sup>



### Structural components

To further enhance structural stability, the housing is reinforced by a titanium stiffening band which makes it up to 30 times stronger than a valve without a stiffening element, minimizing the risk of deformation and consequently, the risk of leaflet dislodgement or lockup.<sup>7</sup>

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.

1. Carbon Biomedical Devices. J.C. Bokros – Carbon, 1977;15:355–71.

2. Platelet responses to silicon-alloyed pyrolytic carbons. Goodman et al. – Wiley Periodicals, Inc. J Biomed Mater Res 83A: 64–69, 2007

3. Obstruction of St Jude medical valves in the aortic position: a consideration for pathogenic mechanism of prosthetic valve obstruction. Aoyagi et al. – Cardiovasc Surg. 2002 Aug;10(4):339–44

4. Entrapment of subvalvular mitral tissue causing intermittent failure of a St Jude mitral prosthesis. Dearani et Al. – J Am Soc Echocardiogr. 2000 Dec;13(12):1121–3

5. Entrapment of mitral chordal apparatus causing early postoperative dysfunction of a St. Jude mitral prosthesis. Greaves et Al. – J Am Soc Echocardiogr. 2002 Aug;15(8):843–4

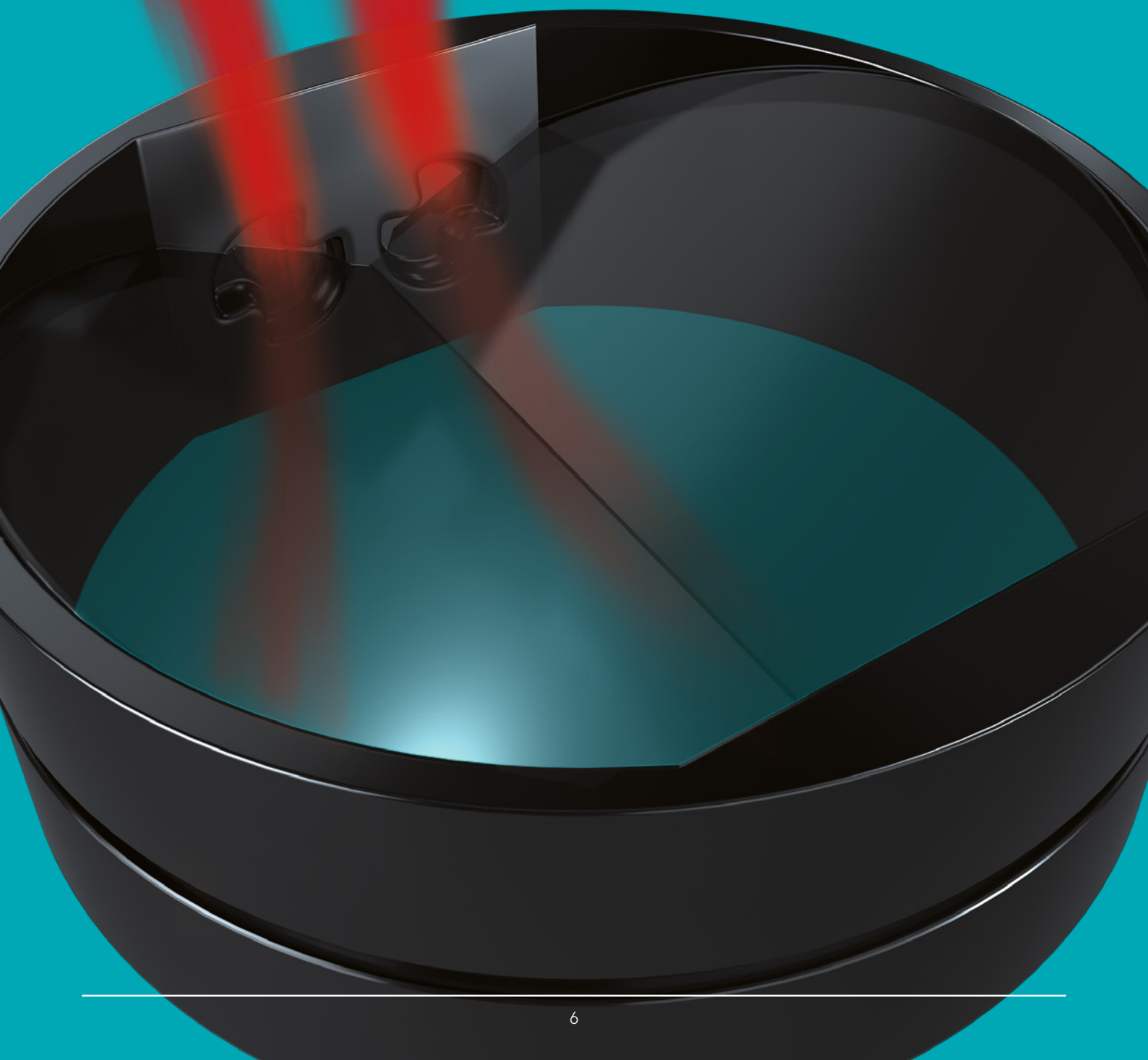
6. Echocardiographic Description Of The Carbomedics Bileaflet Prosthetic Heart Valve. Chambers et al. – J Am Coll Cardiol 1993;21:398–405

7. Leaflet arrest in St Jude medical and Carbomedics valves: an experimental study. Grattan MT, Thulin LI, Eur J – Cardiothoracic Surg. 2004 Nov; 25 (6): 953–7



CARBOMEDICS® FAMILY

**Tailored performance for excellent  
clinical outcomes**

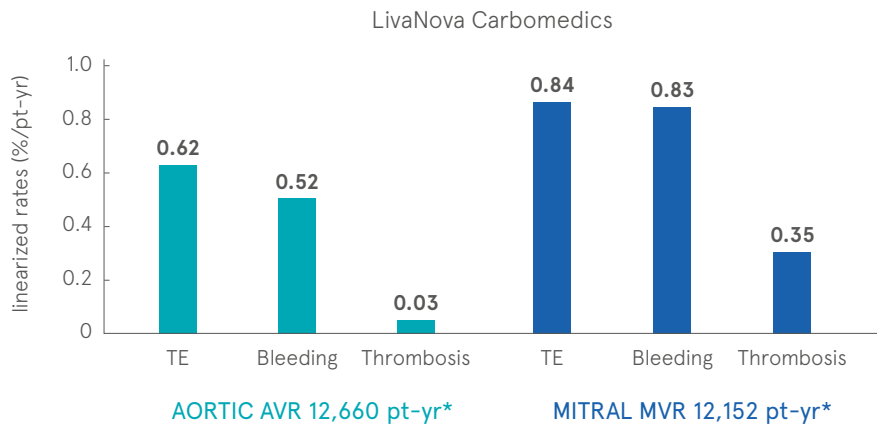


## Carbomedics valves are engineered to achieve true clinical benefits for patients throughout their lifetime

In its long clinical history Carbomedics valve has demonstrated to be of utmost reliability and safety, with no post-operative structural failures and very low incidence of complications.

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.<sup>6</sup>

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

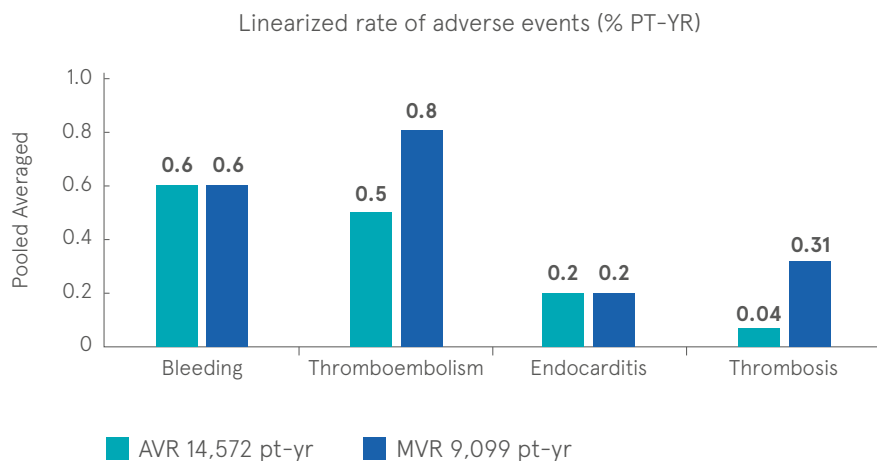


### References:

Carrier. J Heart V Dis 2006 Jan;15(1): 67-72  
 Aagard. J Heart V Dis 2005 Jan;14(1): 82-8.  
 Tominaga. Ann Thorac Surg 2005 Mar;79(3): 784-9  
 Kang. Ann Thorac Surg. 2005 Jun;79(6): 1939-44.  
 Wu. J Heart V Dis 2006 15: 414-420  
 Onoda. Artificial Organs 2002 26(5): 479-82

## Twenty-Year Experience With the CarboMedics Mechanical Valve Prosthesis

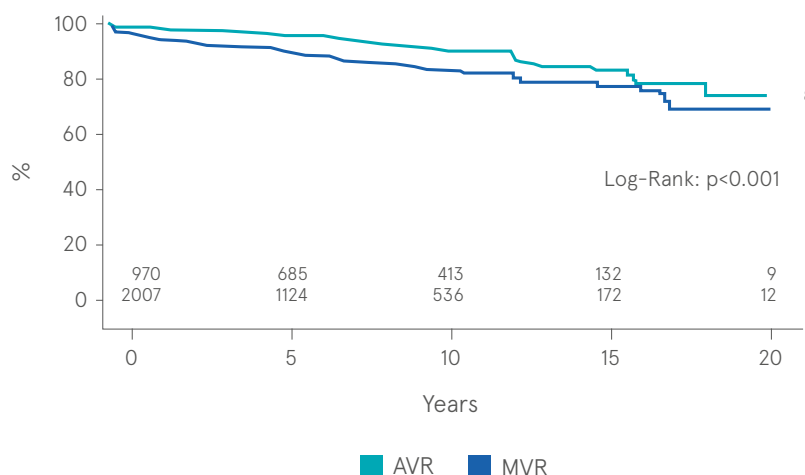
These outstanding clinical results are confirmed by over **twenty years** of published follow up.<sup>8</sup>



\* Pooled analysis of cited references. If follow-up years for subgroups (AVR, MVR) was not reported in the paper, their value was calculated from event rates values and graphs data, and the most conservative value inferred was performed.



## Freedom from valve-related mortality after mitral and aortic valve replacement\*



## Utmost reliability with low thrombogenicity

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.<sup>10</sup>

Carbomedics valves have proven to be safe even at INR ranges well below the recommended target.<sup>11,12,13</sup>

\*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.<sup>9</sup>

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

9. Guidelines for reporting morbidity and mortality after cardiac valvular operations. Edmunds et al., Ad Hoc Liaison Committee for Standardizing Definitions of Prosthetic Heart Valve Morbidity of the American Association for Thoracic Surgery and the Society of Thoracic Surgeons. – J Thorac Cardiovasc Surg 1996;112:708–11.

10. Guidelines on the management of valvular heart disease (version 2012). The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)– European Heart Journal (2012) 33, 2451–2496

11. Low dose warfarin in patients with Carbomedics heart valves prostheses. P.V. Andersen, J. Aagard– Asian Cardiovasc Thorac Ann 2000; 8:11–4

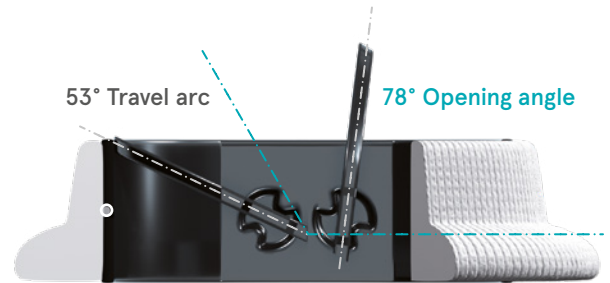
12. Is low anticoagulation intensity more beneficial for patients with bileaflet mechanical mitral valves? A meta-analysis. Zhe Xu et al., The Journal of Cardiovascular Surgery 2016 February; 57 (1):90–9

13. Clinical Observation of Postoperative Warfarin Anticoagulation in 300 Patients Undergoing Mitral Valve Replacement with a Carbomedics Mechanical Valve. Wu et al. The Heart Surgery Forum 2015; 18 (2): E063–E066

## A unique platform with excellent hemodynamics

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 leaflets of the Carbomedics valve have been established 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 operation.

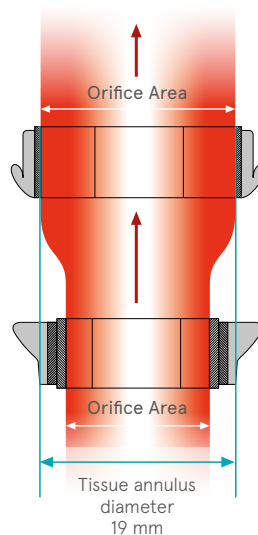


## Top Hat, top hemodynamic performance

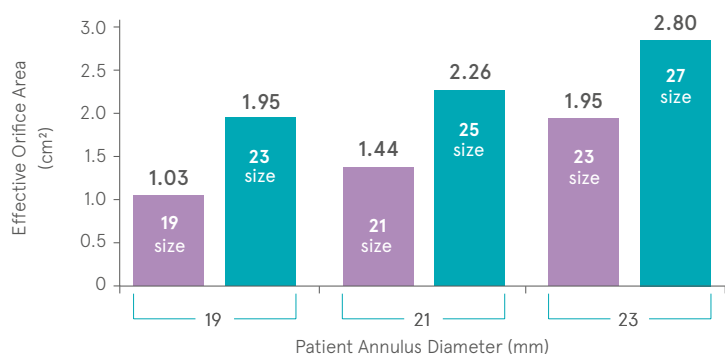
To further optimize hemodynamics, especially in small aortic annuli, LivaNova features in its Carbomedics portfolio the Top Hat prosthesis, a truly totally supra-annular model<sup>14</sup> which provides an advantage of 1 to 2 sizes over intra-annular valves.<sup>15,16</sup> Top Hat improves effective valve orifice area thanks to a 100% orifice to annulus match, thus contributing to reduce the risk of PPM.<sup>17</sup>

***"The Top Hat valve minimizes the risk of patient-prosthesis mismatch, improves hemodynamic performance, and thereby reduces morbidity and mortality."***<sup>16</sup>

### 100% ORIFICE TO ANNULUS MATCH

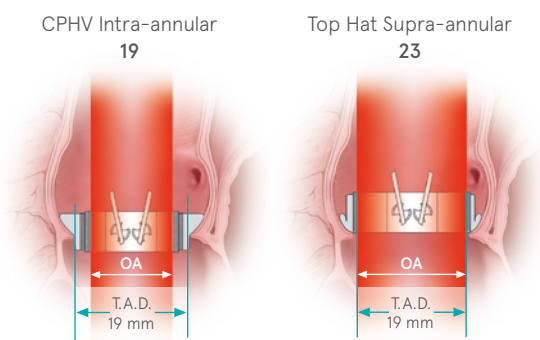


## Carbomedics *in vitro* data\*

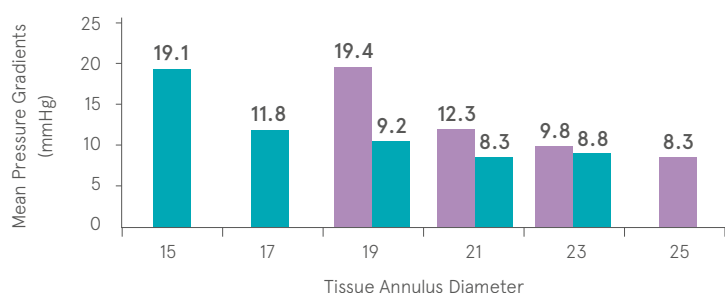


■ CPHV Intra-annular ■ Carbomedics Top Hat

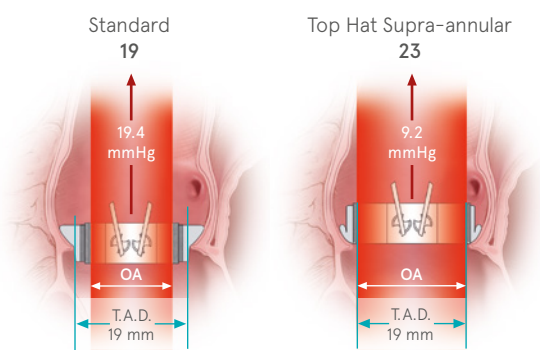
\*In vitro test - 5l/min 70 bpm (Data on file at Livanova)



## Carbomedics *in vivo* data<sup>18,19</sup>



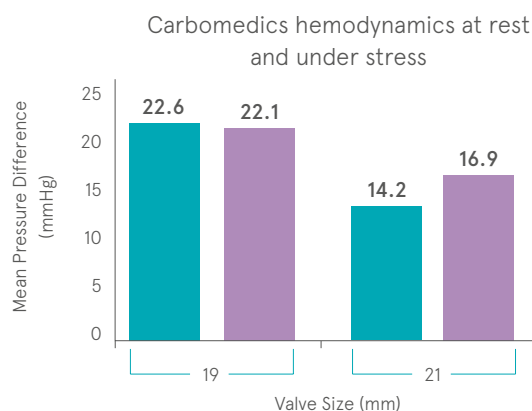
■ Standard ■ Carbomedics Top Hat



Differently from other competitive valves, Carbomedics has also shown an improved Effective Orifice Area under stress.

**"The result is an optimization of the discharge coefficient with exercise, indicating a good design of the moving part of the valve."**<sup>20</sup>

■ Under stress ■ At rest



14. Supra annular model as defined by International Standard for Cardiovascular implants - Cardiac valve Prostheses-Part 2. ISO 5840-2:2015(E)
15. The Carbomedics Supraannular Top hat Valve improves prosthesis size in the Aortic Root. Lundblad R et al. - J Heart Valve Dis 2001;10:196-201
16. Maximizing prosthetic valve size with the Top Hat® supraannular aortic valve. Aagard et al. - The Journal of Heart Valve Disease 2007;16:84-90
17. Hemodynamic and Clinical Impact of Prosthesis-Patient Mismatch in the Aortic Valve Position and its Prevention. Pibarot P, Dumesnil JG. - J Am Coll Cardiol 2000;36:1131- 41
18. The Carbomedics "Top Hat" Supra-annular prosthesis. Bernal et al. - Ann Thorac Surg. 1999;67:1299-303
19. Echocardiographic description of the Carbomedics bileaflet prosthetic heart valve. Chambers et al. - JACC 1993; 21(2): 398-405
20. Hemodynamic performance of small diameter Carbomedics and St. Jude valves. De Paulis et al. - J Heart Valve Dis 1996;5 (Suppl III):S339-43



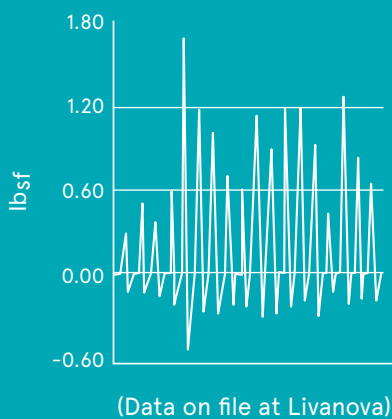
## Tailored ease of implant

### Carbomedics valves are designed for a smooth implant experience

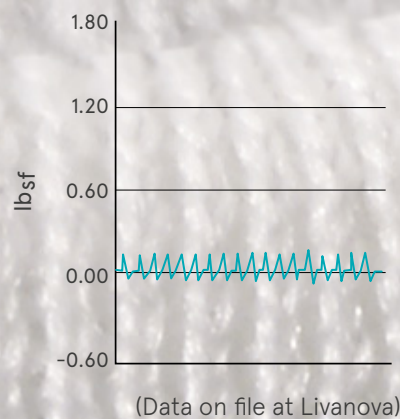
This is why they are considered by many leading cardiac centers the 'most accommodating' valve in the world.

Carbomedics sewing cuffs are optimized for ease of implant and good seating. Compared to other valves in the market, the Carbomedics sewing cuff requires much less force for needle penetration facilitating the suturing phase.

Typical valve  
Sewing Cuff Penetration Force



Carbomedics standard  
Sewing Cuff Penetration Force



Most importantly, the Carbomedics sewing cuff conforms to the tissue rather than forcing the tissue to conform to its shape, thus minimizing the tension on sutures and consequently the risk of dehiscence. This is particularly relevant in fragile or heavily calcified annuli.

A variety of configurations ensures an optimal fit in any anatomical situation.





**Tailored solutions for every patient and  
surgeon's need**



## Unique options that make the difference

### CARBOMEDICS TOP HAT

A truly, totally supra-annular aortic prosthesis for improved hemodynamics.

Top Hat contributes to reduce the risk of PPM especially in small or severely calcified aortic annuli.

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.



### CARBOMEDICS OPTIFORM

A unique mitral prosthesis with versatile positioning to approach even the most challenging situations.

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



### Everted Suture Technique



For atrial positioning (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

## The most complete set of mechanical heart valve solutions in the market

### Four different aortic models

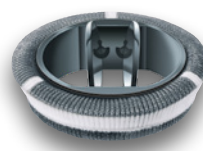
Carbomedics Top Hat



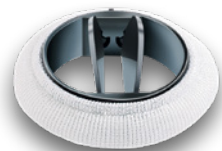
Carbomedics Standard



Carbomedics Reduced

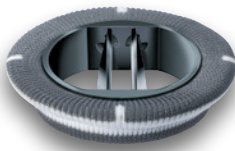


Carbomedics Orbis

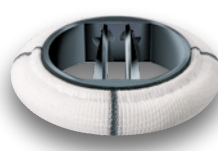


### Three different mitral models

Carbomedics Standard



Carbomedics Optiform



Carbomedics Orbis



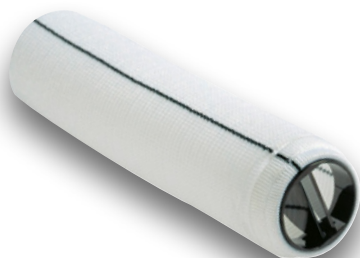
### Pediatric aortic and mitral valves

Carbomedics Standard Pediatric



### Two different conduit models

Carbomedics Carbo-Seal



Carbomedics Carbo-Seal Valsalva







## The voice of experience

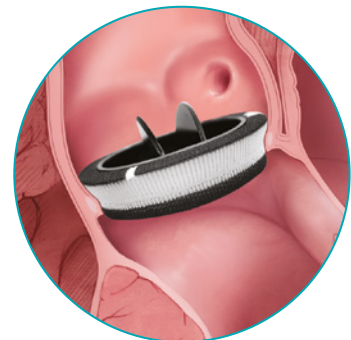
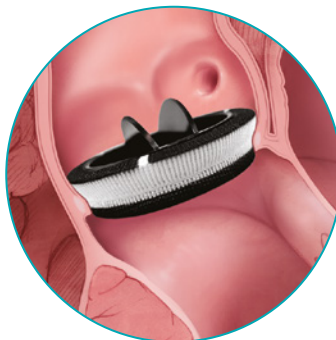
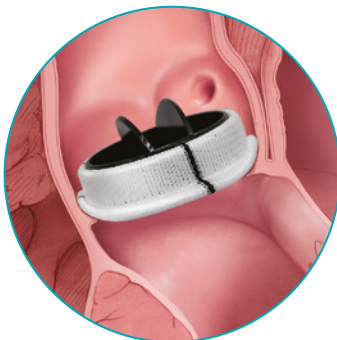
*"We observed that the Carbomedics mechanical prosthesis had excellent durability with no structural failures, good hemodynamics, and a low incidence of TE."*

*"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."*

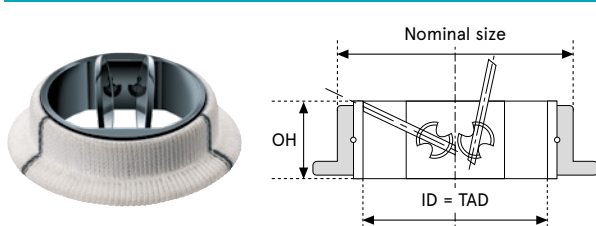
*"In our experience, structural valve failure with this device is inexistent. The Carbomedics mechanical valve is a solid choice for long-term valvular replacement."*



CARBOMEDICS TOP HAT	CARBOMEDICS REDUCED	CARBOMEDICS ORBIS	CARBOMEDICS STANDARD
TOTALLY SUPRA-ANNULAR AORTIC VALVE Sizes 19–27 mm	AORTIC VALVE Sizes 19–29 mm	AORTIC VALVE Sizes 19–31 mm	AORTIC VALVE Sizes 19–31 mm
			
<b>Application</b>			
<ul style="list-style-type: none"> <li>• Aortic procedures</li> <li>• Normal sinus area</li> <li>• Small aortic annulus</li> <li>• Severely calcified aortic annulus</li> <li>• Double valve replacement</li> </ul>	<ul style="list-style-type: none"> <li>• Aortic procedures</li> <li>• Low coronary ostia</li> <li>• Narrow, rigid aortic annulus</li> <li>• Small, inflexible aorta (Sinus of Valsalva)</li> </ul>	<ul style="list-style-type: none"> <li>• Aortic procedures</li> <li>• Low coronary ostia</li> <li>• Narrow, rigid aortic sinus</li> <li>• Large annulus</li> <li>• Redo AVR</li> </ul>	
<b>Implantation Consideration</b>			
<ul style="list-style-type: none"> <li>• Totally supra-annular placement <ul style="list-style-type: none"> <li>– allows for largest valve possible</li> <li>– increases ease and safety of DVR procedure</li> </ul> </li> <li>• Titanium stiffening ring allows for rotatability in-situ</li> <li>• Three orientation markers for suture spacing</li> <li>• Special sizers allow surgeon to assess position of valve within sinus area and clearance of coronaries before implantation</li> </ul>	<ul style="list-style-type: none"> <li>• Titanium stiffening ring allows rotatability in-situ</li> <li>• Orientation markers provide easy visual suture positioning</li> <li>• Smaller, pliable (Carbomedics Reduced only) sewing cuff allows for improved seating in a smaller annulus or small root</li> </ul>	<ul style="list-style-type: none"> <li>• Titanium stiffening ring allows rotatability in-situ</li> <li>• Orientation markers provide easy visual suture positioning</li> <li>• Generous sewing cuff conforms to annulus, minimizing perivalvular leaks</li> </ul>	
<b>Clinical Considerations</b>			
<ul style="list-style-type: none"> <li>• Size upgrades provide improved valve hemodynamics</li> <li>• Totally supra-annular design allows the largest possible orifice available to blood flow</li> <li>• Alternative to aortic root enlargement</li> <li>• Titanium stiffening ring minimizes the possibility of leaflet lockup or escape</li> <li>• Utmost reliable structural stability</li> <li>• Excellent clinical record for valve-related events</li> </ul>	<ul style="list-style-type: none"> <li>• Alternative to aortic root enlargement where supra-annular valve will not fit in sinus</li> <li>• Titanium stiffening ring minimizes the possibility of leaflet lockup or escape</li> <li>• Utmost reliable structural stability</li> <li>• Excellent clinical record for valve-related events</li> </ul>	<ul style="list-style-type: none"> <li>• Low implant profile minimizes housing interference with the coronary ostia</li> <li>• Titanium stiffening ring minimizes the possibility of leaflet lockup or escape</li> <li>• Utmost reliable structural stability</li> <li>• Excellent clinical record for valve-related events</li> </ul>	
<b>Valve placement <i>in-situ</i></b>			

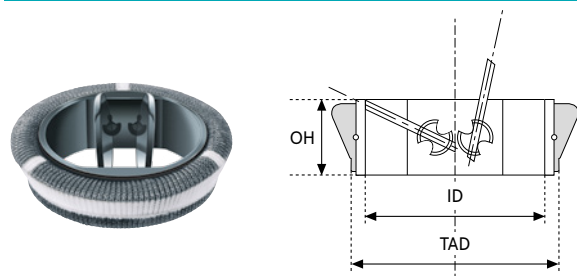


### CARBOMEDICS TOP HAT



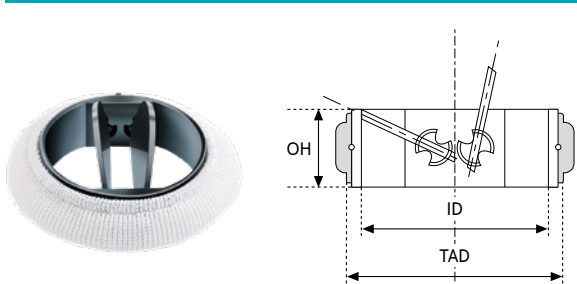
Nominal size	TAD	ID	OH	GOA	EOA	Catalog N.
19	14.7	14.7	6.2	1.59	1.0 <sup>1</sup>	S5-019
21	16.7	16.7	6.6	2.07	1.4 <sup>2</sup>	S5-021
23	18.5	18.5	7.3	2.56	1.9 <sup>2</sup>	S5-023
25	20.5	20.5	7.7	3.16	2.2 <sup>2</sup>	S5-025
27	22.5	22.5	8.4	3.84	2.9 <sup>2</sup>	S5-027

### CARBOMEDICS REDUCED



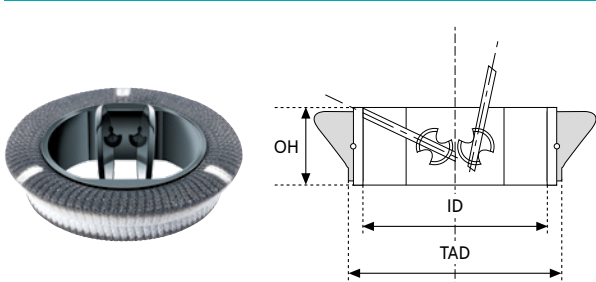
Nominal size	TAD	ID	OH	GOA	EOA <sup>1</sup>	Catalog N.
19	18.8	14.7	6.2	1.59	1.0	R5-019
21	20.8	16.7	6.6	2.07	1.5	R5-021
23	22.6	18.5	7.3	2.56	1.6	R5-023
25	25.0	20.5	7.7	3.16	2.0	R5-025
27	27.0	22.5	8.4	3.84	2.4	R5-027
29	29.0	24.2	8.7	4.44	2.6	R5-029

### CARBOMEDICS ORBIS



Nominal size	TAD	ID	OH	GOA	EOA <sup>1</sup>	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

### CARBOMEDICS STANDARD



Nominal size	TAD	ID	OH	GOA	EOA <sup>1</sup>	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

### Legend

TAD = Tissue Annulus Diameter (mm)

OH = Orifice Height (mm)

ID = Internal Diameter (mm)

GOA = Geometric Orifice Area (cm<sup>2</sup>)

EOA = In vivo Effective Orifice Area (cm<sup>2</sup>)

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

2. Midterm Evaluation of Hemodynamics of the Top Hat Supraannular Aortic Valve. Agard et al. - Asian Cardiovasc Thorac Ann 2010;18:1-5

## CARBOMEDICS STANDARD SMALL SIZES

### AORTIC VALVES

Sizes 16 and 18 mm



Size 16



Size 18

## CARBOMEDICS STANDARD SMALL SIZES

### MITRAL VALVES

Sizes 16, 18 and 21 mm



Size 16



Size 18



Size 21

## Application

- Aortic procedures
- Extremely small aortic annulus
- Design allows for intra (size 18) or partially supra-annular (size 16) placement

- Extremely small annulus
- Design allows for intra-annular placement

## Implantation Consideration

- Excellent orifice-to-annulus ratio without sacrificing safety or efficacy
- Sewing cuff assembly reduces cuff size for maximum orifice area

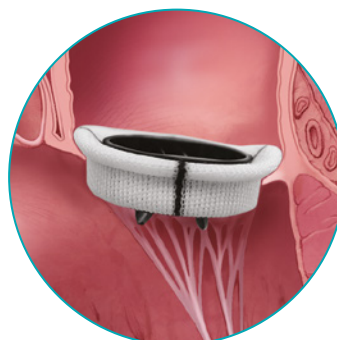
- Sewing cuff assembly reduces cuff size for maximum orifice area
- Titanium stiffening ring allows rotatability in-situ
- Orientation markers provide easy visual suture positioning
- Excellent orifice-to-annulus ratio without sacrificing safety or efficacy

## Clinical Considerations

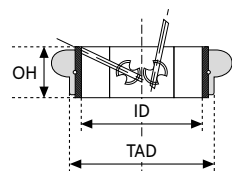
- Minimizes repeated replacements in the growing heart
- Fits where other bileaflet valves will not
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape
- Utmost reliable structural stability

- Minimizes replacements in the growing heart
- Fits where other bileaflet valves will not
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape
- Utmost reliable structural stability

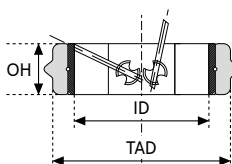
## Valve placement *in-situ*



### CARBOMEDICS STANDARD SMALL SIZES – AORTIC VALVES

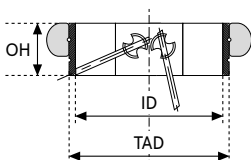


Nominal size	TAD	ID	OH	GOA	EOA <sup>1</sup>	Catalog N.
16	16.2	14.7	6.2	1.59	1	A5-016

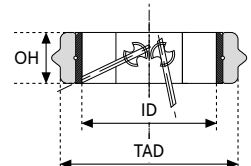


18	18.8	14.7	6.2	1.59	1	A5-018
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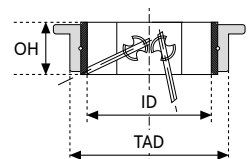
### CARBOMEDICS STANDARD SMALL SIZES – MITRAL VALVES



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
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21	21.8	16.7	6.6	2.07	M7-021
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#### Legend

TAD = Tissue Annulus Diameter (mm)

OH = Orifice Height (mm)

ID = Internal Diameter (mm)

GOA = Geometric Orifice Area (cm<sup>2</sup>)

EOA = In vivo Effective Orifice Area (cm<sup>2</sup>)

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



## CARBOMEDICS CARBO-SEAL VALSALVA

### ASCENDING AORTIC PROSTHESIS (AAP)

Sizes 21-29 mm



## CARBOMEDICS CARBO-SEAL

### ASCENDING AORTIC PROSTHESIS (AAP)

Sizes 21-33 mm



## Application

- Disease conditions of the aorta combined with disease or degeneration of the aortic valve
  - Ascending aortic aneurys
  - Ascending aorta dissection
  - Infective aortitis
  - Marfan's Syndrome
- Disease conditions of the aorta combined with disease or degeneration of the aortic valve
  - Ascending aortic aneurys
  - Ascending aorta dissection
  - Infective aortitis
  - Marfan's Syndrome

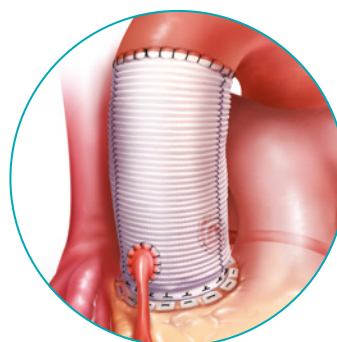
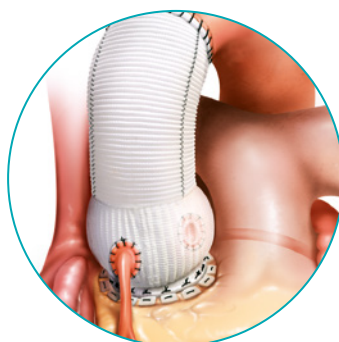
## Implantation Consideration

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

## Clinical Considerations

- Graft is infused with minimally crosslinked gelatin for faster healing, encouraging a secure neo-intimal attachment with reduced inflammatory response
- Collagen gel hydrolyzes within 14 days
- Sinus of Valsalva replicates the native sinus, reducing required dissection of and stress on the coronary anastomoses
- Sinus design encourages natural formation of systolic vortex
- Full-sized standard aortic valve provides excellent hemodynamics
- Excellent thromboembolic performance
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape
- Graft is infused with minimally cross-linked gelatin for faster healing, encouraging a secure neo-intimal attachment with reduced inflammatory response
- Collagen gel hydrolyzes within 14 days
- Full-sized standard aortic valve provides excellent hemodynamics
- Excellent thromboembolic performance
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape

## Valve placement *in-situ*

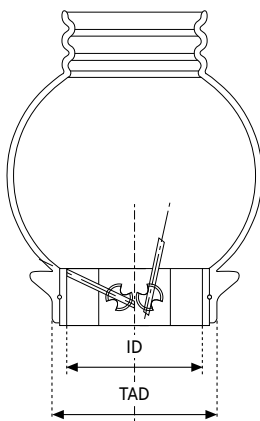


# Product specifications

## CARBOMEDICS® AORTIC MECHANICAL CONDUITS

### CARBOMEDICS CARBO-SEAL VALSALVA

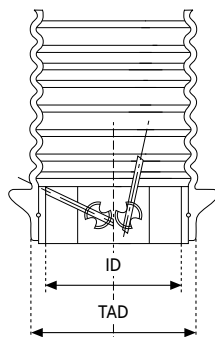
Length of graft: 10 cm · Sinus diameter: Graft ID + 8 mm



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

Length of graft: 10 cm



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)

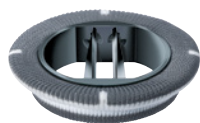
GOA = Geometric Orifice Area (cm<sup>2</sup>)

ID = Internal Diameter (mm)



## CARBOMEDICS STANDARD

**MITRAL VALVE**  
Sizes 23–33 mm



## CARBOMEDICS OPTIFORM

**MITRAL VALVE**  
Sizes 23–33 mm



## CARBOMEDICS ORBIS

**MITRAL VALVE**  
Sizes 21–33 mm



### Application

- Mitral valve replacement with or without using mitral leaflet preservation procedures
- Double valve replacement
- Mitral valve replacement with or without using mitral leaflet preservation procedures
- Heavily calcified annulus
- Mitral redo surgery
- Double valve replacement
- Endocarditis

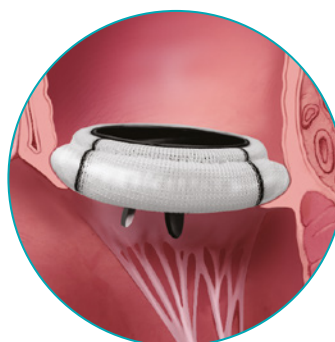
### Implantation Consideration

- Large, flexible sewing cuff promotes coaptation to annulus
- Extra large sewing cuff displaces tissue up and away from orifice and leaflets when seating, minimizing the potential for perivalvular leaks
- Titanium stiffening ring allows rotatability in-situ
- Orientation markers provide easy visual suture positioning
- Symmetrical cuff design allows valve to be placed in a supraannular, intra-annular or subannular position simply by varying suture entry and exit sites
- Flexible, generous cuff easily conforms to difficult patient annular anatomy
- Titanium stiffening ring allows rotatability in-situ
- Orientation markers provide easy visual suture positioning (Carbomedics Optiform only)

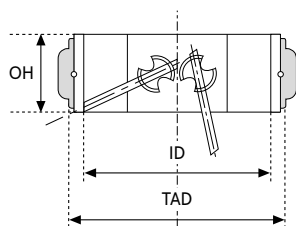
### Clinical Considerations

- Low-profile pivot design minimizes protrusion into low-flow atrial area, reducing potential for thrombus formation
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape
- Utmost reliable structural stability
- Excellent clinical record for valve-related events
- Variable valve placement allows surgeon to choose best valve position for each patient
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape
- Utmost reliable structural stability
- Excellent clinical record for valve-related events

### Valve placement *in-situ*

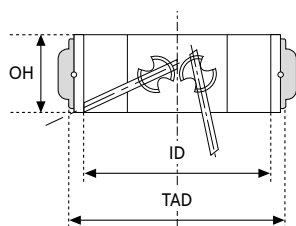


### CARBOMEDICS OPTIFORM



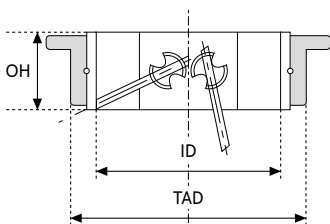
Nominal size	TAD	ID	OH	GOA	Catalog N.
23	22.6	18.5	7.3	2.56	F7-023
25	25.0	20.5	7.7	3.16	F7-025
27	27.0	22.5	8.4	3.84	F7-027
29	29.0	24.2	8.7	4.44	F7-029
31	31.0	24.2	8.7	4.44	F7-031
33	33.0	24.2	8.7	4.44	F7-033

### CARBOMEDICS ORBIS



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 STANDARD



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

### Legend

TAD = Tissue Annulus Diameter (mm)

OH = Orifice Height (mm)

ID = Internal Diameter (mm)

GOA = Geometric Orifice Area (cm<sup>2</sup>)





## Aortic Mechanical Valves

### CARBOMEDICS TOP HAT

Aortic Mechanical Bileaflet Valve

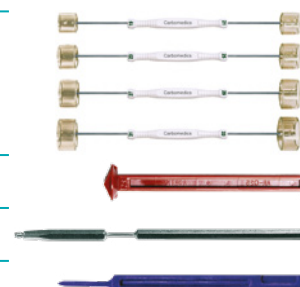
Article	Code	Description
Empty tray	TR-101	1 empty tray
Sizer set	SAS-200	3 sizers 19mm, 21-23mm, 25-27mm
Rotators set	AR-150	6 aortic rotators
Valve handle	VH-100	1 universal bendable handle
Occluder tester	VT-100	10 disposable occluder tester (provided sterile)



### 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
Rotators set	AR-150	6 aortic rotators
Valve handle	VH-100	1 universal bendable handle
Occluder tester	VT-100	10 disposable occluder tester (provided sterile)



## Aortic Mechanical Conduits

### 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

## CARBOMEDICS® 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
Rotators set	RM-399	6 mitral rotators: 16-18mm, 21mm, 23mm, 25mm, 27mm, 29-31-33mm + 1 bendable handle
Bendable handle	RH-100	1 bendable handle to use with mitral valve rotators
Valve handle	VH-100	1 universal bendable handle
Occluder tester	VT-100	10 disposable occluder tester (provided sterile)



## Pediatric Mechanical Valves

### CARBOMEDICS STANDARD PEDIATRIC

#### Aortic Mechanical Bileaflet Valve

Article	Code	Description
Empty tray	TR-101	1 empty tray
Sizer	VS2-1618	1 sizer (16-18mm)
Rotators set	AR-150	6 aortic rotators
Valve handle	VH-100	1 universal bendable handle
Occluder tester	VT-100	10 disposable occluder tester (provided sterile)



### CARBOMEDICS STANDARD PEDIATRIC

#### 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
Rotators set	RM-399	6 mitral rotators: 16-18mm, 21mm, 23mm, 25mm, 27mm, 29-31-33mm + 1 bendable handle
Bendable handle	RH-100	1 bendable handle to use with mitral valve rotators
Valve handle	VH-100	1 universal bendable handle
Occluder tester	VT-100	10 disposable occluder tester (provided sterile)





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

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