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 solutions for patients and surgeons

Tailored performance for excellent clinical outcomes

Tailored ease of implant

Tailored safety and durability
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.¹ 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,¹,² 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. Moreover, it permits a more sophisticated design of the pivot, the shape of which grants total washing of its entire surface, minimizing thromboembolic events.

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.

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.

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.\(^6\)

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

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

These outstanding clinical results are confirmed by over twenty years of published follow up.\(^8\)

### References:


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* 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. Carbomedics valves have proven to be safe even at INR ranges well below the recommended target.

*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.

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 which provides an advantage of 1 to 2 sizes over intra-annular valves. Top Hat improves effective valve orifice area thanks to a 100% orifice to annulus match, thus contributing to reduce the risk of PPM.

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

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.

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 AORTIC MECHANICAL VALVES

<table>
<thead>
<tr>
<th>CARBOMEDICS TOP HAT</th>
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Application

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

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

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

Implantation Consideration

- Totally supra-annular placement
  - allows for largest valve possible
  - increases ease and safety of DVR procedure
- 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

- Titanium stiffening ring allows rotatability in-situ
- Orientation markers provide easy visual suture positioning
- Smaller, pliable (Carbomedics Reduced only) sewing cuff allows for improved seating in a smaller annulus or small root

- Titanium stiffening ring allows rotatability in-situ
- Orientation markers provide easy visual suture positioning
- Generous sewing cuff conforms to annulus, minimizing perivalvular leaks

Clinical Considerations

- Size upgrades provide improved valve hemodynamics
- Totally supra-annular design allows the largest possible orifice available to blood flow
- Alternative to aortic root enlargement
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape
- Utmost reliable structural stability
- Excellent clinical record for valve-related events

- Alternative to aortic root enlargement where supra-annular valve will not fit in sinus
- Titanium stiffening ring minimizes the possibility of leaflet lockup or escape
- Utmost reliable structural stability
- Excellent clinical record for valve-related events

- Low implant profile minimizes housing interference with the coronary ostia
- 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
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**Legend**

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

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

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## CarboMedics Pediatric Mechanical Valves

### Implantation Consideration

**Pediatric Aortic Valve**

- Sizes 16 and 18 mm

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

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

  - 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

**Pediatric Mitral Valve**

- Sizes 16, 18 and 21 mm

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

  - 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 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

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# Product specifications

## CARBOMEDICS STANDARD - Pediatric aortic valve

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¹ Echocardiographic description of the Carbomedics bileaflet prosthetic heart valve. Chambers et al. - JACC 1993, 21(2), 398-405
CARBOMEDICS AORTIC MECHANICAL CONDUITS

**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

**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
- 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

**Valve placement in-situ**
## Product specifications

### CARBOMEDICS CARBO-SEAL VALSALVA

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

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### CARBOMEDICS CARBO-SEAL

Length of graft: 10 cm

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### CARBOMEDICS STANDARD

- **MITRAL VALVE**
  - Sizes 23–33 mm

### CARBOMEDICS OPTIFORM

- **MITRAL VALVE**
  - Sizes 23–33 mm

- **CARBOMEDICS ORBIS**
  - Sizes 21–33 mm

### Application

- Mitral valve replacement with or without using mitral leaflet preservation procedures
- Double valve replacement
- 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
# Product specifications

## CARBOMEDICS OPTIFORM

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<th>TAD (mm)</th>
<th>ID (mm)</th>
<th>OH (mm)</th>
<th>GOA (cm²)</th>
<th>Catalog N.</th>
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<td>7.3</td>
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## CARBOMEDICS ORBIS

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## CARBOMEDICS STANDARD

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<th>TAD (mm)</th>
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<th>GOA (cm²)</th>
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</table>

## Legend

- **TAD** = Tissue Annulus Diameter (mm)  
- **OH** = Orifice Height (mm)  
- **ID** = Internal Diameter (mm)  
- **GOA** = Geometric Orifice Area (cm²)
### Aortic Mechanical Valves

**CARBOMEDICS TOP HAT**  
Aortic Mechanical Bileaflet Valve

<table>
<thead>
<tr>
<th>Article</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Empty tray</td>
<td>TR–101</td>
<td>1 empty tray</td>
</tr>
</tbody>
</table>
| 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

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<tbody>
<tr>
<td>Empty tray</td>
<td>TR–101</td>
<td>1 empty tray</td>
</tr>
</tbody>
</table>
| 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

<table>
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| 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)                              |
### CARBOMEDICS OPTIFORM, ORBIS, STANDARD

**Mitral Mechanical Bileaflet Valve**

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<tr>
<td>Empty tray</td>
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<td>1 empty tray</td>
</tr>
<tr>
<td>Sizer set</td>
<td>VS-200</td>
<td>4 sizers 19-21mm, 23-25mm, 27-29mm, 31-33mm</td>
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<tr>
<td>Rotators set</td>
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<td>6 mitral rotators: 16-18mm, 21mm, 23mm, 25mm, 27mm, 29-31-33mm + 1 bendable handle</td>
</tr>
<tr>
<td>Bendable handle</td>
<td>RH-100</td>
<td>1 bendable handle to use with mitral valve rotators</td>
</tr>
<tr>
<td>Valve handle</td>
<td>VH-100</td>
<td>1 universal bendable handle</td>
</tr>
<tr>
<td>Occluder tester</td>
<td>VT-100</td>
<td>10 disposable occluder tester (provided sterile)</td>
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### Pediatric Mechanical Valves

#### CARBOMEDICS STANDARD PEDIATRIC

**Aortic Mechanical Bileaflet Valve**

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<td>Empty tray</td>
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</tr>
<tr>
<td>Sizer</td>
<td>VS2-1618</td>
<td>1 sizer (16-18mm)</td>
</tr>
<tr>
<td>Rotators set</td>
<td>AR-150</td>
<td>6 aortic rotators</td>
</tr>
<tr>
<td>Valve handle</td>
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#### CARBOMEDICS STANDARD PEDIATRIC

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