The voice of experience

“The Bicarbon Prosthesis continues to perform satisfactorily even in the long term with low incidence of valve-related mortality and morbidity confirming to be an extremely reliable and durable mechanical valve substitute”.*

* Based on LivaNova post-market surveillance. Data illustrated below is presented in cases with no 100000 cases involving a significant number of patients (i.e. >100000 device population) on whom comprehensive data was collected.

“In the present series, a low incidence of embolic events was observed [...] indicating that the innovative changes incorporated into the Bicarbon Prosthesis design, improving transprosthetic flow and reducing turbulence, might positively influence its thrombogenicity”.

“We have also found that other major postoperative complications, [...] are extremely uncommon after AVR and MVR with the Bicarbon Prosthesis”.

“(…) no cases of structural failure were recorded”.*

“The present study gives additional evidence of low rates of valve-related complications after Bicarbon valve implantation. [...] we maintain the INR between 1.8 and 3.0. The rate of thromboembolic events in this study is excellent and the rates of bleeding complications are also acceptable”.

“This single-center study of a 15-year follow-up of the Bicarbon prosthetic heart valve shows excellent clinical results associated with a low incidence of valve-related mortality and morbidity”.*

INDICATIONS

Bicarbon prostheses are indicated for the replacement of damaged natural heart valves or malfunctioning prosthetic devices.

KEY CONTRAINDICATIONS

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

KEY WARNINGS

For single use only. The use of Bicarbon prostheses must be judiciously evaluated in cases where residual calcium is present in the patient’s annulus and in patients with an excessively fragile or irregularly shaped annulus that does not fit prosthesis geometry. The use of the Bicarbon prostheses is not recommended in patients with hypersensitivity to Titanium alloys and to Cobalt Chromium alloys (Stellite). Do not manipulate the Bicarbon prosthesis with instruments other than those supplied by the manufacturer.

TOP POTENTIAL SIDE EFFECTS

The risks or potential adverse events associated with cardiac valve replacement with a prosthetic mechanical heart valve include, but may not be limited to: cardiac arrhythmias, death, endocarditis, hemolysis, anti-coagulation related hemorrhage, leaflet entrapment by tissue ingrowth or impingement on anatomic structures, intravalvular and/or paravalvular leak, prosthetic thrombosis, thromboembolism, structural valve deterioration, reoperation and explant.

MRI conditional

For professional use. Please contact us through our website to receive instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

Not approved in all geographies. Consult your labeling.
Details make the difference: many options for many benefits\(^1,2\)

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

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

Bicarbon mechanical valves feature the exclusive LivaNova Carbofilm\(^\text{TM}\) coating technology which favors both hemo and biocompatibility.\(^6\)

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

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

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

Details make the difference: Hemodynamics$^{1,2}$
Bicarbon's distinguished details make the difference when it comes to hemodynamic performance\textsuperscript{1,2}

**Careful choice of materials**

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

The LivaNova 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.\textsuperscript{3,4}

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

Technical claims are supported by LivaNova data on file.
Innovative Design

Not only a careful choice of materials but also an innovative design are key to Bicarbon’s hemodynamic performance.\textsuperscript{1,2}

Bicarbon is a unique mechanical heart valve featuring curved leaflets specifically engineered to achieve an even flow distribution downstream.\textsuperscript{3} This leads to several benefits to the patient:\textsuperscript{1,3}

\begin{itemize}
  \item low turbulence which prevents blood stasis and thus the risk for thrombus formation
  \item low pressure gradients for favorable hemodynamic performance
  \item reduced energy loss for an efficient functioning and beneficial cardiac workload
\end{itemize}

In addition the special aerofoil profile of the housing, which gently decreases in width from the inflow towards the outflow side, is intended to optimize the organization of the flow, minimizing blood turbulence and favoring pressure recovery.\textsuperscript{3}

The 80-degree opening angle, in combination with curved leaflets has been specifically established to minimize turbulence, while the short travel arc contributes to low regurgitation levels and low energy loss.\textsuperscript{1,3}

The unique two-open-chimney design ensures an effective passive washing of the hinges even when the valve is closed, avoiding blood stasis and hemolysis at the same time.\textsuperscript{3,5}

Technical claims are supported by LivaNova data on file.
The favorable hemodynamic performance of Bicarbon valves is well proven in the published scientific literature.¹,²

In vitro comparisons³ with other commercially available valves have shown that Bicarbon are among the best performing valves with respect to all the relevant parameters:

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

This is confirmed in small aortic annuli, even when compared with valves specifically designed to improve hemodynamic performance.⁴,⁵,⁶

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

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Technical claims are supported by LivaNova data on file.
The hydrodynamic efficiency of Bicarbon valves is reflected by the favorable hemodynamic results reported in the published in-vivo evaluations.9

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

Size 19 Effective Orifice Area (cm²)

Size 19 Mean and Peak pressure gradients (mmHg)

Technical claims are supported by LivaNova data on file.
Overline: engineered for hemodynamic performance

To further optimize hemodynamic performances, especially in small aortic annuli, LivaNova features in its Bicarbon portfolio the Overline aortic prosthesis, a truly totally supra-annular model. A totally supra annular positioning can provide an advantage of 1 to 2 sizes over intra-annular valves.10

Overline improves effective valve orifice area thanks to a 100% orifice to annulus match, thus contributing to reduce the risk of PPM.2,11

“An 18 mm or 20 mm valve was implanted in more than 80% of the present patients. [...] However, no cases of PPM were observed, despite the use of 18 and 20 mm valves.”2

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

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<td>MPG (mmHg)</td>
<td>Preoperative</td>
<td>42 ± 19</td>
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<td></td>
<td>12 months</td>
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MPG: Mean pressure gradient; PPG: Peak pressure gradient

“The in vivo data showed excellent hemodynamic results for all valve sizes [...] In addition, the EOA was significantly increased, from 0.80 ± 0.41 cm² before surgery to 2.01 ± 0.26 cm² after 12 months.”2

Technical claims are supported by LivaNova data on file.
Details make the difference:
Thromboresistance
Bicarbon valves are specifically designed to minimize thrombogenicity:\textsuperscript{1,2}

- Carbofilm coating increases hemocompatibility lowering the risk of thrombus formation.\textsuperscript{3,4*}

- Curved leaflets, aerofoil housing profile, optimized leaflets travel arc and opening angle favor a laminar blood flow which reduces shear stress and hemolysis.\textsuperscript{3} A low degree of hemolysis leads to less platelet activation and consequently less risk of clots.\textsuperscript{5}

- The unique two-open-chimney design ensures an effective passive washing of the hinges avoiding blood stasis and hemolysis at the same time.\textsuperscript{3,6}

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

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{thromboembolic_events}
\caption{Thrombo-embolic events}
\end{figure}

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

Technical claims are supported by LivaNova data on file.
As a further proof of its excellent thromboresistance, Bicarbon is backed by the ‘LOWERING-IT’ trial, an independent prospective controlled randomized study which has established for the first time that a lower INR target (1.5-2.5) is safe and feasible in low risk patients after aortic valve replacement.²

"LOWERING-IT trial established that the proposed LOW-INR target is safe and feasible in low-risk patients after bileaflet aortic mechanical valve replacement. It results in similar thrombotic events and in a significant reduction of bleeding occurrence when compared to the conventional anticoagulation regimen."²

---

2. Torella et al., LOWERing the INtensity of oral anticoaGulant Therapy in patients with bileaflet mechanical aortic valve replacement: Results from the “LOWERING-IT” Trial, Am Heart J; 160:171-8, 2010.

Technical claims are supported by LivaNova data on file.
The Bicarbon design was carefully engineered to last over time.*

- The Titanium housing, with greater structural stability than solid Pyrolytic Carbon housings, ensures correct leaflet functionality.¹

- The unique two-open-chimney design of the hinges avoid blood stasis and hemolysis minimizing the risk of structural valve failure and clinical complications.¹ ²

- The Carbofilm coated PET fabric sewing ring provides a safe anchorage favoring a gentle tissue ingrowth that minimizes pannus formation.**

- The unique, proprietary ‘rolling without sliding’ hinge mechanism, characterized by a constantly varying single point of contact between the pivot and the housing, minimizes friction and wear and consequently the risk of structural valve deterioration.¹ ²

The innovative Bicarbon solution

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


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


Technical claims are supported by LivaNova data on file.
Details make the difference: Clinical outcomes

Bicarbon has proven to be a safe, high performing valve with desirable clinical outcomes in the long term follow up.\textsuperscript{1,3}

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

“The Bicarbon Prosthesis has shown excellent results in terms of clinical improvement and freedom from valve-related complications, even up to 17 years after AVR and MVR.”\textsuperscript{2}

**Linearized rate of adverse events (%PT-YR)\textsuperscript{2}**

- Embolism: 0.24
- Thrombosis: 0.23
- Bleeding: 0.14
- Endocarditis: 0.05

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

**NYHA CLASS\textsuperscript{2}**

- Pre-Op
- Post-Op

**Actuarial Survival and Freedom from valve-related deaths\textsuperscript{2}**

- AVR: Freedom at 17 yrs (%): 90 ± 5
- MVR: Freedom at 17 yrs (%): 92 ± 4

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


Technical claims are supported by LivaNova data on file.
The voice of experience

“The Bicarbon Prosthesis continues to perform satisfactorily even in the long term with low incidence of valve-related mortality and morbidity confirming to be an extremely reliable and durable mechanical valve substitute”.*1

“In the present series, a low incidence of embolic events was observed […] indicating that the innovative changes incorporated into the Bicarbon Prosthesis design, improving transprosthetic flow and reducing turbulence, might positively influence its thrombogenicity”.  
“We have also found that other major postoperative complications, […] are extremely uncommon after AVR and MVR with the Bicarbon Prosthesis”.  
“[…] no cases of structural failure were recorded”.  *2

“The present study gives additional evidence of low rates of valve-related complications after Bicarbon valve Implantation. […] we maintain the INR between 1.8 and 3.0. The rate of thromboembolic events in this study is excellent and the rates of bleeding complications are also acceptable”.  
“This single-center study of a 15-year follow-up of the Bicarbon prosthetic heart valve shows excellent clinical results associated with a low incidence of valve-related mortality and morbidity”.  *3

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

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

Technical claims are supported by LivaNova data on file.
TOTALLY SUPRA-ANNULAR AORTIC VALVE
Sizes 16–24 mm

PARTIALLY SUPRA-ANNULAR AORTIC VALVE
Sizes 17–27 mm

BICARBON MECHANICAL VALVES

**Implantation Consideration**

- Totally supra-annular placement
  - provides an advantage of 1 to 2 sizes over intra-annular valves
  - facilitates double valve replacement procedure
- Orientation of the implanted valve facilitated by a Polyacetal sleeve mounted inside the sewing cuff, which maintains torque at a constant level
- Three orientation markers for suture spacing
- Soft, pliable cuff for easy handling and better conformity to the patient’s annulus
- Special sizers allow surgeon to assess position of valve within sinus area and clearance of coronaries before implantation
- Advanced design optimized for favorable hemodynamic performance
- Special sizers allow surgeon to assess position of valve within sinus area and clearance of coronaries before implantation
- Size upgrades provide improved valve hemodynamics
- Totally supra-annular design allows a 100% orifice to annulus match, maximizing the orifice available to blood flow
- Alternative to aortic root enlargement
- Advanced design allows to achieve a laminar blood flow that minimizes the risk of thrombus formation
- Very low valve-related adverse events
- Proven safety and durability

**Clinical Considerations**

- A partially supra-annular solution when in need of larger orifice areas compared to intra-annular valves
- Orientation of the implanted valve facilitated by a Polyacetal sleeve mounted inside the sewing cuff, which maintains torque at a constant level
- Three orientation markers for suture spacing
- Soft, pliable cuff for easy handling and better conformity to the patient’s annulus
- Special sizers allow surgeon to assess position of valve within sinus area and clearance of coronaries before implantation
- Advanced design allows to achieve a laminar blood flow that minimizes the risk of thrombus formation
- Very low valve-related adverse events
- Proven safety and durability

**Valve placement in-situ**

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


Technical claims are supported by LivaNova data on file.
Product specifications

BICARBON OVERLINE

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Accessories

- **UNI cylindrical sizers set** ICV0867 5 sizers
- **Aortic rotators set** ICV0868 5 aortic rotators
- **UNI handle** ICV0664 1 universal bandable handle to be used with all sizers
- **Valve holder handle** P0593 1 Nitinol bandable handle
- **Occluder tester** VT-100 10 disposable occluder tester (provided sterile)
- **Empty tray** ICV0736 1 orange empty tray compatible with BICARBON OVERLINE accessories

BICARBON SLIMLINE

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Accessories

- **UNI cylindrical sizers set** ICV0728 6 universal cylindrical sizers
- **UNI profile sizers set** ICV0730 6 universal profile sizers
- **Aortic rotators set** ICV0950 6 aortic rotators
- **UNI handle** ICV0664 1 universal bandable handle to be used with all sizers
- **Valve holder handle** P0593 1 Nitinol bandable handle
- **Occluder tester** VT-100 10 disposable occluder tester (provided sterile)
- **Empty tray** ICV0736 1 orange empty tray

Legend

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


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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www.livanova.com
BICARBON MECHANICAL VALVES

**BICARBON FITLINE AORTIC**

**BICARBON FITLINE MITRAL**

**INTRA-ANNULAR AORTIC VALVE**
Sizes 19–31 mm

**INTRA-ANNULAR MITRAL VALVE**
Sizes 19–33 mm

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### Implantation Consideration

- Orientation of the implanted valve facilitated by a Polyacetal sleeve mounted inside the sewing cuff, which maintains torque at a constant level
- Three orientation markers for suture spacing
- Soft, pliable cuff for easy handling and better conformity to the patient’s annulus

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### Clinical Considerations

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

- Orientation of the implanted valve facilitated by a Polyacetal sleeve mounted inside the sewing cuff, which maintains torque at a constant level
- Four orientation markers for suture spacing
- Soft, pliable cuff for an easy handling and to better conform to the patient’s annulus, promotes coaptation to annulus

---


**LivaNova post-market surveillance classifies the incidence of valve structural failure P as very improbable (P ≤ 10⁻⁶) and the incidence of valve-related thromboembolic events P\(_1\) as improbable (10⁻⁶ < P\(_1\) ≤ 10⁻⁵).

**LivaNova post-market surveillance classifies the incidence of valve structural failure P as very improbable (P ≤ 10⁻⁶).

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**Valve placement in-situ**

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## Product specifications

### BICARBON FITLINE AORTIC

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<td>Occluder tester</td>
<td>VT-100</td>
<td>10 disposable occluder tester (provided sterile)</td>
</tr>
<tr>
<td>Empty tray</td>
<td>ICV0735</td>
<td>1 gray empty tray</td>
</tr>
</tbody>
</table>

### Legend

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

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Distinguished details make the dynamic difference

BICARBON FAMILY

Bileaflet mechanical heart valve solutions to meet patient and surgeon needs

The voice of experience

“The Bicarbon Prosthesis continues to perform satisfactorily even in the long term with low incidence of valve-related mortality and morbidity confirming to be an extremely reliable and durable mechanical valve substitute”. *1

“In the present series, a low incidence of embolic events was observed [...] indicating that the innovative changes incorporated into the Bicarbon Prosthesis design, improving transprosthetic flow and reducing turbulence, might positively influence its thrombogenicity”. *2

“We have also found that other major postoperative complications, [...] are extremely uncommon after AVR and MVR with the Bicarbon Prosthesis”. *3

“(…) no cases of structural failure were recorded”. *3

“The present study gives additional evidence of low rates of valve-related complications after Bicarbon valve implantation. […] we maintain the INR between 1.8 and 3.0. The rate of thromboembolic events in this study is excellent and the rates of bleeding complications are also acceptable”. *3

“This single-center study of a 15-year follow-up of the Bicarbon prosthetic heart valve shows excellent clinical results associated with a low incidence of valve-related mortality and morbidity”. *4

INDICATIONS

Bicarbon prostheses are indicated for the replacement of damaged natural heart valves or malfunctioning prosthetic devices.

KEY CONTRAINDICATIONS

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

KEY WARNINGS

For single use only. The use of Bicarbon prostheses must be judiciously evaluated in cases where residual calcium is present in the patient’s annulus and in patients with an excessively fragile or irregularly shaped annulus that does not fit prosthesis geometry. The use of the Bicarbon prostheses is not recommended in patients with hypersensitivity to Titanium alloys and to Cobalt Chromium alloys (Stellite). Do not manipulate the Bicarbon prosthesis with instruments other than those supplied by the manufacturer.

TOP POTENTIAL SIDE EFFECTS

The risks or potential adverse events associated with cardiac valve replacement with a prosthetic mechanical heart valve include, but may not be limited to: cardiac arrhythmias, death, endocarditis, hemolysis, anti-coagulation related hemorrhage, leaflet entrapment by tissue ingrowth or impingement on anatomic structures, intravalvular and/or paravalvular leak, prosthetic thrombosis, thromboembolism, structural valve deterioration, reoperation and explant.

MRI conditional

For professional use. Please contact us through our website to receive instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

Not approved in all geographies. Consult your labeling.

*1 Based on clinical post-market surveillance data for the Bicarbon over 15 years. Some of the data may have been presented previously. For professional use. Please contact us through our website to receive instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

*2 Based on a single-center study of a 15-year follow-up of the Bicarbon prosthetic heart valve showing excellent clinical results associated with a low incidence of valve-related mortality and morbidity. *4

The present study gives additional evidence of low rates of valve-related complications after Bicarbon valve implantation. [...] we maintain the INR between 1.8 and 3.0. The rate of thromboembolic events in this study is excellent and the rates of bleeding complications are also acceptable”. *3

*3 Based on LivaNova post-market surveillance, valve structural failure is expected to occur less than 1 time per 1,000,000 device population, while valve-related thromboembolic events are expected to occur between 0.1 and 1 times per 1,000,000 device population.

Technical claims are supported by technical data on file.