Anatomy of a High Performance Mechanical Heart Valve

Carbomedics Top Hat®
vs. ATS Open Pivot® AP™ Series

SORIN HEART VALVES
**Unmatched Hemodynamics**

- 100% orifice to annulus match
- Nothing in the annulus to interfere with blood flow
- Larger geometric orifice area (GOA)
- Complete leaflet opening for even blood flow distribution

Opening angles measured by cineradiography in 77 patients with the ATS AP heart valve. The dashed line represents an opening angle of 65°.

Manufacturing specifications for the ATS AP valve are 85°, but it has been shown clinically that this angle opening is not achieved and appears to be more pronounced in the smaller size valves.
The Carbomedics Top Hat® Supra-Annular Aortic Valve is the first and only truly supra-annular mechanical heart valve. Initially implanted in 1993, Top Hat was designed to accommodate diverse annulus anatomies, reduce surgical complexities and deliver superior performance.
### Comparison Based on Optimal Patient Annulus Fit

<table>
<thead>
<tr>
<th>Tissue Annulus Diameter (mm)</th>
<th>Valve Size (mm)</th>
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<tbody>
<tr>
<td></td>
<td>ATS Open Pivot</td>
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<tr>
<td></td>
<td>AP Series</td>
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<tr>
<td></td>
<td>Carbomedics Top Hat</td>
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Carbomedics Top Hat provides up to a two size advantage over intra-annular valves and offers a greater flow area for any given patient annulus.\(^{21,22}\)
Outstanding Clinical Performance

- Lower pressure gradients
- Lower thromboembolism and bleeding rates

Pressure Gradients

Carbomedics mechanical heart valves have consistently demonstrated lower complication rates than the leading competitor.

Pooled Comparative Summary* (Linearized % / pt-yr)

<table>
<thead>
<tr>
<th></th>
<th>Aortic</th>
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<th>Mitral</th>
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<tbody>
<tr>
<td></td>
<td>TE*</td>
<td>Bleeding</td>
<td>TE + Bleed</td>
<td>TE*</td>
<td>Bleeding</td>
<td>TE + Bleed</td>
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<tr>
<td>Carbomedics</td>
<td>0.70</td>
<td>0.73</td>
<td>1.43</td>
<td>0.94</td>
<td>0.85</td>
<td>1.79</td>
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<tr>
<td>ATS AP</td>
<td>2.07</td>
<td>2.11</td>
<td>4.22</td>
<td>3.39</td>
<td>1.27</td>
<td>5.22</td>
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* As defined by AATS/STS guidelines for reporting all thromboembolic events
Optimal Design

- Molded recessed pivots prevent interference with blood flow
- Titanium stiffening ring prevents orifice deformation and leaflet lockup

Technologically advanced pivot design—recessed and completely open to washing, resulting in lower thromboembolic rates

Caromedics Top Hat molded leaflet pivots
With over 65,000 implants without a post-operative structural failure, you can be confident our Carbomedics line of bileaflet mechanical valves, including Top Hat, are designed to last.

ATS AP construction: Smaller tapered ring that only supports a portion of the full orifice structure.

The ATS AP open pivot design has protrusions that result in recirculating zones of blood flow, which can be associated with thromboembolism formation.¹⁹

Computational fluid dynamics of recirculating blood flow across the open pivots of the ATS AP valve during systole.¹⁹
**Over 40 Years of Pioneering Advancements in Mechanical Heart Valve Technology**

- **1960**
  - Developed 1st Pyrolytic Carbon aortic valve (DeBakey-Surgitool 1969)

- **1970**
  - Component manufacturer and pyrolytic carbon supplier for 16 major valve companies, including DeBakey-Surgitool, Bjork-Shiley, Medtronic-Hall, St. Jude Medical, ATS Medical, Inc.

- **1980**
  - Developed and manufactured 1st bi-leaflet aortic valve (St. Jude Medical Masters 1977)
  - Developed 1st fully rotatable valve with molded full washing pivots and circumferential titanium stiffening ring (Carbomedics Standard Mitral 1986)

- **1990**
  - 1st Gel Weave® sealed graft ascending aortic valve conduit (Carbomedics Carbo-Seal 1997)
  - 1st pediatric size bi-leaflet aortic valve (Carbomedics Pediatric Aortic 1992)

- **2000**
  - 1st multi positional mitral valve (Carbomedics OptiForm 1999)
  - 1st supra-annular aortic valve with flexible cuff (Carbomedics Top Hat 1993)
  - 1st sinus of valsalva valved conduit (Carbomedics Carbo-Seal Valsalva 2001)

Since 1969, the Carbomedics line has shaped the evolution of mechanical heart valve replacements.
# Ordering Information

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<th>Size</th>
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# References

2. ATS Medical Manufacturer’s specifications.