Anatomy of a Superior Performing Mechanical Heart Valve

Carbomedics Top Hat®
vs. St. Jude Medical® Regent™

SORIN HEART VALVES
Unmatched Hemodynamics

- 100% orifice to annulus match
- Nothing in the annulus to interfere with blood flow
- Larger geometric orifice area (GOA)
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 complexity 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>St. Jude Regent</td>
</tr>
<tr>
<td>19</td>
<td>19</td>
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<td>21</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.\textsuperscript{19,20}
Outstanding Clinical Performance

- Lower thromboembolism and bleeding rates
- Lower pressure gradients

Pressure Gradients

Caromedics 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>
<th></th>
<th>Mitral</th>
<th></th>
<th></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>St. Jude</td>
<td>1.70</td>
<td>2.15</td>
<td>3.85</td>
<td>2.93</td>
<td>2.55</td>
<td>5.48</td>
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* As defined by AATS/STS Guidelines for reporting all thromboembolic events.
**Optimal Design**

- Molded leaflet pivots eliminate the need for pivot guards
- Titanium stiffening ring prevents leaflet lockup and potential escape

Aoyagi, et al. found restricted leaflet movement in 31 of 54 aortic valve patients evaluated. 5 valves were replaced. 3 out of the 5 valves were explanted within an average time of 2.4 years. Pannus formation on the inflow side of all five valves was observed.  

Carbomedics Top Hat molded leaflet pivots

SJM machined leaflet pivot; pivot guards are required for tool access

Pivot guards can deflect and impinge upon the tissue of the ventricular wall, potentially causing pannus to form.  

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The Regent valve does not have a stiffening ring to prevent orifice deformation. The pivot guards of the Regent valve are longer than the Masters HP model. This extra length makes Regent more susceptible to pressure forces, increasing the likelihood of leaflet lockup.

"Force on the valve rings in patients after aortic valve surgery could cause leaflet malfunction and even arrest in some patients."\textsuperscript{27}

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.
Over 40 Years of Pioneering Advancements in Mechanical Heart Valve Technology

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

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

1970
- Developed 1st fully rotatable valve with molded full washing pivots and circumferential titanium stiffening ring (Carbomedics Standard Mitral 1986)

1980
- Developed and manufactured 1st bi-leaflet aortic valve (St. Jude Medical Masters 1977)

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)
- 1st supra-annular aortic valve with flexible cuff (Carbomedics Top Hat 1993)

2000
- 1st multi positional mitral valve (Carbomedics Optiflourm 1999)
- 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

<table>
<thead>
<tr>
<th>Size</th>
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References