St. Jude Medical® vs. Medtronic Advantage®

A Design and Performance Comparison
PART I:
IMPLANTABILITY & HEMODYNAMICS
### Implantability

<table>
<thead>
<tr>
<th>St. Jude Medical® Valve</th>
<th>Medtronic Advantage® Valve</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A large variety</strong> of cuff configurations to accommodate surgeons’ preferences regardless of superb hemodynamics</td>
<td><strong>Only 1</strong> cuff option available:</td>
</tr>
<tr>
<td>- Shape: traditional or Flex Cuff</td>
<td>- Shape: traditional</td>
</tr>
<tr>
<td>- Thickness: Standard or Expanded Cuff</td>
<td>- Thickness: Standard</td>
</tr>
<tr>
<td>- Material: Double Velour Polyester or PTFE</td>
<td>- Material: Double Velour Polyester</td>
</tr>
</tbody>
</table>
Hemodynamics

Design Objective

- 100% utilization of the native annulus area
- Minimal myocardial workload
- Minimal turbulence generation
Importance of hemodynamics

Avoidance patient prosthesis mismatch

- Higher transprosthetic gradients
- LVOT obstruction
- Decreased post-operative cardiac index
- Decreased NYHA functional class improvement
- Decreased Quality of Life
- Higher incidence of late adverse complications (Pibarot, Patracek)
- Decreased late survival (Pibarot, Rao, Rahimtoola)
- Sudden death (Kratz, Hachida, Rahimtoola, Bach, Renzulli)
Comparison
Geometric Orifice Areas (GOA)

SJM Regent: Improvements up to 47% over the Standard and 17% over the HP SJM® Standard Valve
SJM® HP Valve
SJM Regent™ Valve

Medtronic Advantage®

SJM Regent: Improvements up to 41% over the Medtronic Advantage® Valve
**Comparison**

Geometric Orifice Areas (GOA)

<table>
<thead>
<tr>
<th>cm²</th>
<th>SJM® Standard Valve</th>
<th>SJM® HP Valve</th>
<th>SJM Regent™ Valve</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.00</td>
<td>19 Regent ~ 21 HP = 23 Standard ~ 23 Advantage®</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.00</td>
<td>SJM Regent : Improvements up to 47% over the Standard and 17% over the HP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.00</td>
<td>SJM Regent : Improvements up to 41% over the Medtronic Advantage® Valve</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SJM® Standard Valve | SJM® HP Valve | Medtronic Advantage® | SJM Regent™ Valve
Forward Flow Hemodynamics

St. Jude Medical® Valve

Medtronic Advantage® Valve

Test conditions: compliant to ISO 6540 guideline
**Forward Flow Hemodynamics**

**St. Jude Medical® Valve**

**Medtronic Advantage® Valve**

**CONCLUSIONS Medtronic Advantage®:**

Central vs. lateral **pressure battle on leaflets** leads to:

- Incomplete leaflet opening and flutter resulting in
  - SMALLER effective central opening area
  - SMALLER effective lateral opening area
**In-vitro mean gradient and EOA 21mm valves**

**CONCLUSION:**

21mm Medtronic Advantage® Valve = 21mm SJM® Standard Valve
CONCLUSION: 21mm Medtronic Advantage® Valve causes Patient-Prosthesis Mismatch as of BSA > 1.7 m²
PART II: THROMBORESISTANCE & DURABILITY
Thromboresistance: Manufacturing process differences

St. Jude Medical® Valve

Machining & polishing:
results in a smooth & clean carbon surface

Medtronic Advantage® Valve

Surface Engineering & polishing:
results in visual bumps on the carbon surface

CONCLUSION: Medtronic Advantage® carbon surface shows visual bumps, which are potential sites for thrombus formation
**Thromboresistance : Hinge mechanism**

**St. Jude Medical® Valve**

Proven hinge mechanism

- 28 NOV 2000
- Data confirmed in vivo
- 31M-101 S/N 11637
- • 19 years implanted
- • WEAR : LESS THAN 1 MICRON

**Medtronic Advantage® Valve**

Copy of St. Jude Medical’s hinge mechanism; no proven wear rates

**CONCLUSION:** Medtronic Advantage® Sure-Flow™ butterfly pivot recesses is a copy St. Jude Medical’s hinge recess but without St. Jude Medical Quality Control Label.
**Durability: Clinical Evidence**

**St. Jude Medical® Valve**
- **Proven design**: subject of over 1000 clinical papers & >25 years of clinical history
- Over 1.2 million implants

**Medtronic Advantage® Valve**
- **Unproven design**: No follow-up data existing
- Less than 1000 implants

**CONCLUSION**: Medtronic Advantage® is a NEW valve with design question marks and no clinical proof
What are the advantages of the Advantage® valve?

**DESIGN CLAIM**
- Wider central flow area
- SureFlow™ butterfly pivot system
- No obstructive pivot guards
- Lower velocities

**FACT**
- “wider” becomes “smaller” due to incomplete leaflet opening
- Unproven copy of St. Jude Medical’s mated sphere pivot system
- Leads to dysfunctional fluttering of valve leaflets
- Only lower than caged-ball designs
CONCLUSION

There are no advantages to the Advantage® Valve; but there are risks….

- Patient-prosthesis mismatch
- Potential for higher TE or thrombus due to unproven “Surface Engineering”
- Turbulence due to leaflet flutter
- Lack of clinical evidence
- Company with history of bileaflet design issues

…so do you want to put your patients at risk ???
Product specifications*

<table>
<thead>
<tr>
<th>Labeled Size</th>
<th>Valve type</th>
<th>Tissue Annulus Diameter (A) (mm)</th>
<th>Inner Diameter (B) (mm)</th>
<th>Geometric Orifice Area (cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>17</td>
<td>SJM HP</td>
<td>17.0</td>
<td>14.7</td>
<td>1.63</td>
</tr>
<tr>
<td></td>
<td>SJM Regent™</td>
<td>17.0</td>
<td>15.9</td>
<td>1.87</td>
</tr>
<tr>
<td>19</td>
<td>SJM Standard</td>
<td>19.0</td>
<td>14.7</td>
<td>1.63</td>
</tr>
<tr>
<td></td>
<td>SJM HP</td>
<td>19.0</td>
<td>16.7</td>
<td>2.06</td>
</tr>
<tr>
<td></td>
<td>SJM Regent™</td>
<td>19.0</td>
<td>17.8</td>
<td>2.39</td>
</tr>
<tr>
<td></td>
<td>MDT Advantage®</td>
<td>19.0</td>
<td>15.1</td>
<td>1.70</td>
</tr>
<tr>
<td>21</td>
<td>SJM Standard</td>
<td>21.0</td>
<td>16.7</td>
<td>2.06</td>
</tr>
<tr>
<td></td>
<td>SJM HP</td>
<td>21.0</td>
<td>18.5</td>
<td>2.55</td>
</tr>
<tr>
<td></td>
<td>SJM Regent™</td>
<td>21.0</td>
<td>19.6</td>
<td>2.90</td>
</tr>
<tr>
<td></td>
<td>MDT Advantage®</td>
<td>21.0</td>
<td>16.9</td>
<td>2.13</td>
</tr>
<tr>
<td>23</td>
<td>SJM Standard</td>
<td>23.0</td>
<td>18.5</td>
<td>2.55</td>
</tr>
<tr>
<td></td>
<td>SJM HP</td>
<td>23.0</td>
<td>20.4</td>
<td>3.09</td>
</tr>
<tr>
<td></td>
<td>SJM Regent™</td>
<td>23.0</td>
<td>21.4</td>
<td>3.45</td>
</tr>
<tr>
<td></td>
<td>MDT Advantage®</td>
<td>23.0</td>
<td>18.8</td>
<td>2.65</td>
</tr>
<tr>
<td>25</td>
<td>SJM Standard</td>
<td>25.0</td>
<td>20.4</td>
<td>3.09</td>
</tr>
<tr>
<td></td>
<td>SJM HP</td>
<td>25.0</td>
<td>22.3</td>
<td>3.67</td>
</tr>
<tr>
<td></td>
<td>SJM Regent™</td>
<td>25.0</td>
<td>23.0</td>
<td>4.02</td>
</tr>
<tr>
<td></td>
<td>MDT Advantage®</td>
<td>25.0</td>
<td>20.6</td>
<td>3.19</td>
</tr>
<tr>
<td>27</td>
<td>SJM Standard</td>
<td>27.0</td>
<td>22.3</td>
<td>3.67</td>
</tr>
<tr>
<td></td>
<td>SJM HP</td>
<td>27.0</td>
<td>24.1</td>
<td>4.41</td>
</tr>
<tr>
<td></td>
<td>SJM Regent™</td>
<td>27.0</td>
<td>24.9</td>
<td>4.69</td>
</tr>
<tr>
<td></td>
<td>MDT Advantage®</td>
<td>27.0</td>
<td>24.9</td>
<td>3.90</td>
</tr>
<tr>
<td>29</td>
<td>SJM Standard</td>
<td>29.0</td>
<td>24.1</td>
<td>4.41</td>
</tr>
<tr>
<td></td>
<td>SJM HP</td>
<td>29.0</td>
<td>26.0</td>
<td>5.18</td>
</tr>
<tr>
<td></td>
<td>SJM Regent™</td>
<td>29.0</td>
<td>26.8</td>
<td>5.44</td>
</tr>
<tr>
<td></td>
<td>MDT Advantage®</td>
<td>29.0</td>
<td>24.5</td>
<td>4.55</td>
</tr>
<tr>
<td>31</td>
<td>SJM Standard</td>
<td>31.0</td>
<td>26.0</td>
<td>5.18</td>
</tr>
<tr>
<td></td>
<td>MDT Advantage®</td>
<td>31.0</td>
<td>24.5</td>
<td>4.55</td>
</tr>
</tbody>
</table>

*From manufacturers’ data.

Key:
SJM HP = SJM® Masters Series HP Cuffed Valve
SJM Std. = SJM® Masters Series Standard Cuffed valve

**Diagram Diagram**
VISIT OUR WEBSITE AT http://www.sjm.com

CAUTION: FEDERAL LAW restricts this device to sale by or on the order of a physician or properly licensed practitioner.

St. Jude Medical prosthetic heart valves are indicated for use as replacement valves in patients with a diseased, damaged, or malfunctioning native or prosthetic valve. Possible side effects for all valvular implants include, but are not limited to: regurgitation, thromboembolic phenomena, resistance to flow, infection, hemolysis, dysrhythmias, and prosthetic dehiscence or failure. Anticoagulation is recommended for patients with mechanical valve implants. Please see the physician’s manual for a full description of indications, contraindications, side effects, precautions, warnings and instructions for use.

Corporate Headquarters St. Jude Medical, Inc. One Lillehei Plaza, St. Paul, Minnesota 55117 USA 24-Hour Technical/Professional Consultation (800) 328-9634 (USA) (651) 483-2000 Fax: (651) 482-8318 Customer Service (800) 544-1664 (USA) (651) 490-4410 Fax: (651) 481-7702 European Headquarters SJM International, Inc., The Corporate Village, Figueras Building, Avenue Da Vinci, 11, 1930 Zaventem, Belgium Customer Service Tel: 32-2-774-68-11 Fax: 32-2-772-83-84 Asian Headquarters St. Jude Medical Hong Kong Limited, Room 2705-2708, China Merchants Tower, Shun Tak Centre, 168-200 Connaught Road, Central, Hong Kong Tel: (852) 2996-7688 Fax: (852) 2956-0622

Advantage and Sureflow are trademarks of Medtronic, Inc. SJM Regent and The Global Leader in Heart Valve Devices are trademarks of St. Jude Medical, Inc. St. Jude Medical Cardiac Surgery Division. US Patent Nos. 6,007,577; 6,358,278B1; 6,391,053B1; patents and other foreign patents pending. © 2003 St. Jude Medical, Inc. All rights reserved. ITEM XXXX/0303/XM/EN

The Global Leader in Heart Valve Devices™