Surgical Aortic Valve Replacement

Quality data. Better heart decisions.

Discover the largest data set of contemporary surgical aortic valves, analyzed by a single core lab.¹ Using this data set, Medtronic created a tool for cardiac surgeons that is a novel, robust instrument for evaluating valve performance.

Discover the ultimate valve performance evaluation tool you’ve been waiting for.

Study design

Previous publications on hemodynamic performance of multiple surgical valves have been limited²,³ by a small sample size, a lack of contemporary valves and a lack of the standardized echo technique of a single core lab.

Medtronic and Mayo Clinic partnered together to pool data from four large clinical trials of surgical aortic valve replacement (SAVR) and created the largest surgical valve data set with echocardiograms evaluated by a single core lab to date.⁴⁻⁸

PERIGON*: n = 1129
Evolut Low Risk: n = 682
SURTAVI**: n = 793†
CoreValve High Risk: n = 354†

Pooled Cohort: n = 2958
Analysis Cohort: Analyzed by one core lab, n = 2938

¹20 exclusions due to small sample size: 3F™ (8), Enable™ (2), Solo Smart™ (3), Carbomedics™ (2), Flex Cuff™ (1), Oxane-21™ (1), Regent™ (3).
The standardized data acquisition and use of a single core lab help ensure the consistency in echo assessment methods needed for robust hemodynamic analysis.9

Implied valves by study and model, N

- Avalu™ n = 1134
- Perimount™ n = 741
- Trifecta™ n = 394
- Mitroflow™ n = 53
- Mosaic™ n = 232
- Epic™ n = 39
- Hancock™ n = 67
- Freestyle™ n = 67
- Intuity™ n = 116
- Perceval™ n = 95

- High Risk
- SURTAVI
- Low Risk
- PERIGON†

†The Avalus valve size 17 mm is only approved for commercial use in Japan. The Avalus valve size 29 mm is currently limited to investigational use and not approved for sale in the United States. Given that the Avalus valve sizes 17 mm and 29 mm were included in the PERIGON Pivotal Trial, all data, including the 17 mm and 29 mm data, from the Analysis Cohort is disclosed here. The Avalus 17 mm data accounts for less than 0.05% of the total echo data represented in this analysis. The 29 mm data accounts for less than 1% of the total echo data represented in this analysis.
Transvalvular regurgitation (TVR) % at one year

Paravalvular regurgitation (PVR) % at one year
### Transvalvular regurgitation (TVR) % at one year

<table>
<thead>
<tr>
<th></th>
<th>Avalus</th>
<th>Perimount</th>
<th>Trifecta</th>
<th>Mitroflow</th>
<th>Mosaic</th>
<th>Hancock</th>
<th>Epic</th>
<th>Freestyle</th>
<th>Intuity</th>
<th>Perceval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stented Bovine Pericardial</td>
<td>1.9%</td>
<td>0.2%</td>
<td>0.3%</td>
<td>8.8%</td>
<td>5.1%</td>
<td>9.0%</td>
<td>3.8%</td>
<td>2.3%</td>
<td>1.9%</td>
<td>5.2%</td>
</tr>
<tr>
<td>Stented Porcine</td>
<td>15.1%</td>
<td>16.4%</td>
<td>17.1%</td>
<td>20.6%</td>
<td>85.9%</td>
<td>84.4%</td>
<td>84.6%</td>
<td>79.5%</td>
<td>76.9%</td>
<td>75.3%</td>
</tr>
<tr>
<td>Stentless</td>
<td>83.0%</td>
<td>80.2%</td>
<td>76.0%</td>
<td>70.6%</td>
<td>88.0%</td>
<td>88.1%</td>
<td>93.3%</td>
<td>88.0%</td>
<td>90.9%</td>
<td>90.4%</td>
</tr>
<tr>
<td>Sutureless</td>
<td>51.9%</td>
<td>62.2%</td>
<td>58.9%</td>
<td>45.4%</td>
<td>55.1%</td>
<td>51.1%</td>
<td>40.7%</td>
<td>51.1%</td>
<td>48.7%</td>
<td>45.8%</td>
</tr>
</tbody>
</table>

#### Paravalvular regurgitation (PVR) % at one year

<table>
<thead>
<tr>
<th></th>
<th>Avalus</th>
<th>Perimount</th>
<th>Trifecta</th>
<th>Mitroflow</th>
<th>Mosaic</th>
<th>Hancock</th>
<th>Epic</th>
<th>Freestyle</th>
<th>Intuity</th>
<th>Perceval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stented Bovine Pericardial</td>
<td>95.7%</td>
<td>90.7%</td>
<td>81.5%</td>
<td>85.7%</td>
<td>95.7%</td>
<td>90.7%</td>
<td>84.5%</td>
<td>95.7%</td>
<td>90.7%</td>
<td>81.5%</td>
</tr>
<tr>
<td>Stented Porcine</td>
<td>2.7%</td>
<td>6.6%</td>
<td>12.5%</td>
<td>8.6%</td>
<td>2.7%</td>
<td>6.6%</td>
<td>12.5%</td>
<td>2.7%</td>
<td>6.6%</td>
<td>12.5%</td>
</tr>
<tr>
<td>Stentless</td>
<td>1.5%</td>
<td>5.0%</td>
<td>5.7%</td>
<td>5.7%</td>
<td>1.5%</td>
<td>5.0%</td>
<td>5.7%</td>
<td>1.5%</td>
<td>5.0%</td>
<td>5.7%</td>
</tr>
<tr>
<td>Sutureless</td>
<td>90.9%</td>
<td>90.4%</td>
<td>92.1%</td>
<td>90.9%</td>
<td>90.9%</td>
<td>90.4%</td>
<td>92.1%</td>
<td>90.9%</td>
<td>90.4%</td>
<td>92.1%</td>
</tr>
</tbody>
</table>

Legend: None = Dark Blue, Trace = Light Blue, Mild = Green, Moderate = Red, Severe = Orange
What does it mean for your valve choice?

The new data from this robust analysis provides highly convincing clinical evidence of the safety and efficiency of the Avalus valve design.

Durability
First implanted nearly 10 years ago, the Avalus valve is designed to last:
- Highly efficient AOA™ anti-calcification tissue treatment,* used on 500,000+ valves for over 30 years
- Internally mounted leaflet design, the gold standard for valve durability10

Circularity
Unique to the Avalus valve – and not available in other valves – its non-deformable polymer base combined with flexible stent post:11,12
- Enables efficient blood flow
- Allows regular leaflet motion
- Increases valve durability

Hemodynamics
Designed for 100% coaptation, the Avalus valve provides:
- Large and stable EOAs, low and stable MPGs1
- Low rates of TVR and PVR1
- Low rates of PPM in both controlled and real-world studies1

Lifetime management
Engineered in the modern era of TAVI, the Avalus valve provides:
- Cylindrical opening and circular base to accommodate TAVI landing
- Metal-free polymer frame, reducing risk of metal-on-metal corrosion

*The benefits of AOA tissue treatment have been demonstrated through animal testing. No direct clinical evaluation of the benefits of AOA treatment in humans has been conducted.

References:
What does it mean for your valve choice?
The new data from this robust analysis provides highly convincing clinical evidence of the safety and efficiency of the Avalus valve design.

**Durability**
First implanted nearly 10 years ago, the Avalus valve is designed to last:
- Highly efficient AOA™ anti-calcification tissue treatment,* used on 500,000+ valves for over 30 years
- Internally mounted leaflet design, the gold standard for valve durability

**Circularity**
Unique to the Avalus valve – and not available in other valves – its non-deformable polymer base combined with flexible stent post:11,12
- Enables efficient blood flow
- Allows regular leaflet motion
- Increases valve durability

**Hemodynamics**
Designed for 100% coaptation, the Avalus valve provides:
- Large and stable EOAs, low and stable MPGs
- Low rates of TVR and PVR
- Low rates of PPM in both controlled and real-world studies

**Lifetime management**
Engineered in the modern era of TAVI, the Avalus valve provides:
- Cylindrical opening and circular base to accommodate TAVI landing
- Metal-free polymer frame, reducing risk of metal-on-metal corrosion

*The benefits of AOA tissue treatment have been demonstrated through animal testing. No direct clinical evaluation of the benefits of AOA treatment in humans has been conducted.

References:
**Avalus™ Bioprosthesis**

**Indications:** The Avalus bioprosthesis is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves. **Contraindications:** None known. **Warnings/Precautions/Adverse Events:** Only physicians who have received proper training in valve replacement should use this device. Accelerated structural deterioration due to calcific degeneration of bioprosthesis may occur in: children, adolescents, young adults, and patients with altered calcium metabolism (e.g., chronic renal failure, hyperparathyroidism). Adverse events can include: angina, cardiac dysrhythmias, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage, infection other than endocarditis, transvalvular or paravalvular leak, myocardial infarction, nonstructural valve dysfunction (leaflet entrapment/impingement, obstructive pannus ingrowth, suture dehiscence, inappropriate sizing or positioning, or other), pericardial effusion or tamponade, prosthesis regurgitation, prosthesis stenosis, prosthesis thrombosis, stroke, structural valve deterioration (calciﬁcation, leaflet tear or perforation, or other), thromboembolism, tissue dehiscence, and transient ischemic attack. These complications could lead to reoperation, explant of the bioprosthesis, permanent disability, or death.

**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use. For countries that use eIFUs, consult instructions for use at medtronic.com/manuals.

**Mosaic™ Bioprosthesis**

**Indications:** For the replacement of malfunctioning native or prosthetic aortic and/or mitral valves. **Contraindications:** None known. **Warnings/Precautions/Adverse Events:** Accelerated deterioration due to calcific degeneration of bioprosthesis may occur in: children, adolescents, young adults, and patients with altered calcium metabolism (e.g., chronic renal failure, hyperparathyroidism). Adverse events can include: angina, cardiac arrhythmia, cardiac dysrhythmias, death, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage, perivalvular or paravalvular leak, myocardial infarction, nonstructural dysfunction, stroke, structural deterioration, thromboembolism, or valve thrombosis.

**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use. For countries that use eIFUs, consult instructions for use at medtronic.com/manuals.

**Hancock™ II Bioprosthesis**

**Indications:** For patients who require replacement of their native or prosthetic aortic and/or mitral heart valves. **Contraindications:** None known. **Warnings/Precautions/Adverse Events:** Accelerated deterioration due to calcific degeneration of bioprosthesis may occur in: children, adolescents, young adults, and patients with altered calcium metabolism (e.g., chronic renal failure, hyperparathyroidism). Adverse events can include: angina, cardiac arrhythmia, cardiac dysrhythmias, death, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage, transcaval or paravalvular leak, myocardial infarction, nonstructural dysfunction, stroke, structural deterioration, thromboembolism, or valve thrombosis.

**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use. For countries that use eIFUs, consult instructions for use at medtronic.com/manuals.

**Freestyle™ Aortic Root Bioprosthesis**

**Indications:** For the replacement of malfunctioning native or prosthetic aortic valves with the option of aortic root replacement. **Contraindications:** None known. **Warnings/Precautions/Adverse Events:** Accelerated deterioration due to calcific degeneration of bioprosthesis may occur in: children, adolescents, young adults, and patients with altered calcium metabolism (e.g., chronic renal failure, hyperparathyroidism). Adverse events can include: cardiac dysrhythmias, death, endocarditis, hemolysis, hemorrhage, transvalvular or paravalvular leak, myocardial infarction, nonstructural dysfunction, stroke, structural deterioration, thromboembolism, or valve thrombosis.

**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use. For countries that use eIFUs, consult instructions for use at medtronic.com/manuals.

**Important labeling information for other geographies outside the United States**

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.com and select your appropriate country/region.

For applicable products, consult instructions for use on manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat Reader® with the browser.

---

**Medtronic**

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Toll-free in USA: 800.633.8766
Worldwide: 1.763.514.4000
medtronic.com

**Cardiovascular technical support**
Tel: 1.877.526.7890
Tel: 763.526.7890
Fax: 763.526.7888
rs.csstechsupport@medtronic.com

©2023 Medtronic. All rights reserved. Medtronic, Medtronic logo, and Engineering are trademarks of Medtronic. Third-party brands are trademarks of their respective owners. All other brands are trademarks of a Medtronic company.

UC202404501 IE
10/2023