Medtronic

Avalus™

# PERIGON Pivotal Trial 5-year clinical update

The PERIGON Pivotal Trial was designed to evaluate the safety and effectiveness of the Model 400 (Avalus) bovine pericardial stented aortic bioprosthesis in a patient population undergoing surgical aortic valve replacement. Patients were from Canada (268), Europe (475) and the United States (375). Of the 1,288 patients enrolled, 1,118 were implanted with the Avalus valve. At 5 years, the Avalus valve has shown 0 SVD.

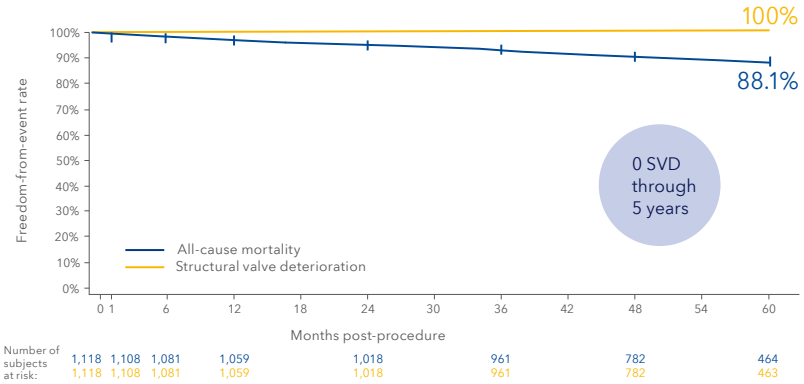
## Key Takeaways

The PERIGON Pivotal Trial 5-year clinical update demonstrated safety and effectiveness of Avalus™ Bioprosthesis:

- EXCELLENT DURABILITY through 5 years: No SVD
- STABLE HEMODYNAMICS: Improvements in mean aortic gradients were stable over time in all valve sizes
- EXCELLENT FUNCTIONALITY: > 95% of subjects had less than mild central regurgitation at 5 years
- STABLE NYHA CLASS: > 95% of subjects reported NYHA class I or II at 5 years
- HIGH survival rate through 5 years

### Kaplan-Meier survival analysis

Freedom-from-event rate for all-cause mortality and structural valve deterioration




### Baseline demographics

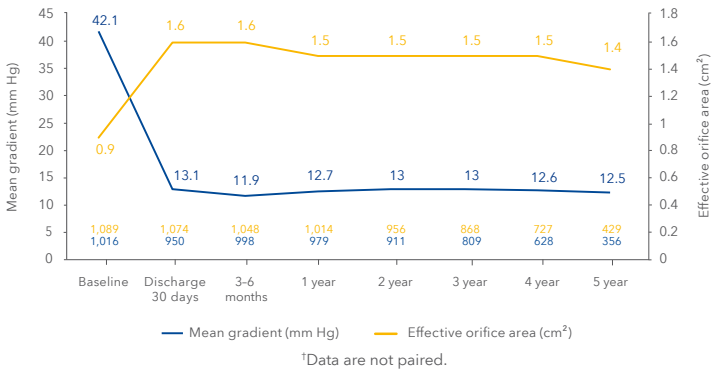
| Patient characteristics | N = 1,118 |
|---|---|
| Age, years | 70.2 ± 9.0 |
| Male sex | 75.1% |
| BSA, $m^2$ | 2.0 ± 0.2 |
| STS risk of mortality | 2.0 ± 1.4% |
| NYHA class I/II | 57.8% |
| NYHA class III/IV | 42.2% |
| Atrial fibrillation | 10.5% |
| Coronary artery disease | 43.6% |

### Procedural data

| Procedural characteristics | N = 1,118 |
|---|---|
| Primary indication | |
| Aortic stenosis | 84.3% |
| Aortic regurgitation | 5.7% |
| Mixed AS/AR | 9.5% |
| Surgical approach | |
| Median sternotomy | 79.6% |
| Less invasive approach | 20.4% |
| Concomitant CABG | 32.4% |

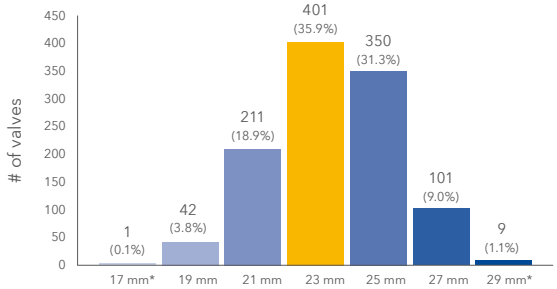
### Echocardiographic findings

All valve sizes†




†Data are not paired.

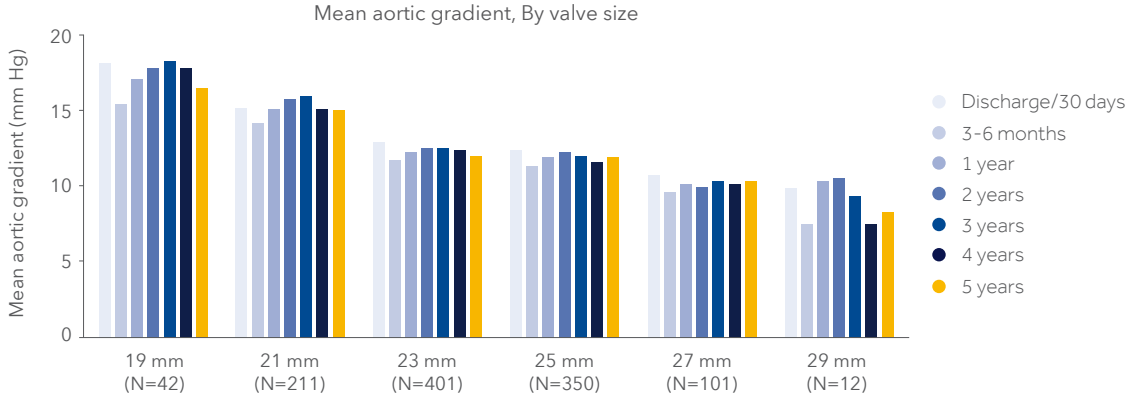
### Valve size distribution




*Not commercially available in the U.S.

## Echocardiographic findings

Mean aortic gradient, By valve size



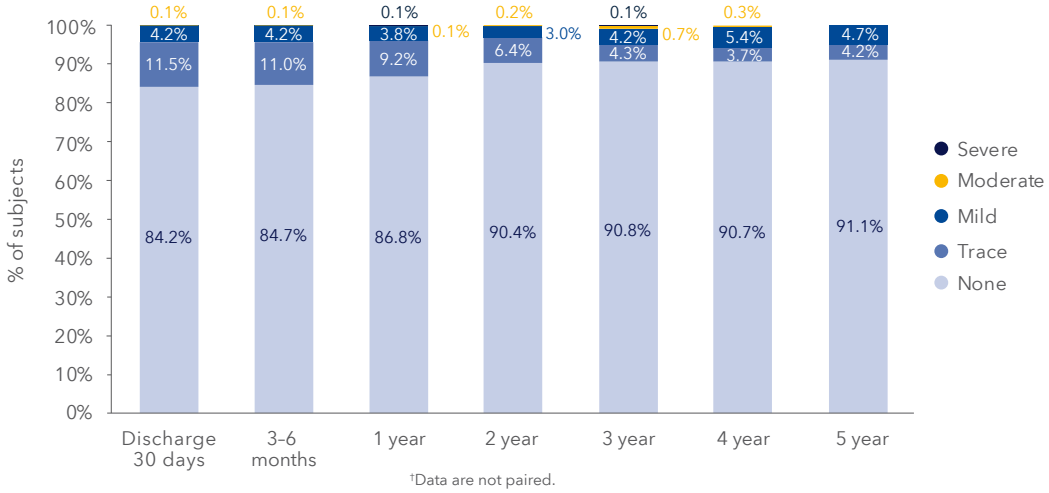

STABLE LOW Mean Aortic Gradients in all valve sizes

N represents number of study patients implanted with mentioned valve size. Number of echocardiography images analyzed to date differ for each study timepoint.

## Echocardiographic findings

Transvalvular regurgitation

All valve sizes†



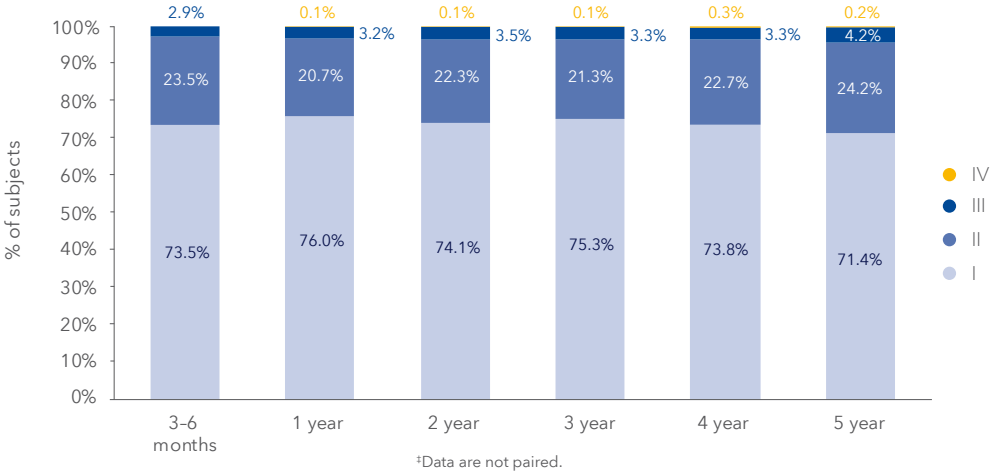

†Data are not paired.

> 95% of subjects had less than mild central regurgitation at 5 years

## NYHA classification by visit

NYHA classification

All valve sizes‡




‡Data are not paired.

> 95% of subjects reported NYHA class I or II at 5 years

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PERIGON Pivotal Trial data on file as of October 2021.

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

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.