Medtronic

Avalus™ Aortic Bioprosthesis

Seven-year results:
Clinical compendium

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Clinical trial overview

Introduction

The Medtronic Avalus aortic bioprosthesis is a contemporary bovine, stented, tissue valve with a supra-annular design and low profile height. It consists of a polyester-covered base frame and trileaflet support frame, which is injection molded using polyetheretherketone (PEEK) material. The valve leaflets are laser cut from bovine tissue that has been cross-linked in a buffered glutaraldehyde solution. The leaflets are mounted internally within the stent, which has been associated with longer durability in bench testing.[1] The valve leaflets are treated with alpha-amino oleic acid (AOA™) tissue treatment, which has been shown to mitigate leaflet calcification in animal studies and is associated with excellent long-term durability.[†,2,3] Risks may include infection, surgical complications, stroke, endocarditis, and death.

The objective of the PERIcardial SurGical AOrtic Valve ReplacemeNt (PERIGON) Pivotal Trial was to evaluate the safety and effectiveness of the Avalus valve, a bovine pericardial surgical bioprosthesis, in a patient population undergoing replacement of the native aortic valve or a failed prosthesis. Previous work has demonstrated a favorable safety profile with good hemodynamic performance and functional recovery through 5 years of follow-up.[4] The first enrollment was May 12, 2014; as of February 14, 2024, 1132 patients had received the study valve. The intermediate follow-up period, from approximately 5 to 7 years postimplant, is a critical time for evaluating the durability and hemodynamic stability of new bioprosthetic valves. This compendium reports the durability, safety, and hemodynamic performance outcomes in the PERIGON study population through 7 years of follow-up.

Methods

Design

The PERIGON Pivotal Trial is a prospective, interventional, nonrandomized, worldwide, multisite trial. The study was designed and conducted in accordance with the recommendations of the International Standards Organization,[5] the Declaration of Helsinki, and good clinical practice guidelines. Valve-related events and deaths were adjudicated by an independent clinical events committee (Baim Institute for Clinical Research, Boston, MA, USA). Echocardiograms were analyzed by an independent core laboratory (Mayo Clinic, Rochester, MN, USA). Safety oversight was provided by an independent data and safety monitoring board (Baim). Explanted valves were evaluated by CVPath Institute (Gaithersburg, MD, USA). This trial is registered at **www.clinicaltrials.gov,** NCT02088554.

† No clinical data that evaluates the long-term impact of AOA treatment in patients are available.

Indications and follow-up

Eligible patients had symptomatic moderate or greater aortic stenosis or chronic, severe aortic regurgitation and a clinical indication for surgical aortic valve replacement. Follow-up visits were performed at discharge (up to 30 days), 3 to 6 months, 1 year, and annually through 5 years. Follow-up was extended to 12 years to continue data collection. Sites with 10 or more active patients at the time of evaluation were invited to continue in the long-term follow-up (LTFU) study. Nineteen sites agreed to participate in LTFU, and 576 patients were re-consented. At the time of this analysis, 441 of 458 patients (96%) with an expected 7-year visit had completed the visit. **Figure 1** provides additional details about the study cohort. Total follow-up was 6412 patient-years, and late follow-up (> 30 days) was 6319 patient-years.[6]

Endpoints

The primary endpoint of this analysis was freedom from surgical explant and/or percutaneous valve-in-valve reintervention due to structural valve deterioration (SVD) through 7 years of follow-up. We also analyzed a composite endpoint of SVD requiring reintervention and/or severe hemodynamic dysfunction (SHD) requiring reintervention to address the limitations of the protocol definition of SVD.[6]

Secondary endpoints were the KM rates of survival (freedom from all-cause mortality), freedom from valve-related reintervention, freedom from valve-related death, New York Heart Association (NYHA) functional classification, and hemodynamic performance, including mean aortic gradient, effective orifice area (EOA), paravalvular leak (PVL), transvalvular leak (TVL), and prosthesis-patient mismatch (PPM).

Valve-related safety endpoints included valve-related thromboembolism, valve thrombosis, hemorrhage, PVL, endocarditis, hemolysis, nonstructural valve dysfunction (NSVD), SVD, reintervention, and explant.[5,7] The safety endpoints were also stratified by surgical procedure.

Data analysis

Categorical variables were expressed as numbers (frequencies), percentages, and continuous variables as means ± standard deviations (SDs). Kaplan-Meier (KM) analyses were performed to summarize the primary, secondary, and valve-related safety endpoints through 7 years of follow-up. Hemodynamic performance was evaluated by analyzing the means and SDs of aortic gradient and EOA, as well as the severity of PVL and TVL.

Results

Patient characteristics

From May 2014 through February 2024, 1312 patients were enrolled at 39 centers in Canada, Europe, and the United States (Table 1). Of these patients, 130 exited the study before valve replacement, and 1132 received the study valve. Total follow-up for the full cohort was 6412 patient-years, and late follow up (> 30 days) was 6319 patient-years. Figure 1 provides details about patient follow-up and exits from the study. The mean age was 70.1 ± 8.9 years (range, 21 to 91 years). Table 2 displays the age of patients at implant. Twenty-five percent of the patients were female. Mean body surface area was 2.0 ± 0.2 m^2. The proportion of patients with cardiac rhythm disturbance, risk factors, and previous cardiovascular surgeries are listed in Tables 3 and 4. Approximately 42% of the patients were in NYHA class III or IV prior to aortic valve replacement (AVR). The most frequently reported primary etiologies of valvular dysfunction were degenerative disease (72%) and congenital bicuspid calcification (30%).[6]

Figure 1. Patient disposition through 7 years of follow-up

Shown are the number of patients expected at the visit (N) and the number of expected patients who completed the visit (n).

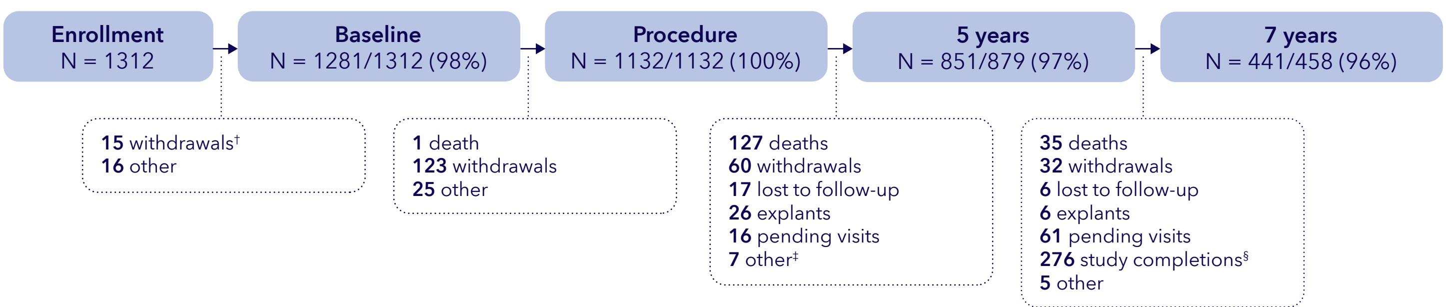


Table 1. Study centers

Center	City	Country	Number of subjects enrolled	Number of subjects implanted
Institut Universitaire de Cardiologie et Pneumologie Québec	Quebec	Canada	159	147
TUM Universitätsklinikum	Munich	Germany	107	89
Hôpital Haut-Lévêque – CHU de Bordeaux	Bordeaux	France	73	70
Leids Universitair Medisch Centrum (LUMC)	Leiden	Netherlands	68	64
Guy's and St Thomas' NHS Foundation Trust – St Thomas Hospital	London	UK	47	45
Helios Health Institute Standort Leipzig	Leipzig	Germany	48	45
Erasmus Medisch Centrum	Rotterdam	Netherlands	53	50
Universitäts Klinikum Frankfurt – Goethe-Universität	Frankfurt	Germany	37	36
Toronto General Hospital	Toronto	Canada	56	47

† Withdrawals include patients who withdrew consent, patients withdrawn by their physicians, and subjects who did not receive a study valve.

‡ In two of these cases, the reason for study exit was entered as study completion, but the patients did not have a 5-year visit.

§ Study completions include patients who completed their 5-year visit and exited the study.

Center	City	Country	Number of subjects enrolled	Number of subjects implanted
London Health Sciences Centre – University Campus	London	Canada	51	40
University of Ottawa Heart Institute	Ottawa	Canada	32	29
Uniklinik Köln	Cologne	Germany	31	25
Medizinische Hochschule Hannover	Hannover	Germany	19	18
Hôpital Bichat – Claude-Bernard	Paris	France	17	16
Inselspital – Universitätsspital Bern	Bern	Switzerland	10	8
Ospedale San Raffaele	Milan	Italy	5	5
Montreal Heart Institute	Montreal	Canada	5	5
Universitätsspital Zürich	Zurich	Switzerland	4	4
ProMedica Toledo Hospital	Toledo	USA	94	84
Houston Methodist Hospital	Houston	USA	51	45
University of Michigan Health System – University Hospital	Ann Arbor	USA	84	51
Piedmont Atlanta Hospital	Atlanta	USA	53	47
The Mount Sinai Hospital	New York	USA	41	30
Heart Hospital of Austin	Austin	USA	47	33
Aurora St. Luke's Medical Center	Milwaukee	USA	19	15
University of Washington (UW) Medical Center	Seattle	USA	14	14
Abbott Northwestern Hospital	Minneapolis	USA	19	19
Cleveland Clinic Foundation	Cleveland	USA	9	5
OhioHealth Riverside Methodist Hospital	Columbus	USA	8	8
New York-Presbyterian Hospital/Columbia University Irving Medical Center	New York	USA	8	5
Massachusetts General Hospital	Boston	USA	6	6
University of Florida Shands Hospital	Gainesville	USA	10	10
Oklahoma Heart Hospital	Oklahoma City	USA	6	4
Maimonides Medical Center	Brooklyn	USA	6	5
Keck Hospital of USC	Los Angeles	USA	4	2
University of Maryland Medical Center	Baltimore	USA	4	2
UCHealth University of Colorado Hospital	Aurora	USA	1	1
Stanford Hospital & Clinics	Stanford	USA	2	0
Hartford Hospital	Hartford	USA	4	3
Total			**1312**	**1132**

Table 2. Distribution of patient age at implant (N = 1132)

Age (years)	n	%
≤ 40	10	0.9
41–50	15	1.3
51–60	94	8.3
61–70	405	35.8
71–80	480	42.4
> 80	128	11.3

Note: Mean patient age at implant was 70.1 ± 8.9 years.

Table 3. Patient characteristics at baseline (N = 1132)

Gender	n	%
Female	278	24.6
Male	854	75.4
NYHA class	**n**	**%**
I	126	11.1
II	533	47.1
III	451	39.8
IV	22	1.9
STS risk score	**N**	**Mean ± SD**
Risk of mortality	1132	2.0 ± 1.4
Risk of morbidity or mortality	1132	14.6 ± 6.1
History of atrial fibrillation	**n/N**	**%**
None	1006/1125	89.4
Paroxysmal	72/1125	6.4
Persistent	32/1125	2.8
Long-standing persistent	15/1125	1.3
Unknown	7	–
Etiology of aortic disease	**n**	**%**
Degenerative	816	72.1
Congenital bicuspid	338	29.9
Rheumatic	16	1.4
Other	52	4.6

NYHA, New York Heart Association.

Table 4. Risk factors and previous CV surgery (N = 1132)

Risk factor	n	%
Coronary artery disease	496	43.8
Congestive heart failure	224	19.8
Hypertension	861	76.1
Angina	427	37.7
Dyslipidemia	698	61.7
Smoking Current smoking	543 89	48.0 7.9
Left ventricular hypertrophy	459	40.5
Diabetes	303	26.8
Previous CV surgery	**n**	**%**
Percutaneous coronary intervention	161	14.2
Coronary artery bypass graft	25	2.2
Implanted cardiac device (i.e., pacemaker or defibrillator)	39	3.4
Previous aortic valve implanted	10	0.9
Percutaneous valvuloplasty	1	0.1
Previous open heart surgery	40	3.5
Valve repair (mitral, tricuspid, or aortic)	4	0.4

Note: Not all risk factors and previous CV surgeries are listed.
CV, Cardiovascular.

Operative data

Table 5 presents details of the implant procedure. Approximately half the patients (51%) underwent at least 1 concomitant procedure. The most common concomitant procedure was coronary artery bypass grafting (32%).

Table 5. Procedural details[6] (N = 1132)

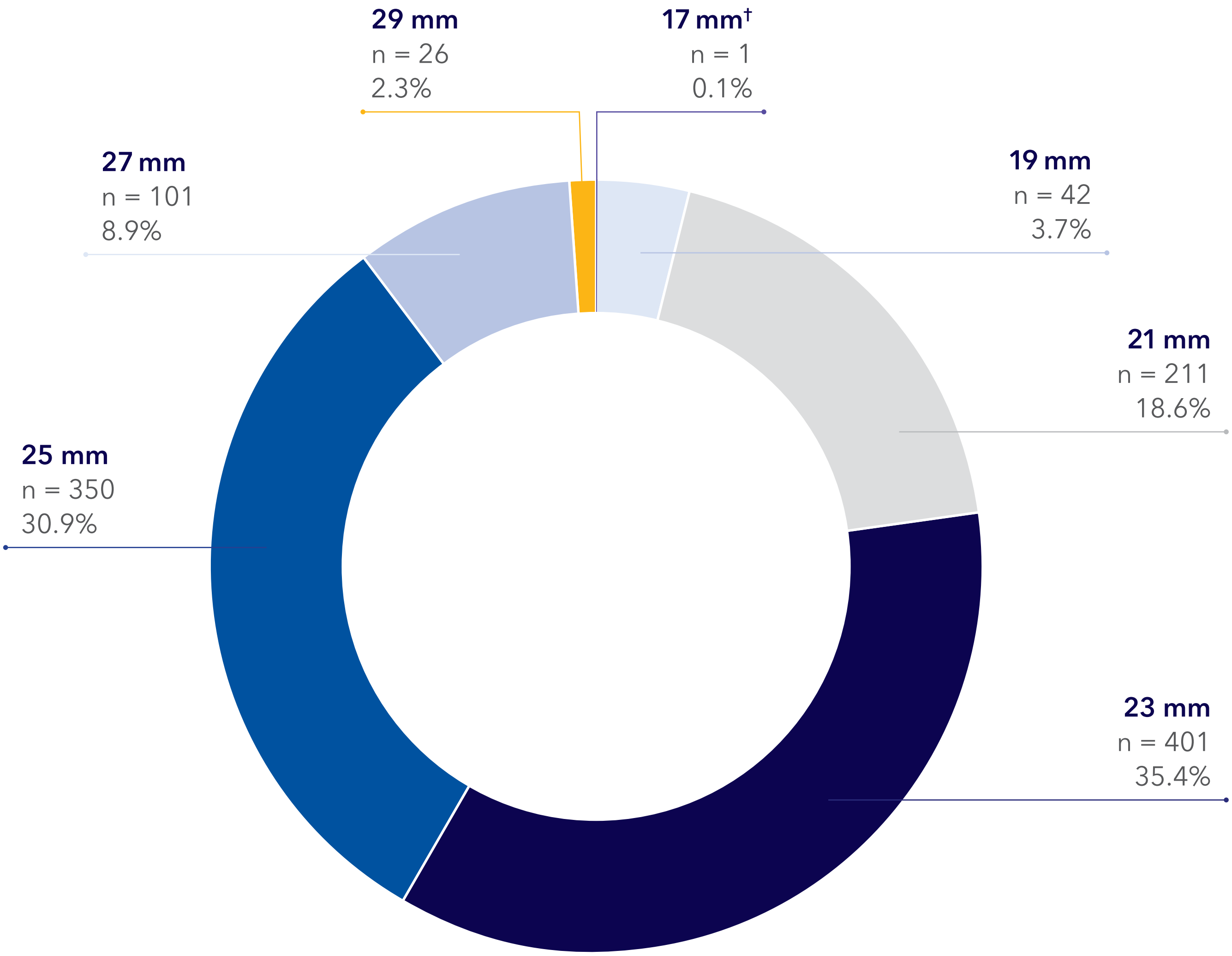
Surgical approach	n	%
Median sternotomy	903	79.8
Hemisternotomy	146	12.9
Right thoracotomy	69	6.1
Other	14	1.2
Concomitant procedures	**n**	**%**
None	555	49.0
Coronary artery bypass graft	365	32.2
Implantable cardiac device (pacemaker, ICD, CRT, etc.)	1	0.1
LAA closure	91	8.0
PFO closure	13	1.1
Resection of sub-aortic membrane not requiring myectomy	21	1.9
Ascending aortic aneurysm repair not requiring circulatory arrest	92	8.1
Dissection repair not requiring circulatory arrest	1	0.1
Other	161	14.2
Aortic bypass	**N**	**Mean ± SD**
Total bypass time, minutes	1131	105.6 ± 41.4
Isolated AVR	555	89.4 ± 29.8
AVR + concomitant procedure(s)	576	121.1 ± 44.9
Total aortic cross-clamp time, minutes	1132	79.4 ± 31.3
Other	**n/N**	**%**
Annular enlargement	33/614	5.4
Aortic root/STJ enlargement	90/617	14.6
Use of Cor-Knot	179/1132	15.8

CABG, coronary artery bypass graft; CRT, cardiac resynchronization therapy; ICD, implantable cardioverter-defibrillator; LAA, left atrial appendage; PFO, patent foramen ovale.

Valve size distribution

Of the 1132 aortic valves implanted, the most common sizes were 23 mm (35%) and 25 mm (31%) (Figure 2).

Figure 2. Avalus bioprosthesis size[6]



† The size 17-mm bioprosthesis is approved for commercial use only in Japan.

Safety outcomes

Freedom from surgical explant and/or percutaneous valve-in-valve reintervention due to SVD/SHD at 7 years was 98.8% (97.5–99.5%) (n = 7). All seven cases were adjudicated as SHD requiring reintervention, and none were adjudicated as SVD. Because of the limitations of the protocol definition, the criteria for SVD were not met for these seven cases, and it was not possible to determine the precise mode of failure. Freedom from valve-related reintervention was 94.3% (92.3–95.7%) at 7 years. Overall survival (freedom from all-cause mortality) was 82.6% (79.8–85.0%), and freedom from valve-related death was 97.4% (95.9–98.3%) (Figure 3).

Table 6 shows the KM rates of valve-related safety events. At 7 years, the KM event rate was 6.3% (4.9–8.1%) for thromboembolism, 0.4% (0.1–1.1%) for valve thrombosis, 9.7% (8.1–11.6%) for all hemorrhage, 1.0% (0.5–1.8%) for PVL, 6.3% (4.9–8.3%) for endocarditis, 5.7% (4.3–7.7%) for reintervention, and 4.4% (3.1–6.0%) for explant. Figures 4–7 show the rates of thromboembolism, endocarditis, hemorrhage, and reintervention when analyzed with death as a competing outcome. The KM event rate at 7 years was 2.8% (1.7–4.6%) for all SHD (requiring/not requiring reintervention) and 1.2% (0.5–2.5%) for SVD/SHD requiring reintervention. The rates for the subcategories were, respectively, 0% (0–0%) and 1.2 (0.5–2.5%). There were no adjudicated cases of SVD not requiring reintervention.

Forty-seven patients underwent a reintervention by the time of analysis. Of the 38 patients who had a surgical reintervention (explant), 33 had endocarditis, 1 had valve thrombosis, 1 had major PVL, and 2 had NSVD (1 major PVL, 1 entrapment by pannus, tissue, or suture). Among the 9 patients who had a percutaneous reintervention, 7 had SHD, 1 had valve thrombosis, 1 had major PVL, and 1 had NSVD (major PVL). Figure 8 shows the KM rates of reintervention stratified by cause.

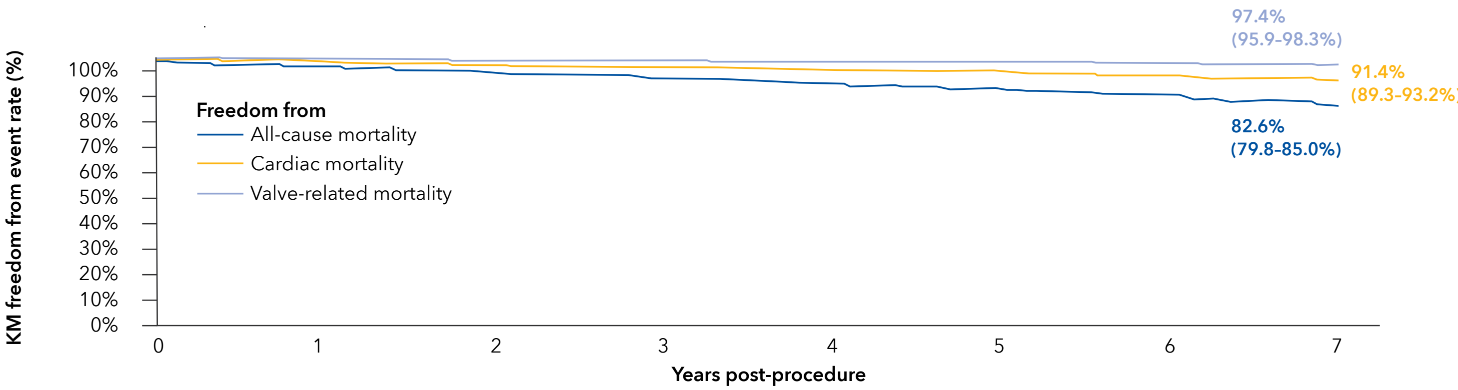
Table 6. Valve-related safety outcomes[6]

Valve-related events†,‡	Early event rate Number of patients (%)	1-Year KM event rate % (95% CI)	5-Year KM event rate % (95% CI)	7-Year KM event rate % (95% CI)
All death	10 (0.9)	3.0 (2.2-4.2)	11.6 (9.8-13.7)	17.4 (15.0–20.2)
Valve-related death	0 (0.0)	0.3 (0.1-0.9)	1.6 (1.0–2.5)	2.6 (1.7-4.1)
Thromboembolism	15 (1.4)	2.7 (1.9-3.8)	5.6 (4.4-7.2)	6.3 (4.9-8.1)
Valve thrombosis	0 (0.0)	0.0 (0.0-0.0)	0.4 (0.1-1.1)	0.4 (0.1-1.1)
All hemorrhage§	17 (1.6)	5.1 (4.0-6.6)	9.7 (8.1–11.6)	9.7 (8.1–11.6)
Major hemorrhage§	11 (1.0)	3.4 (2.5-4.7)	5.8 (4.5-7.4)	5.8 (4.5-7.4)
All paravalvular leak	2 (0.2)	0.5 (0.2-1.2)	1.0 (0.5-1.8)	1.0 (0.5-1.8)
Major paravalvular leak	1 (0.1)	0.2 (0.0-0.7)	0.2 (0.0-0.7)	0.2 (0.0-0.7)
Endocarditis	2 (0.2)	1.2 (0.7-2.0)	4.4 (3.3-5.8)	6.3 (4.9-8.3)
Hemolysis	0 (0.0)	0.0 (0.0-0.0)	1.1 (0.6-2.0)	1.3 (0.7-2.3)
Nonstructural valve dysfunction	2 (0.2)	0.5 (0.2-1.2)	1.3 (0.7-2.2)	1.3 (0.7-2.2)
SVD/SHD requiring reintervention	0 (0.0)	0.0 (NA)	0.2 (0.1-0.8)	1.2 (0.5-2.5)
SHD requiring reintervention	0 (0.0)	0.0 (NA)	0.2 (0.1-0.8)	1.2 (0.5-2.5)
SVD requiring reintervention◊	0 (0.0)	0.0 (NA)	0.0 (NA)	0.0 (0.0-0.0)
Reintervention	4 (0.4)	0.9 (0.5-1.7)	3.3 (2.4-4.6)	5.7 (4.3-7.7)
Explant	4 (0.4)	0.9 (0.5–1.7)	2.9 (2.1-4.2)	4.4 (3.1-6.0)

CI, confidence interval; KM, Kaplan-Meier.

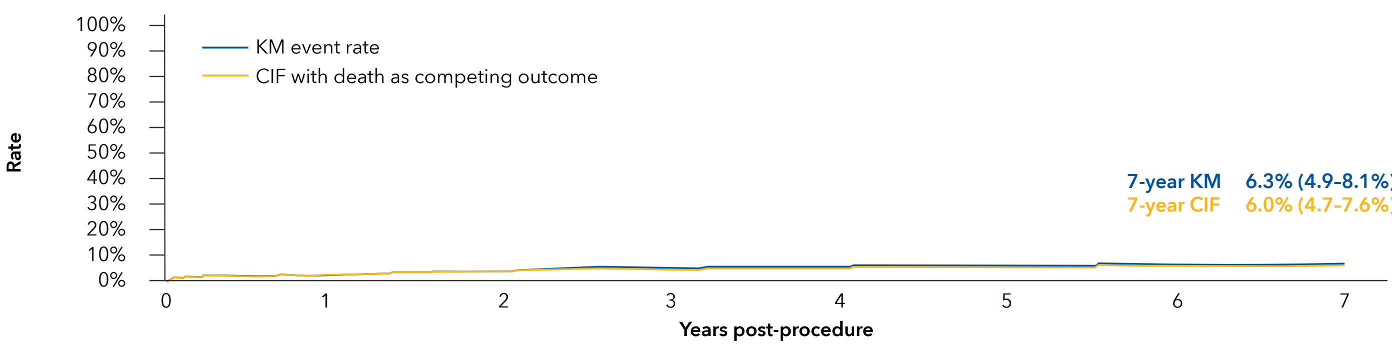
† Analysis cohort is all implanted patients (N = 1132).
‡ Patients may have had > 1 event.
§ Anticoagulant-related hemorrhage only.
◊ There were no adjudicated cases of SVD requiring or not requiring reintervention.

Figure 3. Survival



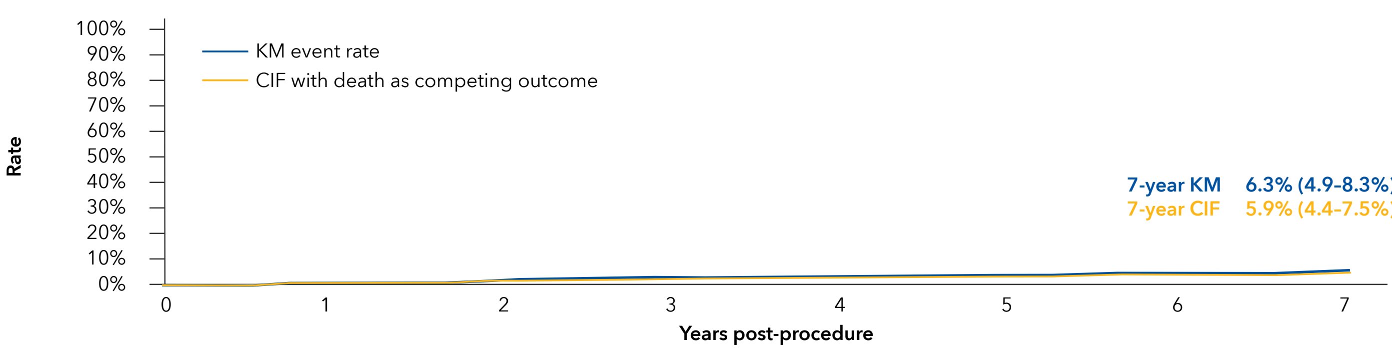
Number at risk							
1132	1070	1021	973	933	786	524	394
1132	1070	1021	973	933	786	524	394
1132	1070	1021	973	933	786	524	394

Figure 4. Thromboembolism analyzed with death as a competing outcome (CIF, cumulative incidence function)



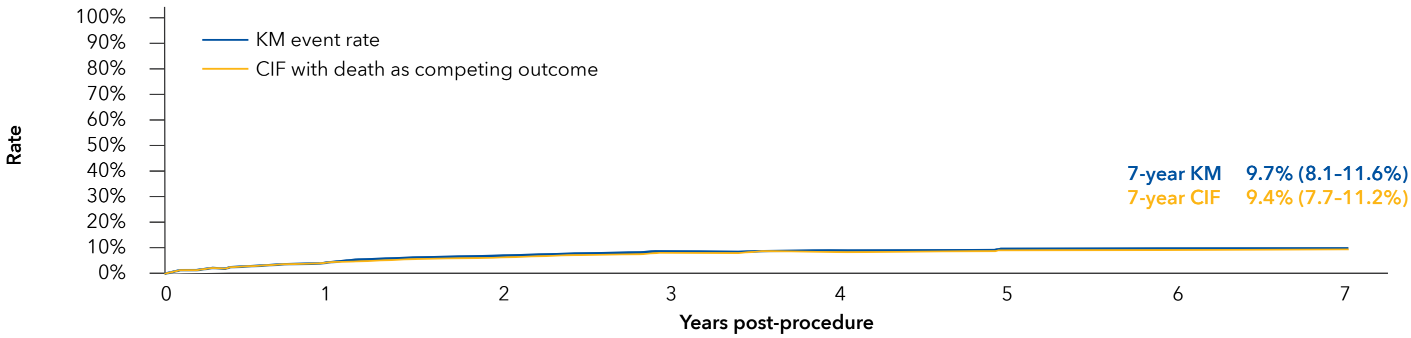
Number at risk							
1132	1040	980	927	886	742	498	374
1132	1041	981	928	886	742	498	374

Figure 5. Endocarditis analyzed with death as a competing outcome (CIF, cumulative incidence function)



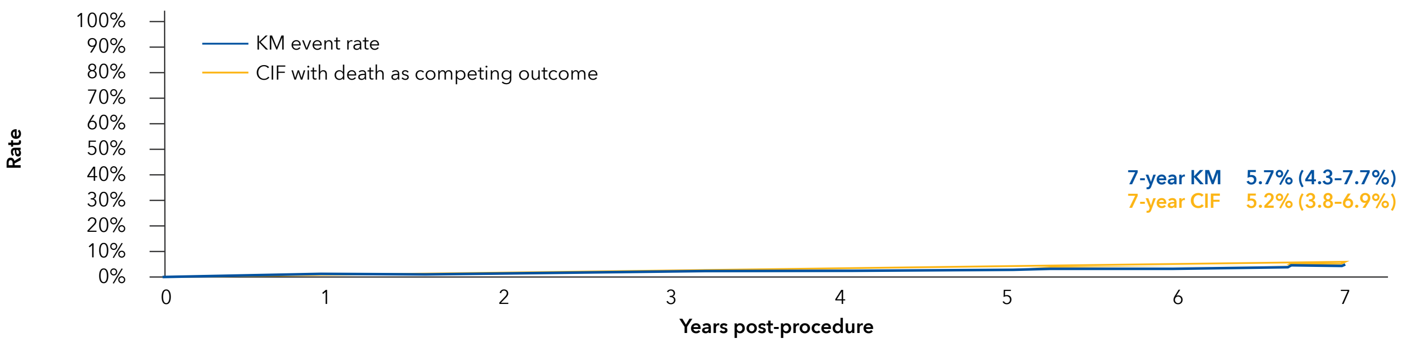
Number at risk							
1132	1065	1010	963	925	776	520	391
1132	1066	1011	964	925	776	520	391

Figure 6. Hemorrhage analyzed with death as a competing outcome (CIF, cumulative incidence function)



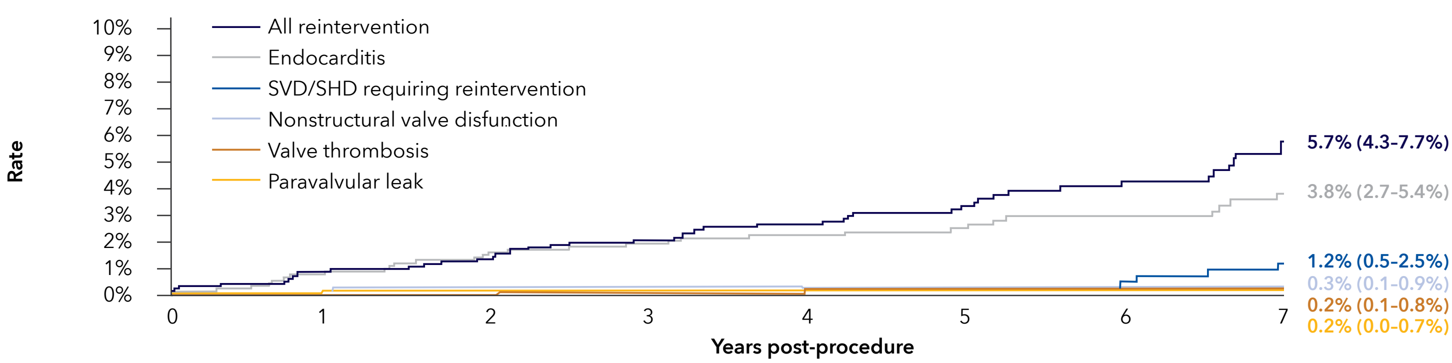
Number at risk							
1132	1023	959	903	863	728	493	367
1132	1024	962	904	863	728	493	367

Figure 7. Reintervention analyzed with death as a competing outcome (CIF, cumulative incidence function)



Number at risk							
1132	1070	1020	972	932	783	524	392
1132	1071	1021	973	932	783	524	392

Figure 8. Causes of reintervention



Number at risk							
1132	1070	1020	972	932	783	524	392
1132	1068	1017	972	933	784	524	394
1132	1070	1021	972	932	786	524	392
1132	1069	1019	971	931	785	524	394
1132	1070	1021	972	931	785	523	394
1132	1069	1020	972	932	785	524	394

Efficacy and hemodynamic performance

NYHA functional classification was improved in patients receiving the Avalus valve, with 95% of subjects in class I or II through 7 years of follow-up (Figure 9). At 7 years, the mean aortic gradient was 13.8 ± 5.9 mmHg, and EOA was 1.99 ± 0.53 (Figure 10). Figure 11 illustrates that 99.0% and 98.3% of patients had none or trace PVL and TVL, respectively. At 7 years, 76.8% of patients had no PPM, 19.6% had moderate PPM, and 3.5% had severe PPM (Figure 12).

Figure 9. NYHA classification from baseline through 7 years of follow-up

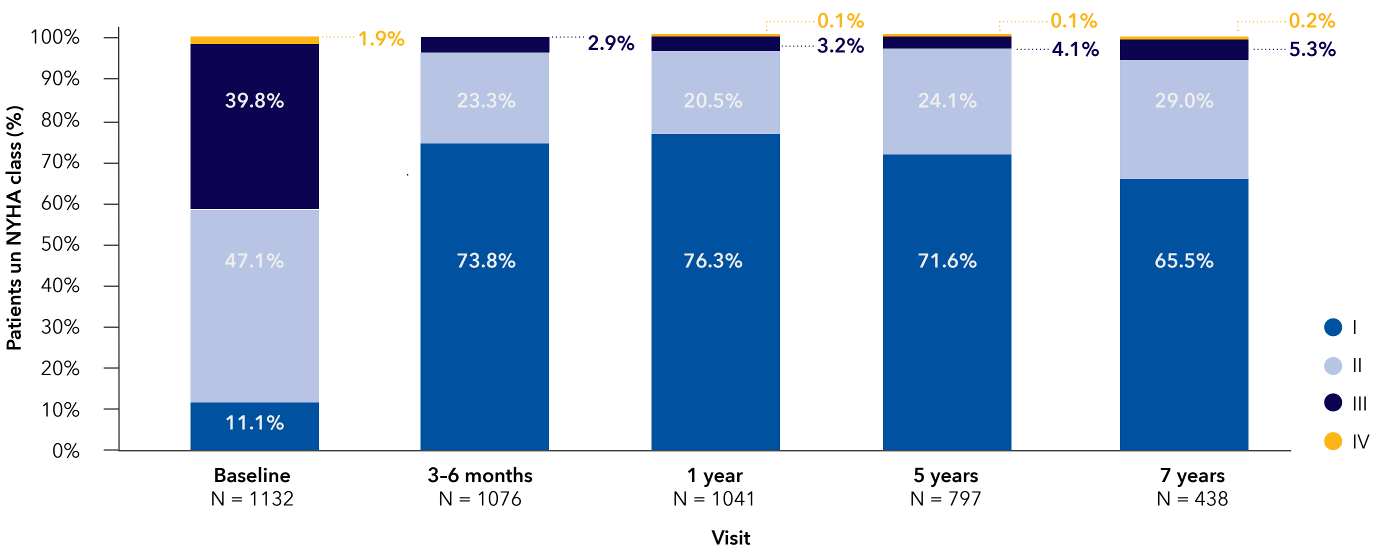
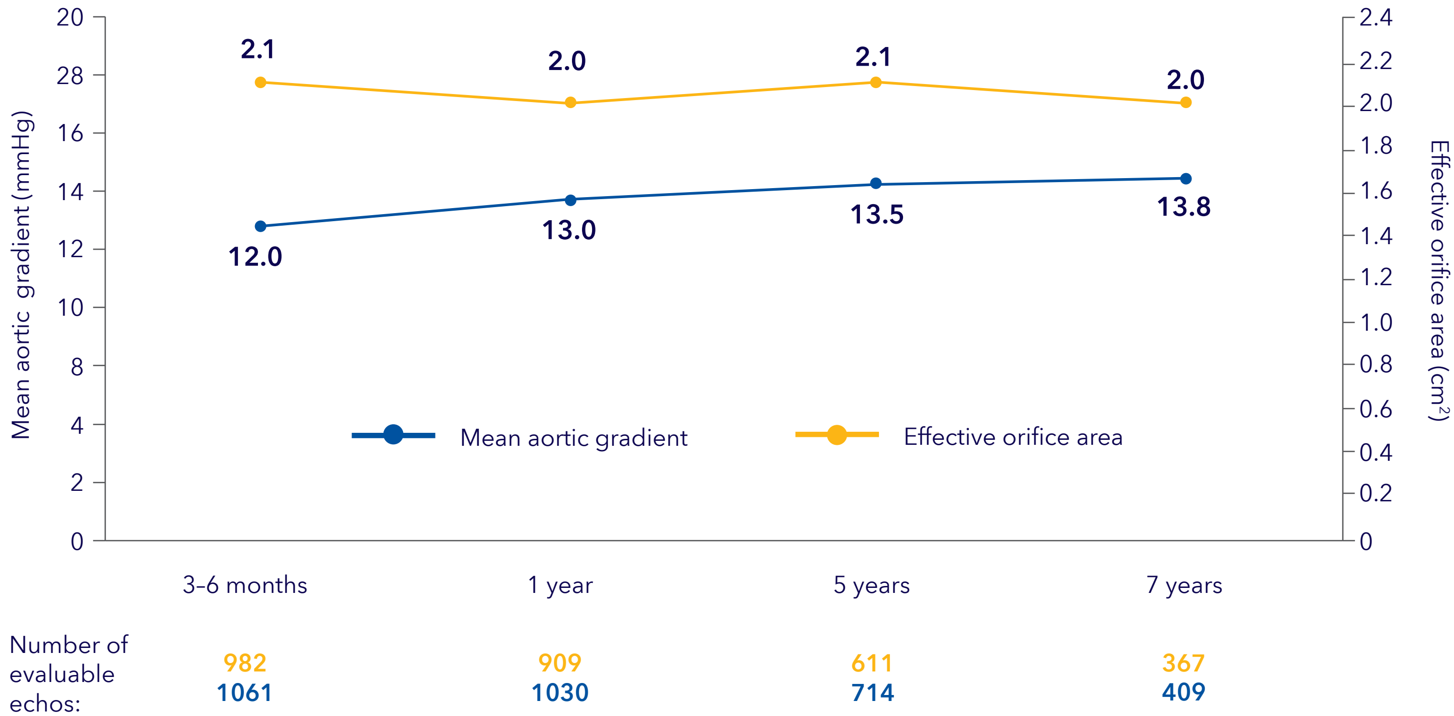


Figure 10. Hemodynamic performance



Data are unpaired. All valve sizes are included.

Figure 11a. Transvalvular regurgitation

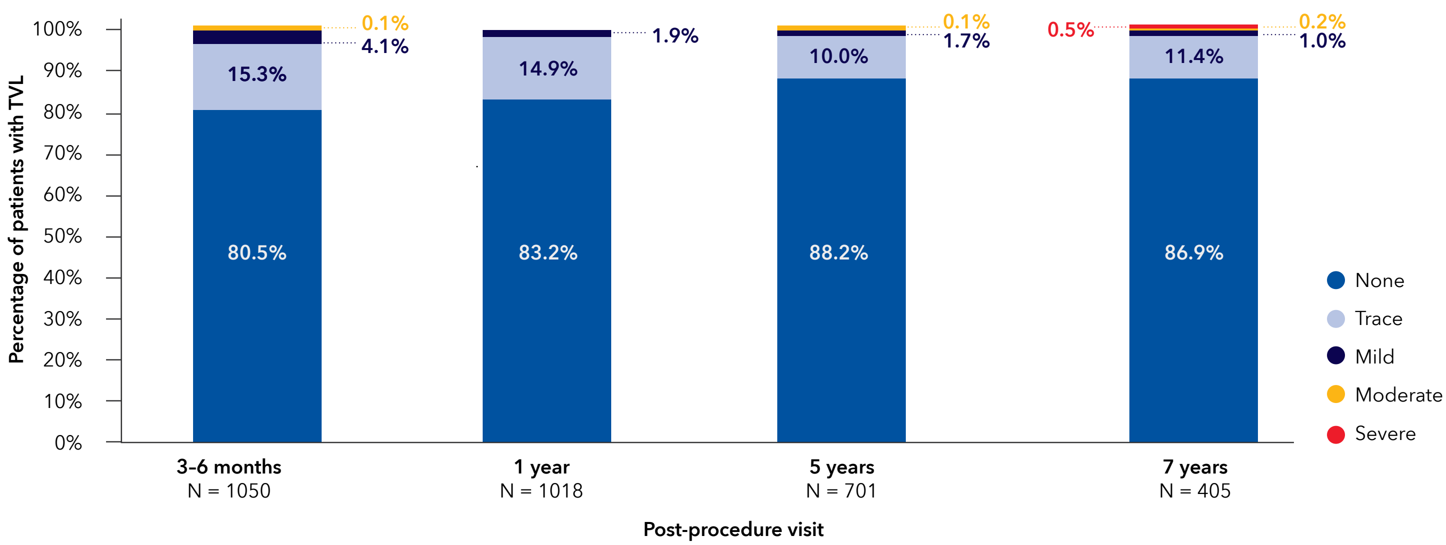


Figure 11b. Paravalvular regurgitation

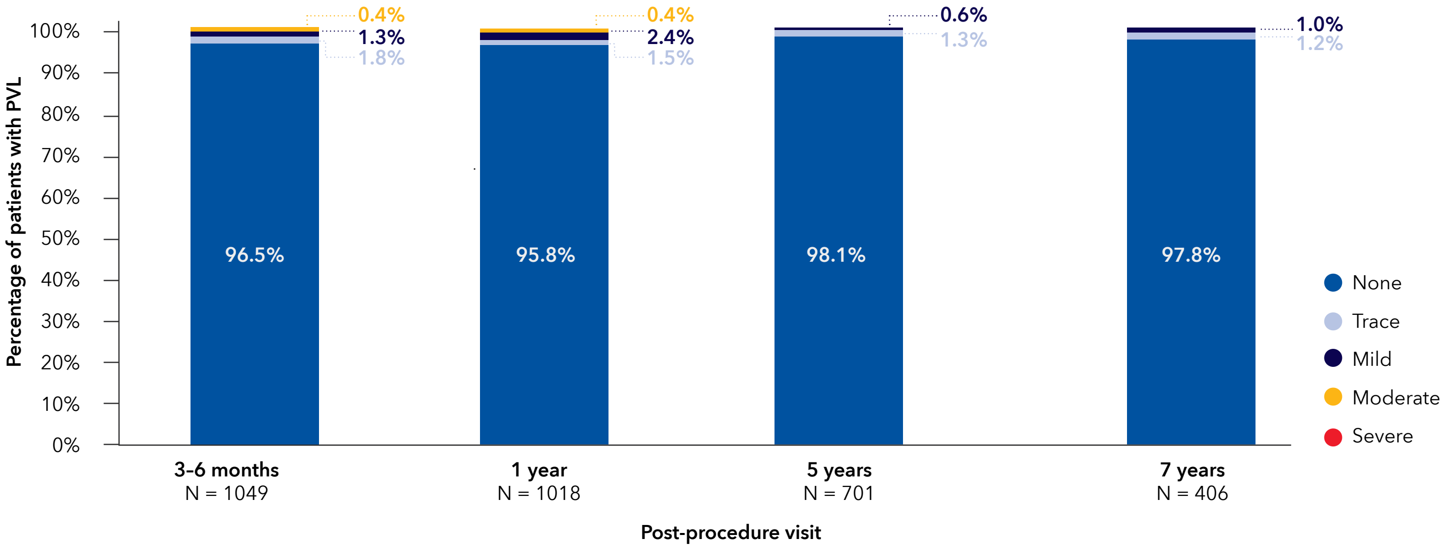
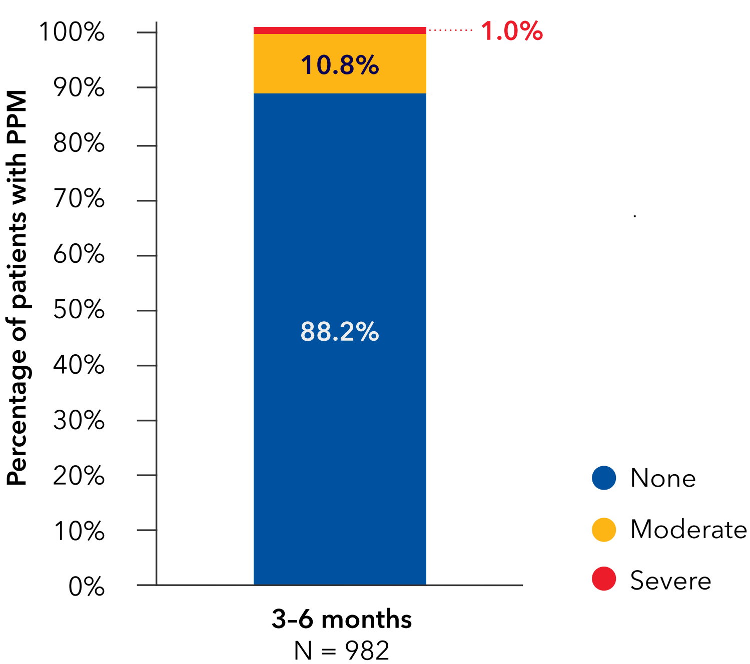


Figure 12. Prosthesis-patient mismatch



Summary

This analysis of the PERIGON trial demonstrates that the Avalus valve delivers excellent clinical outcomes. Over 7 years of follow-up, echocardiographic and clinical data demonstrate consistently stable hemodynamic performance and functional status, underscoring the valve's reliability and efficacy.

Freedom from SVD/SHD requiring reintervention at 7 years was 98.8% (97.5–99.5%), indicating excellent intermediate durability of the valve. Survival from all causes was 83%.

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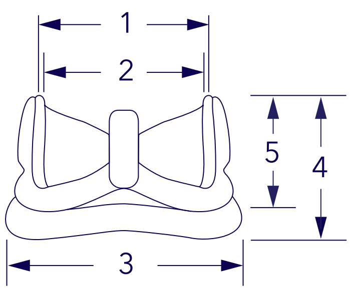
Specifications

Ordering information

Avalus valve order number	Valve size	Stent diameter (TAD)	Internal orifice diameter†		External sewing ring diameter	Valve profile height	Aortic protrusion
		(1)	(2)	(2a)	(3)	(4)	(5)
40017‡	17 mm	17 mm	15.5 mm	16 mm	25.0 mm	12.0 mm	10.0 mm
40019	19 mm	19 mm	17.5 mm	18 mm	27.0 mm	13.0 mm	11.0 mm
40021	21 mm	21 mm	19.5 mm	20 mm	29.0 mm	14.0 mm	12.0 mm
40023	23 mm	23 mm	21.5 mm	22 mm	31.0 mm	15.0 mm	13.0 mm
40025	25 mm	25 mm	23.5 mm	24 mm	33.0 mm	16.0 mm	14.0 mm
40027	27 mm	27 mm	25.5 mm	26 mm	36.0 mm	17.0 mm	15.0 mm
40029	29 mm	29 mm	27.5 mm	28 mm	38.0 mm	18.0 mm	16.0 mm



Accessories

Order number	Description
7420	Valve handle
7400S	Avalus sizers
T7400	Tray, accessory, Avalus

TAD: Tissue annulus diameter
† Measurement shows stent frame including tissue (2) and stent frame excluding tissue (2a).
‡ 40017 is only available in Japan.

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Indications | Contraindications

Avalus™ Bioprosthesis

Important Labeling Information for United States
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, or 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 these devices 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.

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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 **www.medtronic.com** and select your appropriate country/region.

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