Medtronic

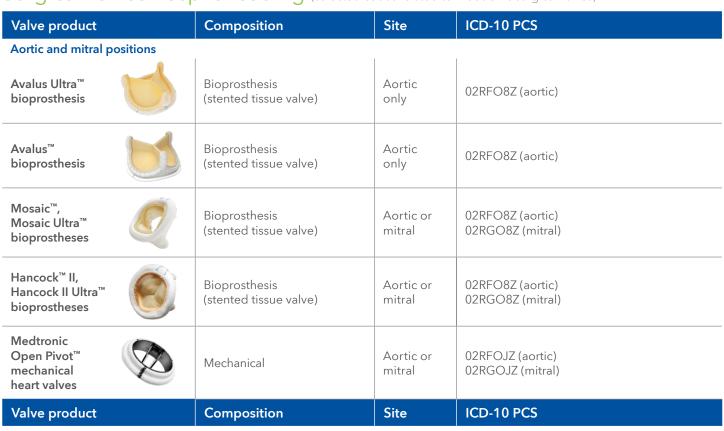
Surgical heart valves

2025 coding and reimbursement

Effective October 1, 2024 through September 30, 2025

This information is provided for your consideration. It is the provider's responsibility to determine and submit appropriate codes, modifiers, and charges for the services rendered.





Aortic root – for replacement of malfunctioning native or prosthetic aortic valves with the option of aortic root replacement

Freestyle[™] aortic root bioprosthesis



Bioprosthesis (stentless tissue valve) Aortic valve only (with aortic root)

02RF08Z for aortic valve replacement.

If coronary arteries ("buttons") are also removed and reimplanted, use additional code, 02S10ZZ.

If ascending aorta is **also** excised and replaced with a synthetic graft, use additional code 02RWOJZ.

Medtronic CardioVascular Reimbursement Hotline: 1-877-347-9662

Surgical valves payment

MS-DRG	Description	Relative weight ¹	Medicare national unadjusted amount ¹
216	Cardiac valve and oth maj cardiothoracic proc w card cath w MCC	9.6511	\$68,875
217	Cardiac valve and oth maj cardiothoracic proc w card cath w CC	6.4579	\$46,087
218	Cardiac valve and oth maj cardiothoracic proc w card cath w/o CC/MCC	5.9493	\$42,457
219	Cardiac valve and oth maj cardiothoracic proc w/o card cath w MCC	7.7375	\$55,219
220	Cardiac valve and oth maj cardiothoracic proc w/o card cath w CC	5.2967	\$37,800
221	Cardiac valve and oth maj cardiothoracic proc w/o card cath w/o CC/MCC	4.5926	\$32,775

Cardiac valve implantation, in combination with other significant procedures

MS-DRG	Description	Relative weight ¹	Medicare national unadjusted amount ¹
212	Concomitant aortic and mitral valve procedures	10.8939	\$77,745

DRG 212 requires a combination of three procedures during the same operative encounter:

- 1. Aortic valve replacement or repair
- 2. Mitral valve replacement or repair
- 3. Other significant cardiovascular procedures, e.g., repair of great vessels, CABG, surgical ablation of aberrant conduction, and repair or replacement of pulmonary or tricuspid valve

Example A:

- 1. Aortic valve replacement 02RF08Z plus
- 2. Mitral valve replacement 02RG08Z plus
- 3. Graft of ascending aorta 02RW0JZ

Example B:

- 1. Aortic valve replacement 02RF08Z plus
- 2. Mitral valve replacement 02RG08Z plus
- 3. CABG from aorta to RCA and LAD via saphenous vein graft 021109W
- 1. FY 2025 IPPS Final Rule Home Page. Centers for Medicare & Medicaid Services. Available at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2025-ipps-final-rule-home-page. Accessed on October 29, 2024.

Assumes payment for a large urban hospital with wage index and geographic adjustment factor of 1.000. Payment = (MS-DRG relative weight) * (labor standardized amount + non-labor standardized amount + capital standardized amount). Does not include additional payment adjustments for IME, DSH, or outliers, which affect payment levels to individual hospitals. Does not include additional payment adjustments for the hospital readmissions reduction program, value-based purchasing, or HAC, which affect payment levels to individual hospitals. Does not include the -2% sequester reduction (mandated by the Budget Control Act of 2011), which affects all hospitals. FY 2025 Final CN standardized amounts are updated by 1.9% compared to FY 2024 Final standardized amounts.

Reimbursement disclaimer

Medtronic provides this information for your convenience only. It does not constitute legal advice or a recommendation regarding clinical practice. Information provided is gathered from third-party sources and is subject to change without notice due to frequently changing laws, rules, and regulations. As a result, Medtronic does not represent or guarantee that this information is complete, accurate, or applicable to any particular patient or third-party payer or guarantees payment.

The provider has the responsibility to determine medical necessity and to submit appropriate documentation, codes, and charges for care provided. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other payers as to the correct form of billing or the amount that will be paid to providers of service. Please contact your Medicare contractor, other payers, reimbursement specialists and/or legal counsel for interpretation of coding, coverage, and payment policies and any applicable laws or regulations that may apply.

This document provides assistance for FDA approved or cleared indications. Where reimbursement is sought for use of a product that may be inconsistent with, or not expressly specified in, the FDA cleared or approved labeling (e.g., instructions for use, operator's manual, or package insert), consult with your billing advisors or payers on handling such billing issues. Some payers may have policies that make it inappropriate to submit claims for such items or related service.

Brief Statements Avalus Ultra™ Bioprosthesis Important Labeling Information for the United States Indications:

The Avalus Ultra bioprosthesis is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves.

Contraindications:

Warnings/Precautions/Adverse Events:

Only physicians who have received proper training in valve replacement should use this device. As with any implanted medical device, there is potential for patient immunological response, including an allergic response. Care should be exercised in patients with hypersensitivities to the device materials. Calcific degeneration could cause accelerated deterioration of the valve in patients with altered calcium metabolism (for example, chronic renal failure, hyperparathyroidism). Calcification may occur earlier in children, adolescents, or young adults. Premature calcification may also occur in older adults who accept a biologic prosthesis. Patients with a bioprosthesis that require chronic anticoagulation are at additional risk of bleeding. Stenosis and regurgitation of the bioprosthesis may occur in patients with coagulation disorders such as AT3 deficiency. Paravalvular leak is more likely to occur in patients with aneurysmal aortic or degenerative conditions, cystic medial necrosis, or Marfan syndrome. Adverse events can include: angina, aortic tissue damage, cardiac dysrhythmias, embolism, endocarditis, heart failure, hemolysis, hemolytic anemia, anticoagulant/antiplatelet-related hemorrhage, immunological response (including allergic response), inflammatory reaction, infection other than endocarditis, transvalvular or paravalvular leak, myocardial infarction, nonstructural dysfunction (leaflet entrapment/impingement, obstructive pannus ingrowth, suture dehiscence, inappropriate sizing), pericardial effusion, pleural effusion, prosthesis regurgitation, prosthesis stenosis, stroke, structural deterioration (calcification, leaflet tear), tamponade, or valve thrombosis. These complications could lead to reoperation, explant of the bioprosthesis, permanent disability or organ damage,

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

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

Avalus™ Bioprosthesis Indications:

The Avalus bioprosthesis is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves.

Contraindications:

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 this device to sale by or on the order of

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 (opens new window). Note: Manuals can be viewed using a current version of any major internet browser

Mosaic[™] and Mosaic Ultra[™] Bioprostheses Indications:

For the replacement of malfunctioning 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, transvalvular or paravalvular leak, myocardial infarction, nonstructural dysfunction, stroke, structural deterioration, thromboembolism, or valve thrombosis.

Caution: Federal law (USA) restricts these devices to sale by or on the order of

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 this website medtronic.com/manuals (opens new window). Note: Manuals can be viewed using a current version of any major internet browser.

Hancock™ II and Hancock II Ultra™ Biobrostheses Indications:

For patients who require replacement of their 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, transvalvular or paravalvular leak, myocardial infarction, nonstructural dysfunction, stroke, structural deterioration, thromboembolism, or valve thrombosis. For additional information, please refer to the Instructions for Use provided with the product.

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

Open Pivot™ Mechanical Heart Valves

The Medtronic Open Pivot™ Heart Valve is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic or

Contraindications:

The Medtronic Open Pivot Heart Valve is contraindicated in patients unable to tolerate anticoagulation therapy.

Potential adverse events:

Adverse events potentially associated with the use of prosthetic heart valves include: cardiac arrhythmias, death, leaflet entrapment (impingement), endocarditis, hemolysis, anticoagulant-related hemorrhage, transvalvular or perivalvular leak, prosthesis thrombosis, structural deterioration, valve

Caution: Federal Law restricts this device to sale by or on the order of a physician or properly licensed practitioner. Refer to the Instructions For Use packaged with each valve for a complete listing of warnings and precautions.

Freestyle™ Aortic Root Bioprosthesis

Indications:

For the replacement of malfunctioning native or prosthetic aortic valves with the option of aortic root replacement.

Contraindications:

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, nonstructural dysfunction, structural deterioration, thromboembolism, valve thrombosis, or intracuspal hematoma. For additional information, please refer to the Instructions For Use provided with

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

Medtronic

Medtronic Cardio Vascular Reimbursement Hotline: 1-877-347-9662

710 Medtronic Parkway Minneapolis, MN 55432-5604

Tel: +1.763.514.4000 Toll-Free: 800.328.2518 LifeLine CardioVascular Technical Support Tel: 877.526.7890 Tel: +1.763.526.7890 rs.cstechsupport@medtronic.com

©2024 Medtronic. All rights reserved. Medtronic, Medtronic logo, and Engineering the extraordinary are trademarks of Medtronic. ™Third-party brands are trademarks of their respective owners. All other brands are trademarks of a Medtronic company.

> UC202408835c EN 11/2024