

Medtronic

Surgical heart valves


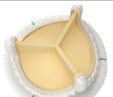



2024 coding and reimbursement




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.

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Surgical valves physician coding (select codes related to Medtronic surgical valves)

Valve product	Composition	Site	CPT ^{®†} code (physician)
Aortic and mitral positions			
Avalus Ultra™ bioprosthesis 	Bioprosthesis (stented tissue valve)	Aortic only	33405 (aortic)
Avalus™ bioprosthesis 	Bioprosthesis (stented tissue valve)	Aortic only	33405 (aortic)
Mosaic™, Mosaic Ultra™ bioprostheses 	Bioprosthesis (stented tissue valve)	Aortic or mitral	33405 (aortic) 33430 (mitral)
Hancock™ II, Hancock II Ultra™ bioprostheses 	Bioprosthesis (stented tissue valve)	Aortic or mitral	33405 (aortic) 33430 (mitral)
Medtronic Open Pivot™ mechanical heart valves 	Mechanical	Aortic or mitral	33405 (aortic) 33430 (mitral)
Valve product	Composition	Site	CPT code (physician)

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)	33410 if coronary arteries are not involved and aortic root is not replaced or 33410-22 if coronary artery reimplantation is performed or 33863 if aortic root replaced, including coronary artery reimplantation in addition to an ascending aorta graft.
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Modifier -22: increased procedural service.

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

† CPT[®] is a registered trademark of the American Medical Association.

Surgical valves payment

CPT code	CPT description	2024 Work RVUs ¹	2024 Total Facility RVUs ¹	2024 Medicare national unadjusted amount ¹
33405	Replacement, aortic valve, with cardiopulmonary bypass; with prosthetic valve other than homograft or stentless valve	41.32	66.76	\$2,222
33410	Replacement, aortic valve, with cardiopulmonary bypass; with stentless tissue valve	46.41	74.68	\$2,486
33430	Replacement, mitral valve, with cardiopulmonary bypass	50.93	82.37	\$2,742
33863	Ascending aorta graft, with cardiopulmonary bypass, with or without valve suspension; with aortic root replacement using composite prosthesis and coronary reconstruction	58.79	92.18	\$3,068

1.CY 2024 payment was calculated with the Conversion Factor (CF) of \$33.2875. CMS CY 2024 Medicare Physician Fee Schedule Final Rule. Available at: <https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeesched/pfs-federal-regulation-notice/cms-1784-f>. Updated CMS RVU files RVU24B. Available at: <https://www.cms.gov/medicare/payment/fee-schedules/physician/pfs-relative-value-files>. Accessed on March 22, 2024. CMS may make adjustments to any or all of the data inputs from time to time without notice.

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.

For questions or more information, contact Medtronic Cardiovascular Health Economics, Policy & Payment at Cardiovascular Reimbursement Hotline 1-877-347-9662 or mail to: rs.cardiovasculartheconomics@medtronic.com

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: None known.

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, 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.

Avalus™ Bioprosthesis Indications:

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

Contraindications
None:

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 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 (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

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 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 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™ Bioprostheses

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 Indications:

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

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 thromboembolism.

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:
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, nonstructural dysfunction, structural deterioration, thromboembolism, valve thrombosis, or intracapsular hematoma. 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.

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

Medtronic

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: +1.763.514.4000
Toll-Free: 800.328.2518

medtronic.com

**LifeLine
CardioVascular Technical Support**
Tel: 877.526.7890
Tel: +1.763.526.7890
rs.cstechsupport@medtronic.com

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