Mosaic Neo™ mitral bioprosthesis

Indications: The Mosaic Neo mitral bioprosthesis is indicated for the replacement of a malfunctioning native or prosthetic mitral heart valve.

Contraindications: No contraindications for use of this device are known.

Warnings/Precautions/Adverse Events: 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, such as nickel. 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: allergic reaction/immunologic response, aneurysm or pseudoaneurysm, aortic tissue damage, cardiac arrest, cardiac arrhythmias, cardiac tamponade, embolism or thromboembolism, endocarditis, heart block, heart failure, hemodynamic instability, hemolysis, hemolytic anemia, anticoagulant/antiplatelet-related hemorrhage, hypertension or hypotension, inflammatory reaction, infection other than endocarditis, transvalvular or paravalvular leak, mitral tissue damage, 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), thrombus or thrombosis. These complications could lead to reoperation, explant of the bioprosthesis, permanent disability or organ damage, 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 (IFU). If applicable, consult electronic IFUs (eIFUs) at www.medtronic.com/manuals. Note: eIFUs can be viewed using a current version of any major internet browser.