SURGICAL HEART VALVE PORTFOLIO

Products designed to help you achieve excellent patient outcomes while enhancing your surgical offerings.
INVESTING IN YOU.
WE’RE DEDICATED TO THE HEART TEAM AND THE LONG-TERM CARE OF YOUR PATIENTS
INVESTING IN INNOVATION
We strive for continuous innovation — not just for innovation’s sake, but to truly advance patient care.

INVESTING IN YOUR EDUCATION AND TRAINING
Our medical education offerings help you stay up-to-date on the latest techniques through a combination of live case observations, didactic sessions, hands-on experience in pig heart simulation labs, and video case reviews.

INVESTING IN YOUR PATIENTS
With a focus on your patient’s long-term quality of life, we work in collaboration with you to develop solutions that achieve excellent patient outcomes.
UNDEMIABLY DURABLE.

- An evolution in durability and implantability
- 80% freedom from explant due to SVD at 16 years in the mitral position
- 81% freedom from explant due to SVD at 17 years in the aortic position
- Cinch™ implant system facilitates ease of valve implant
- Physiologic Fixation promotes long-term valve durability*
- Suitable for future interventions

* No clinical data is available which evaluates the long-term impact of the Physiologic Fixation process in patients.
HEART VALVE REPLACEMENT THERAPIES

TESTED, TRUSTED.

- More than 30 years delivering consistent performance and clinical results
- 97.8% freedom from SVD at 20 years in aortic position
- Impressive long-term performance in all age groups for both aortic and mitral valve
- 85% freedom from SVD at 15 years in mitral position
- Suitable for future interventions

Hancock™ II Bioprosthesis
HEART VALVE REPLACEMENT THERAPIES

MAXIMUM FLOW.

- Designed to function like a native valve with physiologic hemodynamics
- Excellent mean pressure gradients and EOAs out to 10 years\(^5\)
- Strong clinical outcomes and excellent durability at 15 years\(^6\)

Freestyle™
Aortic Root Bioprosthesis
PERFORMANCE IN DESIGN.

- Excellent hemodynamics and reduced hemolysis\(^7,8\)
- Unique axis of suspension responds to physiological demands leading to excellent hemodynamic performance\(^9\)
- Single-plane orifice for implantability
- A remarkably quiet valve
Physiologically-based advanced solutions

Simulus™ Flexible Band
- Allows for continuous movement and natural flexibility

Simulus™ Semi-Rigid Ring & Band
- Restores annular shape while allowing natural saddle shape to reduce mitral stress
- Provides posterior support and accommodates anterior motion
CG Future™ Ring & Band
- Posterior support while preserving annular motion throughout the cardiac cycle\textsuperscript{10}

Profile 3D™ Ring
- Maintains the natural asymmetrical posterior and anterior dimensions with a saddle shape\textsuperscript{11}
NO LONGER THE FORGOTTEN VALVE

Tru-Ad™ Adams Ring

- Flexible repair with targeted support

Contour 3D™ Ring

- Anatomically shaped — 3D remodeling ring
5. Freestyle Aortic Root Bioprosthesis 12-year Clinical Compendium. ©2007 Medtronic.
Hancock II Bioprosthesis 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 leaflets, paraprosthetic leaks, children, adolescents, young adults, and patients with altered calcium metabolism (e.g., chronic renal failure, hypothyroidism). 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 dysfunction, thromboembolism, or valve thrombosis.

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 bioprostheses may occur in children, adolescents, young adults, and patients with altered calcium metabolism (e.g., chronic renal failure, hypothyroidism). Adverse events can include: cardiac dysrhythmias, death, endocarditis, hemolysis, hemorrhage, transvalvular or paravalvular leak, myocardial infarction, nonstructural dysfunction, structural dysfunction, thromboembolism, valve thrombosis, or intracaval hematoma.

Mosaic Bioprosthesis 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 bioprostheses may occur in children, adolescents, young adults, and patients with altered calcium metabolism (e.g., chronic renal failure, hypothyroidism). 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 dysfunction, thromboembolism, or valve thrombosis.

Medtronic Open Pivot Heart Valve - Important Labeling Information for United States 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. Warnings: Persons allergic to cobalt, chromium, or nickel may suffer an allergic reaction specific to the AP360 style device. Adverse events potentially associated with the use of prosthetic heart valves include: angina, cardiac arrhythmia, endocarditis, hemolysis, hemolytic anemia, anticoagulant-related hemorrhage, myocardial infarction, leaflet entrapment (impingement), transvalvular regurgitation, structural dysfunction, parvus, pervalvular leak, transvalvular leak, thrombosis, stroke, thromboembolism. It is possible that these complications could lead to: reoperation, explantation, permanent disability, heart failure, death, stroke.

Medtronic Open Pivot Heart Valve - Important Labeling Information for Geographies Outside of the United States Indications: The Medtronic Open Pivot Heart Valve is intended for use as a replacement valve in patients with damaged, or malfunctioning heart valves. This device may also be used to replace a previously implanted prosthetic heart valve. Contraindications: The Medtronic Open Pivot Heart Valve is contraindicated in patients unable to tolerate anticoagulation therapy. Warnings: Persons allergic to cobalt, chromium, or nickel may suffer an allergic reaction specific to the AP360 style device. Adverse events potentially associated with the use of prosthetic heart valves include: angina, cardiac arrhythmia, endocarditis, hemolysis, hemolytic anemia, anticoagulant-related hemorrhage, myocardial infarction, leaflet entrapment (impingement), transvalvular regurgitation, structural dysfunction, parvus, pervalvular leak, transvalvular leak, thrombosis, stroke, thromboembolism. It is possible that these complications could lead to: reoperation, explantation, permanent disability, heart failure, death, stroke.

Tri-Ad Adams Tricuspid Ring Indications: The Tri-Ad Adams tricuspid annuloplasty rings are for use in patients undergoing surgery for diseased or damaged tricuspid valves. The Tri-Ad Adams tricuspid annuloplasty ring provides support for and restricts expansion of the annulus. Contraindications: Severe, generalized or localized bacterial endocarditis, heavily calcified valves, greatly dilated annulus (not reducible by standard techniques), severe valvular dysfunction (not correctable by standard techniques), valvular retraction with severely reduced mobility, congenital malformations with lack of valvular tissue. Warnings/Precautions/Adverse Events: Only physicians who have received proper training in valve repair should use this device. Adverse events can include: thromboembolic events, death, heart failure, endocarditis, anticoagulant-related bleeding or hemorrhage.

Mosaic Bioprosthesis 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 bioprostheses may occur in children, adolescents, young adults, and patients with altered calcium metabolism (e.g., chronic renal failure, hypothyroidism). Adverse events can include: cardiac dysrhythmias, death, endocarditis, hemolysis, hemorrhage, transvalvular or paravalvular leak, myocardial infarction, nonstructural dysfunction, structural dysfunction, thromboembolism, valve thrombosis, or intracaval hematoma.

Contour 3D Annuloplasty Ring Indications: The Contour 3D ring is indicated for the reconstruction and/or remodeling of pathological tricuspid valves. Contraindications: Heavily calcified valves, valvular retraction with severely reduced mobility, active bacterial endocarditis. Warnings/Precautions/Adverse Events: Only physicians who have received proper training in valve repair should use this device. Adverse events can include: thromboembolic events, dehiscence, hemolysis, stenosis, residual incompetence, heart block, endocarditis, right ventricular outflow tract obstruction, anticoagulant-related bleeding or hemorrhage.

Simulus Semi-Rigid Annuloplasty Ring and Band Indications: The Simulus semi-rigid annuloplasty rings and band are for use in patients undergoing surgery for diseased or damaged mitral valves. The Simulus semi-rigid annuloplasty ring and band provide support for and restrict expansion of the annulus. Contraindications: Severe, generalized or localized bacterial endocarditis, heavily calcified valves, greatly dilated annulus (not reducible by standard techniques), severe valvular dysfunction (not correctable by standard techniques), valvular retraction with severely reduced mobility, congenital malformations with lack of valvular tissue. Warnings/Precautions/Adverse Events: Only physicians who have received proper training in valve repair should use this device. Adverse events can include: thromboembolic events, dehiscence, hemolysis, stenosis, residual incompetence, heart block, endocarditis, systolic anterior motion, left ventricular outflow tract obstruction, anticoagulant-related bleeding or hemorrhage.

Simsus Flexible Annuloplasty Ring and Band Indications: The Simsus Flexible Annuloplasty Ring and Band are for use in those patients undergoing surgery of diseased or damaged mitral or tricuspid valves in whom the surgeon determines that the valve can be preserved by employing the appropriate surgical repair. The annuloplasty ring and band provide support for the mitral or tricuspid annulus and restrict expansion of the annulus. Contraindications: Severe, generalized or localized bacterial endocarditis, heavily calcified valves, greatly dilated annulus (not reducible by standard techniques), severe valvular dysfunction (not correctable by standard techniques), valvular retraction with severely reduced mobility, congenital malformations with lack of valvular tissue. Warnings/Precautions/Adverse Events: Only physicians who have received proper training in valve repair should use this device. Adverse events can include: thromboembolic events, dehiscence, hemolysis, stenosis, residual incompetence, heart block, endocarditis, systolic anterior motion, left ventricular outflow tract obstruction, anticoagulant-related bleeding or hemorrhage.

CG Future Annuloplasty Ring and Band Indications: This device is indicated for the reconstruction and/or remodeling of pathological mitral valves. Valvular insufficiency and/or stenosis may be corrected by appropriate repair and annular remodeling. Contraindications: Heavily calcified valves, valvular retraction with severely reduced mobility, active bacterial endocarditis. Warnings/Precautions/Adverse Events: Only physicians who have received proper training in valve repair should use this device. Adverse events can include: thromboembolic events, dehiscence, hemolysis, stenosis, residual incompetence, heart block, endocarditis, systolic anterior motion, left ventricular outflow tract obstruction, anticoagulant-related bleeding or hemorrhage.

Profile 3D Annuloplasty Ring Indications: This device is indicated for the reconstruction and/or remodeling of pathological mitral valves. Valvular insufficiency and/or stenosis may be corrected by appropriate repair and annular remodeling. Contraindications: Heavily calcified valves, valvular retraction with severely reduced mobility, active bacterial endocarditis. Warnings/Precautions/Adverse Events: Only physicians who have received proper training in valve repair should use this device. Adverse events can include: thromboembolic events, dehiscence, hemolysis, stenosis, residual incompetence, heart block, endocarditis, systolic anterior motion, left ventricular outflow tract obstruction, anticoagulant-related bleeding or hemorrhage.

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 www.medtronic.com. Note: Manuals can be viewed using a current version of any major internet browser.

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