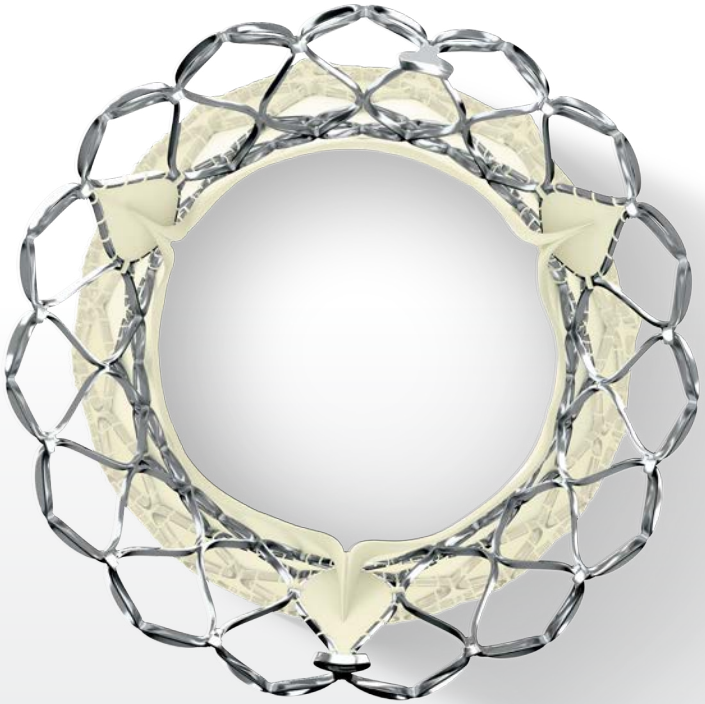
ABOVE **AND** **BEYOND**

Evolut™ PRO+

Transcatheter Aortic
Valve System



Medtronic

THE EVOLUT PRO+ TAVR SYSTEM **ADVANTAGE**

From a design built on a proven platform, the Evolut PRO+ system is taking valve performance and patient outcomes above and beyond.

HEMODYNAMIC PERFORMANCE

for exceptional patient outcomes

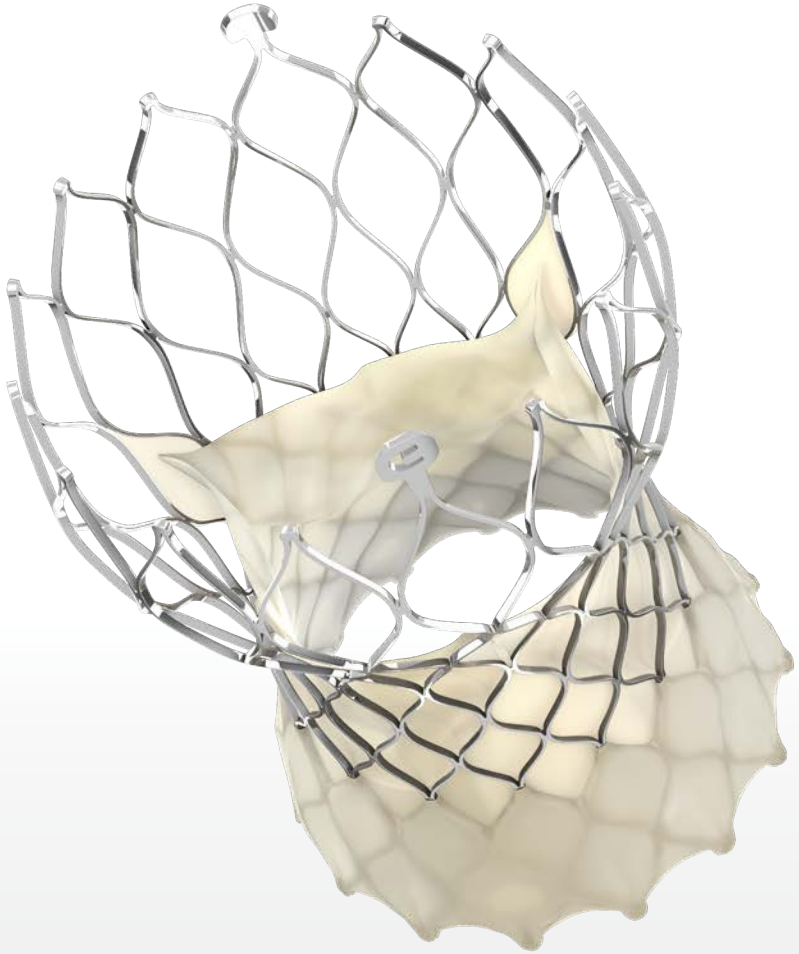
ADVANCED SEALING

for all valve sizes and across the broadest annular range[†]

[†]By CT measurement.

LOWEST DELIVERY PROFILE

for access down to 5.0 mm vessels with the 23-29 mm valves



THE EVOLUT™ HEMODYNAMIC **ADVANTAGE**

Superiority vs. SAVR

The Evolut TAV's supra-annular, self-expanding valve design delivers exceptional hemodynamics and is the only TAVR device to demonstrate hemodynamic superiority in a low-risk clinical trial vs. SAVR.[1]

SUPERIOR
EOAs at 1 year

Evolut TAVR
2.3 cm²
VS.
SAVR 2.0 cm²

SUPERIOR
Gradients at 1 year

Evolut TAVR
8.6 mm Hg
VS.
SAVR 11.2 mm Hg

LARGER EOAs

LOWER GRADIENTS

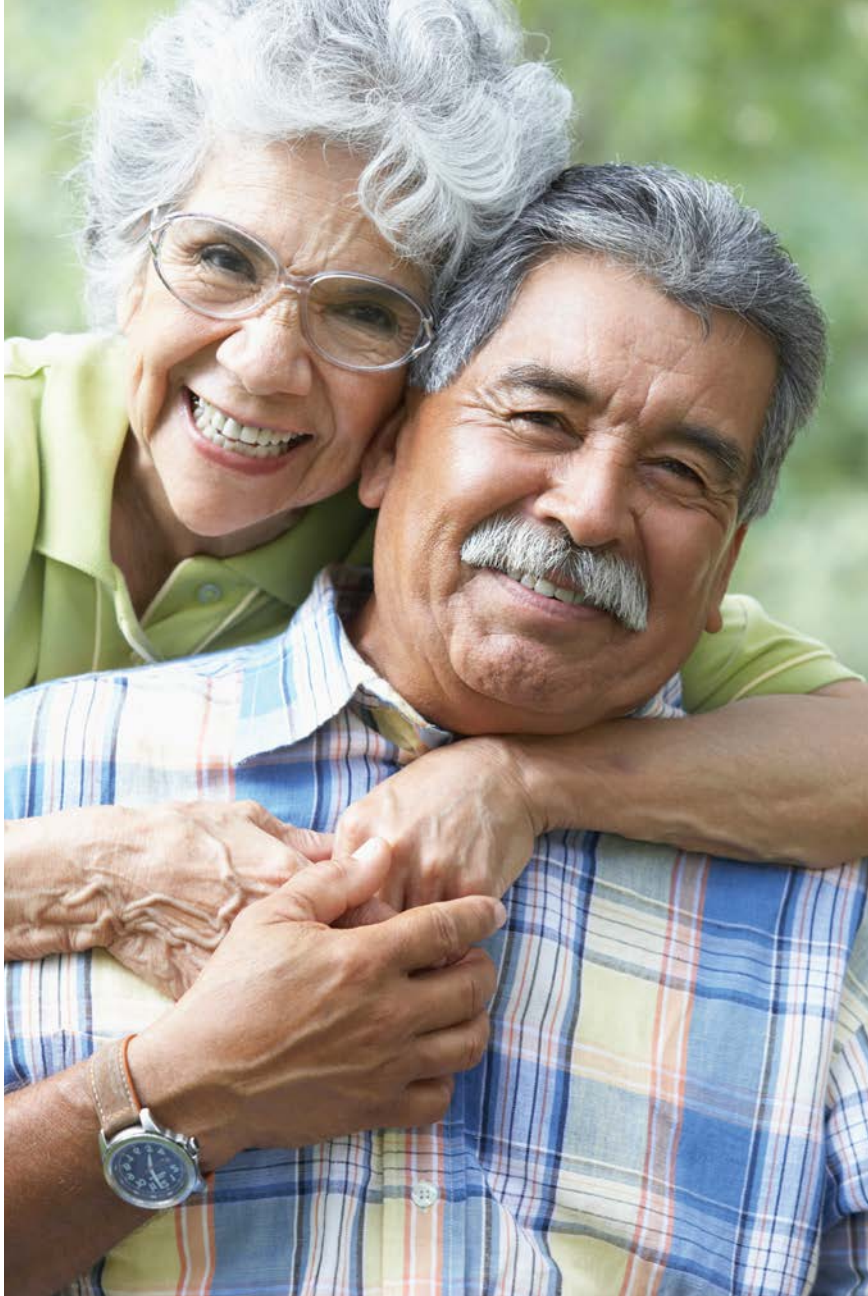
Evolut TAVR has demonstrated large effective orifice areas (EOAs), thereby:

- **Lowering risk of severe patient-prosthesis mismatch (PPM)** and subsequently reducing risk of mortality and heart failure rehospitalizations[2];
- **Promoting increased blood flow** and minimizing PPM, allowing patients to maintain a higher exercise capacity, helping them return to an active life[3,4]; and
- **Suggesting a durable platform** given Evolut TAVR is built on the CoreValve™ supra-annular, self-expanding platform, which has consistently sustained large EOAs and low mean gradients over time.[5]

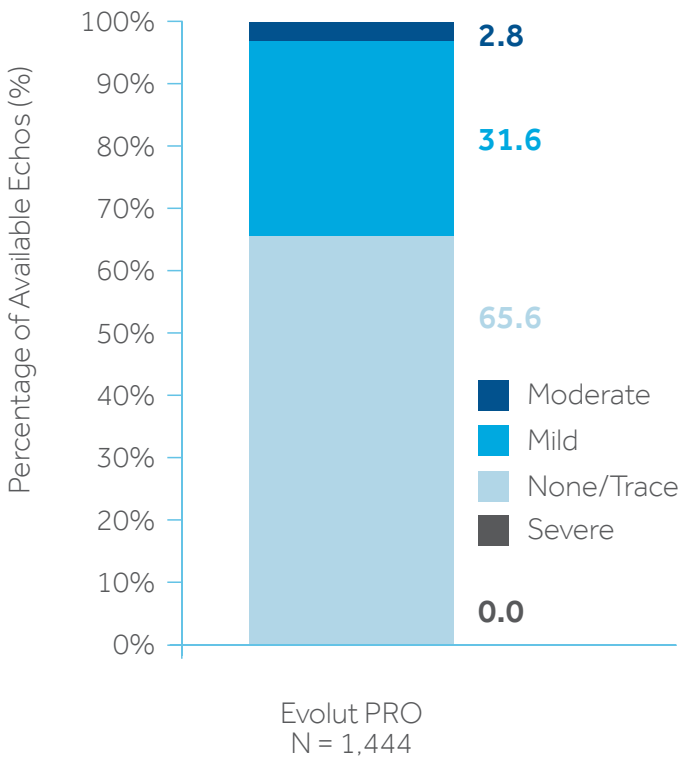
LEADERSHIP IN **VALVE DESIGN**

Advanced Sealing across the Platform

The external tissue wrap on the Evolut PRO valves has shown excellent PVL performance.[6] With the addition of the wrap to the 34 mm PRO+ valve, similar results can be expected — offering advanced sealing across the platform.



Total Aortic Regurgitation at 30 Days[6]



Low Rates of Moderate/Severe PVL

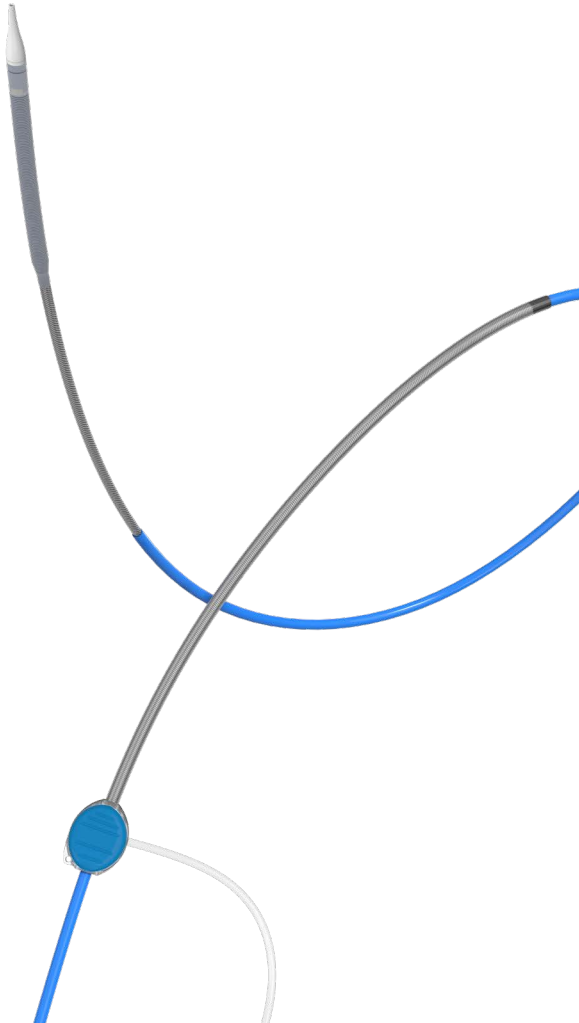
Real-world commercial experience from the STS/ACC TVT Registry™* demonstrates excellent PVL performance.

The views or opinions presented in this document are solely those of Medtronic and do not represent those of the American College of Cardiology, The Society of Thoracic Surgeons, or the STS/ACC TVT Registry™*.

TREAT MORE **PATIENTS**

Broadening Access with an Expanded Platform and Expanded Indication

- With a reduced delivery profile for 23-29 mm valves, only Medtronic is indicated to treat patients with vessels as small as 5.0 mm.
- With the ability to treat the broadest annulus range† of any commercially available TAVR system, Evolut PRO+ valves can treat annulus ranges from 17**/18 mm to 30 mm.
- The Evolut PRO+ system is approved for all symptomatic severe aortic stenosis patients.

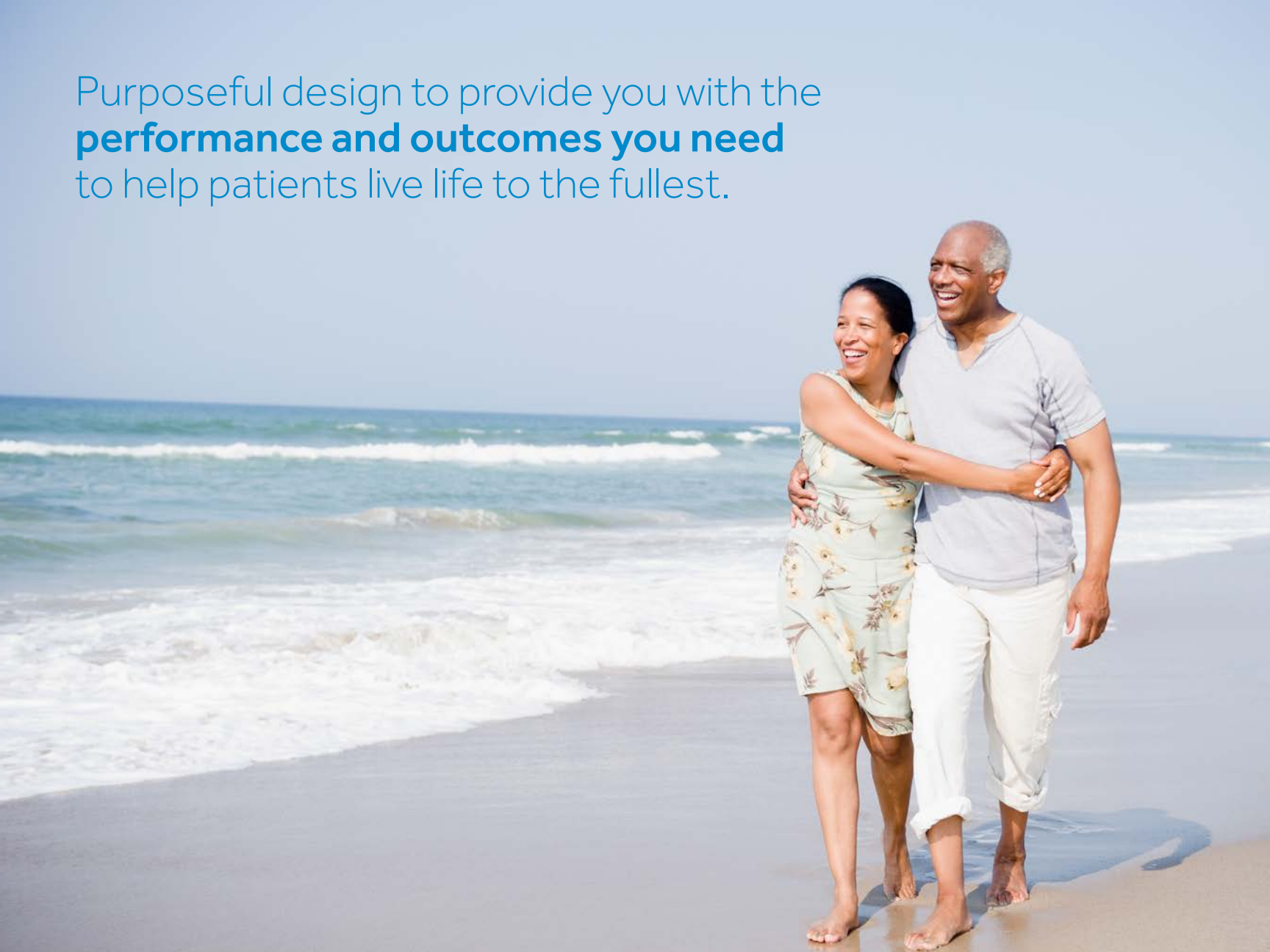


†By CT measurement.
**Measurement is for TAV-in-SAV only.

EVOLUT PRO+
SYSTEM




Purposeful design to provide you with the **performance and outcomes you need** to help patients live life to the fullest.



References
[1] Popma JJ, Deeb GM, Yakubov SJ, et al. Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients. *N Engl J Med*. May 2, 2019;380(18):1706-1715.
[2] Herrmann HC, Daneshvar SA, Fonarow GC, et al. Prosthesis-Patient Mismatch in 62,125 Patients Following Transcatheter Aortic Valve Replacement: From the STS/ACC TVT Registry. *J Am Coll Cardiol*. December 4, 2018;72(22):2701-2711.
[3] Bleiziffer S, Eichinger WB, Hettich I, et al. Impact of patient-prosthesis mismatch on exercise capacity in patients after bioprosthetic aortic valve replacement. *Heart*. May 2008;94(5):637-641.
[4] Van Slooten YJ, van Melle JP, Freling HG, et al. Aortic valve prosthesis-patient mismatch and exercise capacity in adult patients with congenital heart disease. *Heart*. January 2016;102(2):107-113.
[5] Gleason TG, Reardon MJ, Popma JJ, et al. 5-year Outcomes from the Randomized CoreValve US Pivotal High Risk Trial: Final Results. *J Am Coll Cardiol*. September 2018;72(13 Suppl).
[6] Forrest JK, Williams MR, Popma JJ, et al. 30-Day Outcomes Following Transcatheter Aortic Valve Replacement With the Evolut PRO Valve in Commercial Use: A Report from the STS/ACC TVT Registry™. Presented at TCT 2018; San Diego, CA.

The Medtronic Evolut Low Risk Study data included here is based on the primary analysis, as published in the *New England Journal of Medicine*. Subsequently, a supplemental analysis was performed, which included additional follow-up data on the same cohort. These data are summarized in the Instructions for Use and support the findings of the primary analysis.

INDICATIONS The Medtronic CoreValve™ Evolut™ R, CoreValve™ Evolut™ PRO, and Evolut™ PRO+ systems are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.

The Medtronic CoreValve Evolut R, CoreValve Evolut PRO, and Evolut PRO+ systems are indicated for use in patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (e.g., STS predicted risk of operative mortality score ≥ 8% or at a ≥ 15% risk of mortality at 30 days).

CONTRAINDICATIONS The CoreValve Evolut R, CoreValve Evolut PRO, and Evolut PRO+ systems are contraindicated in patients who cannot tolerate Nitinol (Titanium or Nickel), an anticoagulation/antiplatelet regimen, or who have active bacterial endocarditis or other active infections.

WARNINGS *General* Implantation of the CoreValve Evolut R, PRO, and PRO+ systems should be performed only by physicians who have received Medtronic CoreValve Evolut R, PRO, or PRO+ training. This procedure should only be performed where emergency aortic valve surgery can be performed promptly. Mechanical failure of the delivery catheter system and/or accessories may result in patient complications. *Transcatheter aortic valve (bioprosthesis)* Accelerated deterioration due to calcific degeneration of the bioprostheses may occur in: children, adolescents, or young adults; patients with altered calcium metabolism (e.g., chronic renal failure or hyperthyroidism).

PRECAUTIONS *General* Clinical long-term durability has not been established for the bioprosthesis. Evaluate bioprosthesis performance as needed during patient follow-up. The safety and effectiveness of the CoreValve Evolut R, PRO, and PRO+ systems have not been evaluated in the pediatric population. The safety and effectiveness of the bioprosthesis for aortic valve replacement have not been evaluated in the following patient populations: Patients who do not meet the criteria for symptomatic severe native aortic stenosis as defined: (1) symptomatic severe high-gradient aortic stenosis — aortic valve area ≤ 1.0 cm^2 or aortic valve area index ≤ 0.6 cm^2/m^2, a mean aortic valve gradient ≥ 40 mm Hg, or a peak aortic-jet velocity ≥ 4.0 m/s; (2) symptomatic severe low-flow, low-gradient aortic stenosis — aortic valve area ≤ 1.0 cm^2 or aortic valve area index ≤ 0.6 cm^2/m^2, a mean aortic valve gradient < 40 mm Hg, and a peak aortic-jet velocity < 4.0 m/s; congenital bicuspid valve patients who are at low surgical risk (predicted perioperative mortality risk of < 3%); with untreated, clinically significant coronary artery disease requiring revascularization; with a preexisting prosthetic heart valve with a rigid support structure in either the mitral or pulmonic position if either the preexisting prosthetic heart valve could affect the implantation or function of the bioprosthesis or the implantation of the bioprosthesis could affect the function of the preexisting prosthetic heart valve; patients with liver failure (Child-Pugh Class C); with cardiogenic shock manifested by low cardiac output, vasopressor dependence, or mechanical hemodynamic support; patients who are pregnant or breastfeeding. The safety and effectiveness of a CoreValve Evolut R, Evolut PRO, or Evolut PRO+ bioprosthesis implanted within a failed preexisting transcatheter bioprosthesis has not been demonstrated. Implanting a CoreValve Evolut R, Evolut PRO, or Evolut PRO+ bioprosthesis in a degenerated surgical bioprosthetic valve (transcatheter aortic valve in surgical aortic valve [TAV-in-SAV]) should be avoided in the following conditions: The degenerated surgical bioprosthetic valve presents with: a significant concomitant paravalvular leak (between the prosthesis and the native annulus), is not securely fixed in the native annulus, or is not structurally intact (e.g., wire form frame fracture); partially detached leaflet that in the aortic position may obstruct a coronary ostium; stent frame with a manufacturer-labeled inner diameter < 17 mm. The safety and effectiveness of the bioprosthesis for aortic valve replacement have not been evaluated in patient populations presenting with the following: Blood dyscrasias as defined as leukopenia (WBC < 1,000 cells/mm^3), thrombocytopenia (platelet count < 50,000 cells/mm^3), history of bleeding diathesis or coagulopathy, or hypercoagulable states; congenital unicuspid valve; mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation [3-4+]); moderate to severe (3-4+) or severe (4+) mitral or severe (4+) tricuspid regurgitation; hypertrophic obstructive cardiomyopathy; new or untreated echocardiographic evidence of intracardiac mass, thrombus, or vegetation; native aortic annulus size < 18 mm or > 30 mm for Evolut R/Evolut PRO+ and < 18 mm or > 26 mm for CoreValve Evolut PRO per the baseline diagnostic imaging or surgical bioprosthetic aortic annulus size < 17 mm or > 30 mm for CoreValve Evolut R/Evolut PRO+ and < 17 mm or > 26 mm for Evolut PRO; transarterial access unable to accommodate an 18 Fr sheath or the 14 Fr equivalent EnVeo InLine™ sheath when using Model ENVEOR-US/ENVPRO-14-US/D-EVPROP2329US or transarterial access unable to accommodate a 20 Fr introducer sheath or the 16 Fr equivalent EnVeo InLine sheath when using Model ENVEOR-N-US/ENVPRO-16-US or transarterial access unable to accommodate a 22 Fr introducer sheath or the 18 Fr equivalent Evolut PRO+ InLine sheath when using Model D-EVPROP34US; prohibitive left ventricular outflow tract calcification; sinus of Valsalva anatomy that would prevent adequate coronary perfusion; significant aortopathy requiring ascending aortic replacement; moderate to severe mitral stenosis; severe ventricular dysfunction with left ventricular ejection fraction (LVEF) < 20%; symptomatic carotid or vertebral artery disease; and severe basal septal hypertrophy with an outflow gradient.

Prior to Use Exposure to glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to the vapors. Damage may result from forceful handling of the catheter. Prevent kinking of the catheter when removing it from the packaging. The bioprosthesis size must be appropriate to fit the patient's anatomy. Proper sizing of the devices is the responsibility of the physician. Refer to the Instructions for Use for available sizes. Failure to implant a device within the sizing matrix could lead to adverse effects such as those listed below. Patients must present with transarterial access vessel diameters of ≥ 5 mm when using Model ENVEOR-US/ENVPRO-14-US/D-EVPROP2329US or ≥ 5.5 mm when using Model ENVEOR-N-US/ENVPRO-16-US or ≥ 6 mm when using Model D-EVPROP34US, or patients must present with an ascending aortic (direct aortic) access site ≥ 60 mm from the basal plane for both systems. Implantation of the bioprosthesis should be avoided in patients with aortic root angulation (angle between plane of aortic valve annulus and horizontal plane/vertebrae) of > 30° for right subclavian/axillary access or > 70° for femoral and left subclavian/axillary access. For subclavian access, patients with a patient left internal mammary artery (LIMA) graft must present with access vessel diameters that are either ≥ 5.5 mm when using Models ENVPRO-14-US/ ENVEOR-L-US/D-EVPROP2329US or ≥ 6 mm when using Models ENVPRO-16-US and ENVEOR-N-US or ≥ 6.5 mm when using Model D-EVPROP34US. Use caution when using the subclavian/axillary approach in patients with a patent LIMA graft or patent RIMA graft. For direct aortic access, ensure the access site and trajectory are free of patent RIMA or a preexisting patent RIMA graft. For transfemoral access, use caution in patients who present with multiplanar curvature of the aorta, acute angulation of the aortic arch, an ascending aortic aneurysm, or severe calcification in the aorta and/or vasculature. If ≥ 2 of these factors are present, consider an alternative access route to prevent vascular complications. If the patient presents with a bicuspid aortic valve, the heart team should consider the patient's age and the need for ascending aorta intervention when determining the appropriate treatment option for the patient.

During Use After the procedure, administer appropriate antibiotic prophylaxis as needed for patients at risk for prosthetic valve infection and endocarditis. After the procedure, administer anticoagulation and/or antiplatelet therapy per physician/clinical judgment. Excessive contrast media may cause renal failure. Prior to the procedure, measure the patient's creatinine level. During the procedure, monitor contrast media usage. Conduct the procedure under fluoroscopy. Fluoroscopic procedures are associated with the risk of radiation damage to the skin, which may be painful, disfiguring, and long-term. The safety and efficacy of a CoreValve Evolut R, Evolut PRO, or Evolut PRO+ bioprosthesis implanted within a transcatheter bioprosthesis have not been demonstrated.

POTENTIAL ADVERSE EVENTS Potential risks associated with the implantation of the CoreValve Evolut R, CoreValve Evolut PRO, or Evolut PRO+ transcatheter aortic valve may include, but are not limited to, the following: ▪ death ▪ myocardial infarction, cardiac arrest, cardiogenic shock, or cardiac tamponade ▪ coronary occlusion, obstruction, or vessel spasm (including acute coronary closure) ▪ cardiovascular injury (including rupture, perforation, tissue erosion, or dissection of vessels, ascending aorta trauma, ventricle, myocardium, or valvular structures that may require intervention) ▪ emergent surgical or transcatheter intervention (e.g., coronary artery bypass, heart valve replacement, valve explant, percutaneous coronary intervention [PCI], balloon valvuloplasty) ▪ prosthetic valve dysfunction (regurgitation or stenosis) due to fracture; bending (out-of-round configuration) of the valve frame; underexpansion of the valve frame; calcification; pannus; leaflet wear, tear, prolapse, or retraction; poor valve coaptation; suture breaks or disruption; leaks; mal-sizing (prosthesis-patient mismatch); malposition (either too high or too low)/malplacement ▪ prosthetic valve migration/embolization ▪ prosthetic valve endocarditis ▪ prosthetic valve thrombosis ▪ delivery catheter system malfunction resulting in the need for additional recrossing of the aortic valve and prolonged procedural time ▪ delivery catheter system component migration/embolization ▪ stroke (ischemic or hemorrhagic), transient ischemic attack (TIA), or other neurological deficits ▪ individual organ (e.g., cardiac, respiratory, renal [including acute kidney failure]) or multi-organ insufficiency or failure ▪ major or minor bleeding that may require transfusion or intervention (including life-threatening or disabling bleeding) ▪ vascular access-related complications (e.g., dissection, perforation, pain, bleeding, hematoma, pseudoaneurysm, irreversible nerve injury, compartment syndrome, arteriovenous fistula, or stenosis) ▪ mitral valve regurgitation or injury ▪ conduction system disturbances (e.g., atrioventricular node block, left bundle-branch block, asystole), which may require a permanent pacemaker ▪ infection (including septicemia) ▪ hypotension or hypertension ▪ hemolysis ▪ peripheral ischemia ▪ bowel ischemia ▪ abnormal lab values (including electrolyte imbalance) ▪ allergic reaction to antiplatelet agents, contrast medium, or anesthesia ▪ exposure to radiation through fluoroscopy and angiography ▪ permanent disability.

Please reference the CoreValve Evolut R, CoreValve Evolut PRO, and Evolut PRO+ Instructions for Use for more information regarding indications, warnings, precautions, and potential adverse events.

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

The commercial name of the Evolut™ R device is Medtronic CoreValve™ Evolut™ R System, the commercial name of the Evolut™ PRO device is Medtronic CoreValve™ Evolut™ PRO System, and the commercial name of the Evolut™ PRO+ device is Medtronic Evolut™ PRO+ System.

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Medtronic

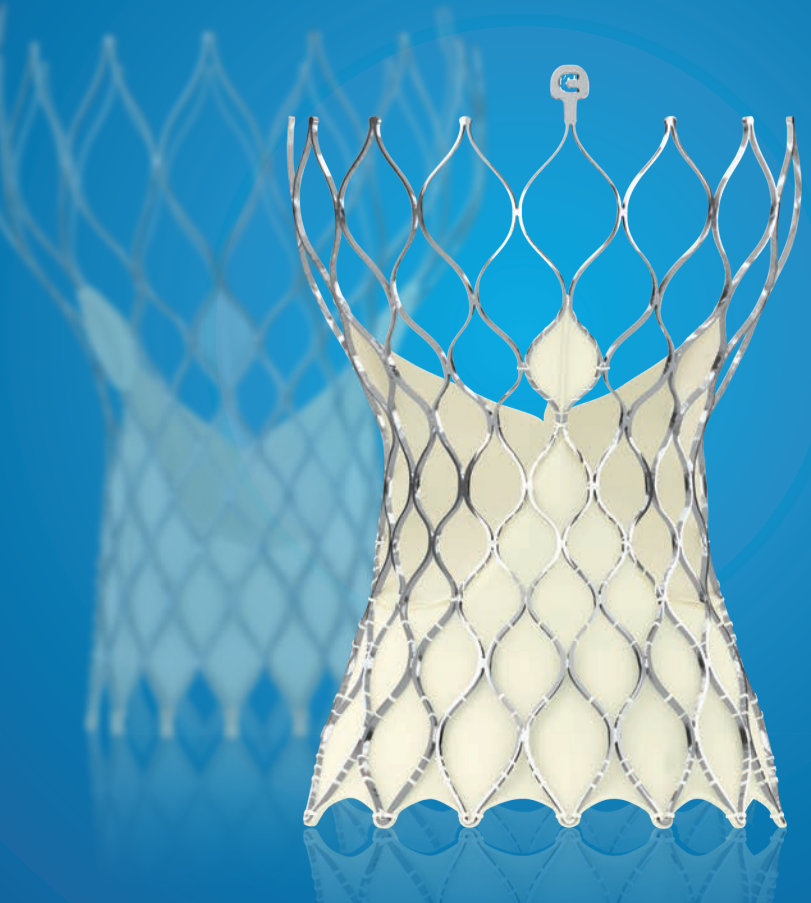
LIFE IS DIFFERENT

CoreValve™
Evolut™ R

Transcatheter Aortic Valve Replacement (TAVR) Platform

Medtronic

BUILT ON A **PROVEN FOUNDATION**



The CoreValve™ System continues to demonstrate exceptional outcomes — and we've taken what we've learned from the design of that platform and applied it to the Evolut™ R System.

Supra-annular Valve Design

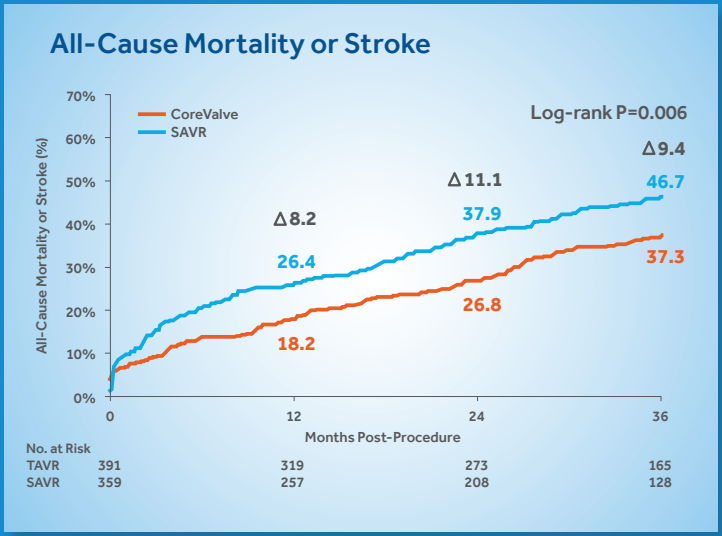
Self-expanding Nitinol Frame

Porcine Pericardial Tissue

Low Delivery Profile

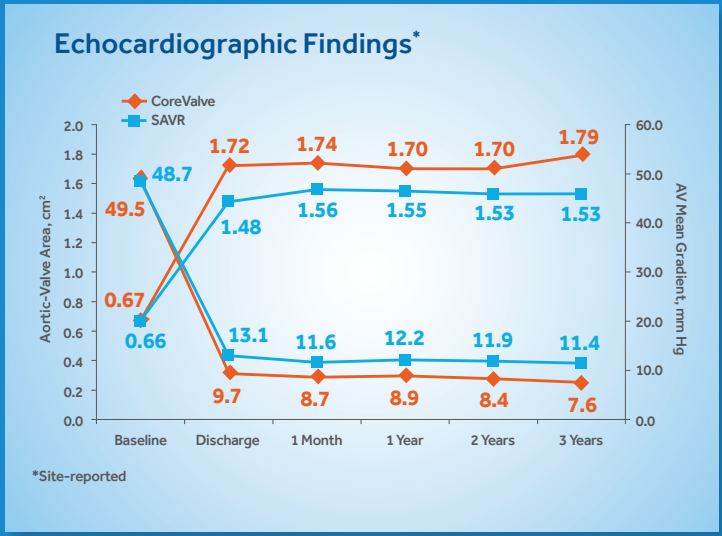
SUPERIOR LONG-TERM CLINICAL OUTCOMES

Lower Rate of Mortality or Stroke



The CoreValve™ Platform shows superior outcomes vs. surgery.[1]

Unsurpassed Sustained Hemodynamic Performance



CoreValve™ system had significantly better valve performance over SAVR at all follow-up visits (P<0.001)[1]

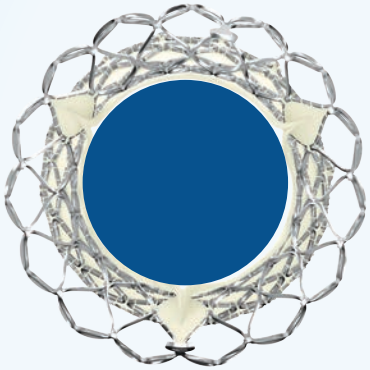
1. CoreValve™ US Pivitol High Risk Trial 3-year Outcomes Presented at ACC 2016.

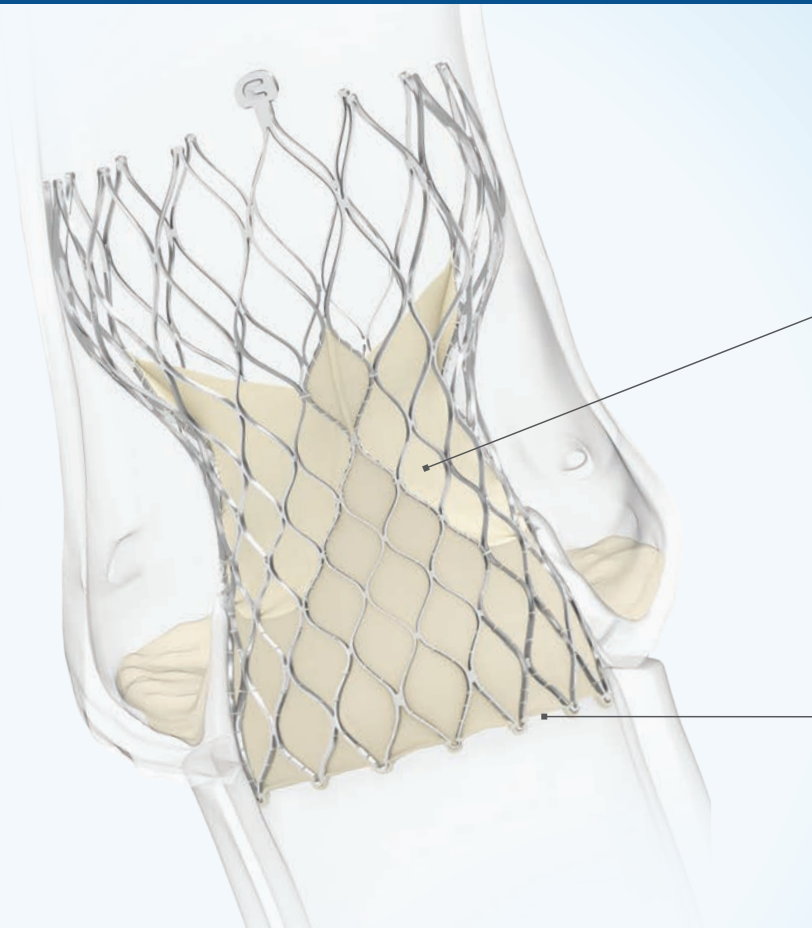
UNSURPASSED **HEMODYNAMICS**

Supra-annular valve design maximizes leaflet coaptation and promotes single digit gradients and large EOA's.

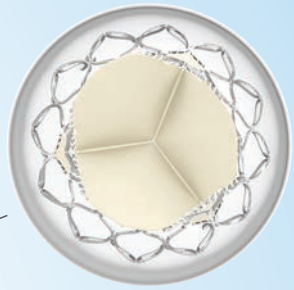
7.5 mm Hg
single digit gradients

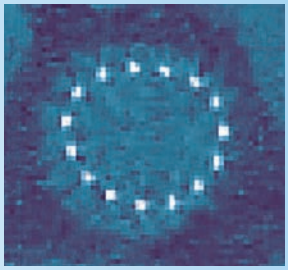
2.0 cm^2
Large EOA



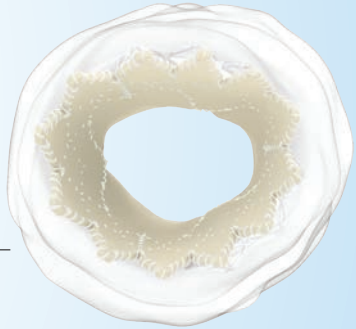


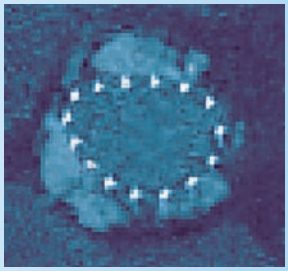
Evolut™ R 30 Day Outcomes.
CoreValve™ Evolut™ R System Instructions for Use 2016 Rev. 1F.





Supra-annular Valve | Optimizes coaptation in non-circular anatomy with supra-annular valve position





Annulus | Conforms to the native annulus

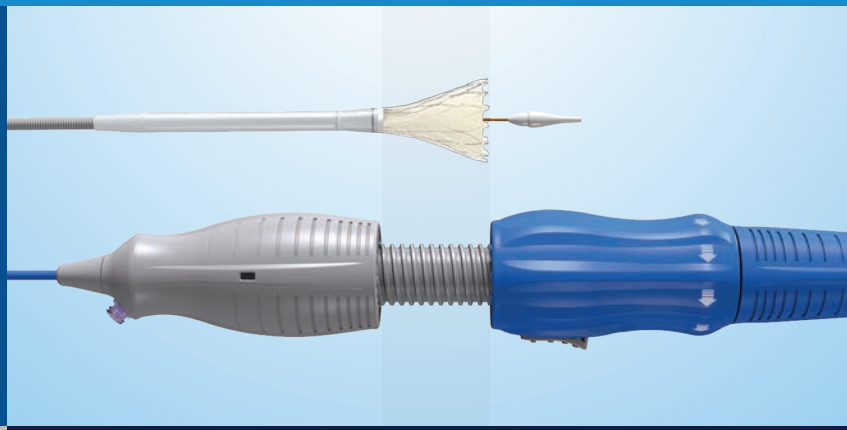
Exceptional Survival

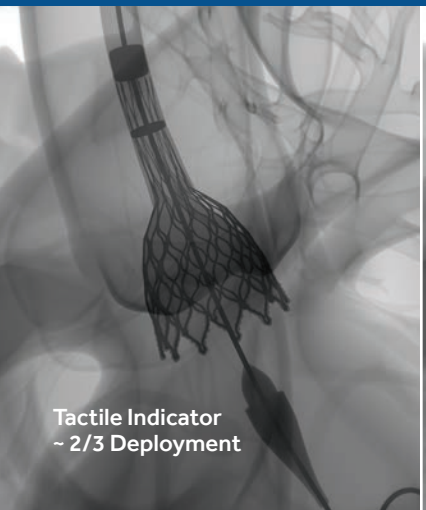
98.8%

CONTROL
DURING DEPLOYMENT

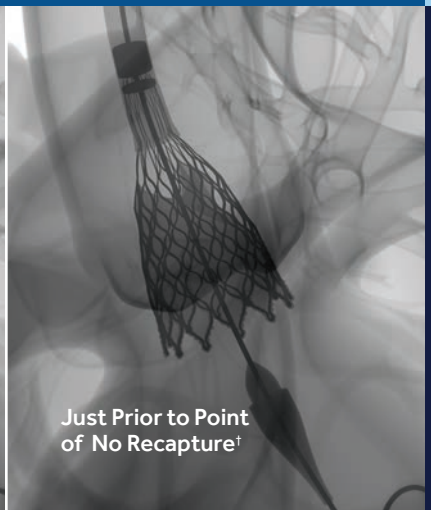
ACCURATE POSITIONING

1:1 response provides immediate feedback between the deployment knob and the movement of the capsule





Tactile Indicator
~ 2/3 Deployment



Just Prior to Point
of No Recapture†

RECAPTURE AND REPOSITION

EnVeo™ R provides option to recapture and reposition for accurate placement.

† Up to 80% deployment.

ACCESS
MORE PATIENTS

BROADEST ANNULUS RANGE ON THE MARKET**

The only TAVR platform indicated to treat annulus up to 30 mm

17/18‡

30 mm

LOWEST DELIVERY PROFILE

The only TAVR system with a vessel indication down to 5.0 mm***

** Broadest annulus range based on CT derived diameters
‡ Measurement for TAV-in-SAV only.
*** Evolut™ R 23, 26 and 29 mm valves. 34 mm valve minimum vessel indication ≥ 5.5 mm

INDICATIONS The Medtronic CoreValve and CoreValve Evolut R systems are indicated for use in patients with symptomatic heart disease due to either severe native calcific aortic stenosis or failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (ie, Society of Thoracic Surgeons predicted risk of operative mortality score ≥8% or at a ≥15% risk of mortality at 30 days).

CONTRAINDICATIONS The CoreValve and CoreValve Evolut R systems are contraindicated for patients presenting with any of the following conditions: known hypersensitivity or contraindication to aspirin, heparin (HIT/HITTS) and bivalirudin, ticlopidine, clopidogrel, Nitinol (Titanium or Nickel), or sensitivity to contrast media, which cannot be adequately premedicated; ongoing sepsis, including active endocarditis; preexisting mechanical heart valve in aortic position.

WARNINGS *General* Implantation of the CoreValve and CoreValve Evolut R systems should be performed only by physicians who have received Medtronic CoreValve training. This procedure should only be performed where emergency aortic valve surgery can be performed promptly. Mechanical failure of the delivery catheter system and/or accessories may result in patient complications. Transcatheter Aortic Valve (Bioprosthesis) Accelerated deterioration of the bioprosthesis may occur in patients presenting with an altered calcium metabolism.

PRECAUTIONS *General* The safety and effectiveness of the CoreValve and CoreValve Evolut R systems have not been evaluated in the pediatric population. The safety and effectiveness of the bioprosthesis for aortic valve replacement have not been evaluated in the following patient populations: patients who do not meet the criteria for symptomatic severe native aortic stenosis as defined: (1) symptomatic severe high gradient aortic stenosis – aortic valve area ≤1.0cm^2 or aortic valve area index ≤0.6 cm^2/m^2, a mean aortic valve gradient ≥40 mmHg; or a peak aortic-jet velocity ≥4.0 m/s, (2) symptomatic severe low-flow/low-gradient aortic stenosis – aortic valve area ≤1.0cm^2 or aortic valve area index ≤0.6 cm^2/m^2, a mean aortic valve gradient <40 mmHg; and a peak aortic-jet velocity <4.0 m/s ; who are at moderate or low surgical risk (predicted perioperative mortality risk of <15%); with untreated, clinically significant coronary artery disease requiring revascularization; with a preexisting prosthetic heart valve with a rigid support structure in either the mitral or pulmonic position if either the preexisting prosthetic heart valve could affect the implantation or function of the bioprosthesis or the implantation of the bioprosthesis could affect the function of the preexisting prosthetic heart valve; with cardiogenic shock manifested by low cardiac output, vasopressor dependence, or mechanical hemodynamic support. The safety and effectiveness of a CoreValve or CoreValve Evolut R bioprosthesis implanted within a failed preexisting transcatheter bioprosthesis has not been demonstrated. Implanting a CoreValve or CoreValve Evolut R bioprosthesis in a degenerated surgical bioprosthesis [transcatheter aortic valve in surgical aortic valve (TAV in SAV)] should be avoided in the following conditions. The degenerated surgical bioprosthesis presents with a: significant concomitant perivalvular leak (between the prosthesis and the native annulus), is not securely fixed in the native annulus, or is not structurally intact (eg, wireform frame fracture); partially detached leaflet that in the aortic position may obstruct a coronary ostium; stent frame with a manufacturer's labeled inner diameter <17 mm. The safety and effectiveness of the bioprosthesis for aortic valve replacement have not been evaluated in patient populations presenting with the following: blood dyscrasias as defined: leukopenia (WBC <1000 cells/mm^3), thrombocytopenia (platelet count <50,000 cells/mm^3), history of bleeding diathesis or coagulopathy, or hypercoagulable states; congenital bicuspid or unicuspid valve; mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation [3-4+]); moderate to severe (3-4+) or severe (4+) mitral or severe (4+) tricuspid regurgitation; hypertrophic obstructive cardiomyopathy; new or untreated echocardiographic evidence of intracardiac mass, thrombus, or vegetation; native aortic annulus size <18 mm or >29 mm for CoreValve and <18 mm or >30 mm for CoreValve Evolut R per the baseline diagnostic imaging or surgical bioprosthetic aortic annulus size <17 mm or >29 mm for CoreValve and <17 mm or >30 mm for CoreValve Evolut R; transarterial access not able to accommodate an 18 Fr introducer sheath or the 14 Fr equivalent EnVeo R InLine sheath when using Model ENVEOR-US or transarterial access not able to accommodate a 20 Fr introducer sheath or the 16 Fr equivalent EnVeo R InLine sheath when using Model ENVEOR-N-US;. sinus of valsalva anatomy that would prevent adequate coronary perfusion; moderate to severe mitral stenosis; severe ventricular dysfunction with left ventricular ejection fraction (LVEF) <20%; symptomatic carotid or vertebral artery disease; severe basal septal hypertrophy with an outflow gradient.

Prior to Use Exposure to glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to the vapors. Damage may result from forceful handling of the catheter. Prevent kinking of the catheter when removing it from the packaging. This device was designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. The bioprosthesis size must be appropriate to fit the patient's anatomy. Proper sizing of the device is the responsibility of the physician. Refer to Instructions for Use for available sizes. Failure to implant a device within the sizing matrix could lead to adverse effects such as those listed below. Patients must present with access vessel diameters of ≥6 mm for the CoreValve system, ≥5 mm for the CoreValve Evolut R system when using Model ENVEOR-US, or ≥5.5 mm when using Model ENVEOR-N-US, or patients must present with an ascending aortic (direct aortic) access site ≥60 mm from the basal plane for both systems. Implantation of the bioprosthesis should be avoided in patients with aortic root angulation (angle between plane of aortic valve annulus and horizontal plane/vertebrae) of >30° for right subclavian/axillary access or >70° for femoral and left subclavian/axillary access. Use caution when using the subclavian/axillary approach in patients with a patent LIMA graft or patent RIMA graft. For direct aortic access, ensure the access site and trajectory are free of patent RIMA or a preexisting patent RIMA graft.

During Use For direct aortic and subclavian access procedures, care must be exercised when using the tip-retrieval mechanism to ensure adequate clearance to avoid advancement of the catheter tip through the bioprosthesis leaflets during device closure. For direct aortic access procedures, use a separate introducer sheath; do not use the EnVeo R InLine sheath. Adequate rinsing of the bioprosthesis with sterile saline, as described in the Instructions for Use, is mandatory before implantation. During rinsing, do not touch the leaflets or squeeze the bioprosthesis. If a capsule becomes damaged during loading or the capsule fails to close, replace the entire system (bioprosthesis, catheter, and CLS). Do not use a catheter with a damaged capsule. After a bioprosthesis has been inserted into a patient, do not attempt to reload that bioprosthesis on the same or any other catheter. AccuTrak DCS Only: During implantation, if resistance to deployment is encountered (e.g., the micro knob starts clicking or is tight or stuck), apply upward pressure to the macro slider while turning the micro knob. If the bioprosthesis still does not deploy, remove it from the patient and use another system. AccuTrak DCS Only: Once deployment is initiated, retrieval of the bioprosthesis from the patient (e.g., use of the catheter) is not recommended. Retrieval of a partially deployed valve using the catheter may cause mechanical failure of the delivery catheter system, aortic root damage, coronary artery damage, myocardial damage, vascular complications, prosthetic valve dysfunction (including device malposition), embolization, stroke, and/or emergent surgery. AccuTrak DCS Only: During deployment, the bioprosthesis can be advanced or withdrawn as long as annular contact has not been made. Once annular contact is made, the bioprosthesis cannot be advanced in the retrograde direction; if necessary, and the frame has only been deployed ≤2/3 of its length, the bioprosthesis can be withdrawn (repositioned) in the antegrade direction. However, use caution when moving the bioprosthesis in the antegrade direction. EnVeo R DCS Only: If a misload is detected, unsheath the bioprosthesis and examine the bioprosthesis for damage (for example, permanent frame deformation, frayed sutures, or valve damage). Do not attempt to reload a damaged bioprosthesis. Do not load the bioprosthesis onto the catheter more than 2 times or after it has been inserted into a patient. EnVeo R DCS Only: Use the deployment knob to deploy and recapture the bioprosthesis. Do not use the trigger for deploying or recapturing because it could cause inaccurate placement of the bioprosthesis. EnVeo R DCS Only: Once the radiopaque capsule marker band reaches the distal end of the radiopaque paddle attachment (point of no recapture), retrieval of the bioprosthesis from the patient is not recommended. Retrieval after the point of no recapture may cause mechanical failure of the delivery catheter system, aortic root damage, coronary artery damage, myocardial damage, vascular complications, prosthetic valve dysfunction (including device malposition), embolization, stroke, and/or emergent surgery. EnVeo R DCS Only: During deployment, the bioprosthesis can be advanced or withdrawn as long as annular contact has not been made. Once annular contact is made, the bioprosthesis cannot be advanced in the retrograde direction; recapture until the bioprosthesis is free from annular contact, and then reposition in the retrograde direction. If necessary, and the radiopaque capsule marker band has not yet reached the distal end of the radiopaque paddle attachment, the bioprosthesis can be withdrawn (repositioned) in the antegrade direction. However, use caution when moving the bioprosthesis in the antegrade direction. While the catheter is in the patient, ensure the guidewire is extending from the tip. Do not remove the guidewire from the catheter while the catheter is inserted in the patient. Use the handle of the delivery system to reposition the bioprosthesis. Do not use the outer catheter sheath. Once deployment is complete, repositioning of the bioprosthesis (e.g., use of a snare and/or forceps) is not recommended. Repositioning of a deployed valve may cause aortic root damage, coronary artery damage, myocardial damage, vascular complications, prosthetic valve dysfunction (including device malposition), embolization, stroke, and/or emergent surgery. Do not attempt to retrieve or to recapture (EnVeo DCS only) a bioprosthesis if any one of the outflow struts is protruding from the capsule. If any one of the outflow struts has deployed from the capsule, the bioprosthesis must be released from the catheter before the catheter can be withdrawn. Ensure the capsule is closed before catheter removal. When using a separate introducer sheath, if increased resistance is encountered when removing the catheter through the introducer sheath, do not force passage. Increased resistance may indicate a problem and forced passage may result in damage to the device and/or harm to the patient. If the cause of resistance cannot be determined or corrected, remove the catheter and introducer sheath as a single unit over the guidewire, and inspect the catheter and confirm that it is complete. Clinical long-term durability has not been established for the bioprosthesis. Evaluate bioprosthesis performance as needed during patient follow-up. Postprocedure, administer appropriate antibiotic prophylaxis as needed for patients at risk for prosthetic valve infection and endocarditis. Postprocedure, administer anticoagulation and/or antiplatelet therapy per physician/clinical judgment. Excessive contrast media may cause renal failure. Preprocedure, measure the patient's creatinine level. During the procedure, monitor contrast media usage. Conduct the procedure under fluoroscopy. The safety and efficacy of a CoreValve or CoreValve Evolut R bioprosthesis implanted within a transcatheter bioprosthesis have not been demonstrated. However, in the event that a CoreValve or CoreValve Evolut R bioprosthesis must be implanted within a transcatheter bioprosthesis to improve valve function, valve size and patient anatomy must be considered before implantation of the bioprosthesis to ensure patient safety (for example, to avoid coronary obstruction). In the event that valve function or sealing is impaired due to excessive calcification or incomplete expansion, a postimplant balloon dilatation of the bioprosthesis may improve valve function and sealing. To ensure patient safety, valve size and patient anatomy must be considered when selecting the size of the balloon used for dilatation. The balloon size chosen for dilatation should not exceed the diameter of the native aortic annulus or, for surgical bioprosthetic valves, the manufacturer's labeled inner diameter. Refer to the specific balloon catheter manufacturer's labeling for proper instruction on the use of balloon catheter devices. Note: Bench testing has only been conducted to confirm compatibility with NuMED Z-MED II™* Balloon Aortic Valvuloplasty catheters where CoreValve or CoreValve Evolut R bioprosthesis device performance was maintained after dilation. Data on File.

For EnVeo R DCS: For transfemoral access, use caution in patients who present with multiplanar curvature of the aorta, acute angulation of the aortic arch, an ascending aortic aneurysm, or severe calcification in the aorta and/or vasculature. If ≥2 of these factors are present, consider an alternative access route to prevent vascular complications. There will be some resistance when the catheter is advanced through the vasculature. If there is a significant increase in resistance, stop advancement and investigate the cause of the resistance (for example, magnify the area of resistance) before proceeding. Do not force passage. Forcing passage could increase the risk of vascular complications (for example, vessel dissection or rupture). Persistent force on the catheter can cause the catheter to kink, which could increase the risk of vascular complications (for example, vessel dissection or rupture).

POTENTIAL ADVERSE EVENTS Potential risks associated with the implantation of the CoreValve or CoreValve Evolut R transcatheter aortic valve may include, but are not limited to, the following: • death • myocardial infarction, cardiac arrest, cardiogenic shock, cardiac tamponade • coronary occlusion, obstruction, or vessel spasm (including acute coronary closure) • cardiovascular injury (including rupture, perforation, tissue erosion, or dissection of vessels, ascending aorta trauma, ventricle, myocardium, or valvular structures that may require intervention) • emergent surgical or transcatheter intervention (for example, coronary artery bypass, heart valve replacement, valve explant, percutaneous coronary intervention [PCI], balloon valvuloplasty) • prosthetic valve dysfunction (regurgitation or stenosis) due to fracture; bending (out-of-round configuration) of the valve frame; underexpansion of the valve frame; calcification; pannus; leaflet wear, tear, prolapse, or retraction; poor valve coaptation; suture breaks or disruption; leaks; mal-sizing (prosthesis-patient mismatch); malposition (either too high or too low)/malplacement • prosthetic valve migration/embolization • prosthetic valve endocarditis • prosthetic valve thrombosis • delivery catheter system malfunction resulting in the need for additional re-crossing of the aortic valve and prolonged procedural time • delivery catheter system component migration/embolization • stroke (ischemic or hemorrhagic), transient ischemic attack (TIA), or other neurological deficits • heart failure • cardiac failure or low cardiac output • ancillary device embolization • individual organ (for example, cardiac, respiratory, renal [including acute kidney failure]) or multi-organ insufficiency or failure • major or minor bleeding that may require transfusion or intervention (including life-threatening or disabling bleeding) • vascular access-related complications (eg, dissection, perforation, pain, bleeding, hematoma, pseudoaneurysm, irreversible nerve injury, compartment syndrome, arteriovenous fistula, stenosis) • mitral valve regurgitation or injury • conduction system disturbances (for example, atrioventricular node block, left-bundle branch block, asystole), which may require a permanent pacemaker • infection (including septicemia) • hypotension or hypertension • hemolysis • peripheral ischemia • bowel ischemia • abnormal lab values (including electrolyte imbalance) • allergic reaction to antiplatelet agents, contrast medium, or anesthesia • exposure to radiation through fluoroscopy and angiography • permanent disability.

Please reference the CoreValve and CoreValve Evolut R Instructions for Use for more information regarding indications, warnings, precautions and potential adverse events.

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

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