Medtronic

Elevate TAVR

Together advancing patient care.

Awareness and detection

Diagnosis and referral

Valve clinic optimization

Treatment and post-procedure

Discharge and follow-up

What is Elevate TAVR?

Elevate TAVR is our go-to solution to support you, your TAVR program, and our shared goal of advancing patient care.

Together we can “Elevate TAVR” through program acceleration with educational offerings, toolkits, templates, and specialized field experts to help overcome common growth barriers within your program.

We take a customized team approach to **meet you where you are**

Elevate

1. Your patient access
2. Your capacity and clinical efficiency
3. Your healthcare economics

Awareness and detection

Diagnosis and referral

Valve clinic optimization

Treatment and post-procedure

Discharge and follow-up

Why Elevate TAVR?

The challenge

The evolution and expansion of transcatheter therapy in structural heart has seen a significant increase in managing and treating aortic stenosis patients. This paradigm shift in management has created common challenges and barriers across the care pathway.

The most common growth barriers in Structural Heart programs today include:

"The resources and support I received was key for improving and ensured we weren't going to sacrifice our patient experience – instead we ELEVATED it!"

Natalie Kelley, MSN, RN, CCRN
Lead Valve Program Coordinator, Christus Hospital

Click here to see the impact of Elevating TAVR at Natalie's hospital.

Patient access from symptoms to treatment

The **undertreatment of Severe AS** is estimated to be **~48%** nationally.[1-10]

Capacity and clinical efficiency across the care pathway

73% Structural Heart programs say they're at **capacity**.[11]

Healthcare economics and reimbursement

53% of Structural Heart programs report **economics** as their biggest growth barrier.[11]

Our impact

Collaborating to Elevate TAVR at your center could result in:

- Improved timely referral of appropriate patients
- Increased program capacity and optimization
- Healthcare economic effectiveness

Awareness and detection

Diagnosis and referral

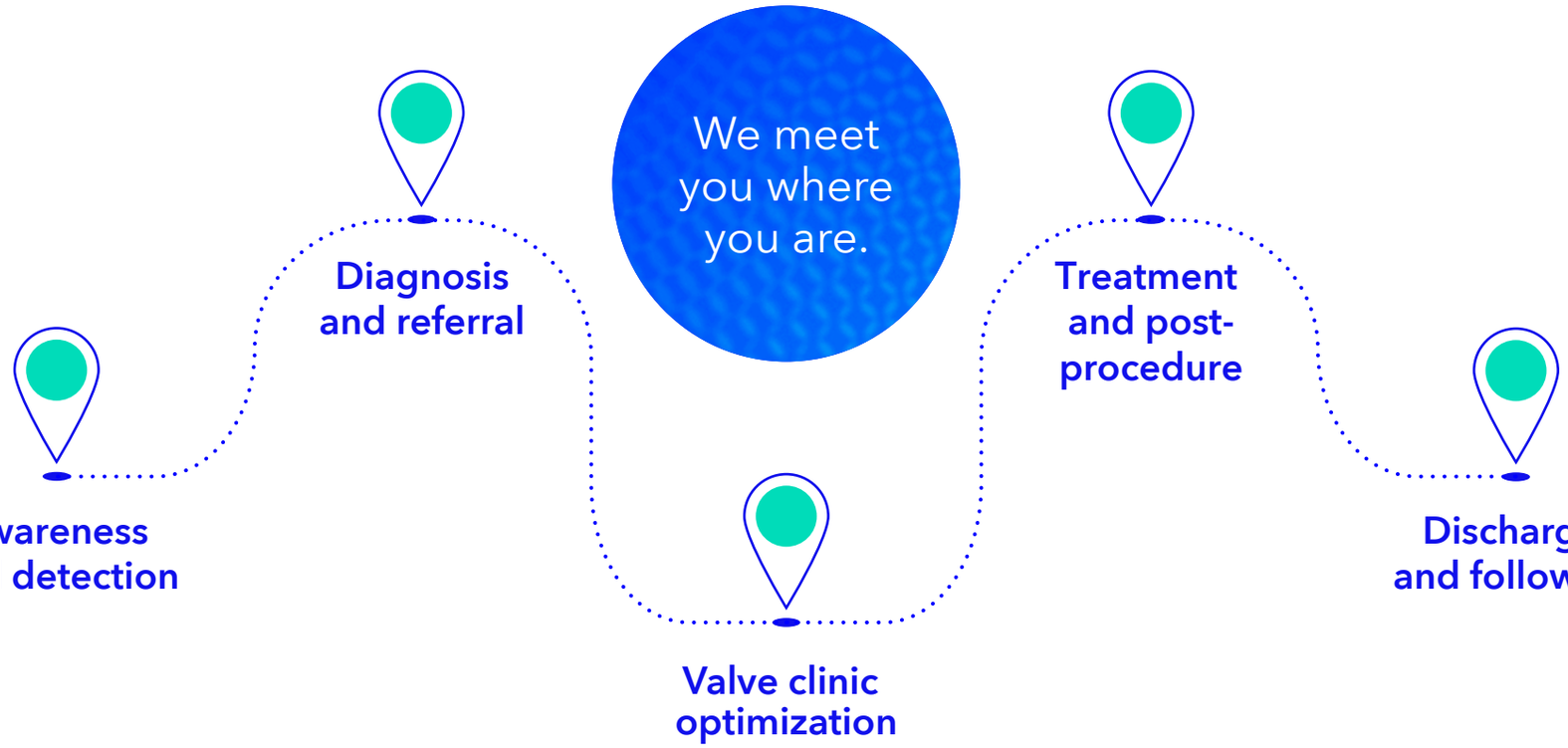
Valve clinic optimization

Treatment and post-procedure

Discharge and follow-up

Guiding operational excellence

From detection to follow-up



Awareness and detection

Patient education

Addressing barriers: peer-to-peer programs

Therapy awareness PR toolkit

AS TAVR app

Diagnosis and referral

Cardiology education

Diagnosing echo: peer-to-peer programs

Referral templates

Market insights

Valve clinic optimization

VPC learning pathway

Pathway optimization: peer-to-peer programs

Healthcare economics support

Clinic observations

Medtronic Academy: On-demand webinars

Treatment and post-procedure

Procedural education: Fellows and Advanced Implanters

Minimalist approach case observations

Timely discharge resources

Staff education

Pathway optimization: peer-to-peer programs

Discharge and follow-up

Discharge planning resources

Referral communication

TVT Registry education

Metric and gradient trackers

Awareness and detection

Diagnosis and referral

Valve clinic optimization

Treatment and post-procedure

Discharge and follow-up

Awareness and detection

The challenge

The incidence of untreated symptomatic severe aortic stenosis (SSAS) remains high due to the following factors:

- Patients do not recognize or report their symptoms[12]
- Heart murmurs go undetected[13]
- Echocardiogram findings are misclassified[13]
- Referrals are delayed or late, causing a delay in treatment and benefits of TAVR to decline[13,14]

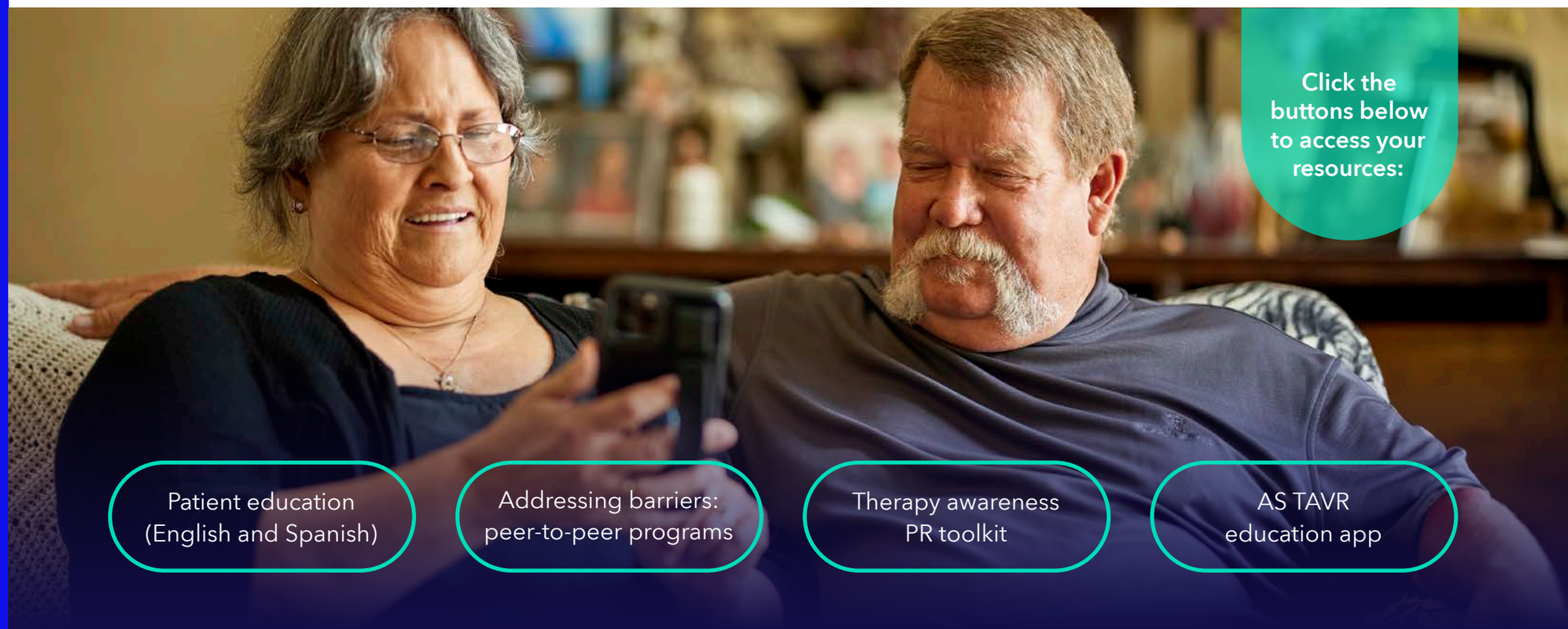
Our solutions

Our resources and offerings are designed to **increase patient awareness of SSAS** and **expedite their pathway to treatment.**

"I didn't realize how bad it was. I knew I was getting short of breath, but I just felt that at 69 years old, that's normal."

– Gary

Evolut™ TAVR patient



Click the buttons below to access your resources:

Patient education (English and Spanish)

Addressing barriers: peer-to-peer programs

Therapy awareness PR toolkit

AS TAVR education app

Awareness and detection

Diagnosis and referral

Valve clinic optimization

Treatment and post-procedure

Discharge and follow-up

Diagnosis and referral

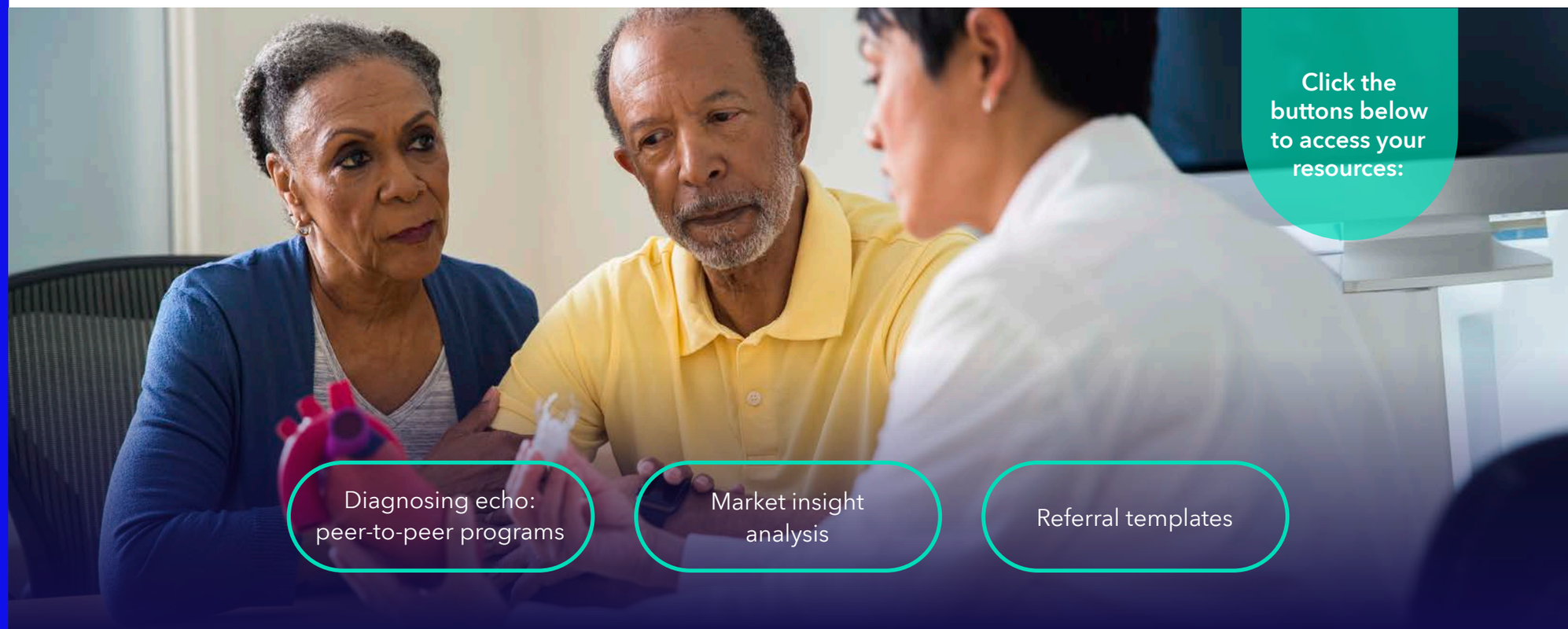
The problem

~48% of patients with symptomatic severe aortic stenosis (AS) are undertreated in the U.S.[1-10] Without adequate infrastructure and detection resources in place, 120,000+ patients may go undetected and miss out on lifesaving treatment for AS on an annual basis.[8]

Our solutions

Our portfolio of educational resources includes strategic tools to train, enable, and empower referring cardiologists to **lead more patients to the right treatments.**

30–50%
of patients with valvular heart disease who met guideline criteria for intervention **were not appropriately recognized or referred.**[15]



Click the buttons below to access your resources:

Diagnosing echo: peer-to-peer programs

Market insight analysis

Referral templates

Awareness and detection

Diagnosis and referral

Valve clinic optimization

Treatment and post-procedure

Discharge and follow-up

Valve clinic optimization

The challenge

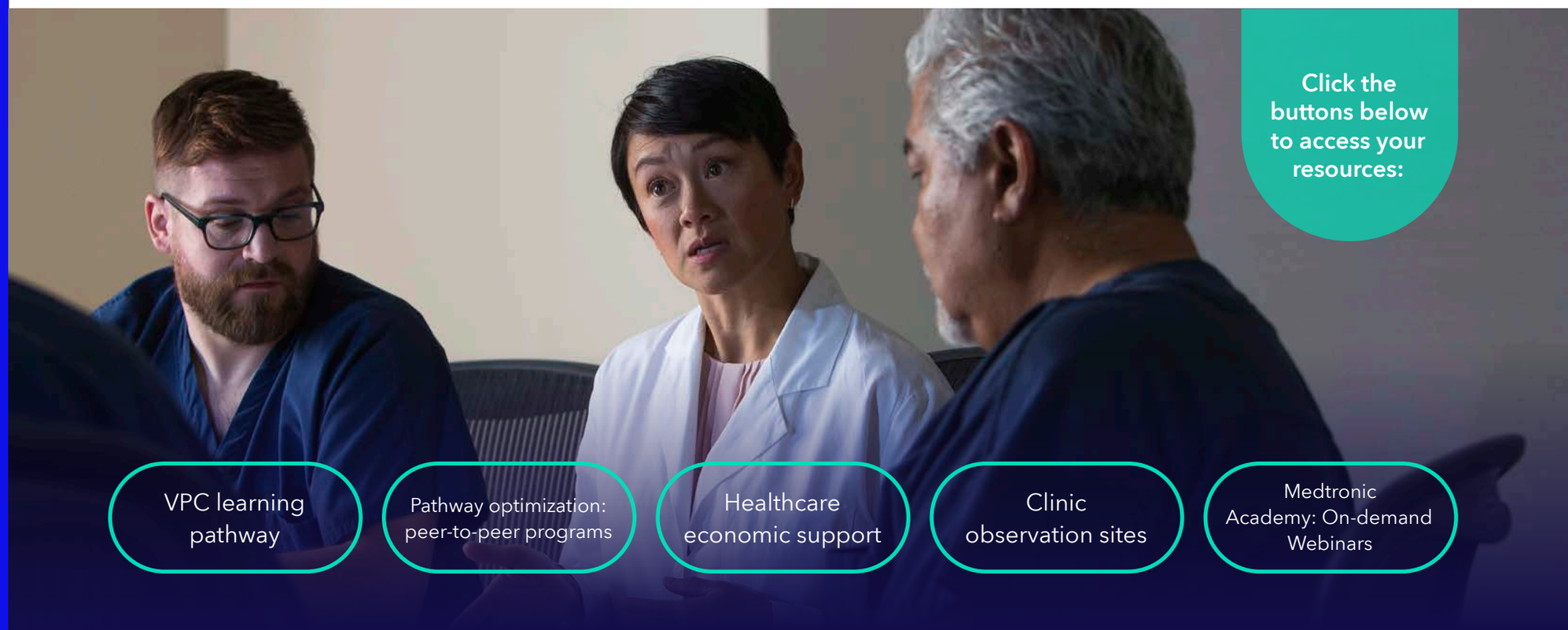
Many valve clinics are challenged with achieving effective leadership, appropriate staffing, and efficient support to ensure timely access to treatment. These inefficiencies result in limited program capacity, meaning longer waitlists for patients and increased probabilities they'll suffer harmful and fatal cardiac events. [1-3,16,17]

"Taking a multidisciplinary team approach to reviewing comprehensive data can showcase the need for change in a growing program."

Kristin Pasquarello, P.A.
Administrative Director of the Heart Valve Center, St. Francis

Our solutions

By utilizing our best-in-class training platforms, materials, and subject matter experts, you can discover how to **treat more patients with greater efficiency.**



Click the buttons below to access your resources:

VPC learning pathway

Pathway optimization: peer-to-peer programs

Healthcare economic support

Clinic observation sites

Medtronic Academy: On-demand Webinars

Awareness and detection

Diagnosis and referral

Valve clinic optimization

Treatment and post-procedure

Discharge and follow-up

Treatment

The challenge

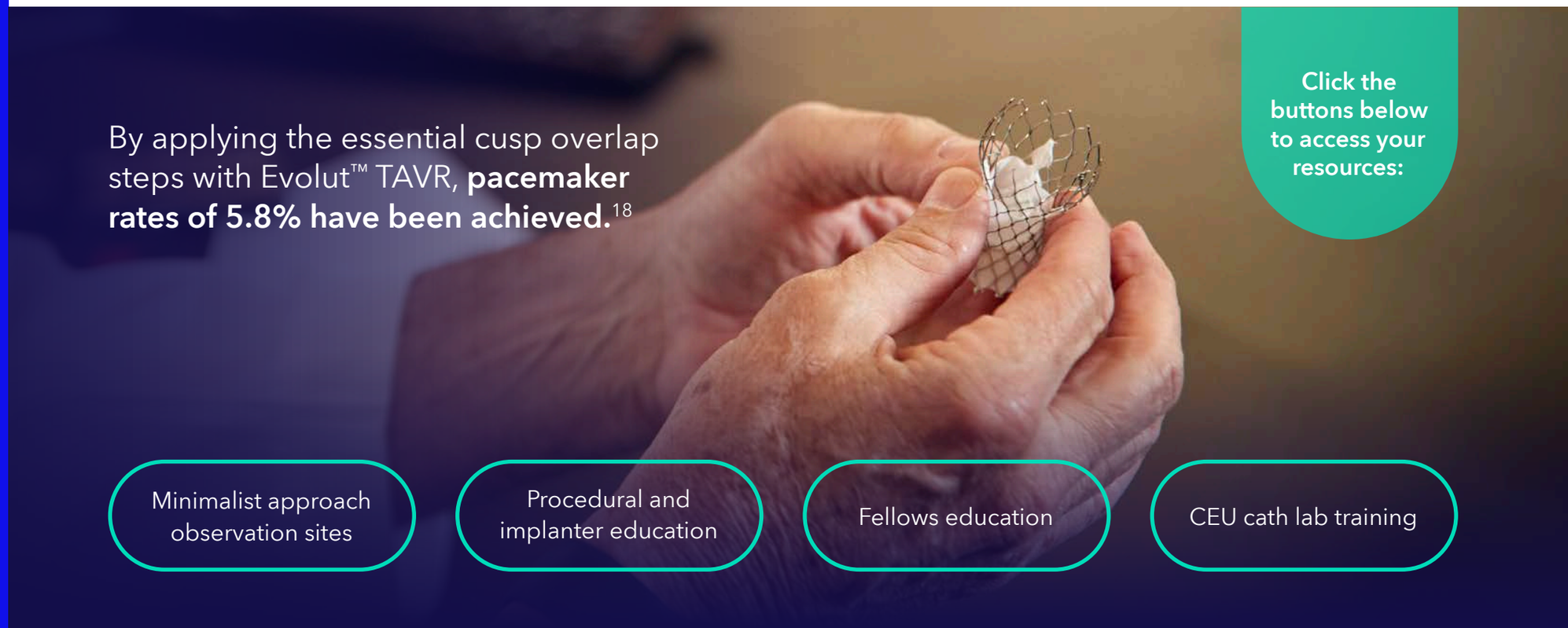
As structural heart therapy continues to expand, TAVR sites are experiencing heightened pressure from the influx of patients. With these growing pains, finding ways to improve procedural capacity while maintaining clinical and operational excellence is an increasingly complex and urgent priority.[11]

- Are you looking to do more in a day?
- Are you striving to increase patient access to treatment?
- Are you working on resource utilization efficiencies?
- Are you looking for increased procedural productivity and success?

Not sure where to begin?

Our solutions

Our Elevate TAVR offerings can help your center manage and nourish growth, starting by **improving procedural efficiencies to expediting referral to treatment time.**



By applying the essential cusp overlap steps with Evolut™ TAVR, **pacemaker rates of 5.8% have been achieved.**[18]

Click the buttons below to access your resources:

Minimalist approach observation sites

Procedural and implanter education

Fellows education

CEU cath lab training

Awareness and detection

Diagnosis and referral

Valve clinic optimization

Treatment and post-procedure

Discharge and follow-up

Post-procedure

The challenge

TAVR has become a well-established alternative to surgery with comparable efficacy and safety. However, hospital stays and recovery plans can still vary significantly by institution.[19]

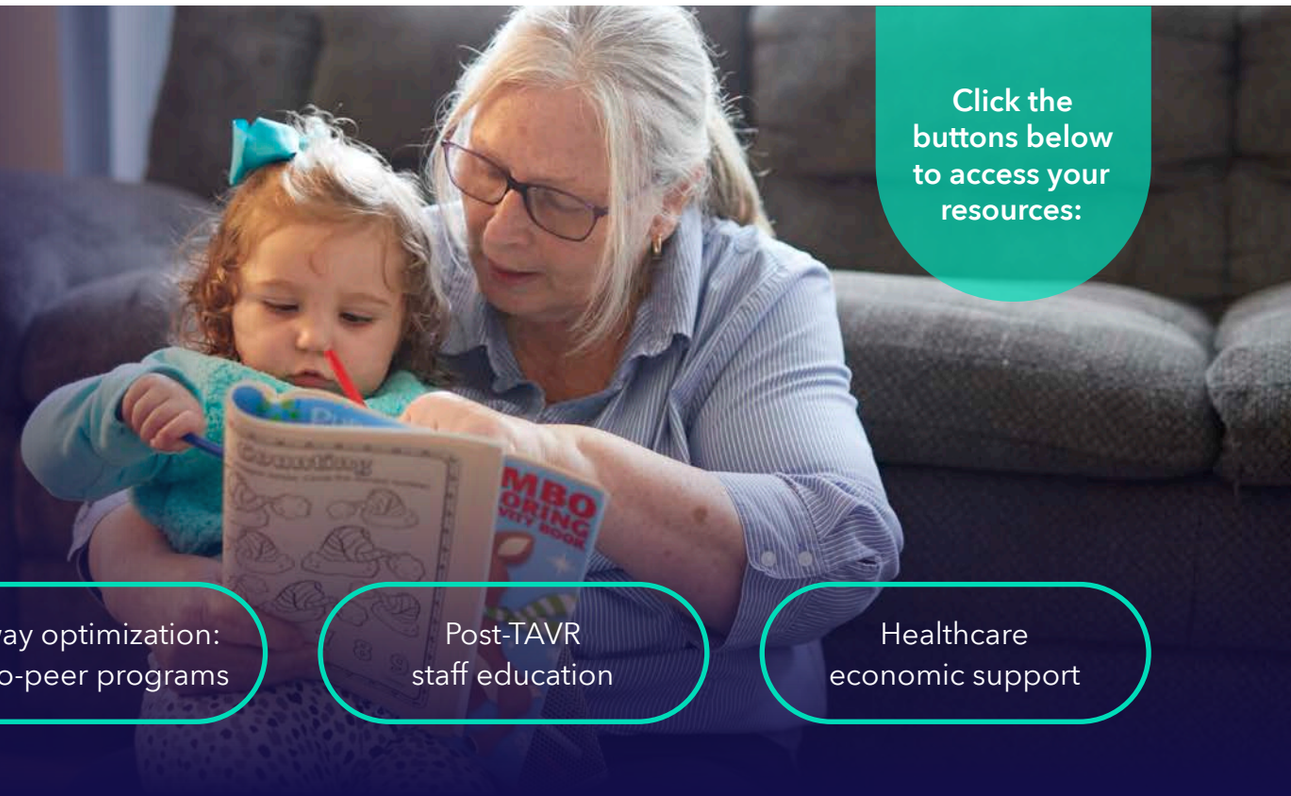
Our solutions

When you tap into our tools and resources, we can help your center **achieve the new standard of care of timely discharge with the patient's safety in mind.**

Adoption of a minimalist approach to TAVR has allowed for:

- a reduction in length of hospital stay
- reduction in hospital-related complications
- reduction in cost[20,21]

Utilizing the Cusp Overlap Technique (COT) with an optimized care pathway provides excellent outcomes, including low pacemaker implantation.[18]



Click the buttons below to access your resources:

Timely discharge

Pathway optimization: peer-to-peer programs

Post-TAVR staff education

Healthcare economic support

Awareness and detection

Diagnosis and referral

Valve clinic optimization

Treatment and post-procedure

Discharge and follow-up

Follow-up

The challenge

The influx of patients entering the hospital for TAVR has forced program optimization to improve outcomes across the care pathway. Follow-up management is equally important but sometimes comes with challenges, such as process variance and limited information-sharing between different centers.

Why is follow-up important?

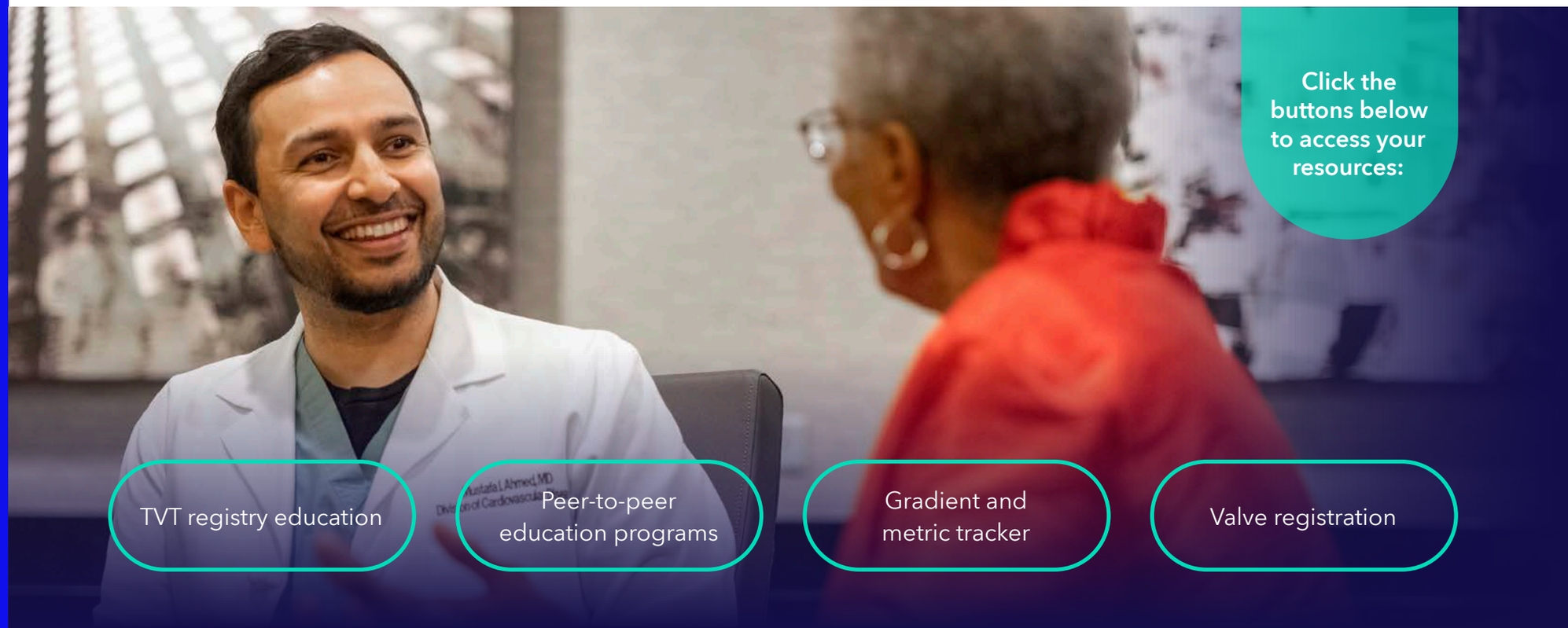
- TVT-Registry requires certain follow-up tests to evaluate patient outcomes and valve performance.[22]
- Evaluating and tracking your patients short and long term can help prevent readmission rates, reduce any post-discharge complications, and evaluate valve performance.[23]

"TAVR doesn't end at the procedure … as we're still learning about valve durability, valve performance, and treatment pathway for low-risk patients, **it's essential that we're following up at 30 days, 1 year, and beyond** to ensure we're collecting the necessary data to **continue making the right treatment plans for our patients.**"

Samer Abbas, M.D., FSCAI, FACC
Medical Director, Structural Heart and Valve Center, Community Hospital – Munster

Our solutions

To improve follow-ups both with patients and referring physicians, we offer resources that can help **communicate structural heart procedure success back to their referring providers** and **ensure patients are following up within the required timeframe.**



Click the buttons below to access your resources:

TVT registry education

Peer-to-peer education programs

Gradient and metric tracker

Valve registration

Awareness and detection

Diagnosis and referral

Valve clinic optimization

Treatment and post-procedure

Discharge and follow-up

Our subject matter experts

Our dedicated field subject matter experts are here to provide specialized guidance focusing on program development, healthcare economics, and clinical evidence.

> "**To achieve the highest standard of care and drive change**, it is important to know who your champions are."
>
> Kristin Pasquarello, P.A.
> Administrative Director of
> the Heart Valve Center, St. Francis

Meet Your TAVR Team

Local team	Role description	Collaborates with:
Therapy consultants (TC)	Your TC serves as your main point of contact for all product, procedural, and program support.	Heart teams Valve program coordinators Implanters Fellows Cath Lab/Hybrid room staff
Therapy development specialists (TDS)	Your TDS will provide technical, clinical, and educational support to ensure the Evolut™ TAVR system is used safely and effectively.	
Subject matter experts	**Role description**	**Collaborates with:**
Program development consultant (PDC)	The PDCs take a holistic approach to support the entire program with expertise in therapy adoption, patient access, and capacity optimization in growing programs.	Heart teams Administrators Valve program coordinators
Regional economic managers (REM)	The REMs have focused expertise on cardiovascular health economics, policy, claims, and reimbursement.	Heart teams Administrators Valve program coordinators Billing/coding Finance
Field clinic leaders (FCL)	The FCLs are our field-based team with expertise in procedural success, clinical excellence, and implanter collaboration.	Heart teams Implanters Fellows Cath Lab/Hybrid room staff

Collaborating to support your program from detection to follow-up

Questions? Reach out to your local representative for further support.

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22. TVT Registry 3.0 Datamart and STS Database, Data Collection Form. October 2021.
23. Kirby AM, et al. *Comput Inform Nurs*. 2018;36:525-529.

Indications: The Medtronic Evolut™ PRO+, Evolut™ FX, and Evolut™ FX+ 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 Evolut PRO+, Evolut FX, and Evolut FX+ 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 Medtronic Evolut PRO+, Evolut FX, and Evolut FX+ Systems are contraindicated in patients who cannot tolerate Nitinol (titanium or nickel), gold (for Evolut FX and Evolut FX+ Systems alone), an anticoagulation/antiplatelet regimen, or who have active bacterial endocarditis or other active infections.
Warnings: General Implantation of the Evolut PRO+, Evolut FX, and Evolut FX+ Systems should be performed only by physicians who have received Medtronic Evolut PRO+, Evolut FX, or Evolut FX+ 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 Evolut PRO+, Evolut FX, and Evolut FX+ Systems have not been evaluated in the pediatric population. The safety and effectiveness of the bioprostheses 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 cm2 or aortic valve area index ≤ 0.6 cm2/m2, 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 cm2 or aortic valve area index ≤ 0.6 cm2/m2, a mean aortic valve gradient < 40 mm Hg, and a peak aortic-jet velocity < 4.0 m/s; 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 an Evolut PRO+, Evolut FX, or Evolut FX+ bioprosthesis implanted within a failed preexisting transcatheter bioprosthesis have not been demonstrated. Implanting an Evolut PRO+, Evolut FX, or Evolut FX+ 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 bioprostheses 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/mm3), thrombocytopenia (platelet count < 50,000 cells/mm3), 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 per the baseline diagnostic imaging or surgical bioprosthetic aortic annulus size < 17 mm or > 30 mm; transarterial access unable to accommodate an 18 Fr introducer sheath or the 14 Fr equivalent Evolut PRO+ inline sheath when using model D-EVPROP2329US or Evolut FX Delivery Catheter System with inline sheath when using model D-EVOLUTFX-2329 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 or Evolut FX Delivery Catheter System with inline sheath when using model D-EVOLUTFX-34; 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.

Before 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 models D-EVPROP2329US/D-EVOLUTFX-2329 or ≥ 6 mm when using models D-EVPROP34US/D-EVOLUTFX-34, 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 patent left internal mammary artery (LIMA) graft must present with access vessel diameters that are either ≥ 5.5 mm when using models D-EVPROP2329US/D-EVOLUTFX-2329 or ≥ 6.5 mm when using models D-EVPROP34US/D-EVOLUTFX-34. 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. Limited clinical data are available for transcatheter aortic valve replacement in patients with a congenital bicuspid aortic valve who are deemed to be at low surgical risk. Anatomical characteristics should be considered when using the valve in this population. In addition, patient age should be considered as long-term durability of the valve has not been established.

During Use If a misload is detected during fluoroscopic inspection, do not attempt to reload the bioprosthesis. Discard the entire system. Inflow crown overlap that has not ended before the 4th node within the capsule increases the risk of an infold upon deployment in constrained anatomies, particularly with moderate-severe levels of calcification and/or bicuspid condition. Do not attempt to direct load the valve. 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 an Evolut PRO+, Evolut FX, or Evolut FX+ bioprosthesis implanted within a transcatheter bioprosthesis have not been demonstrated.

Potential adverse events: Potential risks associated with the implantation of the Evolut PRO+, Evolut FX, or Evolut FX+ 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 • General surgical risks applicable to transcatheter aortic valve implantation: • 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 Evolut PRO+, Evolut FX, and Evolut FX+ 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™ PRO+ device is Medtronic Evolut™ PRO+ System, the commercial name of the Evolut™ FX device is Medtronic Evolut™ FX System, and the commercial name of the Evolut™ FX+ device is Medtronic Evolut™ FX+ System.

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