

Clinical Review Committee

Mahesh Amin, MD Vanessa J. Lucarella, MD Morton Plant Hospital Morton Plant Hospital Rodrigo Bolaños, MD Leslie Miller, MD Winter Haven Hospital Morton Plant Hospital Michael W. Bradner, MD John Ofenloch, MD St. Joseph's Hospital Morton Plant Hospital George Dagher, MD Mohan Reddy, MD Morton Plant North Bay Hospital St. Anthony's Hospital David Evans, MD Christopher Pastore, MD Winter Haven Hospital St. Joseph's Hospital-North Karl Michael G. Reyes, MD Yves Gabriel, MD Morton Plant Hospital St. Joseph's Children's Hospital Juan Garcia-Morell, MD Jeremy Ringewald, MD Morton Plant Hospital St. Joseph's Children's Hospital Joel Hardin, MD Joshua Rovin, MD St. Joseph's Hospital Morton Plant Hospital Lang Lin, MD Andrew Sherman, MD Morton Plant Hospital St. Joseph's Hospital Bernardo Stein, MD

Morton Plant Hospital

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Dear Colleague,

Physicians and team members of the BayCare cardiovascular service line are pleased to present the annual clinical outcomes for 2019. These outstanding clinical results for patients within BayCare are a direct result of dedicated teams of caregivers who use the latest technology to address cardiovascular disease at every level. Our cardiovascular service line is structured to allow multidisciplinary teams to manage the vast range of cardiovascular disease conditions, rigorously

benchmarking our progress against top IBM Watson Health metrics. The following pages will highlight volume and select clinical outcomes within BayCare. We hope you can use the information in this outcomes book to help with patient care and treatment decisions. For more information or to refer a patient to any of our programs, call (844) 344-1990.

Mahesh Amin, MD

Medical Director BayCare Cardiovascular Services

Medical Director

Morton Plant Mease Cardiovascular Services

Rodrigo Bolaños, MD

Clinical Leader, Arrhythmia Management BayCare Cardiovascular Services

Medical Director, Electrophysiology Winter Haven Hospital

Yves A. Gabriel, MD

Clinical Leader, Vascular BayCare Cardiovascular Services

Vascular Surgeon Morton Plant Hospital

Juan C. Garcia-Morell, MD

Clinical Leader, Arrhythmia Management BayCare Cardiovascular Services

Clinical Cardiac Electrophysiologist Morton Plant Hospital

John C. Ofenloch, MD

Clinical Leader, Open-Heart Surgery Clinical Leader, Structural Heart and Valve BayCare Cardiovascular Services

Chief, Cardiothoracic Surgery, and Medical Director, Morgan CVICU/OR Morton Plant Hospital

Christopher J. Pastore, MD

Clinical Leader, Percutaneous Coronary Intervention BayCare Cardiovascular Services

Interventional Cardiologist St. Joseph's Hospital-North

Mohan S. Reddy, MD

Clinical Leader, Heart Failure; Clinical Leader, General Cardiology/Circulatory Support BayCare Cardiovascular Services

Cardiologist
St. Anthony's Hospital

Andrew Sherman, MD

Clinical Leader, Open-Heart Surgery, Clinical Leader, Structural Heart and Valve BayCare Cardiovascular Services

Chief, Department of Cardiac, Vascular and Thoracic Surgery St. Joseph's Hospital



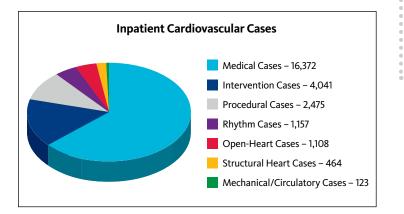
Why Choose Us?

As the largest not-for-profit health care system in West Central Florida, BayCare is proud to once again be awarded the highest three-star rating from the Society of Thoracic Surgeons (STS) in 2019. As leaders in complex arrhythmias, advanced structural heart and valve, open-heart surgery and advanced heart failure, BayCare brings physicians and patients access to cardiovascular experts across Hillsborough, Pasco, Pinellas and Polk counties. Our expansive network of clinically integrated hospitals, outpatient centers, surgery centers, labs and imaging facilities helps patients move easily within the system to get the care and clinical expertise they need, regardless of their location.

With the support of nearly 29,000 team members, BayCare actively fosters a forward-thinking culture that's advancing superior health care and creating an environment that allows quality to flourish.

To refer a patient to any of our cardiovascular programs or facilities: (844) 344-1990 3.91 Days Post Average Length of Stay

25,740 Consider Cardiovascular Cases



3 * * *
Three-star STS Rating

Inpatient state data 4Q2018–3Q2019 for the four-county area (Hillsborough, Pasco, Pinellas and Polk), cardiovascular cases using DRGs and procedure codes, excluding heart transplants, IP rehab, pediatrics and specialty hospitals



Cardiovascular Surgery

When it comes to your patients' care, we realize that quality, outcome and cost are of the utmost importance. BayCare's cardiovascular and cardiothoracic surgeons are all members of the Society of Thoracic Surgeons (STS) whose mission is to enhance the ability to provide the highest quality patient care. BayCare participates in the STS National Adult Cardiac Surgery Database that includes over 1,200 participating institutions throughout the country.

Cardiovascular surgery is currently performed at three BayCare facilities: Morton Plant Hospital, St. Joseph's Hospital and Winter Haven Hospital. Cardiothoracic surgeons Dr. David Evans, Dr. John Ofenloch and Dr. Andrew Sherman acknowledge that "Cardiac surgery remains one of the most scrutinized and publicly reported specialties, with data collection on nearly every aspect of patient care. The BayCare cardiovascular surgeons remain committed to utilizing the extensive information provided to us via the Society of Thoracic Surgeons database in order to implement meaningful changes in the treatment of our patients throughout West Central Florida. Through frequent collaborative meetings and constant evaluation of data-driven best practices, we

have impacted countless patients' lives. We strive to provide the highest quality of care from the moment we meet our patients, at the time of their operative procedures, continuing into the postoperative period and well into their recovery." For information on BayCare's management and treatment of pediatric and adult congenital heart disease, see the Pediatric and Adult Congenital Heart section of this book on page 31.

BayCare's cardiovascular surgical procedures include:

- Aortic aneurysm repair
- Aortic valve repair and replacement
- Carotid endarterectomy and stenting
- Coronary artery bypass
- Endovascular aneurysm repair (EVAR)
- Implantable defibrillator insertion and lead extraction
- Minimally invasive valve replacement/repair
- Mitral valve repair and replacement
- Redo cardiac surgery
- Surgical treatment for atrial fibrillation (*Maze*, *Convergent*, *AtriClip*)

"The BayCare cardiovascular surgeons remain committed to utilizing the extensive information provided to us via the Society of Thoracic Surgeons database in order to implement meaningful changes in the treatment of our patients throughout West Central Florida."

- ~ Dr. David Evans Director, Cardiac Surgery at the Bostick Heart Center at Winter Haven Hospital
- ~ Dr. John Ofenloch Chief of Cardiothoracic Surgery and Medical Director, Morgan CVICU/OR at Morton Plant Hospital
- ~ Dr. Andrew Sherman Chief, Department of Cardiac, Vascular and Thoracic Surgery at St. Joseph's Hospital

A Look at Volume

2019 Open-Heart Surgery Breakdown		
BayCare		
Surgical Valve	547	
Isolated CABG	764	
Other	166	

Surgical valve = Represents total number of valves, not patients; **Other** = Includes all procedures that fall outside any STS procedure identification category

2019 Surgical and Transcatheter Valve Volume		
	BayCare	
Aortic Valve	273	
Mitral Valve	193	
Tricuspid valve	58	
Transcatheter Valve (aortic and mitral)	433	

Represents total number of valves, not patients

Surgical Treatment for Cardiac Arrhythmias

Surgical treatment for cardiac arrhythmias, typically atrial fibrillation, has become increasingly important within advanced cardiovascular surgery programs.

Often these patients are treated in a comprehensive manner incorporating cardiovascular surgeons and cardiac electrophysiologists. Intraoperatively, surgeons have an ideal opportunity to treat atrial fibrillation with a Maze procedure or other type of ablation.

Additionally, the left atrial appendage may be closed or occluded at the time of surgery to potentially reduce patient's stroke risk secondary to atrial fibrillation.

Arrhythmia surgery is commonly performed in conjunction with mitral valve repair or replacement, but can also be performed concomitantly with other valve surgery or CABG. BayCare's cardiovascular surgeons also perform a unique, hybrid approach for the treatment of atrial fibrillation. "Atrial fibrillation (AFib) is a major cause of morbidity and stroke in patients with cardiovascular disease. BayCare cardiovascular surgeons have

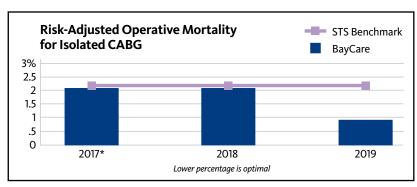
made treatment of AFib a high priority in alignment with the recommendations of the major societies," according to Dr. Andrew Sherman, chief of the department of cardiac, vascular and thoracic surgery at St. Joseph's Hospital. "A multidisciplinary approach provides patients with AFib an individualized treatment approach at the time of their other cardiac procedures and has been proven in recent literature to positively impact their life expectancy. A significant point of emphasis in the management of our shared patients with AFib involves closure of their left atrial appendage (LAA) for stroke prevention. BayCare has one of the highest volumes of minimally invasive approaches to LAA exclusion in the country."

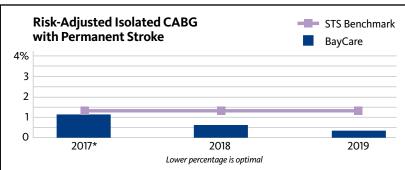
2019 Surgical Treatment of Arrhythmias		
BayCare		
Maze	53	
PVI	79	
Convergent	36	
Total	168	

A Look at Quality

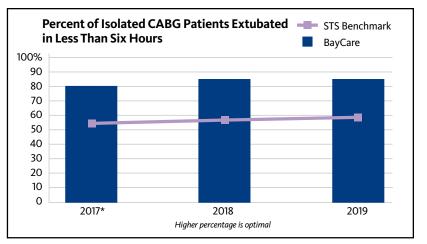
Due to delayed STS reporting, composite scores for BayCare as a health system in 2019 were not available in all previously-reported categories. We have included the risk-adjusted composite scores when available below. For 2017, the risk-adjusted composite scores for BayCare as a health system were also unavailable. To review risk-adjusted cardiovascular surgery data by facility for that year, see the Cardiovascular Surgery Data Addendum by Facility section of this book on page 53.

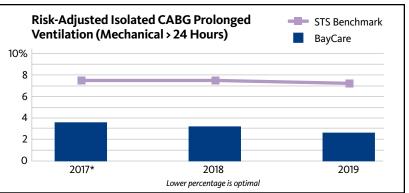
Composite Quality Metrics for Isolated Coronary Artery Bypass Grafting (CABG) at BayCare | 2017–2019





Please note: We inadvertently shared an incorrect figure for the 2018 STS benchmark in last year's outcomes book. It has since been corrected in the above chart.





Deep Sternal Wound Infection for Isolated CABG			
	STS Benchmark BayCare		
2017	0.3%	0.0%	
2018	0.3%	0.0%	
2019	0.3%	0.1%	

Lower percentage is optimal

^{*}Indicates non risk-adjusted data. Composite risk stratification not available in 2017. For riskadjusted data by facility for that year, see the Cardiovascular Surgery Data Addendum by Facility on page 53.



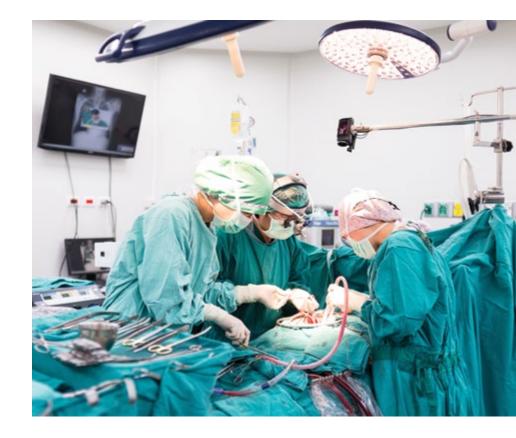
Composite Quality Metrics by Facility | 2017–2019

The following table represents a comprehensive look at cardiac procedures performed throughout BayCare's cardiovascular surgery programs and the consistently low operative mortality rates achieved.

STS Major Cardiac Procedures Mortality			
MPH	Number of Procedures	Operative Mortality (NRA)	
2017	506	2.77%	
2018	565	2.48%	
2019	481	1.25%	
SJH			
2017	377	1.86%	
2018	411	2.43%	
2019	422	1.90%	
WHH			
2017	347	4.61%	
2018	351	3.13%	
2019	356	2.53%	

^{*}MPH = Morton Plant Hospital; SJH = St. Joseph's Hospital; WHH = Winter Haven Hospital

Despite the delay in STS reporting, we want to continue reporting important quality metrics. For those categories where composite scores were unavailable in 2019, we are providing the STS riskadjusted data by BayCare flagship facility* for 2017–2019 on the following pages.

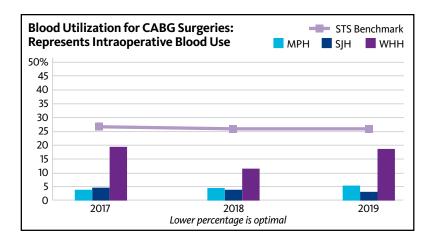


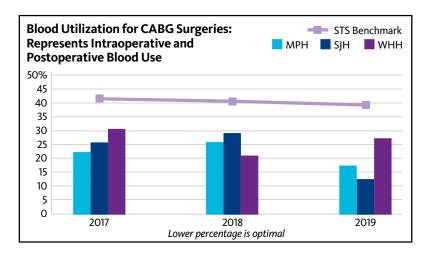


Importance of Blood Conservation

Multiple strategies are utilized within BayCare cardiovascular surgical programs to limit operative blood loss and patient exposure to blood products. Techniques to limit bleeding and return shed blood to the patient include:

- Optimization of patient's own clotting mechanism prior to operation
- Cell saver technology
- Cardiotomy suction
- Meticulous surgical technique
- Medication administration during surgery prior to incision to enhance patient's clotting mechanism
- Specialized medications utilized to address specific deficiencies in coagulation





Emphasis on Arterial Grafting for CABG

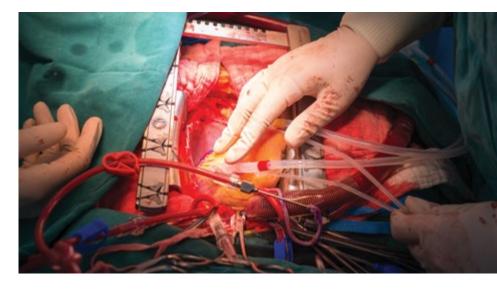
"Arterial bypass grafts have been proven to provide superior long term outcomes and, as such, our utilization of multiple arterial grafts, including radial artery and bilateral internal mammary artery grafts, is significantly higher than regional and national averages," according to chief of cardiothoracic surgery and medical director of the Morgan CVICU/OR at Morton Plant Hospital, Dr. John Ofenloch.

"BayCare cardiovascular surgeons are committed to providing the highest quality surgical care. Not only are in-hospital and 30-day mortality rates important, but also long-term freedom from further cardiovascular events."

BayCare cardiovascular surgeons have utilized the internal mammary artery for CABG surgery in 100 percent of appropriate cases over the past several years. Use of a second arterial graft, either an additional internal mammary artery or a radial artery graft, is increasingly employed as a strategy by BayCare cardiovascular surgeons to enhance long-term freedom from repeat intervention and cardiovascular events.

Radial Artery Usage				
	STS Benchmark	MPH	SJH	WHH
2017	5.0%	57.3%	0.4%	0.9%
2018	6.0%	56.3%	12.0%	2.4%
2019	6.8%	60.6%	21.4%	1.5%

Higher percentage is optimal



Mitral Valve Repair

While the three BayCare cardiovascular surgery programs are actively involved in transcatheter mitral valve repair procedures, these procedures are reserved for patients otherwise felt to be at high risk for open-heart surgery. The gold standard for mitral valve regurgitation in reasonable risk patients remains an open surgical mitral valve repair, of which the BayCare surgeons utilize a variety of techniques. Some of these techniques include mitral leaflet resection, chordal replacement, leaflet augmentation and annular reconstruction. It's imperative that these procedures are performed with very low complications. BayCare cardiovascular surgeons are proud that in 2019, 57 isolated mitral valve repairs were completed with no mortalities.



Advanced Structural Heart and Valve

Structural Heart and Valve Disease Treatment

Team-based advanced treatment for structural heart and valve disease is available within BayCare. Several hospital facilities in Hillsborough, Pinellas and Polk counties have developed dedicated structural heart teams that specialize in the medical and surgical care of these cardiac problems. BayCare's structural heart and valve teams are comprised of physicians and health care providers from multiple heart and vascular specialties who have interest and expertise in the treatment of complex cardiac conditions.

According to Dr. Joshua Rovin, medical director of the Center for Advanced Valve and Structural Heart Care at Morton Plant Hospital, "Our program's success has been built upon the foundation of our experienced multidisciplinary heart team. We always strive to provide the right care at the right time for our patients, following the latest guidelines developed by our collective professional cardiology and cardiovascular surgical societies. Our teamwork and outcomes have allowed us to participate in multiple national research trials. Such trials provide us the opportunity to treat our patients with heart valve disease using the latest minimally invasive technologies."

Our specialists from the divisions of cardiovascular surgery, interventional cardiology, cardiac imaging and cardiac anesthesia work together to provide innovative heart treatment solutions and the best possible outcomes for patients with structural heart abnormalities. Many affiliated health care providers participate on the dedicated heart team as well, including nurses, physician assistants, advanced nurse practitioners and cardiac imaging specialists. Structural heart disease may affect the heart muscle as well as the valves that regulate blood flow within the heart. Some structural heart abnormalities are congenital and others are the result of acquired heart disease. Many of these abnormalities ultimately result in congestive heart failure (CHF). Some of the most common conditions and their treatments are described in the Medical Terminology and Procedure Review section on page 55.

For information on BayCare's management and treatment of pediatric and adult congenital heart disease, see the Pediatric and Adult Congenital Heart section of this book on page 31.

BayCare's advanced structural heart and valve procedures include:

- Balloon aortic and mitral valvuloplasty
- Left atrial appendage closure
- Transcatheter patent foramen ovale (PFO) closure and atrial septal defect (ASD) closure
- Transcatheter aortic valve replacement (TAVR)
- Transcatheter mitral valve repair (MitraClip™)
- Transcatheter mitral valve replacement (TMVR)
- Transcatheter paravalvular leak closure
- Surgical aortic and mitral valve repair and replacement
- Tricuspid valve repair
- Surgical treatment of atrial fibrillation
- Complex repeat heart valve surgery
- Aortic surgery and surgery for aneurysms of the aorta

To refer a patient to any of our cardiovascular programs or facilities: (844) 344-1990



A Closer Look: Guidelines to Refer Patients with Aortic Stenosis

Aortic stenosis (AS) is the most common form of valvular heart disease and is estimated to be *undertreated* in half of affected patients. Patient identification and intervention at the right time have been shown to help patients with AS return to healthy, active lifestyles.

Due to concern for COVID-19 infection, many patients are afraid to seek health care, even for conditions they know may be life threatening. Many patients with severe AS can't afford to wait for intervention, as their survival rapidly diminishes over time, especially after onset of symptoms.

Team-based care has become even more important in the COVID-19 era. To help facilitate and expedite care during these challenging times, telemedicine visits became available immediately during the initial phases of the pandemic and are available for patients when appropriate.

Though most transcatheter aortic valve replacement (TAVR) surgeries were delayed in April 2020 when BayCare and other prominent health care systems were required to postpone elective surgeries, the need to evaluate and treat patients did not disappear. Heart concerns did not go away during the

pandemic and some needed immediate care and treatment. Telemedicine provided BayCare heart teams the opportunity to seamlessly provide our experience and expertise to individuals with heart valve disease, particularly during a worldwide pandemic.

When is the right time to consider a referral for possible intervention? Consider these key elements:

- Does the patient exhibit symptoms? Symptoms may include exertional dyspnea or decreased exercise tolerance, lower extremity edema, exertional angina, syncope or presyncope.
- Does the patient have a murmur indicating valvular disease?

What's the patient's aortic valve area? Patients with aortic stenosis typically have an aortic valve area of less than 1.0 cm².

This chart outlines the different definitions for symptomatic severe aortic stenosis. If the patient meets any element under one of the definitions, they meet the criteria for aortic stenosis and it's time for them to be evaluated by a BayCare structural heart team.

Definition	Valve Hemodynamics
High gradient	 Maximum aortic jet velocity greater than or equal to 400 cm/sec or mean gradient greater than or equal to 40 mmHg OR Aortic valve area index less than or equal to 0.6 cm²/m²
Low-flow/low-gradient with reduced left ventricular (ejection fraction (EF) of less than 50 percent)	 Maximum resting aortic jet velocity less than 400 cm/sec or a mean gradient less than 40 mmHg Dobutamine stress echocardiography will show aortic valve area less than 1.0 cm² with aortic jet velocity greater than or equal to 400 cm/sec at any flow rate
Low-gradient with normal left ventricular ejection fraction or paradoxical low-flow with (ejection fraction (EF) greater than or equal to 50 percent)	 Maximum aortic jet velocity less than 400 cm/sec or mean gradient less than 40 mmHg Stroke volume index less than 35 mL/m², measured when patient is normotensive (defined as systolic blood pressure less than 140 mmHg)

Surgical Innovation

Surgical innovation and advances in cardiovascular surgical care are paramount to the success of the BayCare cardiovascular program. Over the past decade, BayCare hospitals, with the collaboration between cardiovascular surgeons and cardiologists, have implemented many new programs which have benefited many BayCare patients. Valve surgery, in particular, has been an area of rapid progression and growth. As an example, transcatheter valve surgery avoids a sternal incision, and most patients can be discharged home the day after their procedure.

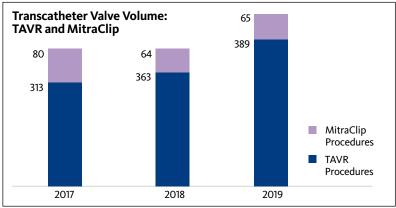
- Greater than fifty percent of all BayCare cardiovascular surgical and transcatheter cases involve valve surgery.
- One quarter of all BayCare cardiovascular cases are transcatheter-based.
- Nearly half of all BayCare valve procedures are currently performed by transcatheter approach.

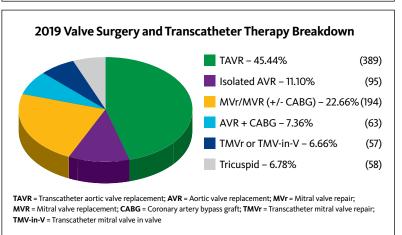


2019 TAVR 30-Day Outcomes (In hospital)		
BayCare		
	*N=400 (%)	
Observed mortality	1.25%	
Stroke (any)	2.00%	
Access site vascular complications	0.00%	

^{*}Includes research cases

A Look at Volume





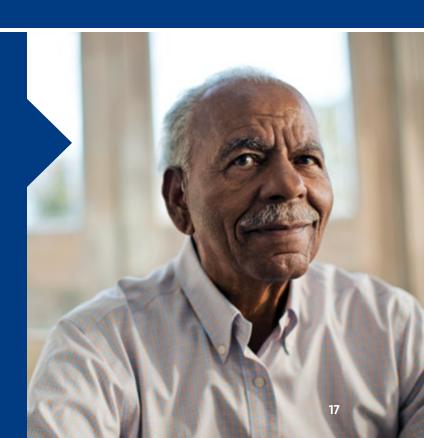


Case Study

A 62-year-old woman was diagnosed with severe aortic stenosis after presenting to the hospital in heart failure. During her work up, she was also diagnosed with advanced stage III breast cancer. Her treatment was discussed with the structural heart and medical oncology teams. It was felt that open-heart surgery would delay her cancer treatment and, due to the advanced nature of her cancer, this would have a significant impact on her long-term prognosis. Therefore, she underwent a percutaneous transfemoral TAVR. Due to the quick recovery following her TAVR, she was able to immediately start chemotherapy and eventually underwent mastectomy for her breast cancer. Today, the patient is doing well from a valvular heart disease standpoint and continues to bravely fight her advanced breast cancer.

Case Study

Patient is a 70-year-old man with multiple medical issues including end-stage renal failure on hemodialysis, coronary artery disease (CAD), chronic ascites and significant mitral regurgitation (MR). He had shortness of breath both at rest and on exertion and needed repeated drainage of his abdominal ascites. After visiting with the multidisciplinary structural heart team at BayCare, the patient was evaluated for possible liver disease, all four of his heart valves were assessed and it was determined that his mitral valve was the most likely culprit of his shortness of breath. His CAD was treated with complex Impella-assisted PCI and the patient subsequently underwent a successful MitraClip procedure to treat his mitral valve regurgitation. The MR was reduced from severe to mild. The patient was discharged from the hospital the following day and upon his return to the clinic for his 30-day follow-up visit, he stated that he no longer had shortness of breath and was back to riding his exercise bike. His quality of life was significantly improved and his activities were no longer restricted.





Arrhythmia

BayCare arrhythmia specialists are internationally recognized for their pioneering work in the field of clinical electrophysiology. For over 25 years, arrhythmia specialists at BayCare helped further the discipline of rhythm disorders by contributing to the body of literature supporting development of procedures, catheter design and ultimately the management of electrical disorders of the heart, and includes one of the only facilities to provide management of arrhythmia for both adults and pediatric patients.

Electrical disorders of the heart encompass a wide range of cardiac diseases. The discipline of electrophysiology involves the diagnosis of arrhythmia using diagnostic equipment which includes tilt table testing, ambulatory monitoring, cardiac imaging using sophisticated equipment including 3-D reformatting of MRI, CT and ultrasound, and invasive testing in the form of catheter-based electrophysiology studies.

Symptoms of arrhythmia can range from the most obvious which include syncope, chest pain, dizziness, symptoms of stroke and palpitations, to the more subtle, such as exertion fatigue and in some cases, no symptoms at all. "The treatment of cardiac arrhythmias is continuously evolving. At BayCare, our Rhythm specialists collaborate in ways not often seen in today's health care environment. All aspects of patient care are periodically reviewed including how to deliver the best care in the most efficient and cost-effective manner for our patients. Through sharing of ideas, techniques and the latest research, BayCare physicians provide cutting-edge treatments and evidence-based care for patients," according to Dr. Rodrigo Bolaños, medical director of electrophysiology at Winter Haven Hospital.

Common arrhythmia disorders and the procedures that manage them are listed in the Medical Terminology and Procedure Review section of this book on page 55. For volume related to surgical management of arrhythmias, see the Cardiovascular Surgery section of this book on page 5.

To refer a patient to any of our cardiovascular programs or facilities: (844) 344-1990 "Through sharing of ideas, techniques and the latest research, BayCare physicians provide cutting-edge treatments and evidence-based care for patients."

~ Dr. Rodrigo Bolaños Medical Director, Electrophysiology at Winter Haven Hospital

A Closer Look: Implantable Cardioverter Defibrillator (ICD) Shared Decision-Making Tool

The number one cause of death in the United States is cardiovascular disease.¹ Of these deaths, 50 percent are due to sudden cardiac death (SCD) with the majority of these being due to lifethreatening ventricular arrhythmias (VA).² The implantable cardioverter defibrillator (ICD) combined with optimal medical therapy plays a central role in protecting against sudden cardiac death from VA.

Last year, CMS updated its National Coverage Determination (NCD) for ICDs for the first time since 2005. A priority of the new NCD is the need for every patient who'll be receiving a primary prevention ICD to be involved in a shared decision encounter with a health care provider utilizing an evidence-based decision tool.

The majority of patients have cardiomyopathies with accompanying heart failure. As health care providers, we need to spend the most time with these patients to ensure that they're making informed decisions for potential ICD implantation.

At BayCare, many of our providers have followed a "shared decisionmaking approach" while counseling their prospective ICD patients since the inception of the therapy. In order to standardize and implement this initiative across BayCare, we've adopted a shared ICD implantation decision tool developed at The University of Colorado Program for Patient-Centered Decisions. This tool focuses on patients with heart failure who are being considered for an ICD. The decision tool guides the patient through a series of questions which facilitates the patient's understanding of what an ICD is, what it does and doesn't do, and the potential consequences for each patient that accompany their decision to proceed or not with the implantation of an ICD.

The tool addresses the patient's most common concerns and questions that often arise during the ICD implantation process, with easy-to-understand diagrams and facts that aid in clarifying the patient's goals and wishes.

It's our responsibility as health care providers to continue to ensure that our patients have the necessary information to make informed decisions. With the BayCare-wide adoption and institution of this ICD decision tool, heart failure patients in our community will be able to make better informed decisions that they can feel good about.

References:

²2017 AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and prevention of sudden cardiac death: A Report of the American College of Cardiology/America Heart Association Task Force on Clinical Guidelines and the Heart Rhythm Society. Al-Khahib SM, Stevenson WG, Ackerman MJ, Bryant WJ, Callans DJ, Curtis AB, Deal BJ, Dickfield T, Fonarow GC, Gillis AM, Granger CB, Hammill SC, Hlatky MA, Joglar JA, Kay GN, Matlock DD, Myerburg RL, Page RL. Heart Rhythm 2018 Oct; 15 (10):e73-e189.

BayCare's arrhythmia programs include:

- Management of complex arrhythmia using ultrasensitive 3-D mapping
- AFib ablation (pulmonary vein isolation) using radiofrequency and cryoballoon
- Hybrid AFib ablation for advanced AFib
- VT/VF ablation with hemodynamic assist
- Left atrial occlusion/ligation
- Surgical Maze procedure
- Convergent hybrid Maze

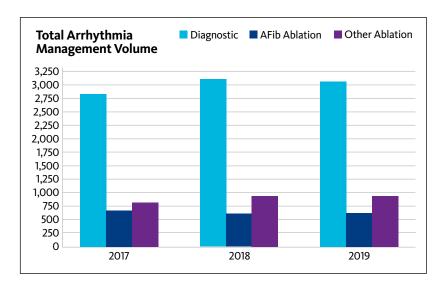
Cardiac rhythm management (CRM) device implants include:

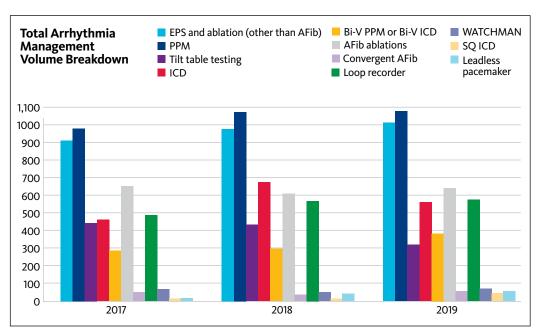
- Diagnostic EP studies as part of implantation
- Transvenous and subcutaneous implantable cardioverter defibrillators (ICD)
- Biventricular, left bundle pacing and His bundle pacing
- Injectable loop recorders
- Permanent and leadless pacemakers (PPM)
- Tilt table testing
- Lead extraction and venoplasty

Information on BayCare's management and treatment of pediatric and adult congenital heart disease can be found in the Pediatric and Adult Congenital Heart section of this book on page 31.

¹Deaths: Leading Causes for 2017. Heron M. National Vital Statistics Reports. 2019 June: 68 (6): 1-77.

A Look at Volume







Percutaneous Coronary Intervention

The landscape of coronary disease treatment is changing and evolving rapidly with more complex diseases being treated with percutaneous techniques. Examples of innovative procedures and technologies include the use of long, drug-eluting stents that provide excellent long-term patency rates, the ability to open arteries that have been occluded chronically and the ability to support the failing heart muscle with different percutaneous devices (i.e. Impella). "Coronary artery disease continues to be one of the main causes of mortality in the world. It is recommended that all patients receive optimal medical therapy to prevent progression of disease and reduce the ischemic burden. Patients who remain symptomatic despite medical therapy, have extensive ischemia based on cardiac testing or develop unstable coronary syndromes greatly benefit from prompt cardiac catheterization and referral for percutaneous coronary intervention. This can result in improvement in quality of life and preservation of myocardial function. For patients with extensive coronary disease, left ventricular dysfunction and

diabetes, coronary artery bypass surgery may constitute the best therapeutic approach," said Dr. Bernardo Stein, medical director of the Cardiac Catheterization Laboratories at Morton Plant Hospital.

Angioplasty, or percutaneous coronary intervention (PCI), is performed at Bartow Regional Medical Center, Mease Countryside Hospital, Morton Plant Hospital, Morton Plant North Bay Hospital, St. Anthony's Hospital, St. Joseph's Hospital, St. Joseph's Hospital-North, St. Joseph's Hospital-South, South Florida Baptist Hospital and Winter Haven Hospital. In addition, Mease Countryside Hospital, Morton Plant Hospital, Morton Plant North Bay Hospital, St. Anthony's Hospital, St. Joseph's Hospital, St. Joseph's Hospital-North, St. Joseph's Hospital-South, South Florida Baptist Hospital and Winter Haven Hospital are also STEMI receiving centers.

Cardiac catheterization procedures can be done by advancing catheters through the radial artery in the wrist as well as the femoral artery in the peripheral groin area. Radial procedures have been linked to a decrease in length-of-stay and bleeding risks, and a shorter duration of bedrest after a catheterization procedure. Many of the physicians within these hospitals are able to perform radial procedures when appropriate.

BayCare's PCI procedures include:

- Diagnostic coronary angioplasty
- Diagnostic peripheral angioplasty
- Mechanical support in cardiogenic shock
- Percutaneous coronary intervention (PCI)
- Peripheral vascular intervention (PVI)

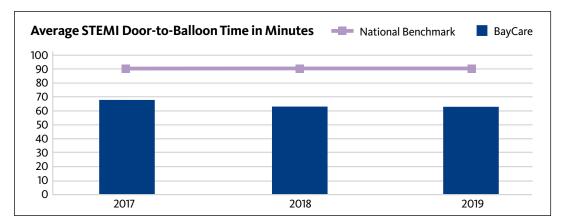
A Look at Volume

PCI Volume			
	2017	2018	2019
PCI volume	5,262	5,873	6,105
Total peripheral vascular intervention volume	1,797	3,315	4,868
Diagnostic cath lab volume	11,936	12,201	12,237

The cardiac catheterization, percutaneous coronary intervention (PCI) and peripheral intervention volumes included in this year's outcomes book reflect cases performed in the cardiac catheterization labs throughout BayCare. These volumes include a variety of procedures that address a multitude of diseases both chronic and acute in nature.

The PCI procedures include the treatment of coronary artery disease by angioplasty, stenting and atherectomy. Many of the peripheral intervention procedures include the treatment of peripheral vascular disease by thrombectomy, angioplasty, stenting and/or catheter-directed thrombolysis to improve quality of life, relieve pain, and in more advanced cases, for limb salvage. These procedures can be performed using a variety of access points including femoral, popliteal and pedal vessels, depending on the lesion being addressed.

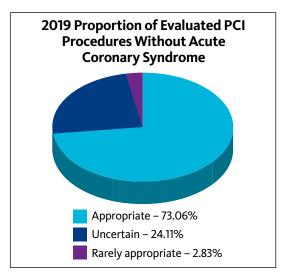
A Look at Quality

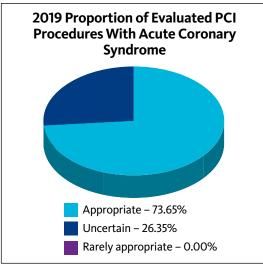


Dr. Lang Lin, co-director, STEMI Program at Morton Plant Hospital, notes "In STEMI care, 'time is heart muscle.' Timely intervention in opening a clotted or closed artery is essential for short- and long-term outcomes and decreased mortality and morbidity." Dr. Bernardo Stein, medical director of the Cardiac Catheterization Laboratories at Morton Plant Hospital adds, "Immediate coronary revascularization represents the optimal strategy for patients who present with acute ST elevation myocardial infarction. This strategy is aimed at reducing the ischemic damage to the myocardium and may result in a lower incidence of heart failure and arrhythmias. Processes to reduce the time interval from the onset of symptoms to the opening of the artery have been in place at BayCare

hospitals for several years. This endeavor requires a multi-prong strategy, including patient education, prompt recognition of symptoms, rapid response of the emergency medical technicians and a collaboration between ER physicians, cath lab personnel and interventional cardiologists. We are happy to report a progressive improvement in the time from first medical contact to coronary revascularization across BayCare hospitals. Currently, nearly 100 percent of our patients achieve coronary patency within 90 minutes of the first medical contact."

To refer a patient to any of our cardiovascular programs or facilities: (844) 344-1990





Appropriate: Meets ACC/NCDR guidelines for performing PCI Uncertain: Currently insufficient evidence Rarely Appropriate: Not generally acceptable



Case Study

A 72-year-old male with a past medical history of coronary artery disease status post two coronary stents approximately four years ago, presented to the emergency room with complaints of chest pain. Patient stated a sudden onset of excruciating chest pressure that radiated to his back, arm and legs with associated diaphoresis and nausea. Upon arrival to the emergency room, an EKG was performed and identified acute STEMI. A STEMI alert was called and preparation was made for patient to be transported to the cath lab.

The cath lab findings were:

- Total distal RCA occlusion, stented using 3.25X18 mm Xience Sierra DES
- Moderate mid RCA (50%) and proximal RPDA (50%) stenosis
- Patent stent in the OM
- Preserved LV systolic function; LVEF 50%, inferior wall hypokinesis
- LVEDP 30mmHg

The recommendation was medical therapy and cardiovascular risk factor modifications along with dual antiplatelet prescription for a minimum of 12 months. Patient was discharged without incident and will be followed by both primary care physician and cardiologist.



Heart Failure

Heart failure is any condition in which the heart is unable to supply the body with needed oxygen and nutrients. Heart failure is a growing epidemic in the United States. It's estimated that roughly 7 million people are currently affected by heart failure. The rate of heart failure increases with age as well and there are an estimated 670,000 new cases of heart failure diagnosed each year in the United States. Many patients with heart failure also have other conditions such as coronary disease, chronic obstructive pulmonary disease (COPD), diabetes, kidney disease and arrhythmia, which further complicate management. BayCare offers comprehensive care for patients with heart failure, whether they're admitted to one of our hospitals, at home or at a skilled nursing facility.

The Heart Function Clinics specialize in the management of heart failure at all stages and from all causes. The clinics serve the needs of patients with secondary heart failure due to other medical conditions as well as heart failure from primary heart muscle diseases (cardiomyopathy).

The Heart Function Clinic network allows BayCare to offer optimal and consistent care to heart failure patients across our entire system. BayCare Heart Function Clinics are located on the campuses of Mease Countryside Hospital, Morton Plant Hospital, St. Anthony's Hospital, St. Joseph's Hospital, St. Joseph's Hospital-North, South Florida Baptist Hospital and Winter Haven Hospital.

Additional services offered are:

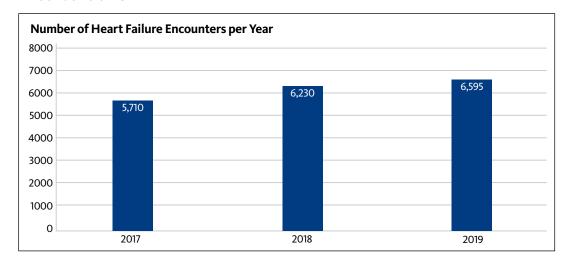
- Comprehensive evaluation for cause of cardiomyopathy
- Emergency room care follow up
- Inpatient continuity of care and transition management
- Team-based longitudinal outpatient care
- Coordination of home-based care and monitoring
- Coordination of multiple chronic condition care
- Home infusion therapy
- Device therapy management
- Hospital readmission risk management
- Opportunity to participate in clinical research trials
- Access to support groups for patients and caregivers

To refer a patient to any of our cardiovascular programs or facilities: (844) 344-1990

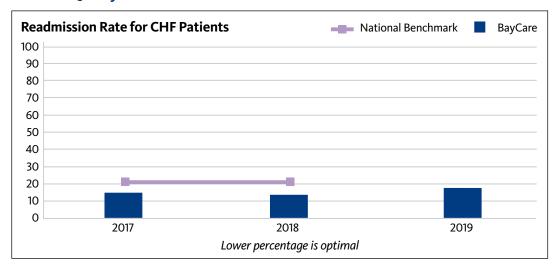
"BayCare Heart Function Clinics were designed to offer a team of cardiologists, cardiac surgeons, advanced heart failure specialists, nurse specialists and other medical professionals who work collaboratively with primary care providers to deliver all the care heart failure patients need in a well-coordinated manner."

~ Dr. Mohan Reddy Chief of Cardiology at St. Anthony's Hospital

A Look at Volume



A Look at Quality



A Closer Look: BayCare's Ventricular Assist Device (VAD) Program Update

Advanced heart failure is defined as those patients who, despite our goal-directed medical therapy, continue to have recurrent episodes of heart failure and require hospitalization.

A left ventricular assist device is an implantable mechanical pump that works with the heart to deliver adequate blood flow to the body. BayCare's Advanced Heart Failure program provides destination therapy for heart failure patients. Destination therapy is defined as those patients who require mechanical support but who aren't transplant candidates. Currently, the Heartmate III is the LVAD that we implant at BayCare.

BayCare's LVAD program at St. Joseph's Hospital currently manages patients who have both Heartmate II and III devices. Our experience has reflected that of the national experience with increased survival and improved quality of life. Patients are able to go from being essentially in the hospital with cardiogenic shock back to their lives and homes, participating in their communities. With LVAD therapy, we've given these patients new life and allowed them to remain active members in society.

Guidelines for LVAD referral:

- NYHA class III/IV, plus one of the following:
 - Inability to walk < one block without dyspnea
 - Serum sodium <136
 - -BUN > 40mg/dl
 - Intolerant or refractory to ACE-I/ARB/BB
 - Diuretic dose > 1.5mg/kg
 - One or more CHF-related hospital admissions within six months
 - CRT nonresponders
 - Hematocrit < 35%



Case Study

A 77-year-old gentleman presented to our advanced heart failure clinic with increasing heart failure symptoms and frequent need for hospitalization secondary to his end stage heart failure. His past medical history was significant for ischemic cardiomyopathy, hypertension, diabetes mellitus and atrial fibrillation. He was undergoing testing when he was admitted again to another hospital. He was quickly transferred to our institution where we stabilized him with multiple medications and an intra-aortic balloon pump. We completed his workup in the inpatient setting and proceeded with left ventricular assist device (LVAD) placement using a Heartmate III device. He also had his left atrial appendage ligated at time of LVAD insertion.

Postoperatively the patient did very well and was discharged. The patient has continued to increase his activity levels and is now a New York Heart Association class I individual. He participates in his community and he and his wife travel regularly.



Pediatric and Adult Congenital Heart

BayCare is home to Tampa Bay's only comprehensive congenital heart disease (CHD) center capable of delivering full-spectrum care for the CHD patient from fetal diagnosis to late adulthood. This unique program is located on the campus of St. Joseph's Children's Hospital in Tampa. In 2018, the Adult Congenital Heart Association awarded the Tampa Bay Adult Congenital Heart Center at St. Joseph's Hospital the status of ACHD Accredited Comprehensive Care Center.

Developed in collaboration with the Children's Hospital of Pittsburgh, the center's congenital heart surgical program is a leader in patient volume, surgical outcomes, early extubation and short length of stay. Surgical planning often begins at fetal diagnosis, allaying family anxiety and ensuring that parents know what to expect when their child is born. Throughout the CHD center and programs, there's a strong belief in quality, excellence and transparency. The CHD center actively participates in various National Databases for Quality Improvement and Benchmarking, including Society of Thoracic Surgeons Congenital Heart Surgery Database (STS CHSD), Improving Pediatric and Adult Congenital Treatment (IMPACT), Pediatric Cardiac Critical Care Consortium (PC4) and **Extracorporeal Life Support Organization** (ELSO).

The physicians at the CHD center specialize in the care of patients with congenital heart disease at all ages, including but not limited to the following conditions:

- Aortic stenosis, mitral stenosis
- Atrioventricular septal defect
- Coarctation of the aorta
- Complex single ventricle
- Ebstein's anomaly
- Hypoplastic left heart syndrome
- Pulmonary and tricuspid valve atresia
- Pulmonary stenosis
- Shone's syndrome
- Tetralogy of Fallot
- Transposition of great arteries

Services and procedures include:

- Specialized pediatric/congenital cardiology services treating a wide range of patients with mild to complex heart conditions
- Cardiac catheterization designed especially for children and adults utilizing a less invasive alternative for some heart conditions. The catheterization laboratory is one of the most widely used congenital laboratories in Florida, performing over 540 procedures annually, most

of which are interventions. Some procedures include:

- Angioplasty
- Atrial septal defect (ASD) device closure
- Atrial septostomy
- Balloon valvotomy
- Coil embolization
- Electrophysiology studies with/ without ablation
- Implantable cardioverter defibrillators (ICD) and pacemakers
- Patent ductus arteriosus (PDA) device closure, including newborns weighing less than 2kg
- Pulmonary valve insertion (Melody* valve, Sapien valve)
- Radiofrequency and cryoablation (often without fluoroscopy)
- Stent implantation
- Ventricular septal defect (VSD) device closure



A Closer Look: Adult Congenital Heart Disease Subspecialty Certification

In the United States, over one million adults live with congenital heart disease (CHD). Since the earliest surgical procedures to palliate and repair congenital heart defects, most children would grow into adulthood with few options for receiving the specialized care they had received in the pediatric cardiology clinic.

In 2015 the American Board of Internal Medicine (ABIM) certified cardiologists in its newest internal medicine subspecialty, adult congenital heart disease (ACHD). ACHD is open only to ABIM-certified cardiovascular medicine cardiologists or American Board of Pediatrics-certified pediatric cardiologists who have also completed an accredited two-year ACHD fellowship program.

Now with ACHD certified cardiologists, the outlook for children nearing adulthood is much better. Pediatric cardiologists

begin the formal transition education for teenage patients at age 12 and hope by age 18, young adults with CHD will have met their new ACHD cardiologist.

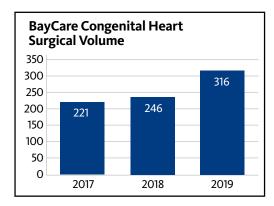
Advocacy efforts on behalf of ACHD patients isn't new, and dates to the formal inception of the national Adult Congenital Heart Association (ACHA) in 1998. This organization now accredits the nation's finest ACHD clinical programs through rigorous application and site visit criteria.

BayCare's St. Joseph's Hospital is the first in the region and second facility in Florida to earn this accreditation. Our board-certified ACHD cardiologists are on-call 24/7 for ACHD patients hospitalized not only at St. Joseph's Hospital, but also at every other BayCare hospital as well as several other acute care hospitals in the region.

- Pediatric and adult congenital cardiac imaging including:
 - Echocardiology laboratory:
 The first accredited center for transthoracic, transesophageal and fetal echocardiography in West Central Florida by the Intersocietal Accreditation Commission (IAC)
 - Fetal echocardiology
 - 3-D echo
 - Cardiac MRI available in collaboration with pediatric cardiologist
- Pediatric and adult congenital cardiovascular surgery serving children and adult congenital heart patients. Some offered procedures include:
 - Arterial switch
 - Atrioventricular septal defect repair
 - Complex valve repair and valve conduits
 - Fontan procedure and Fontan conversion
 - Hybrid, palliation and repair of hypoplastic left heart syndrome (HLHS) and single ventricle heart disease
 - Tetralogy of Fallot (TOF) and TOF with pulmonary atresia repair
 - Various hybrid procedures
 - Pacemakers

Pediatric and adult congenital cardiac anesthesiology serving the particular needs of congenital heart patients including early extubation and pain management that may include more favorable cardiac performance, reduced length of ICU and hospital stay, and a lower rate of ventilator associated respiratory infections. Greater than 60 percent of our congenital heart patients leave the operating room without a breathing tube.

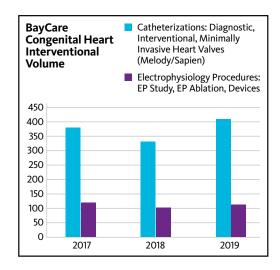
A Look at Volume

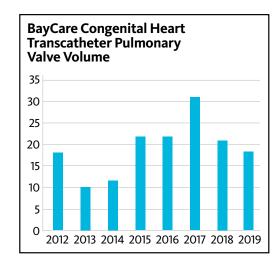


"While medical advances have made it possible for more patients with CHDs to survive into adulthood, it can be difficult for these individuals to find an adult cardiologist with the expertise to treat what was once considered only a childhood disease. The collaboration between our pediatric and adult cardiology specialists provides an easy transition between childhood and adult services for our patients with congenital heart disease."

~ Dr. Joel Hardin Adult Congenital Heart Disease Cardiologist at St. Joseph's Hospital

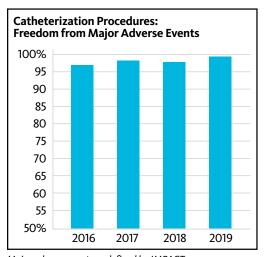
A Look at Volume





A Look at Quality for 2016–19

Due to delayed STS reporting, the charts below represent internal data that has been risk-stratified into STS categories.



 ${\it Major\ adverse\ events\ as\ defined\ by\ IMPACT.}$

Percent of Operative Mortality by Patient Group			
Patient Group	BayCare	STS Benchmark	
STAT 1	0.0%	0.4%	
STAT 2	0.8%	1.4%	
STAT 3 1.3% 2.2%			
STAT 4	5.2%	6.1%	
STAT 5	21.4%	13.1%	

Based on discharged patients. Lower percentage is optimal

What is a STAT group? Data is subdivided into five different groups depending on the level of risk. STAT Category 1 is associated with the lowest and STAT Category 5 is associated with the highest risk of mortality.

Length of Stay (LOS) by Patient Group			
Patient Group	BayCare	STS Benchmark	
STAT 1	3	7	
STAT 2	5	20	
STAT 3	6	15	
STAT 4	12	28	
STAT 5	34.5	46	

LOS is expressed as a median in days. Fewer days is optimal.

Operative Mortality		
BayCare	STS Benchmark	
2.3%	2.8%	

Lower percentage is optimal

Percent of Patients Extubated in Operating Room		
Extubated in the OR	BayCare	STS Benchmark
All Patients	54.1%	26.4%
Neonates	9.0%	3.4%
Infants	46.7%	18.3%

Higher percentage is optimal



Case Study

A full-term baby girl was born at an outside facility, prenatally diagnosed with Turner Syndrome. While there, they noted discrepancies in blood pressure measurements and her echocardiogram showed a borderline hypoplastic arch, bicuspid aortic valve, a patent ductus arteriosus (PDA) and, initially, no evidence of aortic coarctation. However, as her PDA started to close, they then noted some discrepancies and her echocardiogram now showed a postductal coarctation. She was transferred to St. Joseph's Children's Hospital for surgical care. She underwent an aortic arch reconstruction and coarctation resection on her 12th day of life. Despite the extensive operation requiring cardiopulmonary bypass and cooling her body to low temperatures, it didn't take long for her to make a full recovery. Her breathing tube was removed soon after, her vocal chords were checked and she was able to feed quickly. Her echocardiogram showed an excellent surgical result and she was discharged on the eighth postoperative day.



Cardiac Rehabilitation

Cardiac rehabilitation programs are comprehensive inpatient and outpatient services involving supervised exercise, cardiac risk factor modification, nutritional planning, education and counseling. The goal is to limit the physiological and psychological effects of coronary artery disease, reduce the risk of sudden death and stabilize or reverse the atherosclerotic process. Each patient is assessed and an individual treatment plan is developed to help the patients reach their goals.

Cardiac rehabilitation is a class 1 recommendation from the AHA and ACC for patients who have experienced a

cardiac event. It's recognized as an integral component of the continuum of care for patients with cardiovascular disease.

Diagnoses indicated for enrollment include:

- Myocardial infarction (MI)
- Percutaneous coronary intervention (PCI)
- Coronary artery bypass grafting (CABG)
- Valve repair/replacement
- Stable angina
- Heart transplant
- Heart failure

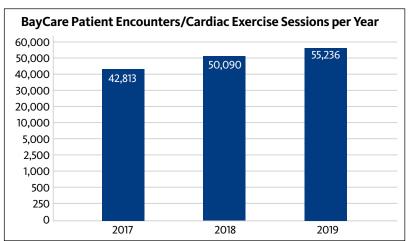
BayCare's cardiac rehabilitation programs are some of the largest in the country, offering seven locations covering a four-county area. Many of our programs are nationally certified by the American Association of Cardiovascular Pulmonary Rehab (AACVPR) and the staff are certified cardiac rehab professionals (CCRP). They have experience working with the patients who have internal cardiac defibrillator (ICD), LifeVest, sudden death syndrome (SDS), postural orthostatic syndrome (POTS) and heart failure (HF).

"A crucial component to the long-term successful outcome of the cardiovascular patient is participation in cardiac rehab.

BayCare's cardiac rehab programs have a well-established track record in improving both physical and psychosocial status in our patients."

~ Dr. Vanessa Lucarella Medical Director, Cardiac Rehabilitation at Morton Plant Hospital

A Look at Volume



Includes some volumes from programs currently working toward certification



Research and Clinical Trials: Currently Enrolling

Clinical research makes the latest scientific discoveries available to the BayCare community long before they become available to the general public.

Kimberly Guy, senior vice president, market leader for Hillsborough and southeast Pasco counties and leader of the cardiovascular service line across BayCare, acknowledges, "Research is a critical component of improving our community's cardiovascular health. BayCare's commitment to advancing new treatments encourages collaboration across clinical care teams and assures our patients have access to the most current treatments."

According to Dr. Leslie Miller, medical director of the Heart Function Clinic at Morton Plant Hospital, "Without research, all of the important advances in medicine that we now depend on would be just observations in a laboratory. Participating in research studies is easy to do and accelerates the availability of new advances in treating common diseases not only to those who are in the trials today, but their children as well. We want to make BayCare a center for research, invite the community to learn about the research going on now, and demonstrate support for this important way to enhance the well-being of all those in the communities we serve."

BayCare facilities currently participate in a multitude of clinical research trials for cardiovascular care. The following are the enrolling trials and the current participating facilities:

Advanced Structural Heart and Valve

ACURATE IDE Transcatheter Replacement of Stenotic Aortic through Implantation of ACURATE in Subjects Indicated for TAVR Participating facility: Morton Plant Hospital

The study objective is to evaluate safety and effectiveness of the ACURATE Transfemoral Aortic Valve System for transcatheter aortic valve replacement (TAVR) in subjects with severe native aortic stenosis who are indicated for TAVR.

Medtronic OPTIMIZE PRO TAVR Post Market Study

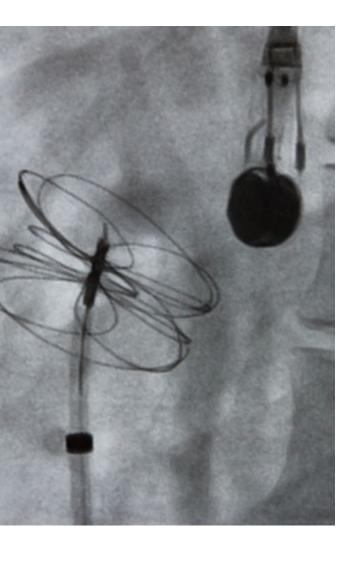
Participating facility: Morton Plant Hospital

The purpose of this study is to collect clinical evidence on valve performance and procedural outcomes associated with an "optimized" TAVR care pathway and using the EvolutTM PRO and EvolutTM PRO+ devices.

"Without research, all of the important advances in medicine that we now depend on would be just observations in a laboratory. Participating in research studies is easy to do and accelerates the availability of new advances in treating common diseases not only to those who are in the trials today, but their children as well."

~ Dr. Leslie Miller Medical Director, Heart Function Clinic at Morton Plant Hospital

For more information on our cardiovascular research and clinical trials: (844) 344-1990



Clinical TRIal to EvaLUate Cardiovascular OutcoMes IN PAtients Treated with the Tricuspid ValvE Repair System Pivotal (TRILUMINATE Pivotal)

Participating facility: Morton Plant Hospital

The objective of this trial is to evaluate the safety and effectiveness of the TriClip device in improving clinical outcomes in symptomatic patients with severe tricuspid regurgitation (TR) who have been determined by the site's local heart team to be at intermediate or greater estimated risk for mortality with tricuspid valve surgery.

APOLLO Trial: Transcatheter Mitral Valve Replacement with the Medtronic Intrepid™ TMVR System in patients with severe symptomatic mitral regurgitation Participating facility: Morton Plant Hospital

Multicenter, global, prospective, randomized, interventional, pre-market trial. Subjects will be randomized on 1:1 basis to either TMVR with the Medtronic Intrepid™ TMVR System or to conventional mitral valve surgery. Subjects ineligible for randomization may be enrolled through a single-arm trial. Subjects enrolled in the single-arm cohort will be assigned to TMVR with the Medtronic Intrepid™ TMVR System.

SUMMIT Clinical Trial to Evaluate the Safety and Effectiveness of Using the Tendyne Mitral Valve System for the Treatment of Symptomatic Mitral Regurgitation

Participating facility: Morton Plant Hospital

The objective of this trial is to evaluate the safety and effectiveness of the Tendyne Mitral Valve System for the treatment of patients with symptomatic, moderate-to-severe or severe mitral regurgitation or for patients with symptomatic mitral valve disease due to severe mitral annular calcification.

Electrophysiology

Product Surveillance Registry
Participating facilities: Mease Countryside

Hospital and Morton Plant Hospital

The purpose of this study is to provide continuing evaluation and periodic reporting of the safety and effectiveness of Medtronic market-released products. The Registry data is intended to benefit and support the interests of patients, hospitals, clinicians, regulatory bodies, payers and industry by streamlining the clinical surveillance process and facilitating leading edge performance assessment via the least burdensome approach.

BIO-LIBRA Study AnaLysIs of Both Sex and Device Specific FactoRs on Outcomes in PAtients with Non-Ischemic Cardiomyopathy

Participating facilities: Mease Countryside Hospital and Morton Plant Hospital

This multicenter, observational study is designed to prospectively assess outcomes of device-treated ventricular tachyarrhythmias and all-cause mortality in nonischemic cardiomyopathy patients indicated for ICD or CRT-D implantation for the primary prevention of sudden cardiac death. Differences in outcomes will be evaluated by sex and by device type.

ECG Belt for CRT Response

Participating facilities: St. Joseph's Hospital, Mease Countryside Hospital and Morton Plant Hospital

The purpose is to compare ECG Belt Research System managed cardiac resynchronization therapy (CRT) patients and a control CRT group with respect to left ventricular (LV) remodeling. The ECG Belt Research System will be used at implant and follow up to help implanters choose a suitable LV pacing site within the recommended locations for LV lead implantation and optimize pacing vector/timing parameters

in line with the EHRA/HRS 2012 expert consensus statement. The first six months of follow up will focus on using the ECG Belt Research System to help choose pacing site, vector and postimplant follow-up pacing programming. From six to nine months, the ECG Belt Research System will be used to further investigate more personalized programming at follow-up visits.

Ultrasensative Electroanatomic Mapping to Adjudicate Endpoints for Ablation in Paroxysmal AF Patients Using Cryoballon Participating facility: St. Joseph's Hospital

The primary objective is to retrospectively analyze electroanatomic maps to determine endpoints that confer acute procedural success and long term arrhythmia free survival in patients with paroxysmal atrial fibrillation undergoing pulmonary vein isolation using cryoballoon.

Heart Failure

CARDIAMP Heart Failure Trial Participating facility: Morton Plant Hospita

Participating facility: Morton Plant Hospital
Randomized Controlled Pivotal Trial of

Autologous Bone Marrow Cells Using the CardiAMP System in Patients with Post Myocardial Infarction Heart Failure

RELIEVE HF: REducing Lung congestIon symptoms using the v-wavE shunt in adVancEd Heart Failure

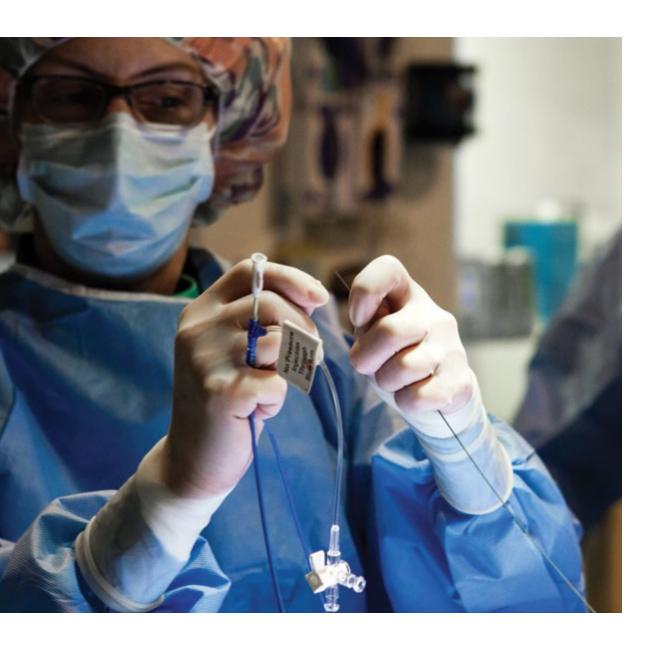
Participating facility: Morton Plant Hospital

This is a prospective, multicenter, 1:1 randomized, patient and observer blinded clinical study, with a Shunt Treatment arm and a non-implant Control arm. A total of approximately 400 patients will be randomized. Patients will be blinded during follow up for a minimum of 12 months to a maximum of 24 months. Control patients will have the opportunity to receive a shunt once unblinded, if they provide consent and continue to meet inclusion/exclusion criteria. All implanted patients will be followed for a total of five years from the time of the study device implantation.

GUIDE-HF

Participating facility: Morton Plant Hospital

This clinical trial is intended to demonstrate the effectiveness of the CardioMEMS™ HF System in patients with New York Heart Association (NYHA) Class II, III or IV Heart Failure (HF) who have an elevated N-terminal pro-Brain Natriuretic Peptide (NT-proBNP) (or an elevated Brain Natriuretic Peptide (BNP)) and/or a prior HF Hospitalization (HFH). This clinical trial



will be conducted under an investigational device exemption (IDE) and is intended to support an expanded indication for the CardioMEMS™ HF System. This clinical trial is sponsored by Abbott.

EMPULSE: A multicentre, randomised, double-blind, 90-day superiority trial to evaluate the effect on clinical benefit, safety and tolerability of once daily oral EMPagliflozin 10 mg compared to placebo, initiated in patients hospitalised for acUte heart faiLure (de novo or decompensated chronic HF) who have been StabilisEd Participating facility: Winter Haven Hospital

The main objective of this study is to assess whether in-hospital administration of empagliflozin results in improvement in HF-related outcomes (clinical benefit including death, heart failure events (HFE) and the burden of symptoms as assessed by the Kansas City Cardiomyopathy Questionnaire (KCCQ) total symptom score) in patients hospitalised for acute heart failure (de novo or decompensated chronic HF) and after initial stabilisation. Secondary objectives are to further assess whether it is safe to start empagliflozin in patients admitted to hospital in this setting.

Coronary Artery Disease

Women's Ischemia Trial to Reduce Events in Non-Obstructive CAD (WARRIOR) Participating facilities: Morton Plant Hospital, Mease Countryside Hospital and St. Joseph's Hospital

This study is being conducted to determine whether aggressive medication treatment to modify risk factors in women with coronary arteries showing no severe obstruction but with cardiac symptoms (i.e. chest pain) will reduce their likelihood of dying, having a heart attack, stroke or being hospitalized. The results of this study will provide the data necessary to inform future guidelines regarding how best to treat this growing population of women, and ultimately improve their cardiac health and quality of life and reduce health care costs.

ASTELLAS A Phase 2 Proof of Concept, Double-blind, Randomized, Placebocontrolled Study to Evaluate the Efficacy of ASP1128 (MA-0217) in Subjects at Risk for Acute Kidney Injury following Coronary Artery Bypass Graft (CABG) and/or Valve Surgery

Participating facility: Morton Plant Hospital

To evaluate the efficacy, safety and tolerability of postsurgical treatment with ASP1128 in subjects at risk for acute kidney injury (AKI) following coronary artery bypass graft (CABG) and/or valve surgery.

cvMOBIUS: The Cardiovascular Multidimensional Observational Investigation of the Use of PCSK9 Inhibitors Participating facility: Mease Countryside Hospital

Primary objective is to evaluate the realworld effectiveness of PCSK9 to reduce cardiovascular events in routine practice in a prospective cohort of adults presenting with a recent ASCVD event and/or revascularization procedure.

For more information on our cardiovascular research and clinical trials: (844) 344-1990

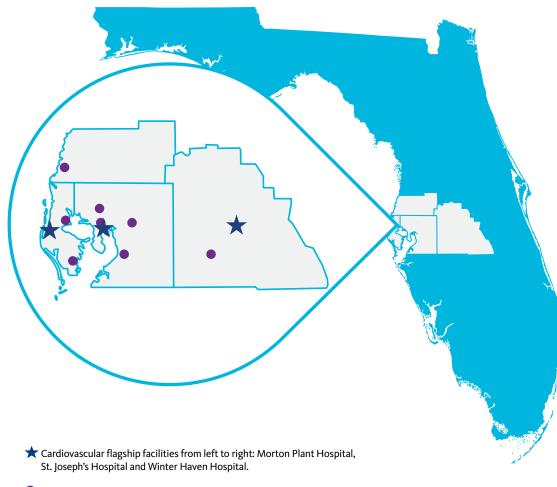


Our Facilities

At BayCare, we take care of more hearts than anyone else in Tampa Bay. In the last year alone, we helped heal more than 24,000 hearts—that's a lot of lives. BayCare provides a multitude of cardiac services at 11 facilities located across Tampa Bay. On the following pages, you'll find a brief description of our different facilities by county.

"As technology advances, physicians have more options available to them to manage patients with complex illnesses. BayCare facilities have embraced the 'heart team' concept to provide optimal care to these patients to achieve the best possible outcomes," according to Dr. Mahesh Amin, medical director, BayCare Cardiovascular Services.

To refer a patient to any of our cardiovascular programs or facilities: (844) 344-1990



Clockwise from top: Morton Plant North Bay Hospital, St. Joseph's Hospital-North,
 South Florida Baptist Hospital, Bartow Regional Medical Center, St. Joseph's Hospital-South,
 St. Joseph's Children's Hospital, St. Anthony's Hospital and Mease Countryside Hospital.

Hillsborough County

Steve and Krista Howard Heart and Vascular Center at South Florida Baptist Hospital





South Florida Baptist Hospital 301 N. Alexander St. Plant City, FL 33563

When the Heart and Vascular Center opened on the campus of South Florida Baptist Hospital, Plant City and the surrounding communities gained greater access to advanced heart care. The Heart and Vascular Center is the first of its kind in the area, offering state-of-the-art diagnostic services in both cardiac and interventional radiology in two hybrid cath lab suites. Interventional cardiology services provided

include percutaneous coronary intervention, peripheral angiography and intervention, cardioversions, pacemaker, implantable cardio-defibrillators (ICD) and loop recorder implants. Additionally, South Florida Baptist Hospital is a STEMI receiving facility. Our hybrid approach with a STEMI team and an IR team on call allows us to provide emergent STEMI and pulmonary embolism (PE) responses to give our patients the best possible outcomes. Staffed by expert physicians, the Heart and Vascular Center features a highly trained and experienced team of technologists and nurses, top-notch recovery rooms, advanced cardiovascular technology and dedicated waiting areas for the patients' loved ones. The Center also provides an array of diagnostic and interventional services for the treatment of vascular disease, such as peripheral artery and venous disease.

St. Joseph's Children's Hospital



St. Joseph's Children's Hospital 3001 W. Dr. Martin Luther King Jr. Blvd. Tampa, FL 33607

In partnership with the Heart Institute at St. Joseph's Hospital, St. Joseph's Children's Hospital is home to Tampa Bay's only comprehensive congenital heart disease (CHD) center capable of delivering full spectrum care for the CHD patient from conception to late adulthood. In 2018, the Adult Congenital Heart Association awarded the Tampa Bay Adult Congenital Heart Center at St. Joseph's Hospital the status of ACHD Accredited Comprehensive Care Center.

St. Joseph's Children's Hospital specializes in diagnosing and treating congenital and acquired heart problems in an innovative and patient-centered environment, and serves as a regional referral center for fetal, pediatric and adult congenital cardiology. The multidisciplinary team of cardiovascular, surgery and anesthesia specialists work in collaboration on all significant patient care decisions for patients of all ages. The CHD center includes one of the busiest congenital cardiac catheterization and electrophysiology labs in the state of Florida that provides a variety of diagnostic and interventional procedures such as angioplasty, pulmonary valve insertion, stent implantations, electrophysiology studies and implantable devices. The CHD center's surgical suites are equipped with the latest technology and staffed with an experienced cardiovascular surgical team for both pediatric and adult patients, and provide surgical intervention for a variety of conditions including arterial switch, complex valve repair and tetralogy of Fallot.

St. Joseph's Hospital Heart Institute



St. Joseph's Hospital 3001 W. Dr. Martin Luther King Jr. Blvd. Tampa, FL 33607

One of the most technologically advanced centers in Florida, St. Joseph's Hospital's Heart Institute provides a multitude of specialized heart services. In 2014, the hospital opened the state-of-the-art \$20 million facility, featuring a combination of nine traditional and hybrid operating suites, cardiac catheterization labs and electrophysiology laboratories with dedicated specialized cardiac equipment. As one of the largest providers of heart attack and stroke care in West Central Florida, the Heart Institute was purposely designed to be located directly above one of the region's busiest emergency rooms, providing quick access for patient procedures.

St. Joseph's Hospital's Heart Institute offers the latest technologies for both openheart and structural heart procedures. Advanced and minimally invasive procedures including complex valve and coronary bypass surgery, TAVR, MitraClip, extracorporeal membrane oxygenation, vascular surgery, targeted hypothermia ablation of advanced atrial fibrillation (AFib) and complex arrhythmia, and a complete suite of offerings to manage implantable cardiac devices. In addition to participating in multicenter clinical trials in arrhythmia, the Institute has recently been identified as the leading cryoballoon AFib ablation center in the world and has been designated a leading teaching facility for the convergent hybrid AFib ablation procedure, minimally invasive AFib surgery, as well as advanced 3-D cardiac mapping, hosting visitors internationally. Recognizing the need for specialization within the discipline of cardiology, the Heart Institute is also a leader in programs for advanced heart failure, cardio-oncology and women's heart disease. The Heart Institute continues to evaluate patients as part of their advanced heart failure program for VAD destination therapy and support the current medical management of LVAD patients. Also, understanding the benefits of rehabilitation, St. Joseph's Hospital's cardiopulmonary rehabilitation program is AACVPR accredited. Additional rehab programs are also available for peripheral vascular and ventricular-assist device patients.

St. Joseph's Hospital-North



St. Joseph's Hospital-North 4211 Van Dyke Road Lutz, FL 33558

Committed to providing advanced cardiac care, St. Joseph's Hospital-North features a highly trained and experienced team dedicated to ensuring the best possible outcomes for those in the surrounding communities of North Tampa. The team performs many advanced heart procedures for both diagnostic and treatment purposes, including diagnostic cardiac catheterizations, percutaneous coronary intervention (PCI), Impella insertion, electrophysiology studies, ablations, defibrillator/pacemaker implants, generator changes, digital loop/event recorder implants, cardioversion and other noninvasive cardiac diagnostic services such as stress testing. Echocardiogram and tilt table studies are also performed on campus. The cardiac catheterization lab at St. Joseph's Hospital-North was one of

the first in BayCare to operate as a hybrid multimodality department, performing cardiac, peripheral and electrophysiology procedures, as well as interventional radiology procedures. St. Joseph's Hospital-North is a STEMI-accredited facility and received the Intersocietal Accreditation Commission (IAC) accreditation for noninvasive cardiology.

St. Joseph's Hospital-South



St. Joseph's Hospital-South 6901 Simmons Loop Riverview, FL 33578

Opened in 2015, St. Joseph's Hospital-South provides advanced cardiac care to patients in Riverview, Sun City, Apollo Beach and the surrounding Southshore areas of southeast Hillsborough County. A team of expert physicians and highly trained cardiovascular technologists and nurses perform advanced heart procedures in three hybrid cardiac catheterization and interventional radiology suites, including

percutaneous coronary intervention (PCI), diagnostic cardiac catheterizations, fractional flow reserve (FFR), intravascular ultrasound (IVUS), defibrillator/pacemaker implants and generator changes, digital loop/event recorder implants, and cardioversion and transesophageal echocardiogram (TEE). Noninvasive cardiac diagnostic services include stress testing, nuclear cardiac imaging studies, echocardiogram, tilt table studies and coronary CT angiography.

Pasco County

Morton Plant North Bay Hospital





Morton Plant North Bay Hospital 6600 Madison St. New Port Richey, FL 34652

Morton Plant North Bay Hospital opened a new cardiac catheterization laboratory in October 2011, providing access to more advanced cardiac diagnostic and treatment

procedures to the New Port Richey area and surrounding communities in Pasco County. The lab includes two specialized imaging rooms and a nine-bed pre/post-procedure area. Services offered include coronary angiography, percutaneous coronary intervention, peripheral angiography and intervention, interventional radiology, cardioversions, pacemaker insertion, implantable cardiac defibrillators and loop recorder implants. Morton Plant North Bay Hospital is a nonsurgical level I Percutaneous Coronary Intervention Center. In 2016, Morton Plant North Bay Hospital opened a cardiopulmonary rehabilitation program designed to help people recover and thrive after a heart event or procedure.

Pinellas County

Mease Countryside Hospital





Mease Countryside Hospital 3231 McMullen Booth Road Safety Harbor, FL 34695

Thanks to its centralized location, Mease Countryside Hospital serves multiple communities in Pinellas, Pasco and Hillsborough counties, and is one of the busiest STEMI locations in the area. Mease Countryside Hospital now offers the Philips Azurion therapy platform as part of its cardiac catheterization lab expansion in 2017. This new platform supports the use of facility quality and safety checklists and protocols to enhance patient safety. It also offers high-quality imaging with low-dose radiation and decreased radiation scatter, providing increased safety for patients, treating physicians and staff. Today, the cardiac catheterization laboratory consists of three imaging rooms that provide a multitude of services including coronary angiography, percutaneous coronary intervention, peripheral angiography and intervention, cardioversions, pacemaker insertion, implantable cardiac defibrillators and loop recorder implants. Mease Countryside Hospital is a nonsurgical level I Percutaneous Coronary Intervention Center.

Morgan Heart Hospital at Morton Plant



Morton Plant Hospital 300 Pinellas St. Clearwater, FL 33756

As a leading heart hospital in Tampa Bay, Morgan Heart Hospital at Morton Plant has one of the most advanced heart care facilities in Pinellas County. The hospital is also the only hospital in the United States to have been awarded the Truven Top 50 Cardiovascular Hospital designation a record 15 times.

The facility has three cardiac catheterization labs that perform a variety of procedures including coronary angiography, percutaneous coronary intervention with Impella support for high-risk patients, peripheral angiography, peripheral intervention, carotid angiography and stenting, balloon valvuloplasty, chronic total occlusion and laser therapy.

Morgan Heart Hospital at Morton Plant has three electrophysiology laboratories that offer diagnostic EP studies, ablations and tilt table testing, and WATCHMAN procedures as well as pacemaker, defibrillator and loop recorder implantation. An 18-bed nursing unit provides pre/post-procedural nursing care.

The hospital maintains five cardiovascular surgical operating rooms including a stateof-the-art cardiac hybrid operating suite. Surgeons perform a variety of procedures including complex aortic surgery, endovascular abdominal (EVAR) and thoracic aneurysm (TEVAR) repair, CABG, minimally invasive and open surgical valve repair and replacement, transcatheter aortic valve replacement (TAVR), MitraClip, extracorporeal membrane oxygenation (ECMO), targeted hypothermia ablation of atrial fibrillation and complex arrhythmias, convergent ablation and comprehensive management of implantable cardiac devices.

Morton Plant Hospital performed the first TAVR procedure in Tampa Bay in February 2012, and has been a national leader for valve procedures and outcomes. As of 2019, the physician team has performed over 1,000 TAVR procedures. In 2014, the heart team physicians performed the first MitraClip treatment for mitral valve

repair in Tampa Bay and have subsequently treated more than 100 patients with this advanced therapy. The inpatient area contains 21 private patient rooms, allowing patients to recover in one location. Postoperatively, patients are cared for by a multidisciplinary team, which includes cardiovascular surgeons and advanced care providers, critical care physicians, nursing and ancillary team members such as social services and pharmacy.

St. Anthony's Hospital



St. Anthony's Hospital 1200 Seventh Ave. N. St. Petersburg, FL 33705

St. Anthony's Hospital has long been a cardiovascular services leader in south Pinellas County, providing state-of-the-art diagnostic and treatment procedures that achieve consistent superior outcomes and patient satisfaction. As part of the hospital's

commitment to providing high-quality cardiac care and growing the cardiovascular services offered to the surrounding community, St. Anthony's Hospital and the team of surgical specialists from Morton Plant Hospital have partnered to provide patients access to advanced cardiovascular and thoracic surgical services.

St. Anthony's Hospital services include three digital cardiac catheterization labs for diagnostic and potentially life-saving interventional procedures, electrophysiology procedures including pacemaker and ICD implants and ablations, electrocardiogram and echocardiogram (EKG/ECHO) equipment to test for heart abnormalities, cardiac stress testing lab with nuclear medicine testing, cardiac rehabilitation, and education and support groups. Additional catheterization lab services have expanded the transradial approach beyond coronary interventions to include peripheral interventions for patients who would benefit from this approach. This is particularly exciting for patients who've had previous bypass surgery terminating in the groin, wounds or infections in the groin area, or who have disease preventing femoral access. The transradial approach also greatly reduces recovery time and minimizes vascular complications post procedure. And, through the use of new

devices, St. Anthony's Hospital now provides treatment of deep vein thrombosis and pulmonary embolism without the need for thrombolytic drugs typically required in the past.

Polk County

Bartow Regional Medical Center





Bartow Regional Medical Center 2200 Osprey Blvd. Bartow, FL 33830

Bartow Regional Medical Center is an acute care hospital serving South Lakeland, Bartow, Fort Meade, Mulberry, rural south Polk County and northern Hardee County. The interventional laboratory at Bartow Regional Medical Center operates as a hybrid laboratory, performing both coronary catheterizations and interventional radiology procedures. Our specialists offer state-of-the-art cardiovascular care from diagnosis to emergency intervention to the latest treatments and preventive education including elective PCI, diagnostic cardiac catheterizations, defibrillator/pacemaker implants and generator changes, digital loop/event recorder implantation, cardioversion, transesophageal echocardiogram (TEE), and other noninvasive cardiac diagnostic services including stress testing and echocardiogram.

The Bostick Heart Center at Winter Haven Hospital



Winter Haven Hospital 200 Ave. F N.E. Winter Haven, FL 33881

The Bostick Heart Center at Winter Haven Hospital is a comprehensive cardiovascular center designed to treat all aspects of adult cardiovascular disease from diagnosis to treatment to recovery. This comprehensive heart program provides a variety of specialized heart services including open-

heart surgery, elective or emergency coronary intervention including treatment of STEMIs, electrophysiology studies and a range of ablation procedures, heart failure care and recovery care in the form of cardiac rehab.

The Bostick Heart Center has an eight-bed, state-of-the-art cardiovascular intensive care unit (CVICU) for care after heart and vascular surgeries, a 12-bed cardiac intensive care unit (CICU) to care for patients after complex cardiac procedures as well as patients with other serious heart problems, a 32-bed cardiovascular unit (CVU), designed for those patients with complex cardiac needs that don't require ICU-level attention, and a 16-bed cardiac observation unit (COU), designed for those patients with suspected heart problems.



Cardiovascular Surgery Data Addendum by Facility

For 2017, the risk-adjusted composite scores for BayCare as a health system were unavailable. The following is the cardiovascular surgery STS risk-adjusted data by BayCare flagship facility* for 2017. BayCare's cardiovascular surgery composite data for 2018 and 2019 can be found in the Cardiovascular Surgery section of this book on page 5.

Risk-Adjusted Isolated CABG with Permanent Stroke				
	STS Benchmark	MPH	SJH	WHH
2017	1.4%	0.9%	1.5%	0.8%

Lower percentage is optimal

Risk-Adjusted Operative Mortality for Isolated CABG				
	STS Benchmark	MPH	SJH	WHH
2017	2.3%	3.1%	0.6%	2.6%

Lower percentage is optimal

Percent of Isolated CABG Patients Extubated in Less Than Six Hours				
	STS Benchmark	MPH	SJH	WHH
2017	54.8%	74.9%	80.0%	83.8%

Higher percentage is optimal

Risk-Adjusted Isolated CABG Prolonged Ventilation (Mechanical > 24 Hours)				
	STS Benchmark	MPH	SJH	WHH
2017	7.6%	7.0%	3.9%	2.1%

Lower percentage is optimal

To refer a patient to any of our cardiovascular programs or facilities: (844) 344-1990

^{*} MPH = Morton Plant Hospital; SJH = St. Joseph's Hospital; WHH = Winter Haven Hospital



Medical Terminology and Procedure Review

This section includes a review of some important medical terminology and procedures related to several sections in this book.

Structural Heart and Valve Terminology and Procedures

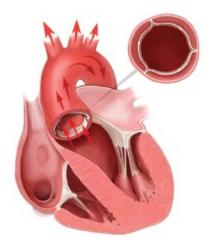
Structural heart disease may affect the heart muscle and the valves that regulate blood flow within the heart. Some structural heart abnormalities are congenital and others are the result of acquired heart disease. Many of these abnormalities ultimately result in congestive heart failure (CHF). Some of the most common conditions and their treatments are described on the following pages.

CHF may be an acute (sudden) or chronic (long-term) problem as a result of a weakened heart muscle. CHF can be a result of multiple causes including but not limited to inadequate blood flow to the heart muscle, valve abnormalities or high blood pressure. Symptoms of CHF include:

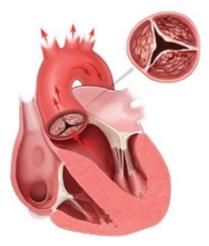
- Chest pain or pressure
- Fatigue
- Persistent cough
- Rapid or irregular heart beat
- Reduced exercise tolerance
- Shortness of breath
- Swelling (edema)
- Weight gain

Physicians categorize heart failure into four classes based on a patient's physical symptoms using the New York Heart Association (NYHA) Functional Classification system:

Class	Patient Symptoms
I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).
II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea.
III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea.
IV	Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.



Aortic Valve opens widely



Aortic Stenosis opening restricted

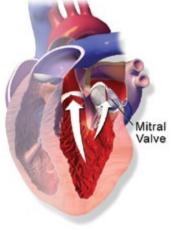
Aortic regurgitation or insufficiency: Aortic regurgitation or insufficiency is a condition in which the aortic valve allows blood to leak backward into the heart. Aortic regurgitation may also lead to symptoms similar to heart failure.

Aortic stenosis: Aortic stenosis is a buildup of calcium deposits on the aortic valve. The aortic valve is the main valve between the heart and the body. Aortic stenosis is a condition in which the aortic valve is so heavily calcified that it's unable to open or close completely. This limits the blood flow from the heart to the brain and body. The heart must then work harder to push blood through the body, which can cause fatigue, shortness of breath and worsening heart function. Declining heart function and the associated symptoms are termed congestive heart failure.

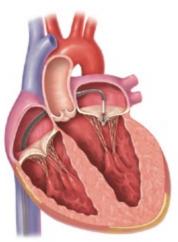
Balloon valvuloplasty: Many patients with degenerative valve disease are ineligible for surgery because of their high-risk status (e.g. advanced age, multiple comorbidities or end-stage disease). For these patients with valves that are too tight or restrictive, balloon valvuloplasty may be a viable alternative to TAVR or open-heart surgery to reduce symptoms. In balloon valvuloplasty, a catheter with a small, deflated balloon attached to the tip is threaded through a blood vessel. Once the catheter reaches the

damaged valve, the balloon is inflated to stretch the valve opening and allow more blood to flow. The balloon is then deflated and guided out through the vessel and removed. The patient is generally awake during this procedure, and the recovery time is considerably shorter than with traditional surgery. However, balloon valvuloplasty isn't a permanent solution and often has to be repeated at a later date. Balloon valvuloplasty can be used to treat aortic and mitral stenosis.

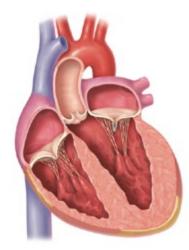
Left atrial appendage closure: The left atrial appendage (LAA) is a small pouch in the left atrium. Patients with atrial fibrillation (abnormal heart rhythm) have a high risk of blood clots forming in the LAA. These clots can dislodge and block blood flow to crucial parts of the body, including the brain (stroke). Oral anticoagulation medications may be used to reduce the risk of clots, but these medications aren't safe or appropriate for some patients. In such cases, LAA occlusion is a viable treatment option. In LAA occlusion, a catheter is used to deliver a closure device to the left atrium. The device is inserted into the LAA and expanded like an umbrella to seal off the entrance to the pouch. Management of the left atrial appendage to reduce the risk of stroke has been performed using novel occlude devices, as well as epicardial ligation devices.







MitraClip deployment



MitraClip - Post procedure

Mitral regurgitation or insufficiency: Mitral regurgitation is a condition in which the heart's mitral valve leaflets don't close tightly. When this happens, blood flows backward from the heart's left ventricle into the left atrium. This reduces the effectiveness of the heart to pump blood to the body, which can cause fatigue.

Mitral stenosis: Mitral stenosis is a result of having rheumatic fever as a child, and leads to calcium deposits on the mitral valve leaflets, preventing them from opening or closing properly. This condition can lead to increased pressure in the lungs, possibly causing permanent damage.

Percutaneous MitraClip placement for mitral regurgitation: During the mitral valve clip placement procedure, a catheter is used to deliver a small clip into the heart via the femoral vein. Once in place, the clip is attached to the leaflets of the mitral valve. to improve their function, and the catheter is removed. Because the procedure is minimally invasive, the recovery time is substantially shorter than with open-heart surgery, the traditional method for treating mitral valve leaks.

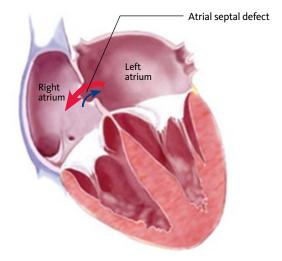
"It has become very clear in the cardiac surgical literature that repairing a patient's leaking mitral valve earlier in the disease process can have significant benefits with respect to decreasing their chances of future heart failure and increasing their overall survival. One of the most important aspects of the decision-making process is that there will be a high likelihood of successful valve repair with a high degree of safety. BayCare surgeons have proven this expertise in both the volume of valves they have repaired and their extremely low mortality rates."

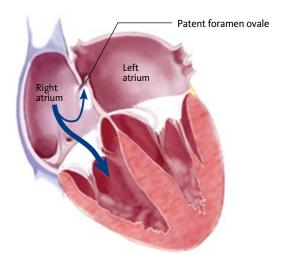
> ~ Dr. Andrew Sherman Chief, Department of Cardiac, Vascular and Thoracic Surgery at St. Joseph's Hospital

Transcatheter aortic valve replacement (TAVR): Transcatheter aortic valve replacement is a minimally invasive procedure for people with severe aortic stenosis who may be unable to undergo traditional open-heart surgery. BayCare physicians offer minimally invasive treatment options for patients with severe aortic stenosis, a narrowing of the aortic valve opening that affects tens of thousands of people each year. The FDA has approved this treatment for high-risk and inoperable patients. Physicians at Morton Plant Hospital received approval to perform TAVR procedures for intermediate- and low-risk patients who want to participate in a research protocol. During TAVR, cardiovascular surgeons and interventional cardiologists place a new valve inside the heart without stopping the heart or opening the chest. Patients often recover more quickly from

Atrial septal defect (ASD)/patent foramen ovale (PFO): An ASD is a hole in the wall (septum) that separates the two upper (atrial) chambers of the heart. A PFO is a condition in which a small opening in the atrial septum fails to seal after birth. Some patients with a PFO can develop stroke when small blood clots cross from the right-sided collecting chamber to the left-sided collecting chamber (atrium), ultimately flowing into the brain.

this minimally invasive approach.





In the past, people with holes in their hearts could face a lifetime of anticoagulant therapy or even open-heart surgery in order to reduce their high risk of stroke. Some BayCare facilities now offer a minimally invasive option to close a variety of cardiac holes, including atrial and ventricular septal defects and patent foramen ovales. During these procedures, a hollow catheter is threaded through a blood vessel and guided to the site of the defect. Once in place, it's used to deliver a collapsed mesh closure device and place it inside the defect. The device is then activated, expanding to block the opening and hold the device in place,

and the catheter is removed. Recovery time following placement is considerably shorter compared with traditional surgery.

Transcatheter paravalvular leak closure:
Paravalvular leaks can occur when a suture holding an artificial valve to the heart tissue breaks, or when the heart tissues around the artificial valve weaken. This defect causes a leak around the valve. Re-operation to repair a paravalvular leak may be a very risky procedure for some patients. This minimally invasive technique uses a catheter to deliver and deploy a closure device at the site of the leak.

Arrhythmia Terminology and Procedures

Common disorders and procedures to manage them are listed below.

Syncope: Syncope is the sudden and transient loss of consciousness associated with the loss of postural tone. Syncope can occur as a result of low heart rate, fast heart rate or dysfunction of the autonomic nervous system.

Supraventricular tachycardia (SVT): SVT, or narrow complex tachycardia, represents a group of rhythm disorders that predominantly occur in the atria. Fortunately, these arrhythmias are easily treatable. They commonly manifest with palpitations, dizziness and, at times, loss of consciousness.

Ventricular tachycardia/fibrillation (VT/VF): VT/VF is an arrhythmia involving the ventricles and are most commonly life threatening. Patients with compromised left ventricular function are at risk for developing ventricular arrhythmias and represent the mechanism of sudden cardiac death in these patients and patients who've had myocardial infarctions. These disorders have been historically managed with defibrillator therapy; however, with advancements in technique and equipment, ablation is now considered an acceptable method of managing this rhythm disorder.

Atrial fibrillation (AFib): Atrial fibrillation is an electrical disorder involving the atria and represents a chaotic electrical process that renders the atria nonfunctional. The end result is stasis of blood in the atria and appendage which can lead to stroke, loss of atrial contractility leading to decreased cardiac output, and in an uncorrected AFib myopathy as a result of chronic uncontrolled ventricular rate. AFib is categorized as either paroxysmal, persistent or chronic.

Channelopathies: The myocardium relies on appropriate functioning of the ion channels. In some patients, genetic abnormalities of these ion channels can result in arrhythmia; at times life threatening. Appropriate management relies on genetic testing and counseling and, in some cases, protection against ventricular arrhythmia with defibrillator therapy.

Bradyarrhythmias: Premature conduction disease may result in low heart rates insufficient to maintain activities of daily living and, in severe cases, loss of consciousness. Management includes removing offending agents or conditions which may cause bradycardia and, in irreversible cases, placement of a pacemaker.

Implantable cardioverter defibrillator (ICD): ICDs represent cardiac devices which protect against sudden cardiac death by effective treatment of ventricular arrhythmias. Traditional devices relied on endovenous wires connected to the heart. Novel devices can be placed under the skin without requiring venous punctures and may be ideal in select patients.

Permanent pacemaker: Traditional pacemakers rely on pacing wires connected to the heart. New generation devices are now completely implantable in the right ventricle and don't require surgery, as the device is delivered through the femoral veins.

Hybrid AFib ablation: Patients with advanced AFib benefit from both epicardial and endocardial ablation. BayCare is a center of excellence in managing advanced AFib using novel techniques.

SVT ablation: Ablation of SVTs can be safely performed using minimally invasive, catheter-based ablation. With the assistance of state-of-the-art 3-D mapping software, eradication of SVTs can be accomplished with unprecedented accuracy and efficacy.

Pulmonary vein isolation for AFib:

Isolation of the pulmonary veins is the cornerstone of managing paroxysmal AFib and can be safely performed using both radiofrequency and cryoballoon ablation techniques.

VT/VF ablation: Ventricular ablations can now be safely performed with the assistance of hemodynamic support devices including Impella and extracorporeal membrane oxygenation. In rare cases, ablation can be performed in the epicardium when endocardial ablation fails.

Lead extraction and venoplasty:

Procedural volume is critical as the main determinant of outcome. BayCare's lead extraction programs have over 20 years of experience and have the most cumulative lead extractions in the area. Typical patients who have lead extractions include patients with device-related infections and patients with multiple abandon leads. Lead extractions are performed in some cases with the assistance of advanced laser cutting sheaths. Patients who develop closure of peripheral veins with pacing leads can also be treated with balloon angioplasty.

His bundle/biventricular pacing:

Patients who require chronic ventricular pacing or have wide QRS intervals with heart failure could benefit from cardiac resynchronization of the ventricles by pacing both chambers using dedicated right and left ventricular leads. A more contemporary technique utilizes a single lead to directly pace the His bundle to promote a narrow QRS interval with each paced beat, thereby maintaining synchrony between both ventricles and improvement in overall cardiac output.

To refer a patient to any of our cardiovascular programs or facilities: (844) 344-1990



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