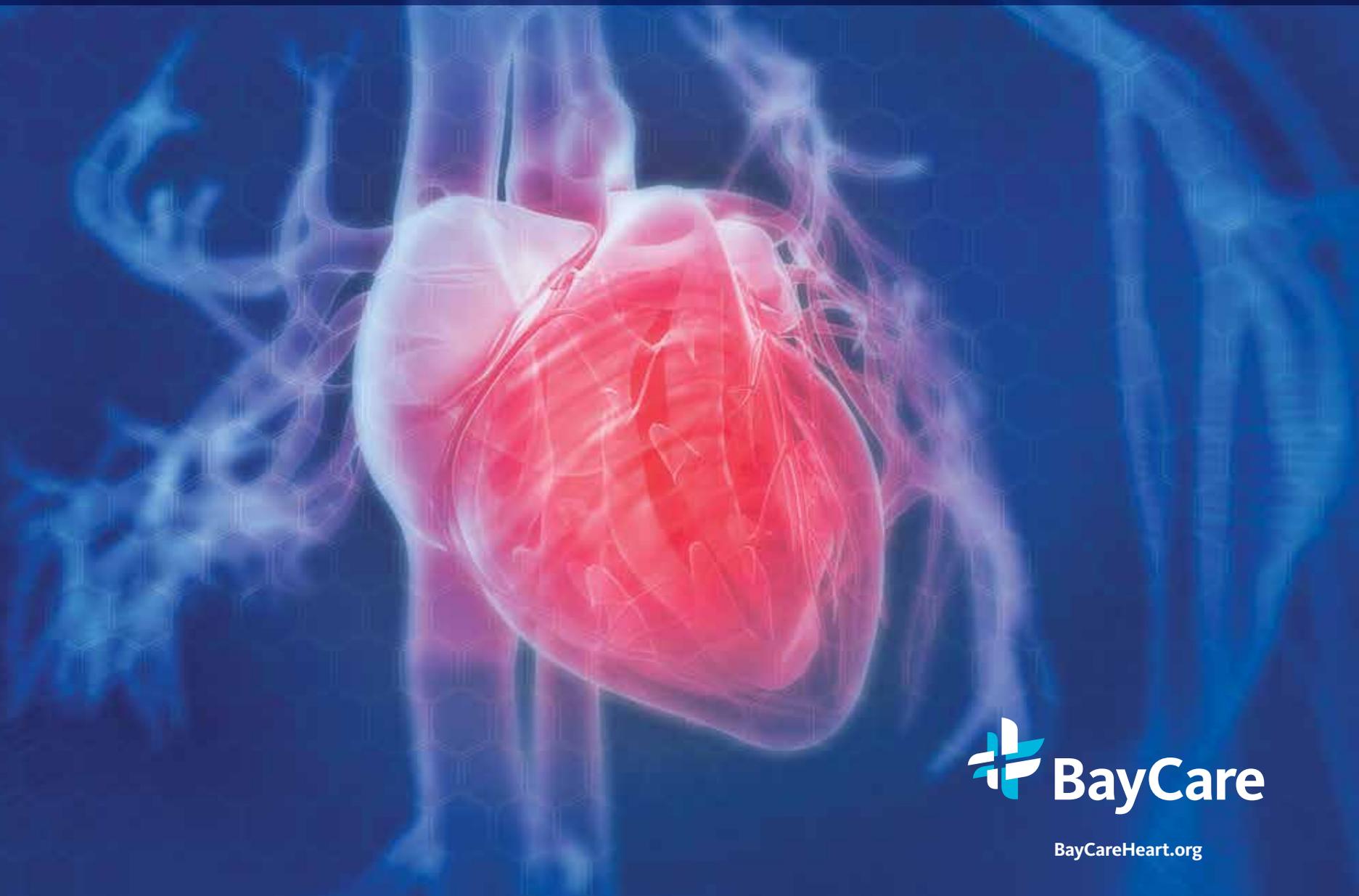


# Cardiovascular and Surgical Outcomes | 2015



[BayCareHeart.org](http://BayCareHeart.org)

Dear Colleague,

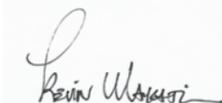
We are pleased to provide this summary of key 2015 cardiovascular program highlights. BayCare's cardiovascular programs are dedicated to providing the highest quality care and services throughout the state of Florida and beyond. Our advanced facilities permit us to care for complex cardiac disease with programs specialized in coronary artery disease, heart failure, structural heart and valve disease, peripheral vascular disease, arrhythmia, congenital heart disease and diseases of the aorta.

BayCare offers comprehensive forums for physicians, staff and administrators to share clinical expertise, outcomes data, research and translation of best practices. Clinical outcomes management, using national benchmarking along with patient-centered care, assures the best treatment for each patient. In addition to our volume and outcomes data, we are excited to highlight some of our world-class programs including our heart failure clinics, many clinical research trials, and fast-growing structural heart programs. As a system of community hospitals within West Central Florida, we are committed to being a leader in providing superior heart care.

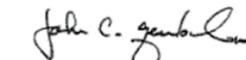
We hope that you can utilize the information in this outcomes booklet to help with patient care and treatment decisions. If you would like more information about our programs, call the appropriate facility at the phone number listed in the back of the booklet.



Mahesh Amin, MD  
Medical Director, Morton Plant Mease  
Cardiovascular Services



Kevin Makati, MD  
Co-Director, Department  
of Electrophysiology  
St. Joseph's Hospital



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



Andrew Sherman, MD  
Chief, Department of Cardiothoracic Surgery  
St. Joseph's Hospital

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BayCare's cardiovascular and thoracic programs offer:

260  
Cardiovascular  
specialists



9  
Cardiovascular  
operating suites



9  
Electrophysiology  
labs



2  
Hybrid  
operating suites



## Experience Matters: An Overview

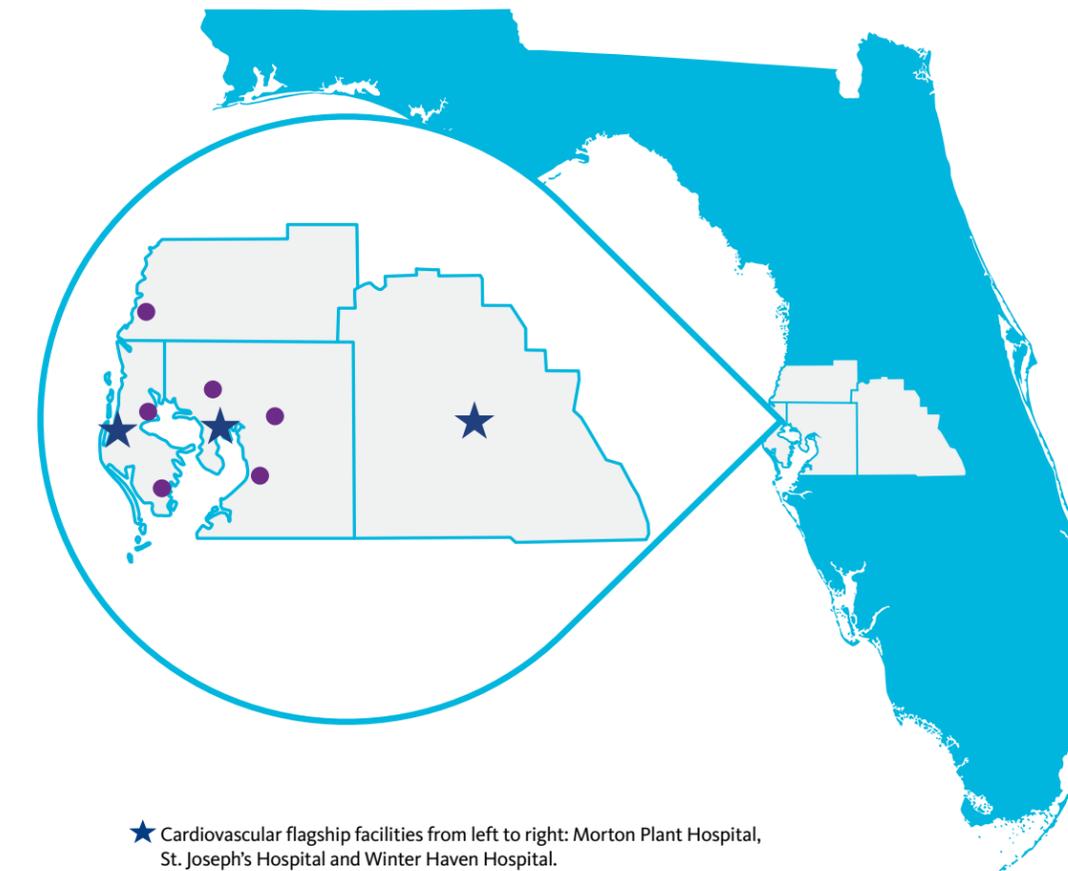
At BayCare, we take care of more hearts than anyone else in Tampa Bay. In the last year alone, we helped heal more than 30,000 hearts—that's a lot of lives.

BayCare provides a multitude of cardiac services at nine facilities located across Tampa Bay. Below you'll find a brief description of our different facilities by county.

### Hillsborough County

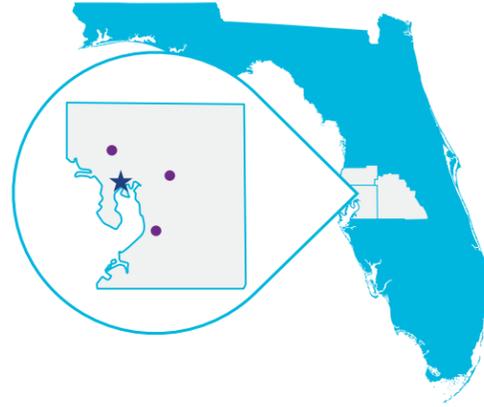
#### Heart and Vascular Center at South Florida Baptist Hospital

When the Heart and Vascular Center opened on campus at South Florida Baptist Hospital, the community of Plant City 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, including diagnostic heart catheterization and interventional heart and vascular procedures. Staffed by expert physicians and highly trained technologists, the Heart and Vascular Center is specifically built for the cardiac patient, with specialized recovery rooms, top-notch cardiovascular technology and dedicated waiting areas for the patients' loved ones. The Center also provides an array of diagnostic and therapeutic services for the treatment of vascular disease, such as peripheral artery disease.



★ Cardiovascular flagship facilities from left to right: Morton Plant Hospital, St. Joseph's Hospital and Winter Haven Hospital.

● Clockwise from top: Morton Plant North Bay Hospital, St. Joseph's Hospital-North, South Florida Baptist Hospital, St. Joseph's Hospital-South, St. Anthony's Hospital and Mease Courtryside Hospital.



### Hillsborough County

#### St. Joseph's Hospital Heart Institute

One of the most technologically advanced centers in Florida, St. Joseph's Hospital Heart Institute provides a multitude of specialized heart services in adult, adult congenital and pediatric cardiovascular medicine. 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 Heart Institute offers the latest technologies for advanced and minimally invasive procedures including complex valve and coronary bypass surgery, TAVR, TMVr (MitraClip®), extracorporeal membrane oxygenation, targeted hypothermia ablation of advanced atrial fibrillation (AF) 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 AF

ablation center in the world and has been designated a leading teaching facility for the convergent hybrid AF ablation procedure, minimally invasive AF surgery, as well as advanced 3-D cardiac mapping, hosting visitors internationally. The Heart Institute has a premier pediatric and adult congenital center, serving as a regional referral center for fetal, pediatric and adult congenital cardiology. It is also the only center in the area to offer congenital interventional and congenital heart surgery alongside an adult cardiac program. With an active heart valve program, the Heart Institute is a national leader in transcatheter pulmonary valve insertion with both the Melody® and Sapien valves. 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, women's heart disease, and cardiac and pulmonary rehabilitation.

#### St. Joseph's Hospital-North

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 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) which includes percutaneous transluminal coronary angioplasty (PTCA) and coronary stenting, intravascular ultrasound (IVUS) and fractionated flow reserve (FFR) measurements, electrophysiologic (EP) studies and ablation procedures. Defibrillator/pacemaker implant and generator change, digital loop/event recorder implant, cardioversion and other noninvasive cardiac diagnostic services such as stress testing, echocardiogram and tilt table study are also performed on campus. The cardiac catheterization lab at St. Joseph's Hospital-North was one of the first in the BayCare system to operate as a dual lab, performing both cardiac catheterization procedures as well as interventional radiology procedures.

#### St. Joseph's Hospital-South

Opened in 2015, St. Joseph's Hospital-South began providing advanced cardiac care to patients in Riverview, Florida, and the surrounding areas. Many advanced cardiac diagnostic and treatment procedures are now available including defibrillator/pacemaker implant and generator change, digital loop/event recorder implant, cardioversion and diagnostic cardiac catheterizations. Other noninvasive cardiac diagnostic services including stress testing, echocardiogram, transesophageal echocardiogram (TEE), tilt table studies and coronary CT angiography are also available.

### Pasco County

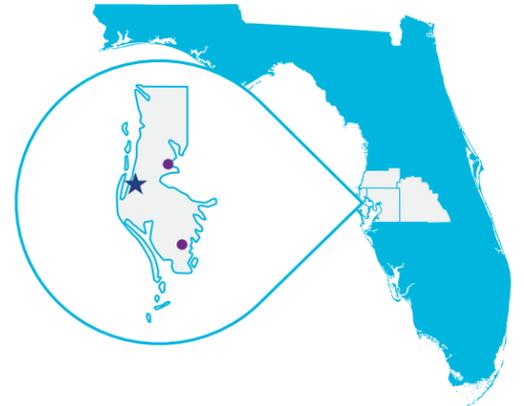
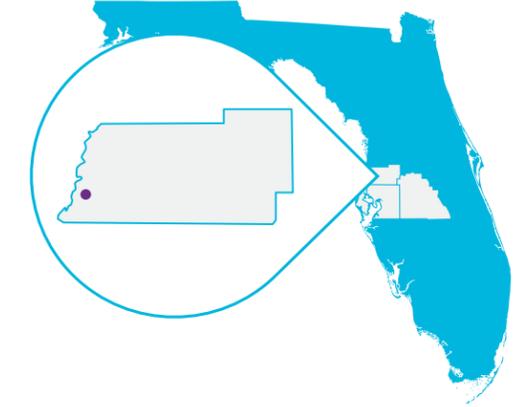
#### Morton Plant North Bay Hospital

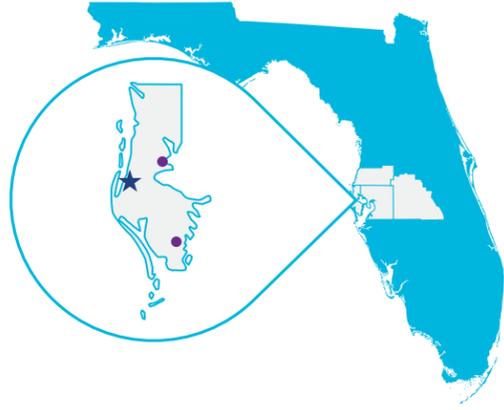
Morton Plant North Bay Hospital opened a new cardiac catheterization laboratory in October 2011, providing access to more advanced cardiac diagnostic and treatment procedures to the New Port Richey area and surrounding communities in Pasco County. The lab includes two specialized imaging rooms and a nine-bed pre/post-procedure area. Services offered include coronary angiography, percutaneous coronary intervention, peripheral angiography and intervention, cardioversions, pacemaker insertion, implantable cardiac defibrillators and loop recorder implants. Morton Plant North Bay Hospital is a nonsurgical Level I Percutaneous Coronary Intervention Center.

### Pinellas County

#### Mease Countryside Hospital

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. Today, the cardiac catheterization laboratory consists of two 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**

As a leading heart hospital in the Tampa Bay community, 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 14 times.

The facility has three cardiac catheterization labs that perform a variety of procedures including coronary angiography, percutaneous coronary intervention, peripheral angiography, peripheral intervention, carotid angiography and stenting with Impella support for high-risk patients, balloon valvuloplasty, chronic total occlusion and laser therapy. Additionally, Morgan Heart Hospital at Morton Plant has three electrophysiology laboratories that offer diagnostic EP studies, ablations and tilt table testing, as well as pacemaker, defibrillator and loop recorder implantation. An 18-bed nursing unit provides pre/post-procedural nursing care.

Morgan Heart Hospital maintains five cardiovascular surgical operating rooms including a state-of-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), transcatheter mitral valve repair (TMVr) or MitraClip, extracorporeal membrane oxygenation (ECMO), targeted hypothermia ablation of atrial fibrillation and complex arrhythmias, 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. The physician team has now performed more than 500 TAVR procedures. The heart team physicians performed the first MitraClip treatment for mitral valve repair in 2014 and have subsequently treated 60 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 staff such as social services and pharmacy.

#### **St. Anthony's Hospital**

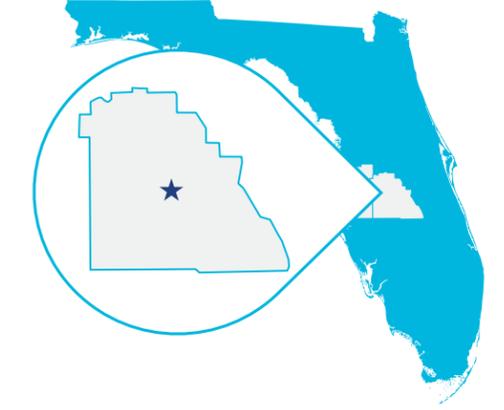
St. Anthony's Hospital has long been a cardiovascular services leader in south Pinellas County, providing state-of-the-art diagnostic and treatment procedures that achieve consistent superior outcomes and patient satisfaction. As part of the hospital's commitment to providing high-quality cardiac care 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 bring you and your patients access to advanced cardiovascular and thoracic surgical services. Current services at St. Anthony's Hospital include three digital cardiac catheterization labs for diagnostic and potentially life-saving interventional procedures, 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.

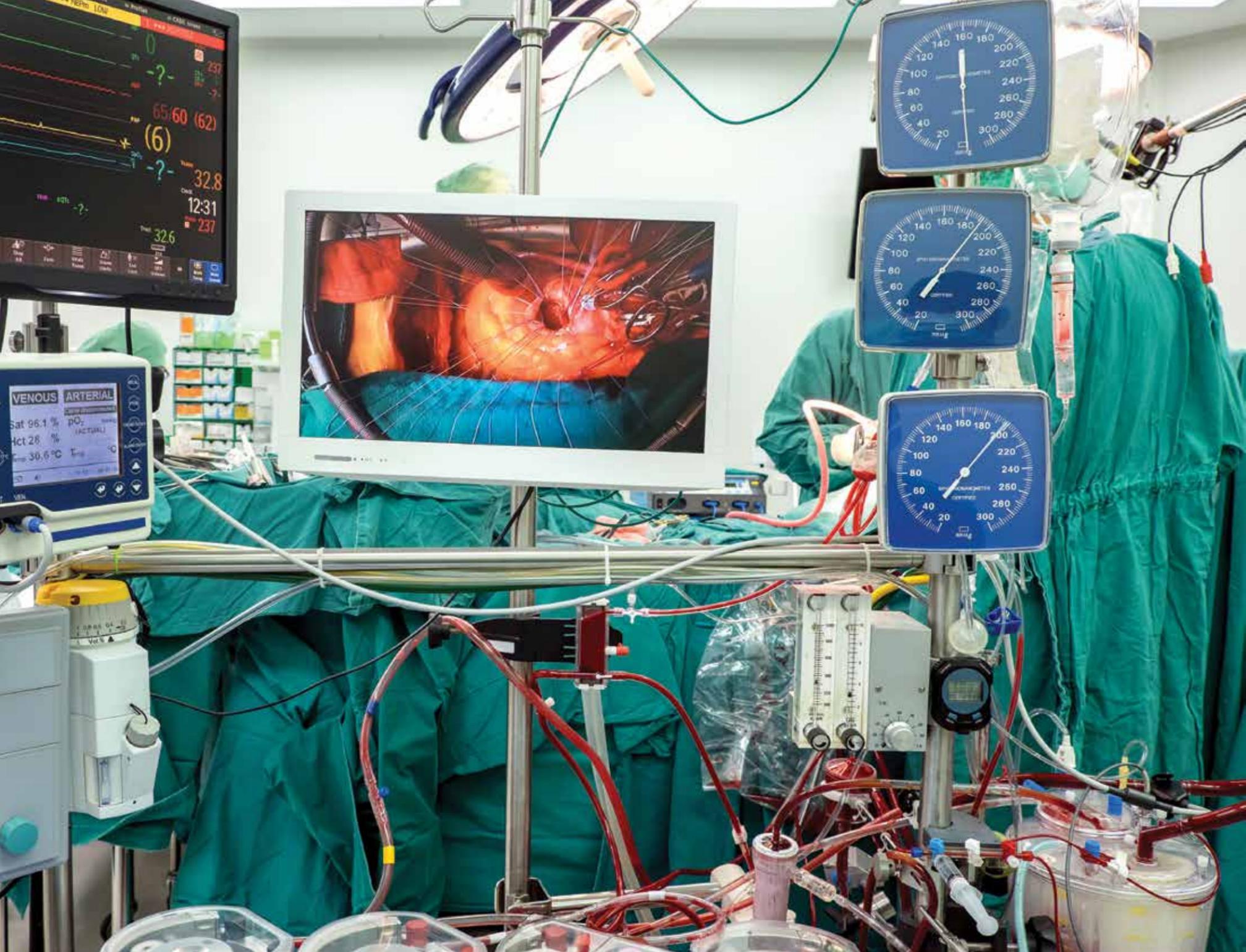
#### **Polk County**

##### **The Bostick Heart Center at Winter Haven Hospital**

The Bostick Heart Center at Winter Haven Hospital is a comprehensive cardiovascular service line 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 do not require ICU level attention, and a 16-bed Cardiac Observation Unit (COU), designed for those patients with suspected heart problems.





## 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.

As a system, we are proud to have been awarded the highest 3-star STS rating for 2015. Dr. Mahesh Amin, medical director of Morton Plant Mease Cardiovascular Services, acknowledges that "Cardiac surgery is one of the most scrutinized specialties that exists. The fact that BayCare has been awarded the STS's highest possible distinction demonstrates our commitment to providing the best, most progressive and transparent level of care to our expanding patient population."

BayCare cardiac surgical procedures include:

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

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*"The fact that BayCare has been awarded the STS's highest possible distinction demonstrates our commitment to providing the best, most progressive and transparent level of care to our expanding patient population."*

~ Dr. Mahesh Amin  
Medical Director of Morton Plant Mease  
Cardiovascular Services

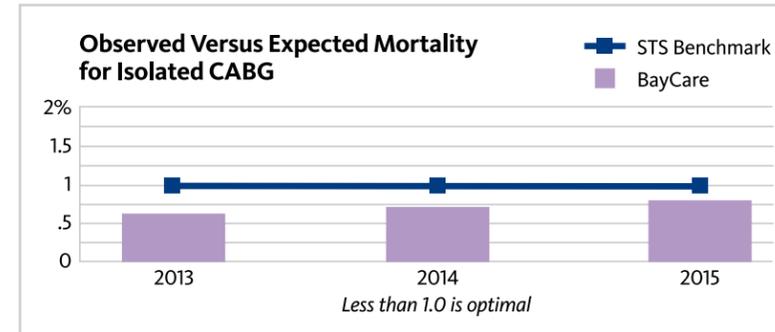
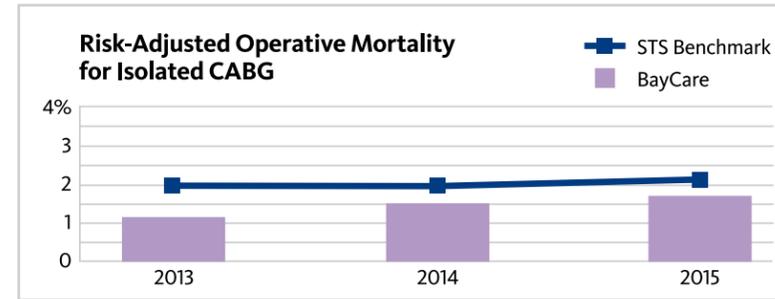
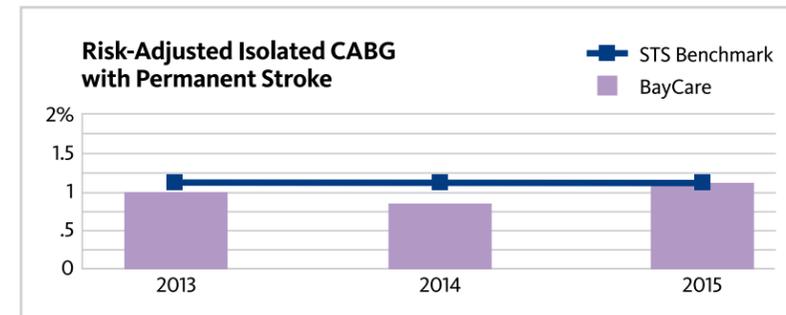
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### A Look at Volume

2015 Open-Heart Surgery Breakdown	
	BayCare
Total Valve	518
Total CABG	701
<b>Total Open Heart</b>	<b>1,219</b>

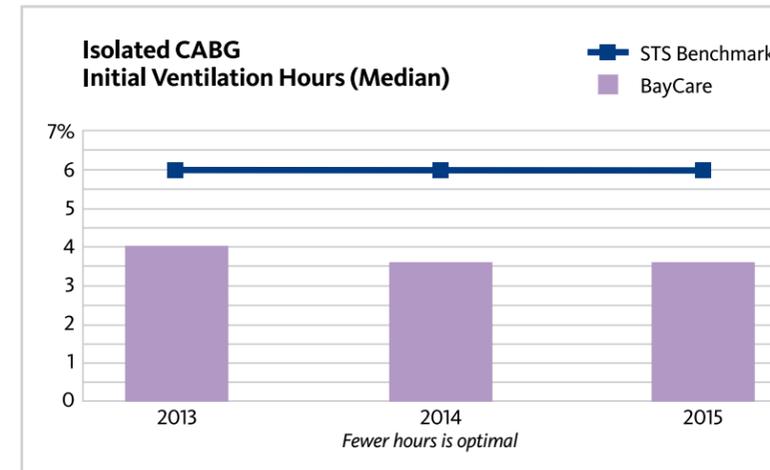
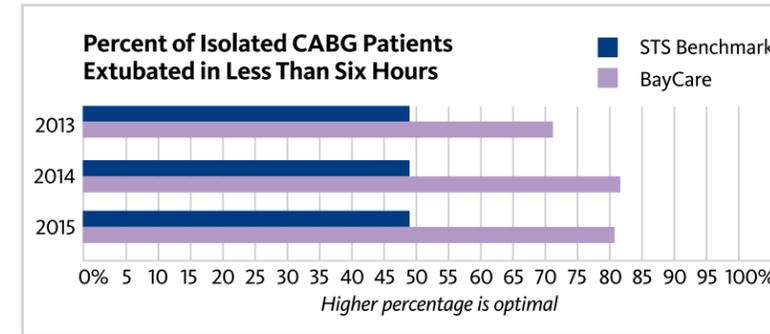
### A Look at Quality

The Society of Thoracic Surgeons (STS) has developed a comprehensive rating system for the quality of coronary artery bypass (CABG) surgery among hospitals across the country. In the current analysis of national data covering the period of January 1, 2015, through December 31, 2015, the CABG performance of BayCare was found to lie in the highest quality tier, thereby receiving an STS 3-star rating. Approximately 12–15 percent of hospitals received the 3-star rating, which denotes the highest category of quality.



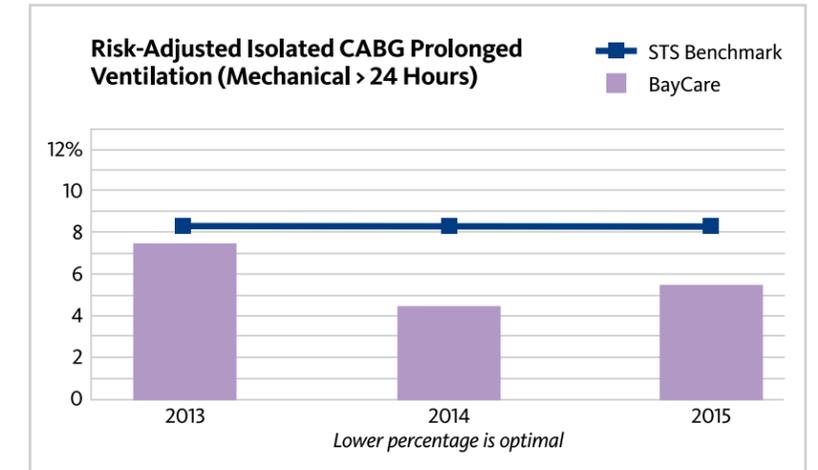
*“BayCare cardiovascular surgeons are committed to providing the highest quality surgical care. Not only are in-hospital and 30-day mortality rates important, but also long-term freedom from further cardiovascular events.”*

~ Dr. John Ofenloch  
Chief of Cardiothoracic Surgery and Medical Director,  
Morgan CVICU/OR



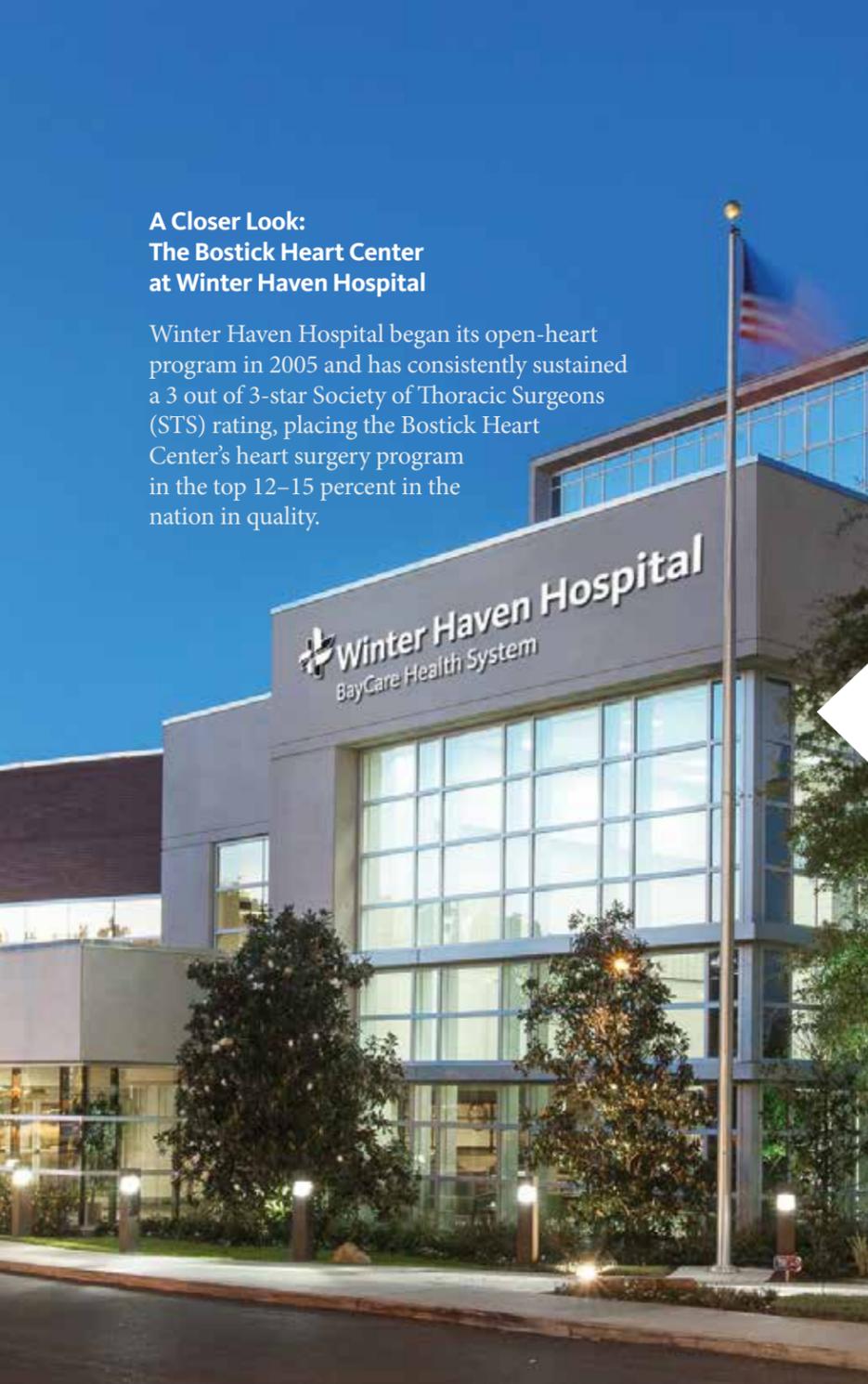
STS Major Cardiac Procedures Mortality				
	Number of Procedures	Operative Mortality	O:E	STS O:E
2013	868	2.0%	0.71	1.0
2014	919	2.3%	0.91	1.0
2015	923	1.7%	0.8	1.0

BayCare's outcomes compare favorably to regional and national outcomes for CABG, valve, and valve plus CABG procedures combined. O:E ratios denote observed versus expected outcomes.



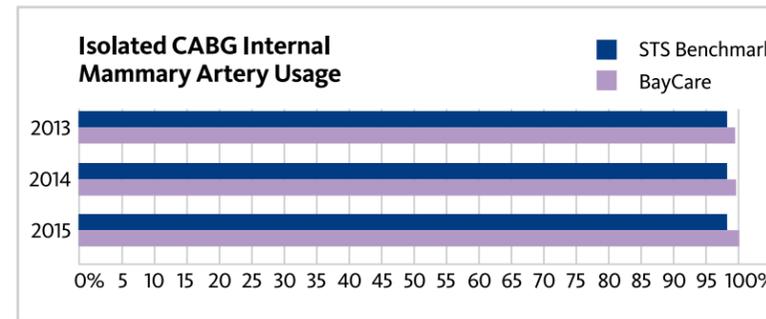
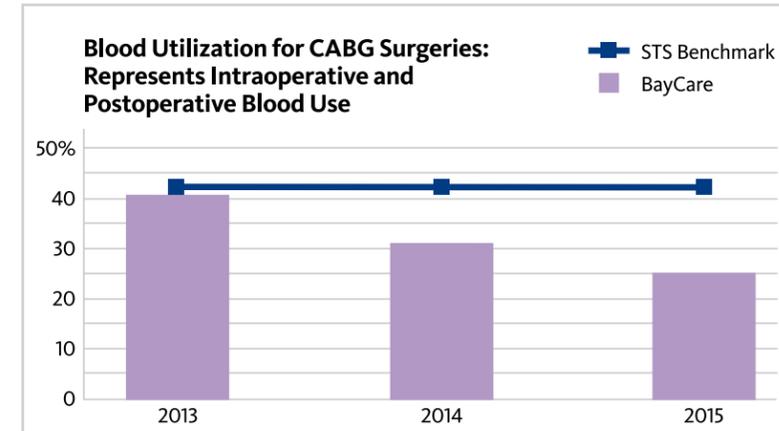
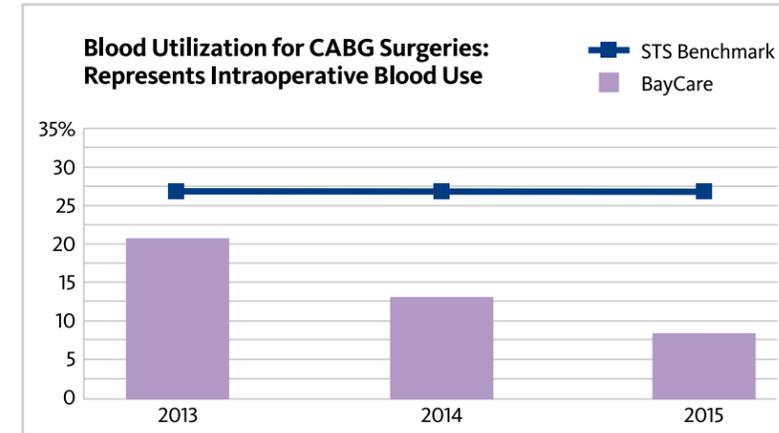
**A Closer Look:  
The Bostick Heart Center  
at Winter Haven Hospital**

Winter Haven Hospital began its open-heart program in 2005 and has consistently sustained a 3 out of 3-star Society of Thoracic Surgeons (STS) rating, placing the Bostick Heart Center's heart surgery program in the top 12–15 percent in the nation in quality.



**Importance of Blood Conservation**

“Conservation of blood and limiting blood transfusions in our cardiovascular surgical patients is of utmost importance,” acknowledges Dr. David Evans, director of cardiac surgery at the Bostick Heart Center at Winter Haven Hospital. “Multiple strategies are utilized to minimize operative blood loss and patient exposure to blood products.”



**Radial Artery Usage**

	STS Benchmark	BayCare
2013	4.2%	13.6%
2014	4.1%	14.6%
2015	4.5%	17.0%

**Bilateral Internal Mammery Artery Usage**

	STS Benchmark	BayCare
2013	4.4%	7.3%
2014	4.5%	10.1%
2015	4.8%	12%

**Emphasis on Arterial Grafting for CABG**

Chief of cardiothoracic surgery and medical director Dr. John Ofenloch acknowledges that BayCare utilizes a variety of arterial grafts when performing CABG surgeries. “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. Arterial bypass grafts have been proven to provide superior long-term outcomes and as such, our utilization of multiple arterial grafts in patients undergoing CABG is several times the regional and national averages.”

**Emphasis on Mitral Valve Repair for Mitral Regurgitation**

For some patients with mitral valve regurgitation, surgically repairing the valve is often the preferred form of treatment over valve replacement. Dr. Andrew Sherman, chief of the department of cardiothoracic surgery at St. Joseph's Hospital, acknowledges BayCare's success, “Over the past two years, BayCare cardiovascular surgeons have performed more than 60 mitral valve repairs. During this time, our health system has experienced zero operative mortalities in mitral valve repair cases.”



## 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 Pinellas and Hillsborough 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.

“The key to our world-class outcomes and success as a center of excellence for structural heart and valve care is the collaborative environment that fosters teamwork amongst all of our specialists. This environment serves as a catalyst for groundbreaking research and for providing the most innovative and advanced structural heart care for our patients,” according to Dr. Joshua Rovin, medical director of the Center for Advanced Valve and Structural Heart Care at Morton Plant Hospital.

These specialists include cardiovascular surgery, interventional cardiology, cardiac imaging and cardiac anesthesia. These physicians work together to provide innovative heart treatment solutions and the best possible outcomes for patients with structural heart abnormalities. A large number of affiliated health care providers participate on the dedicated team as well, including nurses, physician assistants, advanced nurse practitioners and cardiac sonographers.

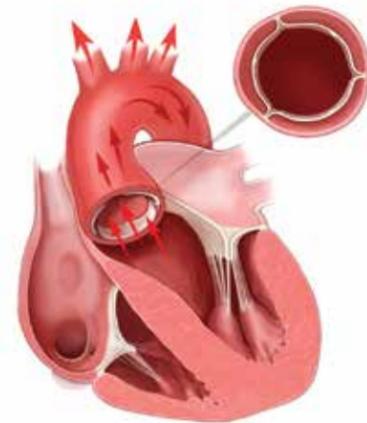
Structural heart disease may affect the heart muscle and the valves that regulate blood flow within the heart. Some structural heart abnormalities are congenital and others are the result of acquired heart disease. Many of these abnormalities ultimately result in congestive heart failure (CHF). Some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

**Congestive heart failure** 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 (adema)
- 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:

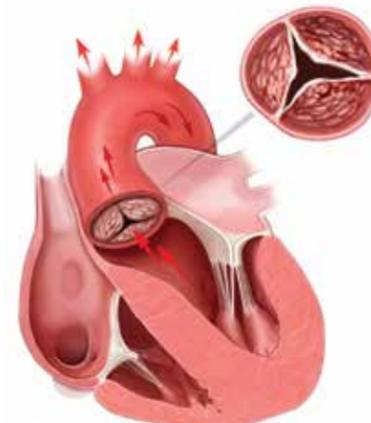
Class	Patient Symptoms
I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).
II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea.
III	Marked 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 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 is 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,



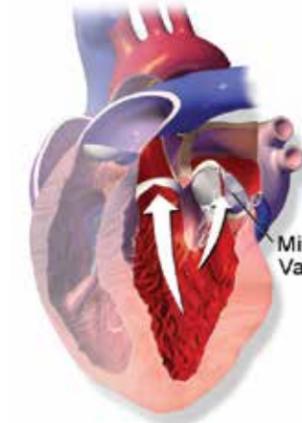
Aortic Stenosis opening restricted

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, 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 is not a permanent solution and often has to be repeated at a later date. Balloon valvuloplasty can be used to treat aortic and mitral stenosis.

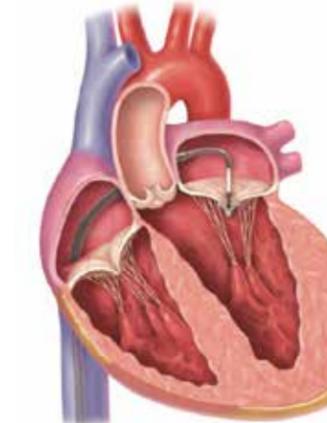
**Left atrial appendage closure:** The left atrial appendage (LAA) is a small pouch in the left atrium. Patients with atrial fibrillation (abnormal heart rhythm) have a high risk of blood clots forming in the LAA. These clots can dislodge and block blood flow to crucial parts of the body, including the brain (stroke). Oral anticoagulation medications may be used to reduce the risk of clots, but these medications are not 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. Occlusion of this structure results in a 95 percent reduction in stroke risk and now can be safely performed using catheter-based techniques. Management of the left atrial appendage to reduce the risk of stroke has been performed using novel occluder devices as well as epicardial ligation devices.



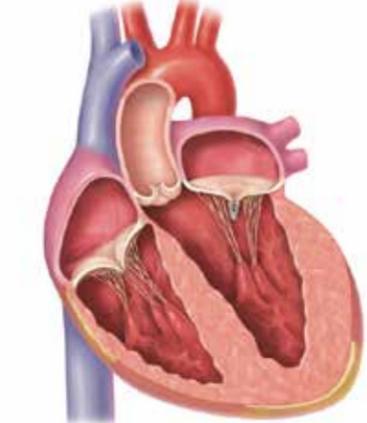
Mitral Valve Regurgitation

**Mitral regurgitation or insufficiency:** Mitral regurgitation is a condition in which the heart's mitral valve leaflets do not 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.



MitraClip deployment



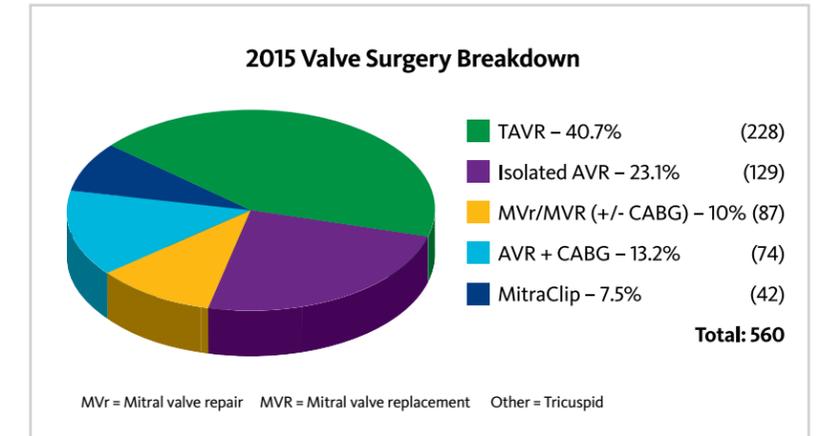
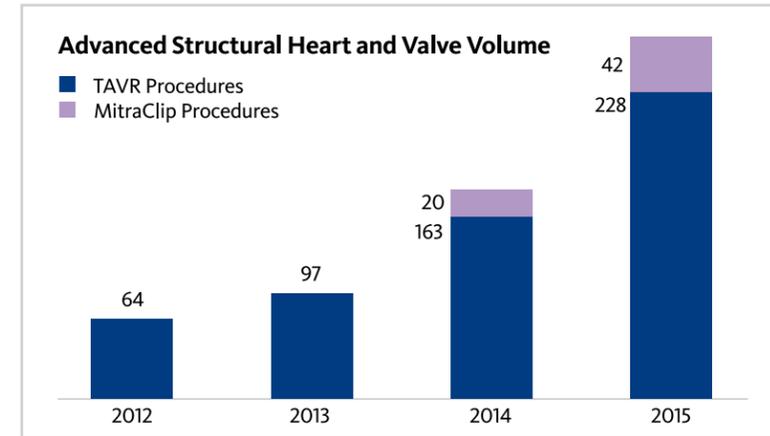
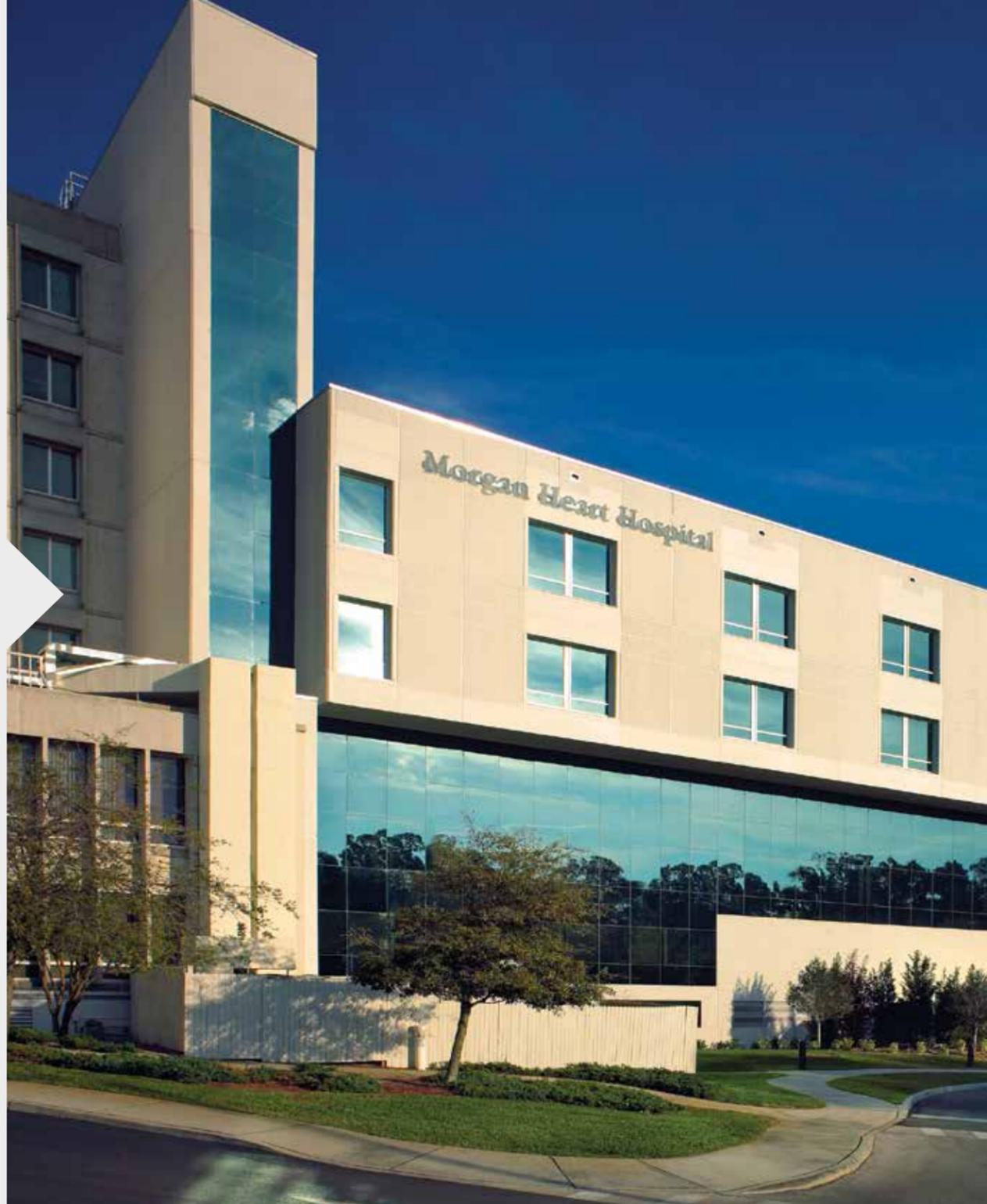
MitraClip - Post procedure

**Percutaneous mitral clip 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.

**A Closer Look:  
Morgan Heart Hospital at Morton Plant**

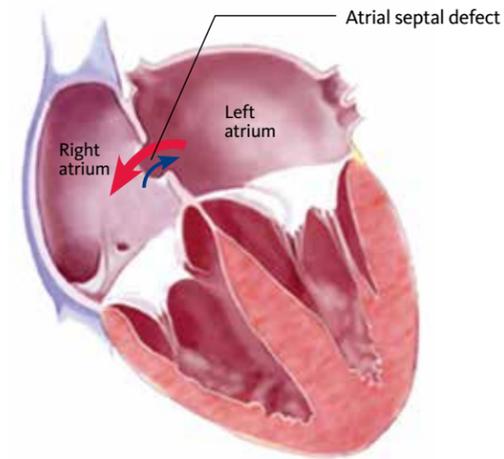
Treating patients since February 2012, the Center for Advanced Valve and Structural Heart Care at Morton Plant Hospital continues the legacy of providing innovative heart care to patients throughout Tampa Bay. As the first multidisciplinary center of its kind in Tampa Bay, the Center for Advanced Valve and Structural Heart Care provides the highest quality care to patients with complex structural heart and valve conditions including aortic valve stenosis, mitral valve stenosis, pulmonary valve stenosis, and aortic or mitral valve regurgitation. To date, the heart team has performed more than 500 TAVR procedures and more than 60 MitraClip procedures.

Less invasive transcatheter methods, as opposed to traditional open-heart surgery, have a lower risk of infection, less trauma to the chest and heart muscle, and reduced length of stay in the hospital, and lead to a speedier recovery without the harmful effects of a heart/lung machine. Transcatheter aortic valve replacement (TAVR) procedures typically take approximately 90 minutes, and most patients are able to go home within two days. "This is quite an advance," said Dr. John Ofenloch, chief, cardiothoracic surgery and medical director, Morgan CVICU/OR. "I've been treating cardiac surgical patients for nearly 15 years, and using this catheter-based technology is really a dramatic improvement in how we can help patients. Rather than performing open-heart surgery, we are able to replace or repair a valve through a peripheral artery utilizing a catheter."

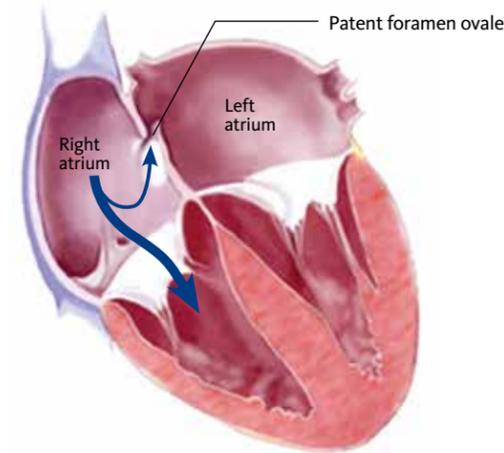


**Transcatheter aortic valve replacement (TAVR):** Transcatheter aortic valve replacement is a minimally invasive procedure for people with severe aortic stenosis who may be unable to undergo traditional open-heart surgery. BayCare physicians offer minimally invasive treatment options for patients with 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. Recently, physicians at Morton Plant Hospital received approval to perform TAVR procedures for intermediate-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 this minimally invasive approach.

2015 TAVR 30-Day Outcomes (In hospital)	
	BayCare
30-day outcome	N=228 (%)
All-cause mortality	1.3%
Major disabling stroke	0.8%
Access site vascular complications	0%



**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. 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 ovals. During these procedures, a hollow catheter is threaded through a blood vessel and guided to the site of the defect. Once in place, it is 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.

**BayCare cardiac transcatheter procedures include:**

- Balloon valvuloplasty
- Left atrial appendage closure
- Transcatheter atrial septal defect closure
- Transcatheter aortic valve replacement
- Transcatheter mitral valve repair—MitraClip
- Transcatheter paravalvular leak closure



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*“It’s quite amazing. After you place the valve, you can immediately appreciate the improvement in the function of the heart.”*

~ Dr. Joshua Rovin  
Medical Director of the Center for Advanced Valve  
and Structural Heart Care

**A Closer Look:  
St. Joseph's Hospital  
Heart Institute**

St. Joseph's Hospital has an established legacy spanning decades in managing arrhythmia, having performed one of the first Wolff Parkinson White surgeries in the late 80s, the first radiofrequency ablation procedure in southeastern United States in the early 90s, the third in the nation to use 3-D electroanatomic mapping software, and eighth center in the nation to use cryoballoon. The Heart Institute is one of few sites in the world to perform the highest volume of cryoballoon ablation, the first center in the world to combine this technology with hybrid epicardial ablation, and one of a handful of sites to participate in pivotal left atrial appendage occlusion trials and novel cryocatheter studies. The hospital is currently a center of excellence and training facility for hybrid ablation, cryoballoon and endocardial mapping software, and a regional referral center for advanced AF ablation, placement of leadless pacemakers and lead extraction.



## 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 disease. 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.

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 have 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 (AF):** 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 AF, myopathy as a result of chronic uncontrolled ventricular rate. AF 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.

**Bradycardias:** 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.

**A Closer Look:  
Convergent Hybrid Ablation**

Patients with persistent atrial fibrillation and failed catheter ablation have traditionally relied on open-heart and thoracoscopic AF surgery and, although effective, resulted in significant morbidity and prolonged recovery times. Cardiothoracic surgeons and electrophysiologists now have formed multidisciplinary teams to provide a hybrid procedure using the same anesthesia. The convergent procedure takes the strengths of each discipline to provide an effective method of managing advanced AF using minimally invasive techniques. Using a small cannula placed under the breast bone, the outside of the heart tissue is safely ablated. Catheters are then placed through the femoral veins to perform an ablation from within the heart. The combination of these two technologies has resulted in significant improvement in managing patients with advanced AF.

**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 selected 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 do not require any surgery, as the device is delivered through the femoral veins.

**Hybrid AF ablation:** Patients with advanced AF benefit from both epicardial and endocardial ablation. BayCare is a center of excellence in managing advanced AF using novel techniques (*see convergent hybrid ablation highlight, left*).

**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 AF:** Isolation of the pulmonary veins is the cornerstone of managing paroxysmal AF 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 include 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 has 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.

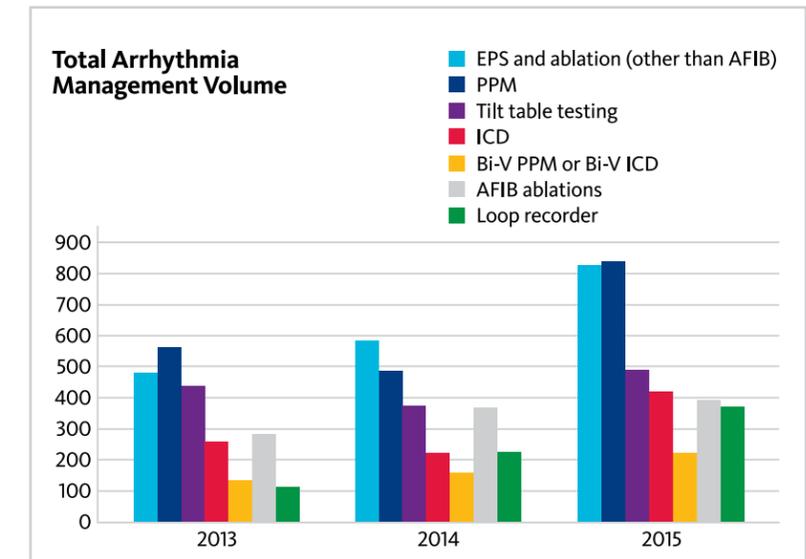
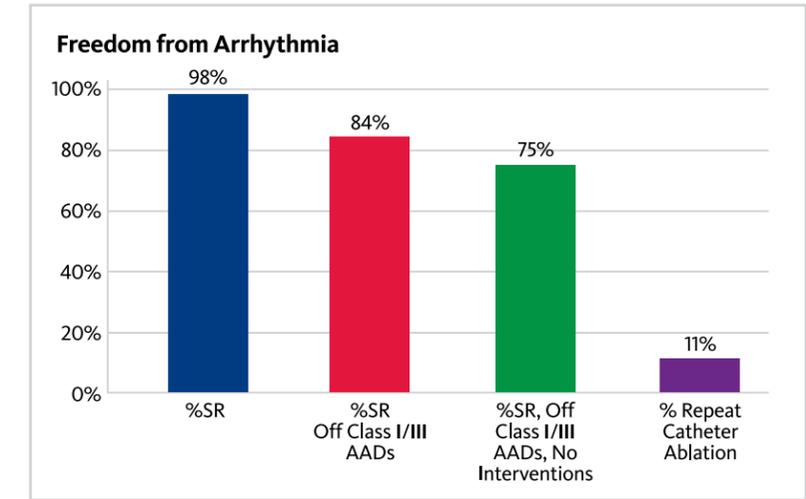
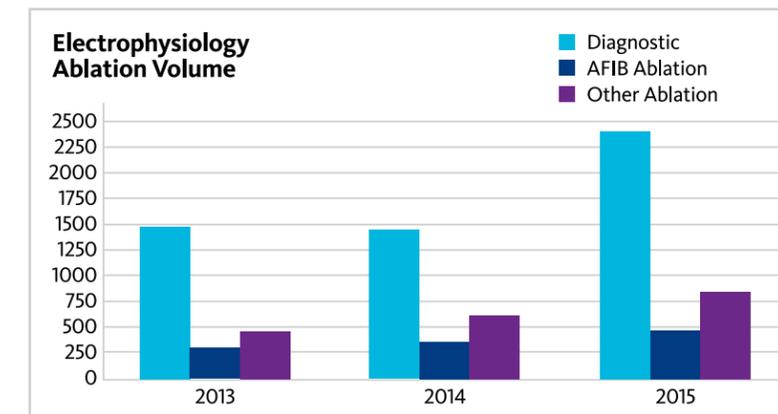
**BayCare arrhythmia programs include:**

- Management of complex arrhythmia using ultrasensitive 3-D mapping
- AF ablation (pulmonary vein isolation) using radiofrequency and cryoballoon
- Hybrid AF ablation for advanced AF
- VT/VF ablation with hemodynamic assist
- Left atrial occlusion/ligation
- Pediatric congenital arrhythmia management

**Cardiac rhythm management (CRM) device implants include:**

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

**A Look at Quality**



# Percutaneous Coronary Intervention

*“The cardiology division at BayCare is proud to offer these and many other techniques to our patients with advanced coronary disease.”*

~ Dr. Bernardo Stein  
 Medical Director, Cardiac Catheterization Laboratories at Morton Plant Hospital

The landscape of coronary disease treatment is changing and evolving rapidly with more complex disease 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, the ability to support the failing heart muscle with different percutaneous devices (i.e. Impella), and the use of absorbable scaffolds that are completely reabsorbed by the body two to three years after being implanted in the coronary arteries. “The cardiology division at BayCare is proud to offer these and many other techniques to our patients with advanced coronary disease,” said Dr. Bernardo Stein, medical director of the Cardiac Catheterization Laboratories at Morton Plant Hospital.

Angioplasty, or percutaneous coronary intervention (PCI), is performed at Mease Countryside Hospital, Morton Plant Hospital, Morton Plant North Bay Hospital, South Florida Baptist Hospital, St. Anthony’s Hospital, St. Joseph’s Hospital, St. Joseph’s Hospital-North and Winter Haven Hospital.

In addition, Mease Countryside, Morton Plant, Morton Plant North Bay, St. Anthony’s, St. Joseph’s and Winter Haven hospitals are also STEMI receiving centers.

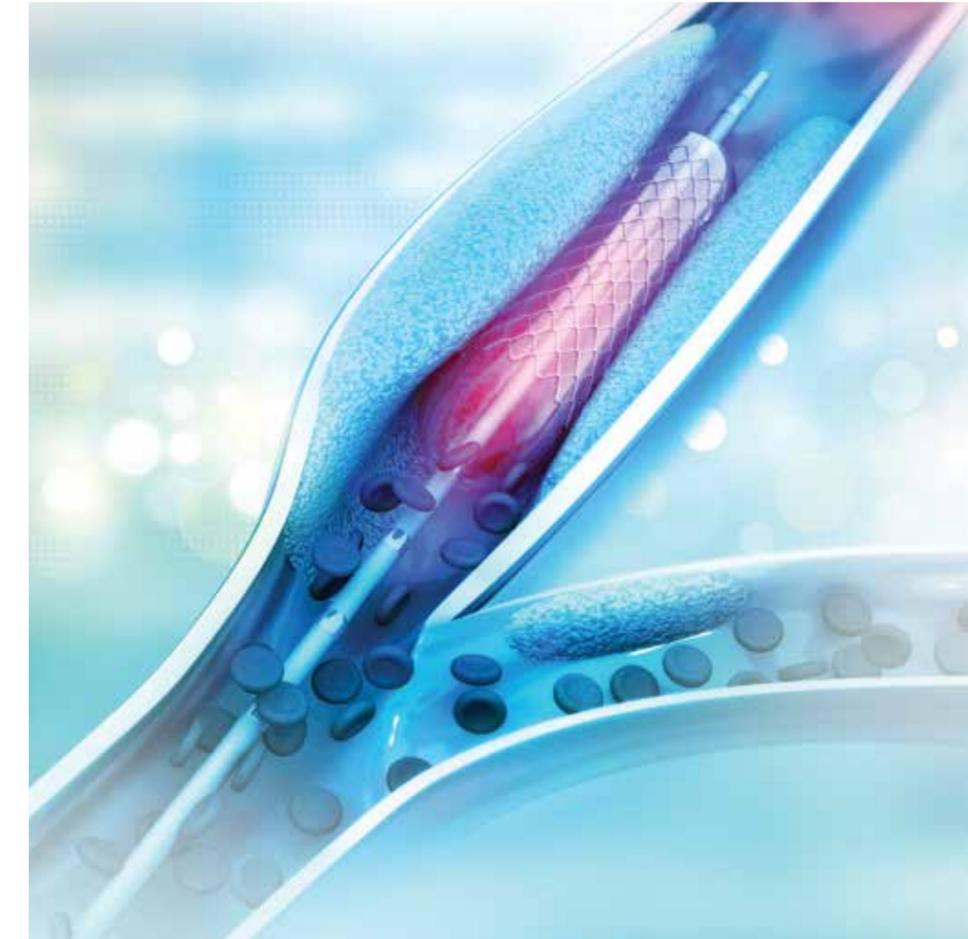
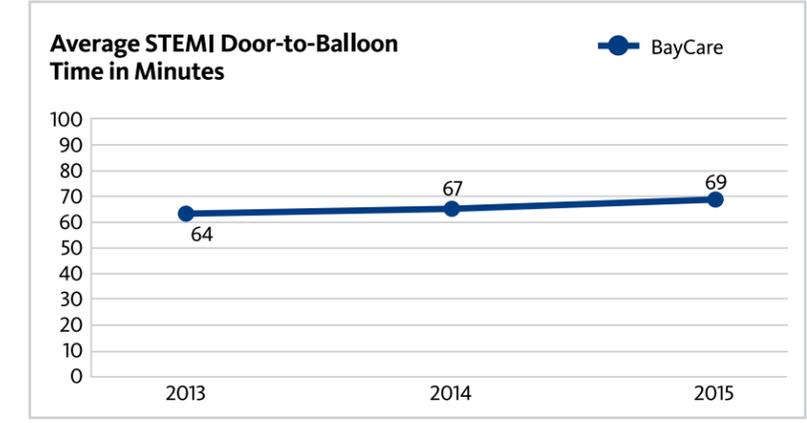
Cardiac catheterization procedures can be done by advancing catheters through the radial artery in the wrist as well as the femoral artery in the peripheral groin area. Radial procedures have been linked to decrease in ambulation, length of stay and bleeding risks. Many of the physicians within these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

- BayCare’s PCI procedures include:**
- Cardiogenic shock
  - Diagnostic coronary angioplasty
  - Diagnostic peripheral angioplasty
  - Percutaneous coronary intervention (PCI)
  - Peripheral vascular intervention (PVI)

### A Look at Volume

PCI Volume			
	2013	2014	2015
PCI volume	4,515	4,615	5,060
Total peripheral vascular intervention volume	1,361	1,833	1,793
Diagnostic cath lab volume	10,434	11,810	11,808

### A Look at Quality



## Heart Failure

*“Heart failure is the most common reason for hospitalization in people over age 65 and effective treatment often requires the collaboration of a health care team that includes primary care physicians, cardiologists, and the specialized doctors and nurses of BayCare’s Heart Function Program.”*

~ Dr. Gus Agocha  
Medical Director, Heart Function Clinic  
at St. Joseph’s Hospital

BayCare’s Heart Function Clinics, for the evaluation and treatment of congestive heart failure (CHF), serve as a resource for primary care physicians and other medical specialists who have high-needs patients who would benefit from the close and continuous oversight of a dedicated heart function team. “As Americans live longer, the number of people suffering from heart failure has grown tremendously and now numbers nearly six million. Heart failure is the most common reason for hospitalization in people over age 65 and effective treatment often requires the collaboration of a health care team that includes primary care physicians, cardiologists, and the specialized doctors and nurses of BayCare’s Heart Function Program,” said Dr. Gus Agocha, medical director of the Heart Function Clinic at St. Joseph’s Hospital.

The Heart Function Clinics specialize in the medical management of heart failure at all stages. The clinics also serve the needs of patients with heart muscle diseases (cardiomyopathy) related to cancer chemotherapy, radiation therapy and other conditions. The Heart Function team is committed to working hand-in-hand with

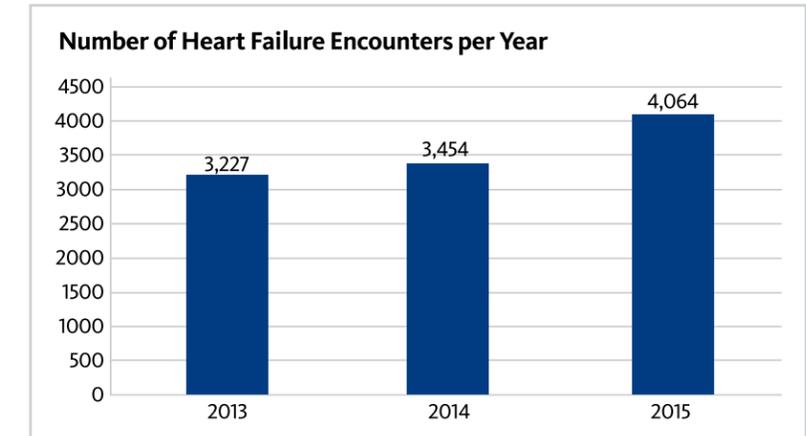
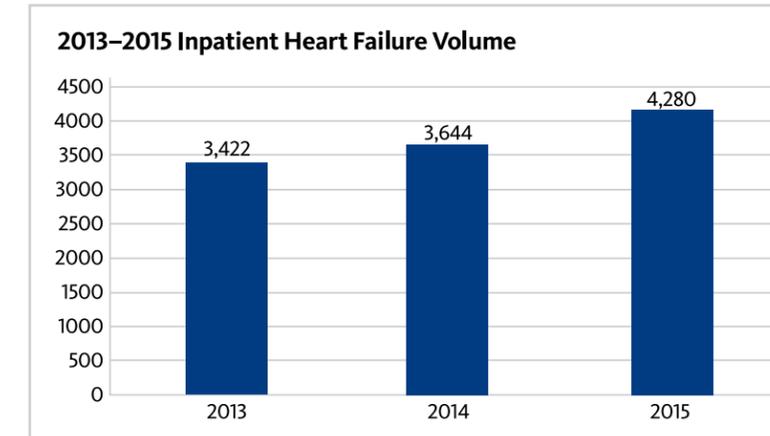
their patients’ primary care physicians and cardiologists to best understand what each individual patient’s needs are.

### Additional services offered are:

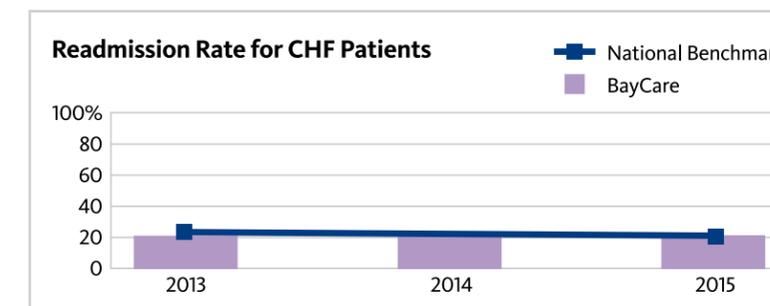
- Emergency room follow up
- Clinical care and research on athletic heart disease
- Comprehensive evaluation of cardiomyopathy
- Coordination of home heart monitoring
- Home infusion therapy
- Hospital readmission risk management
- Inpatient continuity of care
- Opportunity to participate in clinical trials
- Treatment for hypertensive heart disease

BayCare has Heart Function Clinics located on the campuses of Morton Plant Hospital, St. Joseph’s Hospital, St Joseph’s Hospital-North, South Florida Baptist Hospital and Winter Haven Hospital.

### A Look at Volume



### A Look at Quality



# Congenital Heart

BayCare is home to the Tampa Bay area's only comprehensive congenital heart disease (CHD) center capable of delivering full-spectrum care for the CHD patient from conception to late adulthood. Part of the Heart Institute, this unique program is located on the campus of St. Joseph's Hospital in Tampa.

The CHD center features congenital cardiologists who have extensive experience in echocardiography, advanced imaging, electrophysiology, interventional techniques, adult congenital cardiology and heart failure management. The echocardiography laboratory was the first ICEAL-accredited center for transthoracic, transesophageal and fetal in west central Florida. Over 5,000 inpatient and over 14,000 outpatient studies are performed per year, from the fetus to the geriatric adult congenital patient. Additionally, the center's imaging physicians have experience with fetal echocardiography, 3-D echocardiography, transesophageal echocardiography and advanced diastology. They routinely guide the surgical and interventional physicians to ensure optimal results. The catheterization laboratory is one of the busiest congenital laboratories in Florida, performing over 400 procedures annually, most of which are interventions.

The interventional team has extensive experience with device closure, balloon valvuloplasty and balloon expandable stenting. It is a nationally recognized program regarding both volume and quality for transcatheter pulmonary valve implantation with Melody® and Sapien valves. The program is also one of the very few programs in Florida that has performed valve-in-valve replacement of the tricuspid valve.

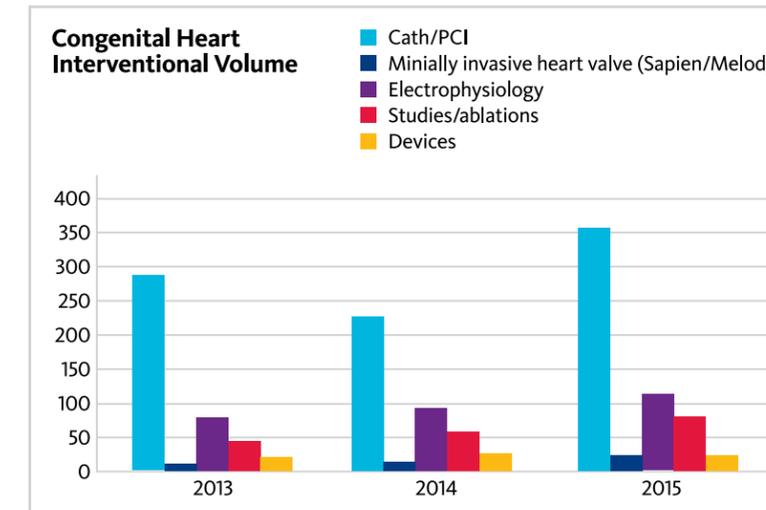
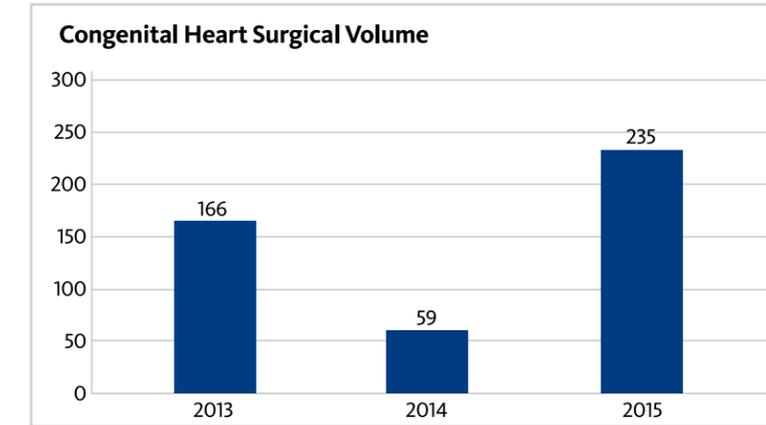
Within the CHD center, the electrophysiology program was established over two decades ago and offers radio frequency ablation and cryoablation utilizing the latest 3-D mapping systems; many procedures these days avoid the use of X-ray entirely. The EP physicians implant both pacemakers and defibrillators and follow hundreds of patients in the center. Developed in collaboration with the Children's Hospital of Pittsburgh, the center's congenital surgical program is a leader in surgical outcomes, patient volume and length of stay. Surgical planning often begins at fetal diagnosis, allaying family anxiety and ensuring parents know what to expect when their child is born. Throughout the CHD center and programs, there is a strong belief in excellence and transparency and the center

submits to national quality improvement databases for surgery (STS Database), cardiac catheterization (IMPACT), and electrophysiology (MAP-IT).

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:

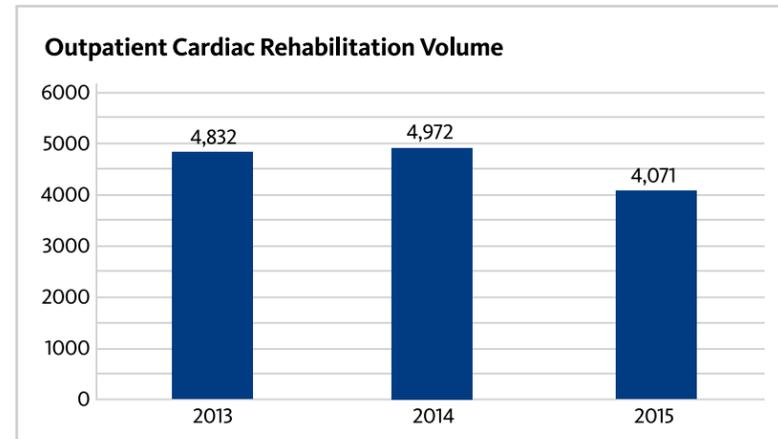
- Aortic stenosis, mitral stenosis
- Atrioventricular septal defect/atrioventricular and canal defect, ventricular...
- Coarctation of the aorta
- Double inlet left ventricle
- D-transposition/complete transposition
- Ebstein's anomaly
- Heterotaxy syndrome
- Hypoplastic left heart syndrome
- Pulmonary and tricuspid valve atresia
- Pulmonary stenosis
- Shone's syndrome/complex
- Single ventricle
- Tetralogy of Fallot

## A Look at Volume



## Cardiac Rehabilitation

Cardiac rehabilitation programs are comprehensive, long-term services involving medical evaluation, supervised exercise, cardiac risk factor modification, education and counseling. They limit the physiological and psychological effects of cardiac illness, reduce the risk of sudden death or reinfarction, control cardiac symptoms, stabilize or reverse the atherosclerotic process, and enhance the psychosocial and vocational status of selected patients. Cardiac rehabilitation improves risk factors, exercise capacity and survival after percutaneous coronary intervention and coronary artery bypass graft surgery. In the most current guidelines of cardiovascular societies worldwide, cardiac rehabilitation is a class I recommendation for patients who have experienced a variety of cardiac events. It is also increasingly recognized as an integral component of the continuum of care for patients with cardiovascular disease.



Includes some volumes from programs currently working toward certification

For patients needing cardiac rehabilitation, BayCare offers inpatient and outpatient programs. The programs are nationally certified by the American Association of Cardiovascular Pulmonary Rehab (AACVPR) and have maintained

certification. Staff members at the cardiac rehab programs are certified as Certified Cardiac Rehabilitation Professionals. Every cardiac rehab patient is assessed by the Cardiac Rehab registered nurse prior to starting the exercise session.

## 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. Kris Hoce, senior vice president, market leader for North Pinellas and West Pasco counties, acknowledges that “BayCare’s involvement in clinical trials supports a collaborative learning environment that raises the level of cardiovascular knowledge across our clinical community, broadening the ability to positively impact the lives of our patients.”

“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 will accelerate making new advances in treating common diseases available not only to those who are in the trials today, but their children as well,” according to Dr. Les Miller, medical director of the Heart Function Clinic at Morton Plant Hospital. “We want to make BayCare a center for research, and invite the community to learn about the research now going on, and express their 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 for cardiovascular care. Below are the open trials and the current participating facilities:

**Advanced Structural Heart and Valve Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation: COAPT Trial**  
Participating facility: Morton Plant Hospital

The purpose of the COAPT Trial is to confirm the safety and effectiveness of the MitraClip system for the treatment of moderate-to-severe or severe functional mitral regurgitation (FMR) in symptomatic heart failure subjects who are treated per standard of care and who have been determined by the site’s local heart team as not appropriate for mitral valve surgery. This randomized controlled trial will provide the opportunity to strengthen or add labeling claims regarding safety and clinical benefits of the MitraClip system for symptomatic heart failure patients with moderate-to-severe or severe functional mitral regurgitation.

*“We want to make BayCare a center for research, and invite the community to learn about the research now going on, and express their support for this important way to enhance the well-being of all those in the communities we serve.”*

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

**Medtronic Transcatheter Aortic Valve Replacement in Low-Risk Patients**  
*Participating facility: Morton Plant Hospital*

The study objective is to demonstrate that the safety and effectiveness of the Medtronic TAVR system as measured by rates of all-cause mortality or disabling stroke at two years is noninferior to SAVR in the treatment of severe aortic stenosis in subjects who have a low predicted risk of operative mortality for SAVR.

**PORTICO IDE/Portico Re-Sheathable Transcatheter Aortic Valve System US IDE Trial**  
*Participating facility: Morton Plant Hospital*

The PORTICO clinical trial is a prospective, multicenter, randomized, controlled clinical study, designed to evaluate the safety and effectiveness of the SJM Portico Transcatheter Heart Valve and Delivery Systems (Portico) via transfemoral and alternative delivery methods.

**REPRISE III/Safety and Efficacy Study of Lotus™ Valve for Transcatheter Aortic Valve Replacement**  
*Participating facility: Morton Plant Hospital*

The objective of this study is to evaluate the safety and effectiveness of the Lotus valve system for transcatheter aortic valve

replacement (TAVR) in symptomatic subjects with calcific, severe native aortic stenosis who are considered at extreme or high risk for surgical valve replacement.

**Arrhythmia**

**Product Surveillance Registry**  
*Participating facility: St. Joseph's 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.

**Percutaneous Coronary Intervention**

**A Long-Term Outcomes Study to Assess STatin Residual Risk Reduction with EpaNova in HiGh Cardiovascular Risk Patients with Hypertriglyceridemia (STRENGTH)**

*Participating facility: BayCare Medical Group Cardiology (North Bay)*

The study is a randomized, double-blind, placebo-controlled (corn oil), parallel group design that will enroll approximately

13,000 patients with hypertriglyceridemia and low HDL and high risk for CVD to be randomized 1:1 to either corn oil + statin or Epanova + statin, once daily, for approximately three to five years as determined when the number of MACE outcomes is reached.

**Themis**

*Participating facility: Morton Plant Hospital*

A multinational, randomized, double-blind, placebo-controlled trial to evaluate the effect of ticagrelor twice daily on the incidence of cardiovascular death, myocardial infarction or stroke in patients with type 2 diabetes mellitus (THEMIS—Effect of Ticagrelor on Health Outcomes in Diabetes Mellitus Patients Intervention Study)

**Theracos**

*Participating facility: Morton Plant Hospital*

A double-blind, placebo-controlled study to evaluate the effects of bexagliflozin on hemoglobin A1C in patients with type 2 diabetes and increased risk of cardiovascular adverse events

**ABLATE/Atherectomy By Laser Ablation with Turbo-Elite**  
*Participating facility: Winter Haven Hospital*

The primary objective for this study is to prove the safety and effectiveness of the Spectranetics Turbo-Elite catheter in atherectomy treatment for infrainguinal arteries with catheter to vessel sizing of at least 50 percent.

**ABSORB IV/Absorb IV Randomized Controlled Trial**  
*Participating facility: Morton Plant Hospital*

ABSORB IV is a prospective, randomized (1:1, Absorb BVS to XIENCE), single-blind, multicenter study, registering approximately 3,000 subjects at approximately 140 sites. ABSORB IV is a continuation of ABSORB III (NCT01751906) trial which are maintained under one protocol because both trial designs are related. The data from ABSORB III and ABSORB IV will be pooled to support the ABSORB IV primary endpoint. Both the trials will evaluate the safety and effectiveness of Absorb BVS.

**ARTEMIS/Affordability and Real-World Antiplatelet Treatment Effectiveness After Myocardial Infarction Study**  
*Participating facilities: Morton Plant Hospital, Winter Haven Hospital and St. Joseph's Hospital*

The ARTEMIS trial is a practical, multicenter, cluster-randomized clinical trial that will assess the impact of copayment reduction by equalizing the copayment of clopidogrel and ticagrelor. ARTEMIS will assess prescribing patterns, patient medication adherence and clinical outcomes up to one year. We hypothesize that reducing out-of-pocket cost for P2Y12 receptor inhibitor will lead to improved adherence. Additionally, copayment reduction of both generic and brand antiplatelet agents may lead to a reduction in MACE risk. This is in part due to greater adherence to an evidence-based secondary prevention medication. Additionally, the reduction in MACE may reflect greater selection of a more potent antiplatelet agent that has been shown to reduce MACE in randomized clinical trials, as provider choice of antiplatelet therapy will be primarily driven by risk-benefit assessment rather than the cost burden to the patient.

**Athersys NSTEMI**  
*Participating facility: Morton Plant Hospital*

A phase 2 trial of AMI Multistem® therapy in subjects with non-ST elevation acute myocardial infarction (MI-MSTEMI). This is a double-blind, sham-controlled clinical study to evaluate the safety and feasibility of AMI MultiStem therapy in subjects who have had a heart attack (non-ST elevation MI).

**RE-DUAL PCI**  
*Participating facility: Winter Haven Hospital*

The main objective of this study is to compare a dual antithrombotic therapy (DAT) regimen of 110mg dabigatran etexilate b.i.d. plus clopidogrel or ticagrelor (110mg dabigatran etexilate dual antithrombotic therapy (DE-DAT)) and 150mg dabigatran etexilate b.i.d. plus clopidogrel or ticagrelor (150mg DE-DAT) with a triple antithrombotic therapy (TAT) combination of warfarin plus clopidogrel or ticagrelor plus ASA <= 100mg q.d. (warfarin-TAT) in patients with atrial fibrillation that undergo a PCI with stenting (elective or due to an acute coronary syndrome (ACS)). The study aims to show noninferiority of both doses of DE-DAT when compared to warfarin-TAT in efficacy and safety. Efficacy will be determined by comparing a composite death and thrombotic event rate of death, myocardial infarction, stroke and systemic embolism. In addition, comparisons will



be made of the rates of clinically relevant bleeding, assessed using the modified International Society of Thrombosis and Haemostasis (ISTH) major classification.

#### **BTK Trial**

*Participating facilities: Morton Plant Hospital and Mease Countryside Hospital*

A prospective, multicenter, single-blind, randomized, controlled trial comparing the Lutonix drug-coated balloon versus standard balloon angioplasty for treatment of below-the-knee (BTK) arteries (Lutonix BTK Trial). The purpose of this Phase 2 study is to assess the safety and efficacy of the Lutonix drug-coated balloon (DCB) for treatment of stenosis or occlusion of native below-the-knee arteries.

#### **PROSPER/Patient-Centered Research into Outcomes Stroke Patients Prefer and Effectiveness Research**

*Participating facility: Winter Haven Hospital*

A three-year research project to create a national, sustainable model to improve decision-making and patient-centered stroke outcomes through comparative effectiveness research. Sponsored by the NIH.

#### **STOP-PAD**

*Participating facility: Morton Plant Hospital*

A Phase 2B randomized, double-blind placebo-controlled study to evaluate the safety and efficacy of JVS-100 administered by direct intramuscular injection as adjunct to revascularization of infrapopliteal lesions in subjects with advanced peripheral artery disease and tissue loss. The purpose of this study is to investigate the efficacy of the administration of JVS-100 delivered via direct intramuscular injections on a three-month and six-month composite endpoint of wound progression, healing and limb loss in patients with severe peripheral arterial disease with nonhealing chronic wounds who undergo an open bypass grafting or endovascular procedure for treatment of infrapopliteal disease and are dosed within two days and three months following the procedure.

#### **VOYAGER PAD**

*Participating facilities: Morton Plant Hospital and Mease Countryside Hospital*

The purpose of the study is to test whether rivaroxaban added to standard-of-care treatment, when compared to placebo, has the potential to reduce the incidence of the clinical events related to the clots and

complications of the heart and brain (CV death, MI or stroke) or the legs (acute limb ischemia or major amputation) in patients who had undergone recent procedure(s) to improve the blood flow of their legs.

#### **Heart Failure**

##### **PARACHUTE V/Percutaneous Ventricular Restoration in Chronic Heart Failure Due to Ischemic Heart Disease**

*Participating facility: Morton Plant Hospital*

A German trial to evaluate the improvement in quality of life and cardiac output following implanting of the Parachute implant system. The CardioKinetix Parachute implant partitions an enlarged ventricle into dynamic and static chambers. The static chamber is a portion of the left ventricular volume that is taken out of circulation. Stresses placed on the partitioned myocardium and the forces transmitted to the apical segment are decreased both in diastole and systole, eliminating the forces responsible for left ventricular dilation. In addition to this regional unloading, the reduction in size of the dynamic chamber results in a decrease of the myocardial stress in the normal myocardium via Laplace Law, providing a global unloading of the ventricle.

#### **PIONEER-HF**

*Participating facility: Winter Haven Hospital*

The purpose of this study is to assess the effect of in-hospital initiation of sacubitril/valsartan (LCZ696) versus enalapril on time-averaged proportional change in NT-proBNP in patients who have been stabilized following hospitalization for acute decompensated heart failure (ADHF) and reduced ejection fraction (left ventricular ejection fraction (LVEF)  $\leq$  40%).

#### **DREAM-HF/TEVA C41750/3100 Study**

*Participating facility: Morton Plant Hospital*

A double-blind, randomized, sham-procedure-controlled, parallel-group efficacy and safety study of allogeneic mesenchymal precursor cells (CEP-41750) in patients with chronic heart failure due to left ventricular systolic dysfunction of either ischemic or nonischemic etiology. The primary objective of this study is to determine whether transcatheter delivery of allogeneic human bone marrow-derived MPCs (CEP-41750) is effective in the treatment of chronic heart failure due to LV systolic dysfunction.

**Hillsborough County**

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**St. Joseph's Hospital-South**  
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Plant City, FL 33563 | (813) 757-1200

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**Morton Plant North Bay Hospital**  
6600 Madison St.  
New Port Richey, FL 34652 | (727) 842-8468

**Pinellas County**

**Mease Countryside Hospital**  
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**Morton Plant Hospital**  
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Clearwater, FL 33756 | (727) 462-7000

**St. Anthony's Hospital**  
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**Polk County**

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[BayCareHeart.org](http://BayCareHeart.org)