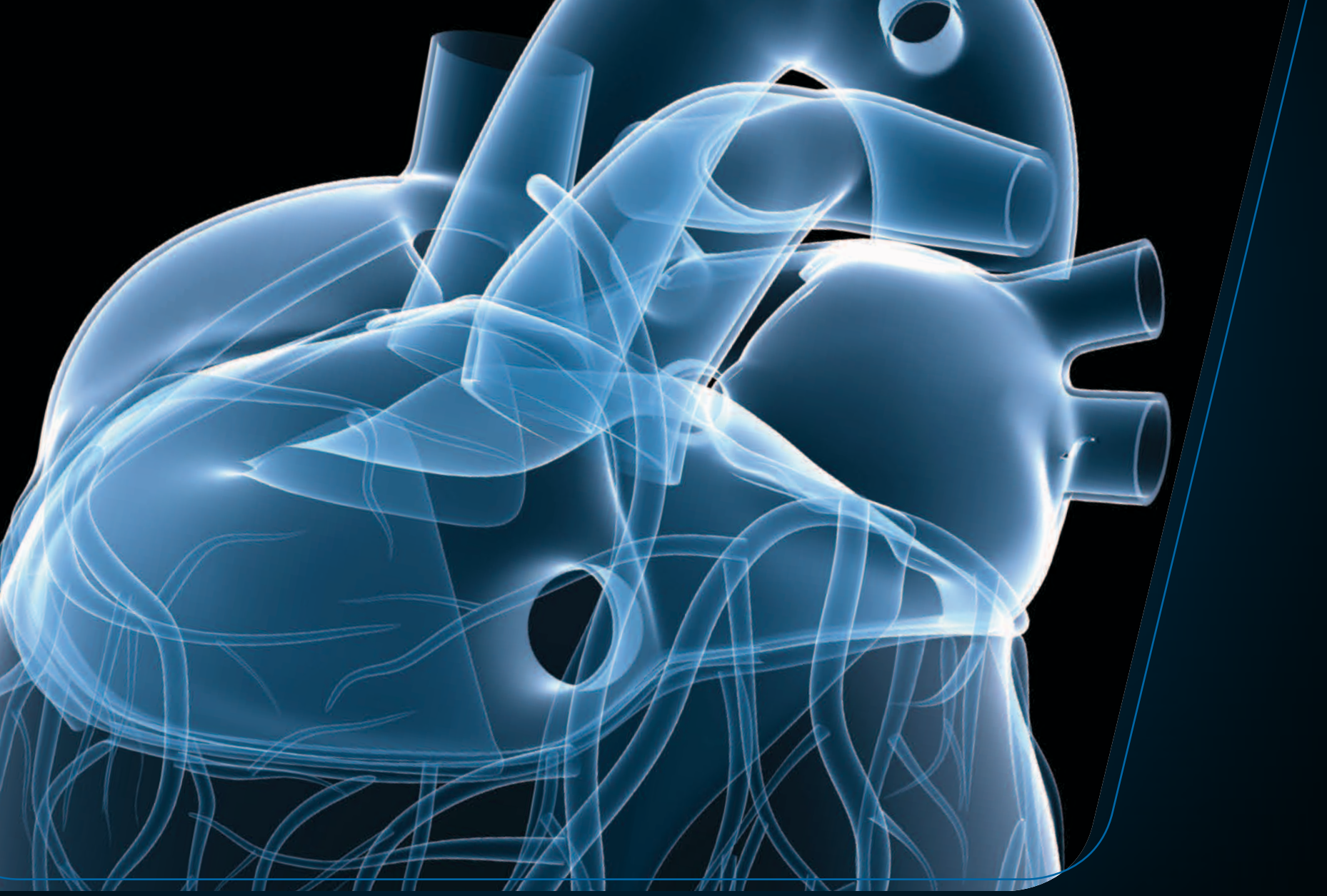


A BLUEPRINT for Health and Wellness

McLaren Northern Michigan

HEART AND VASCULAR ANNUAL REPORT 2014

The HEART:

A BLUEPRINT for Health and Wellness

Accepted protocols.

Proven methods.

Exceptional results.

Heart and vascular care requires a blueprint, a course of direction, and an understanding within the cohort of McLaren Northern Michigan professionals. They know that every decision and every procedure is an endeavor based on best practices, new knowledge, clinical trials, and international research. This approach places McLaren Northern Michigan among the best in the state and in the nation.

INSIDE

2014

Louis Cannon, MD, FSCAI, FACA, FCCP, FACC, FACP, has been repeatedly honored as a leading interventional cardiologist. Author of over 200 medical publications and two United States medical device patents, Dr. Cannon serves on strategic advisory boards for several Fortune 500 companies, as well as many medical technology companies. McLaren Northern Michigan proudly recognizes Dr. Cannon for his significant contributions to heart and vascular health.

To the Medical Community:

A VISION AND A GOAL

We are fortunate to live and work in a thriving community upon which nature has bestowed incredible beauty. But natural abundance is not enough: a truly viable location requires a quality health care system, and we have it here at McLaren Northern Michigan. Our cardiovascular program is committed to providing our residents and visitors with medical care equivalent to the best anywhere. These are not just words for us — it is our promise. State-of-the-art-technology, shared knowledge, professional affiliations, and recruitment of the best medical professionals on a national and even international level places us well beyond the reach and scope of similarly sized facilities. We have established an enviable reputation for expertise in the specialty areas of valve replacements, vascular and cardiac surgery, and STEMI protocols. Significantly, for a hospital of our size, we are truly exceptional.

A SINGULAR ACHIEVEMENT IN ADVANCED PROTOCOLS

McLaren Northern Michigan realizes a depth of programs with access to advanced care not typically found in rural communities. Here are a few examples. McLaren Northern Michigan is the smallest hospital and one of only a handful of non-teaching hospitals in the nation to offer a fully implemented TAVR program. Rest assured, patients always have a very experienced senior cardiologist or surgeon performing the procedure — not a doctor in training. We are one of the only hospitals in Michigan to use drug-eluting balloons in a research protocol for avoiding stent placement in arteries in the leg. We are one of the few hospitals in the Midwest privileged to be involved in an FDA-approved research protocol using a completely bioabsorbable stent to treat coronary artery disease without placement of a long-term metallic foreign body in the heart arteries. And, we will continue to publish and to pursue research and clinical trials both on our own and in cooperation with the worlds' preeminent centers.

A PROMISE OF HEALTH CARE FOR ALL

Health care reform has created change across the industry, and we proactively meet those changes as they transpire. We will maintain and surpass quality levels that drive care for our patients and their families every day. We will continue to provide advanced care for all who need it, not just for those who can afford it. And we will never forget that we are a proud member of one of the largest and most prominent health care systems in the state. We are McLaren Northern Michigan, and WE ARE QUALITY!

Louis A. Cannon, MD, FSCAI, FACA, FCCP, FACC, FACP, Interventional CardioVascular Specialist
SENIOR PROGRAM DIRECTOR, THE HEART & VASCULAR INSTITUTE
PRESIDENT, THE CARDIAC & VASCULAR RESEARCH CENTER OF NORTHERN MICHIGAN

Dedicated to compassionate heart and vascular care, Interventional Cardiologist Thomas Earl, MD, is part of a comprehensive medical team of physicians, physician assistants, technologists, research specialists, and nurses.

Cardiology:

Every Heart, Every Day

McLaren Northern Michigan cardiology services range far beyond that of a similarly sized regional facility. Advanced heart health protocols are administered here, for patients, where they live.

A STEMI heart attack requires a quick medical response to avoid serious complications or death. STEMI intervention uses stents to relieve and reverse the protracted lack of blood flow during myocardial infarction.

Cardiology

RIGHT CARE, RIGHT PLACE, AND RIGHT TIME

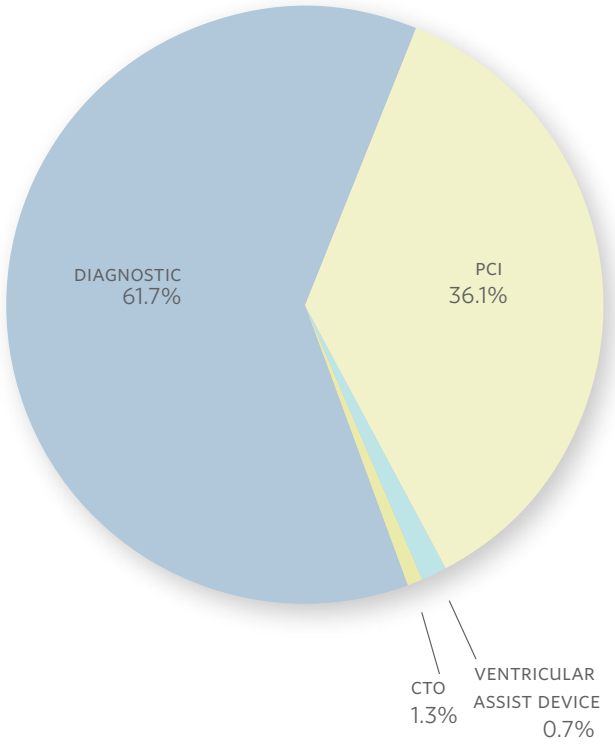
A year of cardiology accomplishments improve STEMI patient outcomes:

- The majority of regional EMS vehicles are now equipped with LifeNet EKG transmission capabilities, thanks to generous donors through the McLaren Northern Michigan Foundation.
- Hiring of a STEMI coordinator facilitates coordination of care throughout the 22-county service area.
- Television and print advertising educates the region's residents about heart attack symptoms and the importance of calling 9-1-1.
- Protocol implementation identifies individuals who should be transferred directly from the field to the cath lab without evaluation in the emergency department, reducing treatment times by 30 minutes.
- Commitment to radial approach (through the wrist instead of the groin) provides markedly improved PCI outcomes and STEMI survival rates.
- Outcomes and concurrent case review direct ongoing revisions to processes and protocols.

2014 CATHETERIZATION VOLUME

1256	DIAGNOSTIC
736	PCI
27	CTO
15	VENTRICULAR ASSIST DEVICE (IMPELLA®/TANDEMHEART®)

Impella® and TandemHeart® technology are used in high acuity patients undergoing percutaneous coronary intervention (PCI), as well as in those treated for acute myocardial infarction and decompensated heart failure. These temporary ventricular assist devices can be used as short-term heart failure solutions, allowing the heart to rest following traumatic episodes or prior to complicated procedures such as open heart surgery or heart transplant.



CODE STEMI:

When Every Minute Counts

Nearly 250,000 Americans experience a STEMI (ST segment elevation myocardial infarction) heart attack every year. A STEMI attack is life threatening and can cause permanent disabilities. Rapid medical response is required from emergency personnel in the field and emergency department physicians at the hospital to properly treat STEMI patients.

Interventional Cardiologist
Jason Ricci, MD

To streamline diagnosis and effectively treat STEMI patients, McLaren Northern Michigan initiated steps to participate in *Mission: Lifeline*®. A project of the American Heart Association (AHA), *Mission: Lifeline* will be a coordinated nationwide effort to establish guidelines and accepted responses for emergency responders and emergency department staff. "*Mission: Lifeline* is an important part of our heart care initiative," says Interventional Cardiologist Jason Ricci, MD. "Our response times from the field to the cath lab continue to best national averages due to the commitment of all team members, from EMS personnel to cardiologists, to expedite diagnosis and treatment. Our participation in *Mission: Lifeline* will validate that commitment."

Paramount to optimal care is the strict timeline governing treatment responses. American Heart Association and American College of Cardiology national guidelines have determined that from initial medical contact to the implantation of a balloon or stent should be completed in 90 minutes or less. Area paramedics responding to a 9-1-1 call use state-of-the-art, on-board electronic technology to determine if the patient is having a STEMI attack, and they can begin treatment while still in the ambulance. Vital signs and electrocardiogram results can be transmitted directly to the emergency department, allowing McLaren Northern Michigan cardiologists to prepare for the patient's arrival at any time, day or night.

"Our goal here at the hospital is to always do better than the national guidelines of 90 minutes," says Ricci. McLaren Northern Michigan is one of only a handful of centers that had 100% of its patients meet the 90-minute timeframe. In fact, the average patient receives life-saving treatment in 42 minutes — less than half of the allotted time. "What makes our times so impressive is the large service area we cover," adds Ricci. McLaren Northern Michigan has developed partnerships with emergency departments in Charlevoix, Cheboygan, and Gaylord to minimize delays for patients in those respective counties. "We are proud of our results and look forward to participation in the *Mission: Lifeline* initiative to implement additional strategies that maximize the care we provide our STEMI patients."

Open heart surgery patient Lois Kircher enjoys views of Walloon Lake from her village home.
"I wouldn't go anywhere else," she expresses about her McLaren Northern Michigan experience.

Cardiothoracic Surgery:

Complex Care is Standard Care

By recruiting the best surgeons and embracing world-class cardiothoracic advancements, McLaren Northern Michigan has become an attractive exception: regional access to nationally recognized care.

Cardiothoracic

The nationally recognized cardiothoracic surgeons of McLaren Northern Michigan, together with their collaborative team of physician assistants, perfusionists, anesthesiologists, and nurses, have consistently exceeded optimal standards for cardiothoracic procedures.

SURGICAL TEAMWORK IMPROVES *AND* SAVES LIVES

Lois Kircher has always led an active and healthy lifestyle. An avid golfer, Kircher knows what it takes to stay on top of her game. But pressure in her chest during a ski vacation led her to share the symptoms with her primary care provider who quickly recommended a stress echocardiogram. Unable to complete the test, she was told her condition was serious and needed immediate surgery.

Cardiothoracic Surgeon J.D. Talbott, DO, performed a coronary artery bypass graft (CABG). The two-and-a-half-hour surgery was uneventful and Kircher was discharged after just six days. Following Cardiovascular Rehabilitation at the John and Marnie Demmer Wellness Pavilion and Dialysis Center, Mrs. Kircher is golfing, skiing, and enjoying her grandchildren.

"Everyone was great to me — nurses, doctors, everyone," she explains. "I wouldn't go anywhere else."

THE SOCIETY OF THORACIC SURGEONS
A Registry of Procedures and Outcomes

Founded in 1964, The Society of Thoracic Surgeons (STS) is a not-for-profit organization representing over 6,800 surgeons, researchers, and health care professionals worldwide, dedicated to ensuring the best possible outcomes for surgeries of the heart, lung, and esophagus, as well as other surgical procedures within the chest. The society mission is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy. — sts.org

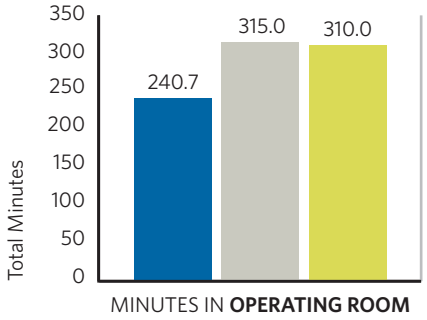
Cardiothoracic Surgeon J.D. Talbott, DO

McLaren Northern Michigan consistently earns the highest quality rating for heart bypass surgery as determined by STS. Of the hospitals that were part of the study, McLaren Northern Michigan performed significantly higher than the mean score, placing it among the top 10 – 15% nationwide. STS, in coordination with Duke Clinical Research Institute, analyzes data on heart programs nationwide. Their comprehensive rating system allows for comparisons regarding quality, complications, pre-and post-operative medication administration, and outcomes. McLaren Northern Michigan has received the STS 3-Star Rating consecutively since January 2012.

2014
OR DURATION

22.4% LESS TIME

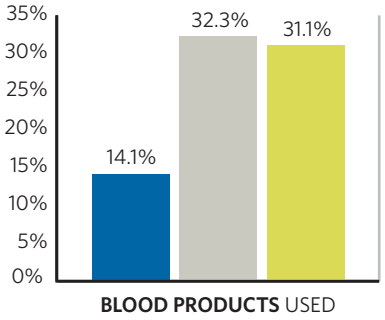
Spent in the Operating Room
than STS National Data



2014 BLOOD
PRODUCTS USED

54.7% LESS BLOOD PRODUCTS

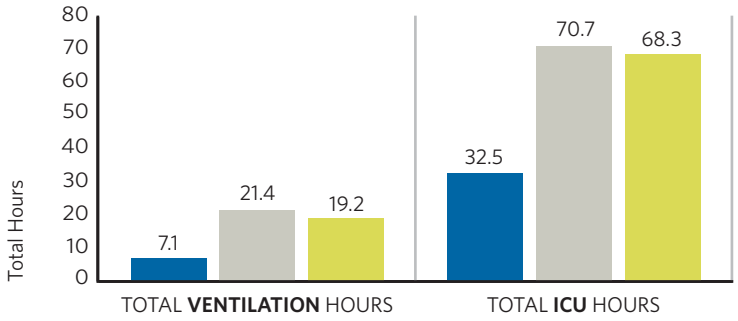
than STS National Data



2014 POSTOPERATIVE
INFORMATION

63.1% LESS VENTILATION HOURS AND 52.5% LESS ICU HOURS

than STS National Data



McLaren Northern Michigan Michigan (Like) Hospitals STS National Data

2014 SURGICAL
COMPLICATIONS

FOLLOWING OPEN HEART SURGERY

0% INFECTION

1.9% Like Hospitals
1.8% STS National Data

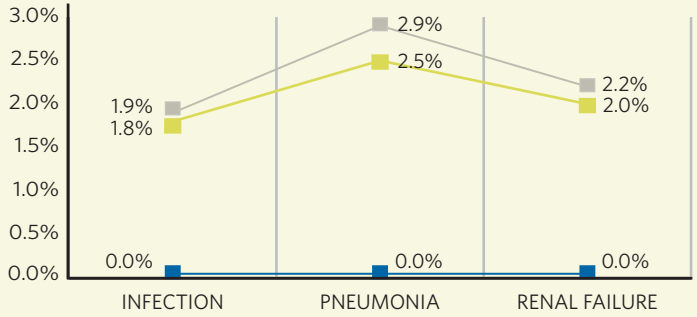
0% PNEUMONIA

2.9% Like Hospitals
2.5% STS National Data

0% RENAL FAILURE

2.2% Like Hospitals
2.0% STS National Data

2014 Surgical Complications



Keith Kester enjoys his Cedarville home, medication-free thanks to his 2013 cryoablation procedure.

Electrophysiology:

Changing and Saving Lives

Electrophysiology has expanded beyond the established standard of care, and every patient benefits from the use of new technologies and advanced procedures. Heart health and premium care are the norm at McLaren Northern Michigan.

Millions of Americans have atrial fibrillation (Afib). Left untreated, the condition increases the size of the heart, weakens its tissue, allows the formation of blood clots, and increases the risk of stroke by 4 to 5 times.

Electrophysiology

RESTORING FUNCTION TO AN AILING HEART WITH CRYOABLATION

Keith Kester of Cedarville was accustomed to living with atrial fibrillation, having been diagnosed years earlier. His heart rate was typically 145 beats per minute. (Ideal heart rate is 60 – 100 BPM.) Kester was referred to Electrophysiologist Naomi Overton, MD. Over the next two years, Dr. Overton treated Kester with medication therapy. But the retired master plumber knew something had changed one day in the summer of 2013 when he began to feel unusual symptoms. "I was sitting on my deck and I started to feel bad," he says. "I called my daughter and said 'Take me to Petoskey.'" Kester's call was a timely one: his Afib had worsened, and after being stabilized, Dr. Overton recommended cryoablation.

Cryoablation changed Keith Kester's life. The procedure is known for its ability to pinpoint the precise area of electrical conduction without damaging surrounding healthy tissue. "If I had to do it over, I would," he says. So successful, Keith Kester no longer needs medication. "I am off everything," he said. "I never liked being on medications, and now I take nothing at all."

The first facility in the region to perform the procedure, McLaren Northern Michigan offers an advanced alternative in the treatment of atrial fibrillation (Afib) — cryoablation. By freezing the tissue that interferes with normal electric conduction, "cryoablation reduces radiation exposure, decreases complication rates, increases accuracy, and shortens procedure time," explains Electrophysiologist Naomi Overton, MD. "Afib was previously associated with morbidity, and cryoablation improves quality of life for many people," says Overton. "It eliminates the need for Afib-correcting medications in most patients."

Previously, atrial fibrillation was treated with radiofrequency (heat generating) ablation. The radiofrequency, administered through the tip of a catheter, cauterizes the tissue where the pulmonary veins connect to the left atrium. The resulting scar tissue blocks the electrical impulses that cause irregular heart rate and rhythms, allowing the chambers of the heart to work effectively together. Dr. Overton indicates that radiofrequency ablation requires the physician to move the catheter tip around each pulmonary vein to isolate their electrical conduction. This can damage healthy heart tissue, necessitating pacemaker implantation.

Cryoablation, on the other hand, uses a catheter balloon and extreme cold, specifically nitrous oxide at -75 degrees F, to occlude blood flow and create scar tissue. When the balloon makes contact with the tissue, the physician fills the balloon with refrigerant. As the refrigerant removes heat from the pulmonary vein it creates scar tissue, effectively blocking the electrical conduction. "It's really amazing," Overton says. "You can see the electrical impulses start to diminish within 30 seconds."

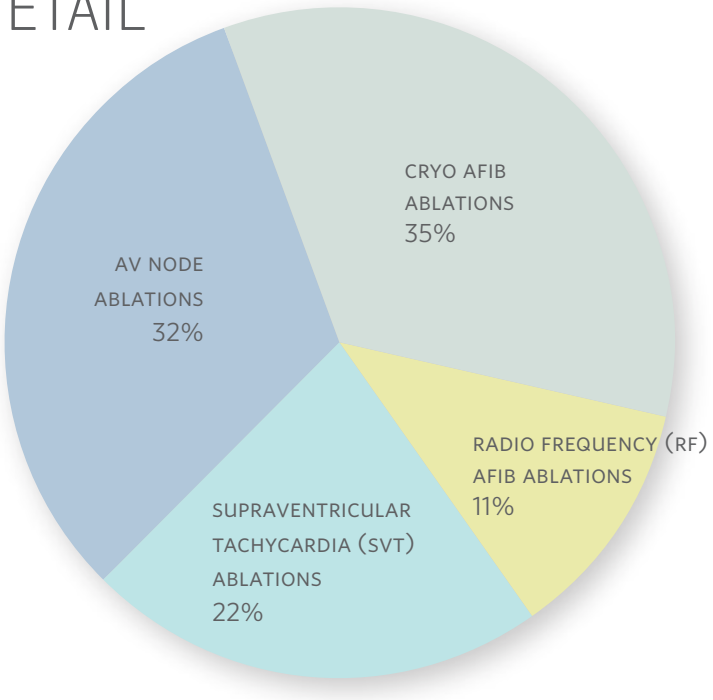
Unlike radiofrequency ablation, if the balloon catheter position is not optimal, the physician can then choose to reapproach the pulmonary vein for a precise scar. "The balloon creates a continuous line of scar tissue where it comes into contact with the pulmonary vein," says Dr. Overton. "This greatly reduces the risk of unnecessarily damaging healthy tissue." Depending upon the patient, cryoablation can be used alone, with medications, or in tandem with radiofrequency (heat generating) ablation.

In the case of Keith Kester, "he was limited in his everyday activities," Overton explains. "Within minutes of cryoablation, his heart had returned to normal rhythm."

2014 ELECTROPHYSIOLOGY VOLUME

PACEMAKER IMPLANTS (PPM/CRT-P)	392
ICD IMPLANTS	68
TILT TABLE TESTING	35
TOTAL EP ABLATIONS *(SUM OF BELOW)*	152
CRYO AFIB ABLATIONS	54
RADIOFREQUENCY (RF) AFIB ABLATIONS	18
SUPRAVENTRICULAR TACHYCARDIA (SVT) ABLATIONS	35
AV NODE ABLATIONS	50

2014 ABLATION DETAIL



DATA SOURCE:
McLaren Northern Michigan Decision Support

AESTHETIC PLACEMENT

Advancements in implantable device design and placement improve both physical and psychosocial outcomes in men and women. Past trials have proven the advantages for altering the device angle and position for Implantable Cardioverter Defibrillator (ICD) and pacemaker candidates. Traditional placement in the chest wall leaves a protrusion a little smaller that a deck of cards near the surface of the chest. Such placement could often cause physical irritation from common items such as bra straps and seat belts, as well as interfere with daily activities.

"The more aesthetic vertical positioning places the device closer to the arm or under the breast tissue and produces several medical outcomes that go beyond the cosmetic advantages," explains Electrophysiologist Naomi Overton, MD. "This point of entry allows for shorter implantation time, produces less stress on the basilic vein, and increases patient safety in the event that re-entry becomes necessary."

Aesthetic device placement continues to gain acceptance as an overall choice for most pacemaker/ICD candidates. Left- or right-handed patients prefer placement that doesn't interfere with the dominant hand. Some patients have hobbies that might be affected by placement, like Barbara Reiter of Gulliver (above); Dr. Overton made device position adjustments to allow Barbara to use her violin chin rest. Obvious medical advantages, coupled with improved outcomes related to body image, lifestyle choices, and physical activities increase the likelihood that aesthetic placement will become the established norm.

Vascular Surgeons (from left to right) Jeffrey Beaudoin, MD, Anton Sharapov, MD, and Andris Kazmers, MD, represent three of a full vascular team at McLaren Northern Michigan.

Vascular:

Improving Vascular Health through Every Avenue

Vascular treatments are reflective of nationally and internationally accepted, evidence-based models. Surgeries, minimally-invasive procedures, and medication-based therapies are routinely considered depending upon individual patient needs.

Vascular

In 2014, vascular surgeons at McLaren Northern Michigan performed nearly 1,000 vascular procedures — endovascular, open, and hybrid approaches for complex conditions. Each patient is evaluated for the appropriate intervention, followed by risk management and lifestyle change management.

EXCEEDING BENCHMARKS, A COLLABORATIVE APPROACH

- Carotid Endarterectomies, Bypass, and Stenting
- Carotid Subclavian Bypass
- Aortoiliac Stenting for Occlusive Disease
- Aortofemoral and Aortovisceral Bypass
- Mesenteric Stenting and Angioplasty
- Renal Artery Stenting and Angioplasty
- SFA and Tibial Angioplasty, Atherectomy, and Stenting
- Femoral Endarterectomy
- Femoropopliteal and Femorodistal Bypass
- Arterial and Venous Thrombolysis
- Arteriovenous Fistula Creation
- Fistulogram and Access Maintenance
- Aortic, Iliac, and Popliteal Endorgraft Stenting for Aneurysmal Disease
- Aortic Snorkel Graft Technology for Paravisceral Aneurysms
- IVC Filter Placement and Removal
- IVC and Iliac Vein Thrombolysis
- Venous Laser, Radiofrequency Ablation, Stripping, Ligation, and Stenting
- Limb Amputations

MAKING THE GRADE THROUGH SELF-MONITORING

Blue Cross Blue Shield of Michigan Cardiovascular Consortium Vascular Interventions Collaborative (BMC2-VIC)

The success of the vascular program at McLaren Northern Michigan results, in part, from actively seeking validation through participation in voluntary programs designed to evaluate performance and ultimately improve patient outcomes.

Vascular Surgeon Andris Kazmers, MD

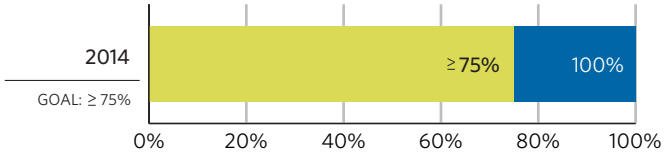
The BMC2-VIC includes 49 participating hospitals throughout Michigan to standardize practices and to monitor and improve the quality and safety of vascular procedures. The consortium measures quality improvement indicators specific to vascular surgical procedures. "We are seriously involved in this consortium for the quality of the data, the professional support, and for the precision in measuring outcomes," says Vascular Surgeon Andris Kazmers, MD. "Through collaborative team participation, we determine an entire patient plan, from evaluation to procedure to post-operative risk assessment, and then use collaborative statewide data to measure success and determine goals for improvement." McLaren Northern Michigan consistently exceeds goals as recognized by BMC2-VIC. "Clearly, our patients do not need to travel to receive superior vascular treatment, and we have the data to prove our success."

2014

VASCULAR SURGERY DATA

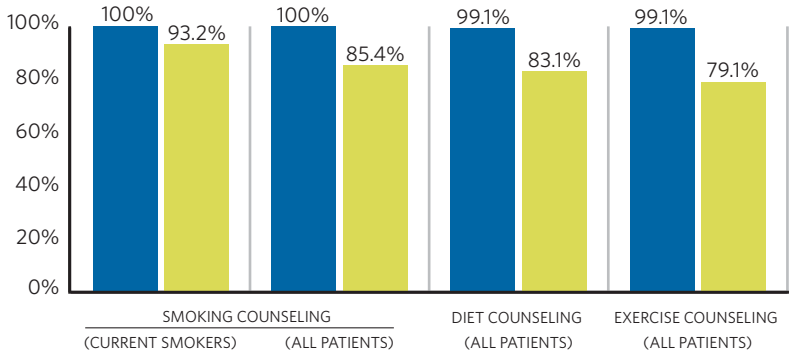
POST CREATININE DRAWN

HIGH RISK PATIENTS (EVAR)



2014 DISCHARGE

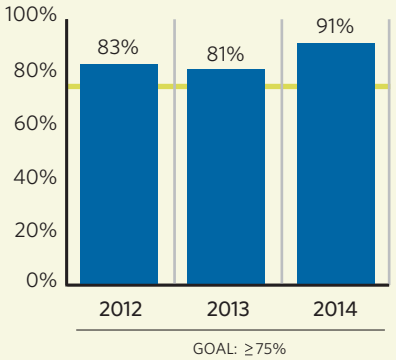
PATIENT EDUCATION/INSTRUCTION



McLaren Northern Michigan BCM2 Collaborative Data

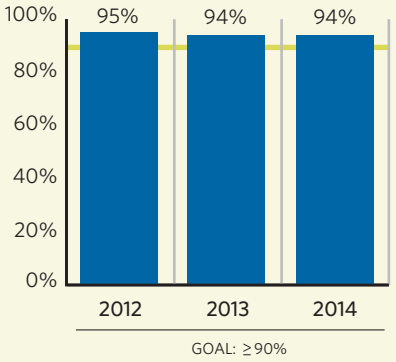
STATIN

AT DISCHARGE



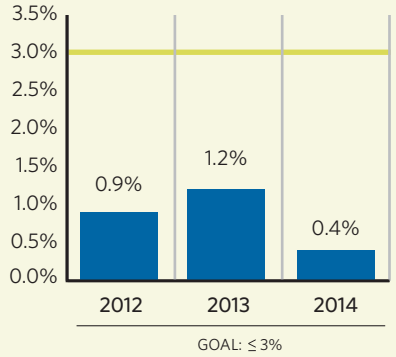
ASA

AT DISCHARGE



POST-OP

MI TO 30 DAYS



McLaren Northern Michigan

BCM2-VIC
Vascular Surgery Goals

Cardiologist Dalton Miranda, MD, consults with a patient about research trial opportunities.

Striving for Excellence, Embracing the Latest Technology

Dedicated research and clinical trials, both on and off the McLaren Northern Michigan campus, drive the quest for new knowledge and best practices. Two research divisions work closely with McLaren Northern Michigan heart and vascular specialists, embracing only the most trusted and proven advancements.

With only 5% of all trials nationwide resulting in FDA approval, the McLaren Northern Michigan cohort is particularly careful in its decision to pursue any research trial. That decision is based on true science and altruism: realistic criteria with real-world application, in which there is a medical necessity with benefits that always outweigh the risk.

DEDICATED HEART AND VASCULAR

RESEARCH TRIALS

56	CARDIOLOGY TRIALS WITH 1,386 PATIENTS ENROLLED
4	CARDIOTHORACIC TRIALS WITH 71 PATIENTS ENROLLED
4	VASCULAR TRIALS WITH 25 PATIENTS ENROLLED
10	NISUS HEART AND VASCULAR-RELATED TRIALS WITH 150 PATIENTS ENROLLED
74	TOTAL TRIALS WITH 1,632 PATIENTS ENROLLED

Renal Dysfunction in Cardiac Patients
Using a Statin Drug to Reduce Inflammation

TRIAL NAME:	Thrasos
LEAD INVESTIGATOR:	David Corteville, MD
START DATE:	12/2013
END DATE:	Continuing Enrollment
ENROLLED PATIENTS:	43
SPONSOR:	Thrasos
CONDITION:	Acute Kidney Injury

Renal Study:
A Closer Look

Acute kidney dysfunction is common after cardiac surgery, yet patients usually recover without suffering any long-term ill effects. Some, however, require the initiation of dialysis therapy that can contribute to long-term morbidity, or chronic kidney failure. Evidence also suggests that those patients requiring dialysis post-surgery have a higher risk of death while in the hospital.

Thrasos Lead Investigator and Cardiologist David Corteville, MD

Researchers are unsure of the exact causes of acute kidney dysfunction after cardiac surgery, but there is evidence that a preexisting condition such as diabetes mellitus or exposure to cardiopulmonary bypass can lead to complications. Coronary bypass involves the use of a heart-lung machine during surgery while the heart is stopped. This process in particular can overactivate the body's immune system and contribute to oxidative stress, an imbalance in the blood that in turn can lead to acute kidney dysfunction. "Cardiac surgery can be an insult to the kidneys because the procedure requires lengthy anesthesia during the cardiopulmonary bypass," says David Corteville, MD, Cardiologist and Thrasos Lead Investigator.

The Thrasos trial studied the effects of THR-184, developed to provide anti-inflammatory activity specifically for the kidney to prevent kidney failure. Researchers hoped that THR-184 would reduce the magnitude of patients who are at high risk for acute kidney dysfunction. "The goal of doctors is to reduce renal inflammation and preserve kidney function," adds Corteville.

Investigators measure kidney function before and after cardiac surgery and the markers for inflammation and oxidative stress in the blood. Patients in the trial are monitored for 90 days and receive four infusions in total.

CARDIOLOGY RESEARCH PROFILE

TRIAL NAME:	Absorb III
LEAD INVESTIGATOR:	Louis Cannon, MD
START DATE:	3/2012
END DATE:	Currently Enrolling
ENROLLED PATIENTS:	61
SPONSOR:	Abbott Vascular
CONDITION:	Coronary Disease

OBJECTIVE

To evaluate the U.S. pre-market safety and efficacy of the Absorb BVS System (bioabsorbable vascular scaffold) in comparison with Abbott's XIENCE, for patients with ischemic heart diseases, and specifically for patients with diabetes mellitus who are at greater risk for complications of heart disease.

DESCRIPTION

Absorb BVS is a drug-eluting stent which begins to dissolve after nine months. Absorption is complete after two years, eliminating the need to surgically bypass the stent if and when surgical intervention is required. "This will dramatically change the protocols for interventional cardiology," says Louis Cannon, MD, Interventional Cardiologist and Absorb III Lead Investigator. "Surgery for progressive heart conditions will have significantly decreased risks and far better outcomes."

ELECTROPHYSIOLOGY RESEARCH PROFILE

TRIAL NAME:	Optisure
LEAD INVESTIGATOR:	Naomi Overton, MD
START DATE:	2008
END DATE:	Currently Enrolling
ENROLLED PATIENTS:	8
SPONSOR:	St. Jude Medical
CONDITION:	Heart Failure

OBJECTIVE

To continuously monitor implanted right ventricular lead (RV lead) in conjunction with the CRT-D and ICD device system for a period of up to five years from implant date with the goal of eliminating complications associated with RV lead.

DESCRIPTION

Patients implanted with an ICD or CRT-D system for treatment of heart failure or life-threatening ventricular tachyarrhythmia(s) are monitored at two- and three-year follow-up appointments through an enhanced chest x-ray. The purpose of this post-approval study is to characterize the chronic performance of the SJM Optisure family of HV leads in patients insuring integrity of the lead before a possible lead fracture.

Pivotal Trial of a Novel Paclitaxel-Coated Percutaneous Angioplasty Balloon

TRIAL NAME:	Illumenate
LEAD INVESTIGATOR:	Jason Ricci, MD
START DATE:	10/2013
END DATE:	12/2019
ENROLLED PATIENTS:	9
SPONSOR:	Covidien LP
CONDITION:	Peripheral Arterial Disease

PAD Study: A Closer Look

Peripheral arterial disease (PAD) affects 10 million Americans. PAD can happen to anyone, regardless of age, but is most common in men and women over age 50. PAD affects 12 – 20 percent of Americans age 65 and older. This serious condition is the most common type of peripheral vascular disease, developing most commonly as a result of atherosclerosis.

Illumenate Lead Investigator and Interventional Cardiologist Jason Ricci, MD

Peripheral arterial disease has poor prognosis and manifests a variety of serious complications. The Illumenate study will test a Paclitaxel-coated PTA catheter for patients with blockages in one leg. While peripheral stents sited in the leg are prone to fracture, the Illumenate PTA catheter can function effectively despite normal leg movement. The balloon therapy has the same medication as a peripheral stent and, if successful, "could significantly change the treatment of PAD," explains Jason Ricci, MD, Interventional Cardiologist and Illumenate Lead Investigator.

The Illumenate study objective is to test a two-part hypothesis related to the use of the percutaneous transluminal angioplasty catheter for the treatment of superficial femoral arterial or peripheral arterial disease. The hypotheses are to 1) evaluate the safety and efficacy of a drug-coated balloon catheter in comparison to a non-coated catheter, and 2) determine that the drug-coated catheter is not only as safe as, but better than, the non-coated device.

NISUS VASCULAR RESEARCH PROFILE

TRIAL NAME:	N-TA^3CT
LEAD INVESTIGATOR:	Andris Kazmers, MD
START DATE:	3/2014
END DATE:	Not Yet Determined
ENROLLED PATIENTS:	12
SPONSOR:	University of Nebraska/NIH
CONDITION:	Abdominal Aortic Aneurysm

OBJECTIVE

To determine if doxycycline will inhibit the increase in greatest transverse diameter of small diameter AAA over a 24-month observation in comparison to a placebo-treated control group. The primary outcome is change in AAA maximum transverse diameter on CT scan from baseline to the follow-up assessment two years after randomization.

DESCRIPTION

The rate of aneurysm growth and the risk of rupture are both exponentially related to aneurysm size; therefore, aortic diameter is the single best predictor of rupture risk. Aortic aneurysms are typically asymptomatic and are often undetected until late when the weakened wall is prone to rupture. A number of studies have suggested that doxycycline, a tetracycline, can suppress aneurysm development.

Subjects enrolled in the study will be randomly assigned to receive either doxycycline 100 mg twice daily or placebo. They will be seen every three months for a minimum of two years with CT scan evaluation every six months.

Nisus Research: **Rich in History**

Research Study Coordinator Denise Antonishen, RN, BSN, CCRC, (right) consults with an intensive care unit patient about a research trial opportunity.

Nisus Research, a department of McLaren Northern Michigan, has been conducting Phase II, III, and IV clinical trials since 1984. To date, Nisus has conducted more than 300 clinical trials with more than 2,000 volunteer participants.

Nisus Research provides administrative and study coordinator support to nearly 200 multi-specialty physicians throughout the McLaren Northern Michigan network. These trials interface well with the inpatient and outpatient medical care provided by physicians.

In addition to heart and vascular trials, Nisus provides trials in many speciality areas, such as rheumatology, endocrinology, and internal medicine to name a few. Access to new therapies and diagnostics provides a unique complement to the high level of care offered to McLaren Northern Michigan patients.

Nisus Certified Clinical Research Coordinators (CCRC) are certified through the Association of Clinical Research Professionals.

A summer 2013 Transcatheter Aortic Valve Replacement (TAVR) patient, John Erickson shows off his baseball memorabilia collection at his Tawas home. TAVR is one of multiple procedures offered through the McLaren Northern Michigan structural heart program that regularly addresses complex heart conditions.

Program Highlights

Expanding the Limits of Heart Care:
Services Beyond the Norm

The face of regional heart and vascular care has changed, and McLaren Northern Michigan is driving the process. By embracing the newest and most innovative advancements in heart care, McLaren Northern Michigan improves outcomes — and lives.

Transcatheter aortic valve replacement (TAVR) is suitable for patients with severe symptomatic native aortic valve stenosis who are not candidates for open heart surgery.

TEAMWORK AND BEST PRACTICES MAKE THE DIFFERENCE

Eighty-six-year-old retired tugboat captain and Tawas resident John Erickson had been living with a pacemaker for eight years, but he says, "I was slowing down; age was against me." Erickson's wife Margaret was concerned as well. "He hadn't been feeling well, and his color didn't look good," she says.

Erickson was referred to Interventional Cardiologist Louis Cannon, MD. "John was a good TAVR candidate because he met all the criteria," Cannon says. "Appropriate candidates for TAVR are 75 years of age or older, have compromised health due to various issues, and have no other heart conditions," explains J.D. Talbott, DO, Cardiothoracic Surgeon for John's TAVR procedure. The procedure went smoothly, and Erickson was discharged two days early because he was doing so well. Home health care nurses cared for him and monitored his progress.

After the procedure, John was anxious to go outside and get back on the riding lawn mower. "Dr. Cannon says I can do whatever I did before the operation," Erickson says.

2014 TAVR DATA

McLaren Northern Michigan is Lower than National Averages in Significant Areas:

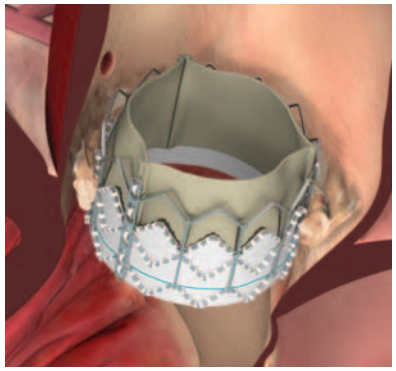
- LOWER than average **PROCEDURE TIMES**
- LOWER than average **ICU STAYS**
- LOWER than average **MORTALITY RATES**

2014 TAVR APPROACH

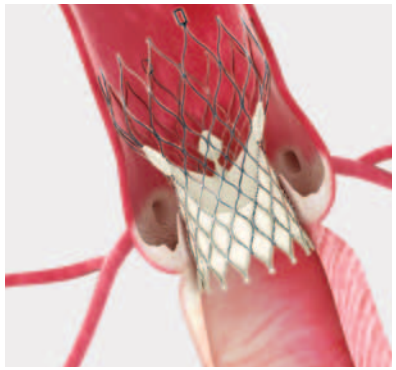
78.5%	TRANSFEMORAL APPROACH
17.8%	APICAL APPROACH
3.7%	AORTIC APPROACH

Transcatheter Aortic Valve Replacement

BEYOND THE LIMITS OF OPEN HEART SURGERY



Edwards SAPIEN XT Transcatheter Heart Valve



Medtronic CoreValve® System

Significantly, McLaren Northern Michigan was one of only a few Michigan hospitals approved to offer transcatheter aortic valve replacement (TAVR) and among the first 25% of all cardiac surgery programs nationwide to set the course for this life-changing procedure. The surgical standard is still the best approach, but for patients who are at high risk for open heart surgery, this advanced life-saving procedure is an incredible option. Physicians can choose between two different valve systems allowing treatment of more patients, based upon their specific needs. McLaren Northern Michigan concluded 2014 with 36 TAVR procedures, success rates above national averages, and increased patient options with femoral, apical, and alternative approaches.

DATA SOURCE: STS and ACCF TVT Registry

Interventional Cardiologist
Louis Cannon, MD

Structural Heart

TREATING COMPLEX HEART DISEASE

Because complex heart disease often means caring for the sickest of the sick, the Structural Heart program at McLaren Northern Michigan uses innovative diagnostic techniques and advanced treatment modalities. An expert team of cardiologists, cardiovascular surgeons, and specialists work collaboratively to develop and implement treatment plans, including minimally invasive procedures, like TAVR, for patients who are high risk or who are not candidates for open heart surgery. Advanced cardiac closure procedures treat atrial septal defect (ASD), ventricular septal defect (VSD), patent foramen ovale (PFO), percutaneous closure of perivalvular leaks, and patent ductus arteriosus (PDA) to name a few.

Mobile Diagnostics

OUTREACH TO PATIENTS IN THEIR OWN COMMUNITIES

The Mobile Diagnostic Unit is efficient, comfortable, and as technologically advanced as any heart and vascular department in a top-tier regional hospital. Beginning in 2013, thanks to generous donors through the McLaren Northern Michigan Foundation, patients of referring physicians received testing and scheduled follow-up cardiology appointments without traveling. Echocardiogram technician, nuclear medicine technologist, registered nurse, vascular ultrasound technologist, and exercise specialist provide diagnostics, imaging, and therapeutic services with 24-hour turnaround of test results from board-certified radiologists. In 2014 alone, the Mobile Diagnostics unit travelled 5,162 miles.

2014 MOBILE DIAGNOSTIC
DATA

NUCLEAR STRESS TESTS	230
NON-NUCLEAR STRESS TESTS	46
TOTAL MILES DRIVEN	5,162

Electrophysiologist
Naomi Overton, MD

Cryoablation

AN ALTERNATIVE TO HEAT ABLATION FOR ATRIAL FIBRILLATION

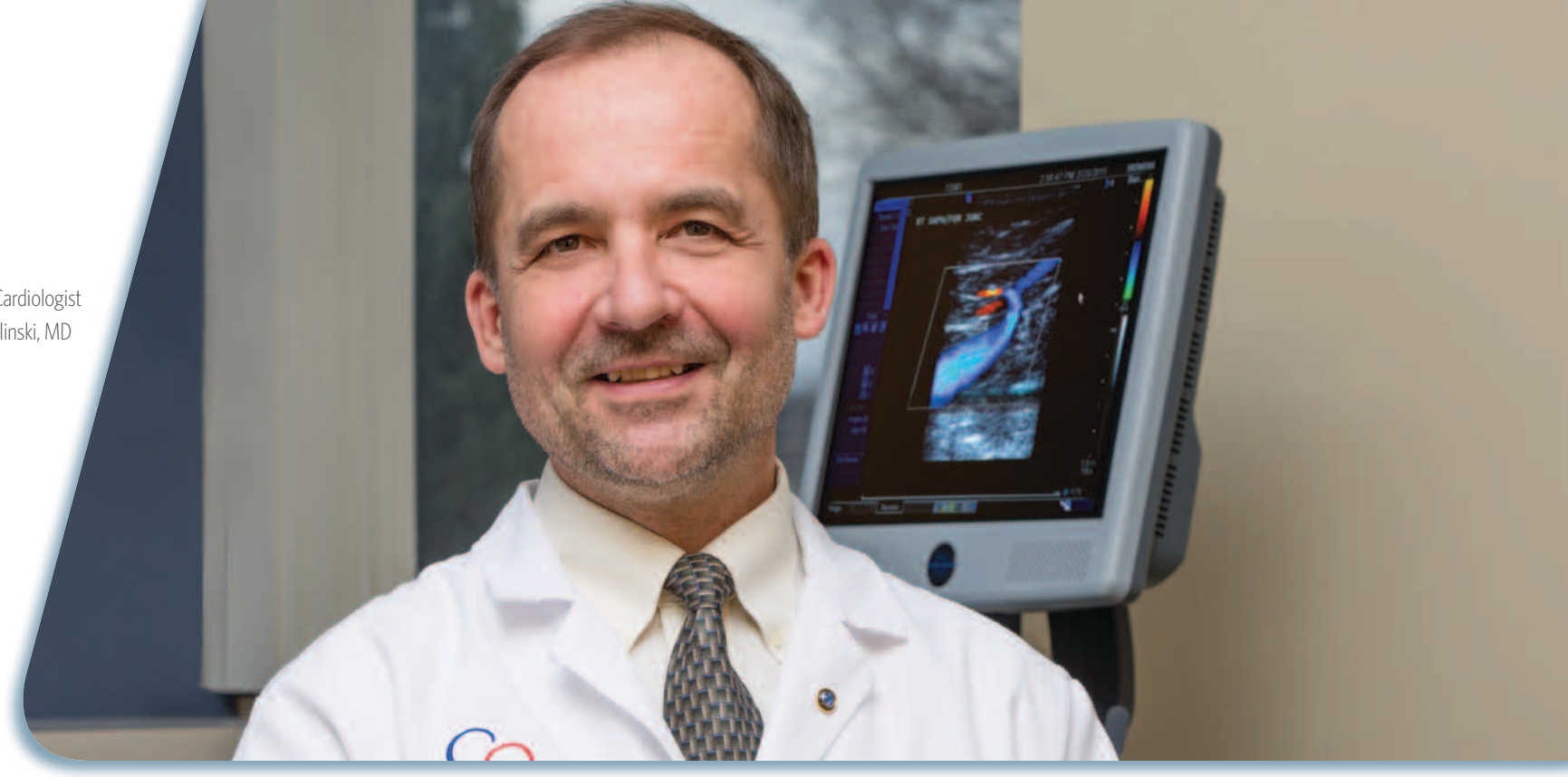
Previously, atrial fibrillation, a type of heart arrhythmia, was treated with radiofrequency (heat) ablation. The procedure, usually done through a traditional catheter, can damage healthy tissue, requiring use of a pacemaker. The alternative, cryoablation, introduced at McLaren Northern Michigan in February 2013, freezes the cardiac cell tissue that interferes with normal electrical conduction. If the physician is dissatisfied with the balloon position, the flexibility in repositioning and ablating the desired area is significant. A complete article and patient case study can be found on page 16.

Blood Autotransfusion

BEST PRACTICES MAKE THE DIFFERENCE

Quality initiatives include adopting new technologies and innovative best practices as they emerge. Statistics show that use of the patient's own recycled blood doubles patient survival rates, proven by consistent STS (Society of Thoracic Surgeons) statistics. Due to risks associated with donated blood, McLaren Northern Michigan has improved the current blood management strategy, a multidisciplinary approach to optimize the use of patient blood, thereby reducing the need for transfusions. Significantly in 2014, McLaren Northern Michigan introduced new techniques for conservation and filtration of the patient's own blood that is routinely hard to recover peri-operatively, at the surgical site. "Blood management significantly impacts our patient outcomes," explains Perfusionist Nausherwan Ansari, CCP, "It dramatically decreases length of hospital stay, improves patient quality of life, and proves cost effective for both the patient and hospital."

Cardiothoracic Surgeon Chris Akins, MD, (right) pictured with Perfusionist Nausherwan Ansari, CCP. In addition to his role as a perfusionist, Ansari has been instrumental in improving surgical blood quality and collecting McLaren Northern Michigan data reported to STS.



Cardiologist
Andrew Teklinski, MD

Radiofrequency Ablation Therapy

TREATING PATIENTS WITH CHRONIC VENOUS INSUFFICIENCY

McLaren Northern Michigan began offering Venefit™ Targeted Endovenous Therapy in 2014, formerly known as VNUS Closure™, for patients with chronic venous insufficiency. The minimally invasive Venefit procedure is a segmental ablation treatment that uses radiofrequency energy for the application of even and uniform heat to contract and seal the walls of a diseased vein. Clinical studies have shown the procedure to have excellent long-term outcomes. Patients report less pain and bruising, and a faster recovery. “The procedure has quickly proven its efficacy,” explains Cardiologist Andrew Teklinski, MD. “Our patients realize substantial improvement in just a matter of days.”

COPD patient Jack O'Malley participates in the Medical Fitness Program at the John and Marnie Demmer Wellness Pavilion and Dialysis Center in Petoskey three days each week. When asked if he's created friendships with other program participants, he laughs "My wife calls it my club."

Comprehensive Care:
Helping Patients Across the Continuum

Eighty-six-year-old Jack O'Malley has COPD, but don't expect him to spend his retirement lounging around. You're more likely to find him using a seated elliptical machine — a piece of gym equipment that allows users to exercise their arms and legs in a seated position. Five years ago, O'Malley joined the Pulmonary Rehabilitation Program at the John and Marnie Demmer Wellness Pavilion and Dialysis Center. He is currently part of a Medical Fitness maintenance program there. "If not for that, I wouldn't be able to do many things I enjoy, such as romping with our dogs," O'Malley says.

HEALTHY LIVING WITH COPD

O'Malley is a former professor of education and philosophy. His career took him to universities around the eastern U.S. After O'Malley retired, he and his wife decided to move to Burt Lake — their former vacation spot. A big factor in their decision: "We like the array of excellent doctors at McLaren Northern Michigan," O'Malley says. As examples, he cites his Pulmonologist Dwayne Griffin, DO, and his Internist Paul Blanchard, MD. "They are simply superb doctors," O'Malley says, "and, in addition, interesting people."

Today, O'Malley enjoys teaching poetry seminars. When the John and Marnie Demmer Wellness Pavilion hosted Pulmonary Rehab Day in March, O'Malley gave a lecture on the late physician-poet William Carlos Williams.

"Such events build a sense of community which keeps motivation high," says Exercise Specialist Terry Whitmore, HFS, who plays a lead role in the pulmonary rehabilitation team. "As patients get to know each other, they start holding each other accountable," Whitmore says. "If someone misses a day, he'll hear about it from other patients."

Pulmonary Rehabilitation at McLaren Northern Michigan is geared toward patients with conditions that can affect breathing including COPD, pulmonary fibrosis, and lung cancer. The program includes an initial assessment, followed by three weekly sessions for three months. Each session includes patient education, breathing techniques, and individualized exercise. Oxygen is available for those who need it.

"People often come here with a specific goal in mind, such as being able to work in the garden or play with their grandchildren," Whitmore says. "Once they achieve the goal, they realize there are lots of other things they can do, as well. They don't need to let breathing problems hold them back."

Jack O'Malley is definitely seeing the effects of this kind of care. "Terry [Whitmore] shares a lot of pragmatic advice with all of us patients," O'Malley says. "For example, he explained that, at a workbench, we'll be able to breathe better if we stand upright rather than bend over. He's always concerned about helping us live well in spite of the incapacity that is COPD."

Mapping the Region:
Targeted Outreach Makes Health Care Inclusive

A decision to provide the best health care works in tandem with the need to reach all who require it, bringing optimal care to the region's communities where and when it is needed.

Community Assessment:
A DEMOGRAPHIC APPROACH TO OVERALL REGIONAL HEALTH

Within the McLaren Northern Michigan 22-county region, both disparities and commonalities are indicative of the need for proactive outreach efforts. McLaren Northern Michigan stresses health and wellness education, appropriate interventions for targeted populations, and affordable medical and clinical access for all.

Specialty Clinics Work within the System:
PUTTING THE FOCUS ON PATIENT-SPECIFIC CONDITIONS OF THE HEART

The clinical model of care uses a full medical team and protocols dedicated to the treatment of a particular condition. Such a model streamlines the process from diagnosis to treatment followed by appropriate inpatient and outpatient therapies. Clinics target the condition and improve outcomes across the continuum of care, focusing solely on the delivery of advanced patient care.

- Arrhythmia Clinic
- Heart Failure Clinic
- Heart Valve Clinic
- Vein Clinic

Continuum of Care:

THE FOCUS ON DESIRED OUTCOMES FOR ALL PATIENTS

Tracking the patient from symptom outset to diagnosis, from treatment to wellness, strengthens the delivery of quality care and enhances the overall patient experience. Attention to all stages of patient involvement within the health system yields significant data which informs future decisions and policies.

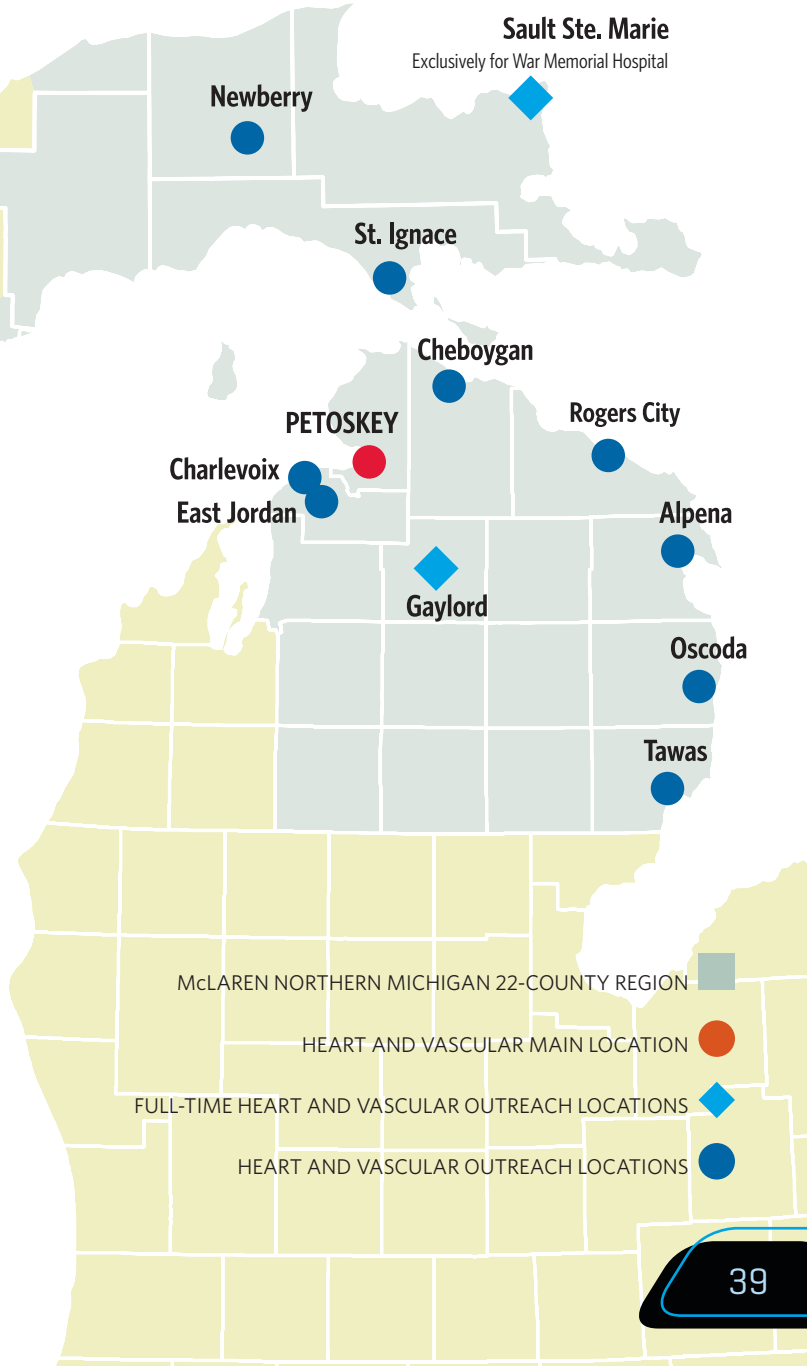
- Primary Care Relationships
- Specialty Heart and Vascular Care: Cardiology, Cardiothoracic Surgery, Electrophysiology, Vascular Medicine
- Acute Rehabilitation — Petoskey Campus
- Outpatient Rehabilitation and Medical Fitness — Petoskey and Cheboygan Campuses
- VitalCare Services — Home Care, Medical Equipment, Private Duty Nursing, Palliative Care, and Hospice Care
- Telemedicine

Community Events:

SPREADING THE WORD, INCREASING KNOWLEDGE

Educational events reflect the statistical measure of health and wellness for members of the communities. The numbers allow planners to target the specific needs and deficits of the region's inhabitants.

- Student Heart Screenings
- Physician Lectures across 22 Counties at Health Events and Community Organization Meetings
- Heart Month Community Education and Events
- Heart and Healing Arts Programs
- Health Fairs
- Support Groups
- Heart Healthy Cooking Classes
- FitKids360



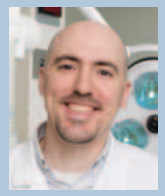
A Complement of Experts

McLaren Northern Michigan specialists are recruited from the nation's top schools and teaching facilities. Their skills support the vision and guide the progress.

Cardiologists, Electrophysiologists, and Cardiothoracic Surgeons

Chris Akins, MD

- CARDIOVASCULAR AND THORACIC SURGERY
- MINIMALLY INVASIVE TECHNIQUES
- CORONARY BYPASS SURGERY AND GRAFTING
- HEART VALVE SURGERY AND REPLACEMENT
- TAVR



David Corteville, MD

- ECHOCARDIOGRAPHY
- NUCLEAR IMAGING
- VALVE DISEASE
- CLINICAL RESEARCH
- TAVR

Linda Gossett, MD

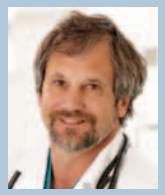
- CARDIOVASCULAR DISEASES
- ECHOCARDIOGRAPHY
- NUCLEAR IMAGING
- HEART FAILURE

Radwan Alkiek, MD

- CARDIOVASCULAR DISEASES
- ECHOCARDIOGRAPHY
- NUCLEAR IMAGING
- HEART RHYTHM MANAGEMENT

Waleed Doghmi, MD

- CARDIOVASCULAR DISEASES
- ECHOCARDIOGRAPHY
- CT ANGIOGRAPHY
- HEART RHYTHM MANAGEMENT

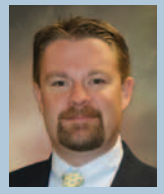


Peter Levanovich, MD

- EVALUATION AND TREATMENT OF RHYTHM DISORDERS
- DEVICE IMPLANTATION

Louis Cannon, MD

- CORONARY AND VASCULAR INTERVENTION
- CAROTID STENTING
- CLINICAL RESEARCH
- TAVR



Thomas Earl, MD

- CORONARY INTERVENTION
- NUCLEAR IMAGING
- CLINICAL RESEARCH
- TAVR

Dalton Miranda, MD

- CARDIOVASCULAR DISEASES
- NUCLEAR IMAGING
- ECHOCARDIOGRAPHY
- HEART FAILURE
- CLINICAL RESEARCH

Harry Colfer, MD

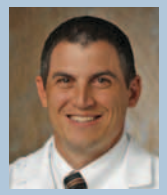
- CORONARY INTERVENTION
- LVAD/RVAD
- DEVICE IMPLANTATION
- CLINICAL RESEARCH

Gerald Gadowski, DO

- CARDIOVASCULAR DISEASES
- ECHOCARDIOGRAPHY
- NUCLEAR IMAGING
- CARDIAC CTA

Naomi Overton, MD

- EVALUATION AND TREATMENT OF RHYTHM DISORDERS, INCLUDING ABLATION
- DEVICE IMPLANTATION
- COMPLEX ABLATION
- VTACH ABLATION



Jason Ricci, MD

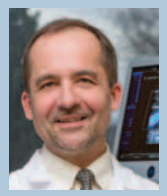
- CORONARY AND VASCULAR INTERVENTION
- ABDOMINAL AORTIC ANEURYSM REPAIR
- PFO CLOSURE
- CAROTID STENTING
- CLINICAL RESEARCH
- TAVR

Duane Schuil, MD, PhD

- CORONARY AND VASCULAR INTERVENTION
- CAROTID STENTING
- LVAD/RVAD

J.D. Talbott, DO

- CARDIOVASCULAR AND THORACIC SURGERY
- MINIMALLY INVASIVE TECHNIQUES
- CORONARY BYPASS SURGERY AND GRAFTING
- HEART VALVE SURGERY AND REPLACEMENT
- TAVR



Andrew Teklinski, MD

- CARDIOVASCULAR DISEASES
- VENOUS DISEASE MANAGEMENT
- NUCLEAR IMAGING
- ECHOCARDIOGRAPHY
- PREVENTION

Advanced Practice Providers

Ashly Ellis, NP-C

Jeffrey Fox, PA-C

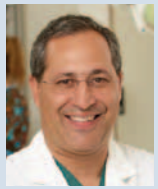
Ryan Houser, AG-ACNP

Marti Linn, PA-C

Rochelle Mitas, ACNP-BC

AJ Nolan, FNP-BC

Vascular Specialists



Michael Angileri, MD

- INTERVENTIONAL RADIOLOGY

Andris Kazmers, MD

- VASCULAR SURGERY

Jeffrey Beaudoin, MD

- VASCULAR SURGERY

Jason Ricci, MD

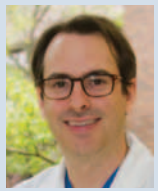
- CORONARY AND VASCULAR INTERVENTION
- ABDOMINAL AORTIC ANEURYSM REPAIR
- PFO CLOSURE
- CAROTID STENTING
- CLINICAL RESEARCH
- TAVR

Louis Cannon, MD

- CORONARY AND VASCULAR INTERVENTION
- CAROTID STENTING
- CLINICAL RESEARCH
- TAVR

Duane Schuil, MD, PhD

- CORONARY AND VASCULAR INTERVENTION
- CAROTID STENTING
- LVAD/RVAD



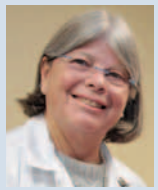
Mark Heilala, MD

- INTERVENTIONAL RADIOLOGY

Anton Sharapov, MD

- VASCULAR SURGERY

Pediatric Specialists



Cathy Webb, MD

- PEDIATRIC CARDIOLOGY

David Bradley, MD

- PEDIATRIC CARDIOVASCULAR

Mark Norris, MD

- PEDIATRIC CARDIOVASCULAR

Excellence Does Not Go Unnoticed

Specialties require an intellectual tenacity and skill set that are unique to some.

These qualities yield exemplary performance in the field and garner professional attention.

PUBLICATIONS

LOUIS CANNON, MD

Kereiakes DJ, Cannon LA, Dauber I, Ball M, Bertolet B, Foster M, Underwood P, Dawkins KD: PERSEUS 5 year Poster presented at JACC: 2014 March

Faculty participate in TCT (Trans Catheter Therapy) Conference October 2014

Paul S. Teirstein MD, FACC1, Ian T. Meredith MBBS, PHD, FACC2, Robert L. Feldman MD, FACC3, A. Charles Rabinowitz MD, FACC4, Louis A. Cannon MD, FACC5, Tommy C. Lee MD, FACC6, Joseph Dens MD, PHD, FACC7, Christophe L. Dubois MD, PHD8,9, Michael R. Mooney MD, FACC10, Vincent J. Pompili MD, FACC11, Shigeru Saito MD, FACC12, Dominic J. Allocco MD, FACC13, Keith D. Dawkins MD, FACC13 and Gregg W. Stone MD, FACC14. Two-year safety and effectiveness of the platinum chromium everolimus-eluting stent for the treatment of small vessels and longer lesions. Catheterization and Cardiovascular Interventions, first published online 2014 July 4

THOMAS EARL, MD

Young K, Earl T, Selzer F, Marroquin OC, Mulukutla SR, Cohen HA, Williams DO, Jacobs A, Kelsey SF, Abbott JD. Trends in Major Entry Site Complications from Percutaneous Coronary Intervention (From the Dynamic Registry). Am J Cardiol. 2014 February 15; 113(4):626-30.

AWARDS AND ACCREDITATIONS

SOCIETY OF THORACIC SURGEONS (STS) HIGHEST RATING FOR HEART BYPASS SURGERY

Consistently since 2012, McLaren Northern Michigan again earned the highest quality rating for heart bypass surgery as determined by the STS. Of the more than 700 U.S. hospitals that were part of the study, McLaren Northern Michigan performed significantly higher than the mean score, placing it among the top 15% nationwide. STS, in coordination with Duke Clinical Research Institute, analyzes data on heart programs nationwide. Their comprehensive rating system allows for comparisons regarding quality, complications, pre-and post-operative medication administration, and outcomes.

GET WITH THE GUIDELINES® — HEART FAILURE GOLD PLUS AND TARGET HEART FAILURE

Recognized by the American Heart Association and American Stroke Association for achieving 85% or higher adherence to all Get With The Guidelines Heart Failure Performance Achievement and Stroke Performance Achievement indicators for consecutive 12 month intervals and 75% or higher compliance in several target areas.

U.S. NEWS & WORLD REPORT BEST HOSPITALS AWARDS

The only hospital in Michigan to receive awards in four categories: two categories each for heart failure and stroke Get with the Guidelines initiatives.

AACN BEACON AWARD — SILVER LEVEL

Cardiovascular Unit Nurses received the American Association of Critical Care Nurses (AACN) Beacon Award for Excellence, recognizing medical units that demonstrate "exemplary levels of patient care, patient outcomes, and overall patient satisfaction." This accomplishment represents one of many significant milestones toward optimal outcomes and exceptional patient care.

JOINT COMMISSION *TOP PERFORMER ON KEY QUALITY* MEASURES®

The Joint Commission recognized McLaren Northern Michigan as a Top Performer on Key Quality Measures®, representing the top 36.9 percent of all Joint Commission-accredited hospitals that reported accountability measure performance data for 2013. McLaren Northern Michigan attained excellence recognition in Heart Attack, Heart Failure, Pneumonia, and Surgical Care.

CARDIOVASCULAR REHABILITATION PROGRAM CERTIFIED BY INDUSTRY LEADER

Three-year certification by the American Association of Cardiovascular and Pulmonary Rehabilitation, signifying our organization as a leader in the field of cardiovascular and pulmonary rehabilitation, offering the most advanced practices available.

McLaren

NORTHERN MICHIGAN

(800) 248-6777

northernhealth.org/heart