Cardiovascular Surgery Research Studies

The cardiovascular surgeons at the Main Line Health Heart Center at Lankenau Medical Center, Bryn Mawr Hospital and Paoli Hospital provide comprehensive services which include in part:

- Off-pump (beating heart) Coronary Artery Bypass Grafting (CABG) Surgery
- Collaborative treatment (hybrid procedures that combine surgery and stent intervention) for coronary artery disease, offering patients the least invasive method to treat their disease
- Three daVinci robots and the latest version of the daVinci® S High Definition Surgical System Robot at Lankenau, which offers cutting-edge technology for minimally invasive cardiac surgeries, including CABG and valves
- Mitral valve repair, our preferred method of treatment for mitral valve disease, although mitral valve replacements are also performed
- Aortic valve replacements for congenital defects, bicuspid leaflets, or adult acquired disease; aortic root replacements are also performed, if required.
- Concomitant procedures including CABG and valve, CABG with other complex procedures, or surgery on multiple valves during the same operation, including that on the tricuspid valve
- Ablation, surgical treatment for atrial fibrillation
- Repair of congenital or adult-acquired anomalies, such as Atrial Septal Defect and Ventricular Septal Defect.
- Transmyocardial revascularization (TMR), with or without CABG. TMR is used for areas of the heart that cannot be bypassed or revascularized surgically; a laser is used to create small channels through the heart to supplement myocardial oxygenation.
- Aortic root wrap for treatment of aortic root dilation
- Ventricular remodeling
- Ventricular assist device (VAD) therapy for heart failure
- Carotid endarterectomy for carotid artery disease
- Plus, a wide array of lung surgery procedures, both open and thorascopic

Each patient being evaluated by our surgeons may be a candidate for a clinical trial which may include some of the latest technology available and most advanced surgical techniques for heart valve repair and replacement, state of art off-pump bypass and robotic cardiac surgery.

Indication	Aortic Valvular Heart Disease
Study Title	ATS 3f® Aortic Bioprosthesis Model 1000, Post Approval study
Sponsor	ATS Medical / Medtronic, Inc.
Purpose	The purpose of this study is to determine if there is an increased incidence and rate of **aortic** regurgitation in younger (</= 60 years of age) patients implanted

	with the **Model 1000** and undergoing isolated **aortic** valve replacement of a diseased or dysfunctional aortic valve or aortic valve prosthesis.

Indication	Peripheral Vascular Disease
Study Title	The U.S. Stu**D**y for Eval**U**ating Endovascula**R** Tre**A**tments of Lesions in the Superficial Femoral Artery and Proximal Popliteal **B**y us**I**ng the Everf**L**ex Nit**I**nol S**T**ent S**Y**stem **P**ost **A**pproval **S**tudy – **DURABILITY PAS**
Sponsor	Covidien
Purpose	This post-approval study is designed to confirm the long-term safety and effectiveness of the EverFlex™ Self-Expanding Stent System for the treatment of atherosclerotic superficial femoral artery (SFA) and proximal popliteal arteries.
General Inclusion Criteria	1. Is at least 18 years old 2. Is willing to comply with all follow-up evaluations 3. Provides written informed consent prior to enrollment in the study 4. Has stenotic, restenotic (from previous procedure not including stents) or occluded lesion located in the native superficial femoral artery or superficial femoral and proximal popliteal arteries suitable for primary stenting

Indication	Aortic Valvular Heart Disease
Study Title	Clinical Investigation of the **Freedom SOLO** Stentless Heart Valve
Sponsor	Sorin Group
Purpose	This is a trial to demonstrate the safety and effectiveness of the **Freedom SOLO** heart valve when used to replace a diseased or dysfunctional aortic valve or aortic valve prosthesis.

Indication	Moderate mitral valve regurgitation with Coronary Artery Disease
Study Title	Comparing the Effectiveness of a Mitral Valve Repair Procedure in Combination With Coronary Artery Bypass Grafting (CABG) Versus CABG Alone in People With Moderate Ischemic Mitral Regurgitation
Sponsor	NHLBI – Cardiothoracic Surgical Network

Purpose	The purpose of this randomized study is to evaluate whether people with moderate mitral valve leakage would be better off undergoing CABG plus the mitral valve repair procedure or undergoing CABG alone, as measured by the degree of left ventricular remodeling, as assessed by left ventricular end systolic volume index (LVESVI) measured at Month 12.
Inclusion	Patients with moderate ischemic mitral regurgitation with a clinical indication for coronary artery bypass grafting.

Indication	Atrial Fibrillation with Mitral Valve Disease
Study Title	Surgical Ablation Versus No Surgical Ablation for Patients With Atrial Fibrillation Undergoing Mitral Valve Surgery
Sponsor	NHLBI – Cardiothoracic Surgical Network
Purpose	The purpose of this randomized study is to determine whether treating atrial fibrillation with surgical ablation during scheduled mitral valve surgery is better than mitral valve surgery by itself without the surgical ablation. There are no new procedures being tested in this study; both mitral valve surgery and surgical ablation are used regularly in patients who have mitral valve problems and atrial fibrillation. What is not known with certainty is whether patients with persistent atrial fibrillation within 6 months prior to randomization who are having planned mitral valve surgery would do better if they also had surgical ablation rather than medication alone to treat their atrial fibrillation, as measured by the freedom from atrial fibrillation at Month 12.
Inclusion	Patients with persistent or long-standing atrial fibrillation and mitral valve stenosis scheduled for valve surgery.

Indication	Acute kidney injury after cardiac surgery with cardiopulmonary bypass
Study Title	Safety & Efficacy of **BCT**197 in Patients Undergoing Cardiac Surgery
Sponsor	Novartis Pharmaceuticals
Purpose	This randomized, double-blind, placebo-controlled study will assess the safety and efficacy of a single dose of **BCT**197 on acute kidney injury in patients undergoing elective cardiac surgery with cardiopulmonary bypass.

Indication	Acute kidney injury after cardiac surgery with cardiopulmonary bypass
Study Title	A Study to Evaluate the Safety and Efficacy of AC607 for the Treatment of

	Kidney Injury in Cardiac Surgery Subjects (ACT-AKI)
Sponsor	AlloCure **Inc**
Purpose	Subjects who experience kidney injury within 48 hours of their surgery will be enrolled and will receive a single administration of AC607 or placebo. Kidney recovery will be evaluated over the subsequent 90 days of dosing. After 90 days, subjects will enter a 3-year extension phase of the study to monitor safety and long-term outcomes.

For additional information on these studies and other clinical trials, contact the Main Line Health Heart Center at 484-476-3030 or

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