Referring your patient

The UPMC Heart and Vascular Institute is a leader in conducting research studies and clinical trials to better understand and treat cardiovascular disease.

To refer a patient, please call 1-84-HVI-TRIAL (844-848-7245) or email HVIresearch@upmc.edu.

For more information about the UPMC Heart and Vascular Institute, please call 1-855-UPMC-HVI (876-2484) or visit UPMC.com/HVI.

**REPRISE III:** REpositionable Percutaneous Replacement of Stenotic Aortic Valve through Implantation of Lotus™ Valve System – Continued Access: Prospective, multicenter, non-randomized, controlled trial designed to evaluate the safety and effectiveness of the Lotus™ Valve System for TAVR in symptomatic subjects who have calcific, severe native aortic stenosis and who are at high or extreme risk for surgical aortic valve replacement (SAVR).

Inclusion criteria: Patients with documented calcific, severe native aortic stenosis with an initial AVA of ≤ 1.0 cm² (or AVA index of < 0.6 cm²/m²) and a mean pressure gradient > 40 mmHg or jet velocity > 4.0 m/s, as measured by echocardiography.

Principal Investigators: Thomas Gleason, MD; Joon Sup Lee, MD

**PORTICO:** Portico™ Re-sheathable Transcatheter Aortic Valve System U.S. IDE Trial: Prospective, multicenter, randomized, controlled clinical study, designed to evaluate the safety and effectiveness of the St. Jude Medical, Inc. Portico™ Transcatheter Heart Valve and Delivery Systems (Portico) via the transfemoral and alternative delivery methods, in high and extreme risk cohorts.

Inclusion criteria: Patients with senile degenerative aortic valve stenosis with echocardiographically derived criteria: mean gradient > 40 mmHg or jet velocity greater than 4.0 m/s or an initial aortic valve area (AVA) of < 0.8 cm² (indexed EOA < 0.5cm²/m²).

Principal Investigators: Thomas Gleason, MD; Joon Sup Lee, MD

continued
Use of the Zenith® Dissection Endovascular System in the Treatment of Patients with Acute, Complicated Type B Aortic Dissection: Clinical investigation designed as a prospective, non-randomized study enrolling patients to receive the Zenith® Dissection Endovascular System.

Inclusion criteria: Patients with an acute, complicated, Type B aortic dissection with at least one of the following characteristics: aortic rupture; or branch vessel obstruction/compromise resulting in malperfusion.

Principal Investigator: Thomas Gleason, MD

Safety & Efficacy of Intramyocardial Injection of Mesenchymal Precursor Cells on Myocardial Function in LVAD Recipients: Prospective, multicenter, double-blind, randomized, single dose cohort, sham procedure-controlled trial. Patients will be enrolled in a single dose cohort randomized in a 2:1 allocation to intramyocardial injection of study product or control at time of LVAD implantation.

Inclusion criteria: Patients with end-stage heart failure, either ischemic or non-ischemic etiology who are being evaluated for LVAD implantation as a bridge to transplant (BTT) or destination therapy (DT).

Principal Investigator: Robert Kormos, MD

Transcatheter Aortic Valve Replacement With the Medtronic Transcatheter Aortic Valve Replacement System In Patients at Low Risk for Surgical Aortic Valve Replacement: Multicenter, international, prospective, randomized, interventional, pre-market. Subjects will be randomized on a 1:1 basis to either transcatheter aortic valve replacement (TAVR) with the Medtronic TAVR system or to SAVR. The trial is to evaluate the safety and effectiveness of the Medtronic TAVR System in patients with severe aortic stenosis at low risk for SAVR.

Inclusion criteria: Symptomatic severe aortic stenosis: aortic valve area $\leq 1.0$ cm$^2$ (or aortic valve area index $\leq 0.6$ cm$^2$/m$^2$), OR a mean aortic valve gradient $\leq 40$ mmHg, OR a max aortic-velocity $\leq 4.0$ m/s, OR asymptomatic aortic stenosis: i) very severe aortic stenosis with an aortic valve area of $\leq 1.0$ cm$^2$ (or aortic valve area index of $\leq 0.6$ cm$^2$/m$^2$) AND maximal aortic velocity $\leq 5.0$ m/sec by echocardiography or cardiac catheterization, OR ii) aortic valve area of $\leq 1.0$ cm$^2$ (or aortic valve area index of $\leq 0.6$ cm$^2$/m$^2$) by the continuity equation, AND mean gradient $\leq 40$ mmHg, or maximal aortic valve velocity $\leq 4.0$ m/sec by echocardiography or cardiac catheterization, AND an exercise tolerance test that demonstrates a limited exercise capacity, abnormal BP response.

Principal Investigators: Thomas Gleason, MD; John Schindler, MD

Evaluation of the Thoraflex™ Hybrid Device for Use in the Repair or Replacement of the Ascending Aorta, Aortic Arch, and Descending Aorta in an Open Surgical Procedure: Prospective, multicenter, open-label, single arm, performance goal design with a primary patient group and an additional group for patients with rupture of the thoracic aorta. The trial is designed to assess the effectiveness and safety of the Thoraflex™ Hybrid Device in the treatment of aortic disease affecting the aortic arch and the descending aorta, with or without involvement of ascending aorta.

Inclusion criteria: Patients with acute aortic dissection who require repair or replacement of damaged or diseased vessels of the aortic arch (with or without involvement of the ascending aorta), and who require descending aorta replacement, or, in the opinion of the investigator, the patient would derive clinical benefit from prophylactic treatment of the descending aorta.

Principal Investigator: Thomas Gleason, MD

MOMENTUM 3 Multi-Center Study of MagLev Technology in Patients Undergoing MCS Therapy with HeartMate 3™: Single arm, prospective, multicenter study for continued evaluation of safety and clinical performance of the HeartMate 3™ Left Ventricular Assist System. The objective of the study is to continue to evaluate safety and clinical performance of the HeartMate 3™ Left Ventricular Assist System for the treatment of advanced, refractory, left ventricular heart failure following completion of enrollment in the the MOMENTUM 3 IDE Study.

Inclusion criteria: Advanced Heart Failure New York Heart Association (NYHA) Class III patients with dyspnea upon mild physical activity, or NYHA Class IV who are refractory to advanced heart failure management.

Principal Investigator: Robert Kormos, MD

TAVR UNLOAD (Transcatheter Aortic Valve Replacement to Unload the Left Ventricle in patients with ADVanced heart failure): International, multicenter, randomized, open-label clinical trial comparing the safety and efficacy of TAVR with the SAPIEN 3 transcatheter heart valve and optimal heart failure therapy versus optimal heart failure therapy in heart failure patients with moderate aortic stenosis. The objective of this study is to determine the safety and efficacy of TAVR via a transfemoral approach in heart failure patients with moderate aortic stenosis as compared with optimal heart failure therapy.

Inclusion criteria: The study population consists of subjects with moderate aortic stenosis and in heart failure with EF<50% and New York Heart Association (NYHA) class II to IV despite optimal heart failure therapy.

Principal Investigator: John Schindler, MD