Researchers with the Division of Vascular Surgery and Endovascular Therapy at Penn Medicine are conducting clinical trials to evaluate investigational stent grafts for the endovascular repair of abdominal, juxtarenal and pararenal aortic aneurysms.

Three of the studies currently enrolling at Penn are examining devices manufactured by Cook Medical (Bloomington, IN) under the Zenith brand name: the p-Branch stent graft, the Low Profile AAA Endovascular Graft, and the Branch Endovascular Graft-Iliac Bifurcation. Under the direction of principal investigator Ronald M. Fairman, MD, the studies are seeking to ascertain the safety and efficacy of these investigational devices.

The Division of Vascular Surgery and Endovascular Therapy has participated in virtually every stent graft clinical study in the United States since 1996. For information about enrolling in the Zenith studies and other endovascular clinical trials at Penn Medicine, please contact:

Heidi Martin, MS, Clinical Research Coordinator.
Phone: 215-662-4320
Email: Heidi.Martin@uphs.upenn.edu

Zenith® p-Branch OTS Multicenter Study
This study is investigating the safety and effectiveness of the Zenith p-Branch stent graft as an off-the-shelf option for the treatment of pararenal or juxtarenal abdominal aortic aneurysms. The p-Branch has a unique “off-the-shelf” design with pivoting renal portals that accommodate a comprehensive range of patients. Advantages include fenestrations incorporated in the design of the graft to maintain perfusion through the renal arteries and visceral vessels (celiac artery and superior mesenteric artery) and avoidance of open surgery. The study device(s) are inserted through a small incision near each hip and guided into place in the aorta.

Zenith® Low Profile AAA Endovascular Graft Clinical Study
This multi-center, prospective non-randomized clinical investigation is designed to evaluate the safety and effectiveness of the Zenith Low Profile AAA Endovascular Graft in conjunction with the Zenith Spiral-Z AAA Iliac Leg Graft. Study endpoints include freedom from major adverse events at 30 days and (for the treatment cohort) device success at 12 months. These findings will be compared to performance goals derived from the results of the Zenith AAA Endovascular Graft clinical study. The Zenith Spiral-Z AAA Iliac Leg Graft is indicated for use during a primary or secondary procedure in patients who have iliac/femoral access that is both adequate and compatible with the graft’s Z-Trak® introduction system.

PRESERVE-Zenith® Iliac Branch Clinical Study
The purpose of this study is to evaluate the safety and effectiveness of the Zenith Branch Endovascular Graft-Iliac Bifurcation in combination with the commercially available Atrium® iCAST™ covered stent in patients with an unsuitable distal sealing site for a Zenith iliac leg component proximal to the common iliac bifurcation.

(Continued on back page.)

* Atrium Medical Corporation Hudson, NH.
PRESERVE is an extended, multi-center, prospective, non-randomized trial. Patients with anatomy amenable to endovascular repair who meet study criteria will be enrolled. Because the Branch Endovascular Graft-Iliac Bifurcation is intended to maintain blood flow to the internal iliac artery and minimize the risk of associated clinical symptoms with the need for re-intervention, the primary assessment will be based on six-month freedom from patency-related intervention.

The Branch Iliac Endovascular Graft-Iliac Bifurcation was designed to reduce the risks of complications for patients with iliac aneurysms by preserving blood flow to the internal iliac. The Atrium iCAST balloon expandable covered stent offers a low foreshortened design and a one-step deployment technique that enhances placement accuracy.

Access

Patient appointments are available at:

Hospital of the University of Pennsylvania
3400 Spruce Street
4 Silverstein Pavilion
Philadelphia, PA 19104

Perelman Center for Advanced Medicine
Penn Heart and Vascular Center
East Pavilion, 2nd Floor
3400 Civic Center Boulevard
Philadelphia, PA 19104

Penn Presbyterian Medical Center
Department of Surgery
266 Wright Saunders Building
39th & Market Streets
Philadelphia, PA 19104

Penn Medicine University City
4th Floor
373 Market Street
Philadelphia, PA 19104

Penn Medicine Radnor
250 King of Prussia Road
Radnor, PA 19087

Penn Medicine Bucks County
Suite 140
777 Township Line Road
Yardley, PA 19067

Cape Regional Physician Associates
217 North Main St., Suite 104
Cape May Court House, NJ 08210

Faculty Team

The Division of Vascular Surgery and Endovascular Therapy at Penn Medicine is currently the regional leader for carotid, aortic, and peripheral arterial repair surgeries, and is among the handful of research centers nationwide involved in clinical trials to expand the indications for endovascular stent grafts. These new indications will include previously underserved patient populations and complex and complicated aneurysmal disease, including juxtarenal and pararenal aneurysms.

Performing Endovascular Clinical Trials at Penn Medicine
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Assistant Professor of Surgery

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Chief, Division of Vascular Surgery and Endovascular Therapy, Clyde F. Barker-William Maul Measey Professor of Surgery

Paul J. Foley, III, MD
Assistant Professor of Clinical Surgery

Michael A. Golden, MD*
Associate Professor of Surgery

Benjamin M. Jackson, MD
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Venkat R. Kalapatapu, MD†
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Paul L. O’Donnell, DO‡
Clinical Assistant Professor of Surgery

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Assistant Professor of Surgery

*Penn Presbyterian Medical Center
†Penn Medicine University City
‡Cape Regional Medical Center

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