



**For immediate release**

## **ClariVein® Catheter for Varicose Veins: Clinical Trial Final Results Announced**

**Madison, Conn. April 21, 2010** — Results from the initial clinical trial of the ClariVein® catheter, used in a new minimally invasive treatment for varicose veins, have been announced. The device combines mechanical and chemical modalities to accomplish vein treatment in an in-office setting.

Steve Elias MD FACS FACPh was the principal investigator of this IRB-regulated trial conducted at Englewood Hospital and Medical Center, NJ. “Results were excellent,” Dr. Elias stated. “The initial success rate is equal to that from radiofrequency or laser treatment of great saphenous vein disease.”

Thirty patients with an average age of 55 were part of this first-in-man trial. Most patients had symptomatic varicose veins, with some having more advanced vein disease such as swelling and skin changes. Mean vein diameter was 8.1 mm. Treatment for each vein averaged 5 minutes and overall procedure time was 14 minutes.

At six-month follow-up, 29 of the 30 veins treated were successfully closed. The only vein that did not respond was that of the first patient. Subsequent to the trial, to date 22 other patients have had the ClariVein® procedure, with all being successful.

“The main advantage of this new technique in comparison to older endovenous therapies,” Dr. Elias said, “is that it does not require tumescence anesthesia infusion, saving significant time and decreasing patient discomfort. In addition, a generator is not required, and therefore capital and maintenance cost is reduced. This in-office procedure takes about 15 minutes to perform and patients resume normal activity that day, including exercise. All patients would recommend the procedure to others.”

Steve Elias MD FACS FACPh, is Associate Professor of Surgery at Mount Sinai Hospital, NY and the Director of The Centers for Vein Disease at Mount Sinai and Englewood Hospitals.

The ClariVein® catheter is a product of Vascular Insights LLC (<http://vascularinsights.com>) of Madison, CT. The company engages in the design, development, manufacture, and marketing of medical devices for the minimally invasive treatment of peripheral vascular disease.

Vascular Insights has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market ClariVein® for infusion of physician-specified agents in the peripheral vasculature. The company holds certification from BSI (the British Standards Institution) that the design, development, manufacture, and distribution of the ClariVein® device comply with the requirements of ISO 13485: 2003.

Photos of the device can be downloaded from <<http://vascularinsights.com/devicepix4-complete.htm>>.

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