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**NON-SURGICAL LASER TREATMENT OF VARICOSE VEINS SHOWS
SUPERIOR RESULTS TO TRADITIONAL SURGERY: JOURNAL STUDY**

***Long-Term Success Rate, Low Complications, Rapid Recovery and No General
Anesthesia for Outpatient Interventional Radiology Treatment***

Fairfax, VA (August 12, 2003) -- A new study published in the latest (August) issue of the *Journal of Vascular and Interventional Radiology* (JVIR)¹ shows that the minimally-invasive laser treatment of varicose veins has a high long-term success rate, low complication rate, and rapid recovery. The study shows a 98 percent success rate and a long-term recurrence rate of less than seven percent for the laser, results that are far superior to traditional surgery. By comparison, surgical ligation or vein stripping fails more often, and requires general anesthesia and up to two weeks recovery. Pain, bruising and scarring are common with surgery. "Even when you remove the vein with surgery, there is a 10 to 25 percent chance of recurrence. We have a less than seven percent recurrence rate for a much less invasive procedure," says Min, an interventional radiologist who helped develop the EndoVenous Laser Treatment (EVLT), which uses heat from the laser to close the great saphenous vein, a common cause of varicose veins.

"The laser treatment is an outpatient procedure that offers many benefits over traditional surgery including little to no pain, no general anesthesia, no scars, less cost, and rapid recovery time," says lead investigator Dr. Robert J. Min, interventional radiologist and director of Weill Cornell Vascular in New York. The procedure is performed with local anesthetic, takes less than an hour, and people can return to normal daily activity immediately.

Although many people think of varicose veins as a cosmetic condition, they are a common medical condition that can cause aching leg pain, night cramps, fatigue, and leg heaviness or restlessness, due to pressure on the nerves from dilated veins. Left untreated, nearly 50 percent of patients with significant varicose veins will eventually experience worsening symptoms, characterized by leg swelling, eczema, pigmentation, hemorrhage and ulceration.

About the Study

The Cornell study included 499 limbs with varicose veins treated over a three-year period with 810-nm diode laser energy, with successful occlusion in 98 percent (n=490) of the great saphenous vein after initial treatment. Eight-seven percent had symptomatic aching leg pain. Patients were evaluated clinically and with duplex ultrasound at 1 week,

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1 month, 3 months, 6 months, 12 months and yearly thereafter to assess efficacy and adverse reactions. The study is still ongoing, but of the 121 limbs followed to at least two years, 93 percent (113 of the 121) of the treated veins have remained closed. All recurrences have occurred prior to 9 months, with the majority noted less than 3 months following endovenous laser treatment. This may indicate that they were not true recurrences, but rather inadequate initial treatments. No new recurrences have been found in any of the veins followed to two or three years that were not present at one-year follow-up. One month after treatment, relief of symptoms and significant improvement in the appearance of the varicose veins was noted. By six months after initial treatment, pain was greatly improved or resolved in all treated limbs.

There have been no skin burns, no abnormal nerve sensation and no deep vein clots. Some patients experienced bruising (24 percent) and most experience a transient sensation of tightness or pulling (90 percent) as the vein shrinks.

About the Laser Treatment

This minimally-invasive treatment is an outpatient procedure performed using duplex ultrasound imaging guidance. After applying local anesthetic to the vein, the interventional radiologist inserts a thin catheter, about the size of a strand of spaghetti, into the vein and guides it up the great saphenous vein in the thigh. Then laser energy is applied to the inside of the vein. This heats the vein and seals the vein closed. There may be minor soreness or bruising, which can be treated with over-the counter pain relievers. There is no scar, because the procedure does not require a surgical incision, just a nick in the skin, about the size of a pencil tip.

About Varicose Veins

Varicose veins are a common condition, affecting one in two people age 50 or older, and about 15 percent of men and 25 percent of women overall. Risk factors include age, family history, female gender and pregnancy. Symptoms caused by varicose veins include aching pain, easy leg fatigue, and leg heaviness, all of which worsen as the day progresses. Many people find they need to sit down in the afternoon and elevate their legs to relieve these symptoms.

Varicose veins are a symptom of venous insufficiency with pooling of blood in the veins. Normally, stop valves in the vein close to keep blood from flowing downward with gravity. When the valves in the vein become weak and don't close properly, they allow blood to flow backward, or reflux. Varicose veins are prominent veins that have lost their valve effectiveness and, as a result of dilation under pressure, become elongated, rope-like, bulged, and thickened.

A common cause of varicose veins is reflux within the great saphenous vein in the thigh, which leads to pooling in the visible varicose veins below. By closing the great

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saphenous vein, the varicose branch veins below shrink and improve in appearance. Once the diseased vein is closed, other healthy veins take over to carry blood from the leg, re-establishing normal flow.

The treatment costs about \$2,000 to \$3,000 per leg; surgery typically costs three times that amount. Many insurance companies cover the treatment of varicose veins because it is not just a cosmetic procedure. Varicose veins indicate venous insufficiency, which is a medical condition that causes symptoms for many people.

Treatment Availability

Weill Cornell Vascular is one of a rapidly growing number of centers offering this relatively new, FDA approved, minimally-invasive treatment of varicose veins. There are about two hundred sites in the United States and many more physicians are now being trained in the technique.

About the Society of Interventional Radiology

Interventional radiology is the medical specialty devoted to advancing patient care through the innovative integration of clinical and imaging-based diagnosis and minimally-invasive therapy. Interventional radiologists are physicians who specialize in minimally-invasive, targeted treatments performed using imaging guidance. Interventional radiology procedures are a major advance in medicine that do not require large incisions – only a nick in the skin about the size of a pencil tip – and offer less risk, less pain and shorter recovery times compared to surgery.

Interventional radiologists pioneered modern medicine with the invention of angioplasty, the first catheter-delivered stent and the coronary angiography technique most used worldwide -- state of the art treatments that are commonplace in medicine today. More information can be found at www.SIRweb.org.

Broadcast quality b-roll available, contact Emily Oehler at 703-460-5572.

1. Robert J. Min, MD, Neil Khilnani, MD, and Steven E. Zimmet, MD. Endovenous Laser Treatment of Saphenous Vein Reflux: Long –Term Results, JVIR 2003; 14: 991-996.

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