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## Vascular Insights Broadens ClariVein™ Horizons

Vascular Insights, the Yale spin-out, has broadened its horizons and will seek to market its ClariVein™ device for uses other than vascular ablation. The varicose vein market remains the primary target, however.

The company's infusion catheter, ClariVein-IC™, is a small caliber (<3 Fr) device that disperses therapeutic fluid via a specially designed dispersion element activated by a battery powered handle mechanism. At the discretion of the physician, it can be used to treat varicose veins (ablation of the greater and lesser saphenous veins) by delivering a sclerosing solution to the diseased vein while mechanically inducing spasm and irritating the endothelium to make the vein more vulnerable to attack by the sclerosing solution.

John Marano, CEO of Vascular Insights, says ClariVein-IC™ will be suitable for a variety of physician specified, physician directed procedures. As such, the company will seek to market it, for example, to Interventional Radiologists for procedures such as Deep Vein Thrombosis, which is responsible for up to 600,000 hospitalizations annually.

Compared with competing infusion catheters, Marano says, no additional guidewire is needed for placement and exchanges are eliminated. The system provides even, controlled irrigation, facilitating well-dispersed drug coverage of the target tissue and reducing the "washing away" of the therapeutic agent into the bloodstream. Yet the device is based on existing technology, which reduces development risk, Marano says.

Treatment of varicose veins with ClariVein-VA™ will remain the primary target for the company. Varicose veins affect between 75 and 150 million people in North America and Western Europe. Traditional therapy for varicose veins is surgery, but worldwide only an estimated one million people per year are willing to submit to the extensive surgical stripping and ligation, or laser burning, required, at a cost of between \$2,500 and \$5,000 per leg.

ClariVein-VA™ is a disposable, single use device. Unlike other recent alternatives to surgery such as radio-frequency or laser-based systems, it is safer and simpler to use and requires no anesthesia, Marano says. In addition, the ClariVein-VA™ device is not powered by an external generator, so a \$30,000 capital expense for the practitioner is avoided.

"The simplicity of the ClariVein-VA™ approach makes it an attractive option for the estimated 30 to 50 million varicose vein sufferers in the US who currently do not seek treatment," Marano says. To serve those patients, Marano would eventually market the ClariVein-VA™ device to a broad range of physicians beyond the specialists who currently treat varicose vein disease. The company would also expand its market beyond saphenous veins to branch and tortuous varicosities, a market not serviceable with laser or radio frequency interventional devices.

With the aid of Yale's Office of Cooperative Research, Vascular Insights was formed in 2005 to build a company around the product ideas of Michael Tal, associate Professor of Diagnostic Radiology and Director of Research in Interventional Radiology at Yale, who is now also chief medical advisor to the company. With seed funding in place from KLP Enterprises of Branford, the company is seeking strategic partners to share risk and accelerate product development.

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