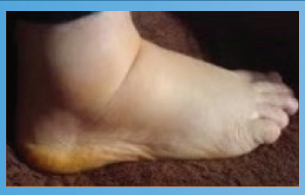
The INFINITE-US Clinical Study

A Study to Evaluate the Safety and Efficacy of the BlueLeaf® Endovenous Valve Formation System for the Restoration of Deep Venous Competence in Patients with Symptomatic Chronic Venous Insufficiency **(CVI).**

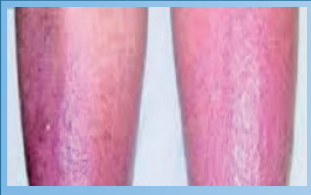
Do you have patients with symptomatic CVI?

Chronic venous insufficiency (CVI) with incompetence of the deep venous valves affects 20% of the adult population. Signs of CVI include edema, telangiectasia, reticular or varicose veins, and skin changes including ulceration. Symptoms caused by CVI include chronic pain, edema, skin hyperpigmentation, dermatoliposclerosis, and ultimately ulceration in some patients.

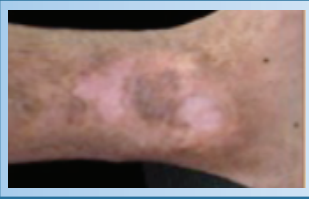
C3: Edema



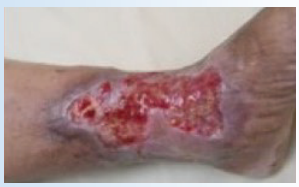
C4: Skin Changes



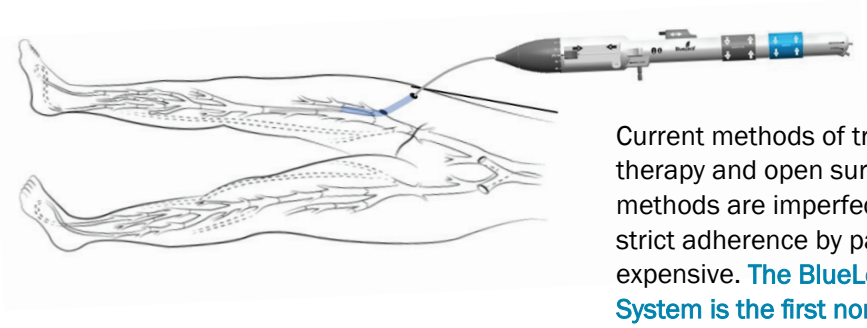
C5: Healed Ulcer



C6: Active Ulcer



The most frequent causes of CVI are from primary abnormalities of the venous wall and vein valves, or secondary changes resulting from previous venous thrombosis. For many patients suffering from primary or secondary CVI, these painful symptoms are caused by failed venous valves in the legs, and subsequent static columns of blood in the lower extremities that cannot move back to the heart.



Current methods of treating CVI include compression therapy and open surgical repair, but both of these methods are imperfect. Compression therapy requires strict adherence by patients, and surgery is difficult and expensive. **The BlueLeaf® Endovenous Valve Formation System is the first non-surgical reconstructive potential treatment for CVI, and uses conventional, less invasive interventional techniques for vein access.** The device is intended to form new tissue leaflets within the vein walls without the use of a permanent vascular implant. The BlueLeaf procedure typically requires a single overnight stay in the hospital.

BlueLeaf

Key Study Criteria

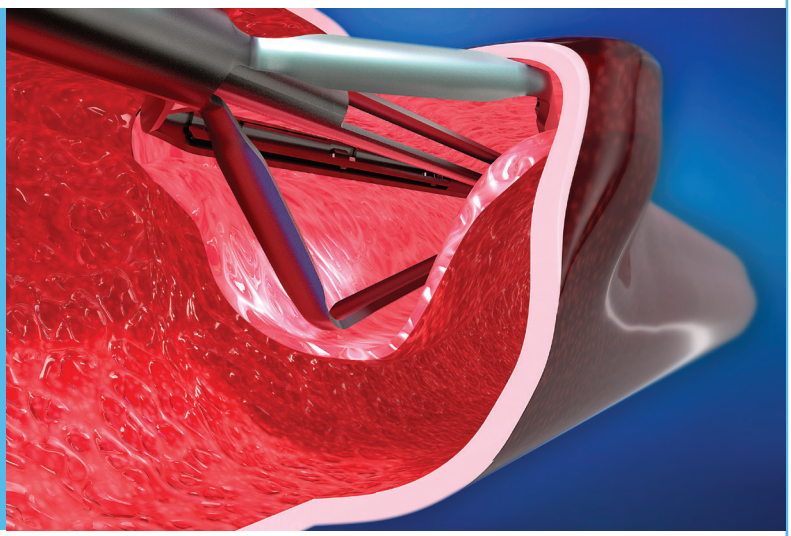
- Eligible patients must have at least skin or color changes to a lower extremity, or an active or healed ulcer at their lower extremity (CEAP score C5-6). Varicose veins alone are not enough to constitute CVI.
- Patients should have a history of attempted standard compression therapy.
- A history of Deep Vein Thrombosis (DVT) is allowed, but not required.
- At least 18 years of age and ambulatory.

Principal Investigator

The INFINITE-US study is being led by Dr. Paul Gagne of the The Vascular Experts. Dr. Gagne had been a member of New York University's Vascular Associates and New York University's Hospital Center, where he served as Director of the Vascular Research Laboratory. Prior to that, Dr. Gagne served in the U.S. Navy as both a general and vascular surgeon. Dr. Gagne specializes in vascular and endovascular techniques for the treatment of arterial and venous disease and is involved in a number of clinical trials. He is an internationally recognized thought leader in the treatment of deep vein disease.

Paul J. Gagne, MD, FACS, RVT

If you have patients with symptomatic CVI who may be interested in the study
please forward their information
or ask them to contact:
Maria Myslinski, Research Coordinator
at The Vascular Experts
Call **203-956-6834** or email
mmyslinski@thevascularexperts.com



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InterVene, Inc.
415 Grand Avenue, Suite 302
South San Francisco, CA 94080
www.intervene-med.com