

# INTERVENE



## Innovation

**The Problem** - Undoubtedly, we all know someone with chronic venous disease — 42% of adults suffer from varicose veins or worse. Millions of these patients suffer from a particular form of advanced venous disease called deep vein axial reflux. These patients experience significant pain, are often unable to work, and many of them live with the embarrassment and life impairment of an unhealing leg ulcer. These patients are left with compression therapy and wound care due to a lack of interventional options available.

**The Solution** - InterVene's ReLeaf Catheter System™ will empower physicians to finally provide these patients with a long-term cure by treating the underlying problem: failed vein valves. The approach is based on an existing open surgical procedure pioneered by an Italian Vascular Surgeon (The Maletti Neovalve). The ReLeaf Catheter **durably creates new vein valves out of a patient's own vein wall**. These autologous valves have been shown to be clinically effective at healing long standing ulcers in open surgery, but unfortunately this procedure has proved to be too invasive and technically difficult to encourage widespread adoption.

### Key Points:

- The minimally-invasive approach enables access to untapped EU and U.S. markets comprising 12 million, desperate, untreatable patients.
- Healthcare economics studies based on currently available high-cost, long-term, palliative treatment regimes and existing reimbursement codes support a **multi-billion dollar market** across the U.S. and Europe.
- A functional device is in hand.
- Successful cadaveric and animal studies have been conducted.
- Confirmed clinical study site in Oslo, Norway — a national referral center for complex venous cases.
- 7 U.S. and international patents are filed, 1 patent is granted.



**For more information, please contact:**

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**Innovation** is the lifeblood of medical advancement and the key to raising the bar for patient care. Yet the traditional process for medical innovation is fraught with obstacles that hinder the development of new ideas. That's why Dr. Thomas Fogarty, a preeminent physician innovator, founded this educational, nonprofit organization. Here, we build upon Dr. Fogarty's invaluable experience to provide a streamlined alternative path for entrepreneurial innovators working on promising new therapies. We hand select several candidates for inclusion in our Innovation Cultivation program, and provide access to expert intellectual, physical, and financial resources designed to propel medical concepts from initiation to application. The program offers direct mentorship every step of the way. InterVene is one of the showcase participants in the program.



**Fogarty Institute  
for Innovation**

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