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**FOR IMMEDIATE RELEASE**

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## **THE CARDIAC & VASCULAR INSTITUTE FIRST IN FLORIDA TO ENROLL PATIENTS IN NEW CLINICAL TRIAL STUDYING LIMFLOW THERAPY**

*Clinical Study of New Treatment Designed to Prevent Amputation and Promote Wound Healing in Patients with No Other Options*

**Gainesville, FL – February 19, 2020** – The Cardiac & Vascular Institute (TCAVI) announced it is the first in Florida to perform a successful procedure in the PROMISE II pivotal study of the LimFlow Percutaneous Deep Vein Arterialization System for the treatment of “no option” Chronic Limb-Threatening Ischemia, a severe form of peripheral artery disease that affects the lower leg. The LimFlow System has been designated as part of the FDA’s Breakthrough Devices program, as it treats a patient population with no commercially available options to avoid amputation of their lower leg or foot. The first case was performed by The Cardiac & Vascular Institute’s Interventional Cardiologist and Principle Investigator Arthur Lee, M.D., FACC at North Florida Regional Medical Center on January 23, 2020.

Patients suffering from severe pain in their legs and non-healing wounds in their feet who are facing amputation may have a new option to avoid the loss of a leg or foot. TCAVI recently began the multi-center, international PROMISE II clinical trial studying an investigational, minimally-invasive therapy for patients who have exhausted all other options to open the blood vessels in their legs and are facing the prospect of amputation. The LimFlow therapy is being studied to determine if it can reroute blood in the legs to bring blood and oxygen back to the leg and foot and potentially resolve pain, promote wound healing and prevent amputation.

A clinical study of LimFlow therapy in the first 32 patients treated in the U.S. found that blood flow was restored in 97 percent of patients, with 74 percent of patients amputation-free at six months, and 100 percent of patients with healed or healing wounds at nine months.

“This is an extremely important study having the potential to be practice changing and life changing for the CLTI patient who is out of options and facing a major amputation. This gives us an option to avoid a major amputation and all of its potentially disastrous downstream sequelae,” says Arthur Lee, M.D.

The symptoms of severe rest pain and non-healing wounds in the feet are caused by a condition called Chronic Limb-Threatening Ischemia, or CLTI. CLTI is the most severe form of peripheral artery disease and often occurs in patients suffering from coronary artery disease, diabetes, chronic kidney disease, obesity, high cholesterol and high blood pressure. In the U.S. and



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Europe, 3.8 million people suffer from the condition, and that number is expected to grow by 43 percent in the next decade.

To relieve the symptoms of CLTI, currently available options are primarily angioplasty or invasive bypass surgery. In many late-stage patients, however, neither option is possible due to extensive disease in the arteries or other physical reasons. At this stage, the only alternative is amputation of the foot or lower leg. Losing a limb dramatically reduces a patient's quality of life and is associated with an increased risk of death, yet more than 50 percent of patients go straight to amputation without any prior intervention or treatment. In fact, every two minutes in the U.S. and Europe, a leg is lost due to lack of blood flow.

If you or a family member are experiencing severe pain in your leg when at rest, have non-healing wounds or ulcers on your foot, have been told there is no option other than amputation, or have been diagnosed with Chronic Limb-Threatening Ischemia, you may be a candidate for the PROMISE II Trial. Please contact The Cardiac & Vascular Institute Research Foundation at (352) 244-0208 for more information. To learn more about the investigational LimFlow therapy being studied, please visit [www.limflow.com](http://www.limflow.com).

### **About The Cardiac & Vascular Institute**

The Cardiac & Vascular Institute (TCAVI) provides specialized cardiology and vascular care to North Central Florida with offices in both Gainesville and Lake City, Florida. TCAVI is committed to providing the highest quality health services to our patients with physicians board certified in every aspect of cardiovascular care. With 18 cardiologists, two electrophysiologists, and two vascular surgeons, TCAVI specializes in areas including atrial fibrillation, hypertension management, heart failure management, minimally invasive valve repair or replacement, peripheral vascular disease, and critical limb ischemia. For more information on The Cardiac & Vascular Institute or to schedule an appointment with one of our board certified physicians, please contact (352)375-1212 or visit [www.TCAVI.com](http://www.TCAVI.com).

### **About the Investigational LimFlow Therapy**

The minimally-invasive LimFlow therapy is designed to divert blood around diseased arteries in the leg and into one of the tibial veins that feed the foot, delivering blood and oxygen to starved tissue in the foot. An abundance of oxygen in the foot is known to relieve pain and promote healing of chronic wounds, which may avoid amputation and improve quality of life.

Unlike existing endovascular therapies that seek to partially unblock the diseased artery to restore blood flow, but often block up again over time, the investigational, minimally invasive LimFlow therapy bypasses the blocked artery. It creates a clear channel from the open artery above the blockage to an open vein that can then return blood flow back to the lower leg and foot. The therapy involves catheters, a balloon, stents and a valvulotome, a unique device that



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disables valves in the vein so that blood can flow down to the foot rather than upwards, which typically happens with veins.

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