

From No Hope to New Hope



**"For No-Option patients, there is now another option."**

*Dr. Michael Lichtenberg, Klinikum Arnsberg, Germany*

**LimFlow**  
Transforming CLI



# Our Unique Solution

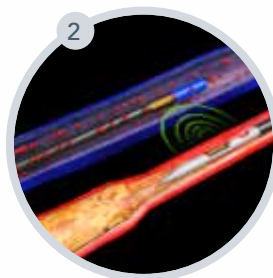
The LimFlow system leverages a scientifically proven method by arterialization of veins in a safe, reproducible and less invasive procedure.

The proprietary LimFlow solution aims to enhance inflow and outflow dynamics by diverting a stream of highly oxygenated blood flow around diseased arteries, through tibial veins and into the ischemic foot. The system consists of a unique family of fully percutaneous products designed to enable crural reconstruction of the pedal arch, optimise perfusion of the critically ischemic foot, facilitate wound healing and ultimately avoid major amputation.



### STEP 1

The venous ultrasound catheter is advanced into the tibial vein at the ankle, while the arterial ultrasound catheter is navigated simultaneously into the tibial artery from the groin.



### STEP 2

After arriving at the occlusion level, the arterial ultrasound catheter is rotated until the peak ultrasound signal identifies the optimal crossing point between the artery and the vein.



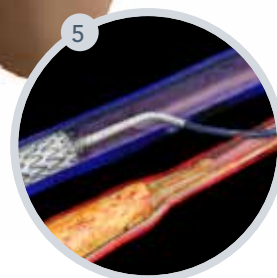
### STEP 3

The embedded needle of the arterial ultrasound catheter is then inserted into the tibial vein. A micro guidewire is exchanged through the crossing needle and a low-profile angioplasty balloon is inflated to allow passage of other devices.



### STEP 4

The 4F Valvulotome is introduced to cut through valves at the bottom of the foot, rendering them incompetent and thus facilitating forward flow.

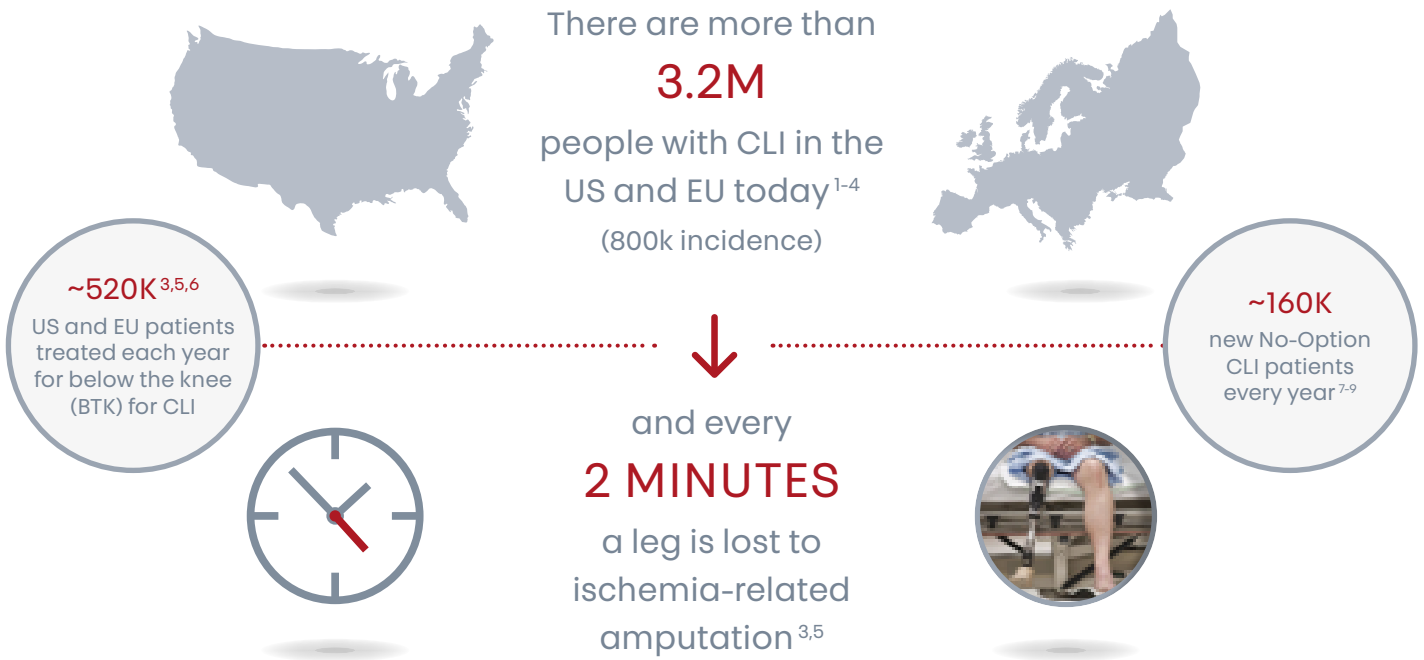


### STEP 5

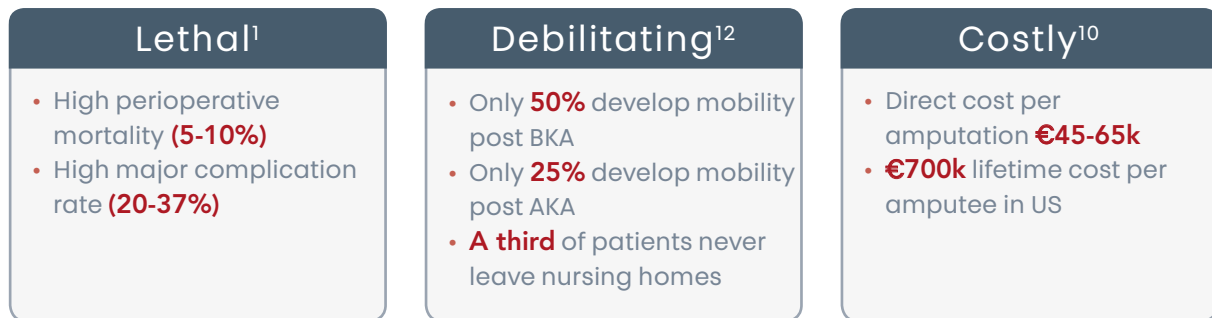
Deployment of nitinol-covered crossing and extension stents finalises the creation of the arterio-venous channel, which rushes blood into the foot.

# From No Hope to New Hope

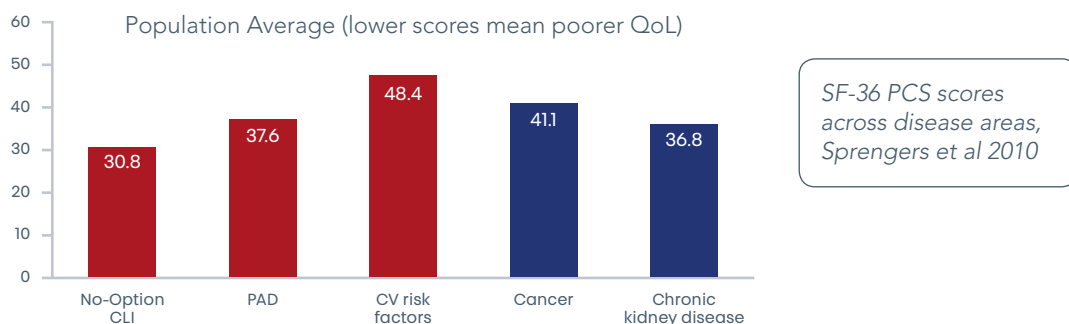
In its late stage Peripheral Artery Disease (PAD) evolves into Critical Limb Ischemia (CLI) and patients' options become limited. Some of these patients can be no longer candidates for angioplasty or bypass surgery and face Limb Amputation as their only therapeutic option.



## The Problem With Amputations



## No-Option\* Patients' Impaired Quality Of Life<sup>11</sup>



\* "No-Option" patients are those in late-stage CLI where revascularization options are no longer feasible. BKA: Below Knee Amputation. AKA: Above Knee Amputation.

# The System Components



## LimFlow Arterial and Venous Catheter Set and LimFlow Ultrasound System

- The arterial catheter has an imbedded ultrasound plate that aligns with the venous catheter indicating optimal crossing for the beveled crossing needle
- The venous catheter has a 360° ultrasound guidance for an optimal, safe, and reproducible crossing into the targeted vein
- The user-friendly monitor system aids determining an optimal crossing point, enabling a safe and uniform deployment of the arterio-venous crossing stent



## LimFlow Valvulotome

- The unique and purpose made Push Valvulotome is designed to cut foot valves in an easy forward motion, rendering them incompetent and maximising forward blood flow for a full and immediate pedal arch arterialization
- A nitinol cutting basket with forward facing hooks preserves the venous walls of the foot and avoids vessel trauma by obviating the need for high pressure balloons to improve outflow



## LimFlow Stent Graft System - Extension Stents

- Novel electrospun PTFE covered nitinol stents maximise outflow to the foot by maintaining full flow through the calf while blocking venous collaterals above the ankle



## LimFlow Stent Graft System - Crossing Stent

- The innovative reverse conical stent-design, with an electrospun PTFE cover, allows for a safe and atraumatic apposition on the artery and a maximum outflow on the more robust vein
- The proprietary crossing stent system offers precise and easy deployment with a distinct nitinol stent design and enhanced pin-and-pull stent delivery system

# Clinical Results

## Pilot and FIM Study\*

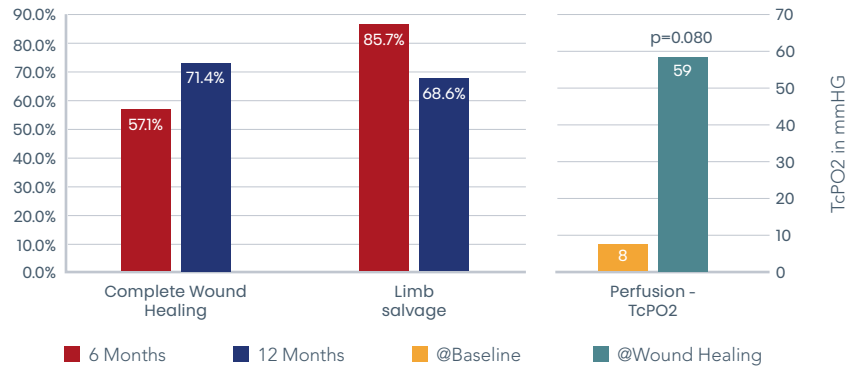
7 PATIENTS, No-Option CLI

- Single center, prospective and open label study
- Enrollment 9/13 to 11/14
- 3 patients R5, 4 patients R6
- 6 "High Risk" Wifl patients

### Primary Safety Endpoints

- No 30 day Death, No 30 day MALE
- 2 non-ST elevated MI (procedure unrelated)

### Secondary Endpoints\*



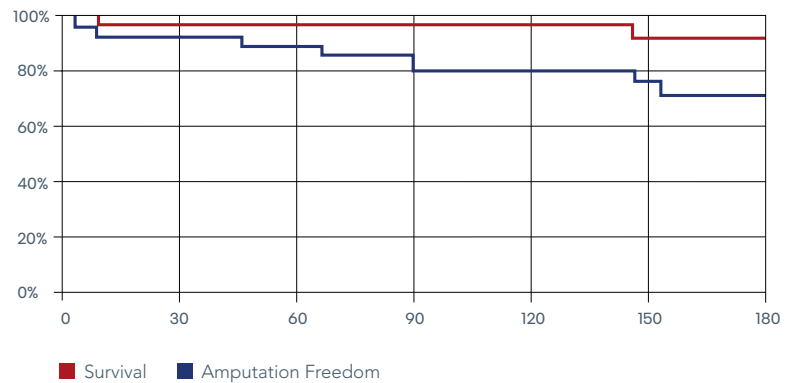
\* Data Source: Journal of Endovascular Therapy website – July 2017

## Pre and Post CE Mark

34 PATIENTS, No-Option CLI  
TREATED 3/15 TO 3/17

- 17 patients treated to gain CE Mark
- 17 patients compassionate/commercial use

### Survival and amputation free Kaplan-Meier



## Currently planned LimFlow Studies Involving 150+ Patients

Study Name	Patients	Study Design	Timeline
Early Feasibility Study	10 Patients	US Feasibility and Safety Study • 3 centres	2017
OUS Post Market Study	50 Patients	Safety and Efficacy • Multicentric, prospective and single arm study • 10 centres	2017
Pivotal and PMA	Being Defined With FDA	Multi-center Safety and Efficacy Study	2018

## The Benefits Of The LimFlow System

Reproducible therapy ✓	Strong safety profile ✓	Fully Percutaneous Procedure ✓	Evident impact on wound healing and amputation risk ✓
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\* R5 Rutherford 5 – R6 Rutherford 6. Major Adverse Limb Event (MALE) defined as major amputation or major surgical reintervention on index limb. Wifl Wound Ischemia foot Infection.

# Ordering information

## LimFlow Stent Graft System

Reference	Description	Stent Length (mm)	Stent Diameter (mm)		Recommended Vessel Diameter (mm)		Compatibility	
			Proximal	Distal	Proximal	Distal	Introducer	Guidewire
SI-01835-001	Conical Crossing Stent	60	3.5	5.5	2.5 - 3.0	4.5 - 5.0	7F (2.34mm)	0.018" (0.457mm)
SI-01835-002	Conical Crossing Stent	60	4.0	5.5	3.0 - 3.5	4.5 - 5.0	7F (2.34mm)	0.018" (0.457mm)
SI-01835-003	60mm Extension Stent	60	5.5		4.5 - 5.0		7F (2.34mm)	0.018" (0.457mm)
SI-01835-004	100mm Extension Stent	100	5.5		4.5 - 5.0		7F (2.34mm)	0.018" (0.457mm)
SI-01835-005	150mm Extension Stent	150	5.5		4.5 - 5.0		7F (2.34mm)	0.018" (0.457mm)

## LimFlow Arterio-Venous Ultrasound Catheter Set and LimFlow Valvulotome

Reference	Description	Usable Length (cm)	Compatibility	
			Introducer	Guidewire
FG-01835-004	7F Arterial Ultrasound Catheter with a Needle	100	7F (2.34mm)	0.014" (0.356mm)
	5F Venous Ultrasound Catheter	100	5F (1.67mm)	0.014" (0.356mm)
FG-01840-001	Self-expanding 4F LimFlow Valvulotome	120	4F (1.35mm)	0.018" (0.457mm)

## LimFlow Ultrasound System

Reference	Description	System Components
MG-01835-001	LimFlow Ultrasound System	Laptop, Power Cable and Transceiver interface box

### References

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www.LimFlow.com T +33 638 747 190

LimFlow SA 95bis Boulevard Pereire, 75017 Paris, France  
LimFlow, Inc 2934 Scott Boulevard, Santa Clara, CA 95054, USA

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