“For No-Option patients, there is now another option.”

Dr. Michael Lichtenberg, Klinikum Arnsberg, Germany
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.

Please refer to products’ IFUs for full procedure recommendation Guidelines.
In its late stage Peripheral Artery Disease (PAD) evolves into Critical Limb Ischemia (CLI) and patients’ options become limited. Some of these patients can no longer candidates for angioplasty or bypass surgery and face Limb Amputation as their only therapeutic option.

There are more than 3.2M people with CLI in the US and EU today (800k incidence) and every 2 MINUTES a leg is lost to ischemia-related amputation.

~520K US and EU patients treated each year for below the knee (BTK) for CLI

~160K new No-Option CLI patients every year

The Problem With Amputations

- **Lethal**
  - High perioperative mortality (5-10%)
  - High major complication rate (20-37%)

- **Debilitating**
  - Only 50% develop mobility post BKA
  - Only 25% develop mobility post AKA
  - A third of patients never leave nursing homes

- **Costly**
  - Direct cost per amputation €45-65k
  - €700k lifetime cost per amputee in US

No-Option Patients’ Impaired Quality Of Life

*“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 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

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 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
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” WIfI patients

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

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

Currently planned LimFlow Studies Involving 150+ Patients

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
Multi-center Safety and Efficacy Study
Being Defined With FDA
2018

Secondary Endpoints*
- Complete Wound Healing
  - 6 Months: 57.1%
  - 12 Months: 71.4%
  - @Baseline: 89.7%
  - @Wound Healing: 68.6%
- Limb salvage
  - 6 Months: 85.7%
  - 12 Months: 88.6%
- Perfusion - TcPO2
  - p=0.080

Survival and amputation free Kaplan-Meier
- Survival
- Amputation Freedom

The Benefits Of The LimFlow System
- Reproducible therapy
- Strong safety profile
- Fully Percutaneous Procedure
- Evident impact on wound healing and amputation risk

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

* R5 Rutherford 5 – R6 Rutherford 6. Major Adverse Limb Event (MALE) defined as major amputation or major surgical reintervention on index limb. WIfI Wound Ischemia foot Infection.
### Ordering information

#### LimFlow Stent Graft System

<table>
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<tr>
<th>Reference</th>
<th>Description</th>
<th>Stent Length (mm)</th>
<th>Stent Diameter (mm)</th>
<th>Recommended Vessel Diameter (mm)</th>
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#### LimFlow Arterio-Venous Ultrasound Catheter Set and LimFlow Valvulotome

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#### LimFlow Ultrasound System

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<tr>
<th>Reference</th>
<th>Description</th>
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<td>MG-01835-001</td>
<td>LimFlow Ultrasound System</td>
<td>Laptop, Power Cable and Transceiver interface box</td>
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References:
8. Discussion with Dr. Roberto Ferraresi, PCR Peripheral, Nov 2016
12. C. Walker Presentation, NCVH May, 2016 “Why every interventionist must understand PAD”

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