

The logo for LINC (Limbic Inflow and Outflow Control) is located in the top left corner. It features the letters 'LINC' in a white, sans-serif font, overlaid on a stylized graphic of a brain or neural pathway. The graphic consists of several curved, brush-stroke-like lines in shades of blue, red, and yellow, suggesting a dynamic and interconnected system.

LINC

Percutaneous deep venous arterialization with the LimFlow procedure

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Disclosure

Speaker name:

Marianne Brodmann

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest

Unmet Need: Lower Limb Ischemic Amputations

Lethal

High perioperative mortality (5-10%)

Risky

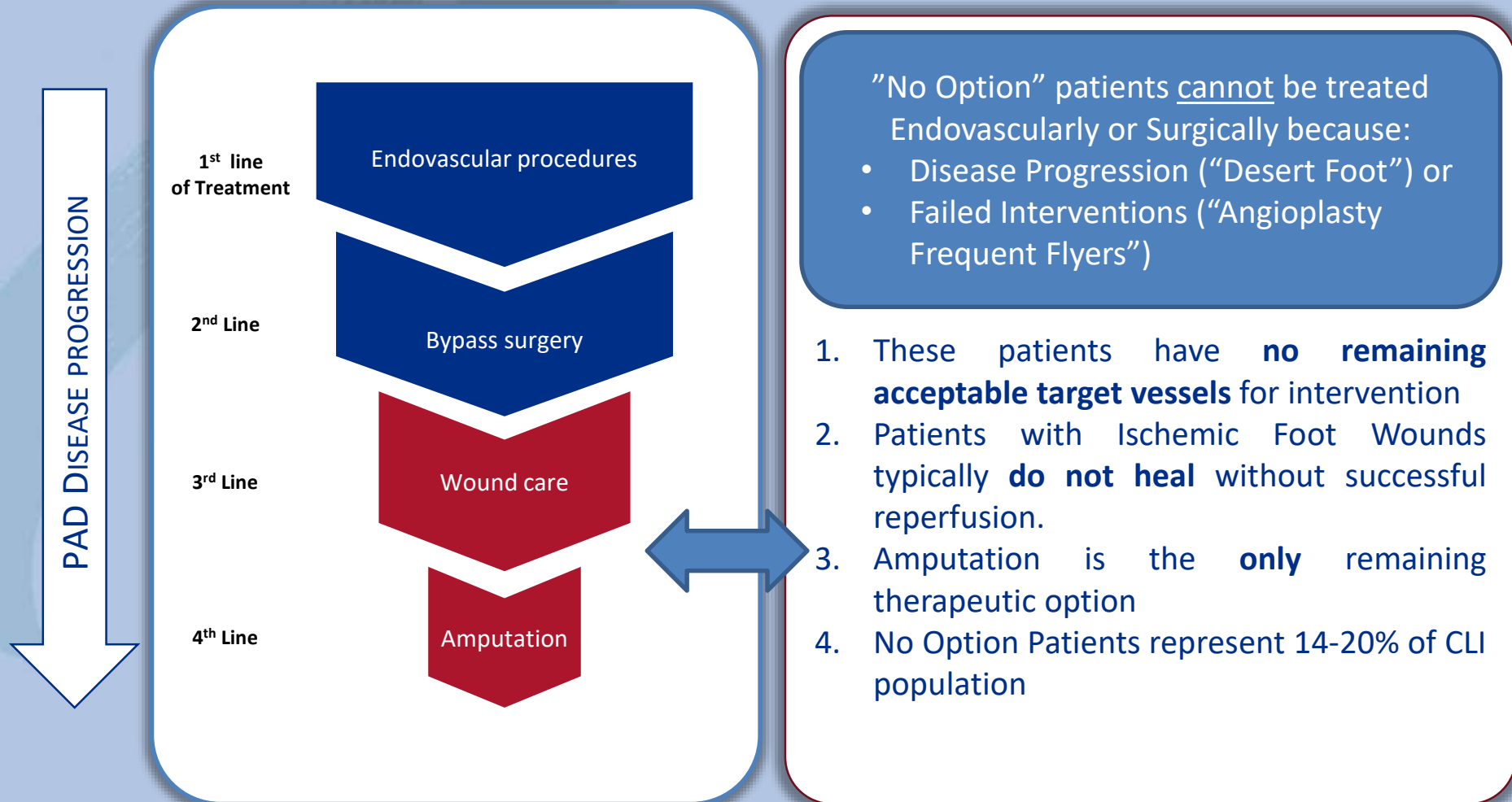
High major complication rate (20-37%)

Costly

- Direct cost per amputation \$45-\$65k
- \$800k Life Time Cost per Amputee in US



The “No Option” Patient Group



pDVA Procedure quick overview

Safe, Reproducible, fully Percutaneous Foot Perfusion

Key Procedure Steps Artery to Vein Crossing



Ultrasound AV
Positioning Kit:

Intended to
determine optimal
Crossing point
safely and
reproducibly



pDVA Procedure quick overview

Safe, Reproducible, fully Percutaneous Foot Perfusion

Key Procedure Steps Pedal Arch Reconstruction



Push Valvulotome:

Designed to maximize outflow by rendering vein valves incompetent



pDVA Procedure quick overview

Safe, Reproducible, fully Percutaneous Foot Perfusion

Key Procedure Steps Percutaneous Bypass Creation

Limflow Self-Expanding
Covered Extension Stents



Covered Stents

Conical and
straight Covered
Stents to maximize
outflow to the foot



Restored Perfusion: LimFlow Clinical Example*



LimFlow Patient #5

* Videos courtesy of Dr. S. Kum, Changi Hospital, Singapore

Wound Healing: LimFlow Clinical Example*

PRE-LIMFLOW



34 WEEKS POST-LIMFLOW



400 DAYS post-LimFlow



Pilot Study – 7 “No-Option” CLI patients

Patient Demographics

7 Patients, No-Option CLI

Average age: 85 years old



*WIFI: Wound Ischemia foot Infection

Results - Primary Endpoints (at 30 Days)¹#



Major Adverse Limb Events



Survival



Technical Success

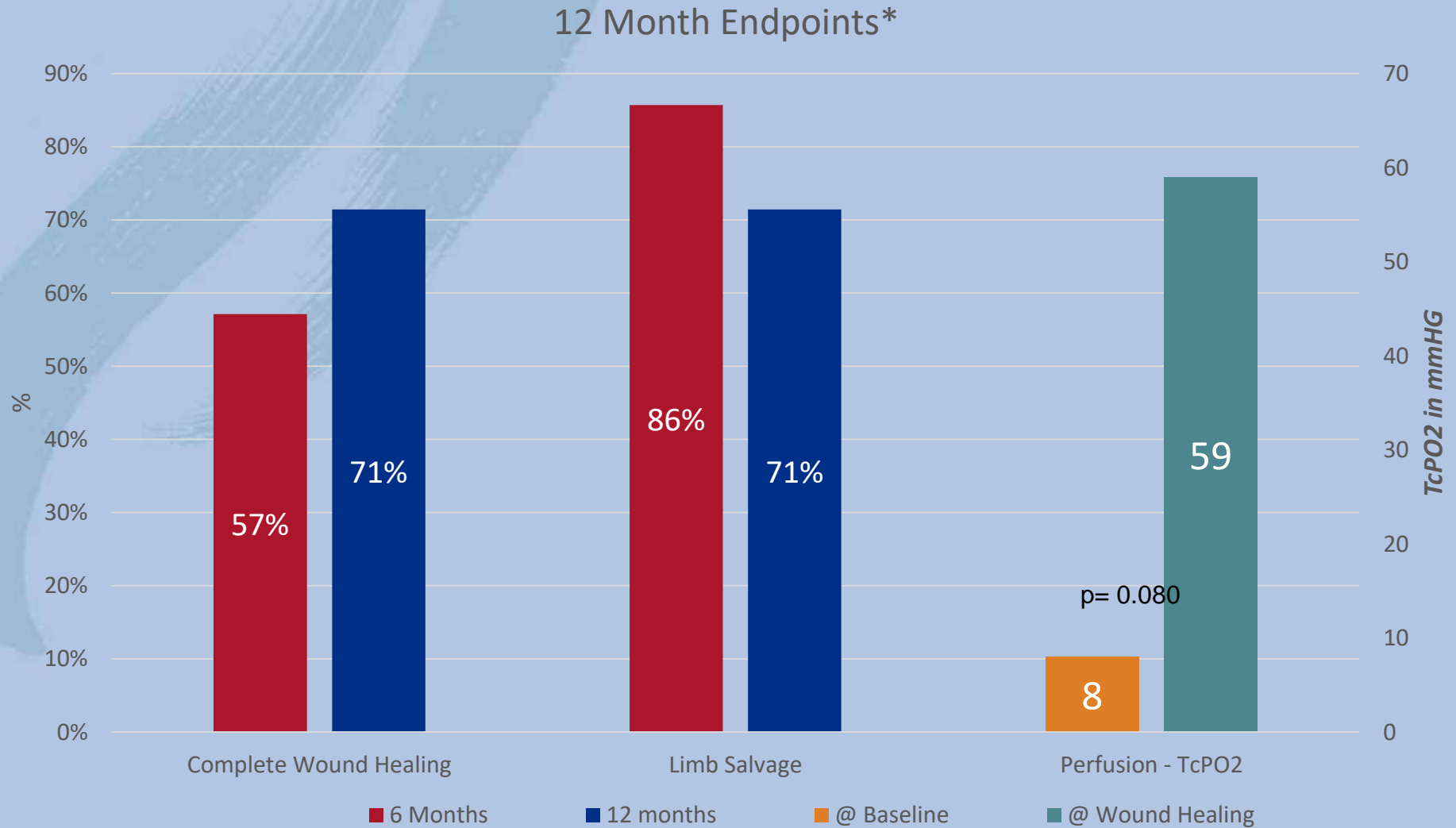
¹MALE (Major Adverse Limb Event) defined as major amputation or major surgical reintervention on index limb

1. Kum S, Tan YK, Schreve MA, Ferraresi R, Varcoe RL, Schmid A, et al. Midterm outcomes from a pilot study of percutaneous deep vein arterialization for the treatment of no-option critical limb ischemia. J Endovasc Ther. 2017 Jul 1;doi: 10.1177/1526602817719283 (epub ahead of print)

* Minor complications: two non-ST, non-procedure related elevated MIs; one patient developed spontaneous retroperitoneal bleeding 8 weeks' post-procedure and was managed conservatively after cessation of anticoagulation.

three procedure unrelated deaths within 12 months: 2 patients died of pneumonia at 6 and 8 months, respectively; 1 patient had a fatal MI at 7 months following above-the-knee amputation.

Pilot Study – 12 months Endpoints



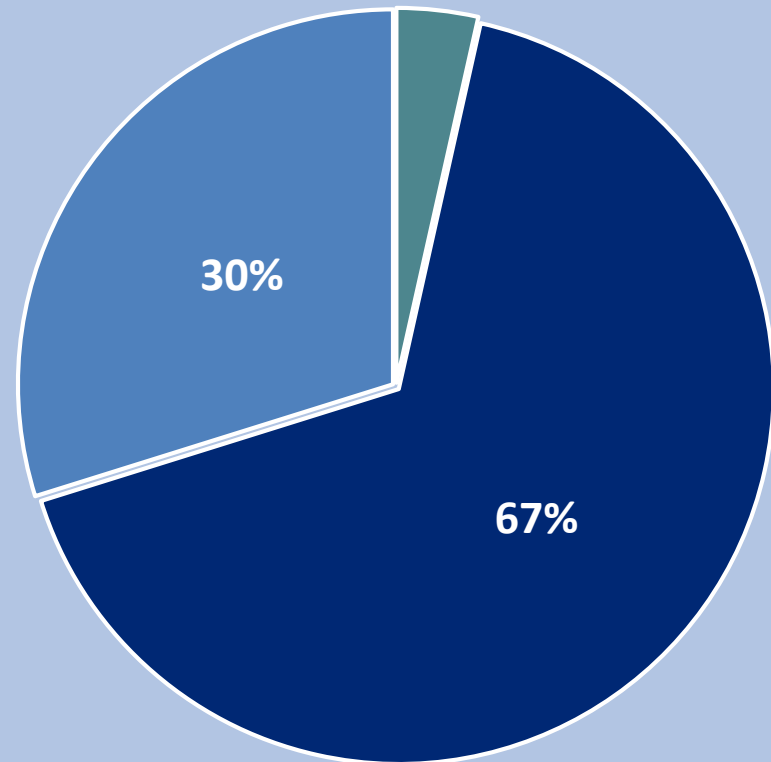
* Data Source: Journal of Endovascular Therapy website – July 2017

Patient Demographics

Clinical Experience

Rutherford classification

- 66 treated “No option” patients
- Mean age 72 y.o. (range 31-89 y.o.)
- Majority of male patients (61% male, 39% female)
- 74% of the patients were diabetic
- Over 20% of patients are on dialysis

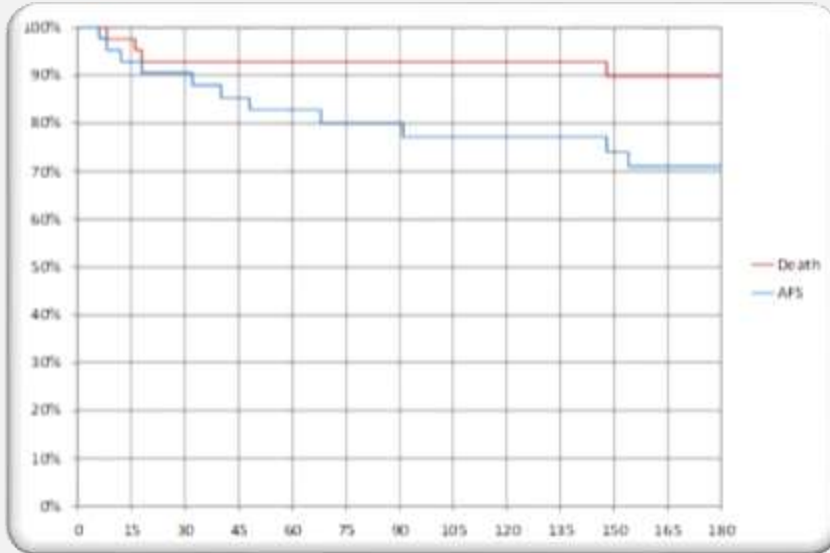


■ Class 4 ■ Class 5 ■ Class 6

Clinical Summary

First 43 LimFlow Treated Patients

**First 43 LimFlow Patients
Survival and Amputation Free Kaplan-
Meier**



**71% patients alive and
amputation free 6 months after
pDVA**

Reproducible Therapy

Strong Safety Profile

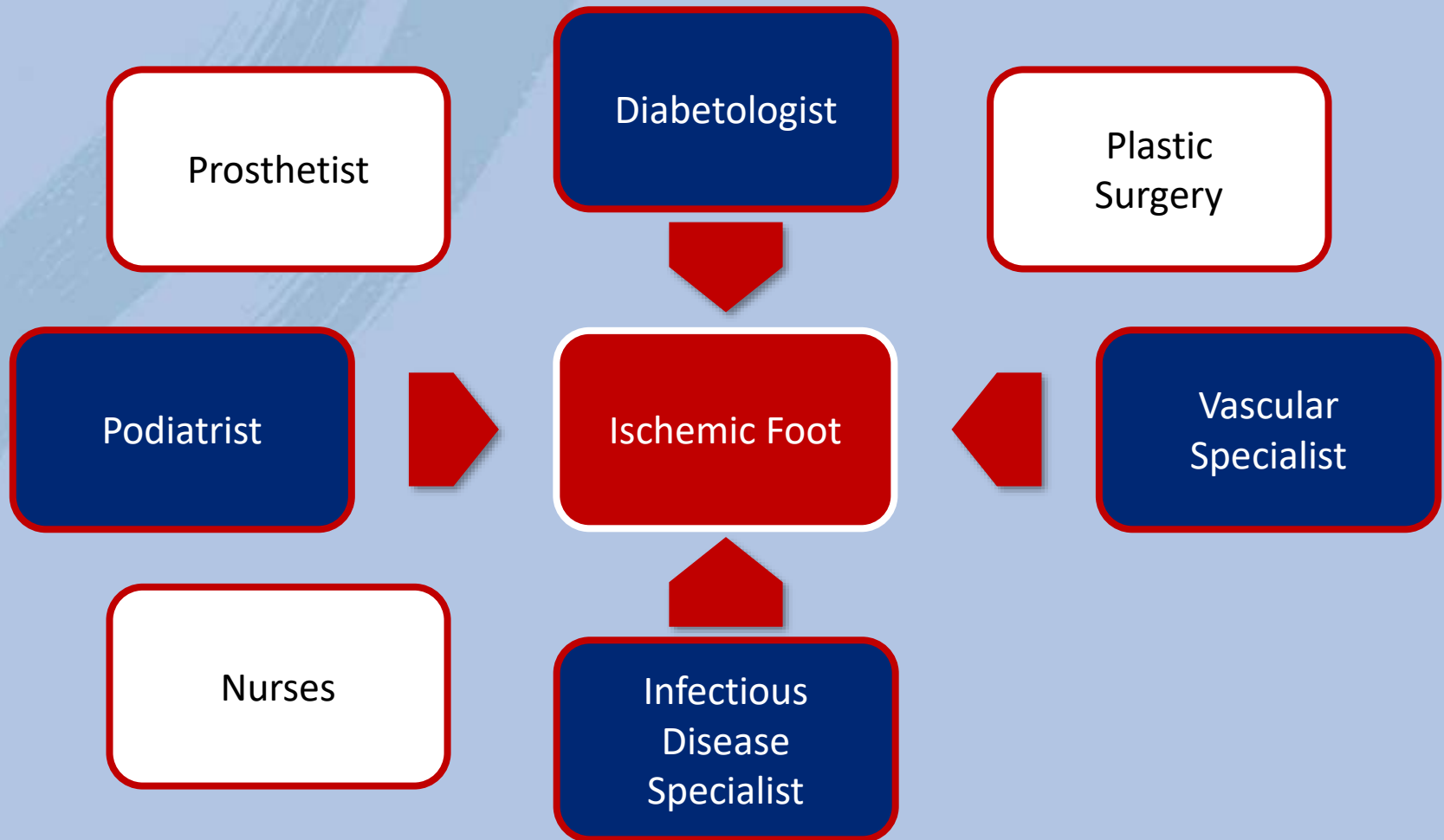
**Survival in line with patients
co-morbidities**

**Evident Impact on Wound
Healing & Amputation Risk**

LimFlow pDVA Clinical Program

	Pilot	Pre and Post CE Mark	U.S. Feasibility	OUS Post-Market	U.S. Pivotal
# Patients	7	34	10	50	TBD
# Centers	1	9	3	10	TBD
Protocol	Single-center, prospective, open label	Multi-center, prospective, open label	Multi-center, prospective, single-arm	Multi-center, prospective, single-arm	Multi-center, prospective, efficacy and safety study
Enrollment	Sep 2013-Nov 2014	Mar 2015 – Mar 2017	Jul 2017 -	2017	2018 Target
Countries	Singapore	France, Germany, Italy, Netherlands, Singapore	U.S.	EU, Singapore	U.S.

Ideal Treatment Environment



Amputation Prevention Multidisciplinary Team

Key Pearls for pDVA Patients

- Recommendations to your wound treatment team
 - Ensure they Follow a well recognized advanced treatment (such as **TIME**)
 - Inform them of differences to expect compared to normal revascularization
 - foot Swelling
 - delayed wound healing
 - Insist they contact you before considering further procedures on the patient
- Infection Management in “No-Option” patient is potentially the most important treatment to avoid major amputation
- Infection management / Infection prophylaxis
 - Regular wound swab/ culture to identify the bacterial burden
 - Treatment: Local, Systemic, or both
 - Control swab after 2 weeks*

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