

# FLOWOX

FLOWOX BY OTIVIO

## Information for Healthcare Professionals

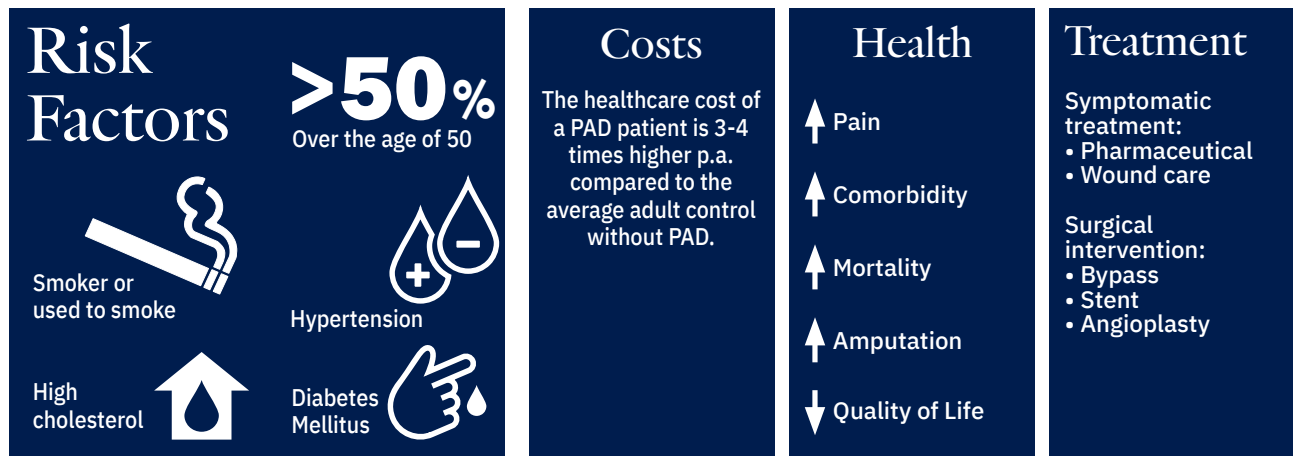
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Peripheral arterial disease (PAD) is a medical condition where the blood circulation in the limbs is reduced and leads to pain, chronic wounds and amputations.

PAD affects the health and quality of life of an estimated 200m people worldwide and is projected to rise disproportionately in the coming years.<sup>1</sup>



PAD is often not diagnosed or proactively treated until it becomes severe, thus increasing the likelihood of a patient requiring a lower limb amputation.<sup>2</sup>

## What is FlowOx™?

FlowOx™ is a novel medical device for the treatment of PAD related problems such as pain, reduced walking distance and chronic ulcers. The system increases blood flow in patients with peripheral arterial disease.<sup>4</sup>

It is a non-invasive, gentle and easy to use device that works by generating pulsating negative pressure, perfusing the lower limb, thus improving the blood flow and oxygenation.<sup>4</sup>

Pulsating negative pressure applied directly onto the skin's surface increases blood flow, due to a combination of dilatation of the arterioles and an increased arteriovenous pressure gradient.<sup>4,5</sup>

## Key benefits of the FlowOx™ therapy

- External, safe and simple application (non-invasive)
- Optimized for home usage
- Supplement and preparation for surgical interventions or contraindicated surgeries
- Usable on existing wounds if they are dressed

### Fact...



1 in 5 people over 50 have some degree of PAD.<sup>6</sup>

It's more common in men than in women.<sup>7</sup>

### Fact...



Around 2% of people with intermittent claudication will eventually undergo amputation, making PAD one of the biggest causes of lower-limb amputation.<sup>8</sup>

### Fact...



Approximately 5000 major amputations are undertaken in England every year, with over 90% being PAD related.<sup>9</sup>

## FlowOx™ - Mode of Action

Intermittent Negative Pressure (INP)

### Acute Effect on Blood Flow

**A**

First 1-3 seconds: Rapid increase of transmural pressure during -40 mmHg phase.

Initiation of transient vasodilation, increased micro and macrocirculation.

**B**

Next 4-6 seconds: Extension of veins, passive stretch of arteries, arterioles and capillaries.

Immediate lowering of venous pressure (suction effect).

**C**

Pressure returns to ambient pressure, myogenic contraction in vessel wall causes vasoconstriction, decrease in blood flow, slow return to baseline (7 seconds).

New cycle begins.

### Translating Acute Effects into Long Term Effect

**3**

Repeated activation of endothelial pathways leads to gene expression and secretion of vascular factors.

**2**

Repeated exposure of shear forces leads to vasodilation through increased blood flow, activation of endothelial signaling pathways.

**1**

Repeated fluctuations in blood flow velocity expose endothelial cells to shear forces

A, B, C

Effects of transmural pressure on brachial artery mean blood velocity dynamics in humans. Lott, et al., 2002 in J.a. physiol.

## Who should use FlowOx™?

- Patients with intermittent claudication
- Patients with critical lower limb ischaemia
- Patients at risk of amputation due to PAD
- Patients with upcoming vascular interventions or amputations
- Patients with acute and chronic arterial/mixed ulcers

## The Effect

Intermittent negative pressure (INP) stimulates the micro- and macrocirculation of blood in the extremities and when applied regularly, it will revitalise the natural endothelial function - similar to the way muscle strength and function can improve through regular exercise. INP will work even in the smallest blood vessels and thereby can improve function and blood flow to the extremities and skin.<sup>4, 5, 10</sup>

## An unmet medical need...

Current treatment strategies for PAD are often limited, inadequate and symptomatic, resulting in poor outcomes. FlowOx™ offers a baseline intervention that works well in conjunction with current Gold Standard and first line treatment guidelines of intermittent claudication, critical limb ischemia and chronic wound care.

## Therapy Strategies



## How to use FlowOx™

To achieve relevant therapeutic effects, it is recommended that the device is used for 2 hours per day, preferably split into smaller and more convenient time slots during the day (e.g. one hour in the morning, and one hour in the evening).

Using FlowOx™ as recommended, patients can expect to experience reduction in pain and visual changes in wound status within 2-3 weeks and can attain long term benefits such as lasting reduction in pain.

In addition, the majority of patients experience positive long-term effects, such as permanent pain reduction, increased walking distance, improved blood flow and positive effects on the healing of arterial chronic wounds.

To ensure compliance, it is important to adjust the use of FlowOx™ to suit the patient's normal daily routine.







## Ordering information

For orders, deliveries and general enquires please contact Otivio AS:

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### References:

1. Medpage Today, August 2, 2013. 2. All-Part Parliamentary Group, 2016. Saving limbs, saving lives: patient access to technologies for the diagnosis and treatment of peripheral arterial disease. 3. Scully, RE., DeBord Smith, A. et al. 2016. Annual Health Care Expenditures in Individuals with Peripheral Arterial Disease, Journal of Vascular Surgery, Vol 64(4), 1180–1181. 4. Sundby Ø. et al., 2017. Blood flow in PAD patients enhanced by FlowOx. 5. Sundby Ø. et al., 2016. Blood flow in healthy volunteers, pulsing patterns. 6. British Heart Foundation, 2019. Peripheral arterial disease. Available at: <https://www.bhf.org.uk/informationsupport/heart-matters-magazine/medical/peripheral-arterial-disease> [accessed February 2019]. 7. BUPA, 2019. Peripheral arterial disease. Available at: <https://www.bupa.co.uk/health-information/heart-blood-circulation/peripheral-arterial-disease> [accessed February 2019]. 8. National Institute for Health and Clinical Excellence, 2011. NICE cost impact statement: QOF indicators for peripheral arterial disease. Available at: <https://www.nice.org.uk/Media/Default/standards-and-indicators/qof%20indicator%20key%20documents/NM33%20cost%20statement.pdf> [accessed February 2019]. 9. Ahmad, N., Thomas, G.N. et al., 2016. The prevalence of major lower limb amputation in the diabetic and non-diabetic population of England 2003-2013. Diabetes & Vascular Disease Research, Vol 13(5), 348-353. 10. Sundby Ø. et al., 2018. Blood flow in paraplegics enhanced by FlowOx. 11. Sundby, Ø.H., Høiseth, L. Ø. et al., 2016. The effects of intermittent negative pressure on the lower extremities' peripheral circulation and wound healing in four patients with lower limb ischemia and hard-to-heal leg ulcers: a case report. Physiological Reports, Vol 4(20), 1-7. 12. Sundby, Ø.H., Mathiesen, I. et al. 2017. Lower limb intermittent negative pressure increases foot circulation and improved wound healing in patients with diabetes and hard-to-heal leg ulcers – a case report. Wounds UK poster.

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