

Press release
Malmö, September 6th, 2021

Arjo receives 510(k) clearance from US FDA for WoundExpress

Arjo has received 510(k) clearance from the US Food and Drug Administration (FDA) for WoundExpress, an intermittent pneumatic compression (IPC) solution for accelerating healing of venous leg ulcers. The FDA clearance follows several recent studies showing that WoundExpress can significantly improve lower leg wound management.

“This is an important milestone for us and we see great potential in now bringing this innovative therapy to the US market as well”, says Joacim Lindoff, President & CEO of Arjo.

“Venous leg ulcers are a rapidly growing and costly problem for healthcare, with annual treatment costs estimated at approximately SEK 300 billion globally¹, whereof the US market represents almost 50%. I am confident that WoundExpress will help solve the current issues both from a clinical and financial perspective”, adds Joacim Lindoff.

WoundExpress is expected to be launched in the US during Q1 2022.

[A recently published research paper](#) showed that WoundExpress, in combination with standard care, increased the probability of wound healing by 58% and improved the health-related quality of life for patients – with significant associated cost savings for healthcare.²

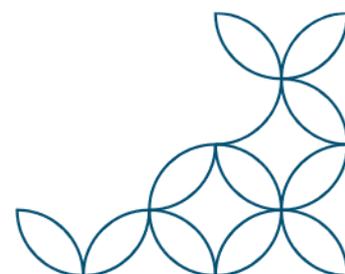
A randomized controlled trial (RCT) for wound care treatment is currently ongoing. Due to delays related to the Covid-19 pandemic, the RCT is expected to be finalized in Q2 2022.

About WoundExpress

Arjo's WoundExpress is an Intermittent Pneumatic Compression (IPC) system to manage lower leg wounds with a garment applied on the patient's thigh, uniquely placed away from the wound site to avoid painful pressure while increasing blood flow to the leg ulcer.

To date, WoundExpress has been introduced to the market in UK, Ireland, Sweden and Denmark – with very positive response. Commercialisation plans are currently under development for other major markets.

Read more about WoundExpress here: <https://www.woundexpress.com/>



- 1) NHS (2019); Wounds International (2015); Reeder et al. (2013); Guest et al. (2017); Corporate Development & Projects: Huntleigh Diagnostics
- 2) Guest et al, (2021)

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About Arjo

At Arjo, we believe that empowering movement within healthcare environments is essential to quality care. Our products and solutions are designed to promote a safe and dignified experience through patient handling, medical beds, personal hygiene, disinfection, diagnostics, and the prevention of pressure injuries and venous thromboembolism. With over 6,000 people worldwide and 60 years caring for patients and healthcare professionals, we are committed to driving healthier outcomes for people facing mobility challenges. www.arjo.com