Arjo initiates a randomized controlled trial for wound care treatment after strong evaluation results

Arjo will today publish the results from a highly successful multi-centre clinical evaluation for the recently launched WoundExpress™. WoundExpress is a ground breaking patented therapy for Venous Leg Ulcers (VLU). Further clinical research studies, including a pivotal randomised controlled trial, are now underway. Arjo aims to establish WoundExpress as the standard of care, given the clear improvements in outcomes for patients and the healthcare system alike.

Venous leg ulcers are a rapidly growing problem worldwide with high ongoing treatment costs amounting to over SEK 100 billion, as current treatment is very labour intensive. Research has shown that almost half (47%) of ulcers do not heal within 12 months and represent approximately 80% of the cost burden.\(^1\) Those affected can face a number of related daily challenges such as pain and limited mobility,\(^2\) in some cases leading to depression, anxiety and social isolation.

“WoundExpress will not only strengthen our already solid product portfolio, but also ensure that we stay at the forefront of wound therapy technology and potentially transform the outlook for wound care beyond VLUs in the next years. The current addressable device market for VLU management is estimated at over SEK 20 billion, and with this unique technology we see major growth potential. We are committed to improving outcomes, both in terms of clinical results and health care efficiency, thereby adding value to both patients and caregivers,” says Arjo President & CEO Joacim Lindoff

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. The simple-to-use device is ideally suited for use at home, thereby empowering patients and minimizing disruptions to lifestyle and daily activities. The accelerated wound healing also implies less dress changes, thereby reducing nursing time substantially, with significant cost benefits for care providers as well.

In recent months, a multi-centre clinical evaluation of WoundExpress has been ongoing, including two highly prestigious wound care facilities, Welsh Wound Innovation Centre in Wales (WWIC) and Accelerate CIC in London. The objective was to evaluate the effectiveness of thigh administered IPC on chronic wounds of mixed or venous aetiology. Wounds at these two facilities had a mean

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\(^1\) Guest et al (2018)
\(^2\) Lernevall et al (2017)
duration of over 40 months and had not made progress towards healing prior to treatment. While on evaluation, patients continued to have their normal course of wound treatment.

The evaluation is showing highly promising results. In over 95% of cases, significant improvement was seen in wound healing and in a third of the cases, the wounds healed entirely. Further, over 95% of patients reported significant reduction of pain and increased quality of life. The results will be presented at the Wound Care Today Conference by Kirsty Kettley, Research Nurse at WWIC, and Kayley Turner-Dobbin, Clinical Delivery Lead Wound Care at CIC. Professor Keith Harding, Medical Director of the Welsh Wound Innovation Initiative, describes the WoundExpress as "an innovative and exciting new approach for treating patients with lower limb problems. It has the potential to be a real game changer in managing a difficult aspect of clinical practice."

WoundExpress has been commercially available from September 2019 to customers in the UK, and significant investments to build up the sales force for the wound care segment are currently ongoing. The treatment costs in the UK alone is estimated at SEK 25 billion annually, of which the addressable device market for VLU management is around SEK 5 billion. EU certification has been granted and investigations to establish relevant sales channels in Europe are in progress. Work to gain necessary approvals to access the North American market is ongoing. Further clinical research studies, including a pivotal randomised controlled trial, to support and further develop WoundExpress applications are now underway and are expected to conclude within 12-18 months. Arjo aims to establish WoundExpress as the standard of care, given the clear improvements in outcomes for patients and the healthcare system alike.

Arjo has a long history of expertise in improving clinical outcomes, such as within PIP and DVT solutions, setting a strong foundation for innovation within wound therapy. This launch is another step in ensuring that Arjo stays relevant for its customers and continues playing an important role in shaping the healthcare of the future.

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About Arjo

At Arjo, we are committed to improving the everyday lives of people affected by reduced mobility and age-related health challenges. With products and solutions that ensure ergonomic patient handling, personal hygiene, disinfection, diagnostics, and the effective prevention of pressure injuries and venous thromboembolism, we help professionals across care environments to continually raise the standard of safe and dignified care. Arjo has approximately 6,000 employees worldwide and customers in over 100 countries. In 2019, Arjo sales amounted to approximately SEK 8.9 billion. Arjo is listed on Nasdaq Stockholm and its head office is located in Malmö, Sweden. Everything we do, we do with people in mind.

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