

ReStore™ Exo-Suit gets FDA approval for Stroke Therapy

06 June 2019 | News

New age innovation offers versatile, affordable medical device to U.S. rehab clinics to treat millions of patients with gait impairment



An Israel based ReWalk Robotics Ltd, a leading manufacturer of robotic medical devices for individuals with lower limb disabilities, announced that the U.S. Food and Drug Administration ("FDA") has cleared the Company's ReStore soft exo-suit system for sale to rehabilitation centers across the United States. ReStore is the only soft exo-suit with FDA clearance, and is intended for use in the treatment of stroke survivors with mobility challenges. Stroke is a leading cause of disability, which affects approximately 17 million people worldwide each year and as many as 80% of people who have had a stroke will suffer

from gait impairments.

"The exo-suit achieves our commercial goal to offer a functional and affordable system that can be utilized in the 'Main Street' clinics in every community," said ReWalk CEO Larry Jasinski. "With a launch price of \$28,900 as well as leasing options, ReStore offers cutting edge innovation with features that redefine therapy at a price that is accessible for a broader range of clinics than existing robotic technologies. The current gait training reimbursement codes enable immediate penetration and sales growth as part of our pathway to become a break even and profitable company."

In 2018, ReWalk launched a multi-center clinical study of the ReStore system across five of the country's leading rehabilitation centers. This data was submitted to the FDA in ReStore's 510(k) submission, and ReWalk expects to publish the results of the clinical study later this year.

The patented soft exo-suit technology was originally developed at Harvard University's Wyss Institute for Biologically Inspired Engineering where it also underwent initial clinical testing that demonstrated its potential to improve walking for stroke survivors. ReWalk and the Wyss Institute entered into a multi-year research collaboration agreement in 2016 which provides ReWalk access to future innovations that emerge from this collaboration and may be relevant to additional stroke products or other therapies.

"The idea of anchoring the body with textiles and flexible soft components is a fundamentally new way of applying assistance with a wearable robot," said Conor Walsh, a Professor of Engineering and Applied Sciences at the John A. Paulson Harvard School of Engineering and Applied Sciences and a Core Faculty member at the Wyss Institute for Biologically Inspired Engineering, who led a multi-disciplinary team to develop the soft exo-suit technology that has the ability to apply force to the body, but not restrict how a person moves. "This technology has broad potential, and we are currently testing additional concepts which can be applied to provide therapy and/ or mobility assistance for individuals with other diseases, such as multiple sclerosis and Parkinson's disease, and also potentially be used by a person at home and in their community," Walsh continued.

How it works: The ReStore system is comprised of a soft, garment-like design which connects to a lightweight waist pack and mechanical cables that help lift the patient's affected leg in synchronized timing with their natural walking pattern. The system provides targeted assistance to the patient during forward propulsion (plantarflexion) and ground clearance (dorsiflexion), two key phases of the gait cycle. The device also provides the physical therapists with extensive data during gait training with ReStore to inform strategies to optimize a patient's treatment and progress using real-time analytics.

ReStore is ReWalk's second major market segment, joining the ReWalk Personal 6.0—a robotic exoskeleton for home use by individuals with paralysis from a spinal cord injury—and the ReWalk Rehabilitation system, which allows for multiple patient uses through height and weight adjustments. "We believe the expansion to soft exo-suits gives ReWalk a diverse offering of innovative technologies and expands the Company's impact to millions of patients worldwide," added Jasinski. ReWalk intends to leverage its existing sales, training and service teams to commercialize the ReStore system. To date, ReWalk has placed nearly 550 exoskeletons in 26 countries and trained more than 270 rehabilitation clinics to conduct exoskeleton training worldwide.