

Bioness Receives FDA Clearance for the L300 Go™ System

The L300 Go™ System is the first functional electrical stimulation device to provide 3D motion detection of gait events

VALENCIA, Calif., February 07, 2017 – Bioness Inc., the leading provider of cutting-edge, clinically supported rehabilitation therapies, today announced that it received clearance from the U.S. Food and Drug Administration (FDA) for the L300 Go™ System. The L300 Go builds upon the global success of the company's NESS L300® Foot Drop System and NESS L300 Plus® System with numerous advancements, including the introduction of 3D motion detection of gait events, multi-channel stimulation and a mobile iOS application to track user activity.

Gait movement disorders, such as foot drop and knee instability, are often associated with an upper motor neuron disease such as stroke and multiple sclerosis as well as injuries to the brain and spinal cord. Individuals with an impaired gait have less control over their lower extremity muscles and are at an increased risk for falls. The L300 Go is the first functional electrical stimulation (FES) system to offer 3D motion detection of gait events and muscle activation using data from a 3-axis gyroscope and accelerometer. Patient movement is monitored in all three kinematic planes and stimulation is deployed precisely when needed during the gait cycle. An adaptive, learning algorithm accommodates changes in gait dynamics, and a high speed processor that deploys stimulation within 10 milliseconds of detecting a valid gait event. This rapid, reliable response is critical and supports user confidence.

The new myBioness™ mobile iOS application allows home users of the system to track activity, set personal goals and review their progress over time using dynamic reporting capabilities. The app has been designed to keep users engaged in the rehabilitation process and motivated to meet their recovery goals.

Multi-channel stimulation is an additional noteworthy L300 Go feature that allows clinicians to precisely control the amount of dorsiflexion and inversion/eversion the system provides. Using a new, proprietary electrode, medial and lateral stimulation can be adjusted independently. This more efficient fitting process saves valuable time and facilitates more productive therapy sessions.

“The healthcare system is being challenged to objectively document and improve functional capabilities. To help meet these demands, clinicians are turning to technologies that speed up rehabilitation timelines and provide a personalized recovery plan,” said Todd Cushman, President and CEO of Bioness. “Technological innovations including 3D motion detection and multi-channel stimulation work together to improve treatment efficiency and promote patient mobility. At Bioness, we are focused on improving the lives of patients through technology and are proud to add the L300 Go into our growing portfolio of products.”

The L300 Go System was cleared by the U.S. Food and Drug Administration on January 27, 2017. The system is indicated to provide ankle dorsiflexion in adult and



pediatric individuals with foot drop and/or assist knee flexion or extension in adult individuals with muscle weakness related to upper motor neuron disease/injury (e.g., stroke, damage to pathways to the spinal cord). The L300 Go System electrically stimulates muscles in the affected leg to provide ankle dorsiflexion of the foot and/or knee flexion or extension; thus, it also may improve the individual's gait.

Bioness will begin commercial release of the L300 Go in the spring of 2017. Initially, the system will only be available to healthcare professionals for clinic use. Home user availability is targeted for the later part of 2017. Current users of the L300 Foot Drop System and L300 Plus System will be eligible for a Customer Loyalty Upgrade Program which is designed to make the new technology more accessible for users in the clinic and community.

About Bioness Inc.

Bioness is the leading provider of innovative technologies helping people regain mobility and independence. Bioness solutions include implantable and external neuromodulation systems, robotic systems and software based therapy programs providing functional and therapeutic benefits for individuals affected by pain, central nervous system disorders and orthopedic injuries. Currently, Bioness offers six medical devices within its commercial portfolio which are distributed and sold on five continents and in over 25 countries worldwide. Our technologies have been implemented in the most prestigious and well-respected institutions around the globe with approximately 90% of the top rehabilitation hospitals in the United States currently using one or more Bioness solution. Bioness has a singular focus on aiding large, underserved customer groups with innovative, evidence-based solutions and we will continue to develop and make commercially available new products that address the growing and changing needs of our customers. Individual results vary. Consult with a qualified physician to determine if this product is right for you. Contraindications, adverse reactions and precautions are available online at www.bioness.com.

Media Relations Contact Information

Next Step Communications

bioness@nextstepcomms.com

781.326.1741

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