

Bioness Inc. Receives FDA Clearance of Its NESS L300 Plus System

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VALENCIA, Calif., May 10, 2011 /PRNewswire/ -- Bioness Inc. today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its NESS L300® Plus System. The device combines the Company's NESS L300® Foot Drop System with a thigh stimulation cuff, to provide knee flexion and extension in addition to ankle dorsiflexion during gait. The NESS L300 Plus is intended for persons with upper motor neuron injury or disease resulting from stroke, multiple sclerosis, traumatic brain injury and spinal cord injury. The device also may facilitate muscle re-education, prevent/retard muscle atrophy, maintain or increase range of motion and increase local blood flow.

People with upper motor neuron injuries or diseases often experience gait movement disorders such as [foot drop](#) [1], which is a result of partial leg paralysis. Gait movement disorders not only result in [difficulty walking](#) [2], but may also lead to fatigue, falls or abnormal walking patterns.

The NESS L300 Plus builds on the proven success of Bioness' NESS L300 Foot Drop System and is designed to additionally stimulate the muscles of the thigh. The addition of the thigh stimulation cuff, synchronized with a wireless heel sensor to detect when the foot is on or off the ground, controls the knee, making it easier to walk. Historically, patients have relied on rigid plastic braces which restrict thigh and ankle movements and can lead to additional problems, including increased falls.

"An estimated 12.5 million Americans live with the effects of central nervous system injuries and disorders, and many of these individuals have gait disorders that make it difficult if not impossible for them to walk with freedom," said Thomas G. Fogarty, president & CEO of Bioness. "The NESS L300 Plus will provide physical therapists an additional modality to optimize the pa

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Links:

[1] http://www.bioness.com/Bioness_For_Foot_Drop.php

[2] <http://www.bioness.com/>

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