



TALKING TO YOUR DOCTOR – A Discussion Guide

TALKING TO YOUR DOCTOR

The L300 is a prescription device used to improve walking.

You may benefit from using the L300 if you have foot drop and the L300 Plus if you also have upper leg weakness resulting from:

- Stroke (CVA)
- Multiple Sclerosis (MS)
- Traumatic Brain Injury (TBI)
- Incomplete Spinal Cord Injury (SCI)
- Other central nervous system disorders, like Cerebral Palsy or Parkinson’s Disease

A recent study of 99 stroke survivors showed the L300 can improve gait speed from the very first use with 86% of the participants rating the device more useful than any other walking aid previously used. Thousands of users worldwide are experiencing the benefits of using the L300 and L300 Plus System.

START A CONVERSATION WITH YOUR PHYSICIAN

It can be as easy as asking, “I want to walk faster with more comfort and less fatigue. Could the L300 System help me achieve those goals?”

QUESTIONS TO ASK MY DOCTOR

1. Do you think the L300 could help me walk better?
2. Have you had other patients use the L300? How did it work for them?
3. I would like to get evaluated. Would you please write me a prescription for physical therapy?



IMPORTANT SAFETY INFORMATION

The L300 and L300 Plus are not intended for woman who are pregnant or may become pregnant, individuals with malignant tumors or lesions on the affected leg or people that have had a recent leg fracture.

If you use a pacemaker or defibrillator, have a history of seizures, use a baclofen pump or have metallic implants consult your physician before being evaluated for the L300 or L300 Plus.

Please see a full list of contraindications, precautions and warnings for the L300 and L300 Plus System at www.bioness.com. the H200 Wireless Hand Rehabilitation System at www.bioness.com.



Walk Back Into *LIFE*

Frequently Asked Questions and Answers about the L300[®] Foot Drop System

What is the L300 Foot Drop System?

The L300 Foot Drop System is a non-invasive advanced functional electrical stimulation (FES) System for individuals seeking to regain their ability to walk more naturally. The system stimulates the nerves in the lower leg, activating muscles to lift the foot, while walking. The L300 may replace the need to wear a rigid ankle foot orthosis (AFO), and may eliminate the need to raise your hip or swing out your leg while walking.

What is Foot Drop?

Foot drop is a condition where the muscles in the foot are too weak to properly lift the foot and toes causing individuals to drag their foot while walking. Foot drop is often present in persons who have conditions such as stroke, traumatic brain injury, incomplete spinal cord injury, multiple sclerosis and cerebral palsy.

How does the L300 work?

The L300 system stimulates the appropriate nerves and muscles of the lower leg and helps re-educate brain signals to help restore function in weak or paralyzed muscles.¹ The L300 has three main components that communicate with each other wirelessly and adapt to changes in walking speed and terrain.

Who may benefit from using the L300?

The L300 is intended for individuals with foot drop who are looking to increase walking speed, improve steadiness and increase confidence.²

What is FES?

Functional Electrical Stimulation (FES) applies low-level stimulation to specific parts of the body to help restore function. The L300 Plus delivers stimulation to activate the nerves controlling the major muscles of the leg to help improve your ability to walk more naturally.

How can the L300 help me?

The L300 may help you by:

- Providing close to natural movement while walking²
- Increasing walking speed and improving steadiness while walking²
- Promoting flexibility of the ankle and foot resulting in reduced stiffness
- Preventing muscle atrophy and improving blood circulation

Is the L300 available in different sizes?

The L300 leg cuff is available in two sizes, the Regular L300 and the Small L300, which is designed to fit calves with a circumference of 12" or smaller.

Why is the L300 unique?

The L300 uses the latest in FES wireless technology designed to help you walk more naturally and increase your mobility. The system offers:

- An ergonomic leg cuff free of dials or switches
- A wireless gait sensor that attaches to your shoe and adjusts to “real-time” changes in walking patterns
- A small, wireless hand-held control unit to safely and easily adjust or turn “on” or “off” the stimulation without removing or adjusting clothing
- The low profile design and wireless technology allows for wearing the system discreetly under most clothing

Where can I go for an evaluation to see if the L300 Plus is right for me?

Contact our Client Relations team at 800.211.9136, option 2 to learn if the system may be right for you, and to find the closest healthcare provider for an evaluation. If it is determined that the device will benefit you, Bioness will work with you and your healthcare provider to help you acquire the device.

Does the L300 require a prescription?

In order to acquire the device for home use, you need a prescription from your physician.

Is the L300 covered by my insurance?

Your health insurance plan may cover some or all of the cost of a L300 for home use, and reimbursement is typically based on medical need at the discretion of your insurance carrier.

Are there financing options for the L300?

Bioness is committed to helping you explore a variety of payment options – from insurance to financing – so we can find a purchase plan that makes the system affordable. To discuss your payment options, contact our Client Relations team at 800.211.9136, option 2.

“ A life *changing* experience...
For the **GOOD!**”

- Lorrie
L300 user

¹ Yan T, et al. 2005. *Stroke*. 36(1):80-85.

² Hausdorff J, Ring H, The effect of the NESS L300 neuroprosthesis on gait stability and symmetry, (abstract) *J Neurol Phys Ther*. 2006 Dec 30 (4):195-200 (included in CSM 2007 Platform Presentations).

Individual results vary. Consult with a qualified physician to determine if this product is right for you.

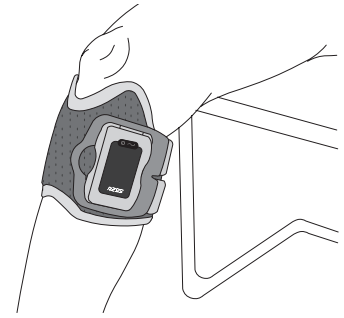
Contraindications, Adverse Reactions and Precautions are available on-line at www.bioness.com (also available in the NESS L300 User's Guide).

NESS®, NESS L300®, Intelli-Gait®, Intelli-Sense Gait Sensor™, Bioness, the Bioness Logo®, LiveOn® and For Function. For Freedom. For Life.™ are trademarks of Bioness Inc. | www.bioness.com | **Rx Only**

©2012 Bioness Inc.

PRODUCT DESCRIPTION

The award winning¹ L300 Foot Drop System is available by prescription Rx only and requires a patient evaluation prior to use. The L300 System is an advanced functional electrical stimulation system (FES) that is intended to help patients correct foot drop and improve walking (gait) following a neurological injury.



PATIENT DIAGNOSIS

- Stroke (CVA) – acute, subacute & chronic
- Multiple Sclerosis (MS)
- Traumatic Brain Injury (TBI)
- Spinal Cord Injury (SCI)
- Cerebral Palsy

INDICATIONS FOR USE

- May provide ankle dorsiflexion which may improve gait and range of motion (ROM)
- May reeducate muscles to function without the system (neuroplasticity/motor recovery)
- May increase local blood circulation
- May prevent or retard muscle atrophy

The System consists of three components:

1. A lightweight leg cuff and stimulator positioned just under the patients' knee that houses two electrodes to stimulate the muscles that lift the foot. Electrodes are sold separately and must be replaced bi-weekly.
2. A low profile Gait Sensor placed in the shoe that detects gait events and wirelessly communicates those events, regardless of terrain, to the stimulator.
3. A remote hand-held control unit is used to turn the system on and off and make small stimulation adjustments.

CLINICAL EVIDENCE AND RESEARCH

The US Veterans Affairs/Department of Defense (VA/DoD Guideline), the American Heart Association (AHA) and American Stroke Association (ASA) have all published practice guidelines strongly supporting functional electrical stimulation (FES) for the rehabilitation of stroke patients.

A 30-week study of 197 patients was recently published in *Stroke* that supports use of the L300 Foot Drop System in sub-acute and chronic stroke patients (n=98, p > 0.001)². Findings include:

1. After 30 weeks, the L300 users demonstrated clinically and statistically significant improvements in gait speed, total steps taken per day, endurance (6-min walk), stroke impact scale (SIS) and Timed Up and Go (TUG).
2. As compared to the AFO Group, L300 users reported a 2:1 satisfaction ratio, with 9/10 participants having an enthusiastic willingness to continue use and rated the L300 as being more useful compared to other walking aides used in the past.
3. Walking Speed Improvements: First Use: 19.0% increase, After 30 weeks: 33.3% increase.

Additional Research

- The L300 offers significant improvements in walking speed, gait symmetry and stride variability when compared to walking without the device.³
- The L300 improves gait speed and stride time when compared to an Ankle Foot Orthosis (AFO).⁴

1. Medical Design Excellence Award, Gold Medal Recipient 2007
3. Hausdorff JM, et al. 2008. *Am J Phys Med Rehabil.* 87(1):4-13

2. Kluding et al. 2013. *Stroke*, ISSN: 0039-2499
4. Weingarden HP, et al. 2007. *Physiother.* 93(Suppl 1): S359