

# Powerful Patient #25, 2008 Week 19

Host: Joyce Graff, WebTalkRadio.net

## Medical Devices and Off-Label Use

Innovative medical devices, like new drugs, have to be tested for safety and effectiveness with a particular condition. Joyce Graff interviews Glen Meidl of Bioness, Inc, about their medical devices for neuron stimulation to complement physical therapy and restore function following stroke, spinal cord injury, and traumatic brain injury. Brad Saul talks about his initiative in using this device to help restore function lost through Multiple Sclerosis, even though the FDA has not yet approved it for use with MS.



Brad Saul at work with one of his sons

### 1) About Our Guests

**Glenn Meidl, Director of Marketing, Bioness Inc.**, is based in Wisconsin. The company is based in California. See <http://www.bioness.com>

**Brad Saul, President of Webtalkradio.net**, is an entrepreneur. He lives with his wife and three children near Chicago. He has multiple sclerosis, uses a wheelchair, and has limited use of his hands. He has been experimenting with a Bioness H200 device to improve hand function.

### 2) Off-label Use

Any medication or device that is prescribed for use with a condition that is not included on the label as having been carefully tested in clinical trials may meet with some resistance from your insurance company, even when it is prescribed by a doctor.

Be sure to have a complete conversation with your doctor to make sure that the benefits of this drug or device are likely to outweigh the costs (not just money, but time, pain, and other costs to your life or quality of life). If the two of you are convinced that this is worthwhile, you may still need the doctor to advocate for you with the insurance company.

### 3) More about Bioness

#### A. For Hands

The NESS H200 Hand Rehabilitation System from Bioness, is a non-invasive, advanced neuroprosthesis indicated for the treatment of upper limb paralysis from hemiplegic stroke, traumatic brain injury or C5-C6 spinal cord injury (SCI). The

system contains a custom-fit orthosis [brace] that uses Functional Electrical Stimulation (FES) to sequentially activate muscle groups in the forearm to produce functional movement patterns in the hand.

Key benefits include:

- Neuromuscular re-education
- Prevention or retardation of disuse atrophy
- Reduction of muscle spasm
- Maintenance or increase of joint range of motion\*
- Increase in local blood circulation
- Providing hand function\*

\* in hemiplegia due to stroke and C5 Spinal cord injury

In clinical studies, the NESS H200 has been shown to improve selected hand function in patients with C5-C6 SCI and improve hand and upper limb function associated with chronic post-stroke paresis, as well as selected functional outcomes in stroke patients including ADL grasp, hold, and release tasks. The H200 has also been proven to minimize pain and spasticity in stroke survivors.

For more information on the H200 including full text of clinical studies and prescribing information, please call 1-800-211-9136, option 2 to speak with a Bioness representative. <http://www.bioness.com>

#### **B. For Foot Drop**

The L300 has three main parts that use wireless communication to "talk" to each other. The leg cuff is a small, light-weight device that fits just below the knee and contains electrodes designed to place stimulation where it helps you most. The gait sensor attaches to your shoe and lets the leg cuff know if your heel is on the ground or in the air. The hand-held remote control lets you adjust the level of stimulation and turn the unit on and off. After the initial fitting by your clinician, you just put the cuff on and you are set to go.

The NESS L300 Foot Drop System from Bioness is a non-invasive, advanced neuroprosthesis indicated for treatment of foot drop in patients with stroke, traumatic brain injury (TBI), Multiple Sclerosis, Cerebral Palsy, and incomplete spinal cord injury (SCI).

Key benefits of the NESS L300 include:

- Facilitation of a more normal gait
- Muscle re-education
- Prevention/ retardation of disuse atrophy
- Maintenance/ increase of joint range of motion
- Increase in local blood circulation

The NESS L300 also has a unique gait sensor that adjusts to accommodate uneven surfaces and changes in elevation to help patients walk safely and confidently, regardless of terrain.

The NESS L300 Leg Cuff is a light-weight device that was designed to be comfortable to wear and easy for patients to put on without assistance. The electrodes are located within the custom fitted device; a clinician positions them prior to initial use and once they are in place, patients don't have to reposition them. Ensuring the electrodes are properly placed for each use promotes consistency in stimulation and patient compliance.

The L300 is available by prescription only. For more information about the L300, please call Bioness at 1-800-211-9136, option 2.

#### **4) Billing and reimbursement**

When you use a Bioness system, or any other medical device, it's important to work with your healthcare professional, who will design a special program to help you meet your personal goals. Use of a Bioness system in the clinic setting is billed by your healthcare professional and often reimbursed if it is medically necessary. When a Bioness system is purchased for home use, there is no guarantee that it will be covered, but your health insurance plan may cover some or all of the cost of a Bioness system. Being the technology is new, claims submitted for reimbursement are often evaluated on a case-by-case basis. To find a facility near you that may have a device you can use to try it out, please contact the manufacturer.