

## *News Release*

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\* Photos/B-Roll Available

### **For Immediate Release**

#### **Myomo Announces FDA Clearance of the Myomo e100 NeuroRobotic System,**

***First FDA cleared device to non-invasively use a person's electrical muscle activity to automatically control movement of partially paralyzed arms impaired by stroke***

**BOSTON, MA (July 10, 2007)** -- Myomo,™ Inc. today announced that the company received U.S. Food and Drug Administration (FDA) 510(k) clearance to market the Myomo e100 NeuroRobotic™ System. Myomo's first product is a wearable, portable therapeutic modality designed to allow patients to self initiate and control movement of partially paralyzed limbs using their own biological signals. By simultaneously engaging and reinforcing both neurological and motor pathways, the device helps people relearn how to move affected muscles. No electrical stimulation or invasive procedures are employed.

Relearning how to move hemiparetic arms after stroke is a significant challenge. Stroke is the country's leading cause of long-term disability, affecting 5.7 million people, according to the American Heart Association<sup>1</sup> ([www.strokeassociation.org/](http://www.strokeassociation.org/)). Research indicates that up to 85% of stroke survivors show initial deficit in the upper limb and recovery of upper limb function is seen in less than half of the patients<sup>2</sup>. Only 5% of survivors regain full arm function after stroke.<sup>3</sup>

"Loss of movement after stroke is due to damage of brain tissue that controls that segment of the body," said Joel Stein, M.D., Chief Medical Officer and Stroke Program Director, Spaulding Rehabilitation Hospital ([www.spauldingrehab.org/](http://www.spauldingrehab.org/)) of Boston, MA, one of the first medical facilities to clinically treat stroke patients with the Myomo system. "Since the neurological pathway is damaged, the patient can't effectively control his or her weak muscles, resulting in partial paralysis."

Clinical studies show that intense repetitive exercise training may facilitate neural plasticity with concomitant improved motor abilities and enhanced functional performance.<sup>4</sup>

"By providing patients the ability to complete intended movement through its 'power assist' function, the Myomo device helps the feedback cycle to the brain, facilitating a patient's ability to improve performance through practice," added Dr. Stein. "The theory is that by facilitating the patient's ability to practice tasks repeatedly, new connections are formed in the brain and existing connections are reinforced, resulting in improved ability to move the arm."

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<sup>1</sup> American Heart Association. *Heart Disease and Stroke Statistics - 2007 Update*

<sup>2</sup> Chen J.C., et al. *Stroke* 2005;36:2665-2669

<sup>3</sup> Gowland C., et al. *Phys Ther.* 1992; 72:624-633

<sup>4</sup> Liepert J., et al. *Stroke* 2000;31:1210-6.

## **How the Myomo e100 NeuroRobotic System Works**

Myomo's therapeutic modality uniquely uses a person's electrical muscle activity signal (EMG) to automatically apply a power assist to facilitate movement of weakened muscles. Through Myomo's patent-pending NeuroRobotics technology, the device detects a person's muscle signal from the skin's surface, and then employs proprietary system software and advanced robotics to allow patients to initiate and continuously control movement of the hemiparetic limb. With this capability, the Myomo e100 NeuroRobotic System is designed to improve and facilitate movement through a feedback-based, closed loop system that both amplifies and rewards a patient with motion in concert with his or her own muscular activation. Wearable, and portable, the device is designed to enable goal-oriented therapy exercises in seated, standing or ambulatory positions, depending on patient skill level.

“We are excited about the Myomo technology since its unique combination of EMG control and portable robotics may improve functional upper extremity motor recovery and function after a neurologic injury,” said Dan Parkinson, P.T., Director of Clinical Services, Braintree Rehabilitation Hospital ([www.braintreerehabhospital.com/](http://www.braintreerehabhospital.com/)), Braintree, MA, and site investigator of the Myomo Functional Task Study. “By providing a tool for therapists to actively engage patients in high dosage, repetitive, meaningful tasks, the Myomo device holds great potential in helping neurologically impaired patients achieve better function.”

## **The Benefits of Patient Controlled Movement**

The Myomo device is designed to provide power assist only if and while a patient's muscles are firing as he or she attempts movement during a therapy session. With this capability, patients have an opportunity to stop, in real time, during execution of a targeted training task, to evaluate performance and re-adjust positioning, as they train toward muscle re-education.

“The patient-controlled aspect of the Myomo device is unique and potentially very motivating for stroke patients who must work hard to recover,” said Paul Petrone, O.T. Practice Leader, Stroke Program, Spaulding Rehabilitation Hospital ([www.spauldingrehab.org/](http://www.spauldingrehab.org/)), and co-investigator of the Myomo inpatient pilot stroke study. “When a patient can attempt movement, and see that they themselves can make their own arm move, their attention and focus is so great that they have already made a huge leap forward. Directing attention to the affected limb also holds tremendous potential for stroke patients who may suffer from “neglect,” a common stroke syndrome where a patient may behave as though one whole side, including his or her body, does not exist.”

## **An Opportunity to Improve Patient Independence**

The Myomo e100 NeuroRobotic System is created to assist therapists in achieving optimal, goal-oriented outcomes with stroke patients. Through its portability and ability to seamlessly interface into a variety of clinical settings, the device can be used to facilitate a range of therapeutic strategies. The device can help patients progress from basic motor training to more complex multi-plane movement patterns when used by patients were their treating clinician.

“The Myomo device provides an opportunity for patients to be able to become more independent,” said Steve R. Williams, M.D., Chief and Chairman, Department of Physical Medicine and Rehabilitation, Boston Medical Center ([www.bmc.org/](http://www.bmc.org/)), Boston, MA. “The sophistication of its electronics picks up early muscle movements and allows patients to activate muscles to become more functional faster. From a clinical perspective, it is compact and relatively easy to use, eliminating the costs and complexity associated with traditional equipment.

## **Clinical Research**

Research studies at MIT and Spaulding Rehabilitation Hospital showed significant gains in motor control and clinically relevant decreases in muscle hypertonicity when the Myomo device was used by severely impaired chronic stroke patients (1.5-10 years post CVA). The size of improvement found in the upper extremity component of the Fugl Meyer scale represented a 23% increase in the severely impaired patient sample (from a mean of 15.5 before treatment to a mean of 19 at the end of treatment).

Based on these results, some clinical experts have suggested that the Myomo device may serve as a therapy gateway for severe chronic patients who are so impaired that they currently are ineligible for other upper extremity stroke treatments.

“As a company, we are dedicated to providing a new category of NeuroRobotic devices, like the Myomo e100, to help improve mobility in persons who suffer from muscle weakness or partial paralysis,” said Steve Kelly, Chairman and CEO of Myomo. “Our first product represents the culmination of years of research and development pioneered at the Massachusetts Institute of Technology in collaboration with prominent medical experts affiliated with Harvard University and Boston area hospitals. With FDA clearance, we are thrilled to be able to expand the use of the product to a broader population.”

## **About Myomo**

Myomo, Inc. ([www.myomo.com](http://www.myomo.com)) is a medical device company with the mission of restoring independence for individuals who suffer from loss of neurological function or debilitating muscle weakness. Through the company’s patent-pending NeuroRobotics platform technology, Myomo devices facilitate and improve movement by enabling individuals to initiate and control affected muscles using their own biological signals. No electrical stimulation or invasive procedures of any kind are required. Myomo, which is the acronym for “My-Own-Motion,” has been developing NeuroRobotics technology since 2002 based on research pioneered at MIT by Myomo co-founders. Myomo is a privately held medical device technology company and is headquartered in Boston, MA. For more information, visit [www.myomo.com](http://www.myomo.com).

*CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician or physical therapist.*

*NOTE: The Myomo e100 System is intended for clinical use by patients with their treating medical professional. The device has not been shown to be safe or effective as a functional aid for use in the home.*

*NOTE: Clinical studies to date have not demonstrated any known side effects or risks associated with the use of the device by stroke patients in therapy.*

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