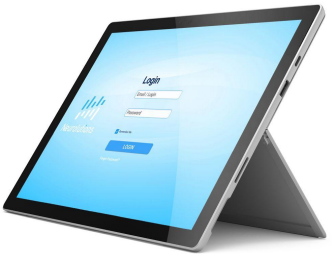
Neurolutions Upper Extremities Rehabilitation System

The Neurolutions IpsiHand Upper Extremity Rehabilitation System is a breakthrough medical device designed to improve the treatment of upper extremity hemiparesis post-stroke. This breakthrough technology has been granted a De Novo breakthrough status, a special designation given to medical devices that provide a significant improvement over existing options for treating a specific condition. As a class II medical device, the IpsiHand System has undergone rigorous testing and evaluation to ensure its safety and effectiveness, meeting the high standards set by the FDA for medical devices in this category. The recognition by the FDA highlights its importance in the field of neurorehabilitation, and underscores its potential to revolutionize the way we treat patients with hemiparesis post-stroke.

What is the IpsiHand System?
The IpsiHand system is a three-part system which includes a dry electrode (no gel required) EEG headset, a motor controlled handpiece worn over the patient's arm/hand, and a standard Windows Tablet to guide the patient through their therapy.

Headset

Handpiece



Windows Tablet

How does IpsiHand therapy work?
The IpsiHand System's Headset, which contains dry electrode electroencephalographic (EEG) sensors, receives electrical signals from the motor or pre-motor cortex of the patient's unaffected hemisphere of the brain, and detects the patient's intentions to move their affected hand. When those brain signals are detected by the Headset, those signals are translated into motor movements of opening and closing of the patient's hand using a motor driven handpiece. The motion of the Handpiece, in turn, opens and closes the patient's impaired hand, enabling them to initiate motor movements of their impaired arm/hand they might not otherwise have been able to complete.

The IpsiHand System functions as a course of upper extremity rehabilitation for the patient's hand using three separate modes: Thought Mode, Stretch Mode, and Active Mode.

Thought Mode: Thought Mode, the main mode of therapy, uses brain-computer interface (BCI) technology to referred to as the brain-computer interface (BCI) or 'thought' mode, where the patient's hand is opened or closed by the Handpiece dependent on brain signals received from the headset.

Stretch Mode: This mode provides comfortable continuous passive motion (CPM) mode in a repetitive fashion. This mode is often used to prime and stretch a patient's hand prior to their therapy.

Active Mode: This 'volitional' mode allows a patient to actively open and close their hand with the system enabling active assisted range of motion.

What is the Clinical Evidence and Patient Outcomes of IpsiHand?
The IpsiHand system has undergone rigorous testing and evaluation to ensure its safety and effectiveness. Results of testing demonstrate that following 12-weeks of use of the Neurolutions System, chronic stroke survivors showed increases in the mean change from their baseline scores on the primary outcome measure for the three respective studies. Ten of the total 40 subjects were assessed utilizing the Action Research Arm Test (ARAT) as the primary outcome measure and the mean scores exceeded the Minimal Clinically Important Difference (MCID) of 5.7 points. In the two other studies, 30 of the total 40 subjects were assessed utilizing the Fugl-Meyer Upper Extremity (UEFM) assessment as the primary outcome measure. For 66.7% of these 30 subjects, mean scores exceeded the MCID of 5.25 points. On average, the improvement on the UEFM was +7.77 points. No patient injury or adverse events occurred in any of the studies. Upon follow up 6 months after using the device, gains in the upper extremity remained consistent, unique to the system in comparison with other rehabilitation technologies which have no carryover in function. While adverse reactions reported during the study included slight fatigue, discomfort, and temporary skin redness after use, the benefits of using the device far outweigh the risks.

Convenience and Ease of Access
Unlike other BCI based technologies, the IpsiHand system is a non-surgical, non-invasive technology that can be used independently by patients at home. This provides convenient access to therapy at home with the intensity required for motor improvement, which is often not achieved in outpatient therapy alone. Additionally, the IpsiHand system can be set up with one hand, and the user interface is made specifically for individuals in this patient population to provide the highest level of independence to complete their therapy. This

feature allows intensive therapy to be completed without direct supervision of an occupational and/or physical therapist.

This feature not only provides greater convenience to patients, but also has the potential for significant cost savings compared to other neuro-technologies that require direct supervision by a licensed occupational and/or physical therapist. The IpsiHand System represents a promising option for stroke survivors to improve their upper extremity function and subsequent quality of life using home-based rehabilitation technology.

Conclusion

In conclusion, the IpsiHand Upper Extremity Rehabilitation System is a groundbreaking medical device that provides a significant improvement in the treatment of hemiparesis of the upper extremity post-stroke. Its non-invasive approach, home-based therapy option, and potential to improve the quality of life for stroke patients make it an essential tool for neurorehabilitation. With the FDA granting market authorization, the IpsiHand is poised to make a significant impact in the lives of stroke patients and their families.

Christopher M. Loftus, M.D., acting director of the Office of Neurological and Physical Medicine Devices in the FDA's Center for Devices and Radiological Health released the following statement,

"*Thousands of stroke survivors require rehabilitation each year. Today's authorization offers certain chronic stroke patients undergoing stroke rehabilitation an additional treatment option to help them move their hands and arms again and fills an unmet need for patients who may not have access to home-based stroke rehabilitation technologies,*" - FDA Release Statement

If you require any additional information, please don't hesitate to contact us,

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