



**FDA Device Indication:**

The Neurolutions IpsiHand Upper Extremity Rehabilitation System is indicated for use in chronic stroke patients (≥ 6 months post-stroke) age 18 or older undergoing stroke rehabilitation, to facilitate muscle re-education and for maintaining or increasing range of motion in the upper extremity.

### PATIENT INFORMATION

FIRST NAME \_\_\_\_\_ LAST NAME \_\_\_\_\_

ADDRESS \_\_\_\_\_ CITY \_\_\_\_\_

STATE \_\_\_\_\_ ZIP \_\_\_\_\_

ICD-10 CODE \_\_\_\_\_ BIRTHDATE \_\_\_\_/\_\_\_\_/\_\_\_\_  
MM DD YYYY

### HEALTH CARE PRACTITIONER

FIRST NAME \_\_\_\_\_ LAST NAME \_\_\_\_\_

NPI NUMBER \_\_\_\_\_ EMAIL \_\_\_\_\_  
NATIONAL PROVIDER IDENTIFIER 10-DIGIT NUMBER

ADDRESS \_\_\_\_\_ CITY \_\_\_\_\_

STATE \_\_\_\_\_ ZIP \_\_\_\_\_ PHONE \_\_\_\_\_

APPEAL STATUS      Submitted to Insurance      Will Submit to Insurance      N/A

### PRESCRIPTION ITEM

LEFT OR RIGHT SIDE

IpsiHand Upper Extremity Rehabilitation System

Left

Right

DATE

\_\_\_\_/\_\_\_\_/\_\_\_\_  
MM DD YYYY

\_\_\_\_\_  
HCP SIGNATURE

# Medical Necessity and Clinical Efficacy

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## FDA Designation:

- **Exclusive FDA Market Authorization:** IpsiHand stands alone as the first and only non-invasive brain-computer interface (BCI) therapy to obtain FDA market authorization. It is important to highlight that **there are no comparable therapeutic alternatives** in the market for its specific indication.
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## Clinical Efficacy and Safety:

- **Superior UEFM Outcomes:** The device remarkably outperforms standard care, achieving an average improvement of **7.7 UEFM points** over 12 weeks. The minimal clinically important difference (MCID) for UEFM is +5.25, indicating significant clinical benefit.
  - **Durable and Retained Gains:** Functional improvements extend to the hand, wrist, and arm, and are retained post-therapy, signifying durable, long-term benefits.
  - **Zero Adverse Events:** Clinical studies report **no patient injury or adverse events**, solidifying its safety profile.
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## Mechanism of Action and Neuroplasticity

- **Proprietary Prosthetic Motor Circuit:** IpsiHand employs a unique prosthetic motor circuit, corroborated by functional MRI and electrophysiological studies, that effectively remodels the brain.
  - **Reset in Phase Amplitude Coupling:** The therapy induces significant changes in phase amplitude coupling between theta and gamma rhythms, directly correlating with motor recovery.
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## Patient Population and Home-Based Therapy

- **Addresses Underserved Population:** Indicated for **chronic stroke patients (≥ 6 months post-stroke) aged 18 or older**, it serves an often-neglected demographic with limited therapeutic options.
  - **Self-Administered Home Therapy:** IpsiHand offers the convenience of self-administered, home-based therapy, requiring just one-hour modules five days per week.
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