



Insertion of Brain-Computer Interface (BCI) Implant

Neuralink N1 Implant

ICD-10-PCS Coordination & Maintenance Committee Update | Fall 2026

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Clinical Need: Patients with Severe Motor Impairment

Conditions	Estimated United States (US) Prevalence
Amyotrophic Lateral Sclerosis (ALS)	~34,000 ¹
Spinal Cord Injury (SCI)	~311,650 ²

1. Mehta P. et al., 2025
2. National Spinal Cord Injury Statistical Center, 2025

Overview of the N1 (BCI) Implant

Intracortical BCI implant enabling functional digital device control in adults with motor paralysis. The N1 Implant decodes movement intent into cursor control, keyboard input, and application access - without physical movement.

- **N1 Implant (Electrode Array + BCI Unit):** surgically placed component; charger & user application are external
- **Electrode Array:** 1,000+ intracortical recording electrodes across 100+ highly-flexible, ultra-thin threads
- **BCI Unit:** Skull-mounted, wireless, externally rechargeable, hermetically-sealed enclosure
- **FDA Breakthrough Device Designation(s):** July 2020 (digital device control) | April 2025 (speech)
- **Ongoing US Early Feasibility Studies:**
 - PRIME (NCT06429735) | VOICE (NCT07224256) | CONVOY (NCT06710626)
- **Ongoing International Early Feasibility Studies:**
 - CAN-PRIME (NCT06700304) | GB-PRIME (NCT07127172) | UAE-PRIME (NCT06992596)

Neuralink Medical Devices (Investigational)



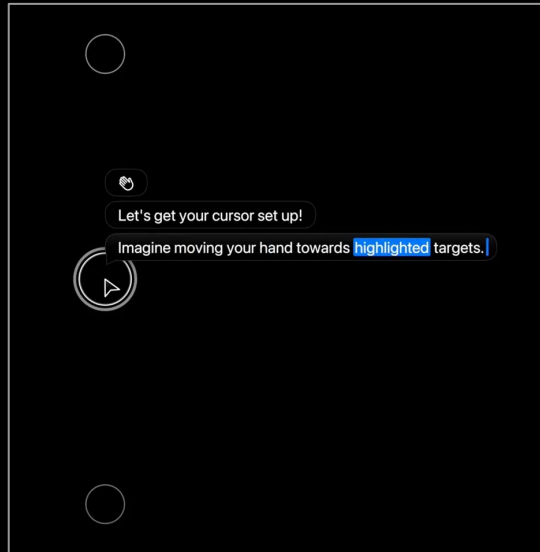
N1 Implant

Fully implantable, wireless BCI
device reads brain signals



R1 Robotic System

Surgically implants the N1 device
threads with micron precision



Neuralink Software Application

Neural decoding software translates
brain signals into useful outputs

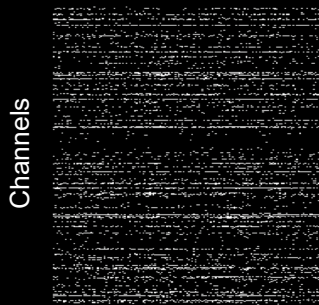
Translating Neural Activity Into Actions

N1 Implant



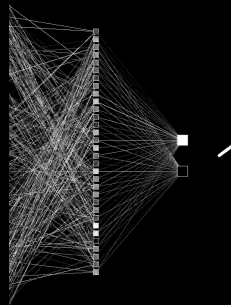
Electrode array implanted in motor cortex and BCI unit mounted on skull

Neural Activity



Electrodes enable high-bandwidth recording of brain spiking activity

Decoding Algorithm



ML models translate spike patterns into movement intentions

Device Control



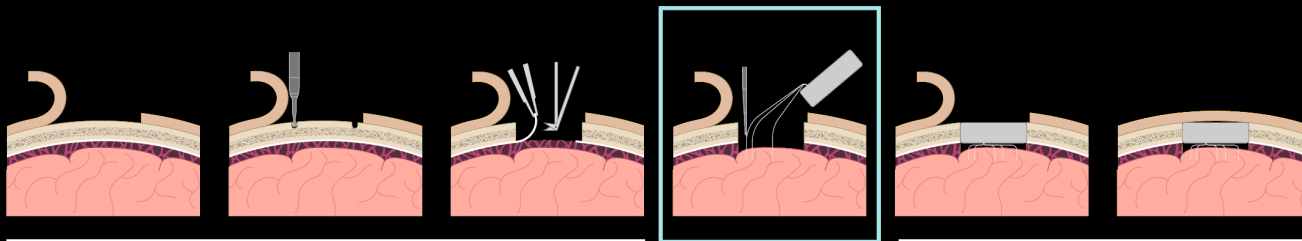
Decoded intent drives real-time control of cursors and digital interfaces

Summary of N1 Device Implantation Procedure

Performed under the supervision of a neurosurgeon using the R1 Robotic System

Primarily expected to be a hospital inpatient procedure

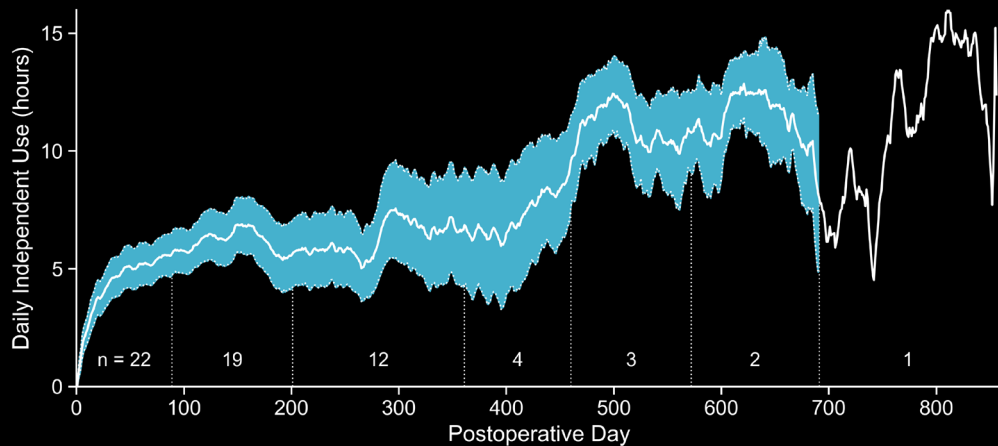
1. Pre-operative imaging and surgical targeting plan
2. Craniectomy and durectomy (if indicated)
3. Insertion of electrode array threads utilizing R1 Robotic System into motor cortex
4. N1 Implantable Device mounted and secured to skull
5. Scalp skin closed



Restoring Autonomy

Early feasibility study (EFS) clinical trial participants demonstrate real-world functional restoration of digital activities of daily living (ADLs)

Independent home use with real-time cursor and keyboard control



Notes: Mean (line) ± 1 SEM (band) of daily independent use (i.e., total inference time) vs. days since implantation; 21-day moving average; band shown where $N \geq 2$ (N = enrolled participants per interval). All PRIME participants; no outlier exclusions. Data cutoff 2026-06-02

25+

Humans using Neuralink

0

Device-related SAEs

>45,000

Neuralink hours of use

>10,000

People on patient registry



Enabling Accurate Hospital Coding

Documentation	Rationale for New Code Request
Operative Report Procedure description, device name, electrode insertion into motor cortex, robotic use Terms Used in Operative Records N1 Implant Brain-computer interface Intracortical BCI Neural recording and processing unit Brain-machine interface	Existing codes do not capture the BCI unique approach: robotic thread insertion, intracortical electrode placement, skull-mounted BCI unit