

## BrainGate Neural Interface System

### Surgical Method Development

Intended to meet human neurosurgical standards.

- Acceptable surgical time
- Standard operative tools
- Minimal foreign materials

BrainGate Cable Assembly

BrainGate Cart

### Design Concepts and Issues

**Neural Sensor** → **Decoder** → **Action**

Thoughts →  $V_i = A \cdot c_i$  → Hand motion → Vector of firing rates → Max. Information → Action

**Principles of Interaction** → **Neural Interpreter 'gateway'** → **Action**

**Assistive software:** Typing, Web Browser, Speech x10

**Assistive technology:** Wheelchairs, Semiautonomous robots, Robotic limbs

*What technology?*

## Preclinical Safety

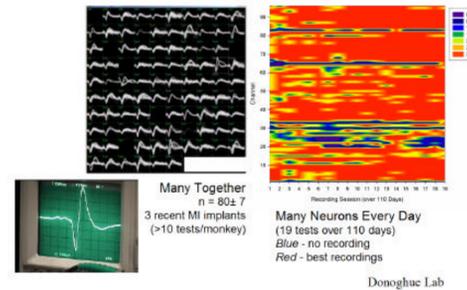
### Overview of non-human primate experience

39 implants in 17 macaque monkeys (February 1999-April 2003)

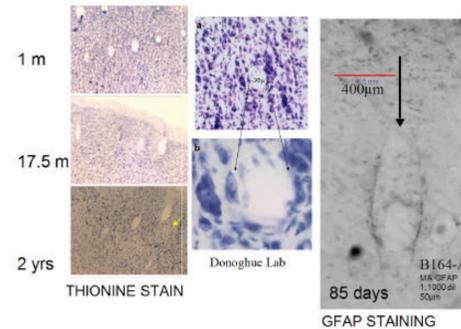
Implant Group	Number of Animals	M1 Implants	Implants Not M1	Minor AE (Skin infection, Erosion, or Connector issue)	Major AE (Infectious focus, necrosis, or seizure)	Duration (Days)
Prior (epi-her coating, all locations)	13	14	11	22	3	1098
Recent (paralene, all locations)	8	6	5	9	0	310
Relevant (paralene, M1)	5	6	-	7	0	385...

Three most recent implants (ongoing) 187, 250, 385 days (L, C, R)

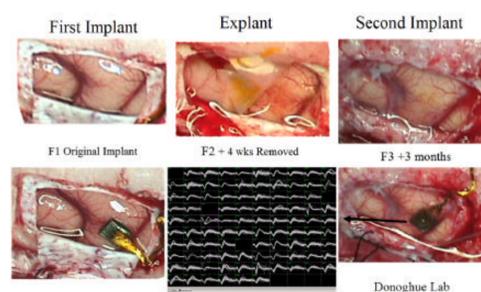
### Long-lasting Recordings From Many Electrodes



### Histology

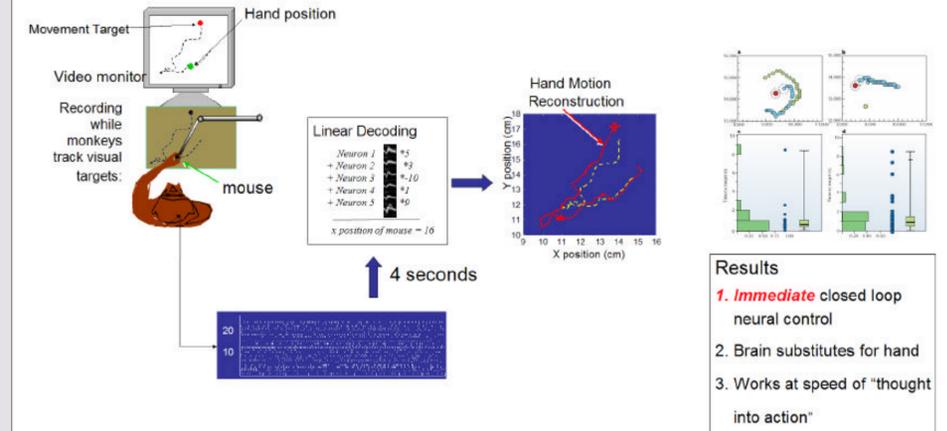


### Removal and Reimplantation



## Preclinical Proof of Concept

### Decoding Hand Motion from Ensemble Spiking



## Transition to Human Studies

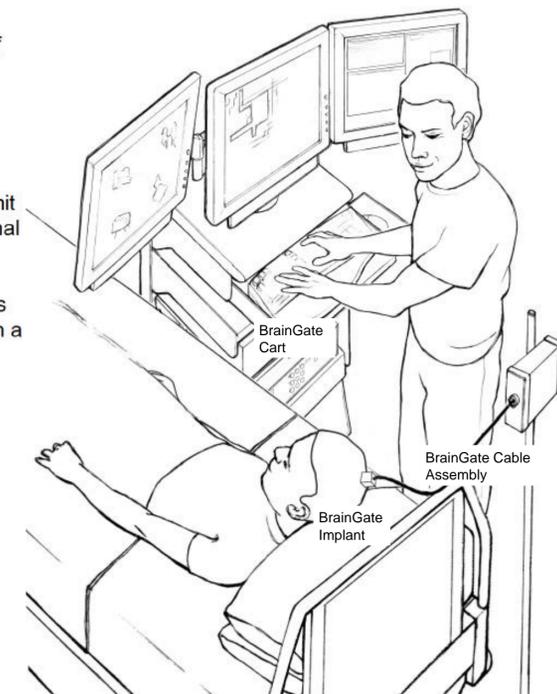
- Proof of concept achieved for a preclinical system
  - Record from appropriate cortical area
  - Decode
  - Use
- Extensive preclinical data
  - Implantation
    - Successful and reversible
    - Long term safety indications
    - No detectable motor control
    - Recording without significant adverse events
    - Histology -minimal tissue reaction
- Pilot device designed for human use
  - Implant
    - Biocompatibility testing
    - Mechanical testing
    - Lifetime testing
    - Sterility testing
  - Cable Assembly
    - Electrical testing
    - Mechanical testing
  - Cart
    - Electrical testing
    - Mechanical testing
    - Software testing
  - System
    - Overall verification and validation
    - Simulation testing

## Proposed Pilot Clinical Plan (Subject to FDA Review)

- Feasibility trial with small number of severely paralyzed patients
- Safety protocol
- Proof of Principle protocol

### Future Goals

- Use **wireless technology** to transmit information from the implant to external components.
- **Reduce the size of components**
- **Automate** operator-assisted actions and/or control these remotely through a **telemonitoring system**.



## Communication Requirements of Motor Impaired Patients

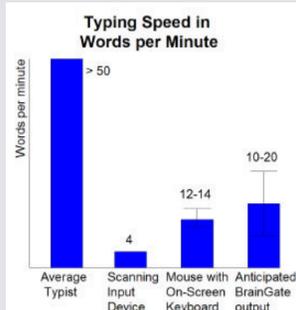
\*Note: The BrainGate is not a human investigational device in the United States. An IDE application has not yet been filled with the FDA. This poster is informational only and is intended to present the overall status of development of the product at Cyberkinetics Inc.

cerebral palsy  
cerebellar disorders  
locked-in syndrome  
other stroke  
spinal cord injury  
spinal muscular atrophies  
ALS  
muscular dystrophy  
limb loss  
multiple sclerosis

Many neurological disorders disrupt the ability to move or communicate, but leave cognition intact

### Current assistive strategies

- Rely on limited number of intact muscles to perform alternate tasks
- Use externally mounted equipment
- Require frequent adjustment
- Slow communication rate



Right chart: Typing Speed Estimates were retrieved from the following two sources:  
[http://www.cc.gatech.edu/classes/AY2003/cs4750b\\_spring/lectures/32](http://www.cc.gatech.edu/classes/AY2003/cs4750b_spring/lectures/32)  
Melissa Schor, *Hands Free Writing Software May Aid Disabled Users*, AT Journal, vol. 56, September 1 2002