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NeuroControl

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November 21, 2000

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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Rm. 1-23
12420 Parklawn Drive
Rockville, MD 20857

CITIZEN PETITION

The undersigned submits this petition under 21 CFR § 898.14 to request the Commissioner of Food and Drugs to allow a variance for NeuroControl Corporation to extend the effective date of 21 CFR § 898 – “Performance Standard for Electrode Lead Wires and Patient Cables” from May 9, 2000 to June 30, 2001 for the Electrode Positioning Kits sold as surgical tools as part of the FREEHAND® System. NeuroControl Corporation, 8333 Rockside Road, Valley View, OH 44125, 216-912-0101 is the manufacturer and distributor of the FREEHAND® System implantable hand grasp neuroprosthesis that is intended to enable persons with C5/C6 level spinal cord injury to grasp, hold, and release objects. The FREEHAND® System was approved under PMA #P950035 on August 15, 1997, and is a class III device.

A) Action Requested

NCC would like to submit a petition to the FDA that the FREEHAND® Electrode Positioning Kits be exempt from 21CFR § 898 – “Performance Standard for Electrode Lead Wires and Patient Cables” in that it meets criteria addressed in a related guidance that exempts part of this kit. According to “Guidance on Electro-Surgical Devices and the Application of the Performance Standard for Electrode Lead Wires and Patient Cables,” issue date 11-15-99, the cathode end is under direct control of the surgeon when it is contact with the patient, and is therefore exempt from the performance standard. The Epimysial Mapping Probe that is part of the Electrode Positioning Kits essentially an Epimysial Electrode with a handle attached. The surgeon uses this probe to identify optimum locations for electrode placement. The Electrode Clip lead is a short patch cord that connects the Surgical Stimulator to an Epimysial Electrode to verify that the electrode elicits the desired muscle contraction. With this in mind, the Epimysial-mapping probe (used with the substitute anode) is exempt from this requirement in that it is under the control of the surgeon.

The Substitute Anode (which is also connected to the surgical stimulator) is a disposable anode electrode that is used intro-operatively with the Surgical Stimulator and is the same dimensions as the exposed anode of the Implantable Receiver-Stimulator. It is placed into the subcutaneous implant pocket in place of the Implantable Receiver Stimulator (IRS) while the electrodes are being placed. Unlike a dispersive electrode patch, this anode is also under the control of the surgeon at all times. The device is used entirely inside the sterile field

The cabling on both cathodes and the anode is long enough for the surgeon to reach from the distal electrode placement locations for stimulus mapping (in the hand) to the

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stimulator and from there to the implant pocket in the region of the clavicle for the substitute anode. See the attached instructions for use located in the FREEHAND® Clinicians Manual.

B) Reason for Request

NCC for the above-mentioned reasons believes that the safety issues addressed by the mandatory performance standard are not present with the FREEHAND® Electrode Positioning Kits. NCC has an inventory of ~25 Electrode Positioning Kits that do not contain compliant lead connectors. These kits are manufactured, Sterilized (EtO), and sold as single use devices. Their average usage time is approximately four hours. The connectors have since been modified to touch proof connectors. This change was made concurrently with other changes including PCB changes for internal standardization. It would not be cost effective to rework the remaining kits, repackage them and resterilize them.

C) Environmental Impact

There is no environmental impact statement required

D) Economic Impact

There is no economic impact statement required.

E) Certification

The undersigned certifies, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that in includes representative data and information known to the petitioner which are unfavorable to the petition.



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NeuroControl Corporation

The Freehand System

Clinician Manual

1/99

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

**NeuroControl Corporation
Cleveland, Ohio USA
Brussels, Belgium**

The authorization to affix the CE Marking, in accordance with the Active Implantable Medical Device Directive (90/385/EEC), for products referenced in this manual was received in 1999.

(P/N 1703-C: Clinician Manual + Clinician's Programming Manual)



NeuroControl Freehand System Clinician Manual

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1.0 INTRODUCTION

This manual is intended to be used as a reference by clinicians that have successfully completed NeuroControl Corporation's Freehand System training program. It provides guidance in the implementation and operation of the Freehand System.

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician or a properly licensed practitioner.

1.1 Device Description

The NeuroControl *Freehand System*® is a RF powered motor control neuroprosthesis, which consists of both implanted and external components. It utilizes low levels of electrical current to stimulate the peripheral nerves that innervate muscles in the forearm and hand providing functional hand grasp patterns. The NeuroControl Freehand System consists of the following subsystems:

- The **Implanted Components** include the Implantable Receiver-Stimulator, Epimysial Electrodes, and Connectors (Sleeves and Springs).
- The **External Components** include the External Controller, Transmit Coil, Shoulder Position Sensor, Battery Charger, and Remote On/Off Switch.
- The **Programming System** consists of the Pre-configured Personal Computer loaded with the Programming Interface Software, the Interface Module, and a Serial Cable.
- The **Electrode Positioning Kit** includes the Surgical Stimulator, Epimysial Probe, Anode Plate, and Clip Lead.

1.2 Intended Use / Indications

The NeuroControl *Freehand System*® is intended to improve a patient's ability to grasp, hold, and release objects. It is indicated for use in patients who:

- are tetraplegic due to C5 or C6 level spinal cord injury (ASIA Classification)
- have adequate functional range of motion of the upper extremity
- have intact lower motor neuron innervation of the forearm and hand musculature and
- are skeletally mature

1.3 Contraindications

The NeuroControl *Freehand System*® is contraindicated in patients with the following characteristics:

- uncontrolled spasticity (upper extremity)
- active or recurrent sepsis
- implanted cardiac pacemaker

1.4 Warnings

The *Freehand System*® may only be prescribed, implanted, or adjusted by clinicians that have been trained and certified in its implementation and use.

- **Magnetic Resonance Imaging (MRI):** Do not expose patients to MRI. There are potential effects of induced currents and radio frequency heating of the device when exposed to magnetic fields and radio frequency fields associated with MRI systems which may result in patient injury.
- **Monopolar Electrosurgical Instruments** should not be used on the implanted upper extremity. These instruments could damage the Implantable Receiver-Stimulator. Bipolar electrosurgical instruments can be used safely in coagulating mode.

- **Electrostatic Discharge (ESD)** may damage the Freehand Implantable Receiver-Stimulator during intraoperative handling. Handle only as instructed in the Clinician's Manual.
- **Neuromuscular Blocking Agents** (long acting) should not be administered during implantation surgery. These agents render nerves unresponsive to electrical stimulation and may compromise the proper installation of the device.

1.5 Precautions

- **Surface Stimulation:** Electrical surface stimulation (muscle stimulator, EMG, or TENS) should be used with caution on or near the instrumented upper extremity as it may damage the system. Contact NeuroControl prior to applying surface stimulation.
- **X-rays, mammography, ultrasound:** X-ray imaging (e.g., CT or mammography), and ultrasound have not been reported to affect the function of the Implantable Receiver-Stimulator or Epimysial Electrodes. However, the implantable components may obscure the view of other anatomic structures.
- **Antibiotic prophylaxis:** Standard antibiotic prophylaxis for patients with an implant should be utilized to protect the patient when invasive procedures (e.g., oral surgery) are performed.
- **Ultrasound:** Therapeutic ultrasound should not be performed over the area of the Implantable Receiver-Stimulator or Epimysial Electrodes as it may damage the system.
- **Diathermy:** Therapeutic diathermy should not be used in patients with the *Freehand System*[®] as it may damage the system.
- **Therapeutic Radiation:** The electronic components in The Freehand System may be damaged by therapeutic ionizing radiation. The damage that occurs may not be immediately detectable. Any changes in sensation or muscle contraction should be reported to the clinician. If the changes are painful or uncomfortable, the patient should stop using The Freehand System pending review by the clinician.
- **Invasive Procedures:** To avoid unintentional damage to implanted components, invasive procedures such as drawing blood or administering

an intravenous infusion should be avoided on the implanted arm or in the area of the Implantable Receiver-Stimulator or near sites of the Epimysial Electrodes.

- **Serum CPK levels:** Exercise and muscle activity are known to cause changes in certain blood enzymes measured by standard laboratory and clinical tests, such as serum CPK. Exercise, whether volitional or induced by electrical stimulation, may produce elevated serum CPK levels. If a Freehand System patient has elevated CPK, fractionation is indicated to differentiate between CK-MM from skeletal muscle and CK-MB from cardiac muscle that could be the result of cardiac injury.
- **Drug Interactions:** Muscle inhibitors and muscle relaxants may affect the strength of muscle contraction achieved using the Freehand System. It is recommended that these medications be stabilized prior to implementing the Freehand System so that muscle response to electrical stimulation can be accurately evaluated.
- **Electrostatic Discharge (ESD)** exposure can cause loss of current amplitude programmability which also produces stimulus current amplitude higher than default. This does not result in any increased safety concerns from stimulation, has not caused compromise in hand function, and device operation will remain stable in this mode of operation. If a patient indicates that an increase in grasp strength is suddenly observed, this malfunction mode should be considered and evaluated. Changes in hand grasp can be managed by reprogramming grasp patterns, usually lowering stimulus pulse widths.
- **Pacemaker Warning Areas:** Patients should avoid areas posted with a warning to persons who have an implanted pacemaker. Contact NeuroControl Corporation for additional information.
- **Studies have not been conducted** on the use of the *Freehand System*® in patients with the following conditions:
 - children who are skeletally immature (usually males < 16 years, females < 15 years)
 - prior history of a major chronic systemic infection or other illness that would increase the risk of surgery
 - poorly controlled autonomic dysreflexia

- seizures and balance disorders
- pregnancy

Risks and benefits in patients with any of these conditions should be carefully evaluated before using the *Freehand System*®

- **Safety critical tasks:** Patients should be advised to avoid performing tasks which may be critical to their safety, e.g., controlling an automobile (throttle or brake), handling an object that could injure the patient (scald or burn), etc.
- The patient should be advised to avoid the use of a compression cuff for measuring **blood pressures** on the arm in which the *Freehand System*® is implanted.
- **Post-operatively**, the patient should be advised to check, daily, the condition of his or her skin across the hand, across the volar and dorsal aspects of the forearm, and across the chest where the *Freehand System*® Receiver-Stimulator, leads and Electrodes are located for signs of redness, swelling, or breakdown. If skin breakdown becomes apparent, patients should contact their clinician immediately. The clinician should treat the infection, taking into consideration the extra risk presented by the presence of the implanted materials.
- **Keep it dry:** The user should avoid getting the external components, cables, and attachments of the *Freehand System*® wet.
- The patient and caregiver should be advised to **inspect the cables and connectors**, prior to each use, for fraying or damage and replace components when necessary.
- The *Freehand System*® should be turned off during any **therapeutic or diagnostic procedures** to assure that the radio frequency of the *Freehand System*® does not interfere with the procedure.
- The *Freehand System* has been tested and found to comply with applicable US and International limits for radio frequency emissions. The *Freehand System*, however, does generate and use radio frequency energy which may cause interference to radio communication devices if the *Freehand System* is not used according to instructions. Most importantly, only the *Freehand Transmitter Coil* should be attached to the associated connector on the *External Controller*.

These limits are designed to provide reasonable protection against harmful interference in residential settings (for the Patient System) and in commercial settings (for the Programming System). Such interference, however, is still possible with some radio or television receivers that are very close to the Freehand System. Should such interference be suspected, it may be minimized or eliminated by moving away from the receiver, or by relocating or re-orienting the receiver's antenna.

The use of the Freehand System aboard a commercial airline should be considered on a case by case basis. Specifically, the system should be turned OFF until the flight crew informs the passengers that the use of personal computing and electronic devices is allowed. The system should then be used only after advising the flight crew that your system might interfere with the radio-navigation equipment of the aircraft and that you will discontinue its use if such interference is identified by the flight crew.

For additional information, please contact NeuroControl Corporation.

1.6 Adverse Events

The Freehand System clinical trial involved 62 devices implanted in 61 patients and 128 cumulative implant years (median implant duration = 1.6 years, range <1 month to 11 years). Adverse events (AEs) reported from this clinical trial included 15 AEs requiring surgery and 79 AEs not requiring surgery. One patient died during the course of this trial. This death was due to cardiac arrest and judged to be unrelated to the device.

1.6.1 Observed Adverse Events

The tables below reports these events and the percent of patients involved for the events requiring surgery and the AEs not requiring surgery.

Table 1. Tabulation of Adverse events

All patients implanted, N=61, 128 implant years

AEs requiring surgery	# Events	# Patients	% of Patients
Receiver reposition or replaced	3	3	5%
Skin opening repaired	4	4	7%
Electrode breakage	3	3	5%
Infection requiring electrode removal	3	3	5%
Infection requiring system explant	1	1	2%
Tendon adhesion	1	1	2%
Total	15	12	20%

AEs – Nonsurgical	# Events	# Patients	% of Patients
Swelling/discomfort over implantables	23	13	21%
Skin irritation from externally applied products	15	14	23%
Irritation from incisions or sutures	13	10	16%
Skin irritation from splints/casts	11	6	10%
Inadvertent excitation of elbow flexors	9	5	8%
Sensation over implant anode during stimulation	5	5	8%
Thumb k-wire snagged	1	1	2%
Splint caught in eye	1	1	2%
Sensation under coil	1	1	2%
Sensation on tongue through metal	1	1	2%
Cigarette burn in hand	1	1	2%
Total	79	31	51%

Adverse Events Requiring Surgery

Infections: Four subjects experienced infections at the electrode sites during the clinical study. Three of the four were local infections, which required only electrode removal. In one case, the entire implant had to be removed.

Receiver-Stimulator Repositioned: The Receiver-Stimulator had to be repositioned in three different subjects. In two cases the device rotated along its axis, and in one case it was repositioned because the electrodes were too tight across the axilla and restricted the shoulder abduction. The procedure for implantation has been modified to include suturing of the silicone skirt to anchor the device.

Electrode Breakage: Two electrodes used for sensory feedback broke during the study in two subjects, one due to implant rotation and one due to a caretaker squeezing a pustule over the electrode. One electrode used for motor function failed in another patient.

Follow-up surgery was necessary in some of the above events and included surgery to remove electrodes, scar revision, stimulator repositioning, and various tenolysis and joint releases or fusion procedures.

Non-Surgical Adverse Events

Inadvertent Excitation of Elbow Flexors: Inadvertent biceps contraction as a result of the return current pathway caused elbow flexion in nine cases. This was corrected by adjustment of the stimulus parameters below the threshold of excitation.

Other Minor Events: A variety of other adverse events were reported in the clinical study including the following. Blisters/sores from exercise splints/casts, swelling/irritation from sutures, swelling/discomfort over implantable components, skin irritation from tape products, unable to turn unit off, warm sensation under coil causing skin irritation, sensation on tongue through metal utensil, cigarette burn

while holding cigarette in insensate hand (1 event).

External Controller Malfunctions - There have been over 100 reports since 1993 of external controller malfunctions. However, modifications to the external controller have substantially reduced the occurrence of these malfunctions. These malfunctions included:

- Corruption of memory due to low battery power or electrostatic discharge.
- Mechanical problems including pinched wiring harnesses, loosened internal hardware, dead battery cells, excessive battery consumption.

1.6.2 Potential Adverse Events

Possible adverse events, including those that have been observed in the clinical trial, include:

- Device malfunction
- Fibrosis and scarring
- Infection
- Rejection (immunologic)
- Skin irritation
- Surgical revision
- Tissue breakdown

2.0 FREEHAND SYSTEM COMPONENTS

The NeuroControl Freehand System is a radio frequency motor control neuroprosthesis, which consists of both implanted and external components. It utilizes low levels of electrical current to stimulate the peripheral nerves that innervate muscles in the forearm and hand in a selective, repeatable, and controlled manner providing functional hand grasp patterns. The implanted portions of the System contain no internal energy source (i.e. batteries) and thus do not have a finite lifetime. The System is comprised of four subsystems: the Patient Implantable System, the Patient External System, the Electrode Positioning Kit, and the Clinical Programming System.

2.1 Patient Implantable System

The patient implantable system is comprised of the components which are surgically implanted. These include the Implantable Receiver-Stimulator (model 1060), the Epimysial Electrodes (model 1320-cm, cm is length in centimeters), and the Connectors (included as part of implantable receiver-stimulator). The connectors are also provided at the surgery in the form of the Connector Spares (model 1647) as backup equipment in instances when electrode connections need to be changed.

2.2 Patient External System

The patient external system is used by the patient to operate the implantable system. This is comprised of the External Controller (model 1205), the Shoulder Position Sensor (model 1331), the Transmit Coil (model 1044), the Battery Charger (model 1674 (Europe), model 1241 (US)), and the Remote ON/OFF Switch (model 1353).

2.3 Electrode Positioning Kit

The electrode positioning kit (model 1111) is used intra-operatively to determine the optimal position the Epimysial Electrodes on the appropriate muscles. It is comprised of the Surgical Stimulator, the Epimysial Probe, the Anode Plate, and the Clip Lead.

2.4 Clinical Programming System

The clinical programming system is used to program the Patient External System with the control parameters for the Patient Implantable System. It is comprised of a pre-configured PC loaded with the Programming Interface Software (model 1346), the Interface Module (1072), two Battery Chargers (one for the interface module (model 1674 (Europe) or 1241 (US)) and the other for the pre-configured PC, model 1849), and a Serial Cable (model 1244).

3.0 PRE-OP ASSESSMENT/SURGICAL PLANNING

3.1 Comprehensive Physical Examination

The comprehensive physical examination of the candidate for the Freehand System should include the following standard clinical laboratory studies:

- Complete blood count and sedimentation rate
- Clotting profile (prothrombin time, partial thromboplastin time, platelet count)
- SMA 6 and SMA 12 or equivalent
- HIV and Hepatitis B screening
- Urinalysis and urine culture and sensitivity
- Nasal swab for culture and sensitivity
- Chest X-ray, mammograms for females
- Recent ultrasound of the renal/urinary tract for stones
- Recent dental exam

3.2 Pre-surgical Planning, Mapping, and Measurement

3.2.1 Determine the Location of Implantable Receiver Stimulator

The Implantable Receiver Stimulator is generally positioned on the chest wall in a location similar to that of a pacemaker. Unlike patients with a pacemaker, however, these patients may require lateral supports or straps when sitting in the wheelchair and/or assistance in transferring between chair and bed, etc. To prevent damage to the implanted components, caused by transfer activities or skin breakdown due to pressure from supports, observe the patient in their wheelchair to assess the proposed location of the Implantable Receiver Stimulator and determine if there are any pressure areas in the upper torso from lateral supports or straps.

The implant is oriented so that the leads come out cranially with the antenna (receiver coil) below. The length of the leads should be selected so that they are not looped or kinked.

In female patients, the Implantable Receiver Stimulator should not be implanted under breast tissue.

3.2.2 Determine the Location of Motor Electrodes

Motor electrodes are placed on the innervated muscles of the arm, forearm, and/or hand: EPL, AdP, AbPB, FDP, FDS, EDC, FPL are key muscles. Muscles selected for electrode placement should have at least a grade 4 response to stimulation for flexors and grade 3 for extensors.

NOTE: If any of the above muscles are denervated, the electrode should be placed on the synergist or transferred muscle. Refer to the discussion of "Substitution Procedures" below.

3.2.3 Determine the Location of the Sensory Electrode

If sufficient motor function can be obtained using only 7 motor electrodes, one electrode can be used to provide the patient with sensory feedback. This electrode is placed in an area of normal sensation, usually the upper shoulder deltoid area. Before implementing the System, this area should be mapped using surface stimulation to be sure that there are no painful or hypersensitive areas at this location.

4.0 IMPLANT SURGERY

4.1 NeuroControl Supplies

In addition to the usual supplies required for surgical procedures, such as sterile goods (gowns, drapes, prep supplies, radiopaque sponges, electrosurgical units and accessories, and dressing materials), there are two additional categories of supplies and equipment necessary for the surgical implantation of the Freehand

System. The first category is dedicated to the implantation and assessment of System function and is obtained from NeuroControl Corporation. The second category consists of materials used for the augmentative and reconstructive surgical procedures (fusions, tenodesis, tendon transfers, etc.) which are performed during the same surgery.

The implantable and surgical components are pre-sterilized using ethylene-oxide (EtO). If the sterile seal is broken or the package is damaged, do not use the device. Return the product to NeuroControl Corporation.

Supplies, which are ordered from NeuroControl Corporation, consist of the Freehand Patient System. Elements of the Freehand System are listed below.

Implantable Components

Model	Qty	Item
1060	1	Implantable Receiver-Stimulator
1320-xx (xx = length in cm)	1	Implantable Electrode Set (sizes 4, 8-70cm supplied for selection of 8 electrodes to be implanted)
1453	1	Neuroprosthesis Implant Record (to be completed and returned to NeuroControl following surgery)
1647	1	Implantable Connector Spares

External Components

Model	Qty	Item
1205	1	External Controller
1331	1	Shoulder Position Sensor (includes chest switch and 2 shoulder rods with mounts)
1044	2	Transmitting Coil
1353	1	Remote On/Off Switch
1674	1	Battery Charger (Europe)
1241	1	Battery Charger (US)
1423	1	Shoulder Position Sensor Tape Package
1385	1	Transmitting Coil Tape Package
1447	1	External Components Carrying Case
1700	1	User's Manual

1701	1	Serial Number Registration Sheet (to be completed and returned to NeuroControl when external components given to patient)
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Surgical Tools

Model	Qty	Item
1111	1	Surgical Electrode Positioning Kit
1108	1	Scanlan Tunneler
1109	1	Coil Sheath (Ultrasound head cover)
1454	1	Coil Sheath Usage Instructions

Surgical Test Station (returned following surgery)

Model	Qty	Item
1346	1	Preconfigured Personal Computer
1244	1	Serial Cable
1072	1	Interface Module
1675	1	Battery Charger, for Personal Computer
1674	1	Battery Charger, for External Controller (Europe)
1241	1	Battery Charger, for External Controller (US)
1702	1	Transmitting Coil Extension Cable

4.2 General Surgical Supplies and Equipment

Implantation of the Freehand System requires both general purpose and the specialized supplies required for hand surgery. Typical equipment, instruments, and supplies used for these procedures are provided below.

Equipment

- hand table
- pneumatic tourniquet
- prep pad with cuff
- Esmarch bandage
- sitting stools
- cast cart
- heating pad (K-pad) for arm table
- power sources (pneumatic or electric, as appropriate)
- electrosurgical unit and dispersive electrodes
- suction containers

Sterile supplies

- gowns and gloves
- towels and drapes
- steri drape
- radiopaque sponges (raytec sponges, lap pads/tapes)
- dressing materials (xeroform gauze, kerlix, fluffs, elastic bandage, ace bandages)
- antibiotic irrigation (polymyxin/bacitracin or equivalent)
- prep set (betadine or equivalent for patients allergic to betadine or iodine)
- half strength peroxide in saline for cleaning skin after surgery

Sterile Instruments

- Drills, drivers, and drill bits of various sizes
- K-wires of various sizes
- Hand instruments
- Tendon instruments
- Bipolar ESU cord and forceps
- Measuring tape
- Rubber bands
- Hand (lead hand)
- Blades

Sutures

-	Ethibond	2-0	SH X-833-H
-	Ethibond	4-0	RB-1 X-871-H
-	Ethibond	0	SH D/A B524-H
-	Vicryl	0	CT-1 27" J340H
-	Vicryl	2-0	CP-2 UNDY J869H
-	Vicryl	4-0	PS-2 UNDY J496H
-	Nylon	4-0	PC-3 1964G
-	Mersilene	5	CTX RIB RS22

4.3 Augmentative, Reconstructive, and Substitution Procedures

Implantation of the Freehand System is generally accompanied by augmentative/reconstructive and substitution procedures (tendon transfer of paralyzed muscles) which are performed during the same surgical procedure and are accomplished before the placement of the Freehand implants.

4.3.1 Augmentative and Reconstructive Surgery

The goals of augmentative and reconstructive procedures of the hand for implementation of the Freehand System are as follows: (1). To provide the patient with as functional a grasp as possible; (2). To compensate for function lost due to weak or denervated key muscles; (3). To position the hand and forearm optimally for functional tasks; (4). To reduce potential grasp problems due to joint contracture or laxity; and (5). To simplify control of grasp by minimizing the degrees of freedom.

Any combination of procedures may be performed with a single patient. Typical procedures are listed in the table below.

Typical Augmentative/Reconstructive Procedures

Procedure	Indication
Thumb IP Arthrodesis or FPL/EPL split	Hypermobility thumb IP joint that prevents transmission of pinch force to the thumb tip
	Use of FPL as primary thumb flexor (AdP denervated)
FDS Synchronization (allows single electrode to move all four fingers; balance fingers w/ digit 5 loose)	Non-synchronous finger flexion
	Partial denervation of FDS
FDP Synchronization	Non-synchronous finger flexion
	Partial denervation of FDP
FDS Zancolli-Lasso	MP hyperextension; lack of IP extension (Claw hand or intrinsic minus hand posture)
Radial Osteotomy	Inability to pronate forearm in supinated position
EDC Synchronization (allows single electrode to move all four fingers)	Non-synchronous finger extension

4.3.2 Substitution Procedures: Tendon transfer of paralyzed muscles

The need for substitution procedures is indicated by weakness or denervation in one of the key muscles (EPL, AdP, AbPB, FDP, FDS, EDC, FPL) with no other available synergist muscle. FES transfer of a paralyzed muscle is recommended to provide the function of a key muscle. The muscle being transferred must be paralyzed with an upper motor neuron lesion and should have a muscle grade of 4 or better with maximum stimulation.

The guidelines provided in the table below provide some of the available options for substitution of lost or deficient function in the key muscle groups. The optimum function is given as a reference point.

Guidelines for Substitution/Transfer Procedures

Muscle Group	Optimum Function	Options to Augment Weak Function
Extensor Pollicis Longus (EPL)	Produces full extension of thumb CMC, MP and IP joints to their PROM limit.	<ol style="list-style-type: none"> 1. Fuse thumb IP joint; use EPB. 2. Transfer EIP to EPL. 3. Transfer to EPL one or more of the following: EPB, AbPL, ECU, ECRL (if paralyzed), ECRB, BR (if paralyzed).
Adductor Pollicis (AdP)	Produces at least 10 Newtons of thumb pinch (1 kg, 2.2 lbs).	<ol style="list-style-type: none"> 1. Fuse thumb IP joint; use FPL. 2. Use FPB as thumb flexor. 3. Transfer EIP to AdP.
Abductor Pollicis Brevis (AbPB)	Produces full abduction of the thumb CMC joint to its PROM limit.	<ol style="list-style-type: none"> 1. Use AbPL and FPB. 2. Transfer to AbPB (or OP): PL, PT, FPL, FCR, FCU.
Flexor Digitorum Profundus (FDP)	Produces full flexion of all three finger joints for all four fingers to their PROM limit and produces approximately 10 Newtons of grip force.	<ol style="list-style-type: none"> 1. Partial denervation: Tie tendons together if remaining tendons produce a grade "4" contraction or better. 2. If FDS produces a grade "4" or better contraction with good closing of the hand, FDS can be used as the only finger flexor. 3. Transfer FCU, FCR, PT, PL, or BR (if paralyzed) to FDP.
Flexor Digitorum Superficialis (FDS)	Produces approximately 10 Newtons of grip force in palmar grasp (all four fingers together).	<ol style="list-style-type: none"> 1. Partial denervation: Tie tendons together if remaining tendons produce a grade "4" contraction or better. 2. Transfer FCU, FCR, PT, PL, or BR (if paralyzed) to FDS.
Extensor Digitorum Communis (EDC)	Produces full extension of all three finger joints for all four fingers to their PROM limit.	<ol style="list-style-type: none"> 1. Often the Zancolli-Lasso procedure on the FDS will provide improved finger extension as long as the EDC shows strong extension of the MP joints. 2. Transfer to EDC one or more of the following: ECU, EIP, EPB, ECRL (if paralyzed), BR (if paralyzed), ECRB.

4.4 Implanting the Freehand System

In addition to the implantation of Freehand System components, the surgery includes augmentative, reconstructive, and substitution procedures. The sequence of events in a typical System implantation procedure, with a description of those events is below.

WARNINGS:

THE FREEHAND SYSTEM IS A SENSITIVE ELECTRONIC DEVICE. ELECTROSTATIC DISCHARGE MAY HARM THE FREEHAND IMPLANTABLE RECEIVER-STIMULATOR. SAFE HANDLING PROCEDURES MUST BE OBSERVED TO PREVENT DAMAGE TO THE DEVICE DURING HANDLING AND IMPLANTATION. SEE BELOW FOR ADDITIONAL HANDLING INSTRUCTIONS.

IF POSSIBLE, THE FREEHAND SYSTEM SHOULD BE IMPLANTED IN AN OPERATING ROOM WITH CONDUCTIVE FLOORS AND WITH SAFE CONDUCTIVE PATHWAYS FOR THE PATIENT AND STAFF, IN ACCORDANCE WITH JCAHO STANDARDS.

NEUROMUSCULAR BLOCKING AGENTS AFFECT ELECTRICAL STIMULATION OF NERVE AND MUSCLE. ANESTHESIOLOGIST/ANESTHETIST SHOULD BE ADVISED NOT TO USE LONG ACTING NEUROMUSCULAR BLOCKING AGENTS WHICH WOULD REDUCE ELECTRICALLY STIMULATED MUSCLE FORCE DURING SURGERY.

ELECTRICAL CURRENTS MAY DAMAGE THE IMPLANT. MONOPOLAR ELECTROCAUTERY INSTRUMENTS MUST NOT BE USED ON THE IMPLANTED EXTREMITY, OR ON INCISIONS MADE FOR THE IMPLANT. BIPOLAR ELECTROCAUTERY CAN BE USED SAFELY IN COAGULATING MODE.

Circulating Nurse:**Passing Freehand Components into the Sterile Field**

The sterile components of the Freehand patient system should be passed into the sterile field in the following sequence:

- Electrode Positioning Kit (including sterile measuring tape), needed during steps 2 through 6 below.
- Epimysial Electrodes (sizes as required), needed at steps 5 and 7.
- Scanlan Tunneler, needed during steps 6 and 8.
- Implantable Receiver-Stimulator, needed at step 6.

- Sterile Coil Sheath (ultrasound head cover) and Transmitting Coil, needed for step 10.

Surgical Procedure Guidelines

1. Thumb IP stabilization, if indicated, is typically performed first.
2. The pocket for the Implantable Receiver Stimulator is created. The Anode Plate is placed into the pocket with the metal side facing towards the skin.
3. Any voluntary muscle transfers are performed. Both sides of the transfer are marked with 4-0 metal suture.
4. Note: Paralyzed muscle transfers and synchronizations should be performed before the placement of Epimysial Electrodes on the muscle. The tension should be set with the elbow flexed at 90 degrees and with the wrist neutral. Tetanic contraction of the muscle should be utilized.
5. The next steps are the placement of the Epimysial Electrodes, the FDS Zancolli-Lasso procedure (if indicated), and synchronization of flexor tendons (AdP, AbPB, FPL, FDS, FDP, EPL, and EDC Electrodes).

Electrode Mapping To determine the optimal placement of the Epimysial Electrodes, the Surgical Stimulator, with the Epimysial Probe inserted into the connector for channel one (red) is used. The Anode Plate is connected into the anode connector (black) and the Anode Plate is placed into the implant pocket.

Stimulation amplitude is generally set at 20 mA and the stimulus frequency at 12 Hz. The pulse duration is varied from 0 to 200 msec to observe the electrode recruitment properties. Stimulus twitches can be used to detect muscle thresholds. The stimulus delivered by the Surgical Stimulator is of the same type and specification of that delivered by the Implantable Receiver Stimulator, which is within the recognized levels for safe stimulation levels.

The Epimysial Probe is moved over the surface of the muscle while the stimulation is delivered. The Epimysial Probe is to be used on the same side of the patient as the substitute Anode Plate and care should be taken not to cross any cardiac pathways of the heart (for example the vagus

nerve of the heart). The muscle response is observed to determine the optimum electrode placement. The most important electrode input/output characteristics are the following (in order of importance):

- **Maximal force w/minimal spillover:** The best electrode placement is one that recruits the entire muscle prior to spillover to another functional muscle group, and generates strong grasp force or, in the case of extensors, moves the joint through maximum range of motion. If no other muscle groups are recruited at the maximum stimulation level, the electrode placement is accepted. If this is not possible, try to find the electrode placement, which gives the maximal muscle force output prior to spillover. Note: Spillover from EPL to EPB usually occurs and is desirable. Spillover between FDS and FDP usually occurs and is not a problem. In general, the more distal an electrode is placed, the more selective while the more proximal the electrode is located, the more strength is recruited. More proximal electrodes also tend to recruit more adjacent muscle groups as their nerve branches are closer in origin to the main trunk.
- **Length Dependency:** Length dependency describes the dependence of the muscle force output on joint angle changes. To test this property, temporarily suture the electrode in the optimum location for maximum force and stimulate the muscle at a constant level. While the stimulation is on, move the distal joints through their range of motion (including the wrist and forearm for extrinsic muscles). If large changes in the muscle force output are detected, the electrode location is poor. Test other locations to determine if length dependence can be reduced without sacrificing force. Large changes in muscle force output occur when the contraction of the muscle draws the electrode closer to the motor point (or away from the motor point), resulting in a positive feedback situation. The most likely solution to this problem is to move the electrode farther away from the motor point, although this is not a guaranteed solution.

- **Gain:** Gain describes the rate at which muscle forces increases as the stimulus is increased. Very high gain can be detrimental to the grasp, although it is less important than maximum force and length dependency. High gain results from the electrode being too close to a nerve branch. Sometimes the effective gain can be lowered by using a lower stimulus amplitude (e.g. reduce from 20 ma to 8 ma), however, it is strongly recommended that optimal placement be determined based upon 20 ma settings. The Surgical Stimulator allows the option of testing the electrode at lower amplitude levels. Later you can program the Implantable Receiver Stimulator to operate individual channels at the same lower amplitude levels.

If there is no response to stimulation, check to assure that the probe and anode are plugged into the Surgical Stimulator that the correct electrode is selected by the switch at top, and that the Stimulator is ON. Attempt to stimulate a muscle with known contraction (from pre-surgical work with the patient). Check to make sure that the muscles have received adequate blood supply and that no neuromuscular blocking agents were used. Try using the backup Epimysial Probe and Anode Plate if necessary to assure that there is not a wire lead problem.

If the response to stimulation suddenly stops, check to make sure that the Epimysial Probe and Anode Plate are still plugged into the stimulator. Check to make sure that the Anode Plate is still located in the implant pocket. If all the connections appear intact, try using the backup epimysial probe and anode or stimulator.

If the response to stimulation seems to diminish, check for adequate blood supply to the muscle and muscle temperature. If the blood supply is good, the muscle may be fatigued. Warm the muscle using arm saline packs for ten minutes and try again.

If the Surgeon's Stimulator does not appear to be working, try using the backup Surgeon's Stimulator.

Placing and Suturing Electrodes Use 4-0 braided non-absorbable suture, with a tapered (not cutting) needle. Place five sutures around the periphery of the Epimysial Electrode, using four knots with each suture. The exposed metal stimulating area must be placed toward the muscle surface for motor electrodes and toward the skin surface for the sensory electrode. Always test the electrode placement after suturing by attaching the Clip Lead to the electrode connector. Make sure that the tissue covers the electrode as if the wound was closed. Record the serial numbers from each electrode used on the Neuroprosthesis Implant Record.

- 6. ATTENTION: IMPORTANT HANDLING INSTRUCTIONS: It is important to minimize the handling of the Implantable Receiver-Stimulator. The Implantable Receiver-Stimulator must remain unopened in its protective package until it is time to surgically implant it. Do not use the implantable receiver-stimulator to determine the location of the inter-lead connection incision.**

Location of the Connector Site

The leads of the Epimysial Electrodes are passed to a common connection site, typically located in the medial upper arm. The Anode Plate is positioned in the location and orientation that the implantable receiver-stimulator will be placed. Using the sterile measuring tape, 19 cm is measured from the distal edge of the Anode Plate to the medial upper arm along the path that the implanted leads will be tunneled. An incision should be made at this location.

Handling the Implantable Receiver-Stimulator

Once the inner package is passed to the surgical table, The Implantable Receiver-Stimulator inner tray should be opened by the scrub nurse and irrigated with saline containing antibiotics, and the tray passed to the surgeon. While holding the tray, the surgeon must touch the patient's skin to discharge any static charge. The Anode Plate is removed from the subcutaneous pocket, and the Implantable Receiver Stimulator is removed

from the tray, and placed in the pocket. The exposed titanium surface (the anode) must be placed so that it faces the skin surface. The Stimulator is secured to the pectoralis fascia with four stitches in the skirt using 2-0 braided non-absorbable suture. A minimum of four knots should be used per suture. **The serial number should be recorded on the Neuroprosthesis Implant Record.**

NOTE: After implantation, the implanted Receiver-Stimulator can be identified by a radiopaque tag. The Freehand System incorporates two code sequences for radiographic identification. The top sequence is "NCC" [for NeuroControl Corporation]. The bottom sequence will be a three or four digit serial number. Devices without a radiopaque NCC-XXXX identifier were manufactured in 1998 and have the same configuration (composition and construction).

Passing Leads to the Connector Site:

The leads of the Epimysial Electrodes are passed to the connector incision site. The Scanlan tunneler is inserted and tunneled subcutaneously between the electrode incision and the connector incision. The leads are passed through the tunneler, which is pulled out through the connector incision, drawing the leads out with it.

7. The Sensory Electrode is placed, if indicated.
8. The Scanlan Tunneler is inserted into the implant pocket and subcutaneously directed to the common connector site.
9. The Electrode leads are connected to the Implantable Receiver Stimulator in the following manner. First insert the Electrode lead pin into the connector sleeve until the collar on the Electrode lead meets the end of the sleeve. The spring must then be gently twisted a half turn in the clockwise direction to insert the pin into it. Once the pin is in the spring, gently tug the Implantable Receiver-Stimulator lead and the Electrode lead to make sure the pins are firmly held by the spring. Do not tie the suture at this time.
10. Each motor channel of the Implantable Receiver Stimulator should be tested, as described below in section 4.5, to verify function before the wound is closed.

5. Surgical Electrode Positioning Kit

5.1 Surgical Stimulator

The Surgical Stimulator, shown in Figure 24 below, is a small hand-held neuromuscular stimulator used intra-operatively with the Anode Plate and the Epimysial Probe to help a surgeon identify the optimal location for placement for the Implantable Epimysial Electrodes. It is powered by internal batteries and allows the surgeon to select the stimulus current, frequency, and pulse duration.

The Surgical Stimulator is provided as a sterile item in the Surgical Electrode Positioning Kit and is intended for a single patient and procedure. The stimulator generates a biphasic stimulus waveform (no net charge transfer) and is intended for use with the subcutaneously placed Anode Plate, the reference electrode. The stimulator generates stimulus outputs identical to the Implantable Receiver-Stimulator of *The Freehand System*.

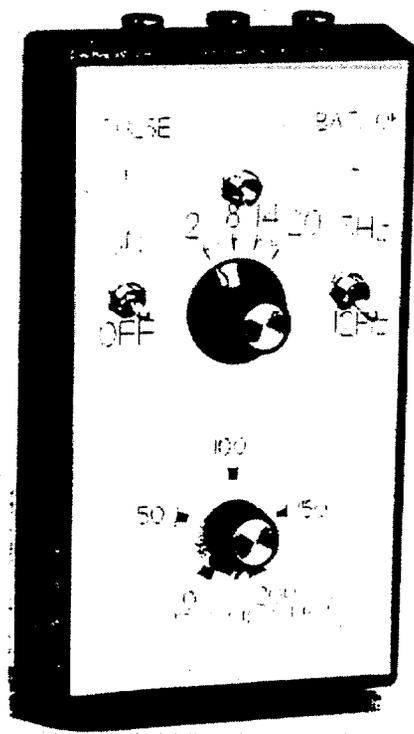


Figure 24. Surgical Stimulator

5.2 Epimysial Mapping Probe

The Epimysial Mapping Probe, shown in Figure 25 below, is essentially an Epimysial Electrode with an attached handle and cord. It uses the same platinum-iridium electrode disk mounted on the end of a hollow acetal (trade name Delrin) rod about 15 cm (6") long. The lead of the electrode is routed up the hollow rod and is spliced to a 1.4m (four feet) length of red test prod wire (rubber insulated). The wire exits the hollow acetal rod with a simple strain relief made with several lengths of heat shrink tubing. The wire is terminated in a 2 mm (0.080") diameter tip plug. The probe is connected to the Surgical Stimulator and is used by the surgical team to identify the best location for placement of the Implantable Epimysial Electrodes. The probe is provided as a sterile item in the Surgical Electrode Positioning Kit and is intended for a single patient and procedure.

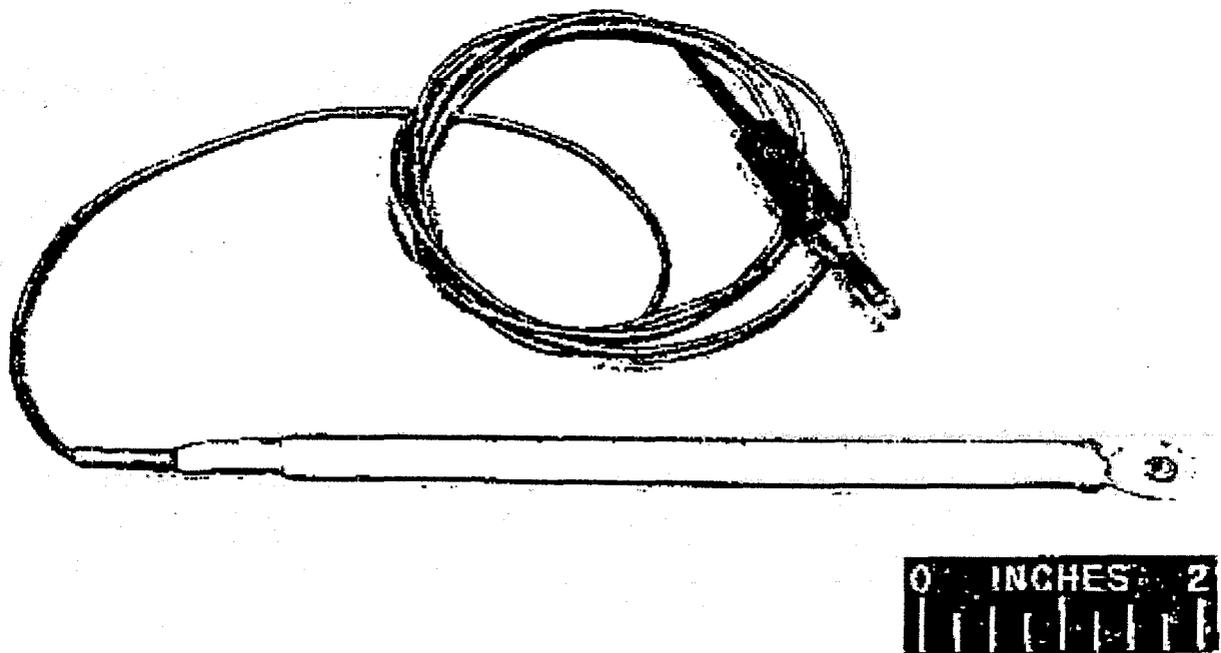


Figure 25. Epimysial Mapping Probe

5.2 Substitute Anode Plate

The Substitute Anode Plate, Figure 26 below, is a copy of the exposed portion of the capsule that forms the anode of the Implantable Receiver-Stimulator. It is made of a thin titanium plate which is surrounded by Epoxy and is coated with silicone elastomer. The exposed area of the anode is identical to that of the Implantable Receiver-Stimulator. A four foot length of test prod wire (rubber insulated) exits the molded silicone elastomer with a simple silicone rubber strain relief. The wire is terminated in a 2mm (0.080") diameter tip plug. It is connected to the Surgical Stimulator during the implantation procedure and completes the electrical circuit for the intra-operative stimulation of muscle. The Anode Plate is provided as a sterile item in the Surgical Electrode Positioning Kit and is intended for a single patient and procedure.

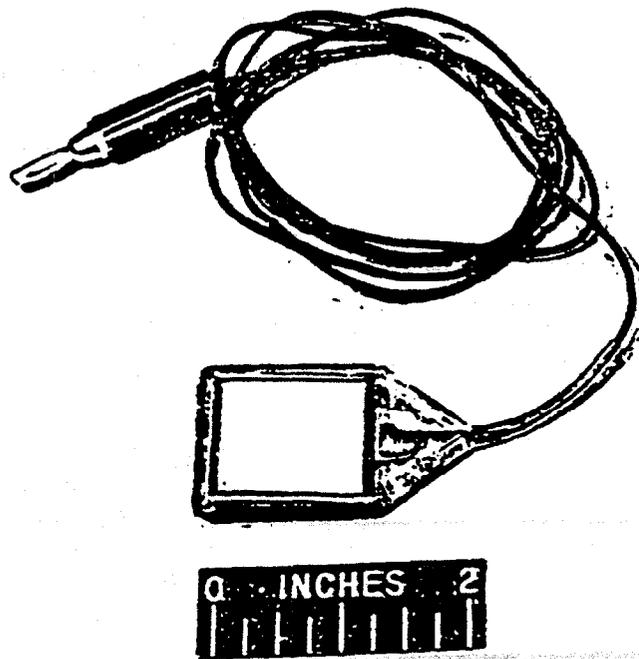


Figure 26. Substitute Anode Plate

5.3 Electrode Clip Lead

The Clip Lead, shown in Figure 27, is used to connect the Surgical Stimulator to the Implantable Epimysial Electrode during the implantation procedure and consists of a 1.8m (6 feet) cable with a 2mm (0.080") tip plug on the proximal end and a small alligator clip on the distal end. It is a legally marketed pacemaker test cable with the two identical leads lightly bonded together (zipped). NeuroControl unzips the cable and packages the individual leads as a component of the Surgical Electrode Positioning Kit. The Clip Lead is provided as a sterile item in the Surgical Electrode Positioning Kit and is intended for a single patient and procedure.

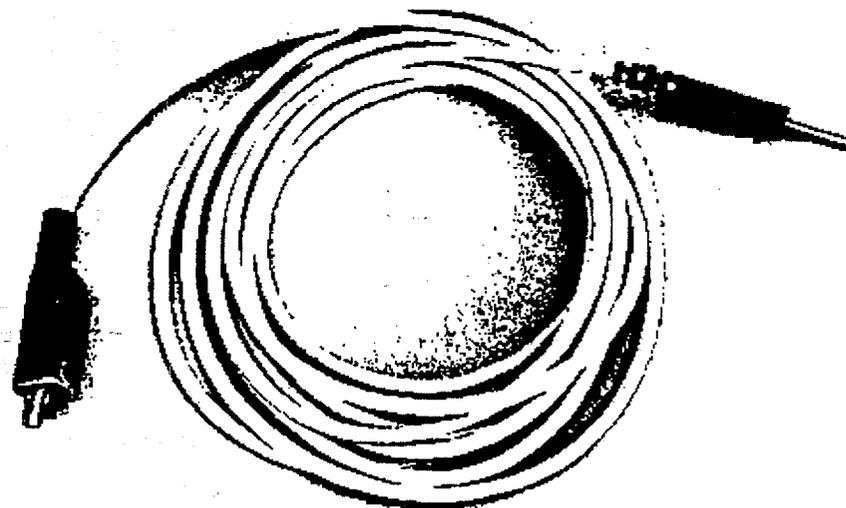
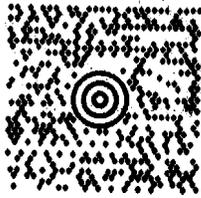


Figure 27. Clip Lead

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