PROFESSIONAL LABELING

Medtronic

RECLAIM™ DBS™ THERAPY FOR OCD

3391

Lead Kit for Deep Brain Stimulation

Implant manual

Rx Only

Humanitarian Device: Authorized by Federal (U.S.A.) law for use as an adjunct to medications and as an alternative to anterior capsulotomy for treatment of chronic, severe, treatment-resistant obsessive compulsive disorder (OCD) in adult patients who have failed at least three selective serotonin reuptake inhibitors (SSRIs). The effectiveness of this device for this use has not been demonstrated.

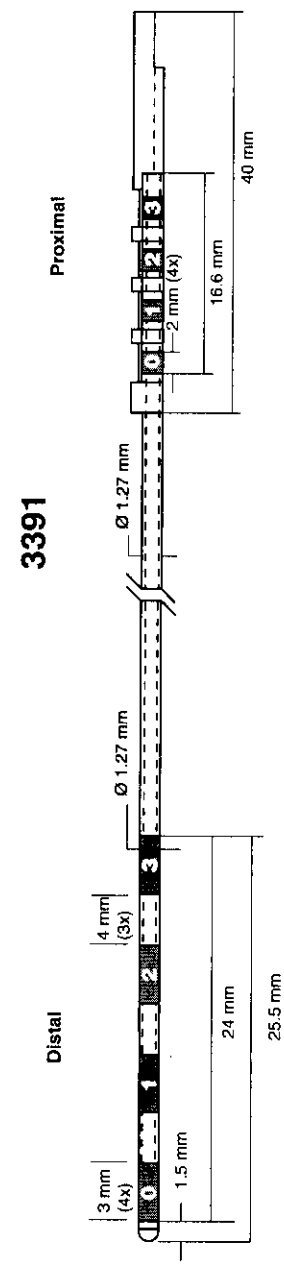

Figure A. Model 3391 DBS Lead

Note: All dimensions are approximate.

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System Description

The Medtronic Reclaim DBS System is an implantable, multiprogrammable system that delivers electrical stimulation to selected areas of the brain.

Reclaim DBS Therapy for Obsessive Compulsive Disorder (OCD)

The power source for bilateral Reclaim DBS Therapy for OCD are one or two dual program Kinetra Model 7428 Neurostimulators or two single program Soletra Model 7426 Neurostimulators. The power source(s) generate electrical signals that are transmitted to the brain via two Model 7482 Extensions and two Model 3391 DBS Leads. These components comprise the implantable portion of the Reclaim DBS System for bilateral OCD therapy.

Lead Description

The Medtronic Model 3391 DBS Lead is designed to electrically stimulate specific areas of the brain. The lead features 4.0- mm spacing between each of the four 3.0- mm electrodes at the distal end. The electrode spread is 24.0 mm (Figure A).

Indications

The Medtronic Reclaim DBS Therapy is indicated for bilateral stimulation of the anterior limb of the internal capsule, AIC, as an adjunct to medications and as an alternative to anterior capsulotomy for treatment of chronic, severe, treatment-resistant obsessive compulsive disorder (OCD) in adult patients who have failed at least three selective serotonin reuptake inhibitors (SSRIs).

Contraindications

Implantation of a Reclaim DBS System is contraindicated for:

- Patients exposed to diathermy. Do not use shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

  Diathermy is further prohibited because it can also damage the neurostimulation system components resulting in loss of therapy, requiring additional surgery for system explantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned "on" or "off." Advise your patients to inform all their health care professionals that they should not be exposed to diathermy treatment.

- Patients exposed to Magnetic Resonance Imaging (MRI). Performing MRI can cause tissue lesions from component heating, especially at the lead electrodes, resulting in serious and permanent injury including coma, paralysis or death.

- Patients who are unable to properly operate the brain stimulator.

Transcranial magnetic stimulation (TMS) is contraindicated for use in patients with an implanted DBS system.

Warnings

Electroconvulsive Therapy (ECT) – The safety of ECT in patients who have an implanted deep brain stimulation (DBS) system has not been established. Induced electrical currents may interfere with the intended stimulation or damage the neurostimulation system components resulting in loss of therapeutic effect, clinically significant undesirable stimulation effects, additional surgery for system explantation and replacement, or neurological injury.

Coagulopathies – Use extreme care with lead implantation in patients with a heightened risk of intracranial hemorrhage. Physicians should consider underlying factors, such as previous neurological injury, or prescribed medications (anticoagulants), that may predispose a patient to the risk of bleeding.

Avoid Excessive Stimulation – There is a potential risk of brain tissue damage when stimulation parameters are set to high amplitudes and wide pulse widths. Parameter values that may be excessively high should only be programmed with due consideration of the warnings concerning charge density (all neurostimulator models) and charge imbalance (Model 7426 neurostimulator) described in "Programming the Neurostimulator" on page 71. The programmer displays a warning when parameter values are chosen that may exceed the charge density limit **(WARNING: CHARGE DENSITY MAY BE HIGH ENOUGH TO CAUSE TISSUE DAMAGE).** If you are using a Model 3391 Lead and having difficulty programming effective stimulation without receiving this warning, please see "Programming the Neurostimulator" on page 71 for more information on calculating safe stimulation parameters.

Case Damage – If the neurostimulator case is ruptured or pierced after implant due to outside forces, severe burns could result from exposure to battery chemicals.

Placement of Lead-Extension Connector in Neck – Do not place the lead-extension connector in the soft tissues of the neck. Placement in this location has been associated with an increased incidence of lead fracture.

Selecting Stimulation Parameters for Reclaim DBS Therapy for OCD – During test stimulation or a programming session, increasing the amplitude or pulse width or selecting suboptimal electrodes may cause side effects, including:

- autonomic effects (e.g. facial flushing, facial muscle contractions, or increased heart rate)
- hypomania
- increased disease symptoms
- sensations such as tingling, smell, or taste

If these side effects appear after programming, reprogram the neurostimulator by reducing the amplitude or pulse width settings or both or by selecting different electrodes until these side effects subside. Because these side effects may not appear immediately, patients should remain in the clinic for monitoring for at least 30 minutes after the session is complete.

In addition, during treatment, patients should be monitored closely for increased depression, anxiety, suicidality, and worsening of obsessive-compulsive symptoms.

Theft Detectors and Screening Devices – Theft detectors found in retail stores, public libraries, etc., and airport/security screening devices may cause the stimulation power source of an implantable neurostimulation system to switch On or Off.[1] It is also possible that sensitive patients, or those with low stimulation thresholds, may experience a momentary increase in their perceived stimulation. For other indications, higher levels of stimulation have been described as uncomfortable ("jolting" or "shocking") by some patients as they pass through these devices. Refer to "Patient Counseling Information" on page 76 for more information.

Precautions

Physician Training

Implanting Physicians – Implanting physicians should be experienced in stereotactic and functional neurosurgery. Refer to "Physician Training Information" on page 76 in this manual for further information.

Prescribing Physicians – Prescribing physicians should be experienced in the diagnosis and treatment of obsessive compulsive disorder and should be familiar with the use of the brain stimulation system.

Storage and Sterilization

Sterilization – Medtronic has sterilized the package contents according to the process indicated on the package label before shipment. This device is for single use only and is not intended to be resterilized.

Storage Temperature – Store the DBS Lead between -30° F (-34° C) and 135° F (57° C). Temperatures outside this range can damage components.

[1] With all neurostimulators referenced in this manual, unexpected On/Off switching of the devices may occur when they are exposed to magnets and strong electromagnetic fields. See the Warnings and Precautions sections of this manual. With the Kinetra Model 7428 neurostimulator, however, the magnet control circuit can be disabled by the clinician programmer software to avoid unexpected switching. If the magnet control circuit is disabled, patients will require a Model 7436 therapy controller to turn their therapy On or Off.

System and Therapy

Component Failures – The brain stimulation system may unexpectedly cease to function due to battery depletion or other causes. These events, which can include electrical short or open circuits, conductor (wire) fracture, and insulation breaches, cannot be predicted. The patient's disease symptoms will probably return or worsen if the device ceases to function.

Components – The use of non-Medtronic components with this system may result in damage to Medtronic components, loss of stimulation, or patient injury.

Inadvertent Programming – If more than one neurostimulator is implanted, then the potential for unintentional programming changes to the other neurostimulator exists. If two neurostimulators are implanted, they must be implanted at least 8 inches apart to minimize interference. Verify final programmed parameters by reviewing both devices at the conclusion of any programming session.

Lead Materials – The polyurethane tubing of the lead may release neurotoxic or carcinogenic compounds. Data are insufficient to assess the likelihood of these effects occurring in patients who receive the device.

Long-Term Safety and Effectiveness – The long-term safety and effectiveness of brain stimulation therapy for obsessive compulsive disorder has not been established.

Programming different neurostimulator models – The Model 7432 Physician Programmer must be turned off and turned back on before attempting to program a different neurostimulator model (for example, if programming a Soletra Model 7426 neurostimulator immediately after programming an Itrel II Model 7424 neurostimulator). If the programmer is not turned off and on, the programmer will display "NO TELEMETRY, POSITION HEAD AND TRY AGAIN" and the software will not allow the different neurostimulator to be programmed.

Rebound Effect – Inform patients and their caregivers that abrupt cessation of stimulation for any reason will probably cause a return of disease symptoms. In some cases, symptoms may return with an intensity greater than was experienced prior to system implant (rebound effect). It is important that the physician discuss the predicted time of battery replacement with the patient and that the battery condition be closely monitored. It is also important that the patient know how to use their therapy controller (or control magnet) in case the neurostimulator is accidentally turned off. If symptoms return or worsen, the patient should contact his or her physician immediately so the status of the system can be assessed and the condition of the patient can be monitored.

Use in Specific Populations – The safety and probable benefit of this therapy has not been established for the following:

- Patients with Tourette's syndrome
- Patients with OCD with a primary subclassification of hoarding

- Patients whose diagnosis of OCD is documented to be less than 5 years duration
- Patients whose YBOCS score is less than 30
- Patients who have not completed a minimum of 3 adequate trials of first and/or second line medications with augmentation
- Patients who have not attempted to complete an adequate trial of cognitive behavior therapy (CBT)
- Patients with a previous surgical ablation procedure (e.g., capsulotomy)
- Patients who are pregnant
- Patients under the age of 18 years
- Patients with dementia
- Patients with coagulopathies or who are on anticoagulant therapy
- Patients without cormorbid depression and anxiety
- Patients with neurological disorders
- Patients with other serious medical illness including cardiovascular disease, renal or hepatic failure, and diabetes mellitus

Use in Patients with Comorbid Psychiatric Disorders – Physicians should carefully consider the potential risks of implanting the brain stimulation system in patients with comorbid psychiatric disorders, including:

- bipolar disorder
- body dysmorphic disorder
- expanded personality impulse-control disorders or paraphilias
- psychotic disorder
- severe personality disorders
- substance abuse
- the inability to control suicidal impulses or a history of suicide attempts

The brain stimulation system may aggravate the symptoms of comorbid psychiatric disorders.

Implantation/Explantation

Body Fluids – Do not resterilize any system component after exposure to body fluids.

Component Disposal – If explanting a brain stimulation system component, please remember the following guidelines:

- Do not incinerate or cremate the neurostimulator; explosion can result if a neurostimulator is subjected to incineration or cremation temperatures.
- Return all explanted components to Medtronic for analysis and safe disposal.

Connections – Wipe off any body fluids on the extension or lead contacts or connector before connecting. Contamination of connections can cause intermittent stimulation or shorts in the neurostimulation circuit.

Connector Block Setscrews – Limit counter-clockwise rotations of neurostimulator setscrews. Rotate enough to provide an unobstructed pathway for the extension connector pins. Too many counter-clockwise rotations may disengage the setscrew from the connector block.

Etched Identification – Place the neurostimulator away from bony structures and with the etched identification side facing outward, away from muscle tissue to minimize pain at the neurostimulator site. This also helps to minimize the possibility of skeletal muscle stimulation, which may be perceived by the patient as twitching or burning.

Excess Extension Wire – Do not place any excess extension wire on top of the neurostimulator's front side (printed side). Wrap any excess extension wire around the perimeter (Figure 1 and Figure 2). This avoids any increase in subcutaneous pocket depth, helps minimize potential damage during neurostimulator replacement surgery, and helps minimize potential kinking of the extension wire.

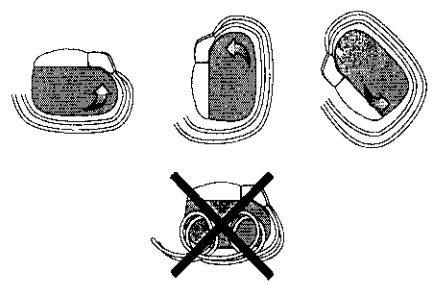


Figure 1. *Wrap excess wire around the perimeter of the Kinetra Model 7428 Neurostimulator*

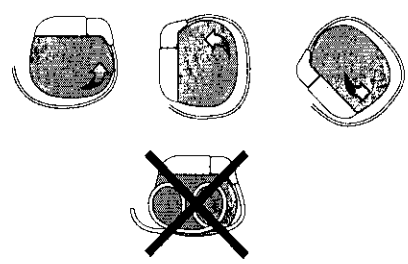


Figure 2. *Wrap excess wire around the perimeter of the Soletra Model 7426 Neurostimulator*

Handling Components – Handle the implanted components of this system with extreme care. These components may be nicked, cut, or damaged by excessive traction or sharp instruments and may require surgical replacement.

- Do not bend, kink, or stretch the lead body whether or not the stylet is in place. Do not bend or kink the tungsten stylet.
- Do not tie a suture directly to the extension or the lead body. Use the burr hole cap and ring provided by Medtronic to secure the lead in place.
- When handling the lead with forceps, use only a rubber-tipped bayonet forceps.

Hex Wrench – Do not overtighten setscrews when using the hex wrench. Excessive torque on setscrews may damage lead contacts. Verify that the sealing grommet has closed on the neurostimulator.

Implant Considerations – Do not implant a component of the system when:

- The storage package has been pierced or altered; or if the component shows signs of damage; or
- The "Use By" date has expired, because this can adversely affect storage package sterility.

Multiple Implants – The long-term safety associated with leads left in place without use, replacement of leads, multiple implants into the target structure, and lead explant is unknown.

Percutaneous Extension Setscrew Connector – If resistance is still felt when removing lead from the percutaneous extension setscrew connector, loosen the setscrews slightly to ensure that they clear the lead contacts. Avoid disengaging the setscrews. Inspect the lead contacts for damage (flattening or stretching of the lead) if resistance was felt prior to removal.

Percutaneous Extension Severing – When severing the percutaneous extension, use gentle traction on the extension to avoid dislodging the lead.

Percutaneous Extension Suture Removal – Do not cut near the lead when removing sutures from the percutaneous extension. Cutting the lead's insulation can result in loss of stimulation and the lead's failure.

Sutures – Do not draw the suture too tightly because damage may occur to the connector boot or to the extension or the lead.

Electromagnetic Interference (EMI)

Electromagnetic interference is a field (electrical, magnetic, or a combination of both) that is generated by various medical or environmental devices. These medical and environmental (home, occupational, and other) devices may generate enough interference to change the parameters of a neurostimulator; turn a neurostimulator off and on; or cause a neurostimulator to surge, shock, or jolt the patient.

In addition, it is possible for the extension, lead or both to "pick up" electromagnetic interference and deliver an excess voltage, which can in turn deliver an excessive amount of heat to the brain. Refer to the following sections for guidelines on the interaction of electromagnetic interference and an implanted deep brain stimulation system.

Medical Environment

Most routine diagnostic procedures, such as fluoroscopy and x-rays, are not expected to affect system operation. However, because of higher energy levels, sources such as transmitting antennas found on various diagnostic and therapeutic equipment may interfere with the brain stimulation system.

Somatic Psychiatric Therapies – The safety of somatic psychiatric therapies using equipment that generates electromagnetic interference (eg, vagus nerve stimulation) has not been established.

Effects on Other Medical Devices – The brain stimulation system may affect the operation of other implanted devices, such as cardiac pacemakers and implantable defibrillators. Possible effects include sensing problems and inappropriate device responses. If the patient requires concurrent implantable pacemaker and/or defibrillator therapy, careful programming of each system may be necessary to optimize the patient's benefit from each device.

Electrocautery – Electrocautery can damage the lead, the extension, or both. It can also cause temporary suppression of neurostimulator output and/or reprogramming of the neurostimulator. If use of electrocautery is necessary, the current path (ground plate) should be kept as far away from the neurostimulator, extension, and lead as possible, and use of bipolar electrocautery is recommended.

External Defibrillators – If a patient requires external defibrillation, the first consideration should be patient survival. Safety for use of external defibrillatory discharges on patients with neurostimulation systems has not been established. External defibrillation may damage a neurostimulator.

If external defibrillation is necessary, follow these precautions to minimize current flowing through the neurostimulator and lead system:

- Position defibrillation paddles as far from the neurostimulator as possible.
- Position defibrillation paddles perpendicular to the implanted neurostimulator-lead system.
- Use the lowest clinically appropriate energy output (watt seconds).
- Confirm neurostimulation system function following any external defibrillation.

High Radiation Sources – High radiation sources, such as cobalt 60 or gamma radiation, should not be directed at the neurostimulator. If a patient requires radiation therapy in the vicinity of the neurostimulator, place lead shielding over the device to prevent radiation damage.

Lithotripsy – Use of high output ultrasonic devices, such as an electrohydraulic lithotriptor, is not recommended for patients with an implanted neurostimulation system. While there is no danger to the patient, exposure to high output ultrasonic frequencies may result in damage to the neurostimulator circuitry. If lithotripsy must be used, do not focus the beam near the neurostimulator.

Home or Occupational Environment

Home Appliances – Home appliances that are in good working order and properly grounded do not usually produce enough electromagnetic interference (EMI) to interfere with neurostimulator operation. However, items with magnets (e.g., stereo speakers, refrigerators, freezers, power tools) may cause the neurostimulator to switch On or Off.

Occupational Environments – Commercial electrical equipment (arc welders, induction furnaces, resistance welders), communication equipment (microwave transmitters, linear power amplifiers, high-power amateur transmitters), and high voltage power lines may generate enough electromagnetic interference (EMI) to interfere with neurostimulator operation if approached too closely.

Patient Activities/Environmental Precautions – Patients should exercise reasonable caution in avoidance of devices which generate a strong electric or magnetic field. Close proximity to high levels of electromagnetic interference (EMI) may cause a neurostimulator to switch On or Off. The system also may unexpectedly cease to function due to battery depletion or other causes. For these reasons, the patient should be advised about any activities that would be potentially unsafe if their symptoms unexpectedly return. For additional information about devices which generate electromagnetic interference, call Medtronic at 1-800-707-0933.

Patient Magnet – The magnet provided to the patient for device activation and deactivation may damage televisions, computer disks, computer monitors, credit cards, and other items affected by strong magnetic fields.

Radio Frequency Sources – Analog and digital cellular phones, AM/FM radios, cordless phones, and conventional wired telephones may contain permanent magnets. To prevent undesired turning On or Off of the stimulation, these devices should be kept at least 4 inches (10 cm) away from the implanted neurostimulator.

Therapeutic Magnets – Therapeutic magnets (for example, those found in bracelets, back braces, shoe inserts and mattress pads) can cause inadvertent on or off activations of the neurostimulator. Therefore, patients should be advised not to use them.

Adverse Events

Reported Adverse Events

There were a total of 347 adverse events reported in 26 of the 26 subjects (100%) in the pooled cohort. The adverse events are categorized as follows:

- Surgical/Procedure-Related – associated with surgical implantation of the deep brain stimulation (DBS) system
- Device-Related – caused by the implanted system
- Therapy-Related – caused by the electrical stimulation of the nervous system while treating the subjects' symptoms
- Disorder-Related – an event that might reasonably be attributed to the patients' underlying disease state, concomitant medications or treatment regimens, or other comorbid conditions

Deaths and Serious Adverse Events

There were a total of 23 serious adverse events reported in 11 subjects (42.3%). All serious adverse events, excluding 1 patient death, were resolved. Table 1 summarizes the serious adverse events.

One death in the 26 patients at the four collaborating centers was reported. The death was identified as being related to a pre-existing condition (cancer progression) in 1 patient and was not considered to be related to Reclaim DBS Therapy.

An additional death in a patient with OCD receiving Reclaim DBS Therapy was reported in the published literature[1]. Abelson et al., (2005) reported 1 suicide in their study of 4 patients, and concluded that the suicide was not related to the Reclaim DBS Therapy. This death is not included in the summary (Table 1) since it was not reported directly and did not occur in the primary patient cohort.

Two instances of intracranial hemorrhage due to surgery were reported. One was asymptomatic and resolved without further consequence. The second resulted in an increase in apathy, which resolved with time. One subject suffered a single tonic-clonic seizure shortly after implantation of the leads. This subject has had no further seizures. There was 1 report of infection, which was treated and resolved.

Seven events of increased depression or suicidality and 3 instances of increased or fluctuating OCD symptoms were reported. Some of these reports occurred during periods when Reclaim DBS Therapy was actively on and several reports were associated with discontinuation of stimulation due to study design or battery depletion.

[1] Abelson JL, Curtis GC, Sagher O, Albucher RC, Harrigan M, Taylor SF, Martis B, Giordani B. Deep brain stimulation for refractory obsessive-compulsive disorder. *Biol Psychiatry.* 2005 Mar 1;57 (5): 510-6.

One subject was involved in a car accident and an incident of domestic disturbance. One occurrence of hypomania and 1 of violent behavior requiring medical intervention were reported. Two subjects had a broken lead or extension, which required surgical replacement. One compression fracture and 1 kidney infection occurred in subjects during the study period.

Table 1. *Serious Adverse Events*

	Events	Patients
Suicidality/increased depression	7	5 (19.2%)
Increased OCD/fluctuating results	3	3 (11.5%)
Hemorrhage, intracranial	2	2 (7.7%)
Lead/extension failure	2	2 (7.7%)
Aggression/violent behavior	1	1 (3.8%)
Car accident	1	1 (3.8%)
Compression fracture	1	1 (3.8%)
Domestic problems/irritability	1	1 (3.8%)
Death	1	1 (3.8%)
Hypomania	1	1 (3.8%)
Infection	1	1 (3.8%)
Pyelonephritis	1	1 (3.8%)
Seizure, post-operative	1	1 (3.8%)
Total	**23**	**11 (42.3%)**

Summary of Reported Adverse Events

Table 2 summarizes the adverse events reported in the Reclaim DBS Therapy for OCD clinical studies.

Table 2. *Reported Adverse Events*

	Events	Patients
Surgical/Procedure-Related	**46**	**14 (53.8%)**
Pain or discomfort at incision/implant sites	21	12 (46.2%)
General post-op discomfort	5	3 (11.5%)
GI symptom (post op)	5	2 (7.7%)
Hemorrhage	2	2 (7.7%)
Infection	2	1 (3.8%)
Apathy	1	1 (3.8%)
Contact dermatitis	1	1 (3.8%)
Headaches	1	1 (3.8%)
Seizure	1	1 (3.8%)
Other	7	3 (11.5%)
Device-Related	**5**	**5 (19.2%)**
Broken lead or extension	2	2 (7.7%)
Erosion of system components through skin	1	1 (3.8%)
Sensation of shock during programming	1	1 (3.8%)
Switched off	1	1 (3.8%)

Table 2. Reported Adverse Events (Continued)

	Events	Patients
Therapy-Related	**188**	**23 (88.5%)**
Increased OCD symptoms	22	12 (46.2%)
Increased anxiety	19	11 (42.3%)
Insomnia	18	12 (46.2%)
Increased depression/suicidality	13	10 (38.5%)
Cognitive disturbance (clouding)	11	8 (30.8%)
Induced muscle contraction	10	7 (26.9%)
Hypomania	9	9 (34.6%)
Restlessness	8	3 (11.5%)
Stimulation induced parasthesia	7	6 (23.1%)
Induced sensation of taste/smell	7	5 (19.2%)
Irritability	6	5 (19.2%)
Weight gain	6	6 (23.1%)
Increased fatigue	5	4 (15.4%)
Upper respiratory infection	5	4 (15.4%)
Headaches	4	4 (15.4%)
Increased tics	4	1 (3.8%)
Dizziness	3	2 (7.7%)
GI upset	3	3 (11.5%)
Decreased appetite	2	1 (3.8%)
Dry mouth	2	2 (7.7%)
Dysarthria	2	1 (3.8%)
Itching at surgical site(s)	2	2 (7.7%)
Nausea	2	2 (7.7%)
Sedation	2	2 (7.7%)
Urinary tract disturbance	2	1 (3.8%)
Weight loss	2	2 (7.7%)
Acne	1	1 (3.8%)
Cervical neck pain	1	1 (3.8%)
Congestion	1	1 (3.8%)
Edema	1	1 (3.8%)
IPG depletion	1	1 (3.8%)
Increased sleeping	1	1 (3.8%)
Induced sensation, IPG pocket	1	1 (3.8%)
Intermittent shocks/jolts	1	1 (3.8%)
Left kidney area pain	1	1 (3.8%)
Lethargy	1	1 (3.8%)
Sore throat	1	1 (3.8%)
Unequal pupils	1	1 (3.8%)
Disorder-Related	**108**	**24 (92.3%)**
Changes in mood, anxiety, or anger	16	10 (38.5%)
Gastrointestinal disturbances	11	9 (34.6%)

Table 2. *Reported Adverse Events (Continued)*

	Events	Patients
Insomnia	10	6 (23.1%)
Headaches	6	5 (19.2%)
Increased fatigue	6	5 (19.2%)
Sedation	4	2 (7.7%)
Urinary tract disturbance	3	2 (7.7%)
Back pain	2	2 (7.7%)
Contact dermatitis	2	1 (3.8%)
Cough	2	1 (3.8%)
Disequilibrium	2	2 (7.7%)
Diverticulosis	2	1 (3.8%)
Restless limbs	2	2 (7.7%)
Tremor	2	2 (7.7%)
Abnormal blood sugar	1	1 (3.8%)
Adenomyosis	1	1 (3.8%)
Aggression/violent behavior	1	1 (3.8%)
Ankle fracture	1	1 (3.8%)
Attention/cognitive deficits	1	1 (3.8%)
Car accident	1	1 (3.8%)
Chronic cough	1	1 (3.8%)
Compression fracture	1	1 (3.8%)
Depersonalization	1	1 (3.8%)
Edema	1	1 (3.8%)
Facial numbness	1	1 (3.8%)
Fall	1	1 (3.8%)
Fatigue	1	1 (3.8%)
Fever	1	1 (3.8%)
Flu	1	1 (3.8%)
General sense of not feeling well	1	1 (3.8%)
Hair twirling	1	1 (3.8%)
Hematoma, subcutaneous (eye)	1	1 (3.8%)
Increased OCD symptoms	1	1 (3.8%)
Increased sexual interest	1	1 (3.8%)
Itching above eye	1	1 (3.8%)
Memory worsening	1	1 (3.8%)
Muscle cramps in neck	1	1 (3.8%)
Muscle rigidity	1	1 (3.8%)
Numbness in arm after coughing	1	1 (3.8%)
Nystagmus	1	1 (3.8%)
Oral paresthesia	1	1 (3.8%)
Paresis/numbness in hand	1	1 (3.8%)
Pneumonia	1	1 (3.8%)
Shortness of breath	1	1 (3.8%)
Sinus inflammation	1	1 (3.8%)

Table 2. *Reported Adverse Events (Continued)*

	Events	Patients
Social withdrawal	1	1 (3.8%)
"Spaciness"	1	1 (3.8%)
Stomach pains	1	1 (3.8%)
Tennis elbow	1	1 (3.8%)
Twitching of nose	1	1 (3.8%)
Weight gain	1	1 (3.8%)
Weight loss	1	1 (3.8%)

Potential Adverse Events

In addition, one may reasonably expect the risks associated with the use of the Activa System for the approved indications of Parkinson's disease (PD) and essential tremor (ET) to be similar in treating OCD.

Over the entire PD study duration, 12/160 patients (7.5%) had intracranial hemorrhage; 17/160 patients (10.6%) had device-related infection; 16 patients (10.0%) had paresis/asthenia; and 13/160 patients (8.1%) had hemiplegia/hemiparesis (Table 3). The rate of stimulation related adverse events was 51.9% (83/160 patients) and the rate of ongoing stimulation-related events was 22.5% (36/160 patients). The rate of serious stimulation-related adverse events was 9.4% (15/160) and the rate of ongoing serious stimulation-related adverse events was 3.1% (5/160) patients. Ongoing serious stimulation-related adverse events included: worsening of motor impairment/PD symptoms (dyskinesia); sensory impairment (pain); and speech/ language (dysarthria, hypophonia, speech disorder). Other stimulation-related adverse events included: worsening of motor impairment/PD symptoms (worse motor fluctuations, incoordination, abnormal gait, akinesia/bradykinesia, tremor, rigidity, myoclonus, and dysphagia); sensory impairment (paresthesia, sensory disturbance, hypesthesia, hearing [tinnitus], and headache); speech/language (voice alteration); eye (visual disturbances [diplopia, abnormal vision, and visual field defect] and eye disorders [twitching]); cognitive (thinking abnormal, confusion, alteration of mentation [dizziness]); general (respiratory [laryngismus], musculo-skeletal [abnormal posture], gastrointestinal [vomiting], urogenital [urinary incontinence], metabolic/nutritional [weight loss], skin and appendages [sweating], and systemic [accidental injury]; sleep [somnolence and insomnia]; neuropsychological (psychiatric disturbances [manic reaction and neurosis]); general paresis/ asthenia; internal system events (shock/jolt, positioning difficulties); cardiovascular (cerebrovascular accident); hemiplegia/hemiparesis (asthenia); and depression.

The rate of device-related adverse events was 36.9% (59/160 patients) and the rate of ongoing device-related events was 10.0% (16/160 patients). The rate of serious device-relàted adverse events was 17.5% (28/160 patients) and the rate of ongoing serious device related adverse events was 6.3% (10/160 patients). Ongoing, serious device-related adverse events included: internal DBS system events (intermittent continuity, electromagnetic interference, and lead breakage); infection, worsening of motor impairment/PD symptoms (worse motor fluctuations, and incoordination) due to loss of effect; and skin and appendages (erosion). Other device-related adverse events included: internal DBS system events (shock/jolt, dislodged, migration, normal battery failure, malfunction, current leak, wire breakage, kinked electrode, electrode problem, positioning difficulties, impedance low); external system events (difficult to program, printer problem); sensory impairment (pain, sensory disturbance, paresthesia, and headache); speech/language (hypophonia); skin and appendages (skin disorder); subcutaneous hemorrhage/seroma (seroma); paresis/asthenia; metabolic/

nutritional (edema); and cerebral spinal fluid abnormality (pneumocephalus). One patient experienced manic symptoms (manic reaction) and attention and cognitive deficits (thinking abnormal) concurrent with exposure to an electronic article surveillance (electromagnetic interference) device.

Table 3. *Summary of Adverse Events Reported in the Parkinson's Disease Clinical Trial*

Major Category	All Patients (n = 160)			
	# of Events (known serious)	Study Related	# (%) of Patients	95% CI**
Intracranial Hemorrhage*	13 (8)	13	12 (7.5%)	(3.4, 11.6)
Device-Related Infection*	32 (23)	31	17 (10.6%)	(5.9, 15.4)
Infection with Explant*	15 (15)	15	9 (5.6%)	(2.1, 9.2)
Infection without Explant*	17 (8)	16	12 (7.5%)	(3.4, 11.6)
Paresis/Asthenia*	16 (1)	6	16 (10%)	(5.4, 14.7)
Hemiplegia/Hemiparesis*	15 (8)	10	13 (8.1%)	(3.9, 12.4)
Worsening of Motor Impairment/ PD Symptom*	357 (48)	130	110 (68.8%)	(61.6, 75.9)
Dyskinesia*	131 (22)	64	60 (37.5%)	(30.0, 45.0)
Worse Motor Fluctuations*	85 (15)	23	56 (35%)	(27.6, 42.4)
Abnormal Gait*	38 (4)	10	30 (18.8%)	(12.7, 24.8)
Incoordination*	33 (3)	14	29 (18.1%)	(12.2, 24.1)
Tremor*	22 (0)	4	18 (11.3%)	(6.4, 16.2)
Akinesia/Bradykinesia*	20 (0)	9	19 (11.9%)	(6.9, 16.9)
Dysphagia*	13 (3)	2	12 (7.5%)	(3.4, 11.6)
Rigidity*	13 (1)	3	12 (7.5%)	(3.4, 11.6)
Myoclonus	1 (0)	1	1 (0.6%)	(0, 1.9)
Therapeutic Response, Decreased	1 (0)	0	1 (0.6%)	(0, 1.9)
Sensory Impairment*	148 (14)	59	79 (49.4%)	(41.6, 57.1)
Pain*	71 (5)	15	50 (31.3%)	(24.1, 38.4)
Paresthesia*	37 (1)	23	29 (18.1%)	(12.2, 24.1)
Sensory Disturbance*	18 (2)	11	16 (10%)	(5.4, 14.7)
Headache*	16 (4)	8	14 (8.8%)	(4.4, 13.1)
Neuralgia	3 (2)	0	3 (1.9%)	(0, 4.0)
Hearing*	2 (0)	1	2 (1.3%)	(0, 3.0)
Neuropathy	1 (0)	1	1 (0.6%)	(0, 1.9)
Cognitive*	142 (21)	61	72 (45%)	(37.3, 52.7)
Confusion*	56 (5)	27	44 (27.5%)	(20.6, 34.4)
Thinking Abnormal*	39 (3)	16	33 (20.6%)	(14.4, 26.9)
Hallucinations	15 (2)	1	11 (6.9%)	(3.0, 10.8)
Alteration of Mentation*	16 (5)	9	14 (8.8%)	(4.4, 13.1)
Amnesia*	9 (2)	6	8 (5.0%)	(1.6, 8.4)
Delusions*	5 (4)	0	4 (2.5%)	(0, 4.9)
Dementia	2 (0)	2	2 (1.3%)	(0, 3.0)

* At least one instance was associated with the system components.

** Note: Exact 95% confidence intervals were used when the # (%) of patients was 0 (0%) because the normal approximation to the binomial does not provide a confidence interval. In every other case, the normal approximation to the binomial was used to calculate confidence intervals.

Table 3. *Summary of Adverse Events Reported in the Parkinson's Disease Clinical Trial (continued)*

Major Category	All Patients (n = 160)			
	# of Events (known serious)	Study Related	# (%) of Patients	95% CI**
DBS System*	93 (33)	80	57 (35.6%)	(28.2, 43.1)
Internal*	86 (33)	74	55 (34.4%)	(27.0, 41.7)
External*	7 (0)	6	6 (3.8%)	(0.8, 6.7)
Speech/Language*	77 (15)	48	59 (36.9%)	(29.4, 44.4)
Dysarthria*	47 (6)	32	42 (26.3%)	(19.4, 33.1)
Speech/Language*	30 (9)	16	23 (14.4%)	(8.9, 19.8)
Neuropsychological*	55 (18)	6	31 (19.4%)	(13.3, 26.0)
Psychiatric Disturbances*	25 (8)	4	14 (8.8%)	(4.4, 13.1)
Personality Disorder	12 (4)	1	9 (5.6%)	(2.1, 9.2)
Hostility	6 (2)	0	5 (3.1%)	(0.4, 5.8)
Manic Reaction*	5 (2)	2	3 (1.9%)	(0, 4.0)
Neurosis*	1 (0)	1	1 (0.6%)	(0, 1.9)
Paranoid Reaction	1 (0)	0	1 (0.6%)	(0, 1.9)
Anxiety*	25 (7)	2	20 (12.5%)	(7.4, 17.6)
Apathy	4 (2)	0	4 (2.5%)	(0, 4.9)
Suicide Attempt	1 (1)	0	1 (0.6%)	(0, 1.9)
Depression*	41 (10)	4	35 (21.9%)	(15.5, 28.3)
Sleep*	45 (1)	8	37 (23.1%)	(16.6, 29.7)
Eye*	48 (6)	25	39 (24.4%)	(17.7, 31.0)
Visual Disturbance*	33 (6)	20	30 (18.8%)	(12.7, 24.8)
Eye Disorder*	10 (0)	5	9 (5.6%)	(2.1, 9.2)
Eye Infection*	5 (0)	0	4 (2.5%)	(0, 4.9)
Subcutaneous Hemorrhage/Seroma*	15 (6)	10	14 (8.8%)	(4.4, 13.1)
Convulsions	7 (6)	5	7 (4.4%)	(1.2, 7.5)
Death	3 (3)	0	3 (1.9%)	(0, 4.0)
Cerebral Spinal Fluid Abnormality	5 (1)	5	5 (3.1%)	(0.4, 5.8)

* At least one instance was associated with the system components.

** Note: Exact 95% confidence intervals were used when the # (%) of patients was 0 (0%) because the normal approximation to the binomial does not provide a confidence interval. In every other case, the normal approximation to the binomial was used to calculate confidence intervals.

Table 3. *Summary of Adverse Events Reported in the Parkinson's Disease Clinical Trial (continued)*

Major Category	All Patients (n = 160)			
	# of Events (known serious)	Study Related Known/Unknown	# (%) of Patients	95% CI**
General*	312 (52)	40	110 (68.8%)	(61.6, 75.9)
Systemic*	75 (14)	7	49 (30.6%)	(23.5, 37.8)
Gastrointestinal*	55 (5)	9	41 (25.6%)	(18.9, 32.4)
Urogenital*	53 (7)	3	43 (26.9%)	(20.0, 33.7)
Respiratory	43 (10)	8	30 (18.8%)	(12.7, 24.8)
Metabolic/Nutritional*	36 (4)	6	29 (18.1%)	(12.2, 24.1)
Musculo-Skeletal*	21 (7)	2	19 (11.9%)	(6.9, 16.9)
Skin and Appendages*	25 (5)	5	22 (13.8%)	(8.4, 19.1)
Ecchymosis	1 (0)	0	1 (0.6)	(0, 1.9)
Erosion*	3 (3)	2	3 (1.9%)	(0, 4.0)
Infection, fungal	2 (0)	0	2 (1.3%)	(0, 3.0)
Lymphedema	1 (0)	0	1 (0.6%)	(0, 1.9)
Petechia	1 (0)	0	1 (0.6%)	(0, 1.9)
Psoriasis	1 (1)	0	1 (0.6%)	(0, 1.9)
Rash	7 (0)	0	7 (4.4%)	(1.2, 7.5)
Skin Disorder*	6 (1)	2	6 (3.8%)	(0.8, 6.7)
Sweating*	3 (0)	1	3 (1.9%)	(0, 4.0)
Ear	4 (0)	0	4 (2.5%)	(0, 4.9)
Cardiovascular*	64 (14)	24	32 (20%)	(13.8, 26.2)

* At least one instance was associated with the system components.

** Note: Exact 95% confidence intervals were used when the # (%) of patients was 0 (0%) because the normal approximation to the binomial does not provide a confidence interval. In every other case, the normal approximation to the binomial was used to calculate confidence intervals.

Clinical Studies

Clinical Rating Scale

The Yale-Brown Obsessive Compulsive Scale (YBOCS) is a 10-item, clinician-administered scale developed to assess the severity of obsessions and compulsions, independent of the number and type of obsessions or compulsions.

According to the OCD treatment consensus guideline,[1] the currently accepted definition of severe OCD, taking into account patient disability, is a score of 30 or greater on the YBOCS instrument, described as follows:

- Mild OCD (YBOCS score of 10-18) causes distress but not necessarily dysfunction; help from others is usually not required to get through the day.
- Moderate OCD (YBOCS score of 18-29) causes both distress and functional impairment.
- Severe OCD (YBOCS score of 30 or above) causes serious functional impairment requiring significant help from others.

Summary

The probable benefit of the Reclaim system in treating OCD was demonstrated in feasibility studies performed at 3 sites in the US and 1 site outside the US. At 1 site in the US and the OUS site, the pilot studies were designed as randomized controlled double blind studies.

Patient Demographics

Results from 26 treatment-resistant OCD patients treated with DBS at 4 collaborating centers, 3 in the US, and 1 in Europe are summarized in Table 4. All patients met stringent inclusion criteria including disease severity (YBOCS >30), treatment refractoriness, and symptom duration (minimum of 5 years).

Mean age for the patient cohort at time of implant was 37 years, with approximately equal numbers of males and females (53.8%/ 46.2%). Mean duration of symptoms for these patients averaged 22 years, demonstrating the long-standing, treatment-resistant nature of the disorder in this population. Treatment duration ranged from 85.6 months to slightly over 3 months for the most recently treated individuals. All patients had been treated with multiple trials of medications and had also undergone cognitive behavioral therapy. Many patients remained on multiple stable medications. A majority of the patients (89%) also reported a history of comorbid depression (major depressive disorder [MDD]) associated with their severe OCD.

[1] March JS, Frances A, Kahn DA, Carpenter D, eds. The Expert Consensus Guideline Series: Treatment of Obsessive-Compulsive Disorder. *J Clin Psychiatry.* 1997;58 (suppl 4).

Table 4. Patient demographics

Center/ Patient	Age at Implant	Implant Dur (Months)	Gender (M/F)	Age at OCD Onset	Symptom Dur (Yrs)	Secondary Diagnosis (Axis I / Axis II)	History of Depression	History of CBT
Butler Hospital								
BH1	32	53.5	M	10	22	MDD (single episode), OCDPD	Y	Y
BH2[a]	40	51.5	F	16	24	MDD (hypomanic episode)	Y	Y
BH3	39	49.2	M	12	27	Dysthymia	Y	Y
BH4[a]	26	40.3	F	15	11	MDD	Y	Y
BH5	32	30.8	M	10	22	MDD	Y	Y
Cleveland Clinic								
CC1[b]	59	12.0	F	19	40	None	N	Y
CC2	35	40.5	F	12	23	MDD	Y	Y
CC3	22	38.8	M	8	14	MDD, schizophrenic traits	Y	Y
CC4	23	34.2	M	7	16	MDD	Y	Y
CC5	45	18.8	M	19	26	None	N	Y
University of Florida								
FL1	32	26.9	F	24	8	MDD (single episode)	Y	Y
FL2	50	21.0	M	34	16	MDD (recurrent)	Y	Y
FL3	38	17.5	M	22	16	MDD (recurrent, in remission)	Y	Y
FL4	32	8.2	M	10	22	MDD (in remission)	Y	Y
FL5	32	3.3	F	15	17	MDD (partial remission)	Y	Y

Table 4. Patient demographics (Continued)

Center/ Patient	Age at Implant	Implant Dur (Months)	Gender (M/F)	Age at OCD Onset	Symptom Dur (Yrs)	Secondary Diagnosis (Axis I / Axis II)	History of Depression	History of CBT
Luevan								
LV1[c]	35	15.0	M	12	23	MDD, Histrionic, narcissistic	Y	Y
LV2	52	85.6	F	24	28	MDD, Generalized anxiety disorder	Y	Y
LV3	39	70.7	F	16	23	MDD, Panic attacks, dependent PD	Y	Y
LV4[c]	35	41.0	M	12	23	MDD (past comorbid)	Y	Y
LV5	40	44.9	F	14	26	MDD (past)	Y	Y
LV6	37	38.8	M	16	21	MDD (comorbid)	Y	Y
LV7	39	27.8	F	15	24	MDD (past)	Y	Y
LV8	40	27.5	M	14	26	MDD (comorbid), panic attacks	Y	Y
LV9	23	10.4	M	12	11	MDD	Y	Y
LV10	30	5.3	F	9	21	None	N	Y
LV11	57	3.5	F	16	41	MDD	Y	Y

Table 4. Patient demographics (Continued)

Center/ Patient	Age at Implant	Implant Dur (Months)	Gender (M/F)	Age at OCD Onset	Symptom Dur (Yrs)	Secondary Diagnosis (Axis I / Axis II)	History of Depression	History of CBT
Mean:	37.1	31.4	M=53.8% F=46.2%	15.1	22.0		Yes=88.5% No=11.5%	Yes=100% No=0%
Min:	22.0	3.3		7.0	8.0			
Max:	59.0	85.6		34.0	41.0			

[a] Stimulators turned off at 12 months post-implant.

[b] This patient died in January 2003 from pneumonia and cancer, not related to the study.

[c] Number of implant months at time DBS system explanted.

Patient Discontinuation

Four of the 26 patients from the 4 collaborating centers have chosen to discontinue deep brain stimulation. These patients are listed in Table 5 (including the patient death). None of these patients were reported as a YBOCS responder (based upon the 35% response criterion) in any prior analyses.

Three of the 4 patients discontinued DBS due to lack of effectiveness. One discontinued DBS because of the inability to achieve an effective level of treatment without adverse effects (hypomania).

Two of these 4 patients elected to have their Reclaim DBS System explanted and proceeded to undergo a capsulotomy.

Table 5. *Patient discontinuation*

Patient	Event	Time of Event (Post-implant)	Reason for Therapy Termination	DBS System Explanted	Last Follow-up (Outcome Measures)
BH2[a]	Stimulators Turned Off	12 months	No change in OCD symptoms	N	36 months
BH4[a]	Stimulators Turned Off	12 months	No change in OCD symptoms	N	36 months
CC1	Death	12 months	Cancer	N	6 months
LV1	Capsulotomy	15 months	Lack of DBS effectiveness	Y	12 months
LV4	Capsulotomy	41 months	Inability to titrate DBS to effective level (between effective therapy and hypomania)	Y	36 months

[a] Data after therapy discontinuation included in outcome measures for intent-to-treat analyses.

OCD Symptoms (YBOCS)

Table 6 shows the YBOCS scores, collected over a period of up to 3 years, for the patients treated with DBS at these 4 centers. On average this patient population showed a progressive and sustained improvement in YBOCS ratings as illustrated in Figure 3.

Table 6. YBOCS scores

Patient	Pre-Stim		Months						
	Base-line	Post-op	1	3	6	12	12 (LOCF)[a]	24	36
BH1	32	28	30	28	16	15	15	24	20
BH2	34	30	27	26	25	25	25	27	30
BH3	35	35	27	26	24	26	26	25	24
BH4	34	30	21	19	27	29	29	32	30
BH5	33	33	30	19	28	26	26	24	.
CC1	38	38	28	30	31	.	31	.	.
CC2	36	35	32	29	24	30	30	20	22
CC3[b]	35	34	30	31	28	30	30	18	18
CC4[b]	33	34	26	16	9	8	8	9	12
CC5[c]	36	36	29	26	27	20	20	21	.
FL1	37	21	36	18	14	26	26	12	.
FL2	31	35	37	28	29	29	29	.	.
FL3	33	28	35	26	31	7	7	.	.
FL4	31	30	36	35	29	.	29	.	.
FL5	32	26	30	20	.	.	20	.	.
LV1	38	.	.	30	33	31	31	.	.
LV2	33	.	25	20	14	25	25	21	21
LV3	30	.	17	12	14	16	16	11	9

Table 6. YBOCS scores (Continued)

	Pre-Stim		Months						
Patient	**Base-line**	**Post-op**	**1**	**3**	**6**	**12**	**12 (LOCF)[a]**	**24**	**36**
LV4	38	.	23	22	18	22	22	22	26
LV5[d]	34	.	30	28	26	25	25	34	32
LV6	30	.	3	24	15	12	12	1	7
LV7	35	.	10	14	9	7	7	3	.
LV8	32	.	18	8	17	14	14	13	.
LV9	31	.	24	5	8	2	2	.	.
LV10	37	.	18	1	5	.	5	.	.
LV11	36	.	13	6	.	.	6	.	.
N	26	15	25	26	24	21	26	17	12
Mean	**34.0**	**31.5**	**25.4**	**21.0**	**20.9**	**20.2**	**19.8**	**18.6**	**20.9**
Median	**34.0**	**33.0**	**27.0**	**23.0**	**24.0**	**25.0**	**23.5**	**21.0**	**21.5**
S.D.	(2.5)	(4.5)	(8.5)	(9.0)	(8.5)	(9.0)	(9.5)	(9.3)	(8.3)
Avg% Chg		**-7.1%**	**-24.7%**	**-37.9%**	**-38.6%**	**-40.7%**	**-41.8%**	**-45.4%**	**-38.7%**
Median% Chg		**-2.9%**	**-21.2%**	**-32.6%**	**-32.4%**	**-29.7%**	**-33.6%**	**-42.1%**	**-36.9%**

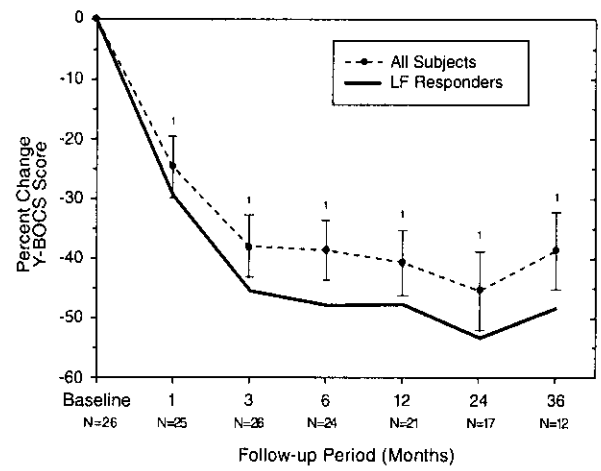
[a] Last observation carried forward (LOCF) conducted for 12-month time point. Data for 5 patients (CC1, FL4, FL5, LV10, LV11) imputed using last measured YBOCS score prior to 12-month follow-up.

[b] Last follow-up for patients CC3 and CC4 occurred at 33 and 32 months respectively. For analyses, the data is reported as the 36-month time point.

[c] Last follow-up for patient CC5 was at 19 months. For analyses, the data are reported as the 24-month time point.

[d] At the time of surgery, this patient was implanted with bilateral DBS electrodes in the anterior limbs of the internal capsule, and a second set of DBS electrodes in the dorsomedial thalamus, to investigate an alternative DBS target. At 27 months, the capsular electrodes were turned off, due to lack of therapeutic response, and the electrodes in the dorsomedial thalamus were turned on. The final data point for this patient (a non-responder) at 36 months is included in the intent-to-treat analysis.

At 12 months, data was available for only 21 of the 26 subjects. At 12 months, the average YBOCS score for the group (n=21) had decreased 40.7%, with a corresponding decrease of 45.4% for the cohort followed out to 24 months (n=17). In the subgroup of patients that met clinical response criterion (>25% or greater reduction on the YBOCS), the magnitude of these improvements were even greater (Figure 3). Using a last observation carried forward (LOCF) analysis for all patients, the average YBOCS reduction was 41.8% at the 12-month time point.



[1] Within-subject change statistically significant ($p \leq .001$, 2-sided test).
LF - Last follow-up.

Figure 3. *Average YBOCS scores following DBS treatment*

On average, patients treated with DBS at these 4 centers had a greater than two-thirds chance of attaining a meaningful clinical benefit (>25% YBOCS decrease at last follow-up), and if a patient reached this response criterion, the average improvement at 6 months and 12 months post-treatment was approximately a 50% reduction in YBOCS score.

According to the Expert Consensus Panel on OCD (1997), a responder is considered a subject who demonstrates a 35% reduction in their YBOCS score and a partial responder is a subject with a 25% reduction in their YBOCS score. At 12 months, 10 subjects met the 35% response criterion and an additional 4 met the 25% responder criterion (Table 7). An LOCF analysis at this time point results in 13 of 26 patients meeting the 35% response level, and 4 patients meeting the 25% level.

At last follow-up, almost two-thirds of the patient population (16/26, 61.5%) met the more conservative criterion for a clinical improvement (>35% YBOCS reduction), and another 11.5% (3/26) met the 25% reduction response criterion (Table 7).

Table 7. Responder rates: Sample size (percent), and [95% Confidence Interval]

		Non-Responders	Partial Responders	Full Responders	Full & Partial Responders
Time	**No. of Patients**	**0 to < 25% Reduction**	**≥ 25% & < 35% Reduction**	**≥ 35% Reduction**	**> 25% Reduction**
6 Months	24	9 (37.5%) [18.8%, 59.4%]	4 (16.7%) [4.7%, 37.4%]	11 (45.8%) [25.6%, 67.2%]	15 (62.5%) [40.6%, 81.2%]
12 Months	21	7 (33.3%) [14.6%, 57.0%]	4 (19.0%) [5.4%, 41.9%]	10 (47.6%) [25.7%, 70.2%]	14 (67.7%) [43.0%, 85.4%]
12 Months (LOCF)[a]	26	9 (34.6%) [17.2%, 55.7%]	4 (15.4%) [4.4%, 34.9%]	13 (50.0%) [29.9%, 70.1%]	17 (65.4%) [44.3%, 82.8%]
Last Follow-up	26	7 (26.9%) [11.6%, 47.8%]	3 (11.5%) [2.4%, 30.2%]	16 (61.5%) [40.6%, 79.8%]	19 (73.1%) [52.2%, 88.4%]

[a] Last observation carried forward (LOCF) conducted for 12-month time point. Data for 5 patients (CC1, FL4, FL5, LV10, LV11) imputed using last measured YBOCS score prior to 12-month follow-up.

These changes in YBOCS scores measured in this patient group reflect a considerable reduction in symptom severity as defined by this clinical rating scale. At baseline, 100% (26/26) of the patients enrolled into the study protocols at the 4 collaborating centers met the criterion for "severe" OCD (YBOCS score of 30 or greater) as defined by the Expert Consensus Panel on obsessive compulsive disorder (1997). Table 8 summarizes the results of the 26 subjects according to this guideline: mild 10-18, moderate 18-29, severe >30. Results at 6 months, 12 months, 12-month LOCF, and last FU, show that over 80% of the patients had decreased in severity from severe at baseline to either mild or moderate.

Table 8. *OCD severity ratings*

		Range of OCD Severity		
Time	**No. of Patients**	**Mild (10-18)**	**Moderate (18-29)**	**Severe (30 or above)**
Baseline	26	0 (0.0%)	0 (0.0%)	26 (100.0%)
6 Months	24	11 (45.8%)	10 (41.7%)	3 (12.5%)
12 Months	21	8 (38.1%)	10 (47.6%)	3 (14.3%)
12 Months (LOCF)[a]	26	10 (38.5%)	12 (46.2%)	4 (15.4%)
Last Follow-up	26	11 (42.3%)	10 (38.5%)	5 (19.2%)

[a] Last observation carried forward (LOCF) conducted for 12-month time point. Data for 5 patients (CC1, FL4, FL5, LV10, LV11) imputed using last measured YBOCS score prior to 12-month follow-up.

A majority of the treatment-resistant patients treated with deep brain stimulation obtained benefit. Approximately two-thirds of the patients met the accepted criterion for a clinical response (25% reduction in YBOCS) at 6 months, 12 months, and last follow-up, and approximately half of the patients met the more stringent criterion of a 35% reduction at these time points. A majority of the patients moved from a severe OCD rating category at baseline, to a mild or moderate rating at subsequent post-treatment time points.

There are 4 subtypes of OCD according to the Leckman[1] scheme. As seen in Table 9, subjects with the obsessions and checking subtype, had the best response, i.e. 74.0%, as measured by the YBOCS. In addition, the majority of subjects had comorbid anxiety and depression which also improved during treatment. No subjects with hoarding as their primary subtype were included in the study.

[1] Leckman JF, Grice DE, Boardman J, Zhang H, Vitale A, Bondi C, Alsobrook J, Peterson BS, Cohen DJ, Rasmussen SA, Goodman WK, McDougle CJ, Pauls DL. Symptoms of obsessive compulsive disorder. *Am J Psychiatry.* 1997;154:911-917.

Table 9. OCD, depression, anxiety improvements by sub-type

OCD sub-type	N	YBOCS		HAM-D		HAM-A	
		Mean	SD	Mean	SD	Mean	SD
Hoarding	0	-	-	-	-	-	-
Cleanliness and washing	11	-31.9%	19.7%	-45.2%	33.1%	-38.5%	33.1%
Obsessions and checking	6	-74.0%	13.7%	-77.4%	16.3%	-66.9%	33.4%
Symmetry and ordering	9	-42.9%	33.2%	-45.6%	31.8%	-52.8%	30.6%

In each of these subtype categories, there were patients that responded to DBS therapy (45% responder rate for cleanliness and washing [n=11]; 56% responder rate for symmetry and ordering [n=9]; and 100% responder rate for obsessions and checking [n=6]).

An analysis of differences in prescribed medications between DBS responders and nonresponders found that patients who responded to DBS showed little change in the number of psychotropic drugs prescribed (-2.8% change) between baseline and last follow-up, compared to nonresponders, who showed an increase (15.4%) in these medications.

Two of the 4 centers incorporated a randomized blinded period of stimulation using a crossover design. As can be seen in the following tables, subjects had a greater reduction in their YBOCS and HAM-D scores during stim on as compared to stim off.

Table 10. *Period 1 results - YBOCS*

STIM	N	YBOCS	Baseline (BL)	Period 1 (P1)	Diff (P1-BL)	%Chg (P1-BL)
ON	9	Mean	34.3	13.1	-21.2	-62.1%
		SD	(3.2)	(8.6)	(8.2)	22.4%
OFF	7	Mean	32.7	30.1	-2.6	-8.3%
		SD	(2.2)	(11.7)	(11.1)	35.7%
P values[a]:			0.253	0.008	0.003	0.006

[a] Two -sample t-test assuming unequal variances (2 tailed).

Table 11. *Period 1 results - HAM-D*

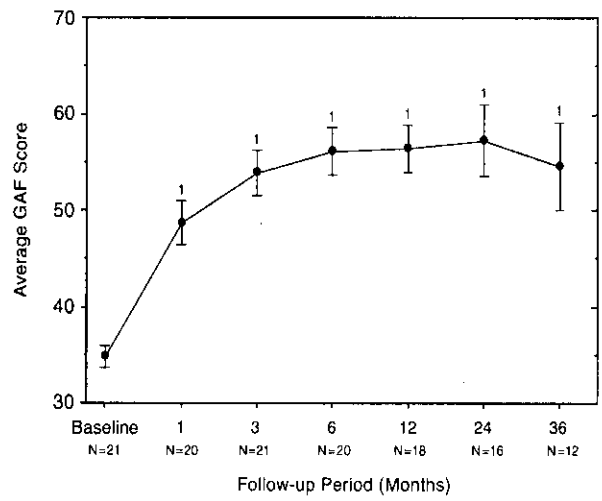
STIM	N	HAM-D	Baseline (BL)	Period 1 (P1)	Diff (P1-BL)	%Chg (P1-BL)
ON	9	Mean	24.2	10.1	-14.1	-59.4%
		SD	(8.2)	(7.8)	(6.0)	21.9%
OFF	7	Mean	14.9	17.3	2.4	27.2%
		SD	(5.8)	(5.3)	(6.0)	54.2%
P values[a]:			0.019	0.047	0.000	0.005

[a] Two -sample t-test assuming unequal variances (2 tailed).

Global Assessment of Function (GAF)

In conjunction with the YBOCS measures, 3 of the 4 centers also collected corresponding ratings of Global Assessment of Function (GAF), a measure of overall psychological, social, and occupational functioning. At baseline, the majority of patients (20/21) had GAF scores ranging between 20 and 40, indicating very severe disability. GAF scores improved over time for the vast majority of patients with the average score increasing from a baseline value of 34.8 (n=21) to 56.1 (n=20) at 6 months, 56.4 (n=18) at 12 months, and 59.0 (n=21)

at last follow-up. An LOCF analysis at 12 months shows a similar level of improvement (mean=57.6) for all 21 patients. This improvement in GAF for the patient population is illustrated in Figure 4, which reflects a gradual and sustained increase in this measure of overall function, following deep brain stimulation.



[1] Within-subject change statistically significant ($p \leq .001$, 2-sided test).

Figure 4. *Average GAF score following DBS treatment*

Table 12 shows the distribution of GAF scores at various time points for the 21 patients. At baseline, 20 of 21 patients exhibited scores of 40 or less, while at last follow-up only 2 patients remained at this relatively low functional level. At 12 months (LOCF) and last follow-up, 48% and 62%, respectively, of the patients scored 51 or greater at last follow-up; no patients were able to achieve this degree of function at baseline. There was a clear, progressive shift in the distribution of scores from baseline to levels of higher function over time following DBS treatment in this patient population.

Table 12. Distribution of GAF scores

Functioning	Ratings	Number of Patients / % of Patients									
		Baseline		6 Months		12 Months		12 Months (LOCF)[a]		Last Follow-up	
Inability to function - all areas (judgment, thinking, mood)	21-30	7	33.3%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Major impairment in several areas (judgment, thinking, mood)	31-40	13	61.9%	0	0.0%	1	5.6%	1	4.8%	2	9.5%
Serious impairment (social, occupational, school)	41-50	1	4.8%	10	50.0%	9	50.0%	10	47.6%	6	28.6%
Moderate difficulty (social, occupational, school)	51-60	0	0.0%	3	15.0%	1	5.6%	1	4.8%	4	19.0%
Some difficulty (social, occupational, school)	61-70	0	0.0%	5	25.0%	6	33.3%	6	28.6%	6	28.6%
Slight impairment (social, occupational, school)	71-80	0	0.0%	2	10.0%	1	5.6%	3	14.3%	2	9.5%
Good functioning	81-90	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	4.8%
		21	100.0%	20	100.0%	18	100.0%	21	100.0%	21	100.0%

[a] Last observation carried forward (LOCF) conducted for 12-month time point. Data for 3 patients (CC1, LV10, LV11) imputed using last measured GAF score prior to 12-month follow-up.

Treating physicians also provided an impression of the overall, global condition of these patients after deep brain stimulation, including psychological, social, functional, occupational, and quality of life considerations. Those impressions were reported on a modified Lickert scale on case report forms, similar to the standard Pippard Postoperative Rating Scale using the 5-point scale shown in Table 13. The results of those ratings were tabulated and are summarized in Table 13. Overall, the treating physicians reported that approximately two-thirds of the patients were much better following deep brain stimulation, compared to their pre-treatment condition.

Table 13. *Clinical global outcome ratings*

Score	Rating	Number of Patients	Percentage
5	Much Better	17	65.4%
4	Slightly Better	5	19.2%
3	No Change	4	15.4%
2	Slightly Worse	0	0.0%
1	Worse	0	0.0%
	Count:	26	100.0%

Individualization of Treatment

Best results are achieved when the patient and caregiver are fully informed about the therapy risks and benefits, surgical procedures, follow-up requirements, and self-care responsibilities. Patients who may benefit from DBS include individuals diagnosed with OCD who meet the following objective criteria:

- Have chronic treatment resistant OCD
- Are suitable candidates for stereotactic surgery
- Have a diagnosis of OCD documented to be of five years or longer duration
- Have a YBOCS score of greater than or equal to 30
- Completed a minimum of three adequate trials of first- and/or second-line medications with augmentation
- Completed or have been unable to complete an adequate trial of Cognitive Behavior Therapy (CBT)
- Have no serious comorbid personality disorder or substance abuse issues
- Have comorbid depression and anxiety
- Meet established criteria for implantation of a DBS system
- Are 18 years of age or older

Use extreme care with lead implantation in patients with a heightened risk of intracranial hemorrhage. Physicians should consider underlying factors, such as previous neurological injury or prescribed medications (anticoagulants), that may predispose a patient to the risk of bleeding.

Physicians should be aware that the risks associated with initial surgery may increase with clinical conditions such as:

- Stroke or neurological disorders
- Cardiovascular disease
- Renal or hepatic failure
- Diabetes mellitus

To help ensure maximum benefits from the neurostimulation system, long-term, post-surgical management of patients is recommended.

Stimulation parameters should be adjusted such that maximal symptom improvement is achieved with minimal side effects. High parameter values may indicate a system problem or less than optimal lead placement. Patients should be informed of the risks of higher stimulation parameters, which may result in possible excessive charge density, as noted in "Programming the Neurostimulator" on page 71.

Directions for Use

The implantation of the DBS Lead requires stereotactic neurosurgical techniques for the initial implant and ongoing postoperative patient management (refer to page 69). Medtronic recognizes that a variety of approaches may be used to accomplish these goals. The following outline is presented as 1 possible approach for the physician's consideration. The target site for the Reclaim DBS Therapy for OCD is the anterior limb of the internal capsule (AIC) and adjacent ventral striatum.

The target site may be localized for stereotactic implantation of the DBS lead using CT scans, MRI, or ventriculography. Microelectrode recording has not been found to be effective in target localizing.

Neurostimulation Selection

If independent rate control of each lead is desired to provide adequate symptom control for your patient, be aware that rate parameter values are not independently programmable with the Kinetra Model 7428 neurostimulator. Consider implanting 2 Soletra Model 7426 neurostimulators or 2 Kinetra Model 7428 neurostimulators if independent rate values are desired.

Lead Implant Procedure

△ **Caution:** The stylet inserted in the Model 3391 DBS Lead is matched specifically to that individual lead; stylets are not interchangeable between the 3391 and other lead models or between individual leads of the same model.

To implant the DBS Lead, an insertion cannula and stylet should be placed to a point approximately 30 mm proximal to the target site for stimulation. The lead should be passed through the insertion cannula and advanced to the target site. To stabilize the lead in the insertion cannula, use the Model 3354 Lead Frame Kit (for Leksell stereotactic frames), or the Model 3353 Lead Frame Kit (for Radionics stereotactic frames).

The following steps outline the suggested lead implant procedure:

1. After placement of the stereotactic frame, use standard imaging techniques to determine coordinates for the lead's target site.

   Notes:

   - Individual patient brain dimensions and morphology are variable. The nominal target coordinate ranges for the tip of the 3391 DBS lead are listed in the following note. However, as in other DBS applications, the exact measurements and coordinates in each case must be individualized according to the patient's own anatomy and brain dimensions.
   - The trajectory through the AIC to the target for the deepest lead contact should enter from a burr hole placed approximately 2.5 cm lateral to the midline and at, or just anterior to the coronal suture, and should follow the course of the anterior limb of the internal capsule toward the point where fibers of the anterior commissure cross the anterior limb of the internal capsule. The nominal range of coordinates for these landmarks based upon the Mai, et al. and Schaltenbrand and Wahren brain atlases[1] is as follows:

     X = 5 to 10 mm lateral to the midline

     Y = 0 to 5 mm anterior to the anterior commissure

     Z = 1 to 5 mm inferior to the anterior commissure (intercommissural line)

2. Prepare the patient per normal stereotactic neurosurgical techniques.
3. Make a skin incision, with consideration given to burr hole placement.
4. Prepare a subgaleal pocket by blunt dissection at the top of the skull at the edge of the burr hole incision for placement of the excess lead wire and connector.

   Note: Placement of the pocket may be on either the left or right side of the skull.

5. Place a 14-mm diameter burr hole approximately 2.5 cm lateral to the midline and at, or just anterior to the coronal suture.

   Notes:

   - Medtronic recommends using a straight-edged 14-mm perforator to form the burr hole.

[1] Mai JK, Assheuer JK, Paxinos G. *Atlas of the Human Brain (First Edition)*, San Diego, Academic Press, 1997.
Schaltenbrand G. Wahren W. *Atlas for Stereotaxy of the Human Brain (Second Edition)*, Stuttgart Georg Thieme, 1977.

- Use the burr hole cap and ring packaged with the lead box or use the Stimloc burr hole cover that is also provided. See the technical manual provided with the Stimloc burr hole cover for instructions for use.

△ **Caution:** Use only the burr hole cap and ring or the Stimloc burr hole cover packaged with this lead to anchor the lead. The safety, effectiveness, and possible effects to the brain stimulation system of other methods (i.e. glues, cements, surgical plates) have not been established.

6. Place the burr hole ring tightly against the bone in the burr hole, using your finger and a curved mosquito hemostat.
7. Attach the lead holder assembly to the stereotactic frame, positioning the guide tube or collimator so that its distal end is 1.25 to 2.5 cm from the skull (Figure 5).

   Note: Refer to the Model 3353 (Radionics) or Model 3354 (Leksell) Lead Frame Kit Instructions.
8. Insert stylet into cannula.
9. Advance the insertion cannula through the guide tube to a point approximately 30 mm proximal to the lead's target site.

△ **Caution:** The lead electrodes must extend beyond the end of the cannula before conducting intraoperative stimulation testing. Test stimulation will be inaccurate or ineffective if one or more electrodes remains in the cannula.

10. Remove stylet from cannula.

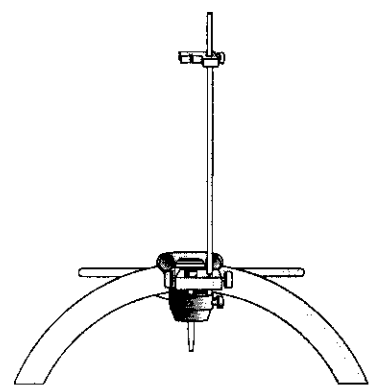


Figure 5. *Attach lead holder assembly to frame*

11. Determine target location with a test electrode.
    a. Place test electrode 10 mm above target. Slowly advance it 1 mm at a time and test stimulate. Maximum therapeutic effect with minimum side effects indicate the appropriate target.

b. Once target is determined, document the location.

Note: It may be necessary to make additional tracks to achieve optimum lead placement. However, additional tracks should be minimized to reduce the risk of hemorrhage.

12. Remove the test electrode. Determine the depth of placement for the DBS Lead.
13. Attach the lead depth stop gauge on the lead at the point calculated in Step 12.
14. Attach proximal end of the lead to the lead holder to within 2.5 cm of the stylet handle.
15. Advance the lead slowly along the track made by the test electrode.

△ **Caution:** An increase in resistance or friction during lead insertion may indicate that the lead is deviating from the intended track. If this occurs, pull the lead back and re-advance until target is reached.

16. Repeat steps 3 through 15 for the second lead.

Intraoperative Stimulation Test

This section outlines the intraoperative stimulation test that helps confirm the desired lead position for optimum symptom improvement and minimization of side effects. This test requires the following components:

- A Model 3625 Test Stimulator and
- An alligator clip or twist-lock screening cable (provided with the lead).

  Note: A spare 9-V battery is recommended.

The procedures outlined in this section provide instructions for test stimulation with the alligator clip or twist-lock screening cable and the Model 3625 Test Stimulator. Refer to the Model 3625 Test Stimulator Operator Manual for detailed instructions.

To ensure patient eligibility for Reclaim DBS Therapy, verify that the screening parameters using the Model 3625 Test Stimulator are within the parameter range available with the neurostimulator being used. Refer to Table 14 and Table 15.

Table 14. *Programmable Stimulation Parameter Values for Kinetra Model 7428*

Programmable Parameters[a,b]	**Values**
Pulse Amplitude	Normal Resolution: 0 to 10.5 V Fine Resolution: 0 to 6.35 V
Rate	66 values from 3 to 250

Table 14. Programmable Stimulation Parameter Values for Kinetra Model 7428

Programmable Parameters[a,b]	Values
Pulse Width	60, 90, 120, 150, 180, 210, 240, 270, 300, 330, 360, 390, 420, 450 µsec

[a] Certain combinations of amplitude, pulse width, and rate are not allowed. See the Kinetra Model 7428 neurostimulator manual for programming limits.

[b] Pulse amplitude and pulse width are independently programmable for Programs 1 and 2; the same value for rate is programmed for both Programs 1 and 2.

Note: High amplitude/pulse width combinations can result in excessive charge density. Refer to "Programming the Neurostimulator" on page 71 for more information.

Table 15. Programmable Stimulation Parameter Values for Soletra Model 7426

Programmable Parameters	Values
Pulse Amplitude	0 to 10.5 V
Rate	2, 5, 10, 15, 20, 25, 30, 33, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 130, 135, 145, 160, 170, 185 pps
Pulse Width	60, 90, 120, 150, 180, 210, 270, 330, 400, 450 µsec

Note: High amplitude/pulse width combinations can result in excessive charge density. Refer to "Programming the Neurostimulator" on page 71 for more information.

Test Stimulation with the Alligator Clip Screening Cable

The alligator clip screening cable is bipolar. The polarity of the black alligator clip is controlled by Electrode Switch 0, and the red alligator clip is controlled by Electrode Switch 3. Electrode switches 1 and 2 on the Model 3625 Test Stimulator are inactive. **Use the alligator clips to select the lead contacts that correspond to the electrodes you want to test. For example, if you want to change the negative electrode from electrode 0 to electrode 1, attach the black alligator clip to the lead contact corresponding to electrode 1.**

Caution: The switches on the 3625 Test Stimulator corresponding to electrodes 0 and 3 must be manually set to establish a circuit. One switch must be positive and the other switch negative. If the 0 and 3 electrode switches are not set accordingly, no stimulation will result. Refer to Figure 9, page 53.

1. Check that the test stimulator External **A**–Amplitude Control (Figure 6) is turned **off**.

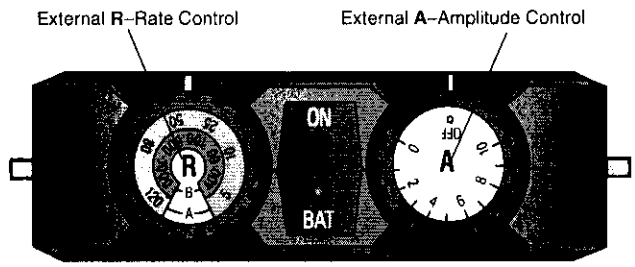


Figure 6. *Model 3625 Test Stimulator external controls*

2. Attach the alligator clips to the applicable lead contacts that correspond to the desired electrodes. Figure 7 provides an example of the connection to the lead contacts for electrodes 0 and 3.

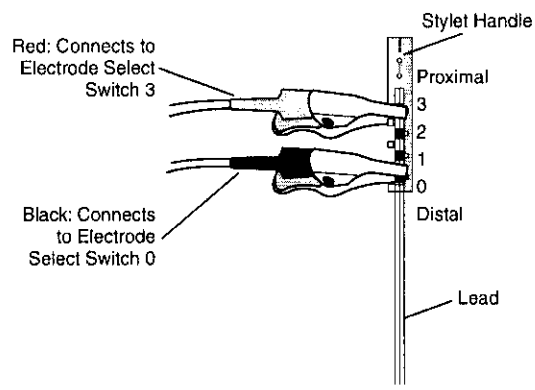


Figure 7. *Connect clips to lead contacts*

Warning: Always turn External A–Amplitude Control off before connecting or disconnecting the screening cable from the test stimulator, or before changing alligator clip connections to the lead contacts to prevent possible uncomfortable patient stimulation.

3. Verify that the test stimulator output (Amplitude) is turned to off, then push the plug on the test stimulator end of the cable into the output jack of the test stimulator (Figure 8). Note the correct plug orientation, with the cord pointing up. **The plug fits in 1 way only.** Refer to the Model 3625 Test Stimulator Operator Manual for detailed instructions on utilization.

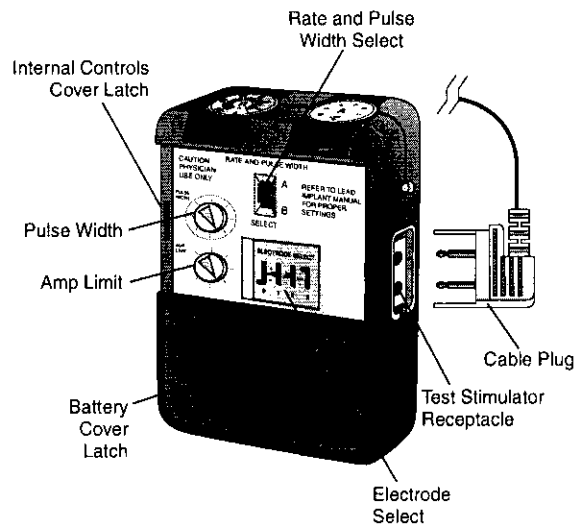


Figure 8. *Model 3625 Test Stimulator internal controls*

4. Remove the Internal Control Cover and set the Internal Controls (Figure 8) as follows:
   a. Set the **ELECTRODE SELECT** switch polarities as shown (Figure 9).

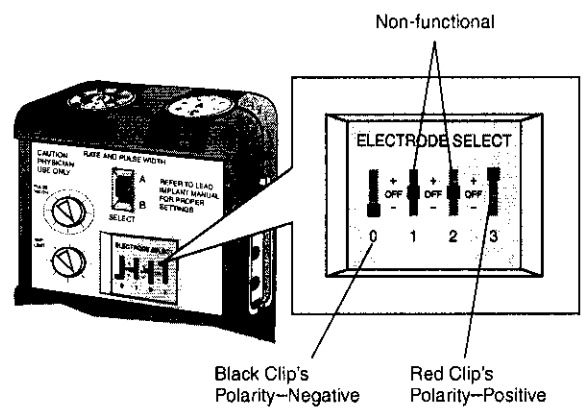


Figure 9. *Set Electrode Select switches*

b. Set the **RATE AND PULSE WIDTH SELECT** switch to **B** (Figure 10).

Note: When the switch is in position B (High Rate, Low Pulse Width):

- Rate = 60-1400 Hz
- PW = 50-250 µsec

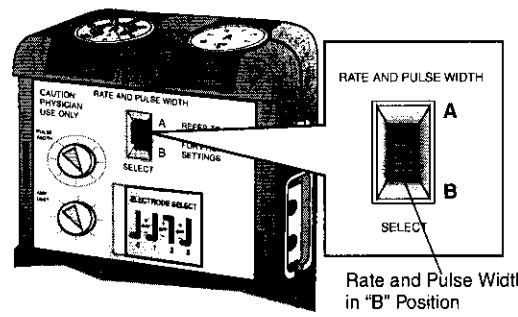


Figure 10. *Set Rate and Pulse Width Select to B position*

c. Set the External Rate to 100 Hz or as desired (typical therapeutic range 100-135 Hz). (Figure 11.)

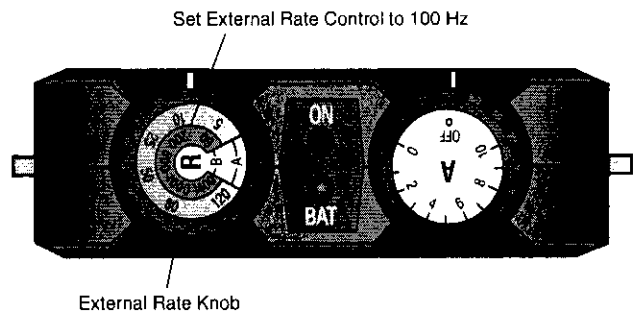


Figure 11. *Set External Rate Control to 100 Hz*

d. Set the **PULSE WIDTH** control to 90 µsec or as desired (typical therapeutic range 90-210 µsec). (Figure 12.)

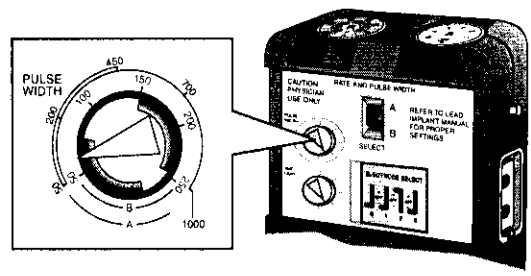


Figure 12. *Set Pulse Width to 60 µsec*

e. Set the **AMP LIMIT** control to 10 V, or as desired (Figure 13).

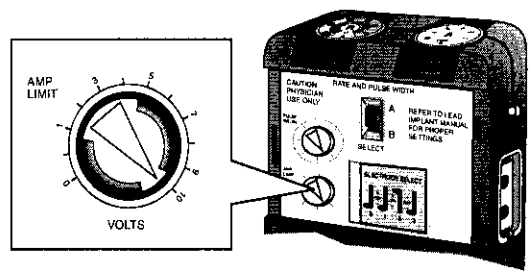


Figure 13. *Set Amp Limit to 10 V*

5. Turn the External A–Amplitude Control on and gradually increase it until the patient indicates an effect, or until a stimulation effect such as the improvement of symptoms is noted.

The desired stimulation effect related to OCD may include obvious anxiety reduction, elevation in mood, increased verbal output, increased alertness, and reported visual brightness. Other stimulation effects that may aid in placement of the lead, but may not be desirable, include acute depression, hypomania, increased disease symptoms, anxiety and panic attacks, oral facial sensations (e.g., tingling, smells, tastes), and autonomic effects (e.g., facial flushing, facial muscle contractions, or increased heart rate).

If test stimulation is unsuccessful or if parameter settings to achieve therapeutic benefit are within the charge density warning area (refer to Figure 38 on page 73), the system should not be implanted.

6. To reverse the output polarity:
   a. Set the External A–Amplitude Control to Off.
   b. Set the ELECTRODE SELECT switch polarities as shown (Figure 14).

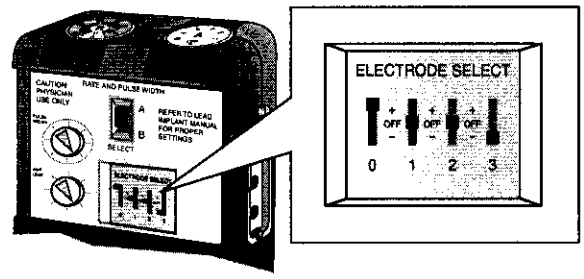


Figure 14. Set Electrode Select switches to reverse polarity

Note: The output polarity can also be reversed by switching the alligator clip-electrode contact connections.

⚠ **Warning: Always turn the test stimulator External A–Amplitude Control to Off before changing ELECTRODE SELECT switches or other Internal Controls to prevent possible uncomfortable patient stimulation.**

7. When the optimum stimulation mode and electrode configuration are determined, and the improvement of symptoms has been achieved with a minimum of side effects, turn the test stimulator's External A–Amplitude Control to Off.
8. When finished with the Internal Controls, replace the Internal Controls cover:
   a. Line up the 2 hinges with the holes in the test stimulator case.
   b. Press down on the cover to close it.
9. Disconnect the screening cable alligator clips from the lead contacts and proceed to "Stylet Removal and Lead Stabilization" on page 59.

Test Stimulation with the Twist-Lock Screening Cable

The twist-lock screening cable is quadripolar. When connected to the Model 3625 Test Stimulator, all 4 Electrode Switches are active.

△ **Caution:** Before connecting the twist-lock screening cable to the stylet handle of the DBS Lead, secure the cable to the frame or another stable object. Otherwise, the weight of the twist-lock connector may cause lead movement.

1. Check that the test stimulator output (Amplitude) is off.
2. Insert and lock the stylet handle on the lead into the twist-lock connector on the screening cable (Figure 15 - Figure 18).

   Note: The handle fits into the cylindrical twist connector in only 1 way (Figure 15).

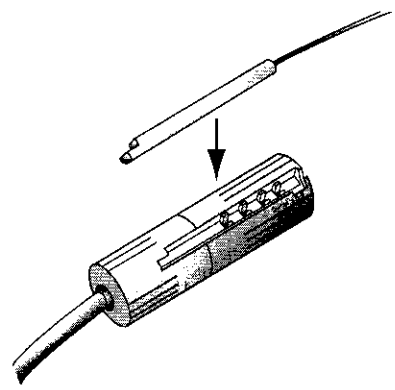


Figure 15. *Insert the pin connector into the twist-lock cable*

a. Place the stylet handle into the groove at a slight angle to secure the handle end (Figure 16).

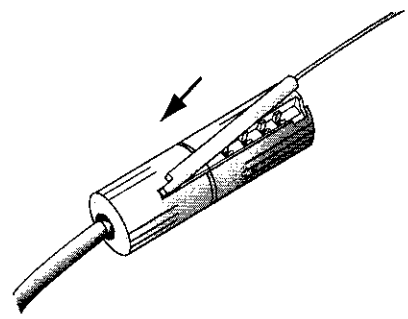


Figure 16. *Secure stylet handle end in groove*

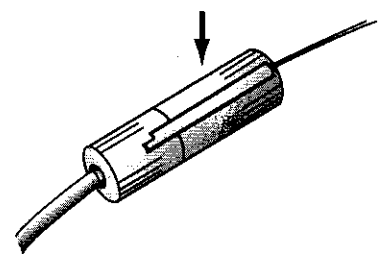


Figure 17. *Insert stylet handle into groove*

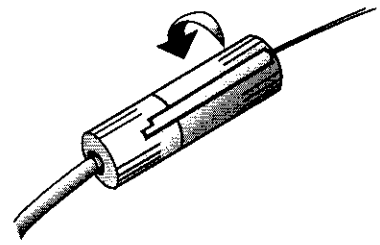


Figure 18. *Lock the twist-lock connector*

3. Verify that the test stimulator output (Amplitude) is turned to Off, then push the plug on the test stimulator end of the cable into the output jack of the test stimulator (Figure 19). Refer to the Model 3625 Test Stimulator Operator Manual for detailed instructions on utilization.

⚠ **Warning: Always adjust test stimulator output (Amplitude) to Off before connecting or disconnecting screening cable to prevent possible uncomfortable patient stimulation.**

Note: The plug of the screening cable only fits 1 way into the test stimulator jack.

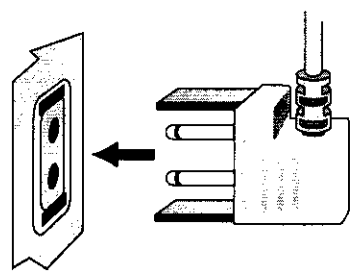


Figure 19. *Connect screening cable and test stimulator*

4. Proceed with the test stimulation. Refer to steps 4-6 of "Test Stimulation with the Alligator Clip Screening Cable" starting on page 53 for stimulation parameter recommendations. **All 4 electrode switches are active with the twist-lock cable.** Electrode selection and activation is controlled by the switches on the back of the Model 3625 Test Stimulator (refer to Figure 8 on page 53).
5. When finished with intraoperative test stimulation, turn the test stimulator off.
6. Unlock the cylindrical twist-lock connector and remove the connector handle.

a. Hold the test stimulator end of the twist connector stationary in the left hand and turn the lead end of the twist connector clockwise with the right hand until the grooves on each side are lined up (Figure 20).

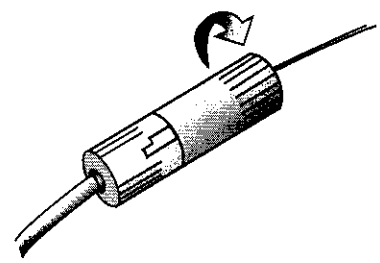


Figure 20. *Unlock the twist-lock connector*

b. Gently pull up on lead end of connector handle until it is free to remove it from the twist connector.

When the optimum stimulation mode and electrode configuration are determined, and improvement of symptoms has been achieved with minimal side effects, record the settings, then proceed to "Stylet Removal and Lead Stabilization" in the next section.

Stylet Removal and Lead Stabilization

When the physician has determined that the lead is properly positioned, the lead may be secured in the burr hole ring.

Complete the following steps to secure the lead in the burr hole ring. If using the Stimloc fixation device, refer to the instructions packaged with that device.

1. Ensure that the DBS Lead is securely fastened in the lead holder groove. The lead holder is provided with the lead frame kit.
   a. Remove the adjustable depth stop gauge from the insertion cannula, taking care not to dislodge the lead.
   b. Carefully pull the insertion cannula up until the lead can be seen between the burr hole and the cannula.
   c. Gently hold the lead at the point it exits the skull. An assistant should hold the insertion cannula to ensure that it stays in position.
   d. Carefully loosen the stylet handle from the lead (Figure 21).
   e. While keeping the lead secure at the exit site, remove the lead from the lead holder.
   f. Remove the stylet from the lead.
   g. Remove the insertion cannula.
   h. Remove the guide tube assembly.

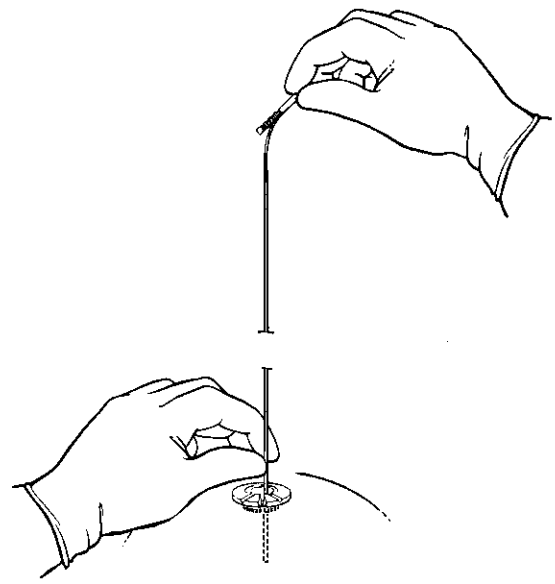


Figure 21. *Loosen the stylet handle from the lead*

2. Gently press the lead into 1 of the precut grooves on the inner side of the burr hole ring, ensuring that the lead exits the burr hole ring on the side in which the neurostimulator will be implanted (Figure 22).

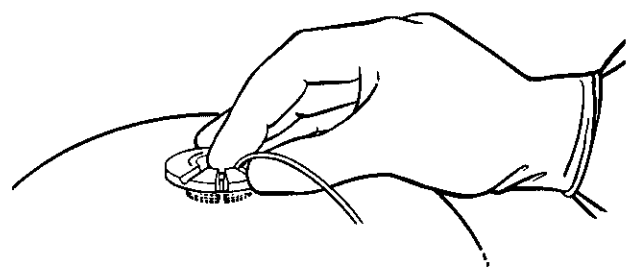


Figure 22. *Gently press the lead into the burr hole ring*

3. To minimize the potential for lead movement, place the burr hole cap into the ring as follows:
   a. Align the tab in the burr hole cap with the slot in the burr hole ring.
   b. Hold the cap tilted toward the slot in the ring where the lead is fixed, and gently press the cap against the edge of the burr hole ring and lead (Figure 23a).

c. Gently press down on the lead exit side of the burr hole cap while rolling the cap downwards into the ring until secure (Figure 23b).

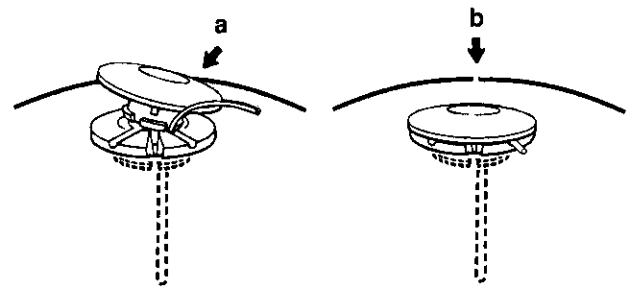


Figure 23. *Gently roll burr hole cap into burr hole ring*

4. Recheck the stimulation effect after stabilizing the lead in the burr hole ring and cap.
5. Check that the test stimulator output (Amplitude) is adjusted to Off.
6. If using the alligator clip screening cable, carefully attach the alligator clips to the desired connector ring contacts on the lead end.

⚠ **Warning: Always adjust test stimulator output (Amplitude) to Off when changing alligator clip connections to connector rings to prevent possible uncomfortable patient stimulation.**

7. If using the twist-lock screening cable, complete the following steps:
   a. Attach the enclosed short stylet to the proximal end of the lead (Figure 24).

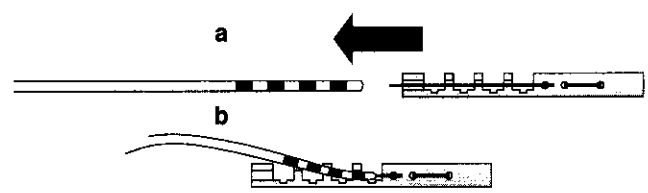


Figure 24. *Attach short stylet to lead*

   b. Insert the short stylet completely into the lead (Figure 24a).
   c. Secure the lead in the stylet handle (Figure 24b).
   d. Insert the stylet handle of the lead into the cylindrical twist-lock connector on the screening cable and lock it (Figure 15 through Figure 18).

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8. Turn on the test stimulator and recheck stimulation effects.

   Note: If lead movement has occurred, it may be necessary to remove the lead and repeat the implant procedure using a new lead.

⚠ **Warning: If lead repositioning is required, do not reinsert stylet into implanted lead. Use a new lead.**

9. Verify lead placement with standard imaging techniques.
10. Coil excess lead in the subgaleal pocket (Figure 25).

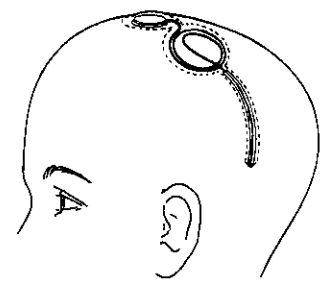

Figure 25. *Coiling the lead in the subgaleal pocket*

11. To implant the second lead, repeat the target localization, lead implant, and test stimulation procedures. (See Figure 26 for lead placement.)

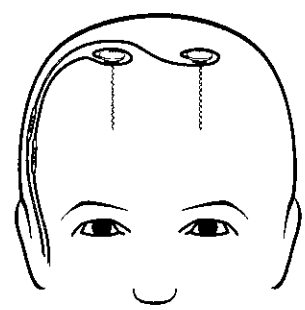

Figure 26. *Lead tunneling when the 2 leads are implanted*

   Note: Place a ligature on 1 of the leads when the bilateral procedure is performed to help identify the leads with their implant locations.

12. Prepare the patient for implant of the neurostimulator.

   Note: If the remainder of the system is not implanted immediately, place the lead in the subgaleal pocket, close the incision, and apply the appropriate dressing.

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Capping the lead

If the remainder of the neurostimulation system is not implanted immediately after lead implantation, perform the following steps:

1. Push the connector boot over the exposed end of the lead (Figure 27).

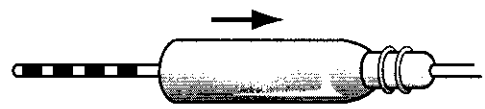

Figure 27. *Push connector boot over lead.*

2. Cover the exposed end of the lead with the lead cap contained in the lead kit (Figure 28). Hold the lead cap firmly on both sides of the setscrew socket. Tighten the single setscrew in the setscrew socket on the number 3 lead contact by turning it clockwise with the torque wrench provided.

△ **Cautions:**

- To avoid overtightening, do not use a hex wrench to tighten the extension setscrews. Overtightening the extension setscrews may damage the lead contacts and cause an open or short circuit, resulting in intermittent or loss of stimulation.
- Discard the torque wrench after making all connections. Reusing a torque wrench may result in undertightening or overtightening and subsequently, intermittent or loss of stimulation.

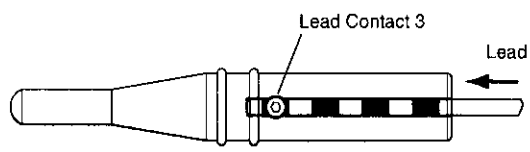

Figure 28. *Insert lead into lead cap.*

3. Slide the connector boot into place over the lead cap.

   Note: If it is difficult to position the boot, sterile water may be used as a lubricant.

4. Place non-absorbable sutures in the channeled area around the proximal end of the boot (Figure 29).

Figure 29. *Suture lead/lead cap.*

5. Place the lead in the subgaleal pocket, close the incision, and apply the appropriate dressing.

Note: The lead cap is designed for temporary use only.

Removing the Lead Cap

For each implanted lead:

1. Locate the lead cap at the proximal end of the lead and make an incision to expose it. Allow room to hold the lead firmly to prevent dislodgement.
2. Cut the suture and the connector boot over the lead cap to expose the setscrew (Figure 30).

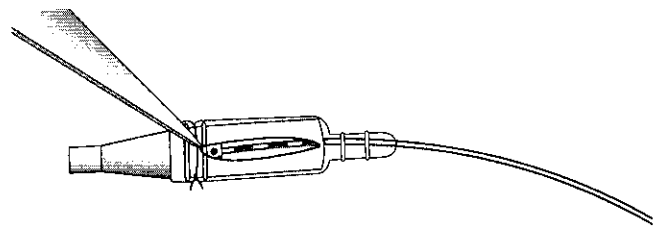

Figure 30. Cut the suture and connector boot to expose setscrew.

3. Using the hex wrench, loosen the setscrew in the setscrew connector by turning the wrench counterclockwise (approximately one turn).
4. Gently remove the lead from the setscrew connector.

△ **Caution:** If resistance is felt when removing the lead from the lead cap, loosen the setscrews slightly to ensure that it clears the lead contact. Avoid disengaging the setscrew. Inspect the lead contact for damage (flattening or stretching of lead) if resistance was felt prior to removal.

5. Hold the setscrew connector and withdraw the lead cap through the incision and discard.
6. Remove the boot from the lead and discard the boot.

Tunneling to the Neurostimulator Site

For instructions on tunneling to the neurostimulator site, refer to the appropriate extension manual.

Making the Lead-extension Connection

For instructions on making the lead-extension connection, refer to the appropriate extension manual.

Making the Extension-neurostimulator Connection

For instructions on making the extension-neurostimulator connection refer to the appropriate extension manual.

Interoperative Test Stimulation

If a postoperative test stimulation period is desired, use the following 4 procedures for Extended Test Stimulation outlined in this section:

- Create Percutaneous Tunnel
- Connect Lead and Percutaneous Extension
- Perform Interoperative Stimulation Test
- Remove the Percutaneous Extension

Create Percutaneous Tunnel

The following procedure provides instructions for attaching and implanting the percutaneous extension in the lead kit. The implanted wires should exit the skin above the ear during the test stimulation period (Figure 31).

1. Remove the percutaneous extension from its tube. Discard this tube.
2. Place 1 of the shorter tubes packaged with the lead over the tunneling tool. Attach the metal PERCUPASS II Tunneling Tip.

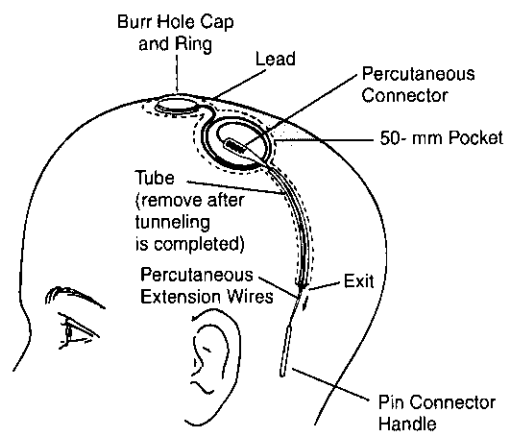

Figure 31. *Tunneling and lead placement*

3. Make a small stab wound where the percutaneous extension wires will exit the skin.
4. Tunnel subcutaneously from the pocket through the exit point.
5. Remove the tunneling tool, leaving the tube in place.
6. Pass the percutaneous extension wires through the tube. Leave only the pin connector and approximately 40 mm of the fine wires protruding from the exit point (Figure 31).
7. Remove the tube.
8. Coil the lead in a circle greater than 25 mm in diameter to prevent bending or kinking. Place the coiled lead in the subgaleal pocket.

△ **Caution:** Be extremely careful when using sharp instruments around the lead body to avoid nicking or damaging the lead.

Connect Lead and Percutaneous Extension

The following procedure provides instructions on how to connect the DBS Lead to the percutaneous extension.

1. Push the connector boot over the exposed end of the lead (Figure 32).

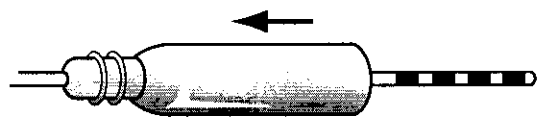

Figure 32. *Push connector boot over lead*

2. Wipe off any remaining body fluids from the surface of the lead contacts and the extension connector, then insert the exposed end of the lead completely into the percutaneous extension connector (Figure 33).

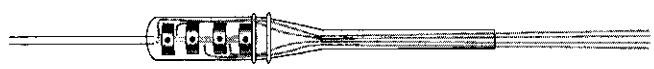

Figure 33. *Insert lead fully into setscrew junction*

3. Use the torque wrench to tighten the setscrews, which completes the electrical circuit with the lead contacts.

△ **Cautions:**

- To avoid overtightening, do not use a hex wrench to tighten the extension setscrews. Overtightening the extension setscrews may damage the lead contacts and cause an open or short circuit, resulting in intermittent or loss of stimulation.
- Discard the torque wrench after making all connections. Reusing a torque wrench may result in undertightening or overtightening and subsequently, intermittent or loss of stimulation.

Note: The setscrews must engage contacts on the lead before stimulation can be attempted.

4. Slide the connector boot into place, completely covering the lead-extension connection.

   Note: If it is difficult to position the boot, sterile water may be used as a lubricant.

5. Place non-absorbable sutures around both ends of the boot in the channeled areas of the connection (Figure 34).

Figure 34. *Suture lead/extension*

△ **Caution:** Do not overtighten suture because damage may occur to either the boot or the lead.

6. Place the lead-percutaneous extension connection into a small pocket made near the incision site.
7. Close the incision site and stab wound, leaving the fine percutaneous extension wires and pin connector protruding from the skin.

Perform Interoperative Stimulation Test

The following procedure provides instructions on how to connect the percutaneous extension to the test stimulator and begin interoperative test stimulation.

1. Check that the test stimulator output (Amplitude) is off.
2. Connect the pin connector on the percutaneous extension into the twist-lock connector on the screening cable and the plug end of the cable to the Model 3625 Test Stimulator. Refer to "Test Stimulation with the Twist-Lock Screening Cable" on page 56 for instructions on connecting and disconnecting the twist-lock cable and the test stimulator.

   Note: Different electrode configurations should be evaluated at various parameter settings (rate, amplitude, pulse width).
3. When finished with interoperative test stimulation, turn the test stimulator off.
4. Unlock the cylindrical twist-lock connector and remove the connector handle.

Remove the Percutaneous Extension

For each implanted lead:

1. Withdraw the external segment of the percutaneous extension approximately 1 cm (0.4 in.) from where it exits the skin (Figure 35).

△ **Caution:** Use gentle traction on percutaneous extension to avoid dislodging the lead.

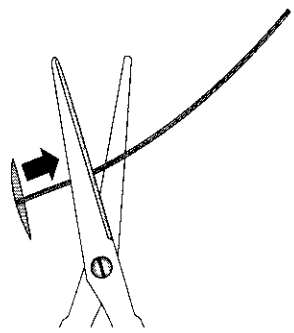

Figure 35. *Withdraw the external segment of the percutaneous extension*

2. Sever and discard this section of extension.
3. Locate the lead's percutaneous extension connector at the proximal end of the lead and make an incision to expose it. Allow room to hold the lead firmly to prevent dislodgement.

   Note: If an identifying mark was not made when the lead was implanted, probe the area with the fingers or use fluoroscopic observation.
4. Cut the suture and the connector boot over the setscrews to expose the setscrews (Figure 36).

△ **Caution:** Do not cut near lead when removing suture from percutaneous extension. Cutting lead's insulation can result in loss of stimulation and lead failure.

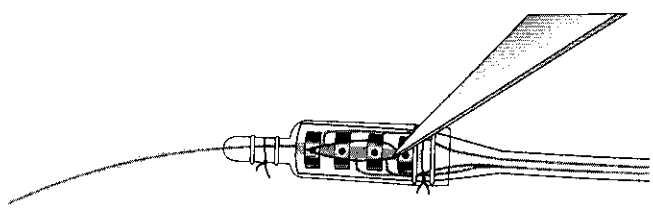

Figure 36. *Cut the suture and connector boot to expose setscrews*

5. Using the torque wrench, loosen each of the 4 setscrews in the setscrew connector by turning the wrench counterclockwise (approximately 1 turn).
6. Gently remove the lead from the setscrew connector.

△ **Caution:** If resistance is felt when removing the lead from the percutaneous extension, loosen the setscrews slightly to ensure that they clear lead contacts. Avoid disengaging setscrews. Inspect lead contacts for damage (flattening or stretching of lead) if resistance was felt prior to removal.

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7. Hold the setscrew connector and withdraw the percutaneous extension through the incision (Figure 37) and discard.

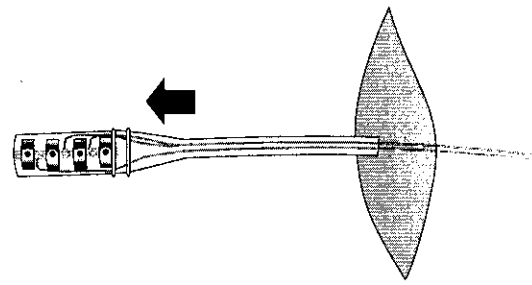

Figure 37. *Withdraw percutaneous extension*

8. Remove the boot from the lead and discard the boot.
9. Repeat Step 1 through Step 8 for other lead if applicable.

Postoperative Patient Management

The treating clinician(s) should be experienced in all aspects of the medical management of patients with OCD. Clinicians using Reclaim DBS Therapy for the first time are encouraged to contact a Medtronic representative for information on the postoperative management of Reclaim patients.

When programming stimulation parameters, give consideration to the following programming recommendations regarding initial stimulation parameters.

Programming Initial Stimulation Parameters for Reclaim DBS Therapy for OCD

The following procedure provides instructions on programming post-operative stimulation parameters for Reclaim DBS Therapy for OCD, and is one approach for the physician's consideration.

Notes:

- If independent rate control of each lead is desired to provide adequate symptom control for your patient, be aware that rate parameter values are not independently programmable with the Kinetra Model 7428 neurostimulator. Consider implanting 2 Soletra Model 7426 neurostimulators or 2 Kinetra Model 7428 neurostimulators if independent rate values are desired.
- High amplitude/pulse width combinations can result in excessive charge density. Refer to "Programming the Neurostimulator" on page 71 for more information.

1. Allow sufficient time for the patient to recover from surgery.
2. Set the neurostimulator to the initial settings provided in Table 16 and Table 17.

3. To evaluate the potential effectiveness of all available electrodes, observe the acute behavioral effect of the stimulation at each electrode such as marked euphoria, disinhibition, hypomania, panic, or irritability that responds to changes in stimulation.

Table 16. *Programming Settings for Reclaim DBS Therapy for OCD with the Kinetra Model 7428 Neurostimulator*

Parameter (Programs 1 and 2)	Typical Initial Setting	Range/Options	Typical Final Setting
Amplitude	0.0 V	Normal: 0-10.5 V Fine: 0-6.35 V	5.0-10.5 V
Pulse Width	60-210 µsec	60-450 µsec	90-210 µsec
Rate[a]	100-135 pps	3-250 pps	100-135 pps
Electrode Polarity	Unipolar (case positive, 0 electrode negative)	Unipolar or Bipolar	Varies
Mode	Continuous	Continuous/ Cycling	Continuous

[a] The same value for rate is programmed for both Program 1 and Program 2.

Table 17. *Programming Settings for Reclaim DBS Therapy for OCD with the Soletra Model 7426 Neurostimulator*

Parameter	Typical Initial Setting	Range/Options	Typical Final Setting
Amplitude	0.0 V	Normal 0-10.5 V	5.0-10.5 V
Pulse Width	60-210 µsec	60-450 µsec	90-210 µsec
Rate	100-135 pps	2-185 pps	100-135 pps
Electrode Polarity	Unipolar (case positive, 0 electrode negative)	Unipolar or Bipolar	Varies
Mode	Continuous		Continuous

4. To expedite electrode selection, program the neurostimulation system to a unipolar electrode configuration, where the neurostimulator case is the positive electrode and electrode 0, 1, 2, or 3 (programmed sequentially) is the negative electrode.

   Note: It may be desirable to ultimately program the neurostimulation system to a bipolar electrode configuration, where both the positive and negative electrical poles are the lead electrodes. This can reduce the potential for electromagnetic interference-related side effects, and may optimize battery life.

5. Gradually increase amplitude by 0.5-1.0 V incrementally every 2 minutes until you observe either a noticeable improvement in mood, anxiety, or interpersonal spontaneity, **or** an adverse effect (e.g., marked euphoria, disinhibition, hypomania, panic, irritability, sensations, or muscular contractions). After selecting active electrodes and parameters, wait approximately 30 minutes for the possible emergence of side effects.
6. If there are side effects, reduce the amplitude to 0 V and select another electrode as the negative electrode. Repeat step 5. Select the electrode or electrode combination that provides the fewest side effects. Ideally, this electrode or electrode combination will also produce acute improvement in mood, anxiety, and interpersonal spontaneity.

   Note: Patients with OCD may not experience immediate symptom improvement from the therapy. The patient should be advised that frequent, non-invasive adjustments to the stimulation parameters may be required to achieve optimal symptom improvement. This adjustment period may take weeks or months.
7. After Amplitude settings are determined, adjust Pulse Width and Rate to improve therapeutic benefit and minimize side effects.

   Notes:
   - The same value for rate is programmed for Program 1 and Program 2 when using a single Kinetra Model 7428 neurostimulator.
   - Symptom improvement is desirable at the lowest possible amplitude, rate, and pulse width in order to improve battery longevity, and minimize charge density.
8. Document final parameter settings for future reference.

Programming the Neurostimulator

When programming stimulation parameters, give consideration to the following recommendations regarding charge density and charge imbalance.

Charge Densities – A survey of literature regarding electrical stimulation of neural tissue suggests that damage may occur above 30 microcoulombs/cm^2/phase. The Reclaim DBS System is capable of producing charge densities in excess of 30 microcoulombs/cm^2/phase.

The neurostimulator's maximum amplitude is 10.5 V, and maximum pulse width is 450 microseconds. The curved lines in Figure 38 represent a charge density of 30 microcoulombs/cm^2/phase at impedance measurements of 500, 750, and 1000 ohms, calculated for the electrode surface area (0.12 cm^2) of the Model 3391 DBS lead. Charge density is determined by plotting a point corresponding to the pulse width setting (x-axis), and the amplitude setting (y-axis). If this point is below the appropriate resistance curve, then the charge density is below 30 microcoulombs/cm^2/phase. Points above the curve indicate a charge density above 30 microcoulombs/cm^2/phase.

Selecting settings that create a point above the resistance curve causes the physician programmer to display the following: **WARNING: CHARGE DENSITY MAY BE HIGH ENOUGH TO CAUSE TISSUE DAMAGE.** For the Model 3391 lead, the programmer issues the warning based on calculations using an electrode surface area of 0.06 cm^2 rather than the actual 0.12-cm^2 area of the Model 3391 lead electrode. Because the surface area of the Model 3391 lead is twice as large as the surface area used in the programmer calculation, the programmer warning may be too conservative. To calculate a more accurate charge density estimate for this lead, use the following equation.

$$\text{Charge density } (\mu C/cm^2) = \frac{\text{Voltage (volts)} \times \text{Pulse Width } (\mu sec)}{0.12\ cm^2 \times \text{Impedance (ohms)}}$$

Figure 38 includes 2 examples of charge density calculated using the Model 3391 electrode surface area. In Example A, 6.0 V and pulse width = 210 µsec. The charge density for Example A is below the shaded warning zone, thus indicating a charge density below 30 microcoulombs/cm^2/phase at the most conservative impedance of 500 ohms.

In Example B, neurostimulator stimulation parameters are set to: amplitude = 9.0 V and pulse width = 250 µsec. The charge density at these settings is in the shaded area indicating it may be high enough to cause tissue damage at an impedance of 500 ohms. However, as shown in Figure 38, if the impedance in this case is 750 ohms or 1000 ohms, the charge density for these settings would be below 30 microcoulombs/cm^2/phase.

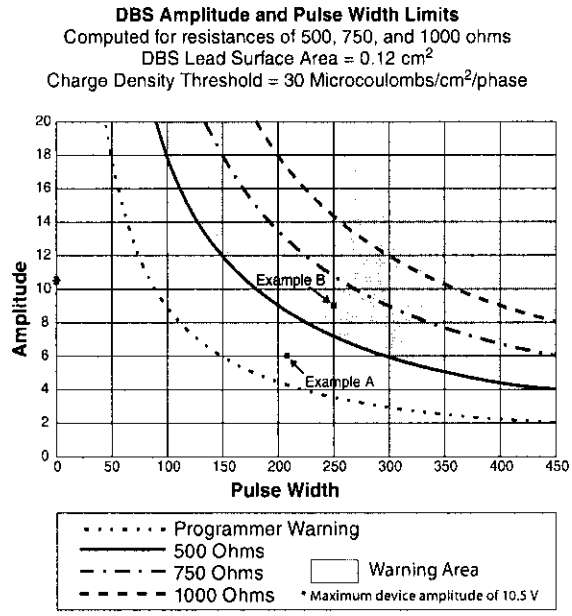

Figure 38. *Charge density with the Model 3391 Lead*

If a programming attempt elicits the "Charge Density" warning, recalculate the actual charge density for the Model 3391 Lead using the equation provided on page 72. Program parameter settings based on the result of the recalculation:

- If the recalculated charge density falls below the warning limit for the Model 3391 lead but above the programmer warning limit, continue programming the selected settings despite the programmer warning.
- If the recalculated charge density exceeds the warning limit for the Model 3391 lead, program a new setting for either amplitude or pulse width until the charge density calculation falls below the limit for this lead.

Charge Imbalance Condition – For certain neurostimulator stimulation parameter settings, the device can produce a **CHARGE IMBALANCE CONDITION (Soletra Model 7426 Neurostimulator only)**. Charge imbalance may occur when the circuit does not recover the total negative charge that is produced by the "on" activations. If the charge imbalance (net DC current) exceeds 1.5 µamps average current, tissue damage may occur. When programming the Soletra Model 7426 Neurostimulator, the following operating conditions should be observed to remain below the 1.5 µamps average current:

- Cycling Mode. **DO NOT PROGRAM** the Soletra Model 7426 Neurostimulator to cycling mode for Activa Therapy. This warning **INCLUDES** the "Special Ramp Stimulation Mode."

- SoftStart/Stop. In this feature, when the device is initially turned on, the voltage is incremental until it reaches the patient's programmed voltage. Each increment is considered an "on" activation. When programming the Neurostimulator using the SoftStart/Stop feature, refer to Table 18 for aid in programming therapy stimulation. Check the amplitude setting and the pulse width setting. The neurostimulator should **not** exceed the number of activations listed for the selected parameters. An activation occurs when the neurostimulator is turned on and off by either the patient magnet or the programmer.

Table 18. Maximum Allowable Device Activations[a] Per 24-Hour Period (for all programmable rates and electrode combinations, SoftStart/Stop ON)

Programmed Amplitude (volts)	Device Activation Per 24-Hour Period Programmed Pulse Width 60 µsec	Device Activation Per 24-Hour Period Programmed Pulse Width 90 µsec	Device Activation Per 24-Hour Period Programmed Pulse Width 120 µsec	Device Activation Per 24-Hour Period Programmed Pulse Width 150-210 µsec	Device Activation Per 24-Hour Period Programmed Pulse Width 270-330 µsec	Device Activation Per 24-Hour Period Programmed Pulse Width 400-450 µsec
0.0-0.1	135,000	135,000	135,000	135,000	135,000	81,000
0.2-1.0	101,000	73,000	73,000	32,000	23,000	13,000
1.1-2.0	81,000	50,000	50,000	17,000	6,500	4,200
2.1-3.0	54,000	50,000	32,000	7,600	3,200	1,800
3.1-3.6	54,000	30,000	19,000	5,600	2,200	1,000
3.7-4.0	29,000	16,000	12,000	5,000	2,200	1,000
4.1-5.0	22,000	13,000	8,300	2,500	1,100	600
5.2-6.0	16,000	8,900	5,500	1,600	580	300
6.1-6.5	14,000	7,800	5,000	1,200	380	200
6.7-7.2	12,000	6,600	3,500	840	240	140
7.4-8.0	10,000	6,200	3,200	840	240	140
8.2-9.0	8,800	4,600	2,500	570	200	120
9.1-9.5	7,900	4,000	2,100	430	160	110
9.7-10.0	7,600	3,500	1,800	330	130	100
10.1-10.5	6,700	3,100	1,500	260	110	90

[a] An activation occurs when the neurostimulator is turned on and off by either the patient magnet or the programmer.

Physician Training Information

Prescribing physicians should have expertise in the medical treatment of patients with OCD. Implanting physicians should have expertise with functional stereotactic neurosurgical treatment of OCD. Such expertise should include knowledge of the anatomical and neurophysiological characteristics of the target anatomy, surgical and/or implantation techniques for brain stimulation systems, operational and functional characteristics of brain stimulation systems, and experience in the continued management of patients by stimulation parameter adjustment.

All brain stimulation system programming should be under the supervision of a physician and performed by experienced medical personnel familiar with the use of the programming software and equipment. Physicians should be thoroughly familiar with brain stimulation system supporting material, including:

- All product labeling, and
- Education and training materials.

Patient Counseling Information

Before surgery, the patient and family should be advised of the known risks of the surgical procedure and the therapy, as discussed in other sections of this manual, as well as the potential benefits. Show the patient and family the device before implant. After the brain stimulation system is implanted, the patient should also be advised to read the Reclaim DBS Therapy patient manual included in the lead package.

Reclaim DBS Therapy is an active therapy that requires both physician and patient involvement to be successful. Ensure the patient understands this will be a long-term relationship between physician, medical staff, patient, and family. Physicians should carefully monitor patients for symptoms of depression, anxiety, or hypomania/mania. Such symptoms may include a change in sleep or eating behavior, disinhibition, anger, aggression, and a predisposition to accidents.

Symptom Improvement

OCD patients may not experience immediate symptom improvement from the therapy. The patient should be advised that frequent, non-invasive adjustments to the stimulation parameters may be required to achieve optimal symptom improvement. This adjustment period may take weeks or months.

Significant OCD symptoms are likely to persist following deep brain stimulation.

Expected Battery Life

Based on the initial clinical data, the neurostimulator battery should last 6 months to 16 months. However, the battery may last longer depending on the neurostimulator setting used. As with the initial implant, neurostimulator replacement will lead to surgical risks, including pain or discomfort at the surgical site, risk of infection, and internal or external bleeding or hemorrhage at or near the implant location.

Rebound Effect

Patients need to be aware that OCD symptoms will probably return following accidental system turn-off, battery depletion, or system failure. It is important that the physician discuss the predicted time of battery replacement with the patient and that the battery condition be closely monitored. It is also important that the patient and caregiver know how the therapy controller works in case the neurostimulator is accidently turned off. If symptoms return, the patient should contact his or her physician immediately so the status of the system can be assessed and the condition of the patient can be monitored.

Therapy Side Effects

Patients and their families should be aware that the brain stimulation system for OCD may cause side effects such as euphoria or disinhibition that the patient may perceive to be enjoyable. If these side effects occur, the patient should contact his or her physician immediately so the status of the system can be assessed and the condition of the patient can be monitored. The family should be aware that the patient may ignore the need for physician attention because of the nature of these side effects. Advise the patient and family how to identify these side effects.

Theft Detectors and Screening Devices

Patients should be advised to use care when approaching security arches or gates (such as those found in airports, libraries, and some department stores) because these devices can turn on or turn off their neurostimulator. If an airport security wand is used, they should ask the security personnel to avoid placing the wand over the neurostimulator.

When approaching these devices, patients should do the following:

1. If security personnel are present, show them the neurostimulator identification card and request a hand search.
2. If patients must pass through the security device, they should approach the center of the device and walk normally (Figure 39).
   a. If 2 security gates are present, they should walk through the middle, keeping as far away as possible from each gate.
   b. If 1 gate is present, they should walk as far away as possible from it.

   Note: Some theft detectors may not be visible.

3. Proceed through the security arch or gate. Do not touch, lean on, or linger near the security arch or gate.

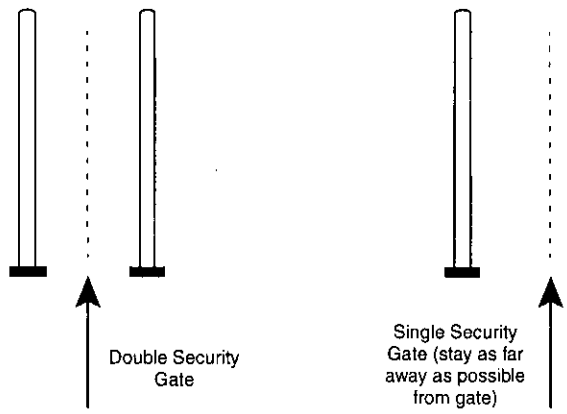

Figure 39. *Approaching security gates*

4. If patients suspect that their neurostimulator was turned off, they should make sure someone is able to turn on the system again. (This person could be the patient, if his or her medical condition allows it. It could also be a family member or clinician who has been taught how to use the system.)

Component Manipulation by Patient

Advise your patient to avoid manipulating the implanted system components (e.g., the neurostimulator, the burr hole site). This can result in component damage.

Detailed Device Description

Lead Materials

A review of the materials, additives, and potential breakdown products used in the DBS Leads resulted in identification of 2 chemicals of concern, including:

- A potential breakdown product of polyurethane is a known animal carcinogen.
- A tin compound is an additive to polyurethane. Some tin compounds are known neurotoxins.

The amount of these compounds released from the DBS Lead over time is unknown.

Note: Each material composing the DBS Lead has been selected for biocompatibility through laboratory testing, animal testing, and clinical experience. The lead and accessories contained in the lead kits are intended for **Single Use Only**.

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Lead Specifications

Lead length	40 cm
Lead shape	Straight
Lead body diameter	1.27 mm
Connector	In-line
Number of electrodes	4
Electrode shape	Cylindrical
Electrode length	3.0 mm
Electrode spacing (edge to edge)	4.0 mm
Number of conductor wires	4
Material:	
Conductor wire	Platinum/Iridium
Proximal connector sleeves	Nickel alloy (MP35N)
Stimulating electrodes	Platinum/Iridium
Insulation:	
Conductor wires	Fluoropolymer
Outer jacket tubing	80A Urethane
Conductor resistance	< 100 Ω
Stylet material	Tungsten
Materials in contact with human tissue[a]	Platinum/Iridium 80A Urethane Nylon Silicone

[a] Includes implanted accessories.

Notes:

- The electrical resistance of leads is proportional to their length. Very long leads have an increased resistance, which may limit pulse amplitude at the electrodes.
- All dimensions are approximate.

How Supplied

Contents of Package

The Medtronic Model 3391 DBS Lead Kit consists of the following:

Lead:

- One Model 3391 Lead

Accessories:

- Straight stylet (inserted in lead)
- Torque wrench
- Short stylet
- Screening cables
  - Alligator clip screening cable
  - Twist-lock screening cable
- Depth stop gauge (lead)
- Burr hole ring and cap
- Connector boot
- Stainless steel PERCUPASS II Tunneling Tool and Tunneling Tip
- Polytetrafluoroethylene tubes (straws)
- Lead cap

  Note: The contents of the inner package are **STERILE** and **NON-PYROGENIC**.

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