

Electrocautery/surgery Standard Letter

Neuromodulation Technical Services US
Minneapolis, MN • 800-707-0933

NEUROMODULATION STANDARD LETTER, 8 August 2014 VERSION 2.0
DEEP BRAIN STIMULATION (DBS) SYSTEMS

Introduction

This standard letter is designed to further explain Medtronic Neuromodulation labeling and is not meant as a substitute for approved labeling. For more information, please refer to the Medtronic® DBS™ Therapy Information for Prescribers (IFP) manual.

It is important to note that the terms “cautery”, “electrocautery”, “bovie” and “electrosurgery” are sometimes used interchangeably. These procedures can generate large surgical currents in the body. The objective of this letter is to describe the principles of using surgical procedures involving electrically driven cutting/coagulating surgical tools near/over a DBS system (INS and leads) using the terms “cautery” and “surgical current”.

During cautery and electrocautery, current is used to heat probes/electrodes that come in contact with tissue. The current does not usually enter the patient’s body. During electrosurgery, high-frequency current enters the patient’s body, making the patient part of the active circuit.

Cautery can be operated in a Bipolar or Monopolar configuration. In Bipolar configuration, two closely spaced electrodes serve as the surgical electrode and return electrode. Surgical current is restricted to a small volume of tissue close to /between the electrode pair.

In Monopolar configuration, an electrical circuit is completed between the generator, cables, surgical electrodes and return electrode (aka grounding pad). The surgical current is dispersed from the surgical electrode through the patient to the return electrode completing the path to the cautery generator.

The remainder of this document will discuss the factors that impact the possible/alternate paths and directions of “Monopolar dispersed current” when used near/over a DBS system. Understanding these factors may help reduce the effects of surgical currents to the patient and/or implanted DBS system.

General Precautions

If electrocautery is used near an implantable neurostimulator or touches an implantable neurostimulator, the following effects may occur:

- The insulation on the lead or extension may be damaged, resulting in component failure or induced currents into the patient that may damage tissue or stimulate or shock the patient.
- The neurostimulator may be damaged, output may be temporarily suppressed or increased, or stimulation may stop because parameters were changed to power-on reset settings (eg, output off, amplitude 0.0 V).

Background

Neurostimulator Electrical Protection and DBS Conductive Path

When used on a patient with an implanted DBS system, high-energy electrical signals may damage the neurostimulator or interfere with DBS system operation.

ELECTRICAL PATH

A neurostimulator typically has over voltage protection mechanisms to reduce the damaging effects of high-energy electrical signals that may appear across the electronic circuits of the neurostimulator. (Figure 1). During any high-energy exposure, the protection devices act as “surge protectors” that limit the voltage level.

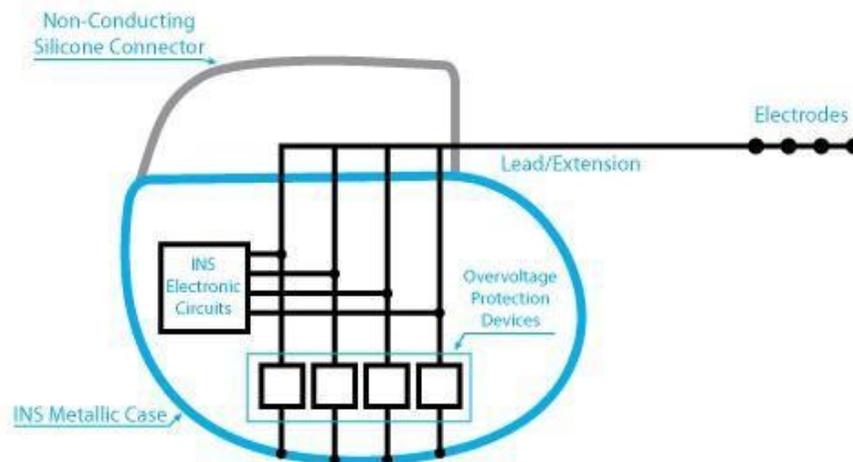


Figure 1: Illustration of the over voltage protection mechanisms that protect sensitive electronic circuits in the neurostimulator. Note that the DBS conductive path (consisting of the neurostimulator’s metallic case, protection devices, leads, and extensions) is still connected when the system is programmed to the OFF state; consequently, cautery signals can flow through it.

When exposure to high-energy electrical signals occurs, the neurostimulator’s metallic case routes the high-energy current through the protection devices, around the electronic circuits, and directly to the implanted DBS leads (Figure 2). Bypassing the electronic circuits will make the neurostimulator’s metallic case, protection devices, leads, and extensions appear as a conductive path (DBS conductive path) in parallel to existing conductive body tissue. High-energy current that tries to flow in the direction of the DBS conductive path will divide itself according to the relative resistance of the DBS conductive path and body tissue path as it flows to the cautery grounding pad.

Even when the neurostimulator is programmed to an OFF state and stops generating stimulation pulses, the lead and extension are still connected to the neurostimulator’s metallic case via the protection devices and will continue to act as a conductive pathway for surgical current.

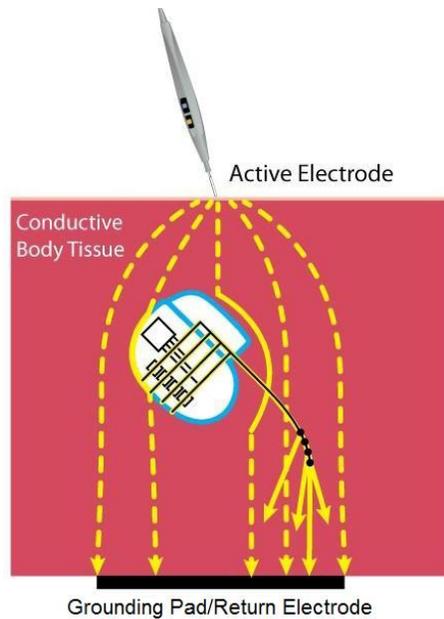


Figure 2: Current flows through both the conductive body tissue path and DBS conductive path. This current will divide itself according to the relative resistance of the DBS conductive path and body tissue path as it flows to the cautery grounding pad. (For illustration purposes only to explain the general concept of an implanted system in the body and not representative of a typical DBS system routing.)

PROGRAMMING AND USE CONSIDERATIONS

Before using cautery, turn off the neurostimulator. Turning the neurostimulator OFF reduces the possibility of compounding cautery voltage generated by the procedure on the programmed therapy voltage. Programming the neurostimulator to 0V, for models with an activated magnetic reed switch, reduces the possibility of compounding the cautery voltage in the event that a neurostimulator (e.g., Medtronic Soletra) inadvertently returns to the ON state.

The decision to program a patient's neurostimulator to the OFF state in order to perform medical diagnostic or therapeutic procedures should be carefully considered based on the patient's underlying medical condition. Consultation with the appropriate medical professionals (prescribing and implanting clinicians) is suggested.

Before the procedure, the following considerations are suggested:

Device type	Considerations for electrocautery
Soletra	<ul style="list-style-type: none"> ▪ Set amplitude to 0.0 V ▪ Turn off neurostimulator
Kinetra	<ul style="list-style-type: none"> ▪ Set amplitude to 0.0 V ▪ Disable magnet switch ▪ Turn off neurostimulator
Activa PC	<ul style="list-style-type: none"> ▪ Turn off neurostimulator
Activa RC	<ul style="list-style-type: none"> ▪ Turn off neurostimulator
Activa SC	<ul style="list-style-type: none"> ▪ Turn off neurostimulator

During the procedure the following considerations are suggested:

- Use the minimum cautery power settings.
- Use short, intermittent, and irregular bursts.

CAUTERY BIPOLAR AND MONOPOLAR CONFIGURATIONS

Bipolar Configuration

If possible, use only a bipolar configuration, which has a definite, confined current path that allows better control of the current and reduces the area for potential interference (Figure 3).

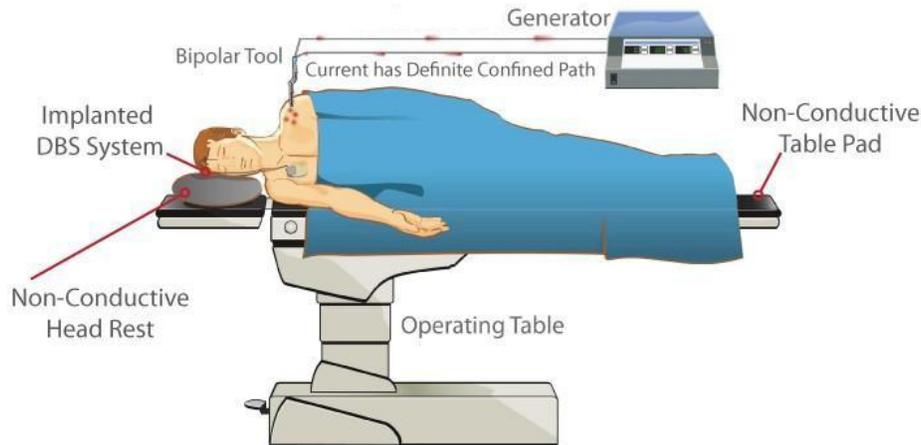


Figure 3: Illustration of a bipolar configuration with a definite, confined current path. A bipolar configuration allows better control of current and reduces the area susceptible to potential interference. An implanted DBS system is illustrated for reference.

Unipolar/Monopolar Configuration

Please see the following guidelines if a unipolar configuration is necessary:

- Do not use full-length operating room table grounding pads. Instead, use a non-conductive table pad (Figure 4).

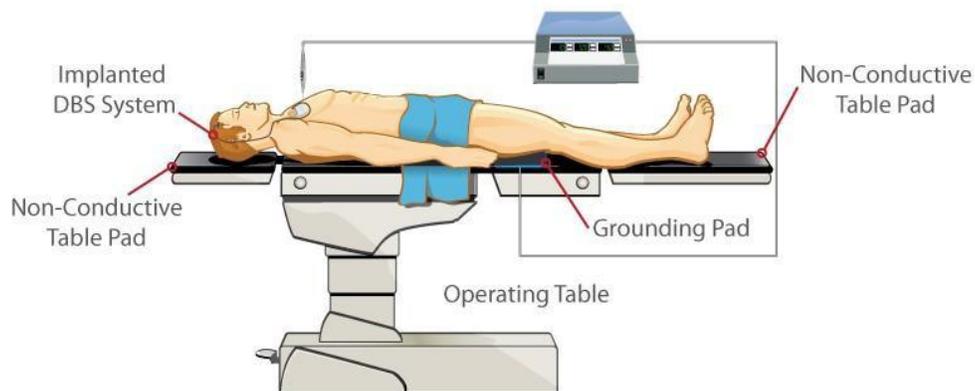


Figure 4: Illustration of a typical unipolar configuration. An implanted DBS system is illustrated for reference.

- Keep the neurostimulator and lead out of the conductive path of the electrocautery/surgery system.
- Use only a low-voltage mode and the lowest possible power setting.
- Pay careful attention to the placement of the electrocautery/surgery grounding pad (also known as the indifferent electrode, electrical grounding pad/plate, or return electrode) with respect to the neurostimulator. Figure 5 is an example of sub-optimal grounding pad placement.

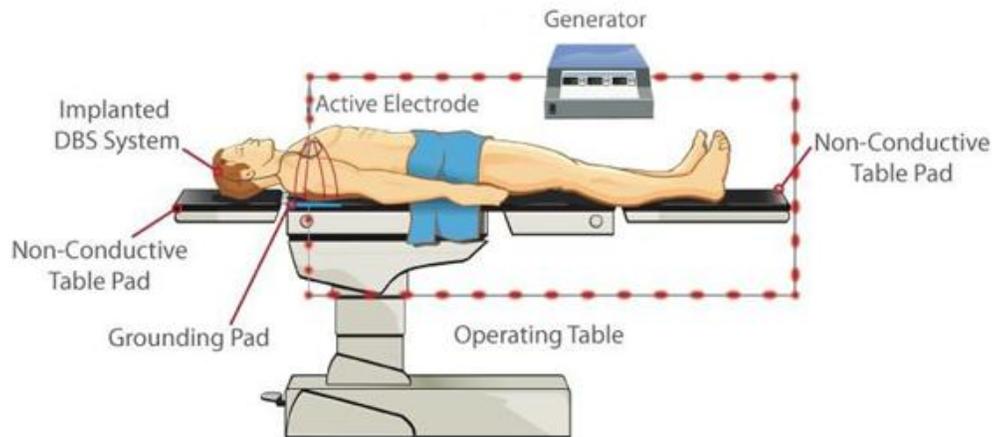


Figure 5: Illustration of sub-optimal placement of a grounding pad in a unipolar configuration. This placement could result in current intersecting with portions of the DBS conductive path. Sub-optimal grounding pad placement also creates the possibility that the current may flow through the DBS conductive path in the event the patient's head becomes grounded. An implanted DBS system is illustrated for reference.

- Place the grounding pad so that the current path between the pad and active electrode of the electrocautery/surgery system is as far away as possible from the DBS conductive path (neurostimulator, lead, and extension). (Figure 6)

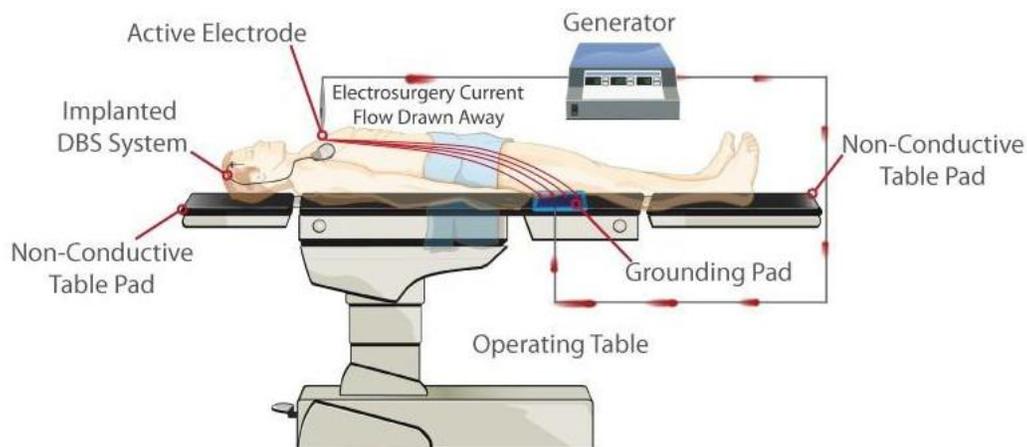


Figure 6: Illustration of grounding pad placement so that the electrocautery/surgery current is drawn away from the DBS conductive path. An implanted DBS system is illustrated for reference.

- Electrodes used for physiological signal monitoring (e.g., EEG, EMG, ECG) should be as large as convenient and placed as far as possible from the active electrode of the electrocautery/surgery system.

- Disconnect any cable connecting the lead or extension to a screener or external neurostimulator.
- Check to see that the patient is not in contact with metal parts of the operating room table (unless required) or with operating room appliances such as an IV pole or instrument tray. (Figure 7) If feasible, place a non-conducting surface between the patient's skin and any metal on the operating table.

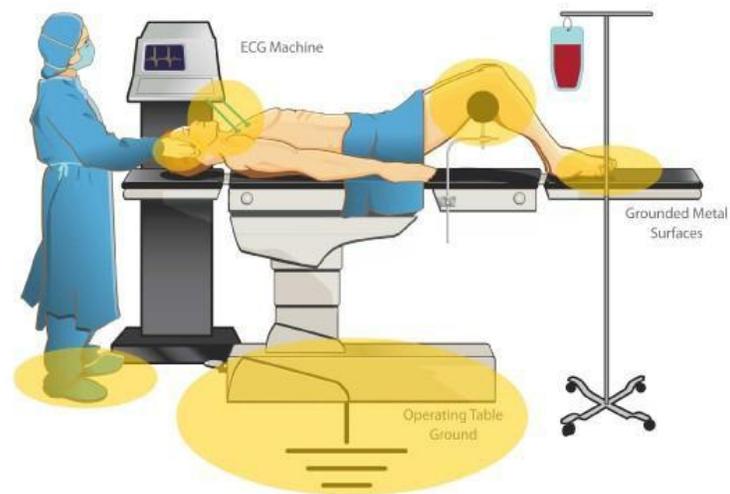


Figure 7: Shaded ovals indicate some of the possible paths of the electrocautery/surgery current flow. These areas may lead to local heating. More importantly, the current can flow through the DBS conductive path, increasing the risk for neurostimulator damage and/or patient injury.

AFTER THE PROCEDURE

After the procedure, the patient may use the patient programmer to turn the Neurostimulator back on. Confirm that the neurostimulator is functioning as intended. Direct the patient to contact his or her managing health care provider with any questions or concerns following the procedure.

Brief Summary Disclosure: Medtronic DBS Therapy for Parkinson's Disease, Tremor and Dystonia

Medtronic DBS Therapy for Parkinson's Disease, Tremor, and Dystonia: Product technical manual must be reviewed prior to use for detailed disclosure.

Indications:

Medtronic DBS Therapy for Parkinson's Disease: Bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) using Medtronic DBS Therapy for Parkinson's Disease is indicated for adjunctive therapy in reducing some of the symptoms of advanced, levodopa-responsive Parkinson's disease that are not adequately controlled with medication.

Medtronic DBS Therapy for Tremor: Unilateral thalamic stimulation using Medtronic DBS Therapy for Tremor is indicated for the suppression of tremor in the upper extremity. The system is intended for use in patients who are diagnosed with Essential Tremor or Parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability. The safety or effectiveness of this therapy has not been established for bilateral stimulation.

Medtronic DBS Therapy for Dystonia: Unilateral or bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) using Medtronic DBS Therapy for Dystonia is indicated as an aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and segmental dystonia, hemidystonia, and cervical dystonia (torticollis), for individuals 7 years of age and older.

Contraindications: Contraindications include patients who will be exposed to MRI using a full body transmit radio-frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area, patients who are unable to properly operate the neurostimulator, or for Parkinson's disease and Essential Tremor, patients for whom test stimulation is unsuccessful. Also, diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy) is contraindicated because diathermy's energy can be transferred through the implanted system (or any of the separate implanted components), which can cause neurostimulation system or tissue damage and can result in severe injury or death. Transcranial Magnetic Stimulation (TMS) is contraindicated for patients with an implanted DBS System.

Warnings/ Precautions/Adverse Events: There is a potential risk of tissue damage using stimulation parameter settings of high amplitudes and wide pulse widths. Extreme care should be used with lead implantation in patients with a heightened risk of intracranial hemorrhage. The lead-extension connector should not be placed in the soft tissues of the neck due to an increased incidence of lead fracture. Theft detectors and security screening devices may cause stimulation to switch ON or OFF, and may cause some patients to experience a momentary increase in perceived stimulation. Although some MRI procedures can be performed safely with an implanted DBS System, clinicians should carefully weigh the decision to use MRI in patients with an implanted DBS System. MRI can cause induced voltages in the neurostimulator and/or lead possibly causing uncomfortable, jolting, or shocking levels of stimulation.

The DBS System may be affected by or adversely affect medical equipment such as cardiac pacemakers or therapies, cardioverter/ defibrillators, external defibrillators, ultrasonic equipment, electrocautery, or radiation therapy. Safety and effectiveness has not been established for patients with neurological disease other than Parkinson's disease or Essential Tremor, previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression; patients who are pregnant; patients under 18 years; and patients over 80 years of age for Medtronic DBS Therapy for Tremor. For patients with Dystonia, age of implant is suggested to be that at which brain growth is approximately 90% complete or above. Depression, suicidal ideations and suicide have been reported in patients receiving Medtronic DBS Therapy for Movement Disorders, although no direct cause and effect relationship has been established.

Abrupt cessation of stimulation should be avoided as it may cause a return of disease symptoms, in some cases with intensity greater than was experienced prior to system implant ("rebound" effect). Adverse events related to the therapy, device, or procedure can include: stimulation not effective, cognitive disorders, pain, dyskinesia, dystonia, speech disorders including dysarthria, infection, paresthesia, intracranial hemorrhage, electromagnetic interference, cardiovascular events, visual disturbances, sensory disturbances, device migration, paresis/asthenia, abnormal gait, incoordination, headaches, lead repositioning, thinking abnormal, device explant, hemiplegia, lead fracture, seizures,

respiratory events, and shocking or jolting stimulation. Patients using a rechargeable neurostimulator for Parkinson's Control Therapy or Tremor Control Therapy should check for skin irritation or redness near the neurostimulator during or after recharging, and contact their physician if symptoms persist.

Humanitarian Device (Dystonia): Authorized by Federal Law for the use as an aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and segmental dystonia, hemidystonia, and cervical dystonia (torticollis), for individuals 7 years of age and older. The effectiveness of this device for this use has not been demonstrated.

USA Rx only Rev1013

Brief Disclosure – Reclaim® DBS Therapy for OCD

Medtronic Reclaim® DBS Therapy for Obsessive-Compulsive Disorder: Product labeling must be reviewed prior to use for detailed disclosure of risks.

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: Contraindications include patients who will be exposed to MRI using a full body transmit radio-frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area, and for patients who are unable to properly operate the neurostimulator. Also, diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy) is contraindicated because diathermy's energy can be transferred through the implanted system (or any of the separate implanted components), which can cause tissue damage and can result in severe injury or death. Diathermy can damage parts of the neurostimulation system. Transcranial Magnetic Stimulation (TMS) is contraindicated for patients with an implanted DBS System.

Warnings/precautions/adverse events:

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.

There is a potential risk of tissue damage using stimulation parameter settings of high amplitudes and wide pulse widths. Extreme care should be used with lead implantation in patients with a heightened risk of intracranial hemorrhage. 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. Theft detectors and security screening devices may cause stimulation to switch ON or OFF, and may cause some patients to experience a momentary increase in perceived stimulation. Severe burns could result if the neurostimulator case is ruptured or pierced. The safety of somatic psychiatric therapies using equipment that generates electromagnetic interference (e.g., vagus nerve stimulation) has not been established. The Reclaim DBS System may be affected by or adversely affect medical equipment such as cardiac pacemakers or therapies, cardioverter/ defibrillators, external defibrillators, ultrasonic equipment, electrocautery, or radiation therapy. Patients should be monitored for at least 30 minutes after a programming session, for 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. In addition, during treatment, patients should be monitored closely for increased depression, anxiety, suicidality, and worsening of obsessive-compulsive symptoms. The safety and probable benefit of this therapy has not been established for patients with: Tourette's syndrome, OCD with a subclassification of hoarding, previous surgical ablation (e.g., capsulotomy), dementia, coagulopathies or who are on anticoagulant therapy, neurological disorders, and other serious medical illness including cardiovascular disease, renal or hepatic failure, and diabetes mellitus. In addition, the safety and probable benefit has not been established for these patients: those whose diagnosis of OCD is documented to be less than 5 years duration or whose YBOCS score is less than 30, who have not completed a minimum of 3 adequate trials of first and/or second line medications with augmentation, who have not attempted to complete an adequate trial of cognitive behavior therapy (CBT), who are pregnant, under the age of 18 years, and who do not have comorbid depression and anxiety. Physicians should carefully consider the potential risks of implanting the Reclaim DBS System in patients with comorbid psychiatric disorders (e.g., bipolar, body dysmorphic, psychotic) as the Reclaim DBS System may aggravate the symptoms. Additionally, the abrupt

cessation of stimulation for any reason should be avoided as it may cause a return or worsening (i.e., “rebound” effect) of disease symptoms. Serious adverse events related to the therapy, device, or procedure can include: suicidality/increased depression, increased OCD/fluctuating results, intracranial hemorrhage, lead/extension failure, aggression/violent behavior, accident proneness, irritability, death, hypomania, infection, pyelonephritis, and post-operative seizure. Adverse events related to the therapy, device, or procedure can include: coma, paralysis, pain or discomfort at incision/implant sites, general post-op discomfort, GI symptom (post op), increased anxiety, insomnia, cognitive disturbance (clouding), induced muscle contraction, restlessness, stimulation induced paresthesia, device migration, shocking or jolting stimulation, induced sensation of taste/smell, weight gain, increased fatigue, upper respiratory infection, headaches, dizziness, dry mouth, itching at surgical site(s), nausea, sedation, and weight loss.

Humanitarian Device: Authorized by Federal (U.S.A) law for use as an adjunct to medications and as 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.

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