



ACTIVA™ DBS DEVICES PROTECTED BY DESIGN

**Working to prevent device
electromagnetic interference (EMI) for
your — and your patient's — peace of mind**

The potential for electromagnetic interference (EMI) is common in our modern-day environment. It comes from everyday devices such as cell phones and televisions and from powerful medical equipment such as electrocautery tools.

EMI can affect sensitive electronics and metal-containing components, including those in DBS systems. Because we know how important continuous therapy is to you and your patients, we design EMI protection into our devices, all the way down to the smallest component.



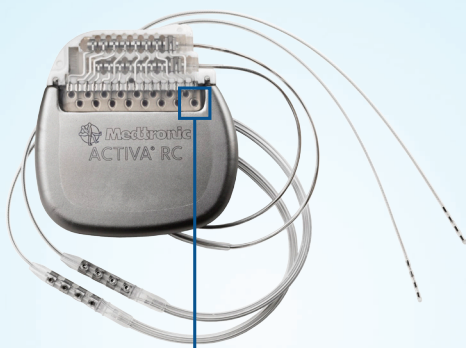
Medtronic
Further, Together

THOUGHTFULLY DESIGNED

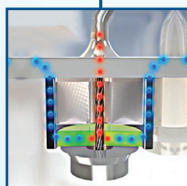
We design and manufacture all the major components of our implantable devices, so we are able to meet exacting standards and complete rigorous testing for common sources of EMI.

Unique features are designed into our devices to protect performance, including:

- **Filtered feedthrough technology:** Prevents radio waves (EMI) from entering and damaging the device
- **Minimal ferrous materials:** Reduces potential for unwanted device and lead movement caused by magnetic pull
- **Protective diodes:** Helps prevent device failure when exposed to EMI



Unfiltered



Filtered

Filtered feedthroughs and coiled lead wire design work together to dissipate RF energy.

THOROUGHLY TESTED

All of our major implantable components of the Atronic family system — including leads and extensions — are designed and manufactured to meet or exceed industry standards.

To ensure performance, our devices undergo rigorous testing at a variety of frequencies and intensities to account for the types of EMI the device may reasonably encounter. Because many different types of EMI sources exist, it is impossible to specify all interference sources here.

We test on the individual component level and on the system level. Devices that do not pass all tests go back to design.

System performance exposure testing includes, but is not limited to:

- Electrocautery
- Transthoracic defibrillation
- Various intensities of 60Hz EMI (typical environmental exposure)
- MRI

The labeling includes detailed instructions for safe use of medical equipment or exposure to EMI.

WHY DO WE GO TO SUCH LENGTHS?

EMI sources 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 excess voltage, which can in turn deliver an excessive amount of heat to the brain (or other tissues in contact with the lead or extension).

EXTENSIVELY TRACKED

To best serve you and your patients, we need a thorough understanding of how our devices perform, not only in the lab, but also in real life. That's why we have tracked more than 2,100 patients and have logged 12,000 years of device experience from multiple locations around the globe.

Find more information in our annual Product Performance report.

Product Performance reports, with a summary of data from the Medtronic post-market registry, are available at <http://professional.medtronic.com/ppr>.

FULLY SUPPORTED

Design and testing cannot prevent all types of EMI. It is important to read and understand how EMI could interfere with your patient's implant, including specifically contraindicated procedures. No other DBS manufacturer gives you the level detail and recommendations on how to minimize the potential for device damage, therapy disruption, patient injury, or discomfort due to EMI. If you would like to know more, consult product labeling or contact us.

We know making informed choices is important to you, and that's why we provide technical support 24/7. Contact us for local and national support at 1-800-707-0933.

See product insert for important safety information about EMI:
<http://manuals.medtronic.com>



Brief Statement: 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 in individuals with levodopa-responsive Parkinson's disease of at least 4 years' duration that are not adequately controlled with medication, including motor complications of recent onset (from 4 months to 3 years) or motor complications of longer-standing duration.

Medtronic DBS Therapy for Tremor: Unilateral thalamic stimulation of the ventral intermediate nucleus (VIM) 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.

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/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis), in patients seven years of age or above.

Contraindications: Medtronic DBS Therapy is contraindicated for patients who are unable to properly operate the neurostimulator and, for Parkinson's disease and Essential Tremor, patients for whom test stimulation is unsuccessful. The following procedures are contraindicated for patients with DBS systems: diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy), which can cause neurostimulation system or tissue damage and can result in severe injury or death; Transcranial Magnetic Stimulation (TMS); and certain MRI procedures 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 if they have an implanted Soletra Model 7426 Neurostimulator, Kinetra Model 7428 Neurostimulator, Activa SC Model 37602 Neurostimulator, or Model 64001 or 64002 pocket adaptor.

Warnings and Precautions: There is a potential risk of brain tissue damage using stimulation parameter settings of high amplitudes and wide pulse widths and, for Parkinson's disease and essential tremor, a potential risk to drive tremor using low frequency settings. Extreme care should be used with lead implantation in patients with an increased risk of intracranial hemorrhage. Sources of electromagnetic interference (EMI) may cause device damage or patient injury. 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. 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. MRI conditions that may cause excessive heating at the lead electrodes which can result in serious injury, including coma, paralysis, or death, or that may cause device damage, include: neurostimulator implant location other than pectoral and abdominal regions; unapproved MRI parameters; partial system explants ("abandoned systems"); misidentification of neurostimulator model numbers; and broken conductor wires (in the lead, extension or pocket adaptor). The safety of electroconvulsive therapy (ECT) in patients receiving DBS Therapy has not been established. The lead-extension connector should not be placed in the soft tissues of the neck due to an increased incidence of lead fracture. 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). Onset of status dystonicus, which may be life-threatening, may occur in dystonia patients during ongoing or loss of DBS therapy. Patients using a rechargeable neurostimulator for Parkinson's disease or Essential Tremor should check for skin irritation or redness near the neurostimulator during or after recharging, and contact their physician if symptoms persist. 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.

Adverse Events: Adverse events related to the therapy, device, or procedure can include intracranial hemorrhage, cerebral infarction, CSF leak, pneumocephalus, seizures, surgical site complications (including pain, infection, dehiscence, erosion, seroma, and hematoma), meningitis, encephalitis, brain abscess, cerebral edema, aseptic cyst formation, device complications (including lead fracture and device migration) that may require revision or explant, extension fibrosis (tightening or bowstringing), new or exacerbation of neurological symptoms (including vision disorders, speech and swallowing disorders, motor coordination and balance disorders, sensory disturbances, cognitive impairment, and sleep disorders), psychiatric and behavioral disorders (including psychosis and abnormal thinking), cough, shocking or jolting sensation, and ineffective therapy.

Safety and effectiveness has not been established for patients with previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression, patients who are pregnant, or patients under 18 years. Parkinson's disease and essential tremor: safety and effectiveness has not been established for patients with neurological disease other than idiopathic Parkinson's disease or Essential Tremor. Essential tremor: safety and effectiveness has not been established for bilateral stimulation or for patients over 80 years of age. Dystonia: age of implant is suggested to be that at which brain growth is approximately 90% complete or above.

Humanitarian Device (Dystonia): Authorized by Federal Law to aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis), in patients seven years of age or above. The effectiveness of the devices for treating these conditions has not been demonstrated.

USA Rx only Rev0616

Brief Statement for 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: Medtronic Reclaim DBS Therapy for OCD is contraindicated for patients who are unable to properly operate the neurostimulator. The following procedures are contraindicated for patients with DBS systems: diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy), which can cause neurostimulation damage or tissue damage and can result in severe injury or death; Transcranial Magnetic Stimulation (TMS); and certain MRI procedures 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 if they have an implanted Soletra Model 7426 Neurostimulator, Kinetra Model 7428 Neurostimulator, Activa SC Model 37602 Neurostimulator, or Model 64001 or 64002 pocket adaptor.

Warnings and Precautions:

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 brain tissue damage and other side effects using stimulation parameter settings of high amplitudes and wide pulse widths. Extreme care should be used with lead implantation in patients with an increased risk of intracranial hemorrhage. Sources of electromagnetic interference (EMI) may cause device damage or patient injury. 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. 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. The safety of somatic psychiatric therapies using equipment that generates electromagnetic interference (e.g., vagus nerve stimulation) has not been established. MRI conditions that may cause excessive heating at the lead electrodes which can result in serious injury, including coma, paralysis, or death, or that may cause device damage, include: neurostimulator implant location other than pectoral and abdominal regions; unapproved MRI parameters; partial system explants ("abandoned systems"); misidentification of neurostimulator model numbers; and broken conductor wires (in the lead, extension or pocket adaptor). The lead-extension connector should not be placed in the soft tissues of the neck due to an increased incidence of lead fracture. Abrupt cessation of stimulation may cause a return of disease symptoms in some cases with intensity greater than was experienced prior to system implant ("rebound effect").

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, and sensations such as tingling, smell, or taste. During treatment, patients should be monitored closely for increased depression, anxiety, suicidality, and worsening of obsessive-compulsive symptoms.

Adverse Events: Adverse events related to the therapy, device, or procedure can include intracranial hemorrhage, cerebral infarction, CSF leak, pneumocephalus, seizures, surgical site complications (including pain, infection, dehiscence, erosion, seroma, and hematoma), meningitis, encephalitis, brain abscess, cerebral edema, aseptic cyst formation, device complications (including lead fracture and device migration) that may require revision or explant, extension fibrosis (tightening or bowstringing), new or exacerbation of neurological symptoms (including vision disorders, speech and swallowing disorders, motor coordination and balance disorders, sensory disturbances, cognitive impairment, and sleep disorders), psychiatric and behavioral disorders (including psychosis and abnormal thinking), cough, shocking or jolting sensation, ineffective therapy, sensory symptoms, and autonomic 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, who are 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.

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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