

## References

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### Brief Statement: Medtronic DBS Therapy for Dystonia

#### Product labeling must be reviewed prior to use for detailed disclosure of risks.

**INDICATIONS:** Bilateral stimulation of the internal globus pallidus (GPi) using Medtronic DBS Therapy for Dystonia is indicated as an aid in the management of chronic, intractable (oral and/or injectable medication refractory) primary dystonia, including:

- generalized dystonia, segmental dystonia of the head and neck, and cervical dystonia (torticollis) in adult patients.
- generalized dystonia in pediatric patients twelve years of age or above.

**CONTRAINDICATIONS:** Medtronic DBS Therapy 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 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 the patient has an implanted Soletra™ Model 7426 Neurostimulator, Activa™ SC Model 37602 Neurostimulator, or Model 64001 or 64002 pocket adaptor.

**WARNINGS:** There is a potential risk of brain tissue damage 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 implanted cardiac devices (e.g., pacemaker, defibrillator), external defibrillation/cardioversion, ultrasonic equipment, electrocautery, or radiation therapy. MRI conditions that may cause excessive heating at the lead electrodes which can result in serious and permanent 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. 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 during ongoing or loss of DBS therapy. Depression, suicidal ideations and suicide have been reported, although no direct cause-and-effect relationship has been established.

Patients should avoid activities that may put undue stress on the implanted components of the neurostimulation system. Activities that include sudden, excessive or repetitive bending, twisting, or stretching can cause component fracture or dislodgement that may result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery to replace or reposition the component. Patients should avoid manipulating the implanted system components or burr hole site as this can result in component damage, lead dislodgement, skin erosion, or stimulation at the implant site. Patients should not dive below 10 meters (33 feet) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA) as this could damage the neurostimulation system, before diving or using a hyperbaric chamber, patients should discuss the effects of high pressure with their clinician. Patients using a rechargeable neurostimulator must not place the recharger over a medical device with which it is not compatible (eg, other neurostimulators, pacemaker, defibrillator, insulin pump). The recharger could accidentally change the operation of the medical device, which could result in a medical emergency. Patients should not use the recharger on an unhealed wound as the recharger system is not sterile and contact with the wound may cause an infection.

**PRECAUTIONS:** Loss of coordination in activities such as swimming may occur. Patients using a rechargeable neurostimulator should check for skin irritation or redness near the neurostimulator during or after recharging, and contact their physician if symptoms persist.

**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, weight gain or loss, hemiplegia, and hemiparesis. Pediatric patients may have increased risks of infections, device-related complications (for example, hardware breakage), revisions, and explants compared to adults due to continued growth, increased physical activity, and potential for longer duration of use.

Safety of this device for use in the treatment of dystonia with or without other accompanying conditions (e.g., previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression, or for patients who are pregnant) has not been established. The impact of DBS on overall cognitive and neurological development and behavioral changes in pediatric patients is unknown.

USA Rx only Rev 12/25

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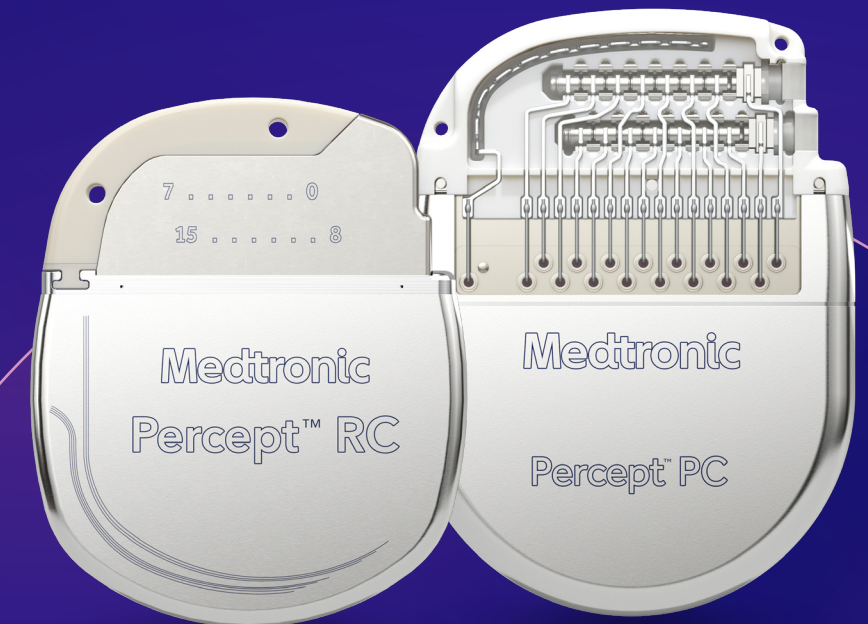
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## Medtronic

### Deep brain stimulation (DBS) for dystonia

# Restore movement, improve control

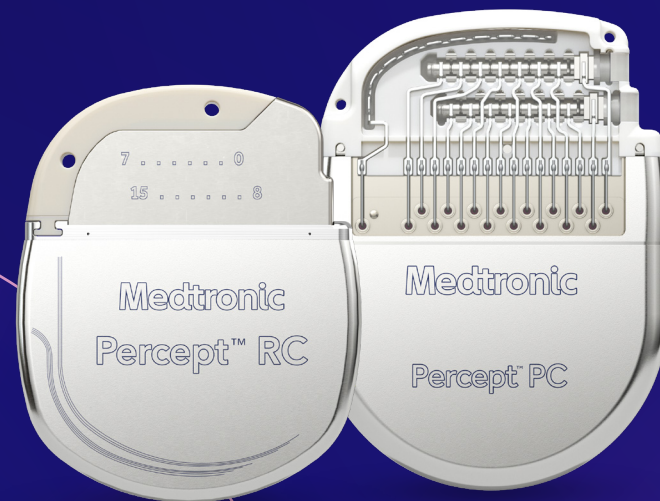
The only DBS system in the U.S. shown to be safe and effective for treating dystonia symptoms in adults and children age 12 years and older.



# A trusted choice for more than 20 years<sup>†</sup>

With over 200,000 patients served<sup>1</sup> across our indications in over 70 countries around the world,<sup>1</sup> we are the originator and world leader in DBS.

Our commitment to the dystonia community is underscored by decades of research, investment in innovation, and 20 years of experience serving patients with dystonia.



More than  
**80%**  
of adult patients

with generalized (n=24) and segmental dystonia of the head and neck (n=16) at 6 month experienced a beneficial response ( $\geq 25\%$ ) on the BFMDRS motor score and was sustained up to 10 years (75%).<sup>2</sup>

# Improves motor, disability, and severity scores over time

Improvement in BFMDRS  
motor/severity scores

**Pediatrics**  
(Generalized)

**71%**

average improvement in  
BFMDRS motor score<sup>3</sup>  
(n=143)

**Adult**

[Generalized (n=130) or  
segmental (n=94)  
of the head and neck]

**>60%**

average improvement in  
BFMDRS motor score<sup>3</sup>

Improvement in TWSTRS  
severity scores

**Adult  
cervical**

**58%**

average improvement in  
TWSTRS severity scores  
(n=245)<sup>3</sup>

The primary clinical evidence of safety and effectiveness was compiled from a systematic review of published scientific literature, an analysis of a subset of clinical data purchased from a published randomized controlled trial (RCT) by Kupsch (2006),<sup>5</sup> collectively referred to as the "Investigator Study" and data from the Medtronic Product Surveillance Registry (PSR). Sample sizes differ across studies and populations.

## Improves quality of life



### Significant improvement in quality of life

at 6 months (n=34), and benefits were sustained for up to 5 years (n=29) in adult patients with generalized and segmental dystonia of the head and neck<sup>4,5</sup>



### Significant reduction in depression and anxiety

in adult patients with generalized and segmental dystonia of the head and neck<sup>4,5</sup>

(n=40)

## Reduces pain<sup>†</sup>

### 51% reduction in pain

at 6 months for adult patients with cervical dystonia<sup>8</sup>

(n=58)

### Pain reduction sustained up to 10 years

experienced by adult patients diagnosed with generalized and segmental dystonia of the head and neck<sup>2-5</sup>

(n=28)

## Regain daily function



DBS therapy may maintain improvement of movements as well as the ability to perform daily activities for several years.<sup>3</sup>

## Risks

DBS therapy may help manage some of the symptoms of dystonia, including involuntary movements, but it is not a cure. Potential risks related to the device, therapy, or surgery can include implant site pain, tingling sensations, ineffective stimulation, and implant site infection. Possible side effects with DBS therapy for dystonia might include:

- Status dystonicus
- Risk of depression, suicidal ideations, and suicide
- Rebound effect: an abrupt cessation of stimulation may cause a return of disease symptoms and in some cases with a greater intensity than prior to implant
- Pediatric patients may have increased risk of infections and device-related complications.

<sup>†</sup> clinical data only available for adult dystonia patients

# Engineered to adapt



## Percept™ family with BrainSense™ technology

The Percept™ family with exclusive BrainSense™ technology† empowers you to adapt DBS therapy to your patients' evolving needs.

## The Medtronic advantage

### Personalized therapy

The Percept™ family with BrainSense™ technology† is the only sensing-enabled DBS system offering insights into a patient's condition inside and outside of the clinic throughout the patient journey.

† The sensing feature of the Percept™ PC system and Percept™ RC system is intended for use in patients receiving DBS where chronically-recorded bioelectric data may provide useful, objective information regarding patient clinical status. Signal may not be present or measurable in all patients treated for dystonia.

## MRI access

Medtronic offers the world's first full-body MRI capable DBS device portfolio<sup>‡,§</sup>, including:

- Access to 1.5T and 3T MRI scans for when your patients need high-quality imaging<sup>‡</sup>
- Ability for DBS therapy to remain on (in bipolar mode) during an MRI scan<sup>‡</sup>

**~7/10**  
adult movement disorder patients who are eligible for DBS therapy may need an MRI within 10 years following their implant.<sup>7</sup>

‡ Medtronic DBS systems are MR Conditional. Refer to product labeling for full list of conditions: <https://manuals.medtronic.com/manuals/mri/region>

§ For implant depths of up to 2 cm.

∅ Based on current actual battery level and on therapy settings from last 7 days.

¶ Percept™ RC as compared to Boston Scientific Vercise Genus™ R16 (MP92328632-10 REV A), accessed February 24, 2026, and Abbott Liberta RC™ IPG (ARTEN600340313 B), accessed February 24, 2026. Boston Scientific and Abbott DBS devices are not approved for the treatment of dystonia symptoms.

## Battery power

- **Choice of recharge-free** (Percept™ PC neurostimulator) or **rechargeable** (Percept™ RC neurostimulator) battery options.
- **Rapid recharge:** Patients can charge under normal conditions (from 10% to 90% full) in less than an hour with Percept™ RC device.<sup>§</sup>
- **15-year life with no shut-off:** Greater than 99% capacity at 15 years with weekly recharge, designed to offer a more consistent recharge experience over time with Percept™ RC device.
- Personalized prediction of remaining battery life for Percept™ PC device.<sup>∅</sup>

## Patient comfort

- Smallest, thinnest rechargeable neurostimulator available.<sup>¶</sup>

# Is your patient a candidate for DBS therapy for dystonia?

DBS for dystonia may be appropriate if your patient has chronic primary dystonia, including:

- Generalized, segmental of the head and neck, or cervical dystonia (torticollis) in adult patients
- Generalized dystonia in patients 12 years of age or above
- Cannot manage symptoms with medications and/or injections or tolerate their side effects

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.

To discover more about Medtronic DBS for dystonia, visit: **[medtronic.com/DBSdystonia](https://www.medtronic.com/DBSdystonia)**

Or scan:

