DYSTONIA®
FACT SHEET

What is it?
The Medtronic Deep Brain Stimulation (DBS) System for dystonia is unilateral or bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) 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. Deep brain stimulation started in 1987 and in 2003, Medtronic DBS Therapy for Dystonia was approved by the FDA. More than 175,000 patients worldwide have received from Medtronic DBS Therapy.

What are the treatment options for dystonia?
Dystonia is a neurological movement disorder characterized by involuntary muscle contractions. These contractions force certain parts of the body into repetitive, twisting movements or painful postures that may interfere with everyday functions like walking, sleeping, eating, and talking. Although dystonia has no cure, there are several treatments such as medication and injections, drug therapies, rhizotomy and pallidotomy, and DBS therapy.

Safety and Probable Benefit of DBS Therapy
The safety and probable benefit of DBS Therapy for dystonia is approved by the FDA under a Humanitarian Device Exemption (HDE). The therapy delivers stimulation to targeted areas of the brain that may decrease some or all symptoms. Symptoms will return when the stimulation is turned off.

During DBS Therapy, a small, pacemaker-like device sends electrical signals to an area in the brain that controls movement. These signals block some of the brain messages that cause frustrating and disabling motor symptoms. The device is placed under the skin in the chest (or abdomen). Very thin wires connect the device to the brain to enable the signals to reach the source of symptoms. Most people don’t feel the stimulation at all as it reduces their symptoms. Some people may feel a brief tingling when the stimulation is first turned on. Following the procedure, stimulation settings are adjusted by the physician to manage individual symptoms. The physician may provide the patient with a small hand-held programmer to adjust stimulation withing physician set limits, and turn the device on and off. Over time, settings can be adjusted by physicians as symptoms change. A few weeks after the procedure, people can go back to normal daily activities following their physician’s instructions.

The stimulation targets used in DBS Therapy for dystonia as well as the implant procedure are the same as for DBS Therapy for Parkinson’s disease and DBS Therapy for essential tremor. Therefore, risks associated with DBS Therapy for dystonia are similar to risks associated with DBS Therapy for Parkinson’s disease or essential tremor. DBS Therapy is not for everyone. DBS Therapy requires brain surgery which can have serious and sometimes fatal complications. Other complications can occur and may require additional surgery. DBS Therapy may cause new or worsening neurological or psychiatric symptoms. In patients receiving DBS Therapy for dystonia, depression, suicidal ideations, and suicide have been reported, although no direct cause-and-effect relationship has been established. Onset of status dystonicus, which may be life-threatening, may occur in dystonia patients during ongoing or loss of DBS Therapy.

Why is DBS therapy important to the treatment continuum?
Dystonia is a challenging disease complex to treat because the various pathophysilogies leading to the disease conditions are not well understood. No cures and no treatments exist to reverse the course of the disorder. Medtronic DBS therapy for patients with dystonia is considered advantageous because:

- treatment is reversible (device can be turned off or removed);
- stimulation parameters are adjustable for optimal therapy; and
- DBS therapy is non-destructive, an especially important feature in a developing brain because is does not foreclose the possibility for future therapeutic interventions.

Unlike other DBS manufacturers, Medtronic DBS systems are full-body MR Conditional** at 1.5T and 3T. Activa systems (1.5T) Percept Systems (1.5 and 3T).

The probable benefit to health from the use of Medtronic DBS therapy for dystonia outweighs the risk of injury or illness from its use.

* Humanitarian Device: The effectiveness of the devices for the treatment of dystonia has not been demonstrated.

** Based on sales information dated January 2020 and includes the following indications; Parkinson’s disease, essential tremor, obsessive–compulsive disorder, dystonia, and epilepsy.

*** Medtronic DBS systems are MR Condition and safe in the MR environment as long as certain conditions are met. If the conditions are not met, a significant risk is tissue lesions from component heating, especially at the lead electrodes, resulting in serious and permanent injury including coma, paralysis, or death. Refer to the MRI Guidelines for Medtronic Deep Brain Stimulation Systems for a complete list of conditions: http://professional.medtronic.com/mri.
REFERENCES:

1. Medtronic DBS Therapy for Dystonia - Clinical Summary 2015.

Worrying about the consequences of a potential failure to monitor patients properly can be a significant burden. Inadequate monitoring can lead to potentially serious complications, including acute neurological events such as seizures or dyskinesias, as well as chronic complications such as infections or device failures. The importance of monitoring cannot be overstated, as it can directly impact patient outcomes and quality of life.