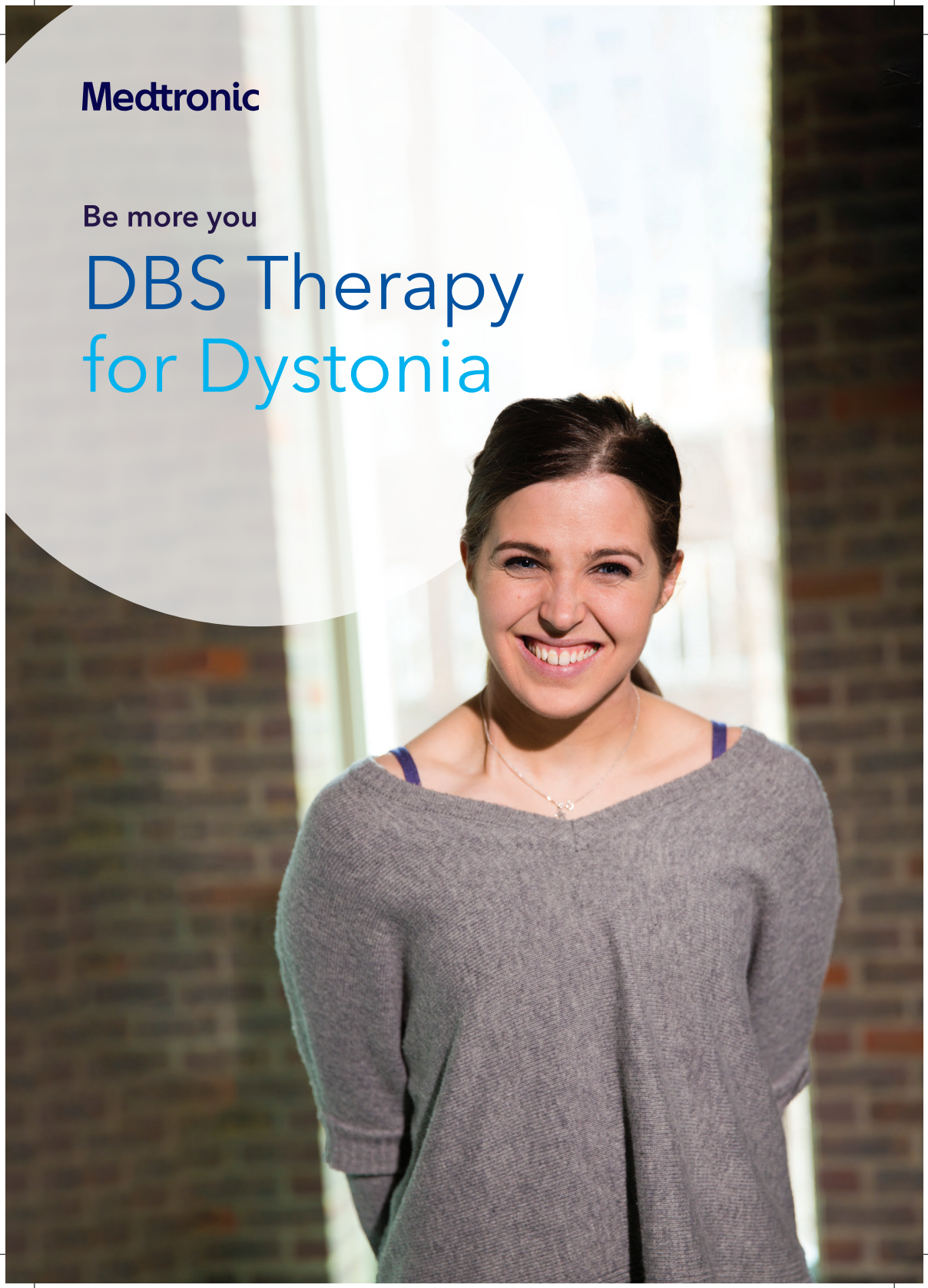
Medtronic

Be more you

DBS Therapy for Dystonia



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*Number of unique patients implanted (i.e"new patients") as of January 2020.


Today more than
175,000*
people have benefited
from Medtronic DBS
Therapy worldwide

Approximately

500,000

adults and children in Europe suffer from the movement disorder known as Dystonia.[1]

About Dystonia

Dystonia is a neurological movement disorder characterised by involuntary muscle contractions. These contractions force certain parts of the body into repetitive, twisting movements or painful postures. Dystonia is the third most common movement disorder after Essential Tremor and Parkinson's disease.[1]

There is no existing cure and all treatments aim to reduce symptoms.

Leading the way in DBS

For over 30 years, we've been developing DBS technology and expanding treatment to more medical conditions. Medtronic Deep Brain Stimulation (DBS) Therapy has been approved in Europe to treat Dystonia since 2003.

Medtronic is a global leader in medical technology, services, and solutions — serving millions of people around the world every day.

So far, more than 175,000* people have had Medtronic DBS Therapy for a variety of movement disorders including Dystonia. Medtronic DBS is now a standardised procedure performed in more than 1,200 hospitals around the world.

We are committed to making sure you have the information and support you need to decide whether Medtronic DBS Therapy is right for you.

* Number of unique patients implanted (i.e"new patients") as of January 2020.

What is DBS Therapy?

DBS Therapy is a treatment for movement disorders such as Dystonia, Parkinson's disease and Essential Tremor.

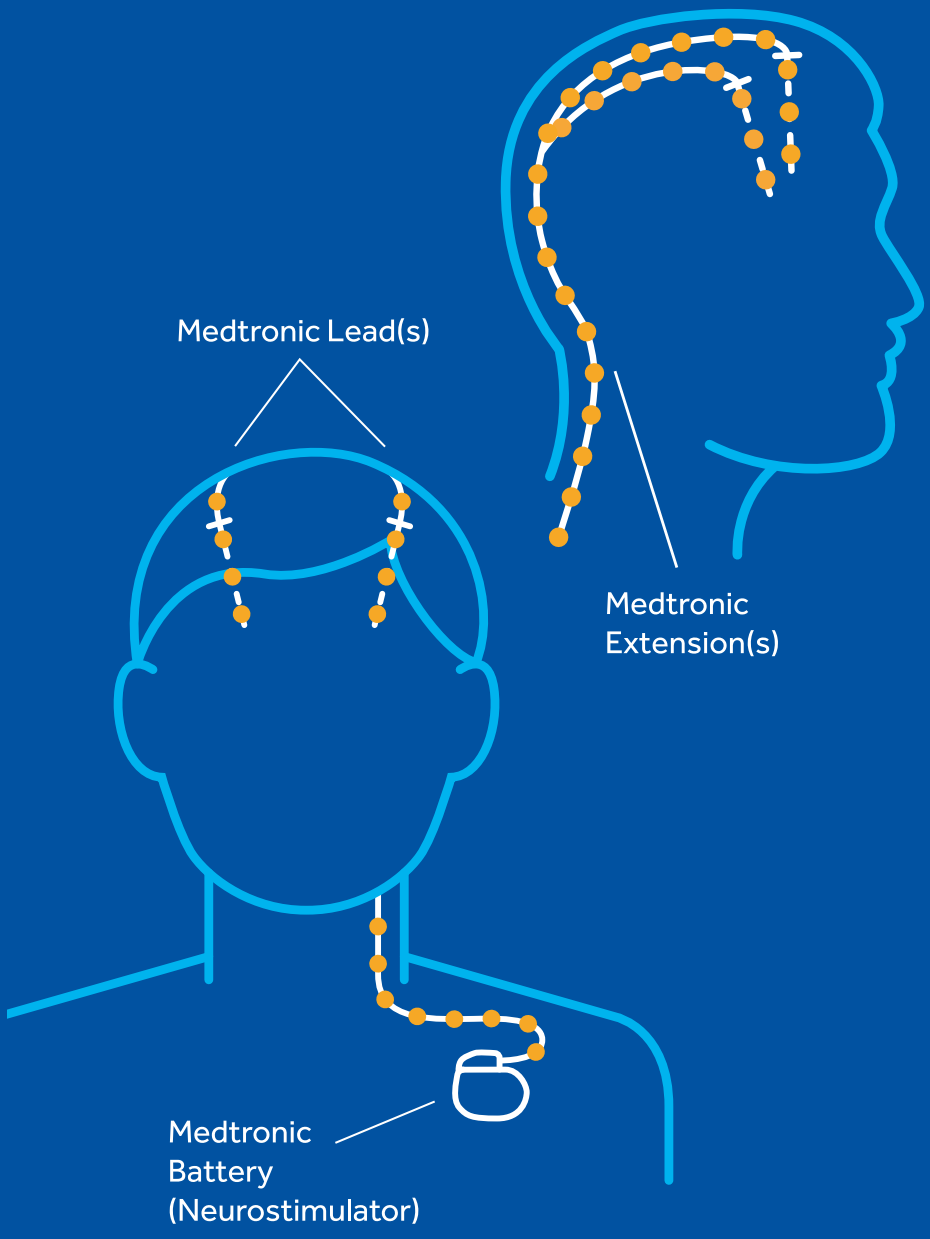
Just like a pacemaker for the heart, a small neurostimulator is surgically placed under the skin in the chest or abdomen to deliver DBS Therapy.

The device sends electrical pulses through extension cables to the leads and electrodes that are placed in an area of the brain that controls movement.

These pulses disrupt some of the brain's messages that cause the symptoms associated with Dystonia. DBS Therapy is reversible and can be discontinued at any time by turning off the neurostimulator or surgically removing the device.

Patient programmer

The patient programmer enables you to switch the stimulator on and off, check the battery level and modify settings in certain instances.


Medtronic Lead(s)
Medtronic
Extension(s)
Medtronic
Battery
(Neurostimulator)

How can DBS help me?

Medtronic DBS therapy helps control the primary symptoms of Dystonia such as muscle spasms, twisting, involuntary contractions and posturing.

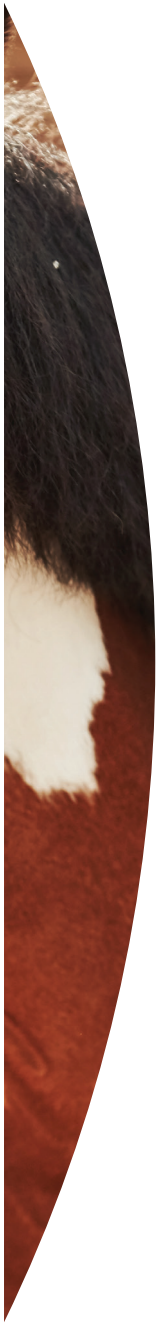
Here you can find out about the benefits of DBS Therapy for Dystonia and safety considerations.

It's very important to mention that the success of the therapy depends on:

- **Appropriate candidate selection which takes into account type of disease, duration of symptoms, response to medications and risks of important disability, with loss of independence and impaired quality of life**[2-8]
- **Appropriate surgical placement of the DBS electrodes**[3]
- **Appropriate programming of the neurostimulator**

Be more **confident** like Rafael

"After the surgery, what improved the most was my posture. The aspect of my recovery that made me feel the happiest was when I was able to go down and up the steps without holding the handrail"



Improves quality of movements and posture

The features of Dystonia are not static and vary according to activity. In order to better characterise the clinical course, and to evaluate the efficacy of treatments, the assessment of Dystonia severity on body movements and on the ability to perform daily activities is measured by specific and well-known scores.[9]

According to those score indicators, the improvement of movements of specific body regions like eyes, mouth, arms and legs in most patients with Dystonia after DBS Therapy ranges from 34% to 88%.[10–15]

Improves ability to perform daily activities

The improvement to perform daily activities (such as eating, hygiene, dressing, speaking, writing and walking) in most people with Dystonia after DBS Therapy ranges from 27% to 70%, thus enabling them to regain their independence and re-engage in their social life.[12,14]

Reduces the need for medication

Many people with Dystonia take multiple doses of multiple medications. Keeping track of these can be difficult. DBS is not a medication and it does not contain medication. DBS Therapy may significantly reduce – and in some people eliminate the need for medication.[15]

Reduces pain

It may reduce the pain that you can experience with Dystonia, especially Cervical Dystonia.[16-19]

Maintains improvements for several years

DBS therapy may maintain improvement of movements and postures as well as the ability to perform daily activities for several years.[12–15]

Adjustable

The electrical stimulation is adjustable and can be changed according to your specific needs with the help of your neurologist. No further surgery is necessary to make adjustments. Your neurologist may provide you with a small, handheld patient programmer. This programmer lets you turn the system on and off or allow small stimulation adjustments pre-programmed by your clinical team.

Medtronic DBS Therapy is not for everyone. Not everyone will receive the same results. Please consult your doctor for further information.

Be more **teenager** like Brooke

"DBS changed my life, I was finally pain free, I could sit comfortably, I was able to eat a little again and I started to go back to school".

When is the best time to consider DBS Therapy?

You may be eligible for DBS if you meet the following criteria:[2,6]

- **Have a chronic, intractable (drug refractory) primary Dystonia, including generalised and/or segmental Dystonia, Hemidystonia, and Cervical Dystonia (Torticollis)**
- **Have not had success managing your symptoms with medication**
- **Are 7 years of age or above**

The right time to talk with your doctor about DBS is now – so you know all your options and can act at the right time.

Only your doctor can determine if DBS Therapy is right for you. At the end of the brochure you will find some tips to prepare yourself for your appointment.


Don’t wait, discuss
DBS Therapy
with your
neurologist
early in your
treatment plan

Be more **active** like Kamri

"You might not even know she has dystonia"

Casey, Kamri's mother

Does DBS have a safety profile?

As with any surgery there are some risks associated with the procedure itself, but these are low when DBS Therapy for movement disorders is performed by an experienced team.[20]

- The risk of permanent neurologic morbidity is around 1%[21]
- As with other surgeries, death can occur. The risk of death within 30 days of surgery is 0.4%[21]
- The risk of potentially severe complications, including intracranial hemorrhage is 1% to 4%[21,22]

Device complications

Due to the mechanical stress to which the system is exposed, some of the device complications can include:

- Lead revision
- Lead fracture
- Lead erosion through scalp and infection

Stimulation related side effects

Side effects induced by stimulation have been rarely reported in Dystonia patients and included some speech problems such as dysarthria (difficulty in articulating words), difficulty in writing and walking.

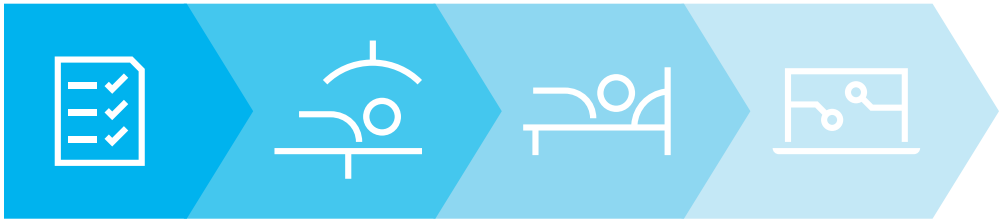
However, it is important to note that these side effects are usually reversible and can be reduced or solved by changing the stimulation parameters (although in some cases this may lead to a reduction in the improvement of Dystonia).[15,23]

Understanding the DBS procedure

Learn more about what is involved in the DBS Therapy surgical procedure with the summary that follows. Remember, the duration and procedural steps can vary by doctor and hospital.

In general, you can expect the surgery to last several hours. You will spend a few days in the hospital for:

Hospital stay



Your DBS surgical team may include: a neurosurgeon specialised in DBS Therapy, neurologist, anaesthesiologist, radiologist, other healthcare professionals such as neuropsychologists and a DBS specialised nurse.

Be more **Independent** like Amybel

"Having my DBS working, how it is now, is so important to me and it's difficult to remember that, because it works so well for me – it's difficult to imagine life without it".

Pre-operative assessment

This step is designed to get you and the surgical team ready for DBS surgery. You may need an MRI scan to capture an image of your brain. The MRI image helps the neurosurgeon to plan and place the leads exactly in the right place.

Implanting the leads and neurostimulator

DBS Therapy works through very thin wires called leads that deliver electrical stimulation from the neurostimulator to your brain. Using your brain images, your neurosurgeon places the leads precisely in specific areas of the brain. During this procedure you will be under general anesthesia.

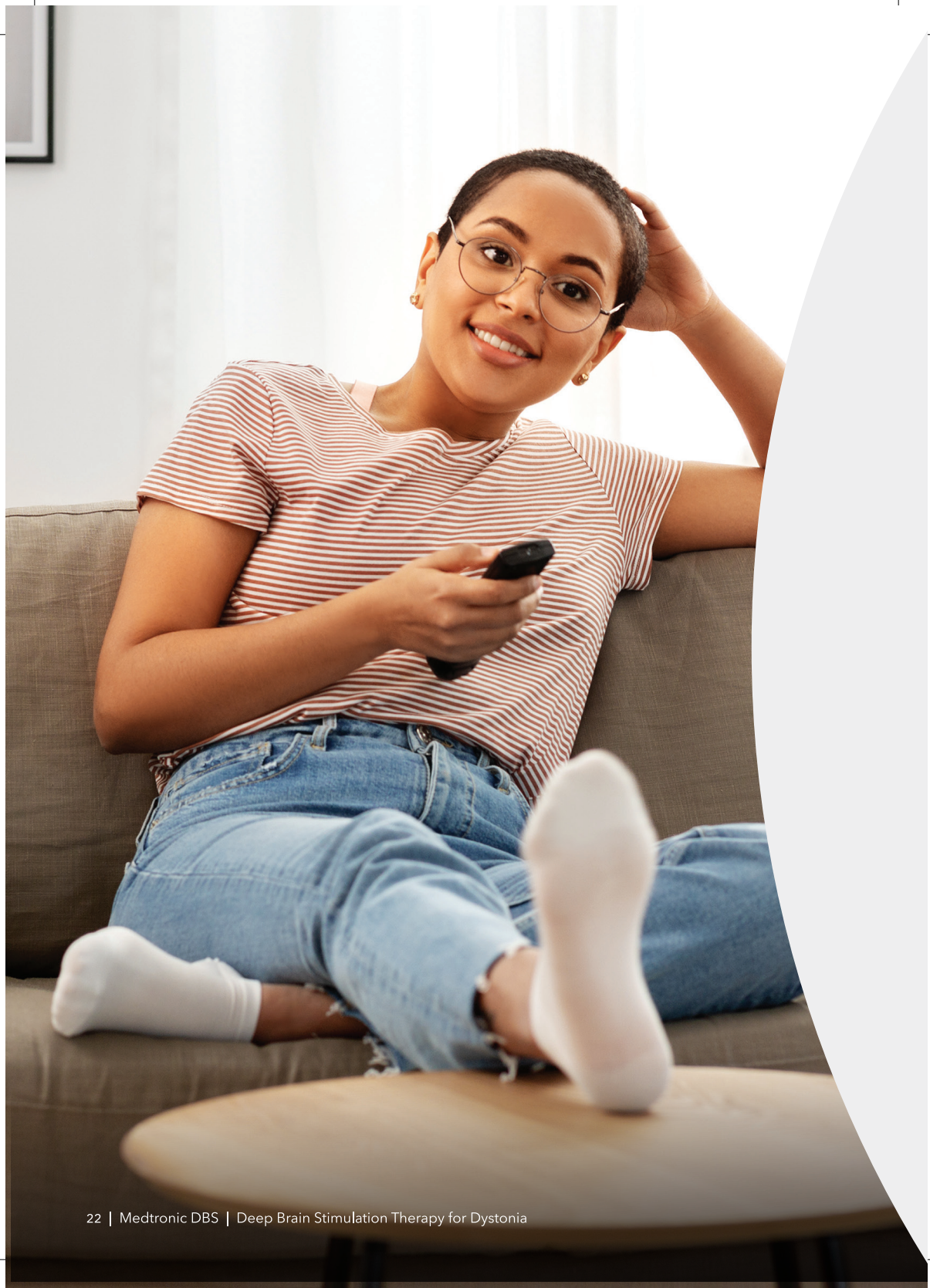
The same day – or shortly after the leads are implanted – your surgeon will implant the neurostimulator just under your collarbone or abdomen. You'll be asleep for this part of the procedure too. Your surgeon will connect the leads to the device using stretchable extensions that are placed under your skin, from the chest up to the neck and head.

Healing

Generally, you will be ready to return home or to be transferred to a rehabilitation unit for programming a few days after surgery. Healing at home can then continue for several weeks. It's normal to feel some discomfort or pain at the incision sites, and this is managed with medication. The neurologist or DBS specialised nurse will discuss resuming activity and exercise.

Programming

The device will be turned on at the first programming session. At that time, medication may also be adjusted. Programming begins after you have healed from surgery. With the help of a clinician-programmer device which receives and sends signals from and to your neurostimulator, the neurologist can select the optimal stimulation parameters to control your symptoms.



Medtronic DBS
DBS therapies – tailored to each individual's need

Percept™ PC
Neurostimulator with Brainsense™ technology
Size: 68 x 51 x 11 mm

- Non-rechargeable
- BrainSense™ technology captures brain signals using therapy lead while delivering therapy stimulation, in and out of clinic
- Full-body MRI conditional*
- Smaller battery and increased longevity**
- Provides extended, maintenance-free symptom control
- Ideal for patients who prefer a low-maintenance or maintenance-free implanted device
- Stimulates two sides with one device

* Medtronic DBS systems are MR Conditional, which means they are safe for MRI scans only under certain conditions. If the conditions are not met, the MRI could cause tissue heating, especially at the implanted lead(s) in the brain, which may result in serious and permanent injury or death. Before having an MRI, always talk with the doctor who manages your DBS Therapy to determine your eligibility and discuss potential benefits and risks of MRI. For further information, please call Medtronic at +44 (0) 1923 205101.
** When compared to the previous generation Activa™ PC device.

Activa™ RC
Neurostimulator
Size: 54 x 54 x 9 mm

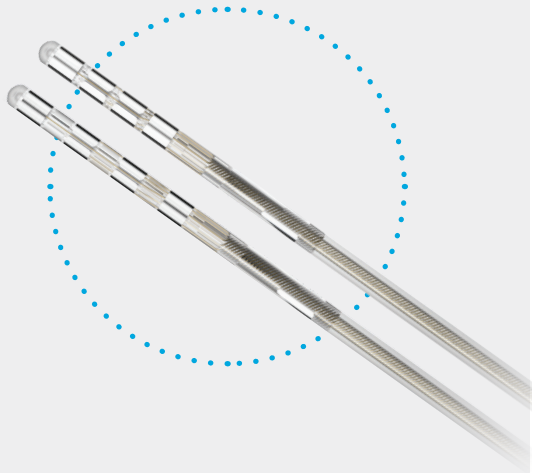
- Rechargeable battery
- MRI conditional*
- Powered by a rechargeable battery that lasts up to 15 years**
- Patients are free from replacement surgery for more than a decade**
- Patients can choose to recharge their neurostimulator battery daily or weekly using the new wireless recharger
- Stimulates two sides with one device

Activa™ SC
Neurostimulator
Size: 55 x 60 x 11 mm

- Non-rechargeable
- MRI conditional†
- Powered by a long-life battery
- Provides extended, maintenance-free symptom control
- Ideal for patients who prefer a low- or maintenance-free implanted device
- Stimulates one side of the brain

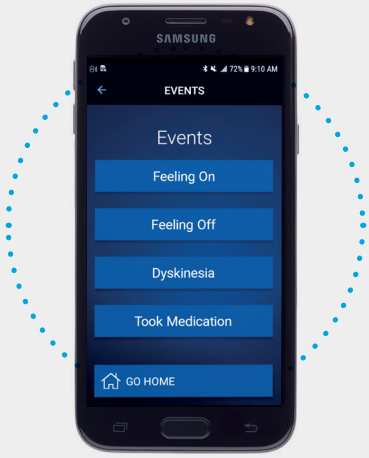
SenSight™
Directional leads
Size: 54 x 54 x 9 mm

- Leads designed with contact spacing for the specific anatomy target site
- Gives surgeon the right options for each patient's unique needs
- MRI conditional†
- Works seamlessly with Percept™ PC neurostimulator



Medtronic DBS
Patient programmer

- The Medtronic DBS patient programmer has an intuitive interface that resembles familiar consumer technology
- Protects patient's device and data with defense-grade security capabilities
- Empowers patient's to manage their therapy discreetly with a device that looks like a smartphone
- Battery checks are easier than ever with intuitive icons and labels
- Automatically generates calculation of expected battery longevity***
- Tutorial videos are directly available in the Patient Programmer



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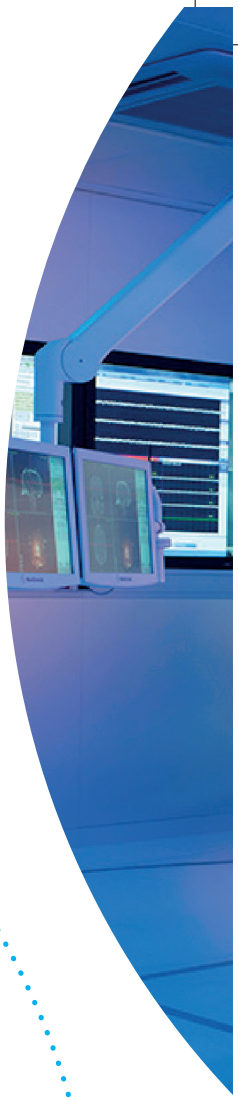
** Activa™ RC devices eligible for the 15 year service life extension are those that have successfully been interrogated with the A610 application on the Medtronic Activa™ Clinician Programmer prior to reaching End of Service (EOS).
*** when used with Percept™ PC neurostimulator.
† Under specified conditions; see approved labeling.

We do more for you

Medtronic provides services and technologies to optimise your surgery, such as imaging capabilities, and brain signal recording. We are also dedicated to supporting the surgical team to help maximise clinical outcomes.



The quality improvement of movements and postures ranges from

34% to 88%

with Medtronic DBS Therapy[11–17]


MORE
olutions
ORE
vices
O-arm
O-arm

How can your decisions today protect your future?

About

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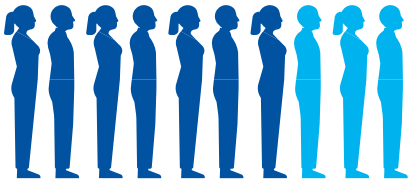

Movement disorder patients eligible for DBS Therapy may need an MRI within 10 years following their implant[24]

What is MRI?

MRI is short for Magnetic Resonance Imaging and is a non-invasive way to examine organs, tissues and the skeletal system. MRI is used to diagnose causes of common medical conditions of the **heart, brain and spine**. It produces high-resolution images that help diagnose a variety of problems.

Compared to CT (X-ray), MRI is safer, provides your doctor with a much better chance of the correct diagnosis. **It is now the preferred mode of diagnostic imaging for many disease states, both in terms of guidelines and clinical practice**.[25,26]

The first full body MRI conditional portfolio

Medtronic offers the world's first full body MRI capable DBS device portfolio.* People with Dystonia with implanted DBS systems feel reassured knowing that with proper safeguards, **MRI is an option for them**.

The therapy decisions you make today, **may impact your future**

* Medtronic DBS systems are MR Conditional, which means they are safe for MRI scans only under certain conditions. If the conditions are not met, the MRI could cause tissue heating, especially at the implanted lead(s) in the brain, which may result in serious and permanent injury or death. Before having an MRI, always talk with the doctor who manages your DBS Therapy to determine your eligibility and discuss potential benefits and risks of MRI. For further information, please call Medtronic at +44 (0) 1923 205101.

Our support, technology, and experience - all for you

Medtronic is a global leader in medical technology, services, and solutions - serving millions of people around the world every day. Your Medtronic DBS will be backed by our decades of research, innovation and experience. Our technology is designed to meet your needs now and into the future.

We provide you with unparalleled resources and one-on-one support while you are deciding whether DBS is right for you.

We are committed to making sure you have the information and support you need to decide whether Medtronic DBS Therapy is right for you.

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Leading the way in DBS

Deep brain stimulation started in 1987 and Medtronic has been the leader in the field ever since. In 2003, Medtronic DBS Therapy for Dystonia has received CE mark and a Humanitarian Device Exemption from the U.S. Food and Drug Administration to treat the movement symptoms of Dystonia.

Access to MRI scans anywhere on the body

We know it's important that you have safe* access to MRI if you need this important test to diagnose a medical condition or injury. We offer the first full-body MR Conditional DBS systems, which means it is safe to have scans anywhere on the body with some Medtronic DBS devices under certain conditions.

Personalised for You

Your doctor programs your DBS system to provide the best symptom control for you. As your symptoms change over time, the programming can be changed and personalised with BrainSense™ technology.

Minimise side effects

DBS may cause some of your symptoms to get worse or may affect your speech. Your doctor can adjust the settings to minimise side effects while providing the best possible symptom control.

Keep your future options open

Unlike some surgeries for Dystonia, deep brain stimulation is reversible. The system can be turned off or removed, in most cases, and won't limit your future treatment options.

DBS frequently asked questions (FAQs)

Does DBS prevent a person from using future treatments or cures that may come along?

No. DBS Therapy will not reduce future therapy options. DBS Therapy is reversible and the system can be removed.

Is DBS something to put off as a last resort?

Definitely not. The right time to talk with your doctor about DBS is now – so you know all your options and can act at the right time.

If left too late, DBS Therapy will not be able to help as much as it could have.

Will I feel the stimulation?

Many people with a DBS system will not feel the stimulation at all. Some people may feel a brief tingling sensation when the stimulation is first turned on. If the stimulation changes or becomes uncomfortable, the doctor should be contacted immediately.

How effective is DBS Therapy?

DBS Therapy extends the control you already get from your medication over the movement symptoms of Dystonia.

It's very important to mention that the success of Medtronic DBS depends on:

- Appropriate candidate selection which takes into account type of disease, duration of symptoms, response to medications and risks of important disability, with loss of independence and impaired quality of life[2-8]
- Appropriate surgical placement of the DBS electrodes[3]
- Appropriate programming of the neurostimulator

The improvement to perform daily activities (such as eating, hygiene, dressing, speaking, writing and walking) in most patients with Dystonia after DBS Therapy ranges from 27% to 70%, thus enabling them to regain their independence and re-engage in their social life.[12,14]

How long will it take for the DBS Therapy to work after the implant procedure?

Typically, a DBS system is not activated until a patient has healed from the surgery. Once activated, troubling symptoms may decrease. Optimal results are usually achieved after multiple programming sessions with the doctor or nurse who programmes the device.

Will my symptoms get better immediately after the surgery?

Depending on the centre, the DBS system can be activated 1–2 days or a few weeks after surgery. Your symptoms will start to decrease a few days after activation, but the improvement in Dystonia is gradual and may take weeks or months to reach its full extent. During this time, the healthcare professional who programs the device will go through several programming sessions with you to achieve optimal results. It is important that you are aware of the delay in the effects of treatment, to help manage expectations more effectively.

For more FAQ's and further information, visit our website:
http://www.medtronic.com/uk-en/patients/treatments-therapies/neurostimulator-dystonia.html

* Activa™ RC devices eligible for the 15 year service life extension are those that have successfully been interrogated with the A610 application on the Medtronic Activa Clinician Programmer prior to reaching End of Service (EOS).

Is DBS Therapy permanent?

No. DBS Therapy is adjustable so that the stimulation can be changed over time to maintain control over a patient's symptoms. The system can also be turned off or surgically removed if necessary.

How long does the neurostimulator last?

Depending on the model used and the amount of electrical stimulation required to control a patient's particular symptoms, the battery that supplies the neurostimulator can last from 2 to 15 years* depending on whether the system is rechargeable or not . New rechargeable batteries are in many cases recommended to Dystonic patients to avoid frequent surgical replacements, which in Dystonia tend to be often due to the high energy consumptions. However, the choice of the system should be discussed between physicians and patients to ensure that the choice is the adequate one for each particular case. When it is time to replace the battery, the incision over the stimulator is reopened (usually under local anaesthesia), the old device is removed and a new one is implanted. This procedure usually takes about 30 mins -1 hour.

Can normal daily activities be resumed?

For the first few weeks after surgery, patients who have received DBS should avoid strenuous activity, arm movements over the shoulder, and excessive stretching of the neck. Each individual should talk with their doctor about gradually trying activities that were difficult before surgery.

How many follow-ups with the DBS team will I need after surgery?

The number and time period of follow-ups depends on several factors and should be discussed with the DBS team and referral neurologist.

Will I be able to have an MRI scan with a DBS system?

About 7 out of 10 movement disorder patients eligible for DBS Therapy may need an MRI within 10 years following their implant.[24] Only Medtronic offers DBS systems that are CE approved for MRI full body scans, under specific conditions of use. Patients should talk to their doctors if an MRI scan is prescribed.

Will the neurostimulator be visible?

Depending on a person's body build, the neurostimulator may be noticeable as a small bulge under the skin. However, the therapy is fully implantable and generally not visible.

Your DBS resources and support

DBS Technical Patient Helpline - How can we help?

The helpline offers a central support channel for people implanted with Medtronic neuromodulation devices and their physicians. The helpline provides support on technical and utilisation-related questions about Medtronic neuromodulation devices.

Medtronic DBS Helpline: +44 (0) 1923 205101

More information about DBS available on the Medtronic website:
http://www.medtronic.com/uk-en/patients/treatments-therapies/neurostimulator-dystonia.html

Be more **empowered** Like Natalia

"I want to inspire people with Dystonia and tell them, 'Even if you think you will spend your life in a wheelchair, you should never give up. There are people and technologies that can help you live a better life."

Talking to a doctor about DBS

When you're ready to start the conversation about DBS, look for a neurologist who specialises in treating Dystonia. The right doctor will understand your needs and treatment options and will be your partner through this journey.

A movement disorder specialist is a neurologist with extra training in movement disorders, like Dystonia. These specialists have experience with the full range of treatment options. Some general neurologists are also experienced in treating Dystonia.

Whether you see a general neurologist or movement disorder specialist, be honest about your symptoms and how your treatment is working. Ask about other options you could try. And don't hesitate to get another opinion.

Preparing for the appointment

Here are a few questions to help you prepare yourself for your appointment:

1. **How troublesome do my symptoms need to be before I think about DBS Therapy as a treatment option?**

2. **How does DBS compare to other treatment options?**

3. **If I wait, will DBS Therapy always be an option for me?**

4. **What happens during the implant procedure?**

5. **How does the stimulation get adjusted?**

6. **How often will I need to return for follow-up visits?**

7. **For how long will DBS Therapy help alleviate my symptoms?**

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Brief Statement: Information contained herein does not replace the recommendations of your healthcare professional. See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your Health Care Professional.

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Results may vary from patients to patients. Not everyone who receives Medtronic DBS Therapy will experience the same results. Some people may experience significant symptom relief from DBS Therapy, and others may experience minimal relief. Talk to your doctor to see if Medtronic DBS Therapy is right for you. For further information, please consult your healthcare professional who can explain the benefits & risks and important safety information.

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