Deep Brain Stimulation Handbook

A learning resource on DBS therapy for patients with movement disorders.

DBS HANDBOOK

"It is very critical for DBS to be *explained to a patient at the right moment...*

and to *make a referral* decision together."

JENS VOLKMANN Professor and Chair of Neurology, University of Würzburg, Germany.

DBS HANDBOOK

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PATIENT PRESENTS WITH MOVEMENT DISORDER

DBS is used most commonly to treat neurological conditions that affect the body's ability to control or initiate movement.

If you have a patient with **Parkinson's disease, dystonia** or **essential tremor**, they may be an appropriate candidate for DBS.



Parkinson's disease is caused by a deficiency of dopamine-producing cells. The shortage of dopamine, a substance that is used in the brain to transmit signals, causes the symptoms of Parkinson's disease to appear in patients.



Dystonia is a condition that causes sustained muscle contractions that trigger twisting and repetitive movements or unintended postures in patients. Dystonia can affect a specific area of the body or be more widespread throughout several muscle groups. These muscle contractions can be painful and interfere with patients' day-today activities.



Essential tremor is an involuntary and rhythmic tremor that can affect any part of the body, although manifestation in the hands is most common.

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UNDERSTANDING DBS AND ITS BENEFITS

Once you have identified a patient who may be a suitable candidate for DBS, it is important to understand what undergoing the treatment will involve and what kind of results they can expect, such as improvements to their day-to-day life.

DBS uses a small medical device that is implanted in the patient's body to stimulate a portion of the brain. A device similar in shape and size to a cardiac pacemaker is placed under the skin in the chest, which is connected to insulated wires, or leads, placed in the brain. When the stimulator device is turned on, it produces mild electrical impulses that stimulate a specific target within the brain. The stimulation may help to regulate incorrect signalling in the brain to improve some of the symptoms of the movement disorder.



For Parkinson's disease patients, the treatment may help to improve motor functions, such as tremor, slowness and rigidity. Most patients will continue to need medication, but often at a reduced dosage, and may therefore experience a reduction in medication-related side effects, such as motor fluctuations and involuntary movements (dyskinesia).^{1,2}



For dystonia patients, DBS is considered to be a safe and effective treatment³ for reducing some of the primary symptoms⁴ and improving daily life.



For essential tremor patients, undergoing DBS may lead to control⁵ and reduction of symptoms,⁶ to improve patients' quality of life.

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PATIENT SCREENING

Once you have assessed the potential benefits of DBS, we are here to help support you throughout the treatment journey: from the selection and referral of an appropriate DBS candidate to ongoing follow-up sessions.

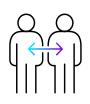
Our support materials are here to help you:





SUPPORTING YOUR PATIENT'S DECISION

After you have identified and screened a potential candidate for DBS, it is important to fully support your patient in their decision-making process, whether they decide to undergo DBS or not.



Our Patient Support materials are designed to guide your conversations with patients, so that they can make a well-informed decision about DBS. Every patient should make an individual decision, based on their unique symptoms, feelings and situation.

> Access the Patient Support materials

FINDING AN APPROPRIATE NEUROSURGEON FOR REFERRAL

Once a patient has decided to undergo DBS, we understand how important it is for you to feel confident that they will remain in a safe pair of hands throughout the treatment journey.



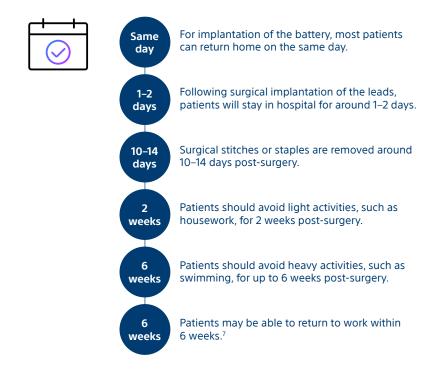
Our Physician Locator tool enables you to find a suitable neurosurgeon to refer your patient for DBS.

Access the Physician Locator tool

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PATIENT UNDERGOES DBS SURGERY

Once you have referred your patient for DBS, their surgery will be carried out by an experienced neurosurgeon, as part of a wider interdisciplinary team. During the procedure, the two thin electrodes will be inserted into the brain and connected to the stimulator, which will be placed in the chest or abdomen. The expert team may use visualisation software to 'see' electrode placement in relation to your patient's specific brain anatomy. This will arm them with the knowledge of how certain lead placement and contact decisions will impact symptoms, offering greater precision and personalisation of DBS.





WHAT LIFE LOOKS LIKE FOR YOUR PATIENT AFTER SURGERY

Once you have referred your patient for surgery, you should remain a part of their interdisciplinary healthcare team and should be updated on progress and success of the treatment.

Depending on their condition and symptom severity, your patient may experience symptom reduction, such as motor functions for **Parkinson's disease** patients, and an overall improved quality of life for **dystonia** and **essential tremor** patients.



While battery life is dependent on each patient's unique situation, Boston Scientific's rechargeable system is designed to last for up to 25 years. Our pap rechargeable system could last 3. Expansion for a patient with Barkingon's

Our non-rechargeable system could last 3–5 years for a patient with Parkinson's disease.

Our Patient Support material section is packed full of resources to help you best support your patients on their DBS journey.

Access the <u>Patient Support materials</u>

You can also direct your patients to association groups, such as **Dystonia Europe** and **European Parkinson's Disease Association (EPDA)**, where patients and their families can join a supportive community of people who share similar experiences and come together to champion the voice of the patient.





"A referrer neurologist plays an invaluable role in the DBS patient journey...

It is our responsibility to engage with neurologists and encourage them to refer more patients."

HARITH AKRAM

Consultant Neurosurgeon, National Hospital for Neurology and Neurosurgery and the Unit of Functional Neurosurgery, Queen Square, UK.

DBS HANDBOOK

Referrer frequently asked questions

Our handy FAQs document supports your understanding of DBS, in bite-size sections, so you can explore the areas that are most pertinent to you: from the process of identifying and referring a candidate, to understanding what your patient's day-to-day life will look like.

IS DBS SAFE FOR MY PATIENT? ARE THERE POSSIBLE RISKS?

The short- and long-term safety of DBS has been well-established. DBS has been around for over two decades. More than 160,000 patients have been treated with DBS for a variety of illnesses.



As with any surgical procedure, there are risks involved with DBS, which should be considered and discussed with your patient before a decision is reached on whether to proceed with DBS.

WHAT ARE THE POSSIBLE BENEFITS OF DBS FOR MY PATIENT?

DBS may help to control some of the disabling symptoms of your patient's condition. They may be able to increase daily life activities and see improved overall quality of life.



DBS is a non-destructive form of surgery. It is also reversible. The stimulator and lead can be removed, or the entire system can be turned off at any time.

WILL MY PATIENT STILL NEED TO TAKE MEDICATION?

Although DBS is not a cure, it may help improve your patient's day-to-day experiences.



For **Parkinson's disease** patients, most people will continue to take their medications but often at a reduced dosage. Because their medication may be lessened, they may also have a reduction in some of the medication-related side effects such as motor fluctuations (ON-OFF condition) and involuntary movements, also referred to as dyskinesia.



For **dystonic and tremor patients**, DBS therapy may reduce some of the primary symptoms and improve daily life.

HOW DO I KNOW IF MY PATIENT IS A CANDIDATE FOR DBS?



For **Parkinson's patients**, the ideal candidate has responded positively to levodopa treatment but is unable to control the motor symptoms of his or her disease with medication alone.



For **dystonic patients**, the ideal candidate is at least 7 years old and no longer achieves sufficient dystonia symptom relief with medications alone.

HOW DO I GO ABOUT REFERRING A PATIENT FOR DBS?



Once you have assessed that your patient is a suitable candidate for DBS, you can use our <u>Physician Locator tool</u> to find a DBS expert to refer your patient to. You can feel reassured that your patient will remain in a safe pair of hands, with a DBS expert.

HOW DO I SUPPORT MY PATIENT'S DECISION?



Our patient support materials and patient FAQs have been designed to support your conversations with patients, so that you can guide them through the decision-making process. We understand how important it is to equip patients with the knowledge they need to make a fully informed decision.

WILL I BE KEPT UPDATED ABOUT MY PATIENT'S PROGESS?

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Yes, once you have referred your patient to a DBS expert using our <u>Physician Locator tool</u>, you will remain a key part of their multidisciplinary team and be kept up-to-date with progress and success of the surgery.

WHEN WILL MY PATIENT'S DBS SYSTEM NEED REPLACING?

While results will vary depending on each individuals' settings, Boston Scientific's rechargeable system is designed to last up to 25 years. The battery longevity is dependent on the individual settings your patient's condition may require. On average for Parkinson 's disease, the system may last for 3–5 years.

CAN PATIENTS TRAVEL WITH A DBS SYSTEM?



Yes, patients can still travel with a DBS system. Metal detectors, X-ray machines, security scanners and other security devices will not damage the implant but may cause unintentional stimulation. The implant may also activate metal detector alarms. Remind your patients that it is recommended that they carry their patient ID card at all times.

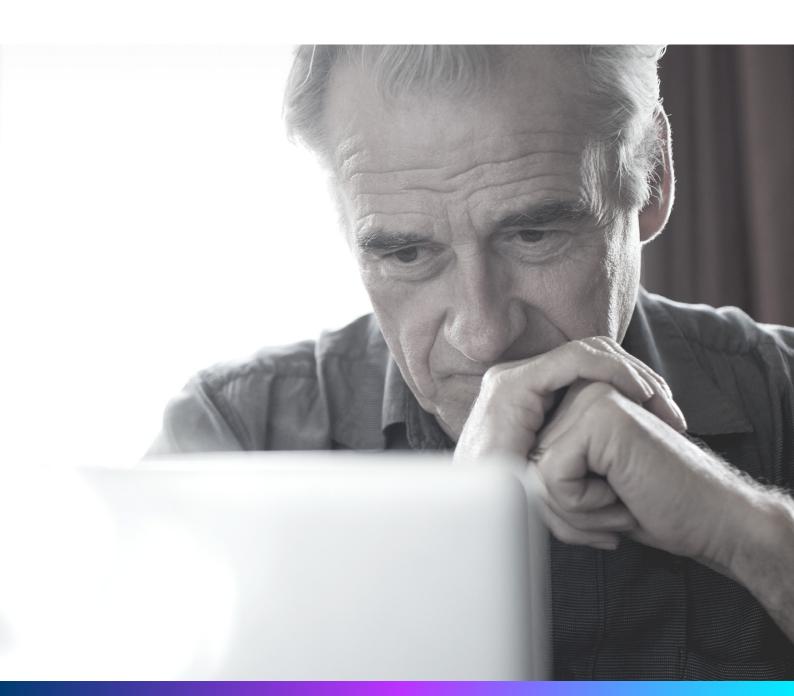
CAN PATIENTS STILL HAVE AN MRI?



While it may be possible for patients to have an MRI after undergoing DBS, it is best to consider each patient's unique case before determining their individual MRI eligibility.



By addressing some common concerns and sharing other patient experiences, as well as answering FAQs in patient-friendly language, our resources support your conversations with patients and help you to equip them with all the information they need to make a decision about undergoing DBS.



DEEP BRAIN STIMULATION (DBS) WITH BOSTON SCIENTIFIC

Making long-term, reliable and consistent symptom relief a reality



When making the decision on whether or not to undergo DBS, it is important that you have all of the necessary knowledge of the process and an understanding of what your life might look like on DBS. This brochure is designed to inform your decision, so that you can make the best choice for you and your unique situation.

ABOUT MOVEMENT DISORDERS

Movement disorders are neurological conditions that affect the body's ability to control or initiate movement. Tens of millions of people are afflicted with a movement disorder worldwide. Three of the most common movement disorders are Parkinson's disease, dystonia and essential tremor.



Parkinson's disease

Parkinson's disease is caused by a deficiency of dopamine-producing cells. The shortage of dopamine, a substance that is used in the brain to transmit signals, causes the symptoms of Parkinson's disease to appear.



Dystonia

Dystonia is a condition that causes sustained muscle contractions triggering twisting and repetitive movements or unintended postures. Dystonia can affect a specific area of the body or be more widespread throughout several muscle groups. These muscle contractions can be painful and interfere with day-to-day activities.



Essential tremor

Essential tremor is an involuntary and rhythmic tremor that can affect any part of your body, although manifestation in the hands is most common.

UNDERSTANDING DBS

DBS is a treatment that can help reduce some of the symptoms of movement disorders. DBS uses a small medical device that is implanted in your body to stimulate a portion of your brain. The treatment may help to improve your motor functions that are affected by Parkinson's disease, such as tremor, slowness, and rigidity. Although DBS is not a cure, it may help improve your day-to-day experiences.



For **Parkinson's disease** patients, most people will continue to take their medications but often at a reduced dosage. Because your medication may be lessened, you may also have a reduction in some of the medication-related side effects such as motor fluctuations (ON-OFF condition) and involuntary movements, also referred to as dyskinesia.



For **dystonic** and **essential tremor** patients, DBS therapy may reduce some of your primary symptoms and improve daily life.

"We are seeing *exponential growth of patients implanted with DBS.* In the future, we should make sure that this is possible and *available to the entire human race.*

ALFONSO FASANO

Professor in the Department of Medicine (Division of Neurology), University of Toronto, Canada.

HOW DBS WORKS

DBS uses a device similar in size and shape to a cardiac pacemaker. It sends signals to your brain to help control the symptoms of movement disorders.



Your doctor will place one or two insulated wires called "leads" in the brain. The leads are then connected to the stimulator, and the stimulator is placed under the skin in the chest.



When the stimulator is turned on, it produces mild electrical impulses that stimulate a specific target within the brain. The stimulation may help regulate the incorrect signalling in the brain, improving some of the symptoms of movement disorders.

VERCISE[™] PORTFOLIO OF DBS SYSTEMS



Comfort, to help you live your life to the fullest

Our ultra-lightweight, thin battery was designed with smooth and gently rounded edges to maximise your comfort and reduce visibility after implantation.



Intelligence, with options designed around you

All our systems come with industry-leading precision technology standard, enabling your doctor to deliver therapy with precision, and the flexibility to adapt your treatment as the needs of your condition change.



You are front-of-mind, at every step of the journey From start to finish, we design our products with patients in mind.

And we're with you every step of the way.

GIVING YOU THE CHOICES YOU DESERVE



Boston Scientific is the only company that offers directional stimulation with Multiple Independent Current Control (MICC) technology

Boston Scientific's Vercise Directional System is designed to give your doctor control over the size and shape of your stimulation. This ability to direct the therapy to the area of your brain responsible for co-ordinating movement, and steer it away from regions associated with side effects, may result in a more precise therapy. As a patient, you may make fewer trade-offs to achieve the results you want.



What is MICC and why is it so important in DBS?

Doctors use MICC to control the placement and intensity of your DBS therapy with precision. As a movement disorder patient, this means that as the needs of your condition change, your DBS system from Boston Scientific gives you and your doctor the options you need, when you need them.





DBS HANDBOOK

Patient frequently asked questions

Designed to guide your conversations with patients around the decision on whether or not to undergo DBS.

WHAT IS DBS?

Deep Brain Stimulation (DBS) is a treatment that can help reduce some of the symptoms of movement disorders, such as **Parkinson's disease**, **dystonia**, and **essential tremor**. DBS uses a device similar in size and shape to a cardiac pacemaker. It sends signals to your brain to help control the symptoms of movement disorders.



Your doctor will place one or two insulated wires called "**leads**" in the brain. The leads are then connected to the stimulator, and the stimulator is placed under the skin in the chest. When the stimulator is turned on, it produces mild electrical impulses that stimulate a specific target within the brain. The stimulation may help regulate the incorrect signalling in the brain, improving some of the symptoms of movement disorders.

IS DBS SAFE?

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WHAT ARE THE POSSIBLE BENEFITS OF DBS?



DBS may help you to control some of the disabling symptoms of your condition. You may be able to **increase your daily life activities** and improve your overall quality of life.



DBS is a non-destructive form of surgery. It is also reversible. The stimulator and lead can be removed, or the entire system can be turned off at any time.

"Neurologists have to be fully involved, not only in the selection of the patient, but also during [DBS] surgery and the following of the patient...

It is always a close collaboration.".

STEPHAN CHABARDÉS Head of the Neurosurgery Department, Grenoble Alpes University Hospital, France.

WHAT WILL LIFE ON DBS LOOK LIKE? CAN I EXPECT COMPLETE SYMPTOM RELIEF AND WILL I STILL NEED TO TAKE MEDICATION?

Although DBS is not a cure, it may help improve your day-to-day experiences.



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HOW LONG WILL MY DBS SYSTEM LAST?

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CAN I TRAVEL WITH MY DBS SYSTEM?



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CAN I STILL GET AN MRI?



You must consult with your healthcare provider to determine your individual MRI eligibility.

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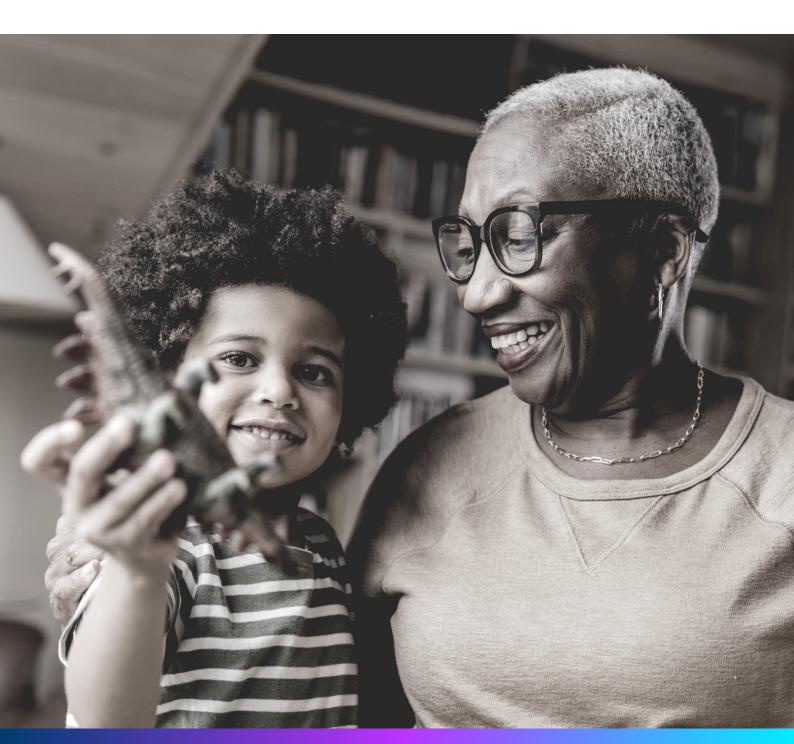


For **dystonic patients**, the ideal candidate is at least 7 years old and no longer achieves sufficient dystonia symptom relief with medications alone.

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DBS surgery should becarried out by an experienced neurosurgeon working as part of an interdisciplinary team. Your neurologist and other physicians with whom you work closely can determine if DBS is a suitable therapy for you and your symptoms.





DBS HANDBOOK

Patients' stories

To support your decision around DBS, explore first-hand accounts from patients who have undergone DBS therapy to see the potential benefits of the treatment and consider what your life could be like after experiencing stable symptom relief.



MATT EAGLES' STORY

"DBS has helped me tremendously. It energises me and it's given me so much more confidence. I'm not looking behind me, I'm in control now. That's a beautiful thing to have. It is actually the most wonderful piece of kit I can say that I have ever had... It's better than any tablets I've ever had, and it's actually given me my life back."

Matt Eagles, Parkinson's Disease patient

Matt Eagles was diagnosed with Parkinson's disease in 1975, when he was just 8 years old. In 2006, as part of his therapy for Parkinson's disease, Matt was implanted with a DBS system. When the battery that was implanted in his chest came to the end of its life, Matt had a discussion with his neurologist and DBS team to identify the best device for replacing it. Matt chose to undergo a change to the Boston Scientific battery.

As someone who has spent most of his life on various medications for Parkinson's disease, DBS has given Matt stable symptom relief: improvements in his voice, communication, balance, sleep and his overall confidence and quality of life. He's been able to work more, as he feels more energised and feels that life is looking up. A self-professed adrenaline junkie, Matt recently took on the world's fastest zipline.

"DBS is a very powerful tool because it is reversable. If you don't like the effects, you can switch it off...

You can have very dramatic effects in a family of diseases."

LUDVIC ZRINZO

Professor of Functional Neurosurgery, Clinical and Movement Neurosciences, UCL Queen Square Institute of Neurology, UK.



PEDRO CURRY'S STORY

"I feel really lively, like I'm young again. I've got my life back. I now have huge expectations for the future. I still have a lot to do."

Pedro Curry, Parkinson's Disease patient

Retired architect Pedro Curry loved to paint and draw, but when his Parkinson's disease progressed, he could no longer draw a straight line. Unable to walk and confined to a wheelchair, he consulted a physician who suggested he might be a candidate for DBS. After a series of preoperative tests, Pedro decided to move ahead with the surgery. He entered the hospital in a wheelchair and, following a successful procedure, was able to walk away on foot three days after his surgery. Today Pedro is living his life again, walking, painting and spending time with family.

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Indication for Use: The Boston Scientific Vercise[™] PC, Vercise Gevia[™], Vercise Genus[™] Deep Brain Stimulation Systems are indicated for use in: Bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy in reducing some of the symptoms of moderate to advanced levodopa-responsive Parkinson's disease (PD) that are not adequately controlled with medication. Unilateral thalamic stimulation of the ventral intermediate nucleus (VIM) 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 Boston Scientific Vercise Deep Brain Stimulation System is indicated for use in: Bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy in reducing some of the symptoms of moderate to advanced levodopa-responsive Parkinson's disease (PD) that are not adequately controlled with medication. Unilateral therapy in reducing some of the symptoms of moderate to advanced levodopa-responsive Parkinson's disease (PD) that are not adequately controlled with medications, warnings, precautions, side effects: The Boston Scientific Deep Brain Stimulation (DBS) Systems or any of its components, are contraindicated for: Diathermy as either a treatment for a medical condition or as part of a surgical procedure, Electroconvulsive Therapy (ECT) and Transcranial Magnetic Stimulation (TMS) as the safety of these therapies in patients who are unable to operate the system, patients who are poos surgical candidates or who experince unsuccessful test stimulation. Patients implanted with Boston Scientific DBS System with M8 Adapter or Vercise DBS Lead-Only System (Defore Stimulator is implanted) with ImageReady M MRI Technology should not be exposed to Magnetic Resonance Imaging (MRI). Patients implanted with Vercise Gevia or Vercise Genus Mixed System with M8 Adapter or Vercise DB