Medtronic

Activa® Neurostimulators

FOR DEEP BRAIN STIMULATION

INNOVATION
CHOICE
CONFIDENCE

Innovative Choices.

Activa® SC

- Small, single-channel neurostimulator
- Connects directly to any Medtronic DBS extension for a simplified device replacement procedure

Activa® PC

- Smallest dual-channel primary cell neurostimulator

Activa® RC

- Thinnest dual-channel rechargeable neurostimulator
- Nine-year interval between device replacement procedures

Medtronic Confidence.

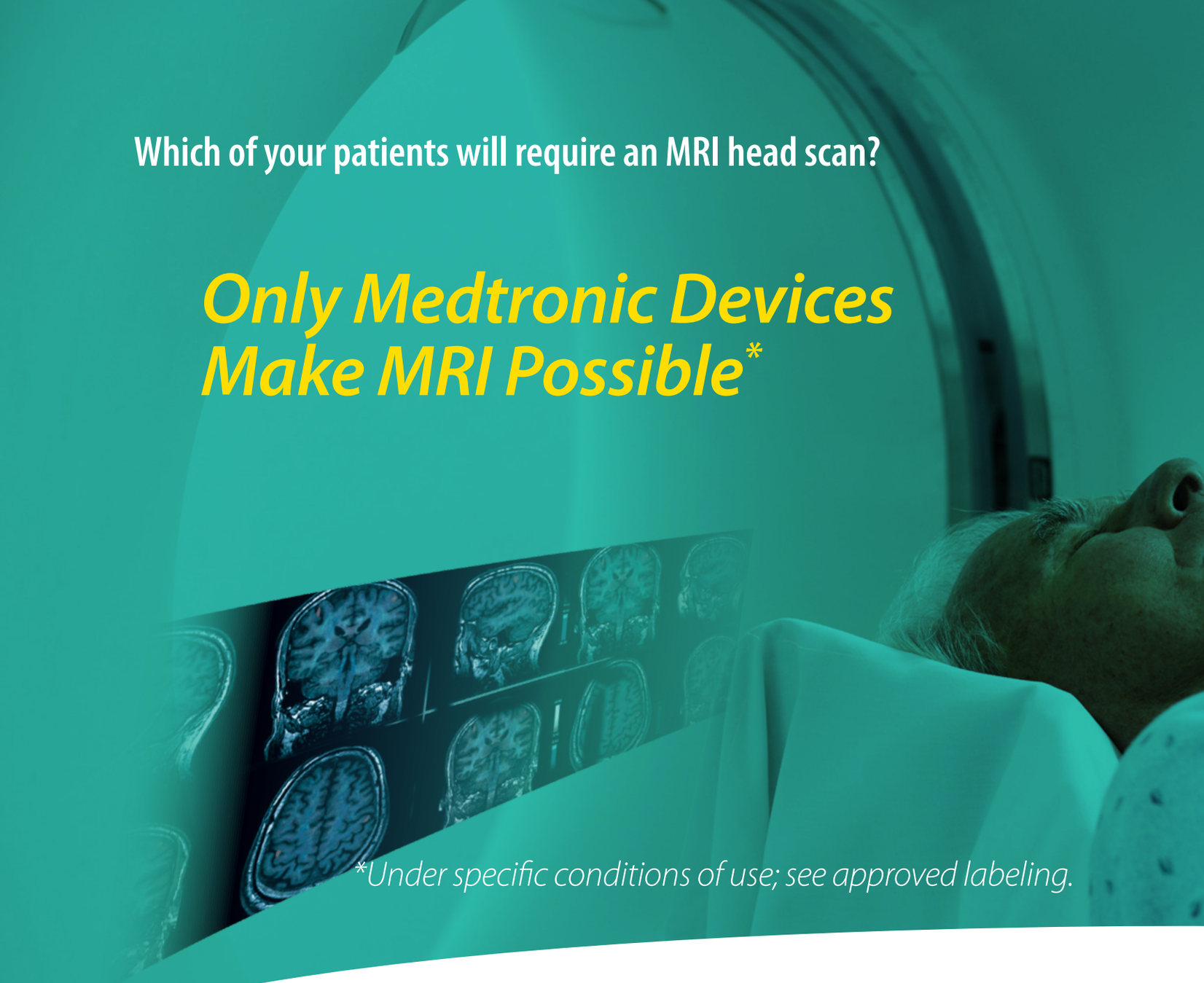
- Advanced Programming
- Predictable Replacement Planning
- Makes MRI Possible*
- Information Access

The risks associated with the implant procedure for DBS Therapy may include serious complications such as coma, intracranial hemorrhage, seizures, paralysis, cerebral spinal fluid leakage, and weakness. Some of these may be fatal. Once implanted, device-related infection, skin erosion, and/or system migration may occur. DBS Therapy could suddenly cease because of mechanical or electrical problems. Any of these situations may require additional surgery or cause symptoms to return.

*Under specific conditions of use; see approved labeling.

Which of your patients will require an MRI head scan?

*Only Medtronic Devices Make MRI Possible**



*Under specific conditions of use; see approved labeling.

How accurately can you predict battery longevity for scheduling replacements?

Using advanced battery technology, **Medtronic Activa neurostimulators ensure predictable battery life** *and typically give warning more than 3 months before replacement is needed.*

How many programming visits does it take to optimize patients' stimulation?

Advanced programming options in the Activa Portfolio may allow patients to

reach optimized settings sooner.

How critical is programming history to your patients' future care?

Patient-specific data—including historical settings and therapeutic response—is **stored in each Activa neurostimulator** *for easy access from any N'Vision® programmer.*

How do you define world class support?

The Activa Portfolio builds on more than 2 decades of experience

more than **100,000** Medtronic DBS implants

Get answers when you need them from DBS technical experts. For ongoing support, contact Medtronic technical service representatives at 800-707-0933.

Specifications

	ACTIVA SC	ACTIVA PC	ACTIVA RC
HEIGHT	55 mm	65 mm	54 mm
WIDTH	60 mm	49 mm	54 mm
CASE THICKNESS	11 mm	15 mm	9 mm
WEIGHT	*model 37603*—44 g *model 37602*—45 g	67 g	40 g
VOLUME	*model 37603*—27 cc *model 37602*—28 cc	39 cc	22 cc
BATTERY TYPE	Silver vanadium oxide Primary cell	Silver vanadium oxide Primary cell	Lithium ion Rechargeable
BATTERY LONGEVITY	4-6 years*	3-5 years*	9 years**
CONNECTOR TYPE	*model 37603*—Octapolar, compatible with stretch coil extension *model 37602*—Quadrapolar, compatible with 2-pronged extension	Octapolar, compatible with stretch coil extension	Octapolar, compatible with stretch coil extension

**Depending on stimulation parameters and use*

*** Assumes appropriate battery maintenance*

NEUROSTIMULATOR PARAMETERS

AMPLITUDE	0–10.5 V *(voltage mode)* 0–25.5 mA *(current mode)*
RATE	2–250 Hz *(voltage mode)* 30–250 Hz *(current mode)*
PULSE WIDTH	60 to 450 µs
GROUPS	1 to 4–Program up to 4 sets (A-D) of therapy parameters, selectable by the patient
NUMBER OF PROGRAMS PER GROUP	1 to 4 (Activa PC and RC); 1 to 2 (Activa SC)
SOFTSTART/STOP®	Off, On
RAMP DURATION	1, 2, 4, 8 seconds
CYCLING	Off, On
ELECTRODE CONFIGURATION	Up to 4 electrodes per lead defined as anode, cathode, or Off
CASE	Defined as anode or Off
EXTERNAL SHIELD	Titanium

DEVICES SHOWN ACTUAL SIZE

Medtronic DBS Therapy for Parkinson's Disease and Tremor: 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 of advanced, levodopa-responsive Parkinson's disease that are not adequately controlled with medication.

Medtronic DBS Therapy for Tremor: Unilateral thalamic stimulation 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. The safety or effectiveness of this therapy has not been established for bilateral stimulation.

Contraindications: Contraindications include patients who will be exposed to MRI using a full body radio-frequency (RF) coil or a head transmit coil that extends over the chest area, patients who are unable to properly operate the neurostimulator, or for Parkinson's disease and Essential Tremor, patients for whom test stimulation is unsuccessful. Also, diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy) is contraindicated because diathermy's energy can be transferred through the implanted system (or any of the separate implanted components), which can cause neurostimulation system or tissue damage and can result in severe injury or death. Transcranial Magnetic Stimulation (TMS) is contraindicated for patients with an implanted DBS System.

Warnings/ Precautions/Adverse Events: There is a potential risk of tissue damage using stimulation parameter settings of high amplitudes and wide pulse widths. Extreme care should be used with lead implantation in patients with a heightened risk of intracranial hemorrhage. The lead-extension connector should not be placed in the soft tissues of the neck due to an increased incidence of lead fracture. 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. Although some MRI procedures can be performed safely with an implanted DBS System, clinicians should carefully weigh the decision to use MRI in patients with an implanted DBS System. MRI can cause induced voltages in the neurostimulator and/or lead possibly causing uncomfortable, jolting, or shocking levels of 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. Safety and effectiveness has not been established for patients with neurological disease other than Parkinson's disease or Essential Tremor, previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression; or for patients who are pregnant, under 18 years, over 75 years of age (Parkinson's Control Therapy) or over 80 years of age (Tremor Control Therapy). 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.

Abrupt cessation of stimulation should be avoided as it may cause a return of disease symptoms, in some cases with an intensity greater than was experienced prior to system implant ("rebound" effect). Adverse events related to the therapy, device, or procedure can include: stimulation not effective, cognitive disorders, pain, dyskinesia, dystonia, speech disorders including dysarthria, infection, paresthesia, intracranial hemorrhage, electromagnetic interference, cardiovascular events, visual disturbances, sensory disturbances, device migration, paresis/asthenia, abnormal gait, incoordination, headaches, lead repositioning, thinking abnormal, device explant, hemiplegia, lead fracture, seizures, respiratory events, and shocking or jolting stimulation.

USA Rx only Rev 0311

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