

DBS THERAPY FOR PARKINSON'S

## GETTING BACK TO YOU



## **GET CONNECTED**

We're here to help you get the information you need to make a confident decision about DBS.



For more information about DBS and Medtronic, please visit our website.

MEDTRONIC.COM/PD



For news, updates, and events, follow the Medtronic Parkinson's Facebook page.

FACEBOOK.COM/
MEDTRONICPARKINSONS



Watch patient stories and videos about DBS Therapy on our YouTube page.

YOUTUBE.COM/ MEDTRONICDBSTHERAPY



GETTING BACK TO MAKING THE MOST OF YOUR DAY "I don't have to time my hikes. I don't have to time my games. I don't have to time my meals. I can do pretty much whatever I want whenever I want. Yes, I still have a bit of an 'off' period but it's—but it's not very bad."

**Brian**Receiving DBS Therapy

EXPLORE MORE PATIENT STORIES AT MEDTRONIC.COM/PDSTORIES

#### WHAT IS DBS THERAPY?



# DBS MOVES YOU FORWARD WHEN PARKINSON'S IS HOLDING YOU BACK

Living well with Parkinson's means being able to do what's important to you — taking care of yourself, having lunch with friends, continuing to work or volunteer, enjoying your favorite activity. The right treatment may control your symptoms so you can live life your way.

Deep brain stimulation (DBS) may help control the movement symptoms of Parkinson's disease, including tremor (shaking), slowed movement (bradykinesia), and stiffness (rigidity), so you can Get Back to You.

The quotes in this brochure recount the experiences of individuals who are receiving Medtronic DBS Therapy for Parkinson's disease. 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.



GETTING BACK TO COFFEE DATES "We are so grateful for each other and the new lease on life DBS Therapy gave us."

**Karen and Jim**Both receiving DBS Therapy

READ KAREN AND JIM'S FULL STORY AT MEDTRONIC.COM/PDSTORIES

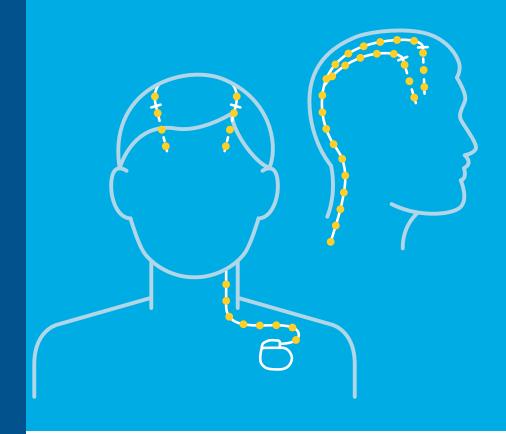


# A 24-HOUR THERAPY THAT FITS YOUR LIFESTYLE

DBS helps control some of your movement symptoms when your medications aren't working as well as they used to. For many people with Parkinson's, DBS makes a difference when even small tasks have become challenging. DBS has helped some people stay as independent as possible and keep doing the activities they love.

Compared to medications alone, DBS provides additional hours of good movement control each day. Good movement control makes it easier to do everyday things like writing, bathing and dressing, and drinking and eating.

At this point, you may be scheduling activities for the time during the day when the medications tend to be working better. With DBS, some people have been able to get back to planning their lives around what they want to do, rather than around their medications.



DBS uses a small, pacemaker-like device, placed under the skin of the chest, to send electronic signals through very thin wires (leads) to an area in the brain that controls movement. To give you relief, these signals block some of the brain messages that cause the movement symptoms of Parkinson's.

SEE THE DIFFERENCE DBS CAN MAKE — WATCH THE VIDEOS AT MEDTRONIC.COM/PDDEMO

## THE BENEFITS OF DBS THERAPY















## LESS MEDICATION, MORE RELIEF

Medtronic DBS Therapy may reduce Parkinson's medication.<sup>1</sup> This may reduce medication-related side effects like unintended movements (dyskinesia). Less medication may also simplify your medication routine, with fewer pills or less frequent doses.

## A BETTER START TO YOUR DAY

DBS delivers therapy 24 hours a day — it doesn't wear off while you sleep. It's already working the moment you wake up.

## A THERAPY THAT FITS YOUR DAILY LIFESTYLE

Unlike some other therapies used to treat Parkinson's symptoms, the DBS system requires no daily cleaning or refilling; you can bathe and shower without worrying about your device.

## ADDITIONAL HOURS OF GOOD MOVEMENT CONTROL<sup>1,2</sup>

DBS Therapy provides additional hours of good movement control ("on" time) without unintended movements (dyskinesia) each day compared to medication alone.

## ENJOY A BETTER **QUALITY OF LIFE**

With DBS Therapy, some people have been able to continue the everyday things that are important to them — things like dressing and bathing, brushing their teeth, and putting on makeup. In fact, when combined with medication, people with DBS therapy experience improved quality of life, compared to those taking medication alone.<sup>1</sup>

## KEEP YOUR **OPTIONS OPEN**

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

FOR MORE ON DBS, VISIT MEDTRONIC.COM/PD

#### THE RIGHT TIME FOR DBS





## **SYMPTOMS**DBS TREATS

While some people believe deep brain stimulation treats **tremor** (**shaking**) only, DBS also treats other movement symptoms of Parkinson's disease, including **slowed movement** (**bradykinesia**) and **stiffness** (**rigidity**).

Symptom control may help you continue to do what's important to you, like taking care of family, continuing to work, or participating more fully in an event like a vacation or a family wedding.



## GETTING BACK TO THE FARM

"When you think you're down for the count, and you get your life back, it's indescribable. It's a second chance. Every day is precious."

**Gary**Receiving DBS Therapy

WATCH GARY'S FULL STORY AT MEDTRONIC.COM/PDSTORIES



## WHEN IS THE RIGHT TIME FOR DBS?

Research shows that DBS may be appropriate for people who have had Parkinson's for at least 4 years with at least 4 months of movement symptoms not well controlled by medications or medication side effects such as unintended movements (dyskinesia).<sup>1</sup>

DBS Therapy is also appropriate for people who have had movement symptoms for a longer period of time, and there is no upper age limit.<sup>2</sup>

If you wait until your medications no longer help, DBS will no longer be an option — so don't think of DBS as "a last resort." Instead of just putting DBS off until someday in the future, talk with your doctor about it now. That way, you will be ready to start at the right time.

## WHY WAIT TO GET BACK TO YOU? YOU MAY BE ELIGIBLE FOR DBS IF YOU MEET THESE CRITERIA:



Parkinson's diagnosis for at least 4 years



Movement symptoms or medication side effects for a **minimum of 4 months** or longer-standing



**Responds** to Levodopa (a common Parkinson's medication)



Movement symptoms **not** adequately controlled with medication

Only your doctor can determine if DBS therapy is right for you.

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

**DAILY** 

Asleep

"On" Time with troublesome dyskinesia "On" Time without

"Off" Time

troublesome dyskinesia

**TRACKER** 

in movement disorders, like Parkinson's disease. These specialists have experience with the full range of treatment options. Some

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.

- three days of your symptoms
- ng the completed Symptom
- options with your doctor

MEDTRONIC.COM/PDSPECIALIST

A movement disorder specialist is a neurologist with extra training Parkinson's Medications (table: strength in mg) Parkinson's Medications (tablet strength in mg) Parkinson's Medications (tablet strength in mg) Parcopa®, Rytary®, Sinemet® Carbidopa/Levodopa (mg) general neurologists are also experienced in treating Parkinson's. Whether you see a general neurologist or movement disorder Stalevo® Levodopa/Entacapone ( mg) Symmetrel® Amantadine HCL ( mg) Azilect® Rasagiline ( mg) Requip® Ropinirole HCL ( mg) Use the Symptom Tracker to track Mirapex® Pramipexole DIHCL ( mg) Comtan<sup>®</sup> Entacapone ( mg) Tracker to your next doctor visit **Artane®** Trihexphenidyl ( mg) Discuss available treatment Other: Other: Third-party brands are Notes (e.g., troubling side effects): **Notes** (e.g., troubling side effects): **Notes** (e.g., troubling side effects): trademarks of their respective owners. All other brands are trademarks of a READY TO TALK TO A DOCTOR ABOUT DBS? FIND A SPECIALIST IN YOUR AREA AT Medtronic company

DAY 2

DAY 1

Medtronic

DAY 3

### AFTER COMPLETING **THE 3-DAY TRACKER** ANSWER THE **FOLLOWING QUESTIONS**

How troublesome are your "off" periods (periods when medication is not helping enough and you are

> experiencing symptoms)? Circle the option that applies.

I have difficulty,

I want to do

most things I want to do

low troublesome is your dyskinesia (involuntary excessive movements)?

Circle the option that applies.

I harely notice

They interfere

They interfere with most activities

are your most troublesome movement symptoms?

What are your most troublesome side effects?

Hallucinations

Confusion/other thinking problems Lightheadedness upon standing

Behavioral/ personality changes

INSTRUCTIONS FOR COMPLETING YOUR **SYMPTOM** TRACKER

Asleep

"Off" Time

drugs not listed

(see sample).

**EVERY HOUR** 

**SYMPTOM CONTROL CATEGORIES** 

"On" Time with unintended movements (dyskinesia)

causing troublesome, involuntary, excessive movements.

(rigidity), or slowed movement (bradykinesia).

**BEFORE YOU START** 

motor control (see sample).

Periods of time when medication is giving you good motor control.

Periods of time when medication is not helping enough and you are

experiencing troublesome symptoms like tremor (shaking), stiffness

Next to the name of the drugs listed, write the strength of the pills you take

1. Mark with an "X" the row that best describes your overall

2. When you take medications, write how many pills you took

3. In the notes section at the bottom of each day, write any

troublesome side effects you experience.

(in mg). Look at the container label if necessary. Use "other" row for Parkinson's

You will be recording your symptom control every hour in one of four categories:

Periods of time when medication is giving you good symptom control but is

"On" Time without troublesome unintended movements (dyskinesia)







## **SUMMARY** FOR HEALTHCARE PROFESSIONAL USE ONLY



## SYMPTOM TRACKER

You can help your doctor make good treatment decisions by tracking your symptoms. A well-kept Symptom Tracker provides a clear picture of when you are taking your medications, when you are feeling well, and when you are not feeling so well. The tracker will help your doctor determine if DBS Therapy may be right for you.

#### ← OPEN HERE

#### Medtronic

Idiopathic Parkinson's disease?	YES	NO
Years since diagnosis:		years
At least 4 months since onset of motor complications not adequately controlled with medication?	YES	NO
Good levodopa response (even if brief)?	YES	NO
Recommend Medtronic DBS Therapy evaluation?	YES	NO
	Circle the option that applies.	

### Referring physician name: Signature: Referring physician phone number: Movement Disorder Center/Practice name: Medtronic DBS Therapy Center fax: Center physician: Scheduling phone number: Patient name: Patient phone number:

#### NOTE TO HEALTHCARE PROFESSIONAL:

You can photocopy and fax this and the patient questionnaire to a DBS Center of your choice, as well as ask your patient to take the Symptom Tracker to the evaluation at the DBS Center.

#### WHY CHOOSE MEDTRONIC?



#### GETTING BACK TO INDEPENDENCE

"Before DBS Therapy, I couldn't tie my shoes, button my shirts, or tie my own tie. After the therapy, I could do all of those things myself."

Jerry

Receiving DBS Therapy

WATCH JERRY'S FULL STORY AT MEDTRONICOBS.COM/STORIES



## 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.



## **LEADING**THE WAY IN DBS

Deep brain stimulation development started in 1987 and Medtronic has been the leader in the field ever since. The Medtronic DBS Therapy system has been rigorously tested with clinical evidence and is FDA approved for people with Parkinson's who had recent onset of movement symptoms as well as those with longer-standing movement symptoms.



#### 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 now 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.



#### PERSONALIZED 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.



#### MINIMIZE SIDE EFFECTS

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

## LEARN MORE ABOUT THE ADVANTAGES OF MEDTRONIC DBS AT **MEDTRONIC.COM/PDWHYMEDTRONIC**

\*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 1-800-328-0810.

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#### **SAFETY INFORMATION**



This therapy is not for everyone. Not everyone will receive the same results. For further information, please call Medtronic at (1-800) 328-0810 and consult Medtronic's website at medtronic.com. A prescription is required.

As you consider these possible benefits, you should also explore the risks. This brochure discusses the benefits, risks and side effects associated with DBS Therapy. Be sure to discuss the risks of this therapy with your physician. A prescription is required. This therapy is not for everyone. Individual results may vary.

Placing the DBS system requires brain surgery which can have serious and sometimes fatal complications such as bleeding inside the brain, stroke. seizures and infection. This therapy is not for everyone. This therapy should not be used for patients who will be exposed to diathermy (deep heat treatment) or transcranial magnetic stimulation. Magnetic Resonance Imaging (MRI) should only be performed as described in the product labeling. Once implanted, infection may develop, parts may wear through your skin, and the lead or lead/ extension connector may move. Tunneling the extension may cause nerve or tissue injury, and scar tissue may form around the extension. Medtronic DBS Therapy could stop suddenly because of mechanical or electrical problems. Any of these situations may require additional surgery or cause symptoms to return or worsen. The DBS system may interact with other medical devices and other sources of electromagnetic interference which may result in serious patient injury or death, system damage or changes to the neurostimulator or to stimulation. Medtronic DBS Therapy may cause new or worsening neurological or psychiatric symptoms. In patients receiving Medtronic DBS Therapy, depression, suicidal thoughts and suicide have been reported.

#### Rev 12/17

In a study of people with Parkinson's who had recent onset of movement symptoms, over the course of 2 years: Patients experience an additional 11% of serious adverse events (SAEs) compared to those taking medications alone.

1% of all people with DBS Therapy experience SAEs that were ongoing when the study was completed.  $^{\rm 1}$ 

DBS patients experience comparable rates of serious adverse events (SAEs) regardless of recent onset or longer-standing movement symptoms.<sup>1</sup>

1. Schuepbach WMM, Rau J, Knudsen K, et al. Neurostimulation for Parkinson's disease with early motor complications. N Engl J Med. February 14, 2013;368:610-227.

This therapy should not be used for patients who will be exposed to diathermy (deep heat treatment) or transcranial magnetic stimulation. Magnetic Resonance Imaging (MRI) should only be performed as described in the product labeling. The DBS system may interact with other medical devices and electromagnetic interference.

There are risks to performing MRI scans in people with DBS implants. Failure to follow all warnings and guidelines related to MRI can result in serious and permanent injury including coma, paralysis, or death.



## GETTING BACK TO PAINTING

"DBS doesn't make things exactly like they used to be, but it makes things possible."

#### Anna

Receiving DBS Therapy

READ ANNA'S FULL STORY AT MEDTRONIC.COM/PDSTORIES



## **ASK A NURSE** YOUR QUESTIONS

Schedule a free phone consultation with a nurse who specializes in caring for people with DBS.



### **TALK WITH SOMEONE** WHO HAS DBS

Talk one-on-one with someone who already has DBS for Parkinson's. Ask the questions that only people living with DBS Therapy can answer.\*



Use our online directory to find a Parkinson's specialist in your area.

st Medtronic does not monitor for control, and cannot be responsible for, an ambassador's statements. Ambassadors are instructed not to disclose your personal information, but we cannot quarantee this will not happen. Therefore, please do not share your personal information with the ambassador unless you wish to do so. Ambassadors' comments relate to their particular experience only. As with any treatment, individual results will vary.

## **GET SUPPORT TODAY**



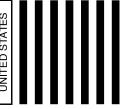
ONLINE AT MEDTRONIC.COM/ **PDSUPPORT** 



BY MAIL USING THE FORM ON THE NEXT PAGE



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START **GETTING** BACK **TO YOU** 

By completing and submitting this form, you are granting Medtronic permission to add your personal information, including your contact information and basic healthcare information, to its patient database, and to share that information with Medtronic representatives as appropriate. You also agree to being contacted by Medtronic in the future by mail, telephone, or by non-password protected electronic communications, such as

Medtronic may exchange information regarding our products or services, inquire about your experience, or determine how Medtronic can support you through your journey.

emails or text messages.

Medtronic respects the confidentiality of your personal information. We will not share your personal information except as described above. If at any time you wish to revoke all or part of this permission, you can email us to rsneuropatientsupport@medtronic.com or send a request in writing to: Medtronic Patient Support, 7000 Central Ave NE, RCE 230, Minneapolis, MN 55432. This permission will expire 10 years after the date of your signature.\*

\*If you live in Maryland, the consent expires automatically in one year. We may contact you then to see if you would like to renew it.

## LEARN MORE ABOUT DBS FOR PARKINSON'S

Medtronic

I HAVE PARKINSON'S	I CARE FOR SOMEONE WITH PARKINSON'S	
FIRST NAME	LAST NAME	
ADDRESS		
CITY	STATE ZIP	
EMAIL	PHONE	
PARKINSON'S DIAGNOSIS YEAR		
PHYSICIAN NAME		
CLINIC NAME		
SIGNATURE (IF 18 OR OLDER)	DATE	
WHICH PARKINSON'S SYMPTOMS/SIDE EFFECTS ARE YOU EXPERIENCING?	Stiffness rigidity Slowed Movement bradykinesia  Shaking Unintended Movements dyskinesia	

**ADHESIVE PANEL** 

OMPLETE REGISTRATION FORM BEFORE SUBMITTIN



## GETTING BACK TO GIVING BACK

"Shortly after my DBS surgery I took over running our local Parkinson's Support Group. We try to educate people to keep things upbeat. I want people to realize there's hope."

#### Beverly

Receiving DBS Therapy

READ OTHER DBS STORIES AT MEDTRONIC.COM/PDSTORIES



#### GETTING BACK TO GARDENING

"I feel so much better.
My energy level is
improved and I'm
smiling all the time.
If I didn't have DBS
Therapy, I believe I'd be
in a nursing home."

#### Clare

Receiving DBS Therapy

EXPLORE MORE PATIENT STORIES AT **MEDTRONIC.COM/PDSTORIES** 

#### References

- 1. Medtronic DBS Therapy for Parkinson's Disease and Essential Tremor Clinical Summary, 2015.
- 2. Schuepbach WMM, Rau J, Knudsen K, et al. Neurostimulation for Parkinson's disease with early motor complications. N Engl J Med. February 14, 2013;368:610-227.

#### Brief Statement: Medtronic DBS Therapy for Parkinson's Disease

 $\label{lem:median} \mbox{Medtronic DBS Therapy for Parkinson's Disease: Patients should always discuss the potential risks and benefits with a physician. \\$ 

Indication: 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 in individuals with levodopa-responsive Parkinson's disease of at least 4 years' duration that are not adequately controlled with medication, including motor complications of recent onset (from 4 months to 3 years) or motor complications of longer-standing duration.

Contraindications: Medtronic DBS Therapy is contraindicated for patients who are unable to properly operate the neurostimulator and patients for whom test stimulation is unsuccessful. 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<sup>™</sup> Model 7426 Neurostimulator, Activa SC Model 37602 Neurostimulator, or Model 64001 or 64002 pocket adaptor.

Warnings and Precautions: There is a potential risk of brain tissue damage using stimulation parameter settings of high amplitudes and wide pulse widths and a potential risk to drive tremor using low frequency settings. 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 cardiac pacemakers or therapies, cardioverter/defibrillators, external defibrillators, ultrasonic equipment, electrocautery, or radiation therapy. MRI conditions that may cause excessive heating at the lead electrodes which can result in serious 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. Tunneling the extension too superficially or too deeply may result in nerve or vascular injury, or tunneling through unintended anatomy. The lead-extension connector should not be placed in the soft tissues of the neck due to an increased incidence of lead fracture. Abrupt cessation of stimulation may cause a return of disease symptoms in some cases with intensity greater than was experienced prior to system implant ("rebound effect"). Patients using a rechargeable neurostimulator should check for skin irritation or redness near the neurostimulator during or after recharging. Loss of coordination in activities such as swimming may occur. Depression, suicidal ideations and suicide have been reported in patients receiving Medtronic DBS The rapy for Movement Disorders, although no direct cause-and-effect relationship has been established.

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 and weight gain or loss.

Safety and effectiveness has not been established for: patients with neurological disease other than idiopathic Parkinson's disease, previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression; patients who are pregnant; and patients under 18 years.

USARxonly Rev 11/17

#### Medtronic

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Tel. 1-763-505-5000 (24-hour technical support for physicians and medical professionals)

Medtronic.com/DBS

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