



ST. JUDE MEDICAL INFINITY™ DBS SYSTEM

INTRODUCING THE ST. JUDE MEDICAL INFINITY™ DBS SYSTEM

- Directional lead technology
- App-based programming via Bluetooth® wireless communication
- Bilateral, independent frequency control
- User-friendly Apple™ mobile digital devices¹
- Upgradeable technology platform



DIRECTIONAL LEAD = PERSONALIZED THERAPY

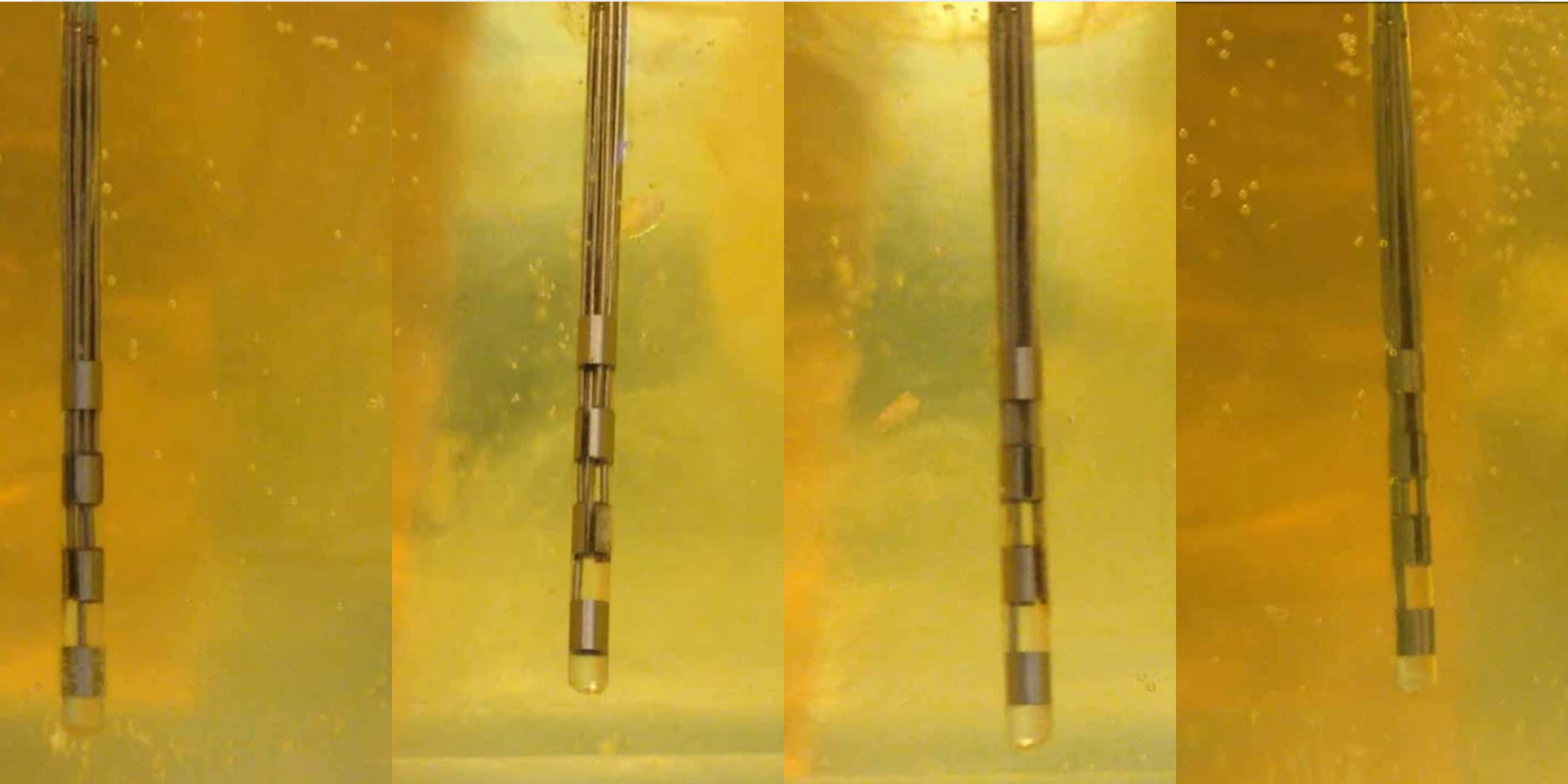
Directional lead technology gives you the ability to provide omnidirectional or targeted stimulation through the use of segmented electrodes.

- Directional lead technology
 - Allow for targeting of selected brain structures. The segmented electrode design allows for programming of therapeutic current that may use less total energy than radial current field
- 1.27 mm lead diameter—compatible with standard cannulas
- Provide physicians with precise control over the direction of the current flow and targeting of the intended site of stimulation



**Directional lead for the
St. Jude Medical Infinity™
DBS system**

ST. JUDE MEDICAL INFINITY™ DIRECTIONAL LEAD EGG WHITE DEMONSTRATION



Full Band

1 Segment

2 Segments

3 Segments

*Not representative of clinical use or clinical effect

INTUITIVE, WIRELESS CLINICIAN PROGRAMMER

Easier, more familiar platform for physician and patient interaction.¹

- Secure Bluetooth® wireless communication with IPG—no wires or wands required
- Intuitive interface for easier programming¹
- Real-time battery estimation allows for replacement management²
- User-initiated lead impedance checks within 2 seconds³
- App-based programming can be performed by clinicians on an iPad mini™ mobile digital device



**Clinician Programmer App
for the St. Jude Medical Infinity™
DBS system**

DISCREET, MODERN PATIENT CONTROLLER

Discreet, modern disease management.

- Uses familiar Apple™ products for patient familiarity and ease of use
- Intuitive user interface design¹
- Secure Bluetooth® wireless communication with IPG —no wires or wands required
- Real-time battery estimation with six month replacement notification²



**Patient Controller App for the
St. Jude Medical Infinity™
DBS system**

MAINTENANCE-FREE, UPGRADEABLE IPG

The St. Jude Medical Infinity™ DBS system offers bi-lateral conventional cell IPGs with:

- Recharge-free, Bluetooth® wireless communication with the programming devices²
- The ability to program two different frequencies in the same IPG⁴
- Lowest skin pressure of all conventional cell IPGs (based on FEA data)^{5,6}
- Upgradeable technology that allows for non-invasive software upgrades⁷ (upon market approval) that give patients access to future innovations and therapies without the cost and pain of a surgical replacement



**Implantable Pulse Generator (IPG)
for the St. Jude Medical Infinity™
DBS system is available in two sizes**

LONG-LASTING, DURABLE EXTENSIONS⁸

Flexibility designed to endure.^{2, 8}

- Durable: Zero breaks reported since launch of St. Jude Medical™ DBS coiled extensions (2011—present)⁸
- Simple connection with a single set screw and built-in ball seals (no boot cap needed)²
- Flexible extension for easy and secure coiling²

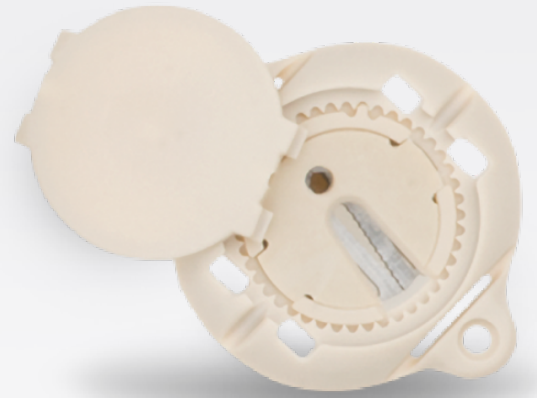


**Extensions for the
St. Jude Medical Infinity™
DBS system**

GUARDIAN™ BURR HOLE COVER: AUTO-LOCKING LEAD FIXATION

Designed with auto-locking technology to deliver more control in lead fixation.

- Auto-locking technology secures lead fixation for lead capture
- Designed for patient comfort and appearance with low profile design and flexible screw tabs to conform to curvature of skull⁹
- Auto-locking clip can be deployed on the guide tube or directly on the lead

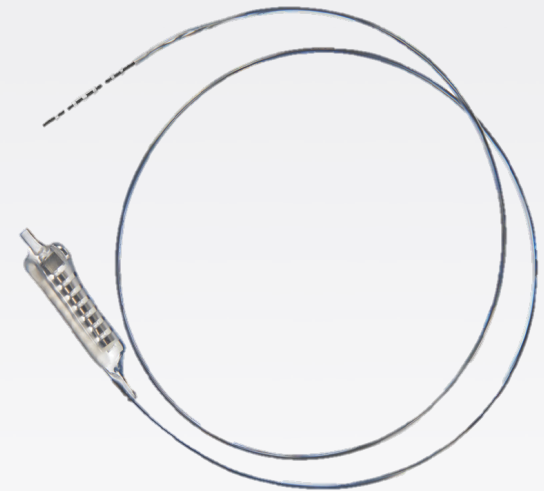


**Guardian™ Burr Hole Cover used
with the St. Jude Medical Infinity™
DBS system**

EXPANDING ACCESS TO UPGRADABLE TECHNOLOGY

Now patients needing a replacement IPG can get access to all the benefits of wireless technology and upgradeability.

- Adapters compatible with Medtronic™ DBS extensions and St. Jude Medical™ DBS IPGs*
- Available in 10 cm and 60 cm lengths for flexibility
- Provides patients access to the advancements enabled by the St. Jude Medical Infinity™ DBS System
 - Modern patient controller with familiar Apple™ products and wireless communication for ease of use
 - Access to future innovations and therapies upon regulatory approval, without the cost and pain of a surgical replacement
 - Real-time battery estimation with six month replacement notification¹



Pocket Adapters used with the St. Jude Medical Infinity™ DBS system

*Consult user manuals for additional information on compatibility.

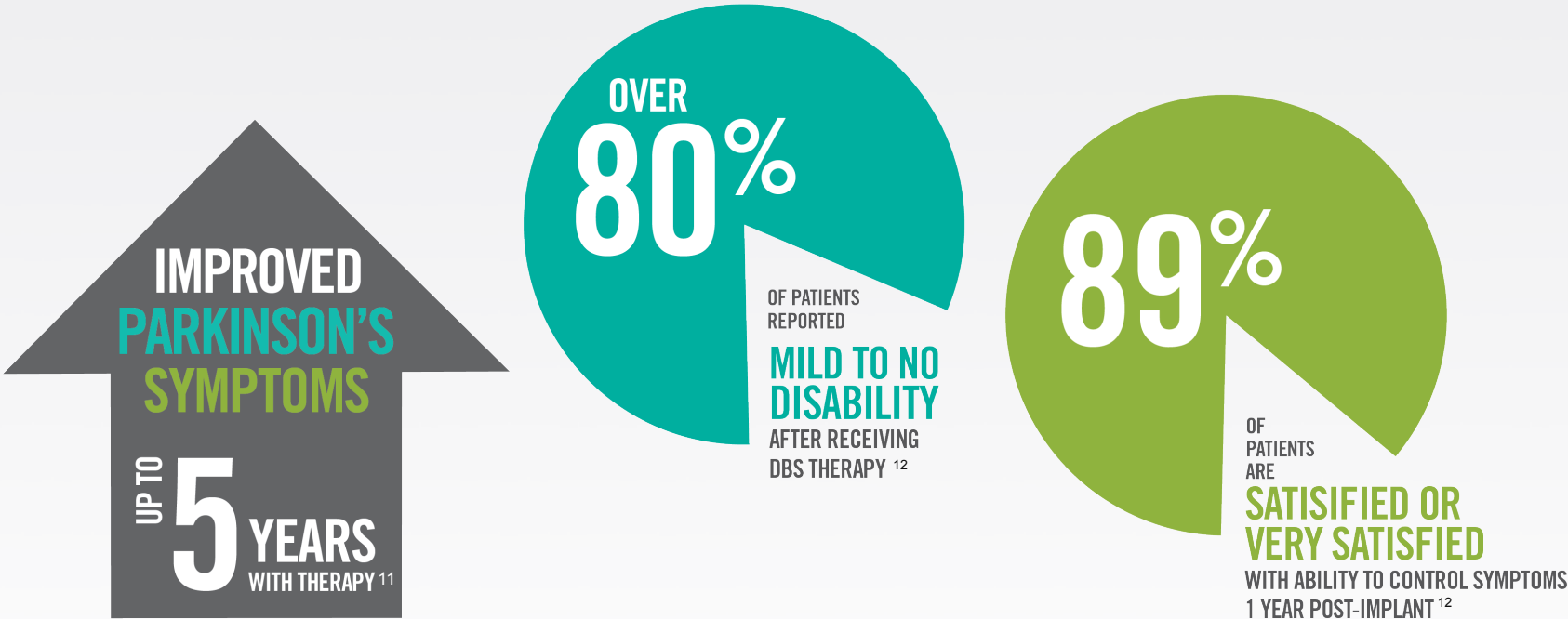
INDICATIONS FOR USE

St. Jude Medical has the broadest indication for use in the movement disorders DBS market¹⁰

	St. Jude Medical	Medtronic	Boston Scientific
Parkinson's	The St. Jude Medical Infinity™ Deep Brain Stimulation (DBS) system is indicated for use in <i>unilateral or bilateral</i> stimulation of the <i>thalamus</i> , including the <i>internal globus pallidus (GPi)</i> , or <i>subthalamic nucleus (STN)</i> in patients with <i>levodopa-responsive Parkinson's disease</i> .	<i>Bilateral</i> stimulation of the <i>internal globus pallidus (GPi)</i> or the <i>subthalamic nucleus (STN)</i> using Medtronic DBS Therapy for Parkinson's Disease is indicated for <i>adjunctive therapy</i> in <i>reducing some of the symptoms</i> of advanced, levodopa-responsive Parkinson's disease that <i>are not adequately controlled with medication</i> .	The Vercise™ Deep Brain Stimulation (DBS) System is indicated for use in unilateral or bilateral stimulation of the subthalamic nucleus (STN) or internal globus pallidus (GPi) for treatment of levodopa-responsive Parkinson's disease which is not adequately controlled with medication and also for treatment of intractable primary and secondary Dystonia, for persons 7 years of age and older.
Dystonia	The St. Jude Medical Infinity™ DBS system is indicated for unilateral or bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) for the management of intractable, chronic dystonia, including primary and secondary dystonia.	Medtronic Activa™ Deep Brain Stimulation (DBS) therapy is indicated as an <i>aid in the management of chronic, intractable (drug refractory) primary dystonia</i> , including generalized and segmental dystonia, hemidystonia, and cervical dystonia (torticollis) for individuals 7 years of age and older	
Tremor	The St. Jude Medical Infinity™ DBS system is indicated for unilateral or bilateral stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the management of tremor.	Unilateral thalamic stimulation of the ventral intermediate nucleus (VIM) using Medtronic DBS Therapy for tremor is indicated for the suppression of tremor in the upper extremity. The system is intended for 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.	Thalamic stimulation using the Boston Scientific Vercise™ DBS System is indicated for the suppression of tremor not adequately controlled by medications in patients diagnosed with Essential Tremor or Parkinson's disease.

POWER OVER OUTCOMES

St. Jude Medical™ DBS for Parkinson's, tremor and dystonia offers innovative therapies that conveniently help patients control symptoms and regain independence.



UPGRADE YOUR CHOICE

	St. Jude Medical	Medtronic	Boston Scientific
Directional lead technology ²	✓	—	✓
User-friendly Apple™ mobile digital devices ¹	✓	—	—
Lowest skin pressure of all conventional cell IPGs* ^{5,6}	✓	—	—
System compatibility with other manufacturers' leads and extensions with an adapter ¹³	✓	—	—
Flexible, reliable extension for easy and secure coiling in IPG pocket ^{2,8}	✓	—	—
Upgradeable DBS system - capable of receiving post-implant software upgrades ⁷	✓	—	—

*Based on FEA analysis

REFERENCES

1. St. Jude Medical. Engineering Report 68-3997 Rev A. 2014
2. St. Jude Medical Infinity™ IPG Clinician's Manual. Plano, Tex. 2015
3. St. Jude Medical. System Test Report 90207342 2015
4. St. Jude Medical Infinity™ Programming Options Claims Memo, Zinc # SJM-INF-0815-0010
5. St. Jude Medical Infinity™ Size Related Claims Memo, Zinc # SJM-INF-0815-0007
6. St. Jude Medical. Engineering report 90191496 2015
7. St. Jude Medical Infinity™ IPG First and Only Related Claims Memo, Zinc # SJM-INF-0815-0008
8. St. Jude Medical Infinity™ Coiled Extensions No Fractures Claim Memo, Zinc SJM-INF-0815-0012
9. St. Jude Medical. Product Drawing 40-0184.
10. St. Jude Medical Infinity™ Broadest Indications Claims Memo, Zinc # SJM-INF-0815-0011
11. St. Jude Medical Parkinson's Disease Study 2012
12. St. Jude Medical Tremor Study 2014
13. St. Jude Medical. St. Jude Medical™ 8-Channel Adapter Clinician's Manual. Plano, Tex. 2014.



Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Product referenced is approved for CE Mark. CE marking does not necessarily indicate regulatory approval status for all markets. Device depicted may not be available in all countries. Check with your St. Jude Medical representative for product availability in your country.

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