



AN EVIDENCE-BASED DISCUSSION

OPTIMIZING OUTCOMES WITH ABBOTT'S DIRECTIONAL DBS SYSTEM

ABBOTT'S ST. JUDE MEDICAL INFINITY™ DBS SYSTEM

ADVANCING DBS THERAPY THROUGH DIRECTIONAL
STIMULATION WITH SINGLE SEGMENT ACTIVATION



**DIRECTIONAL LEAD
TECHNOLOGY**



**RECHARGE-FREE
SYSTEM**



**UPGRADEABLE
TECHNOLOGY**



**FAMILIAR
CONSUMER
iOS® INTERFACE**



**WIRELESS
BLUETOOTH®
COMMUNICATION**

DBS = deep brain stimulation

SSA = single segment activation

PROPRIETARY AND CONFIDENTIAL — DO NOT DISTRIBUTE

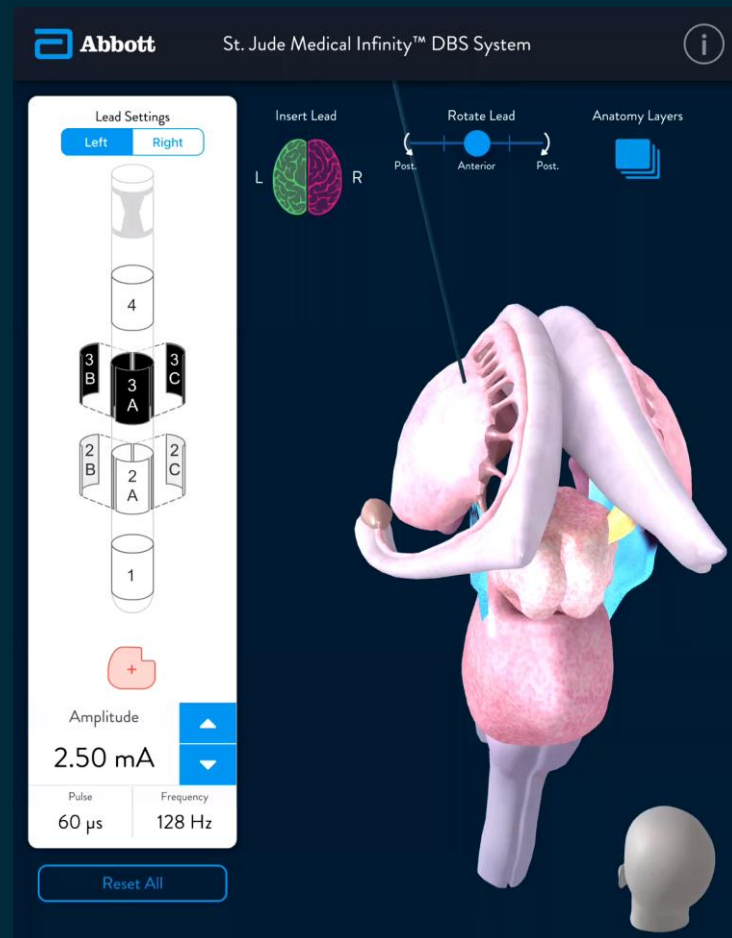
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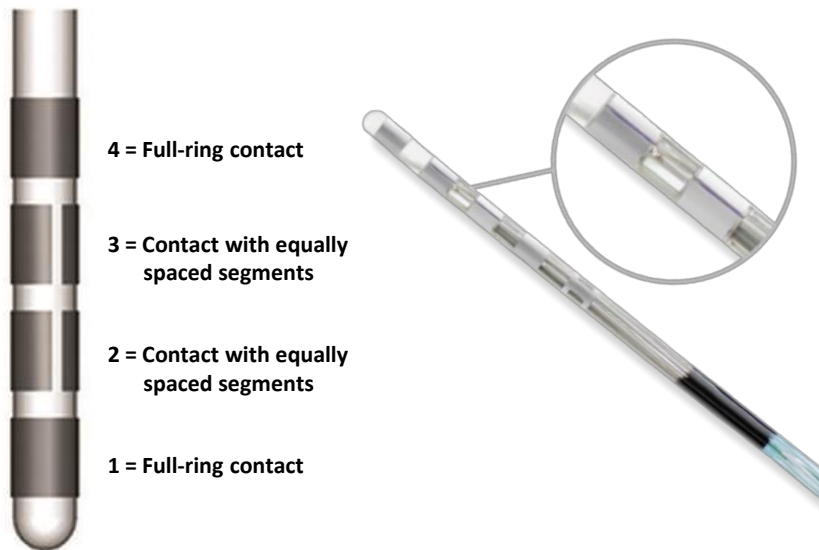
DIRECTIONAL LEADS ADVANCE DBS THERAPY

SEGMENTED DIRECTIONAL LEADS OFFER ENHANCED CONTROL^{1,2}

- Designed to direct stimulation toward desired targets¹
- Offer wider programming range between symptom relief and sustained side effects²
- Provide increased volume of tissue activation (VTA) with directional¹



ABBOTT'S DIRECTIONAL LEAD TECHNOLOGY



ELECTRODE LENGTH	1.5 mm
ELECTRODE SPACING	0.5 mm/1.5 mm
LEAD DIAMETER	1.29 mm
SEGMENTED CONTACTS	~ 120° of span

OPTIMIZING OUTCOMES WITH DIRECTIONAL DBS AND SSA

CHALLENGES WITH CONVENTIONAL (OMNIDIRECTIONAL) DBS THERAPY



COMPLEX
REGIONAL ANATOMY

makes precise
stimulation necessary.^{3,4}



SIDE
EFFECTS

can limit therapeutic benefit
and may contribute to long-
term complications.^{5,6}



PROGRESSION OF
PARKINSON'S DISEASE

is tied to increased therapy
requirements.⁷⁻⁹



INADEQUATE
CLINICAL BENEFIT

is a frequent cause of DBS
revisions and explants.¹⁰

CONVENTIONAL DBS — OMNIDIRECTIONAL¹¹



CONVENTIONAL
DBS

COMPLEXITY

3.1.
MONOPOLAR
STIMULATION

BASIC FIELD

3.1.
BIPOLAR
STIMULATION
MONTAGE

FIELD RESTRICTION

VARY
PULSE WIDTH/
FREQUENCY

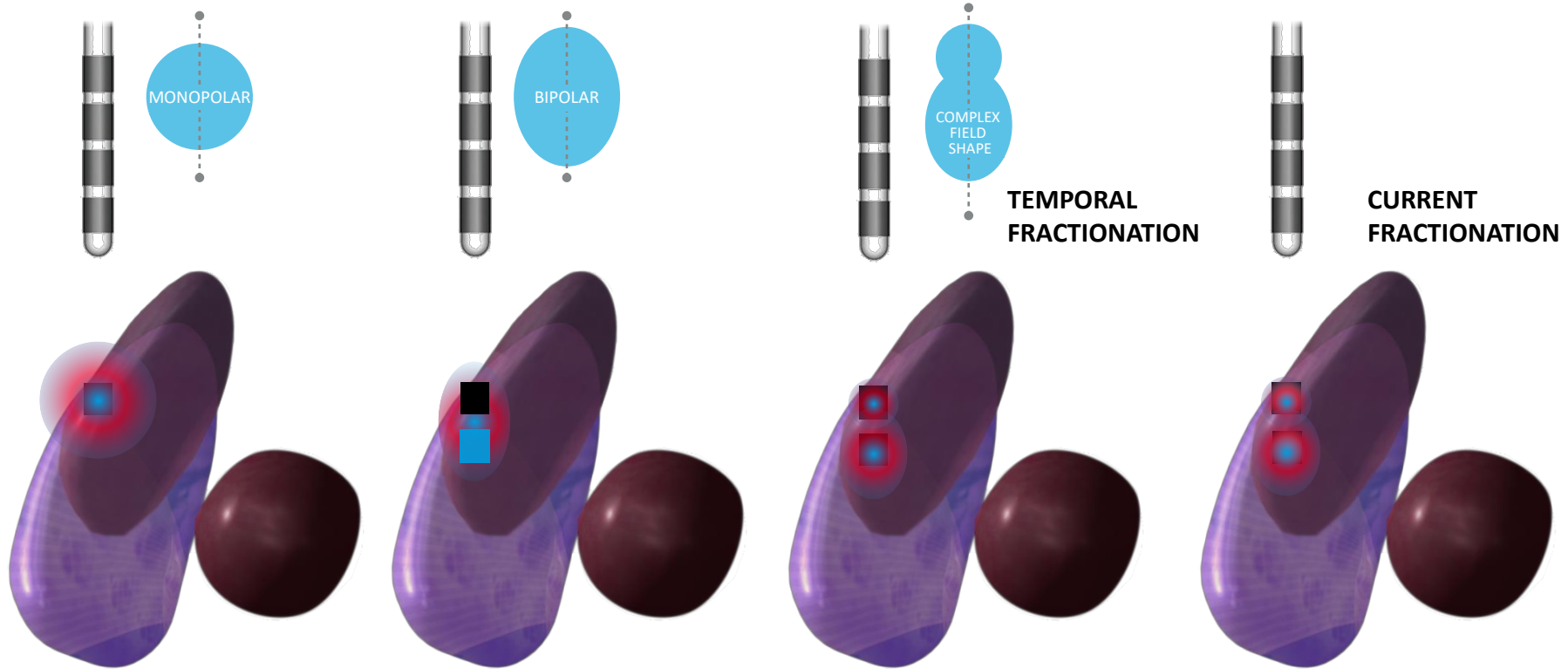
SUBSELECTION OF
ACTIVATED NEURAL
ELEMENTS

COMPLEX FIELD
SHAPING —
INTERLEAVING

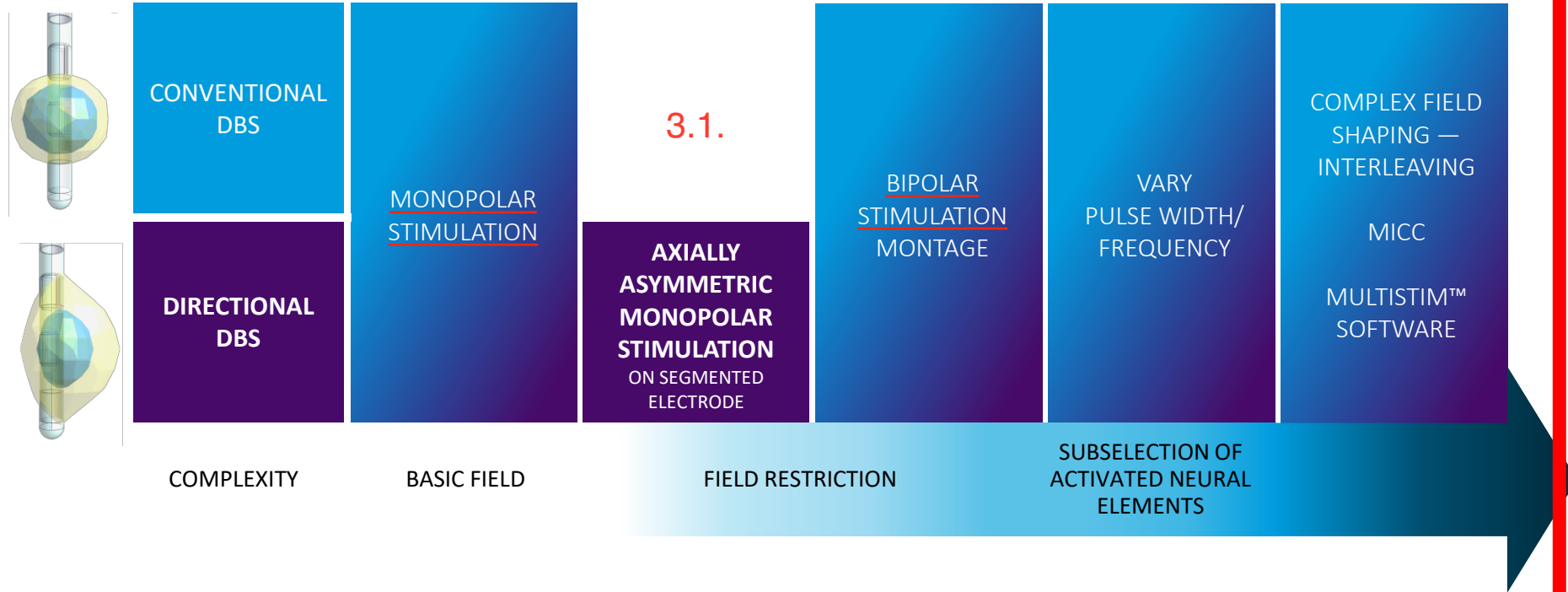
MULTIPLE
INDEPENDENT
CURRENT
CONTROL
(MICC)

MULTISTIM™
SOFTWARE

CONVENTIONAL DBS — OMNIDIRECTIONAL¹²

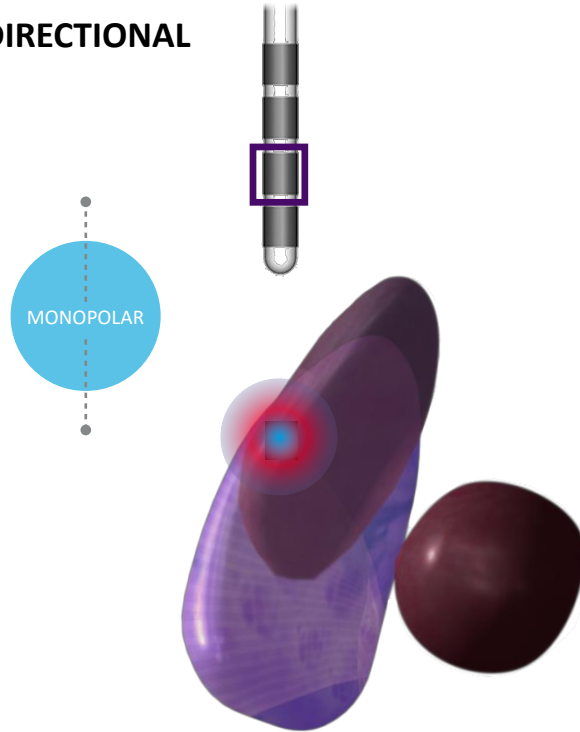


DIRECTIONAL DBS — UNIQUE FIELD SHAPING OPTION¹¹

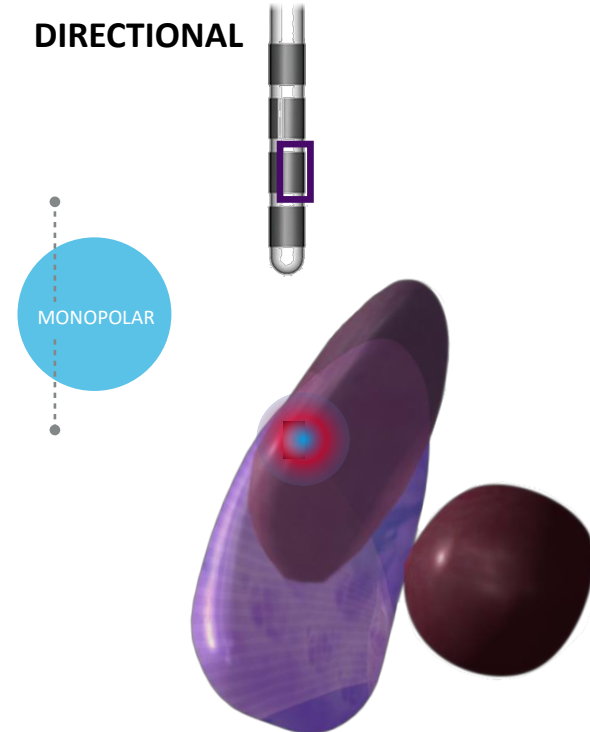


DIRECTIONAL DBS — UNIQUE FIELD SHAPING OPTION¹²

OMNIDIRECTIONAL



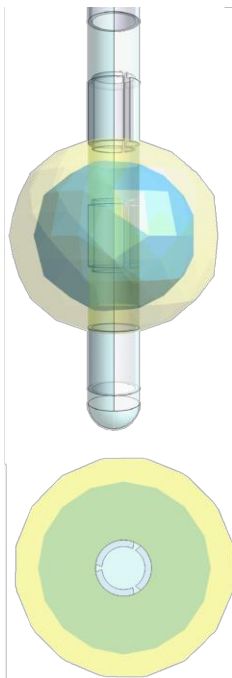
DIRECTIONAL



DIRECTIONAL DBS — AXIALLY ASYMMETRIC FIELD RESTRICTION¹³

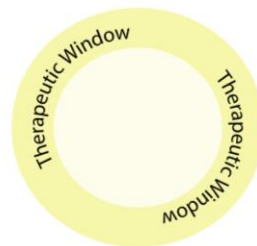
TW	1 mA
----	------

10ABC	mA	VTA (mm ³)
TCS	1.2	25.2
SET	2.2	58.7



Volume of
Tissue Activated
at Therapeutic
Current Strength
(TCS)

Volume of
Tissue Activated
at Side Effect
Threshold
(SET)



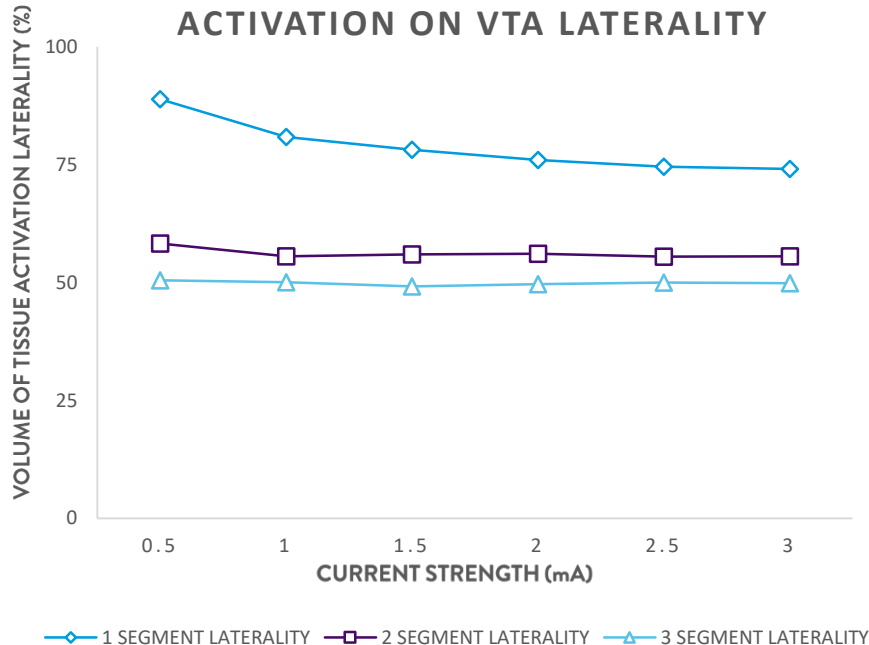
TW	1.75 mA
----	---------

10B	mA	VTA (mm ³)
TCS	0.75	18
SET	2.5	95.7

TW = therapeutic window

DIRECTIONAL DBS — IMPROVED DIRECTIONALITY¹⁴

IMPACT OF SINGLE SEGMENT, TWO SEGMENT AND THREE SEGMENT ACTIVATION ON VTA LATERALITY

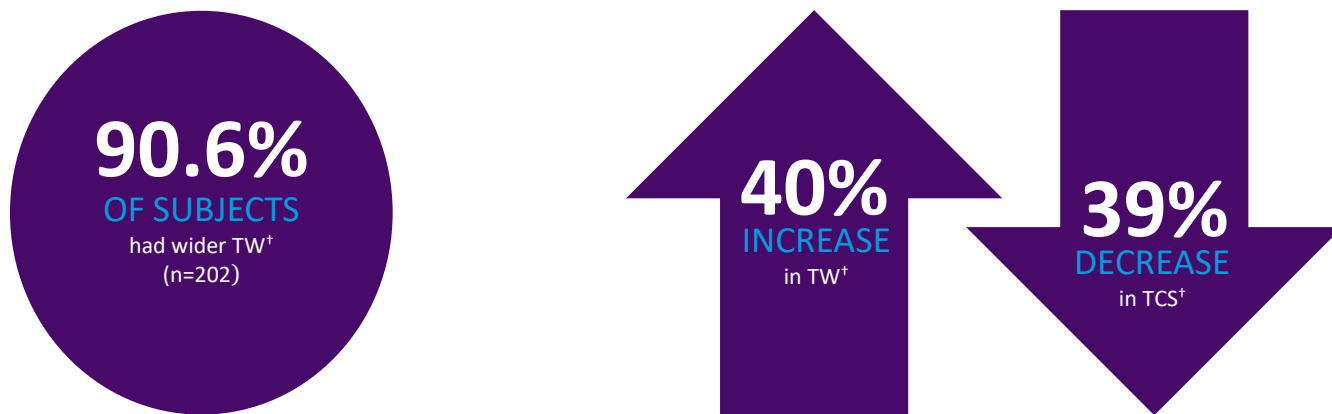


KEY TAKEAWAYS

DEGREE OF DIRECTIONALITY IS:

- Greatest with Single Segment Activation (SSA)
- Lower with 2 segment activation and more similar to 3 segment activation (Ring mode)
- Decreased at higher amplitudes, but still highest with SSA

DIRECTIONAL DBS – OPTIMIZED OUTCOMES²



Patients and clinicians prefer directional DBS when compared sequentially.*

[†]As compared to conventional DBS

*Post hoc analysis

DIRECTIONAL DBS — SSA

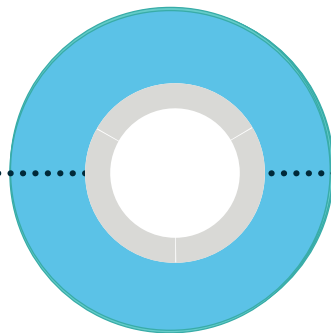
A COMMON
MISCONCEPTION:

**LARGER SURFACES
PRODUCE LARGER VTAs**

**SSA PRODUCES
LARGER VTA VS. RING¹**



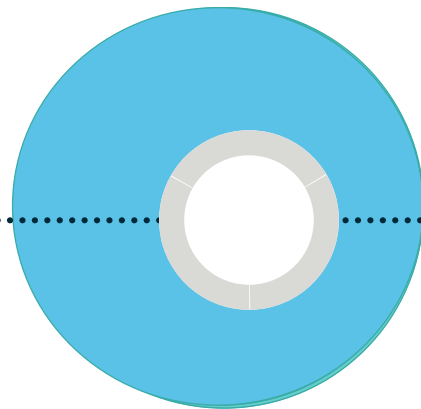
SSA PROVIDES GREATEST LATERALITY¹



1.5 mA

COACTIVATION SPREADS THE FIELD MORE BROADLY,
REDUCING THE SIGNIFICANCE OF DIRECTIONAL EFFECT.

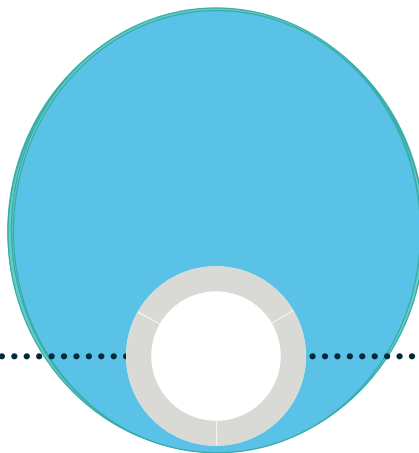
SSA PROVIDES GREATEST LATERALITY¹



1.5 mA

COACTIVATION SPREADS THE FIELD MORE BROADLY,
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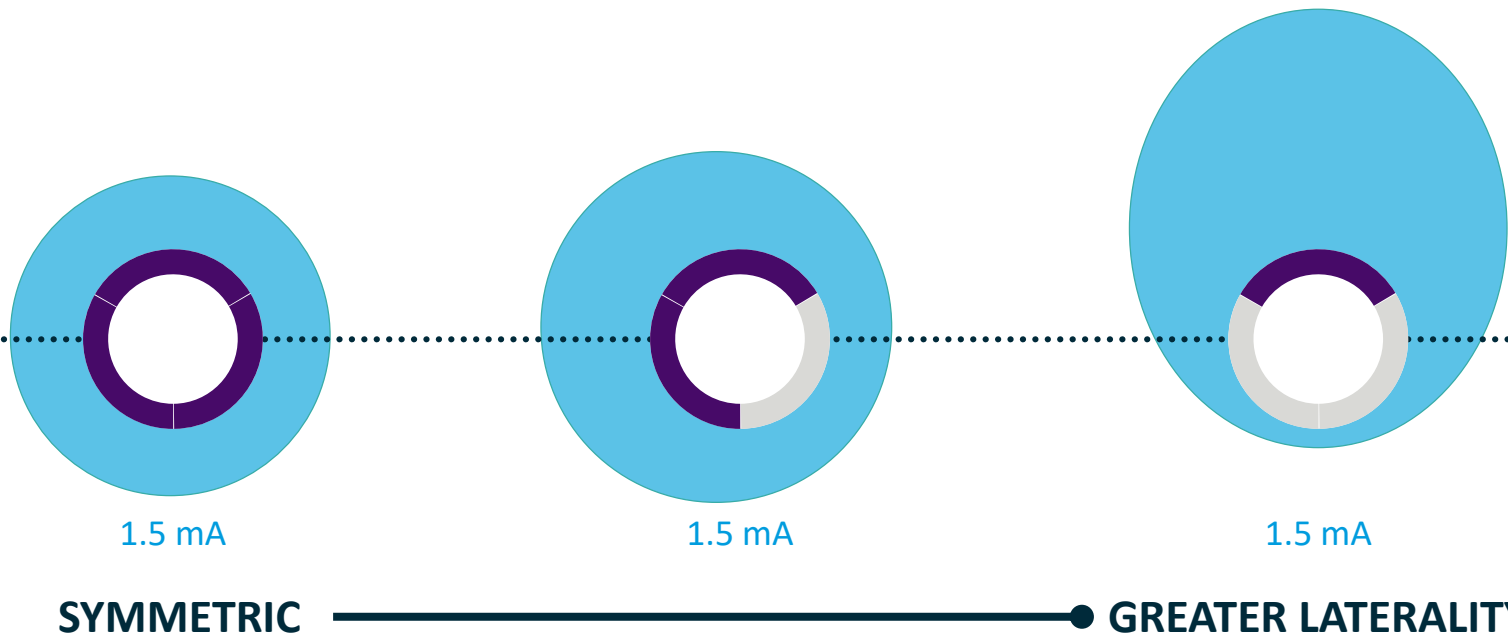
SSA PROVIDES GREATEST LATERALITY¹



1.5 mA

COACTIVATION SPREADS THE FIELD MORE BROADLY,
REDUCING THE SIGNIFICANCE OF DIRECTIONAL EFFECT.

SSA PROVIDES GREATEST LATERALITY¹



COACTIVATION SPREADS THE FIELD MORE BROADLY,
REDUCING THE SIGNIFICANCE OF DIRECTIONAL EFFECT.

SSA ENABLES MORE EFFICIENT RECRUITMENT OF NEURAL TISSUE¹



COACTIVATION SPREADS THE FIELD MORE BROADLY,
REDUCING THE SIGNIFICANCE OF DIRECTIONAL EFFECT.

SSA PRODUCED WIDER TW²



SSA produced **WIDER TW** than conventional stimulation in 86.6% of subjects.²

Post hoc analysis



Image: Rebelo et al. Thalamic Directional Deep Brain Stimulation for Tremor: Spend less, get more. *Brain Stimulation*. 2018.

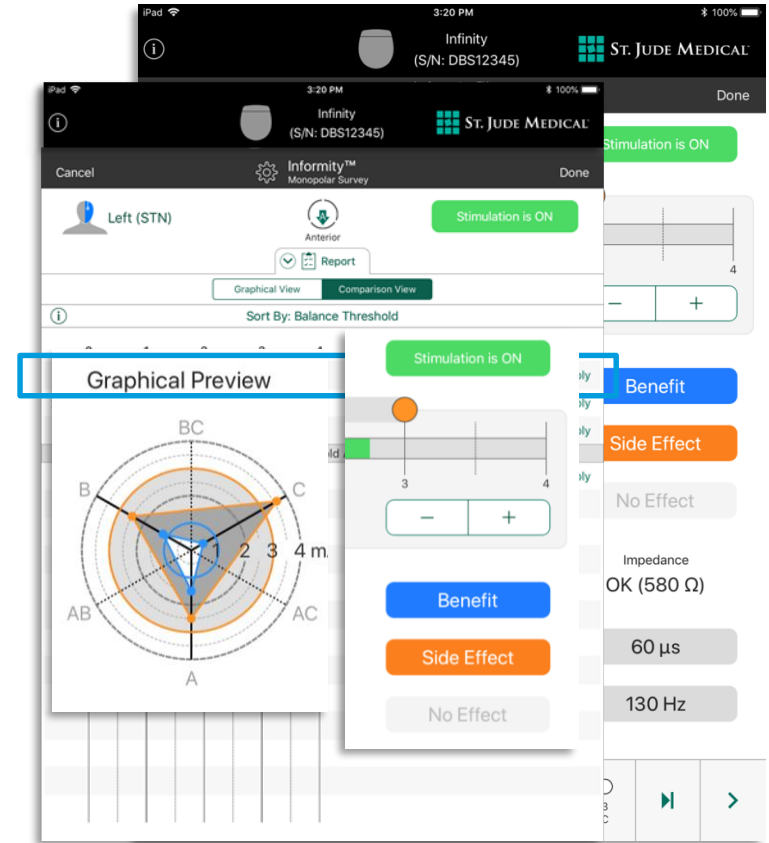
DIRECTIONAL DBS, SIMPLIFIED.

INFORMITY™ PROGRAMMING SOFTWARE

INFORMITY™ PROGRAMMING SOFTWARE — PROGRAMMING, SIMPLIFIED.

STREAMLINED PROGRAMMING

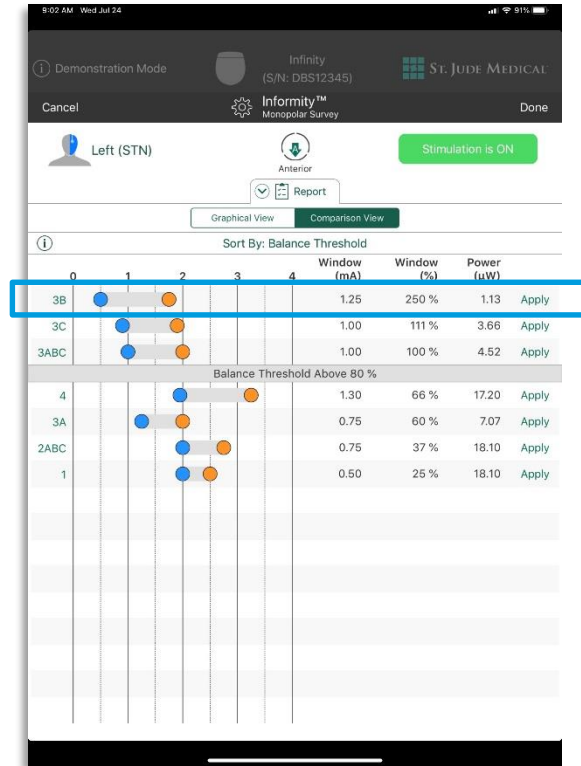
- Integrated, consistent programming documentation
- Simplified data management
- Built-in best practices
- Program directionally from a single screen, wirelessly



INFORMITY™ PROGRAMMING SOFTWARE — PROGRAMMING, SIMPLIFIED. (CONTINUED)

DECISION SUPPORT TOOL

- Simplified sorting of monopolar review by:
 - Electrode number
 - TW
 - TW%
 - Power (μ W)
 - Balanced threshold — optimizing for TW% and power



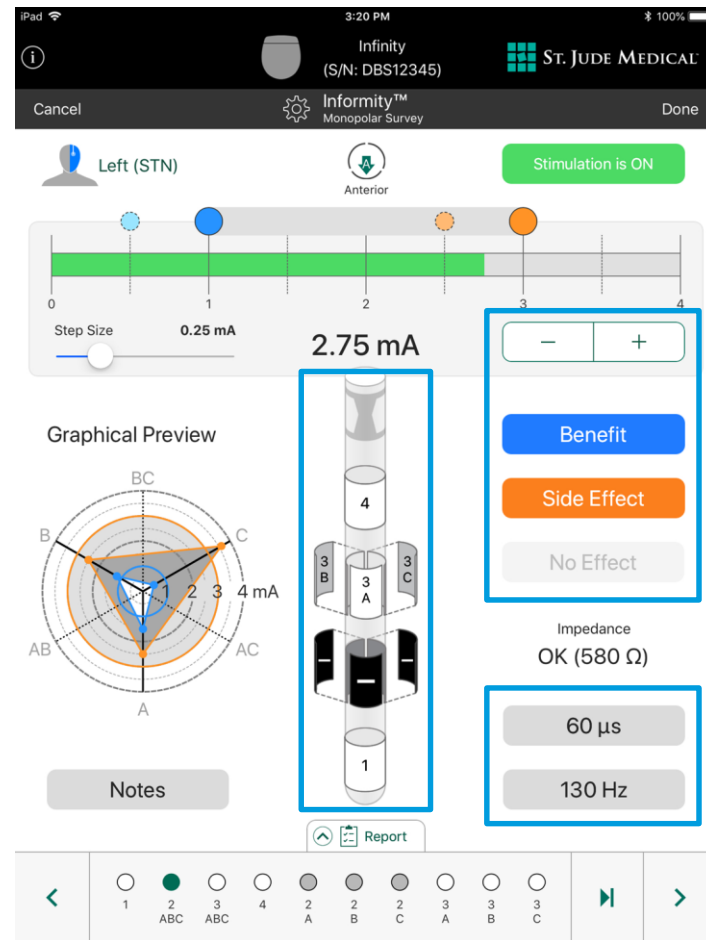
INFORMITY™ PROGRAMMING SOFTWARE

DIRECTIONAL PROGRAMMING — MONOPOLAR REVIEW

HOW TO DETERMINE THE OPTIMAL RING

SELECTING THE OPTIMAL RING AND COMBINATION OF SEGMENTS

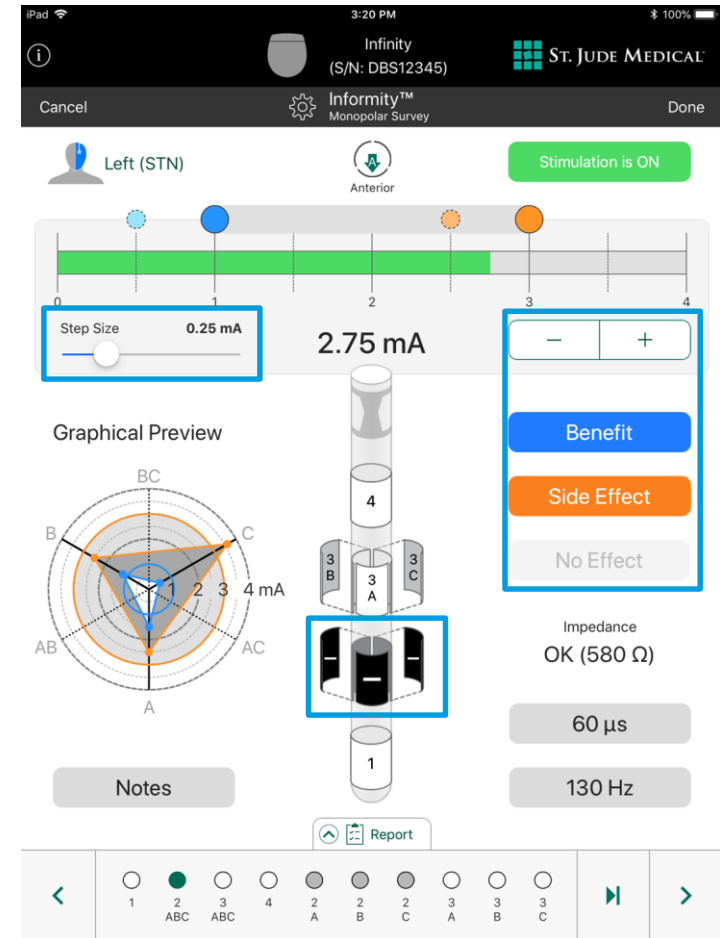
- Perform monopolar review on all four rings
 - For segmented rings, select all three segments
- Use clinically relevant values for pulse width and frequency
- Capture TW for each ring to determine the best level



HOW TO DETERMINE THE OPTIMAL SEGMENT

AFTER SELECTING THE OPTIMAL RING

- Perform monopolar review on each segment and combination of segments to determine the best TW
- Optimize amplitude to achieve meaningful symptom control at the lowest amplitude settings
- To determine the segment with the best TW% + energy consumption, sort by balanced threshold
 - May extend battery life span¹³



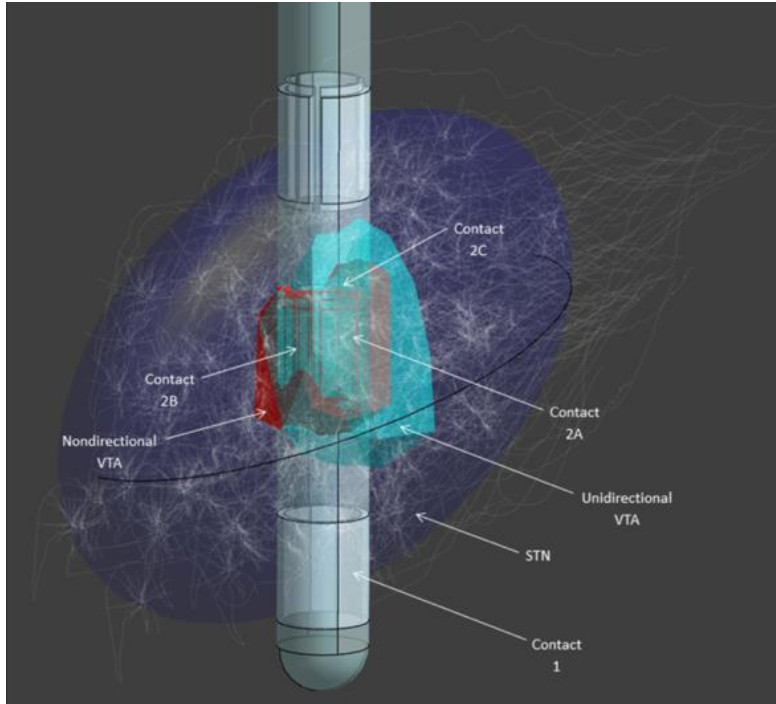
INFORMITY™ PROGRAMMING SOFTWARE

DIRECTIONAL PROGRAMMING BEST PRACTICES IN THREE STEPS

With so many
combinations,
how do you
STAY IN CONTROL?

- 1 Smaller step size
- 2 Prioritize SSA
- 3 Be ruthlessly reductive

RULE 1: SMALLER STEP SIZE

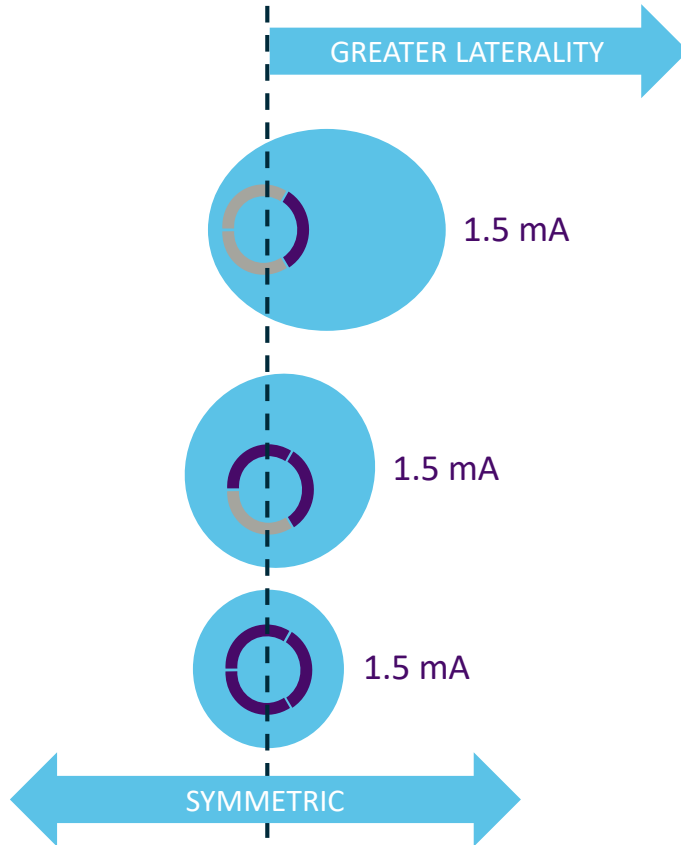


Cheeran B, et al. "Thalamic Directional Deep Brain Stimulation for Tremor: Spend Less, Get More." *Brain*. 2017.

SUMMARY

- Anticipate benefits at lower amplitudes²
- Use smaller steps during screening of segmented electrodes¹⁶

RULE 2: PRIORITIZE SSA



SUMMARY

- Degree of directionality is greatest with SSA¹
- Find the best level and best directionality¹⁴

RULE 3: BE RUTHLESSLY REDUCTIVE



4 ELECTRODES =
24
MONTAGE
PERMUTATIONS



8 ELECTRODES =
40,320
MONTAGE
PERMUTATIONS

SUMMARY

- Be ruthlessly reductive
- Follow a systematic approach to screening
 - Adapt screening method (e.g., documentation)
 - Adapt screening schedule

EXPANDED POSSIBILITIES FOR CURRENT DBS PATIENTS

MR CONDITIONAL SYSTEM

- Directional DBS with access to full-body MRI

MULTISTIM™ PROGRAMMING SOFTWARE

- Complex field shaping for patients who require interleaving

SHARED OR INDEPENDENT FREQUENCIES IN ONE DEVICE

- Independent frequencies allow for fine-tuning of stimulation for each hemisphere, which may decrease power consumption

LOW PULSE WIDTHS

- Low pulse widths may broaden TW and lower energy consumption¹⁷

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Rx Only

Brief Summary: Prior to using these devices, please review the Clinician's Manual for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use. The system is intended to be used with leads and associated extensions that are compatible with the system.

Indications for Use: U.S.: Bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy to reduce some of the symptoms of advanced levodopa-responsive Parkinson's disease that are not adequately controlled by medications, and unilateral or bilateral stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the suppression of disabling upper extremity tremor in adult essential tremor patients whose tremor is not adequately controlled by medications and where the tremor constitutes a significant functional disability.

International: Unilateral or bilateral stimulation of the thalamus, internal globus pallidus (GPi), or subthalamic nucleus (STN) in patients with levodopa-responsive Parkinson's disease, unilateral or bilateral stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the management of disabling tremor, and 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, for patients who are at least 7 years old.

Contraindications: U.S.: Patients who are unable to operate the system or for whom test stimulation is unsuccessful. Diathermy, electroshock therapy, and transcranial magnetic stimulation (TMS) are contraindicated for patients with a deep brain stimulation system.

International: Patients who are unable to operate the system or for whom test stimulation is unsuccessful. Diathermy and magnetic resonance imaging are contraindicated for patients with a deep brain stimulation system.

Warnings/Precautions: Return of symptoms due to abrupt cessation of stimulation (rebound effect), excessive or low frequency stimulation, risk of depression and suicide, implanted cardiac systems or other active implantable devices, magnetic resonance imaging (MRI), electromagnetic interference (EMI), proximity to electrosurgery devices and high-output ultrasonics and lithotripsy, ultrasonic scanning equipment, external defibrillators, and therapeutic radiation, therapeutic magnets, radiofrequency sources, explosive or flammable gases, theft detectors and metal screening devices, activities requiring excessive twisting or stretching, operation of machinery and equipment, pregnancy, and case damage. Patients who are poor surgical risks, with multiple illnesses, or with active general infections should not be implanted.

Adverse Effects: Loss of therapeutic benefit or decreased therapeutic response, painful stimulation, persistent pain around the implanted parts (e.g., along the extension path in the neck), worsening of motor impairment, paresis, dystonia, sensory disturbance or impairment, speech or language impairment, and cognitive impairment. Surgical risks include intracranial hemorrhage, stroke, paralysis, and death. Other complications may include seizures and infection. Clinician's Manual must be reviewed for detailed disclosure.

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