PROGRAMMING DEEP BRAIN STIMULATION LEADS IN:

STN ▪ GPI ▪ VIM ▪ ANT ▪ ALIC

3D BRAIN ANATOMY

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SUBTHALAMIC NUCLEUS (STN)

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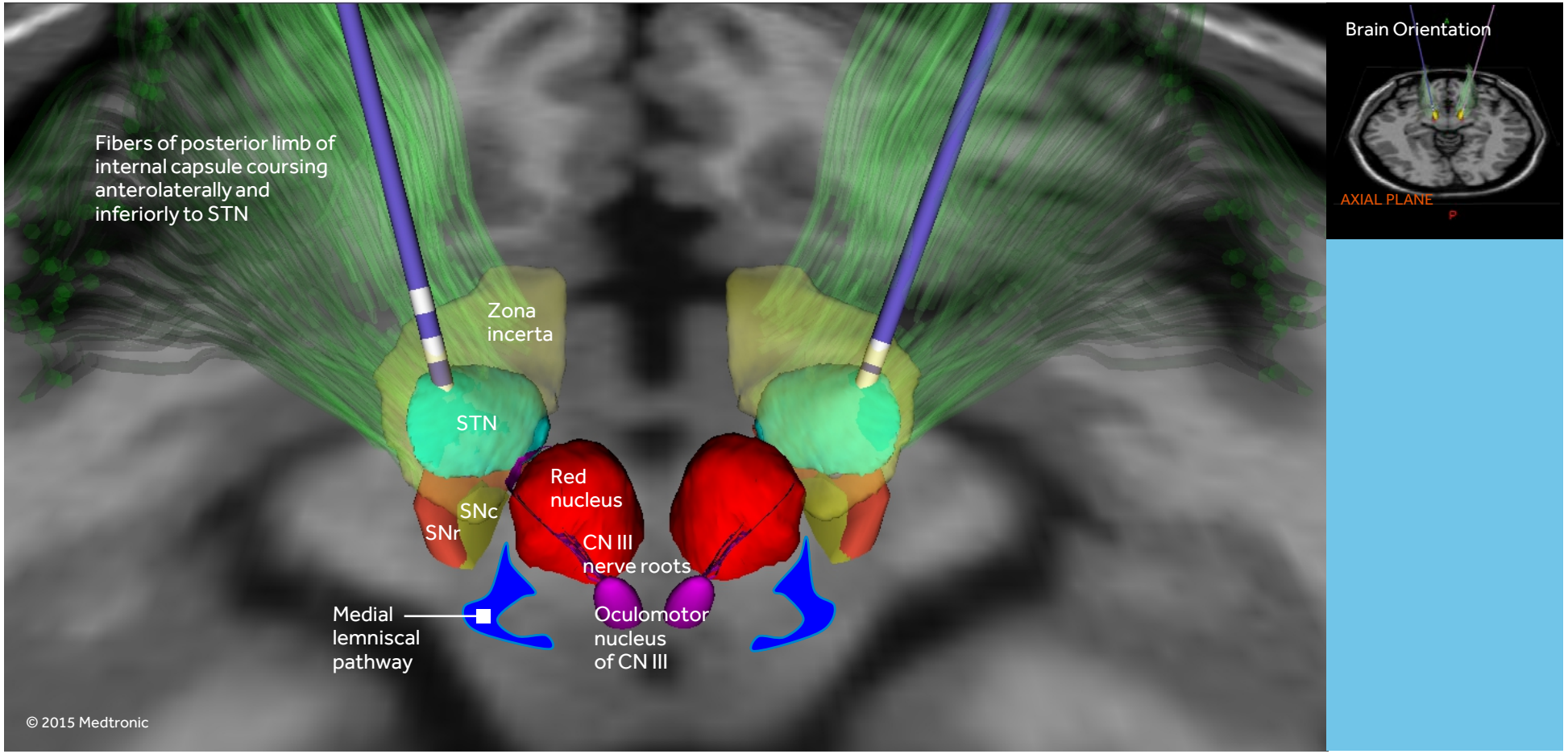
STN: EFFECTIVELY PLACED BILATERAL LEADS



For comparative purposes:

- Medtronic DBS Lead Model 3387 DBS shown in left hemisphere, Medtronic DBS Lead Model 3389 DBS shown in right hemisphere

Anatomy	Preferred Location for DBS Lead	Observed Effect if Stimulated
STN	Dorsolateral aspect of STN	Reduction in parkinsonian symptoms, dyskinesia

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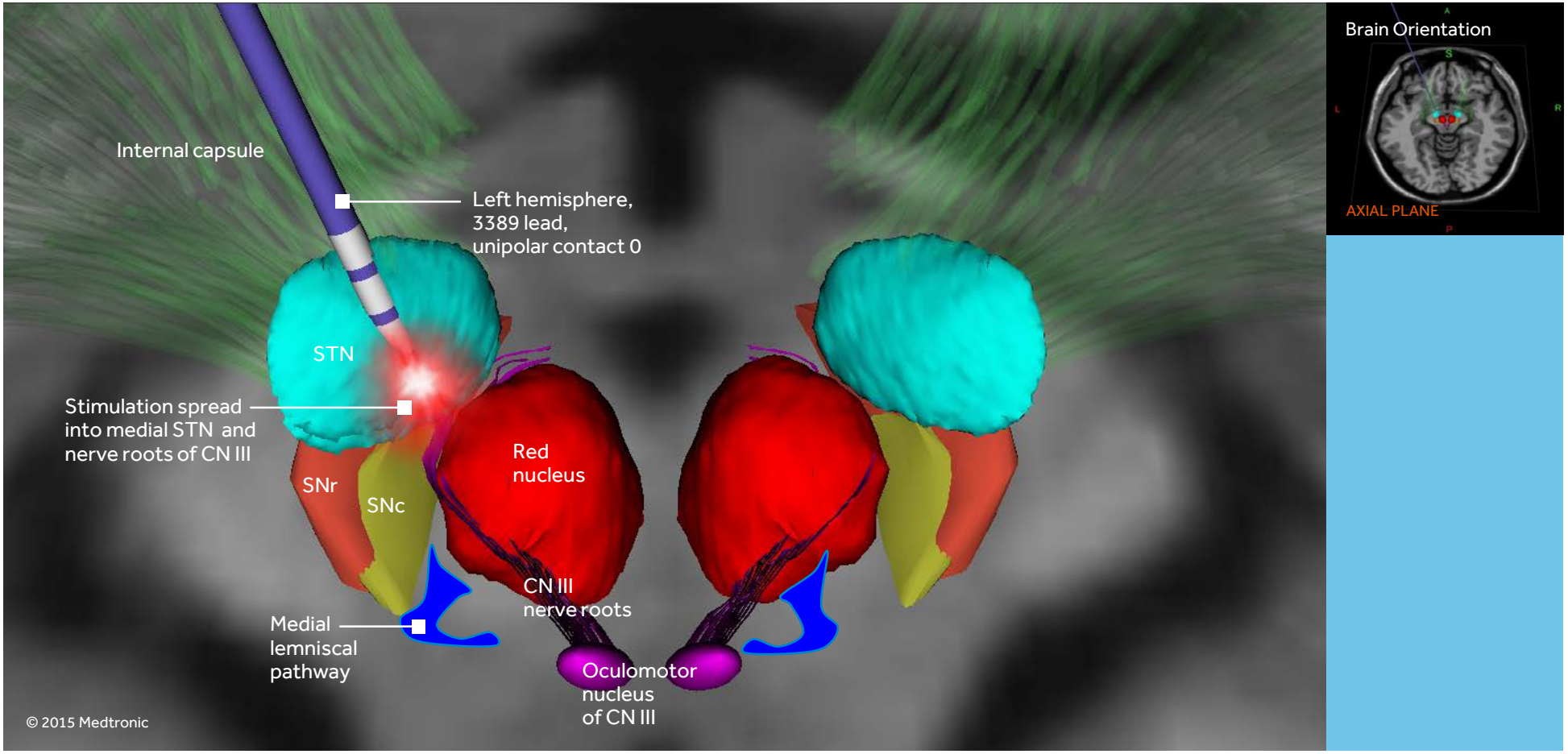
STN: MEDIAL OBSERVED EFFECTS



Anatomy	Location Relative to STN	Observed Effect if Stimulated
Nerve roots of CN III	Medial and ventromedial	Diplopia, eye deviation, dizziness, apraxia of eyelid opening (ALO)
Red nucleus	Posteromedial	Sweating, nausea, extreme discomfort, paresthesias, warm sensations
Limbic STN	Ventromedial aspect of STN	Possible personality or impulsivity changes, depression

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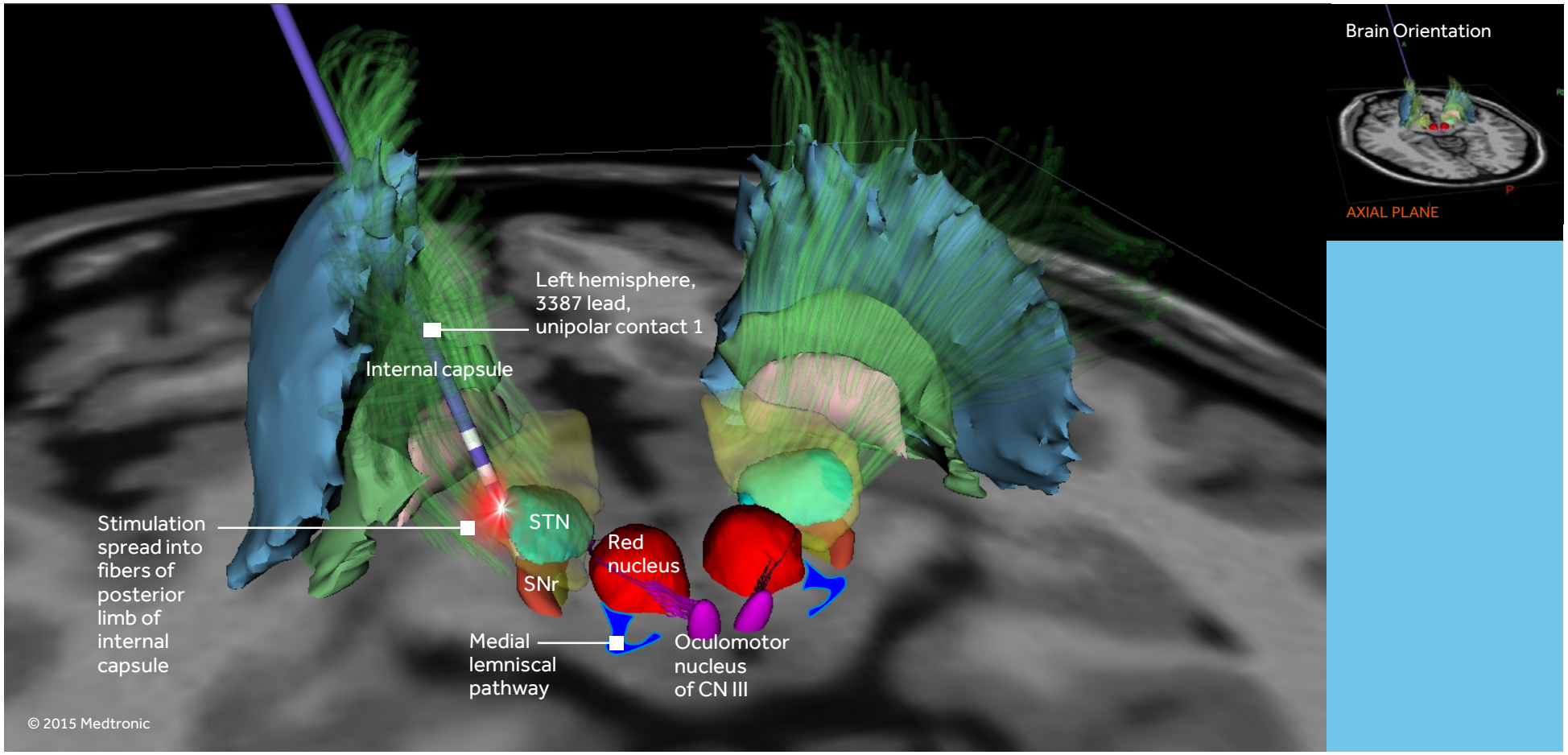
STN: LATERAL OBSERVED EFFECTS



Anatomy	Location Relative to STN	Observed Effect if Stimulated
Corticospinal fibers of internal capsule	Lateral and anterior	Muscle contractions (contracting muscles correspond to the region of the capsular homunculus)
Corticobulbar fibers of internal capsule	Lateral and anterior	dysarthria
Front eye field fibers of internal capsule	Lateral	Contralateral gaze deviation

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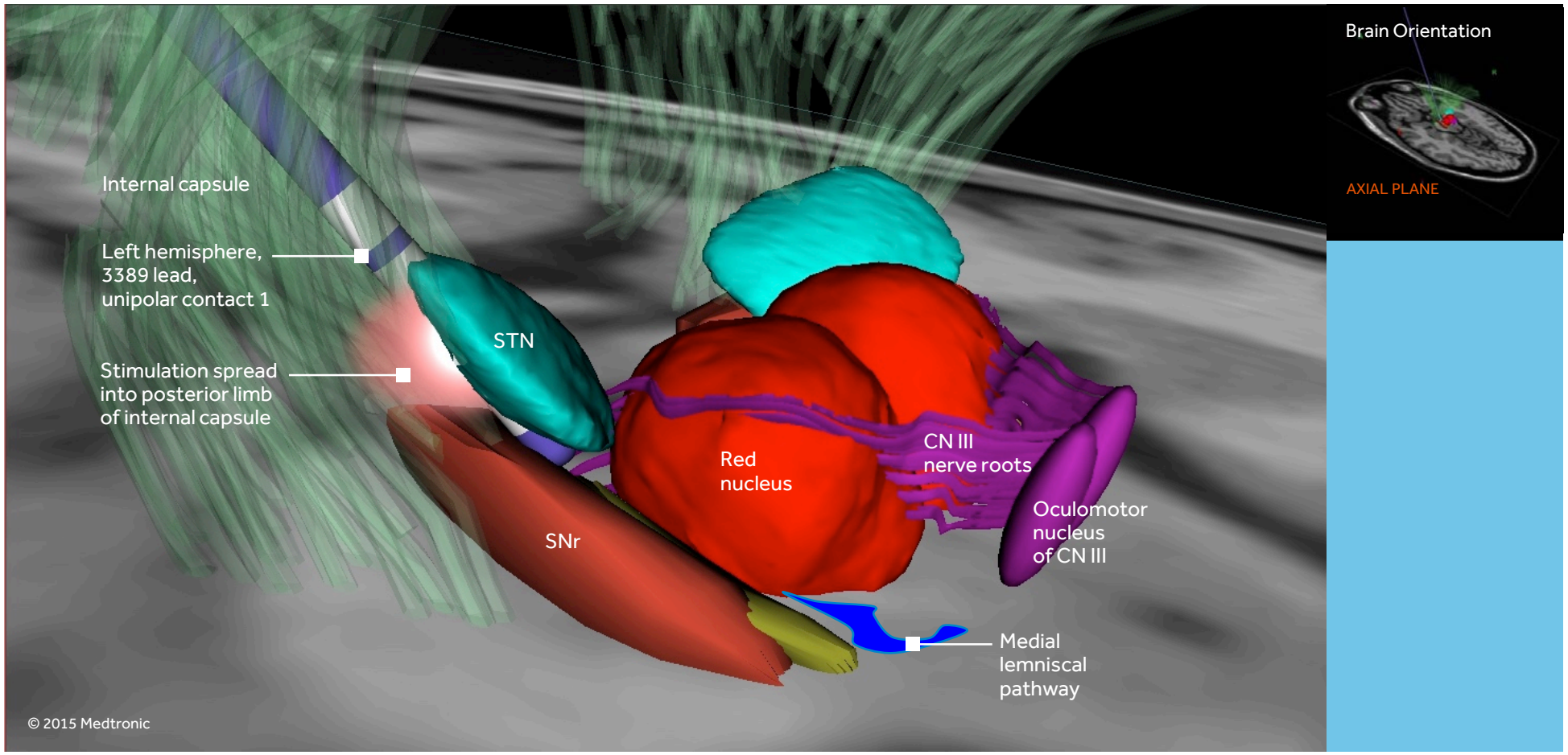
STN: ANTERIOR OBSERVED EFFECTS



Anatomy	Location Relative to STN	Observed Effect if Stimulated
Corticospinal fibers of internal capsule	Anterior and lateral	Muscle contractions in limbs and body
Corticobulbar fibers of internal capsule	Anterior and lateral	Facial and tongue pulling, dysarthria
Hypothalamus	Very anteromedial	Autonomic symptoms (flushing, sweating)

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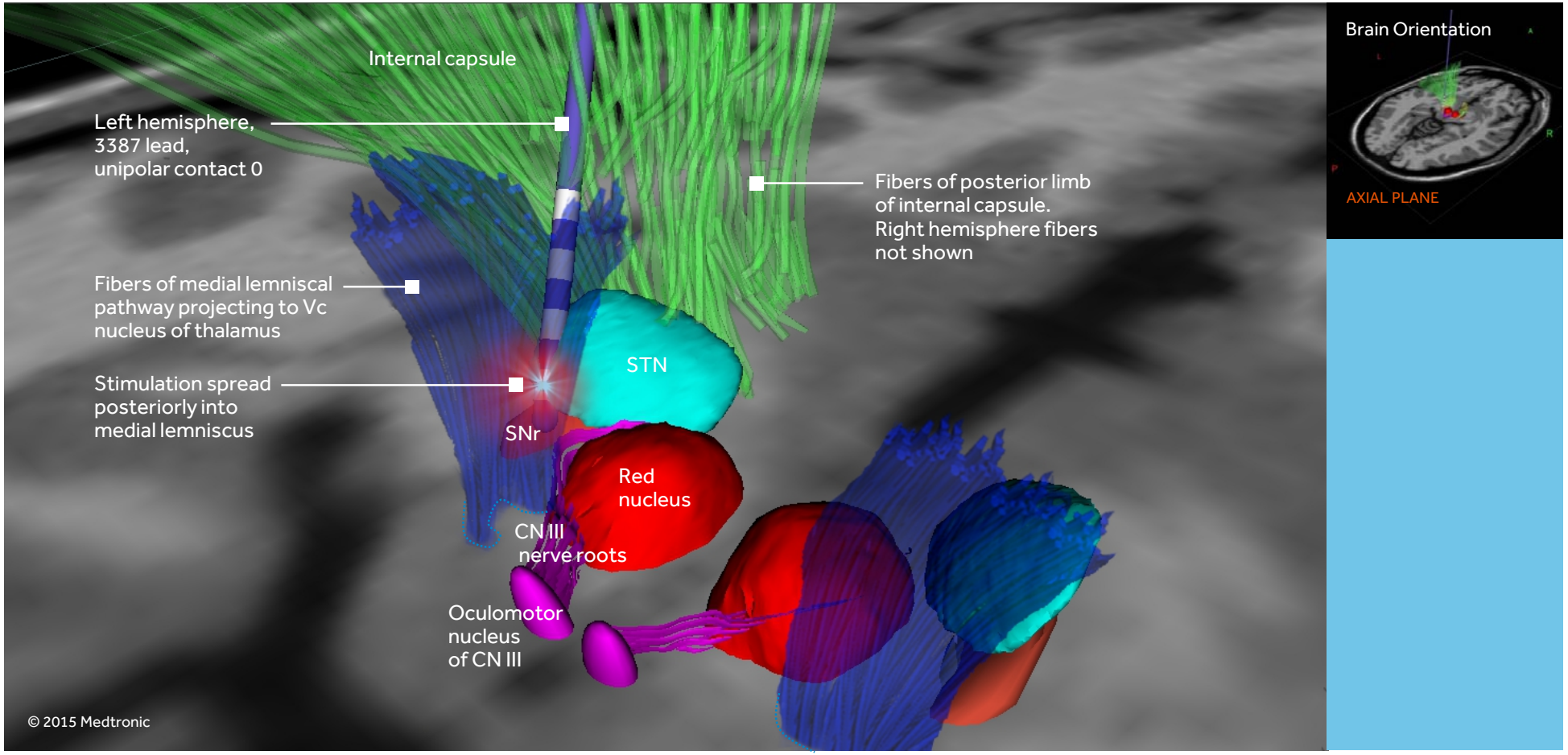
STN: POSTERIOR OBSERVED EFFECTS



Anatomy	Location Relative to STN	Observed Effect if Stimulated
Medial lemniscus	Posterior	Paresthesias (numbness, tingling, electrical sensations)

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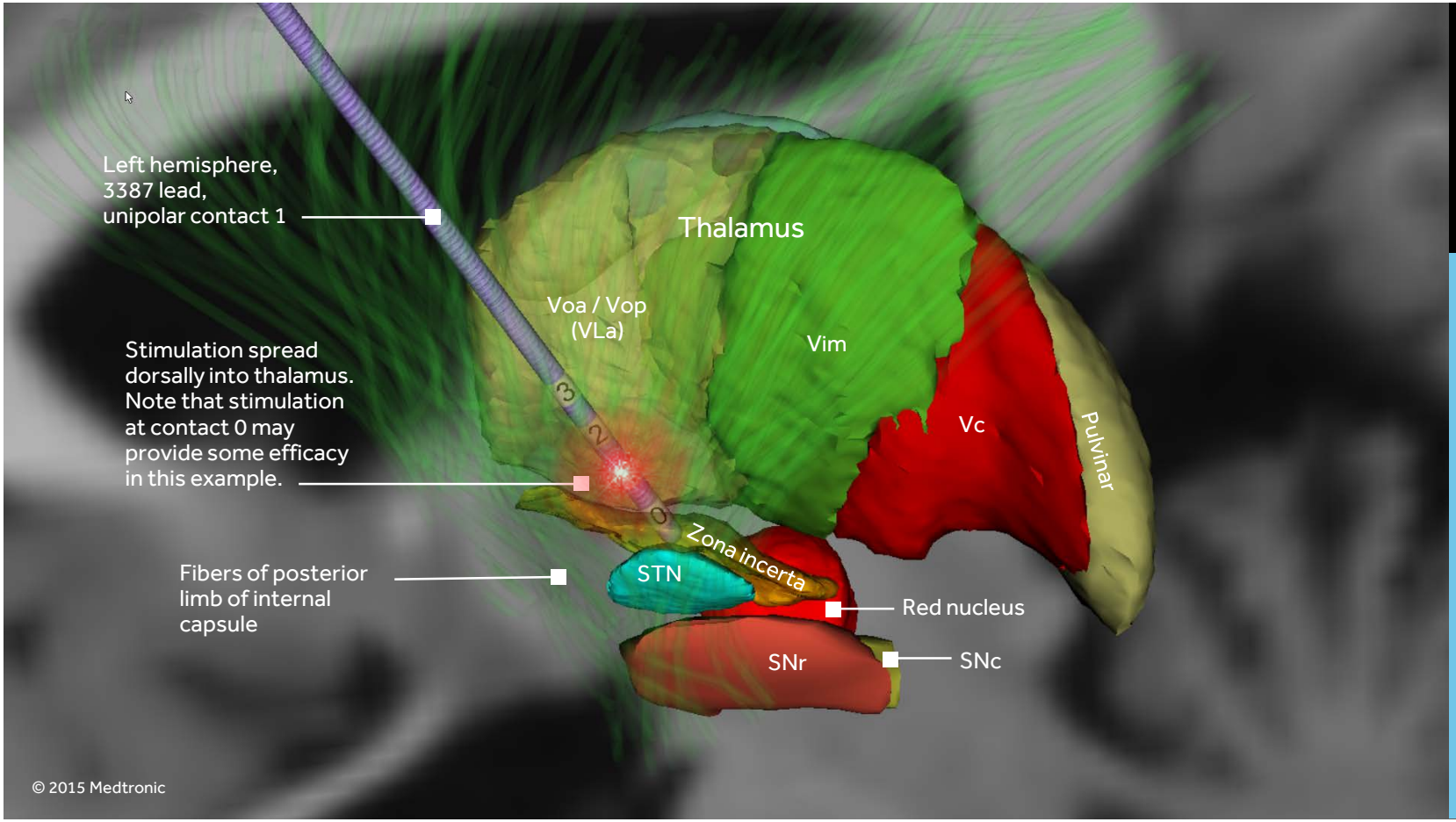
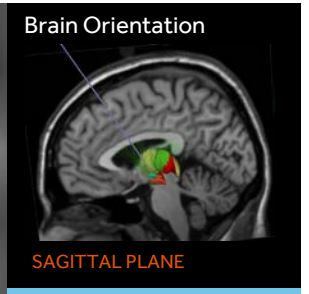
STN: SUPERIOR (DORSAL) OBSERVED EFFECTS





Anatomy	Location Relative to STN	Observed Effect if Stimulated
Zona incerta	Superior	Possible impact on dyskinesias and/or tremor
Thalamus	Superior to STN and zona incerta	Possible impact on dyskinesias, tremor
Internal capsule	Lateral to STN and thalamus	Muscle contractions, dysarthria

*Point to consider: This example illustrates the DBS lead positioned dorsally along the **trajectory path**.*

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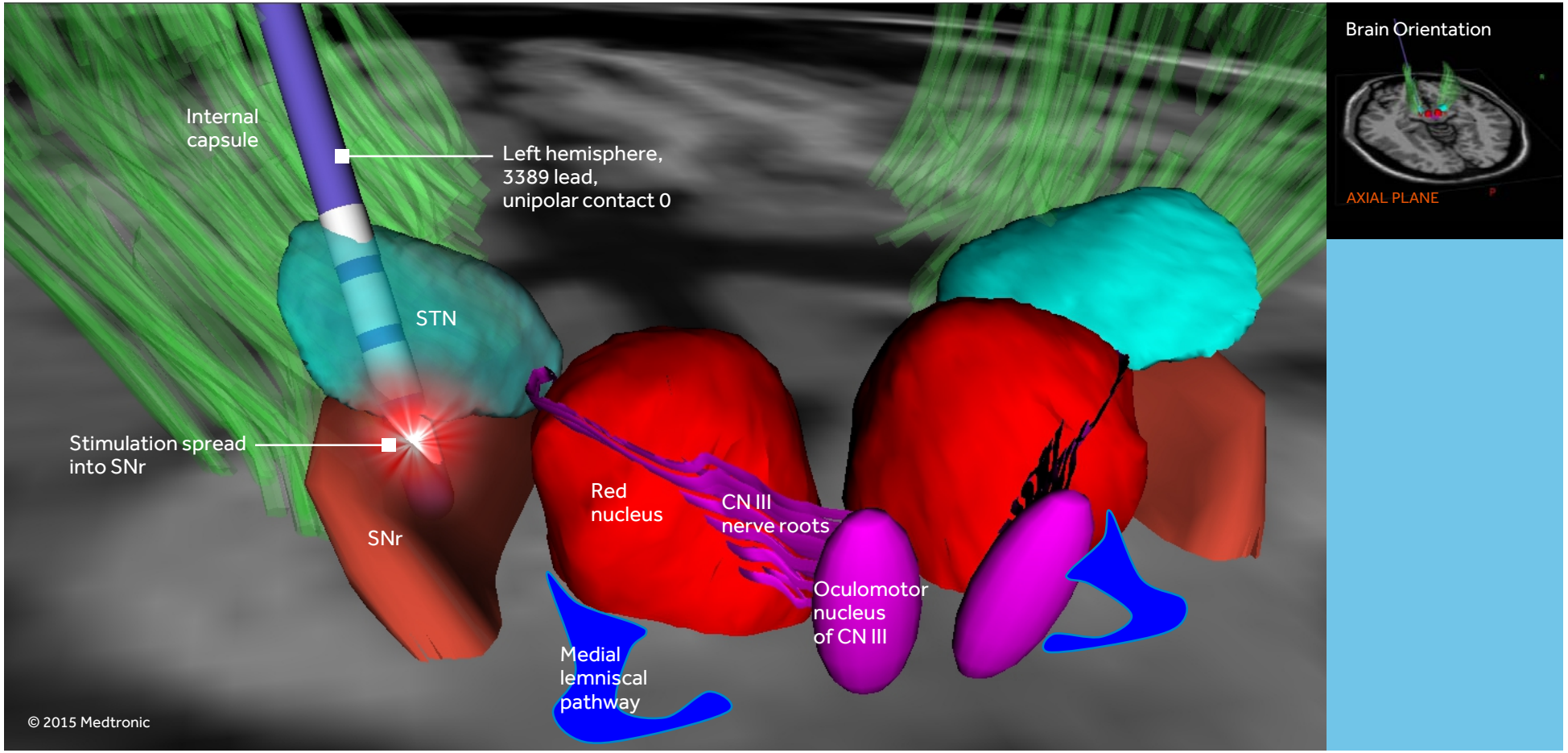
STN: INFERIOR (VENTRAL) OBSERVED EFFECTS



Anatomy	Location Relative to STN	Observed Effect if Stimulated
SNr	Ventral	Possible mood changes, akinesias
Internal capsule fibers	Ventral (not shown above)	Muscle contractions

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GLOBUS PALLIDUS INTERNUS (GPI)

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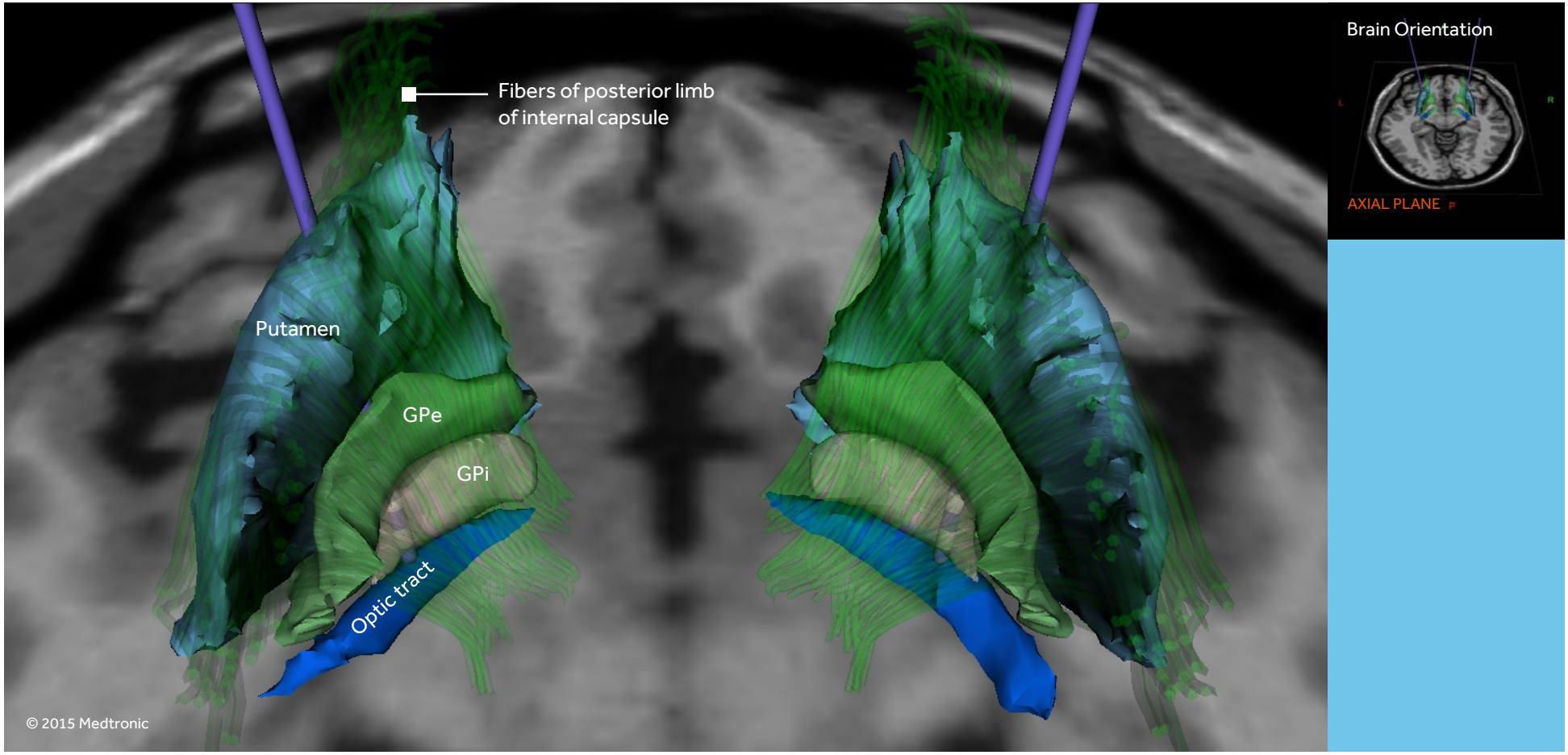
Further, Together

GPi: EFFECTIVELY-PLACED BILATERAL LEADS



- Medtronic DBS Lead Model 3387 shown in both hemispheres

Anatomy	Preferred Location for DBS Lead	Observed Effect if Stimulated
GPi	Posteroventral aspect of GPi	Reduction in parkinsonian symptoms or Reduction in dystonia symptoms following adequate duration of stimulation

Point to consider: The DBS lead may intentionally be placed slightly anterior or lateral in dystonia patients to allow for the use of higher voltages during programming.

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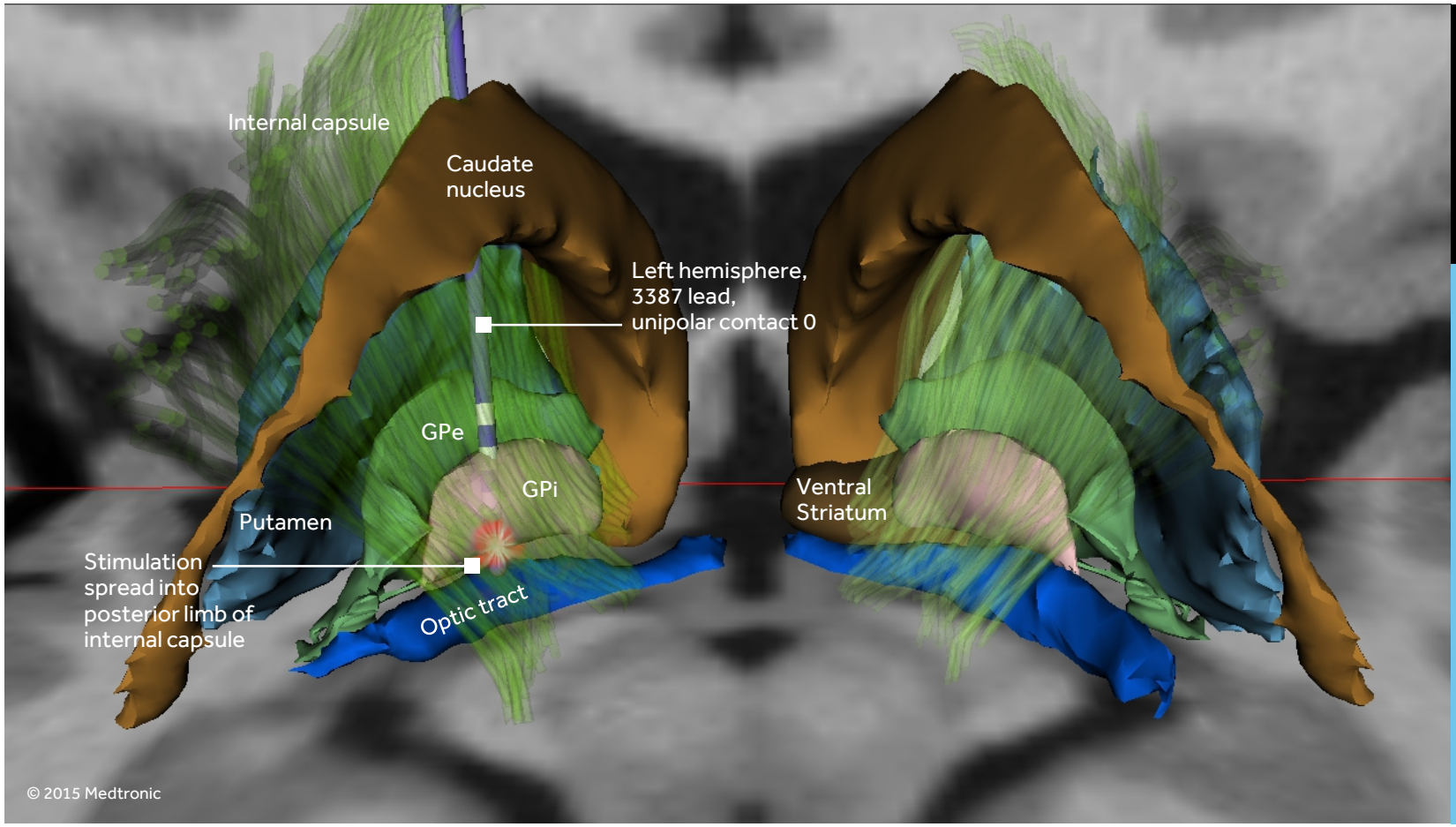
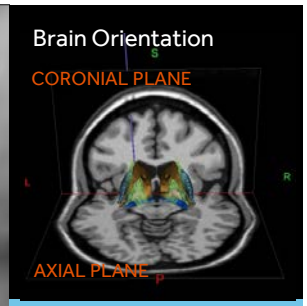
GPi: MEDIAL OBSERVED EFFECTS

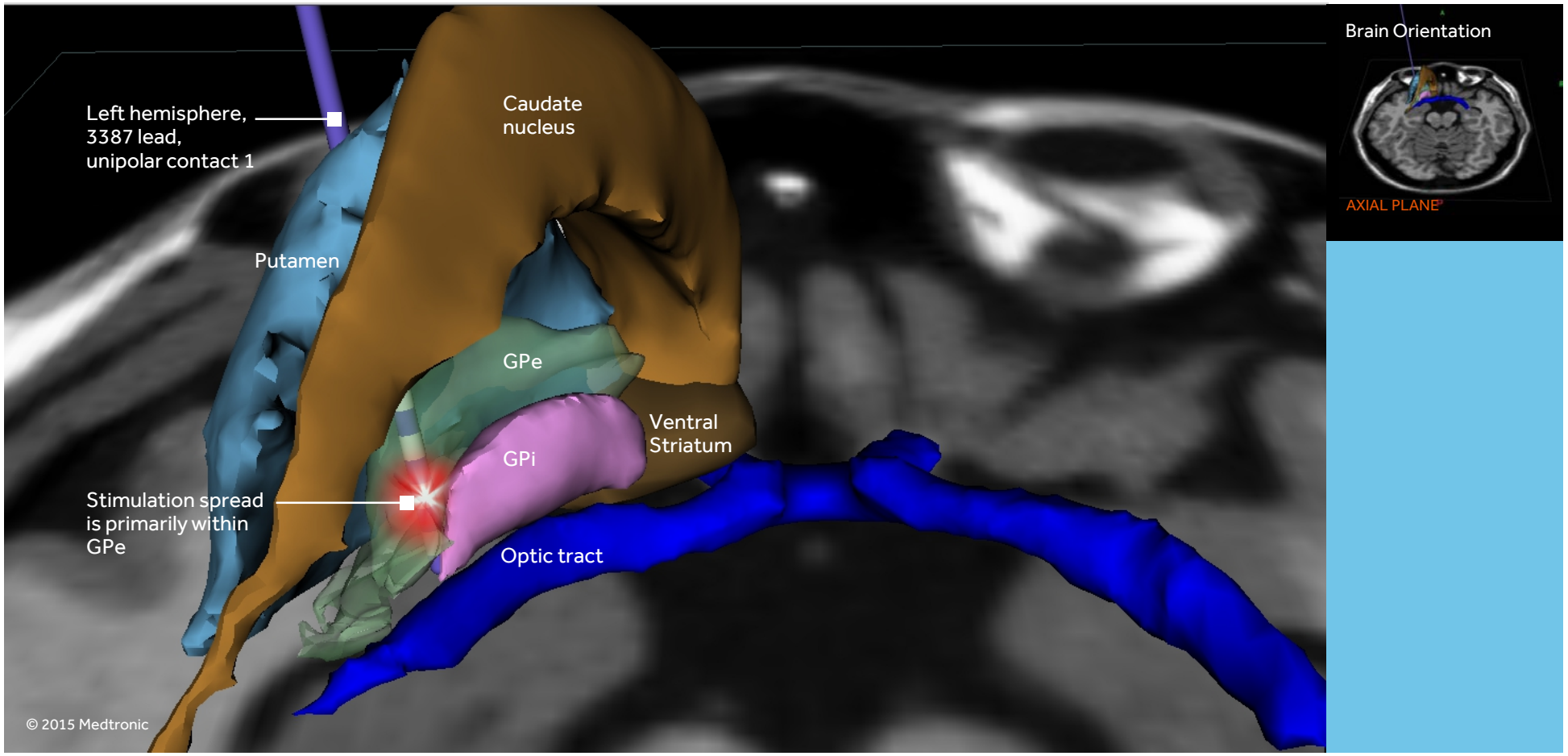




Anatomy	Location Relative to GPi	Observed Effect if Stimulated
Posterior limb of internal capsule	Medial and posterior	Muscle contractions

Medtronic

GPi: LATERAL OBSERVED EFFECTS



Anatomy	Location Relative to GPi	Observed Effect if Stimulated
GPe	Lateral and anterior	No effect (possible mild impact on symptoms)
Putamen	Lateral and anterior to GPe	No effect

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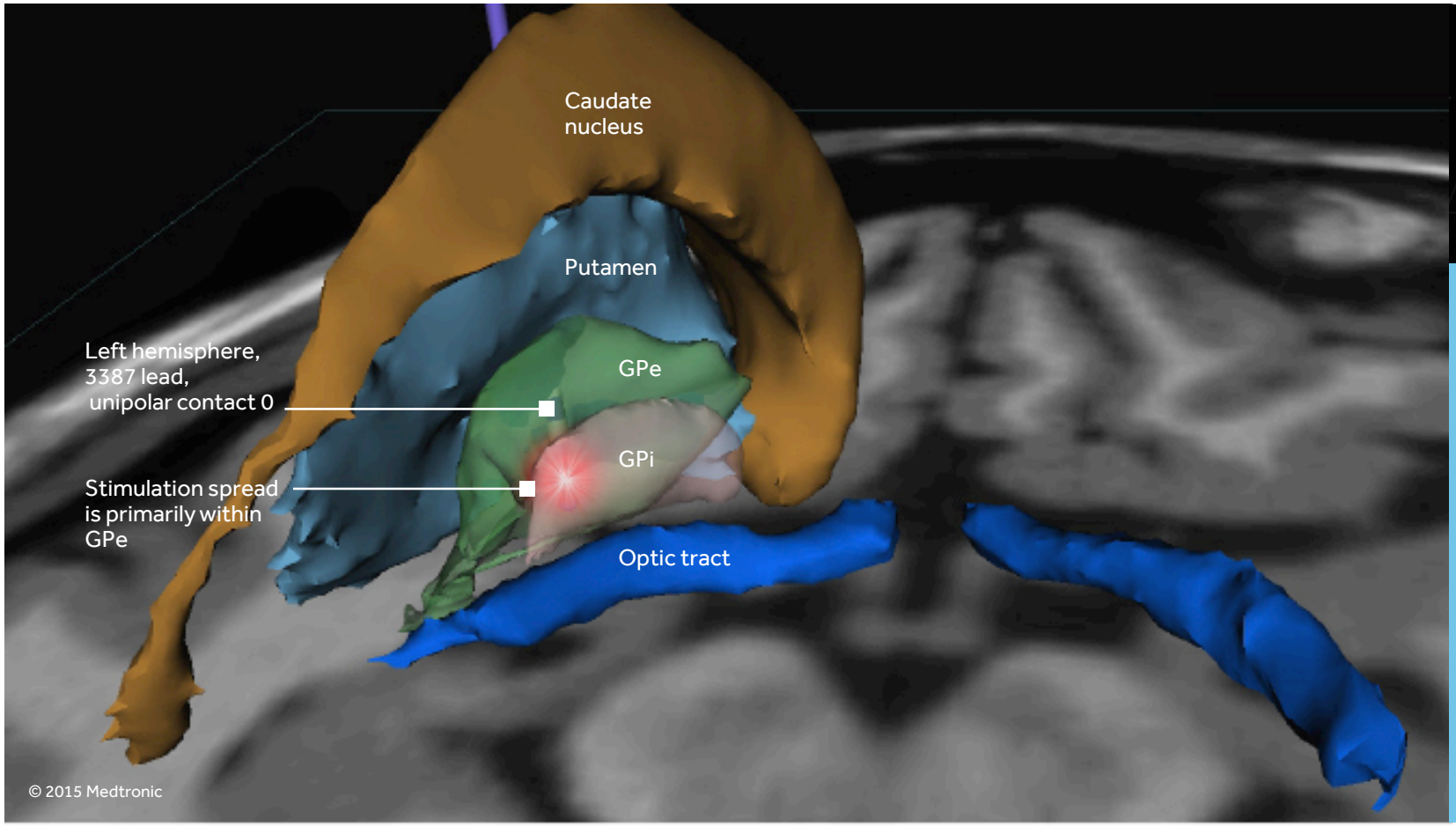
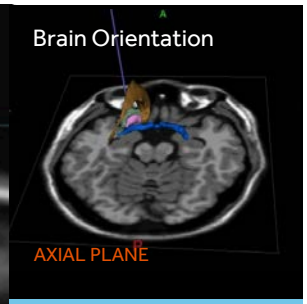
GPi: ANTERIOR OBSERVED EFFECTS

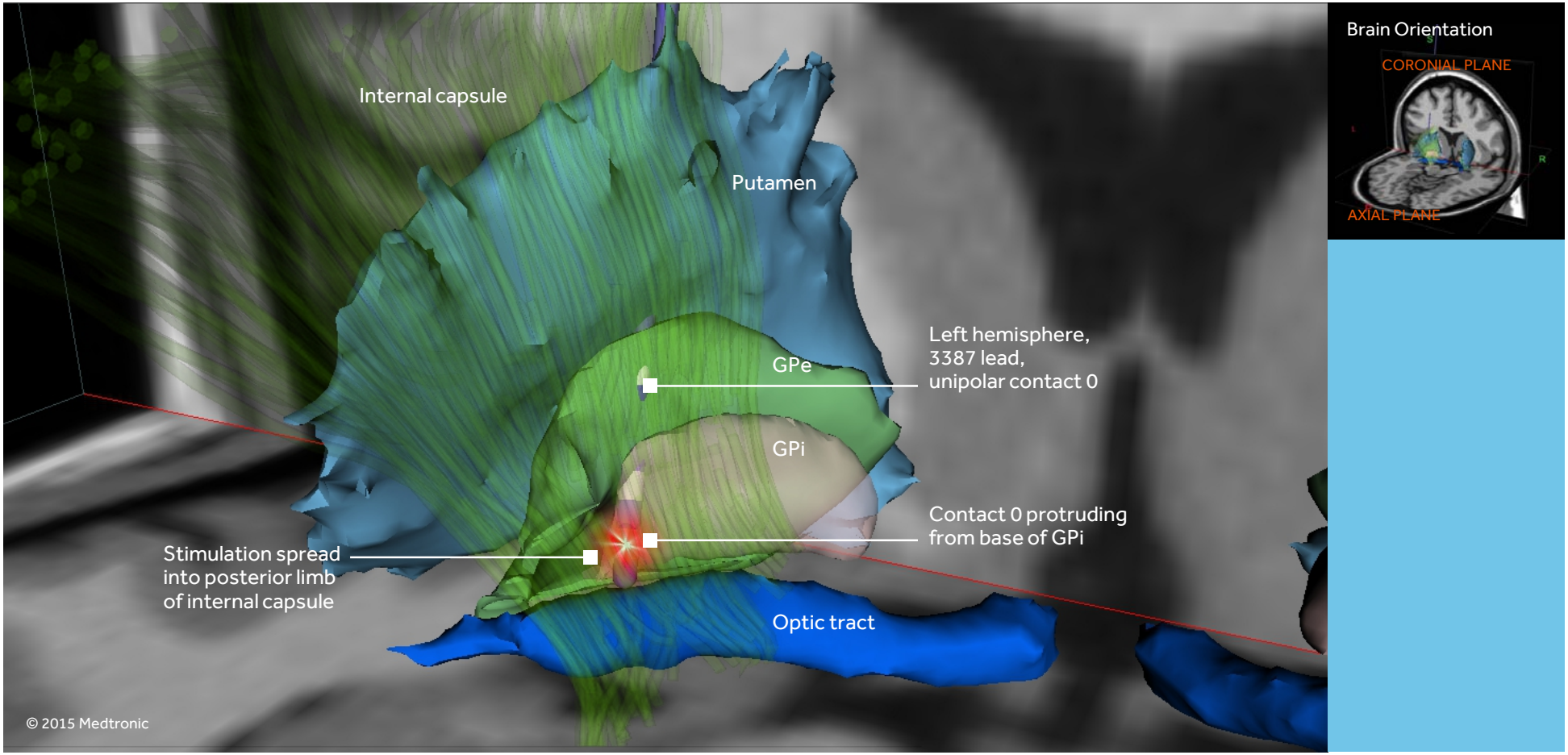




Anatomy	Location Relative to GPi	Observed Effect if Stimulated
GPe	Lateral and anterior	No effect
Putamen	Lateral and anterior to GPe	No effect

Medtronic

GPi: POSTERIOR OBSERVED EFFECTS



Anatomy	Location Relative to GPi	Observed Effect if Stimulated
Posterior limb of internal capsule	Medial and posterior	Muscle contractions

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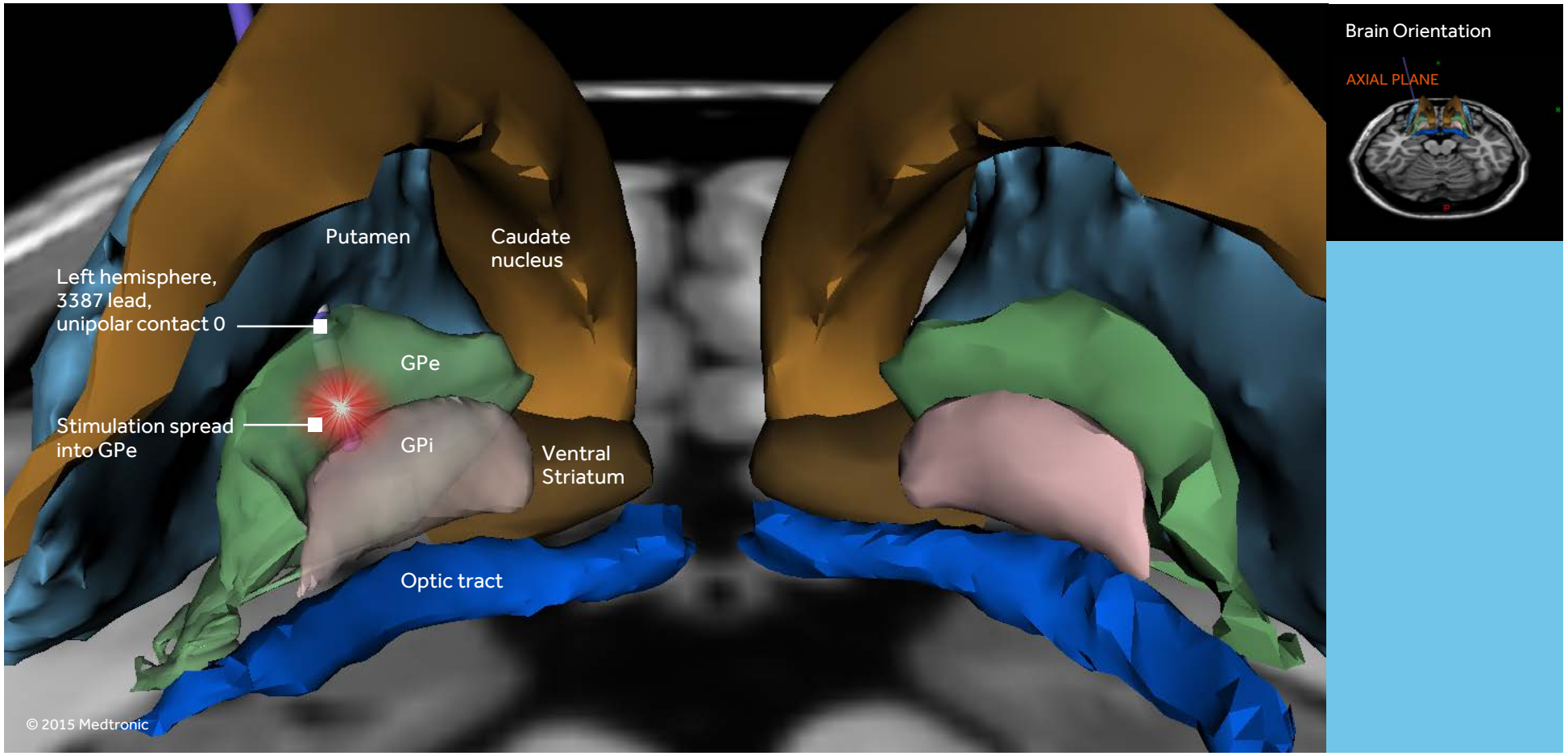
GPi: SUPERIOR (DORSAL) OBSERVED EFFECTS



Anatomy	Location Relative to GPi	Observed Effect if Stimulated
GPe	Lateral and anterior	No effect
Putamen	Lateral and anterior to GPe	No effect

*Point to consider: This example illustrates the DBS lead positioned dorsally along the **trajectory path**.*

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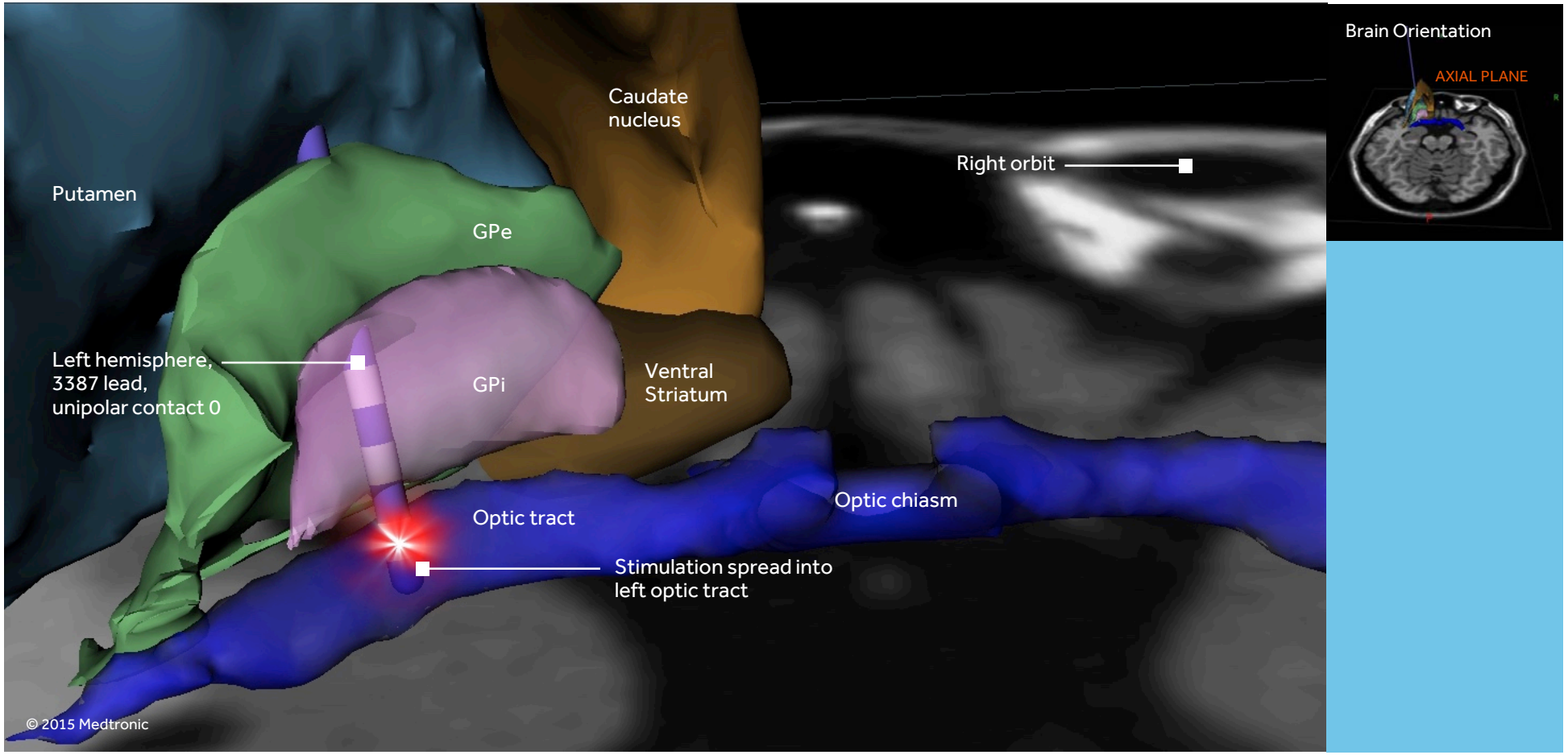
GPi: INFERIOR (VENTRAL) OBSERVED EFFECTS



Anatomy	Location Relative to GPi	Observed Effect if Stimulated
Optic tract	Inferior	Phosphenes (“flashing lights”) in contralateral visual hemifield

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VENTRALIS INTERMEDIUS (VIM) NUCLEUS OF THE THALAMUS

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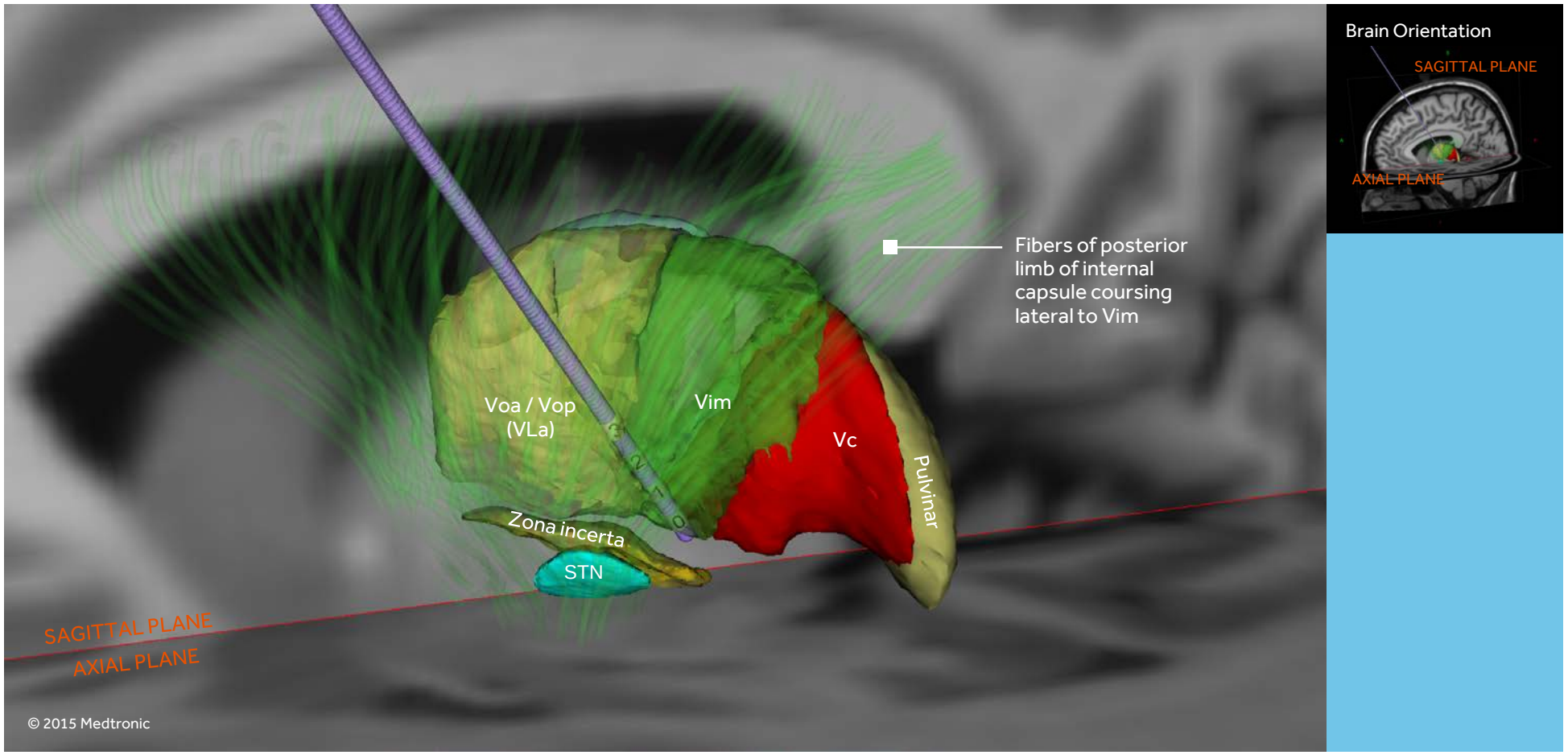
Further, Together

VIM: EFFECTIVELY-PLACED UNILATERAL LEAD



- Medtronic DBS Lead Model 3387 shown in left hemisphere
- Voa and Vop nuclei are shown as a single structure (Ventrolateral anterior (VLa) nucleus) throughout this document.

Anatomy	Preferred Location for DBS Lead	Observed Effect if Stimulated
Vim	Middle of nucleus, DBS tip 1-3 mm anterior to VC border, contact 0 at base of VIM	Tremor arrest

Point to consider: The Vim nucleus is somatotopically organized along a medial-lateral axis. Face/tongue representation is medial, foot is lateral.

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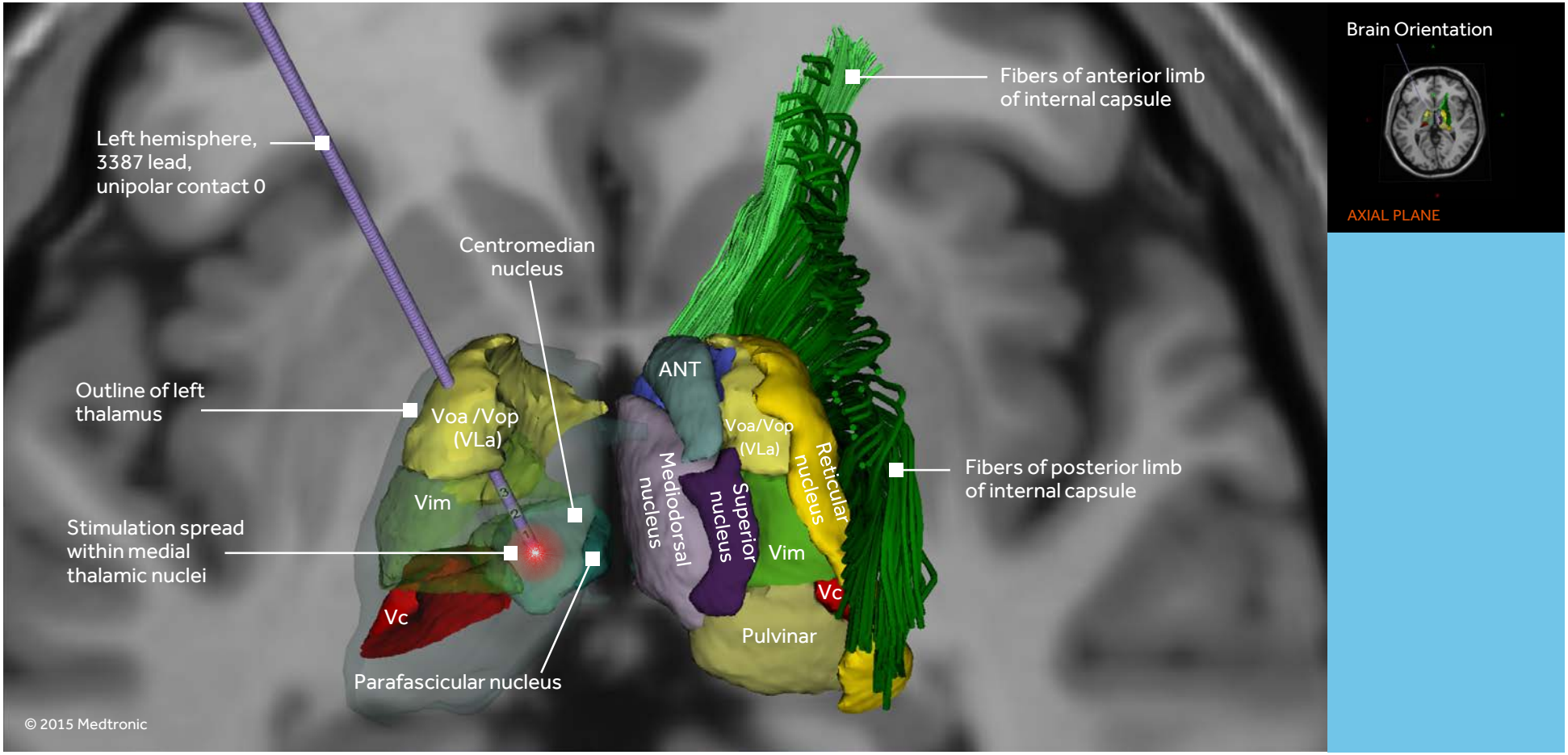
VIM: MEDIAL OBSERVED EFFECTS



- For clarity, only Vim, Vc, Voa/Vop and CM/Pf thalamic nuclei are shown in left hemisphere. Full thalamus shown in right hemisphere

Anatomy	Location Relative to Vim	Observed Effect if Stimulated
Medial Vim	Medial aspect of nucleus	Possible dysarthria in addition to tremor control
CM/Pf	Medial	No effect (possible impact on tremor)

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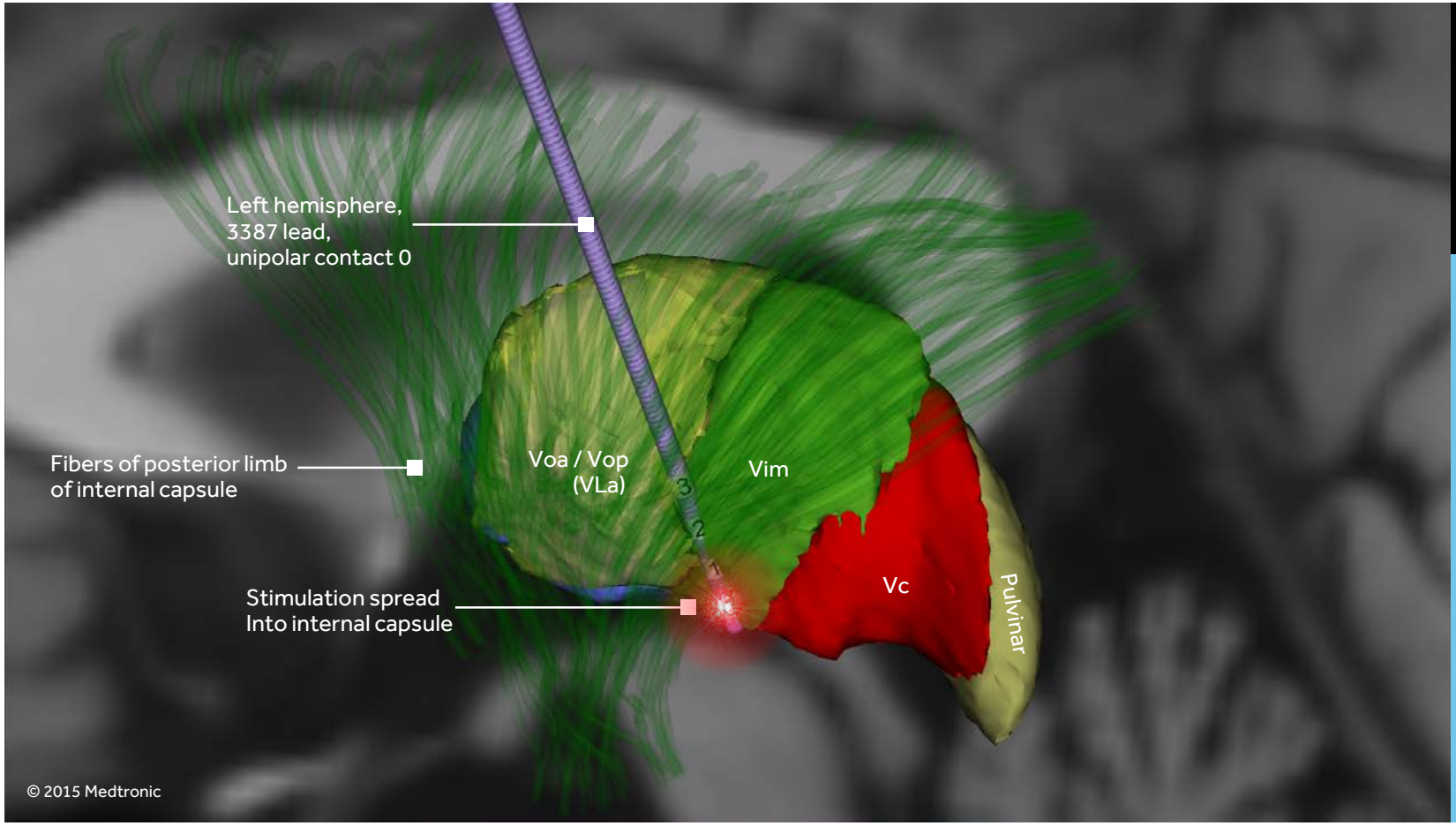
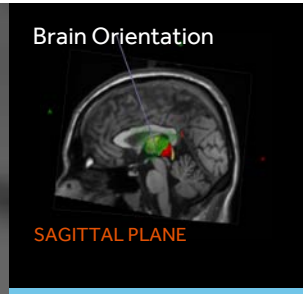
VIM: LATERAL OBSERVED EFFECTS





Anatomy	Location Relative to Vim	Observed Effect if Stimulated
Posterior limb of internal capsule	Lateral	Dysarthria, muscle contractions (contracting muscles correspond to the region of the capsular homunculus)

Point to consider: The internal capsule is somatotopically organized along an anterior-posterior axis. Face representation is anterior, foot is posterior.

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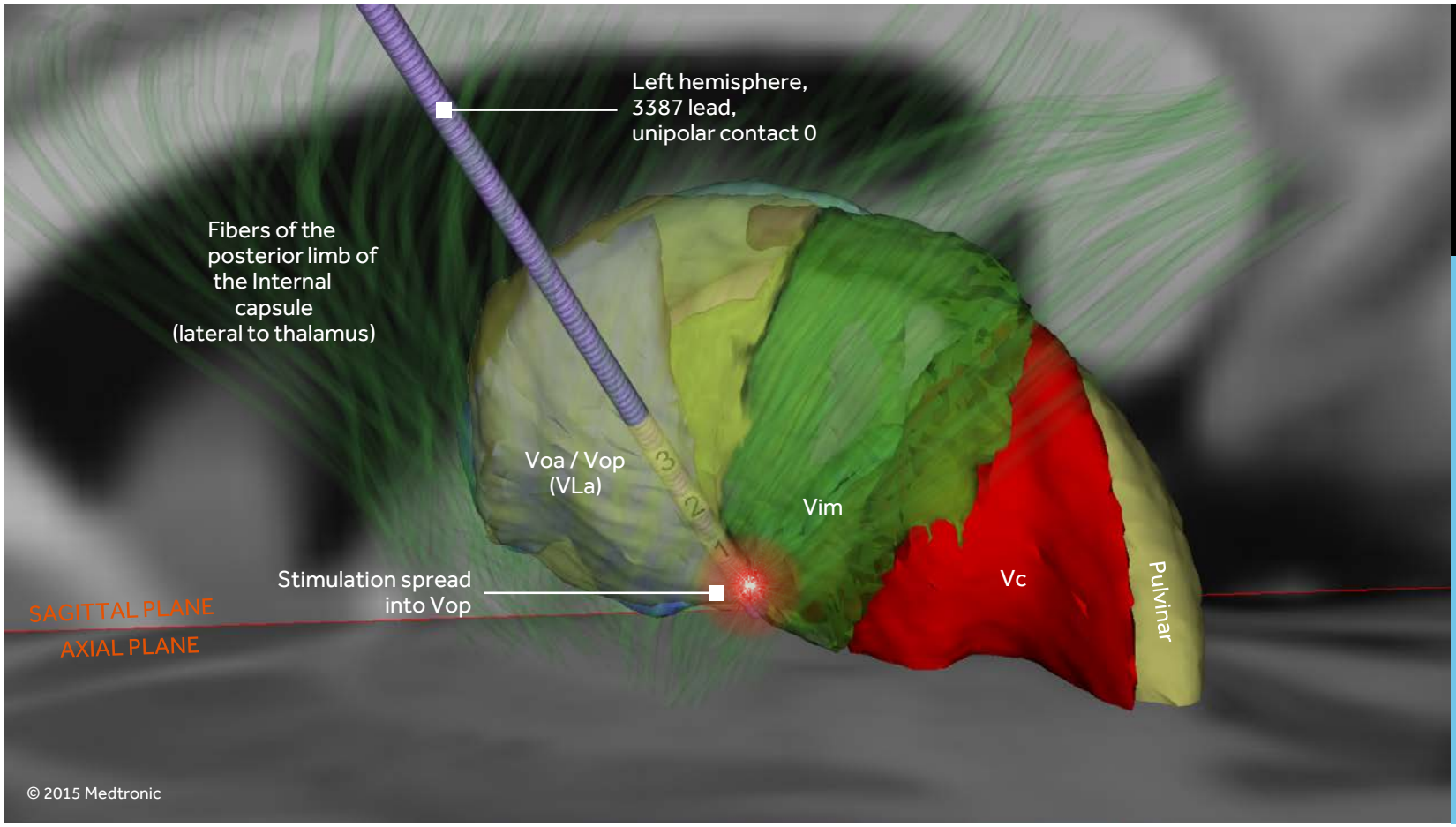
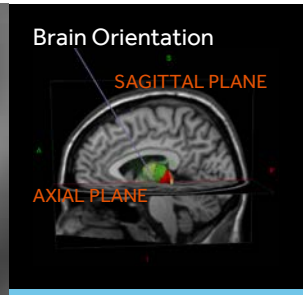
VIM: ANTERIOR OBSERVED EFFECTS

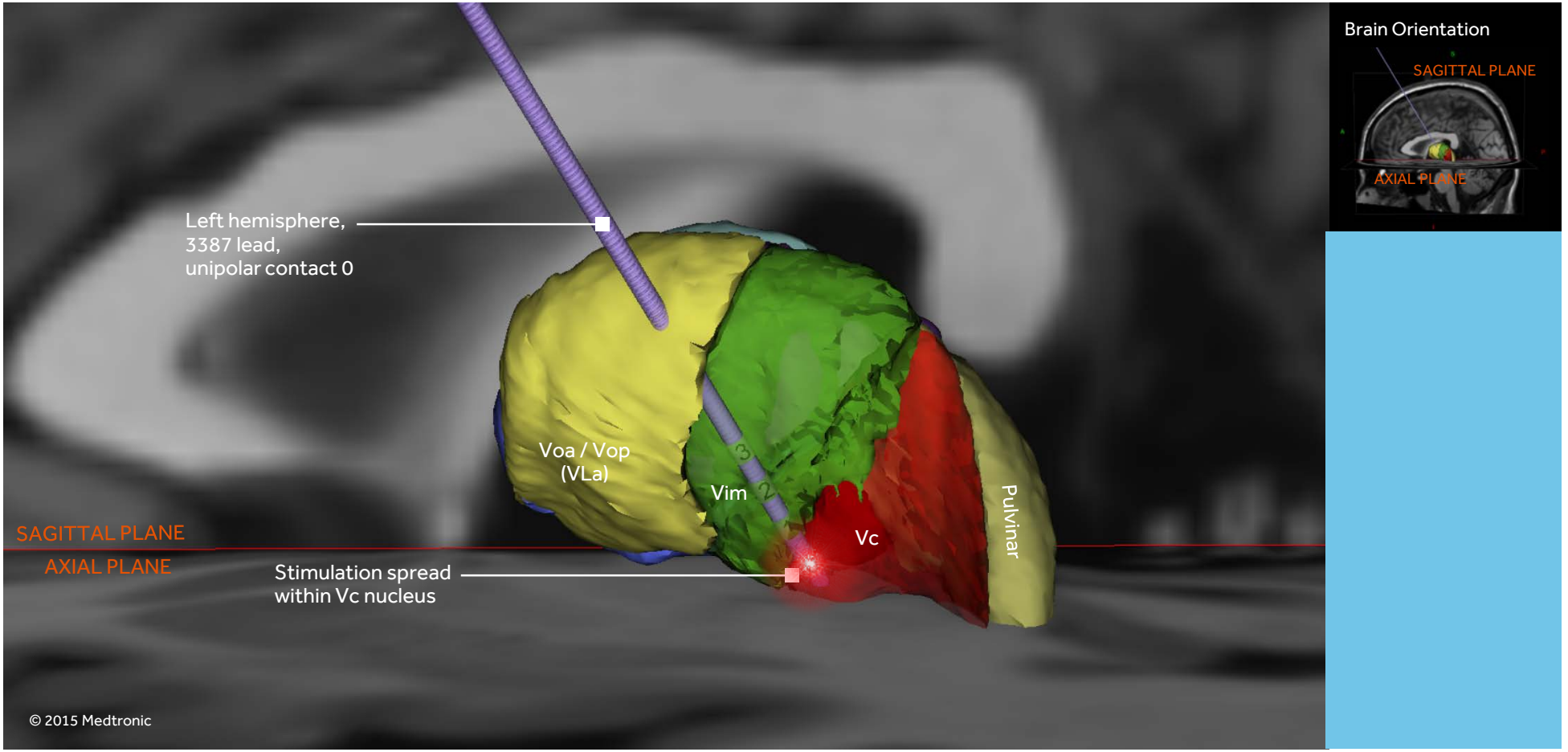




Anatomy	Location Relative to Vim	Observed Effect if Stimulated
Vop	Anterior	Possible reduction in tremor at voltages higher than typically used in Vim
Voa	Anterior to Vop	No effect

Medtronic

VIM: POSTERIOR OBSERVED EFFECTS



Anatomy	Location Relative to Vim	Observed Effect if Stimulated
Vc	Posterior	Paresthesias that increase in severity with increasing voltage

Points to consider: The Vc nucleus is somatotopically organized along a medial-lateral axis. Face/tongue representation is medial, foot is lateral. Transient paresthesias do not necessarily indicate a lead that is too posterior.

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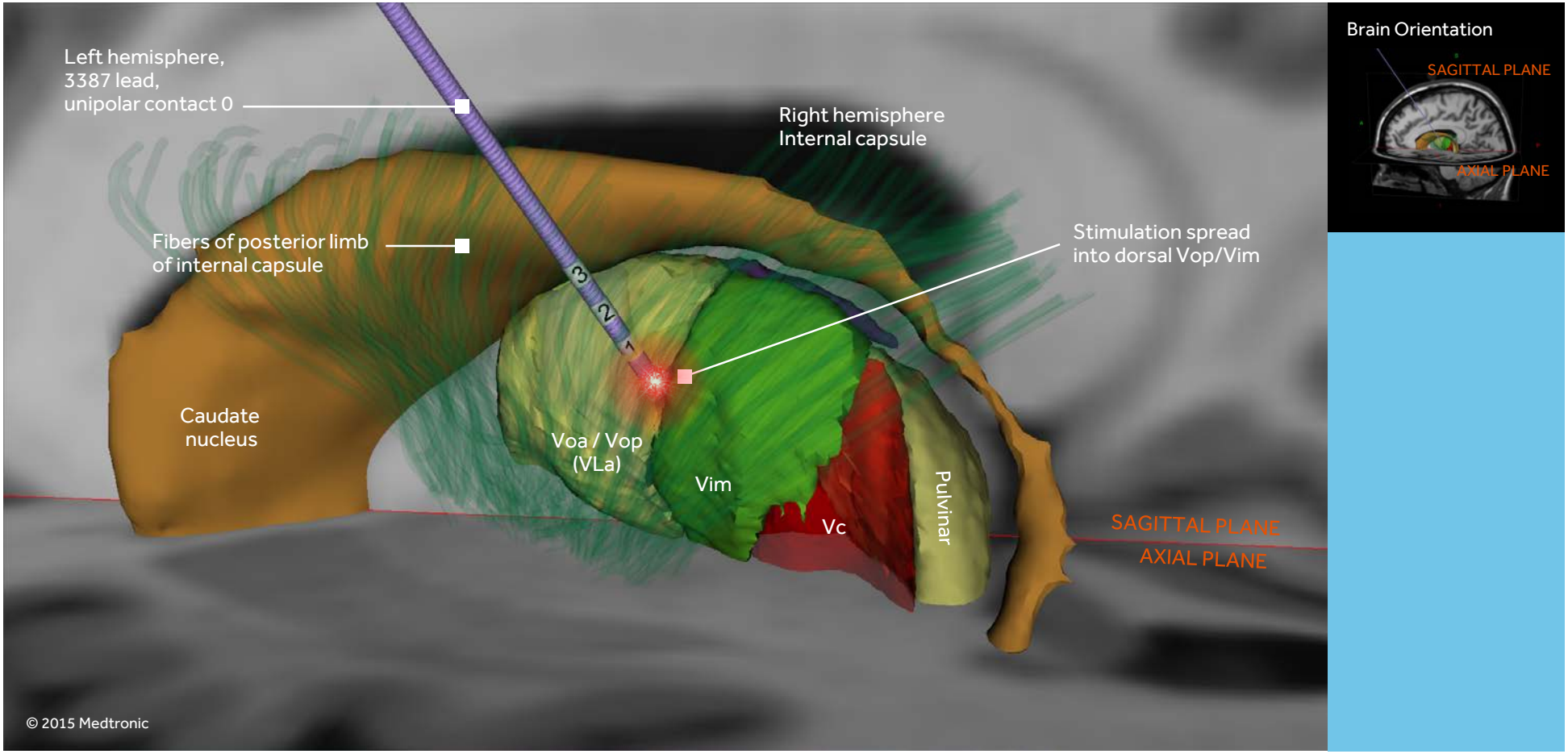
VIM: SUPERIOR (DORSAL) OBSERVED EFFECTS



Anatomy	Location Relative to Vim	Observed Effect if Stimulated
Dorsal thalamic nuclei	Dorsal	No effect
Dorsal Vop/VIM	Dorsal aspect	Possible impact on tremor at higher voltages
Internal capsule	Lateral and dorsal	Dysarthria, muscle contractions

*Point to consider: This example illustrates the DBS lead positioned dorsally along the **trajectory path**.*

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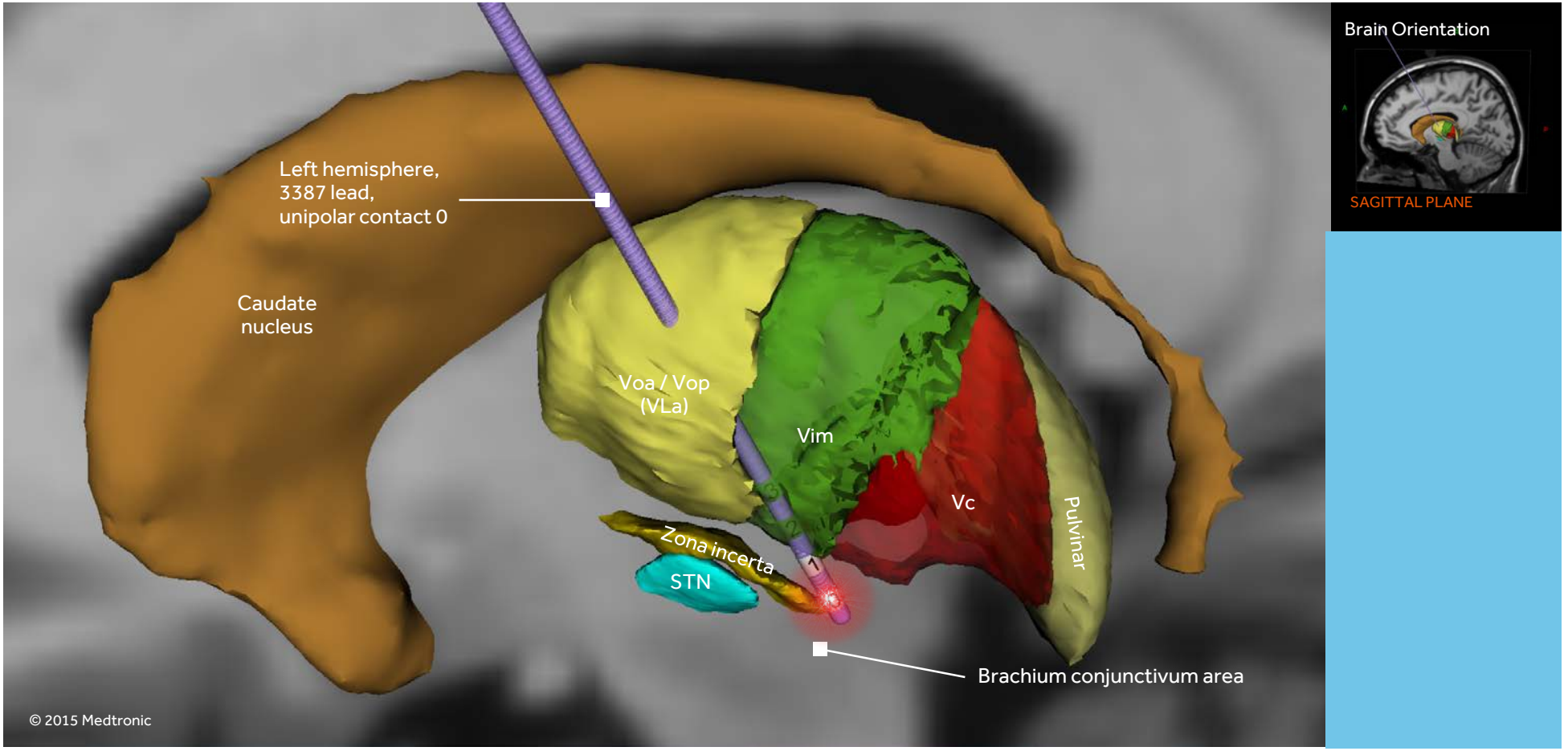
VIM: INFERIOR (VENTRAL) OBSERVED EFFECTS



Anatomy	Location Relative to Vim	Observed Effect if Stimulated
Brachium conjunctivum (cerebral fibers)	Ventral and medial	Ataxia
Zona incerta	Ventral	Possible impact on dyskinesias and/or tremor
Medial lemniscal pathway (not shown)	Ventral and posterior	Paresthesias
Internal capsule (not shown)	Ventral and lateral	Dysarthria, muscle contractions

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ANTERIOR NUCLEUS OF THE THALAMUS (ANT)

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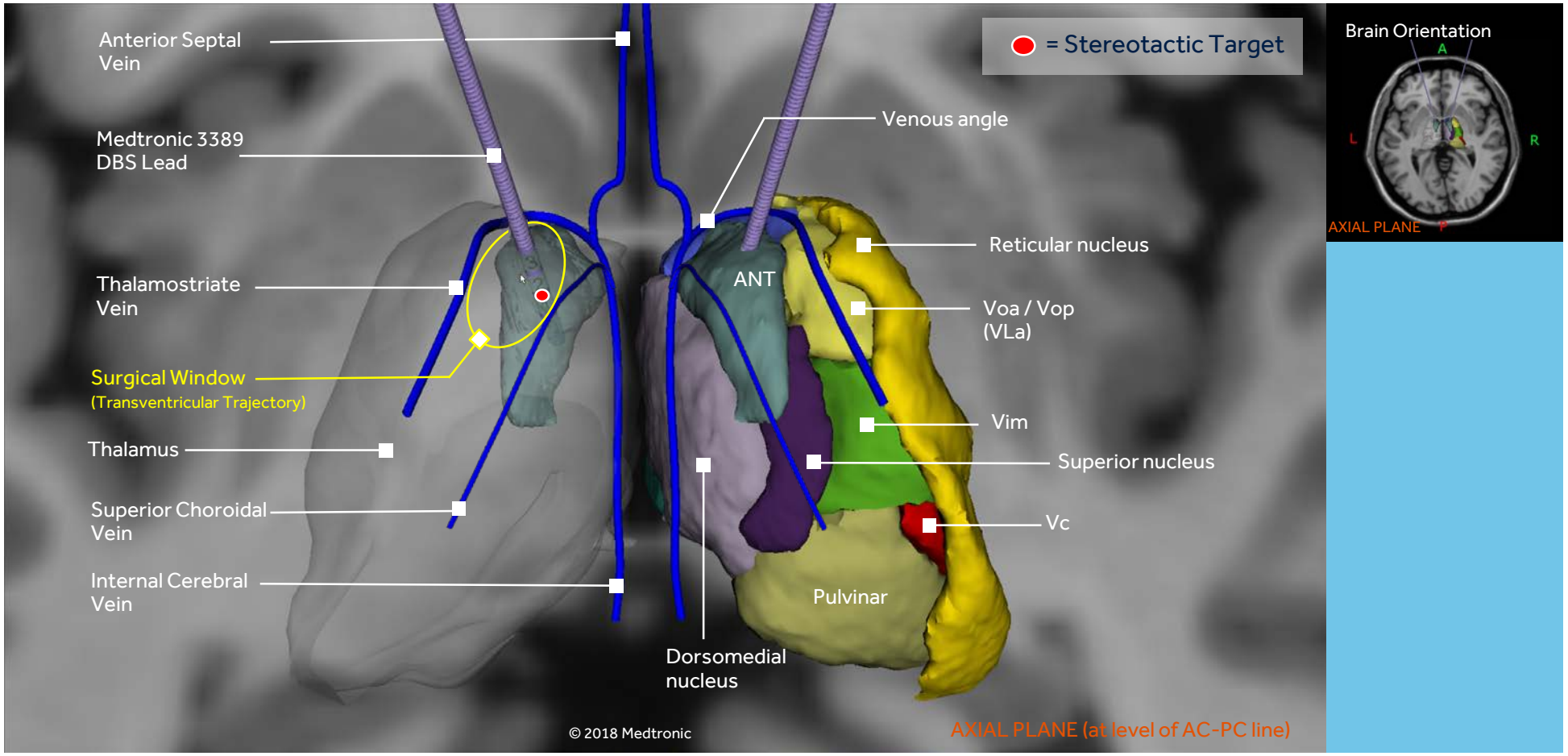
Further, Together

ANT: EFFECTIVELY-PLACED LEADS (DORSAL VIEW)

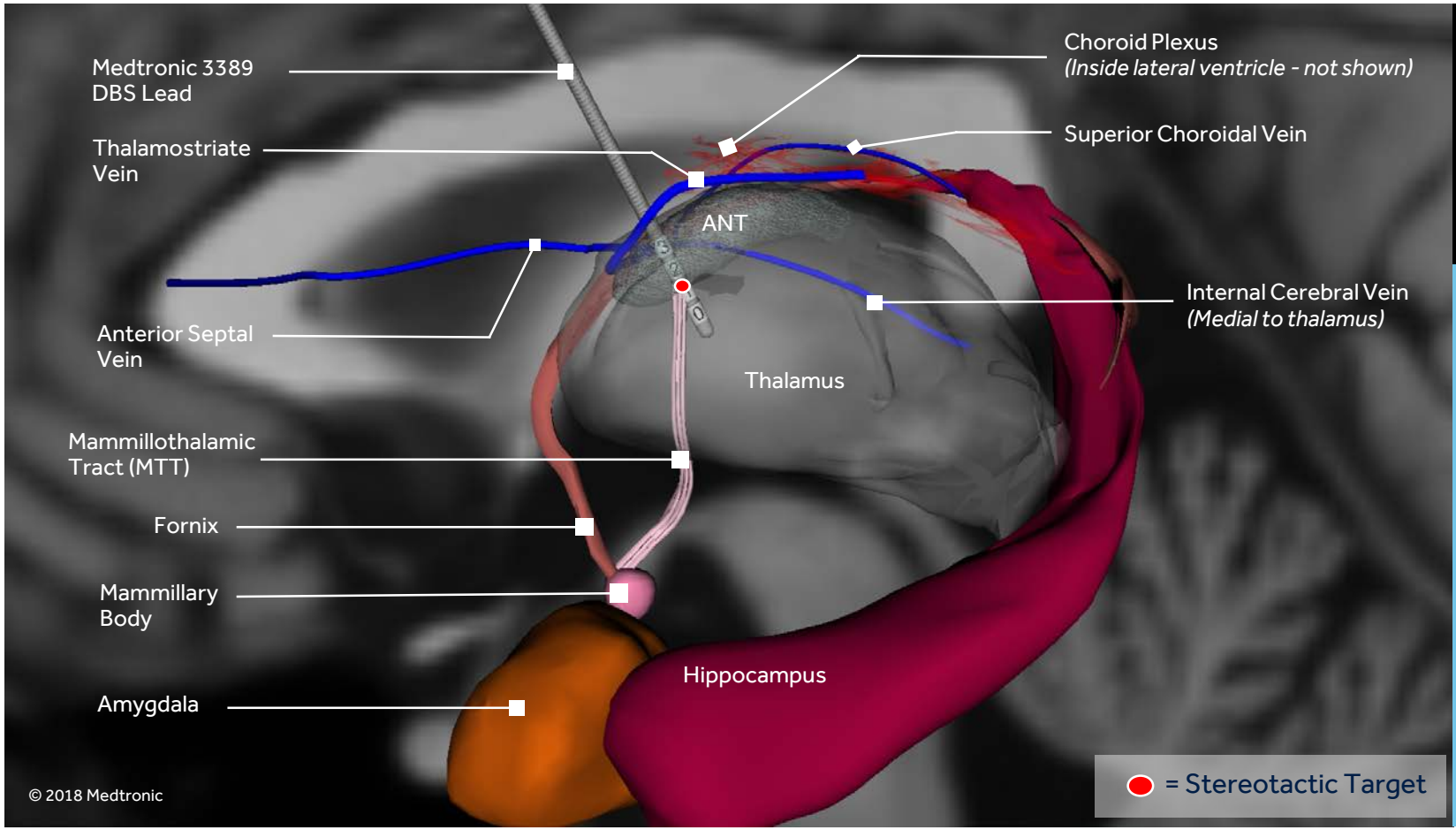


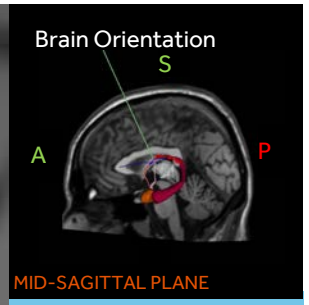
- Medtronic DBS Lead Model 3389 shown in both hemispheres. Only ANT is shown within left thalamus.
- Transventricular trajectory approach depicted
- Desired area for stimulation in this illustration is at contact(s) 2 and/or 3

Anatomy	Preferred Location for DBS Lead	Observed Effect if Stimulated
ANT	Surgical target at termination point of mammillothalamic tract. Lead implanted such that contacts 2 & 3 are within ANT (or contacts 1 & 2 if contact 3 is intentionally placed within the ventricle	Reduction in seizure frequency following adequate duration of stimulation

Medtronic

ANT: EFFECTIVELY-PLACED LEAD (LATERAL VIEW)





- Medtronic DBS Lead Model 3389 shown in left hemisphere. Only ANT is shown within the left thalamus to aid lead visualization.
- Transventricular trajectory approach shown.
- Desired area for stimulation in this illustration is at contact(s) 2 and/or 3

Anatomy	Preferred Location for DBS Lead	Observed Effect if Stimulated
ANT	Surgical target at termination point of mammillothalamic tract. Lead implanted such that contacts 2 & 3 are within ANT (or contacts 1 & 2 if contact 3 is intentionally placed within the ventricle	Reduction in seizure frequency following adequate duration of stimulation

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ANTERIOR LIMB OF THE INTERNAL CAPSULE (ALIC)

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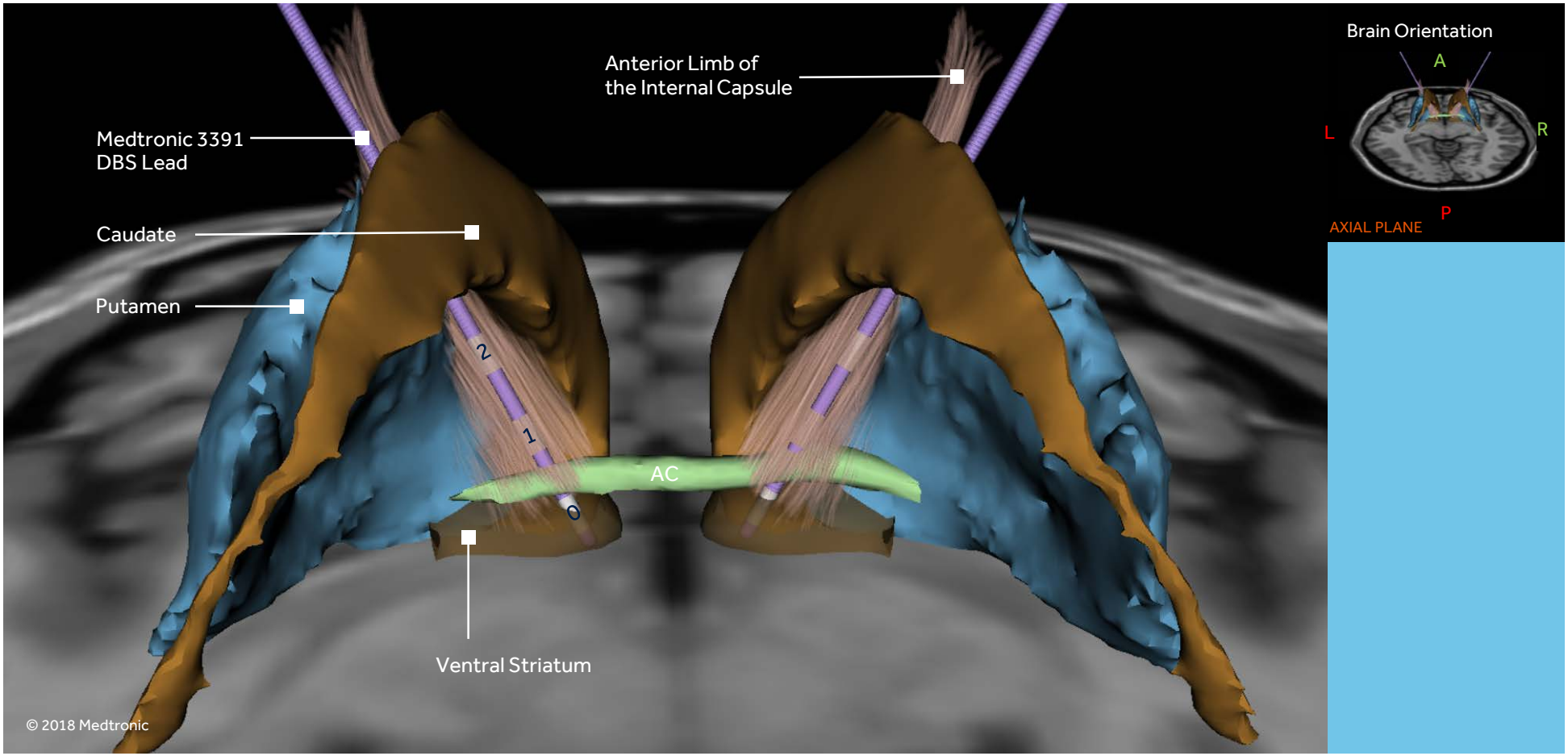
ALIC: EFFECTIVELY-PLACED LEADS



- Medtronic DBS Lead Model 3391 shown in both hemispheres. Contact 3 is within the anterior limb of the internal capsule but hidden behind the body of the caudate nucleus.

Anatomy	Preferred Location for DBS Lead	Observed Effect if Stimulated
VC/VS	Contacts 1, 2 & 3 within the anterior limb of the internal capsule. Contact 0 within the ventral striatum.	Reduction in OCD symptoms following adequate duration of stimulation

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ACRONYM LEGEND AND DISCLAIMER STATEMENT

AC/PC	Anterior Commissure/Posterior Commissure
ALIC	Anterior limb of the internal capsule
ALO	Apraxia of eyelid opening
ANT	Anterior nucleus of the thalamus
CM/Pf	Centromedian/Parafascicular complex
CN	Cranial nerve
DBS	Deep brain stimulation
GPe	Globus Pallidus externus
GPi	Globus Pallidus internus
MTT	Mammillothalamic tract
SNc	Substantia nigra pars compacta
SNr	Substantia nigra pars reticulata
STN	Subthalamic Nucleus
Vc	Ventralis caudalis nucleus
Vim	Ventralis intermedius
VLa	Ventrolateral anterior nucleus
Voa	Ventralis oralis anterior nucleus
Vop	Ventralis oralis posterior nucleus
ZI	Zona Incerta

Disclaimer Statement: The effects of stimulation due to sub-optimal lead placement in this presentation are for reference and training purposes only. Side effects observed may be the result of incorrect stimulation parameters being applied in addition to, or instead of, a misplaced lead. Consider orientation of the DBS lead within the brain when determining a stimulation strategy (for example, dorsal lead contacts are always more anterior and typically more lateral within the brain than ventral lead contacts).

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- 3D DBS Simulator developed by Kirk W. Finnis, ©2006 Medtronic

- *MRI Source:* Holmes CJ, Hoge R, Collins L, Woods R, Toga AW, Evans AC. Enhancement of MR images using registration for signal averaging. J Comput Assist Tomogr. 1998:22(2):324-333

BRIEF STATEMENT: MEDTRONIC DBS THERAPY FOR PARKINSON'S DISEASE, TREMOR AND DYSTONIA

Medtronic DBS Therapy for Parkinson's Disease, Tremor and Dystonia: Product labeling must be reviewed prior to use for detailed disclosure of risks.

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 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.

Medtronic DBS Therapy for 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 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.

Medtronic DBS Therapy for Dystonia: Unilateral or bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) using Medtronic DBS Therapy for Dystonia is indicated as an aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis), in patients seven years of age or above.

Contraindications: Medtronic DBS Therapy is contraindicated for patients who are unable to properly operate the neurostimulator and, for Parkinson's disease and Essential Tremor, 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 they have an implanted Soletra™ Model 7426 Neurostimulator, Kinetra™ Model 7428 Neurostimulator, Activa™ SC Model 37602 Neurostimulator, or Model 64001 or 64002 pocket adaptor.

BRIEF STATEMENT: MEDTRONIC DBS THERAPY FOR PARKINSON'S DISEASE, TREMOR AND DYSTONIA

Warnings and Precautions: There is a potential risk of brain tissue damage using stimulation parameter settings of high amplitudes and wide pulse widths and, for Parkinson's disease and essential tremor, 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 should be avoided as it may cause a return of disease symptoms, in some cases with intensity greater than was experienced prior to system implant ("rebound" effect). Onset of status dystonicus, which may be life-threatening, may occur in dystonia patients during ongoing or loss of DBS therapy. Patients using a rechargeable neurostimulator for Parkinson's disease or Essential Tremor should check for skin irritation or redness near the neurostimulator during or after recharging, and contact their physician if symptoms persist. Loss of coordination in activities such as swimming may occur. 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.

BRIEF STATEMENT: MEDTRONIC DBS THERAPY FOR PARKINSON'S DISEASE, TREMOR AND DYSTONIA

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 previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression, or patients who are pregnant. Parkinson's disease and essential tremor: safety and effectiveness has not been established for patients under 18 years or patients with neurological disease other than idiopathic Parkinson's disease or Essential Tremor. Essential tremor: safety and effectiveness has not been established for bilateral stimulation or for patients over 80 years of age. Dystonia: age of implant is suggested to be that at which brain growth is approximately 90% complete or above.

Humanitarian Device (Dystonia): Authorized by Federal Law as an aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis), in patients seven years of age or above. The effectiveness of the devices for treating these conditions has not been demonstrated.

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Medtronic

BRIEF STATEMENT: MEDTRONIC DBS THERAPY FOR EPILEPSY

Medtronic DBS Therapy for Epilepsy: Product labeling must be reviewed prior to use for detailed disclosure of risks.

Indications: Bilateral stimulation of the anterior nucleus of the thalamus (ANT) using the Medtronic DBS System for Epilepsy is indicated as an adjunctive therapy for reducing the frequency of seizures in individuals 18 years of age or older diagnosed with epilepsy characterized by partial-onset seizures, with or without secondary generalization, that are refractory to three or more antiepileptic medications.

The Medtronic DBS System for Epilepsy has demonstrated safety and effectiveness for patients who average six or more seizures per month over the three most recent months prior to implant of the DBS system (with no more than 30 days between seizures). The Medtronic DBS System for Epilepsy has not been evaluated in patients with less frequent seizures.

Contraindications: Medtronic DBS Therapy is contraindicated for patients who are unable to properly operate the neurostimulator. 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™ Model 7426 Neurostimulator, Kinetra™ Model 7428 Neurostimulator, Activa™ SC Model 37602 Neurostimulator, or Model 64001 or 64002 pocket adaptor.

BRIEF STATEMENT: MEDTRONIC DBS THERAPY FOR EPILEPSY

Warnings and Precautions: There is a potential risk of brain 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. 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. Cessation, reduction, or initiation of stimulation may potentially lead to an increase in seizure frequency, severity, and new types of seizures. Symptoms may return with an intensity greater than was experienced prior to system implant, including the potential for status epilepticus. Loss of coordination in activities such as swimming may occur. Depression, suicidal ideations and suicide have been reported in patients receiving Medtronic DBS Therapy for Epilepsy, although no direct cause-and-effect relationship has been established. Preoperatively, assess patients for depression and carefully balance this risk with the potential clinical benefit. Postoperatively, monitor patients closely for new or changing symptoms of depression and manage these symptoms appropriately. Patients should be monitored for memory impairment. Memory impairment has been reported in patients receiving Medtronic DBS Therapy for Epilepsy, although no direct cause and effect relationship has been established. The consequences of failing to monitor patients are unknown. When stimulation is adjusted, monitor patients for new or increased seizures, tingling sensation, change in mood, or confusion.

Medtronic

BRIEF STATEMENT: MEDTRONIC DBS THERAPY FOR EPILEPSY

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.

The safety and effectiveness of this therapy has not been established for patients without partial-onset seizures, patients who are pregnant or nursing, patients under the age of 18 years, patients with coagulopathies, and patients older than 65 years.

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