



INSIGHTEC

January 2025

Transforming tomorrows, today.

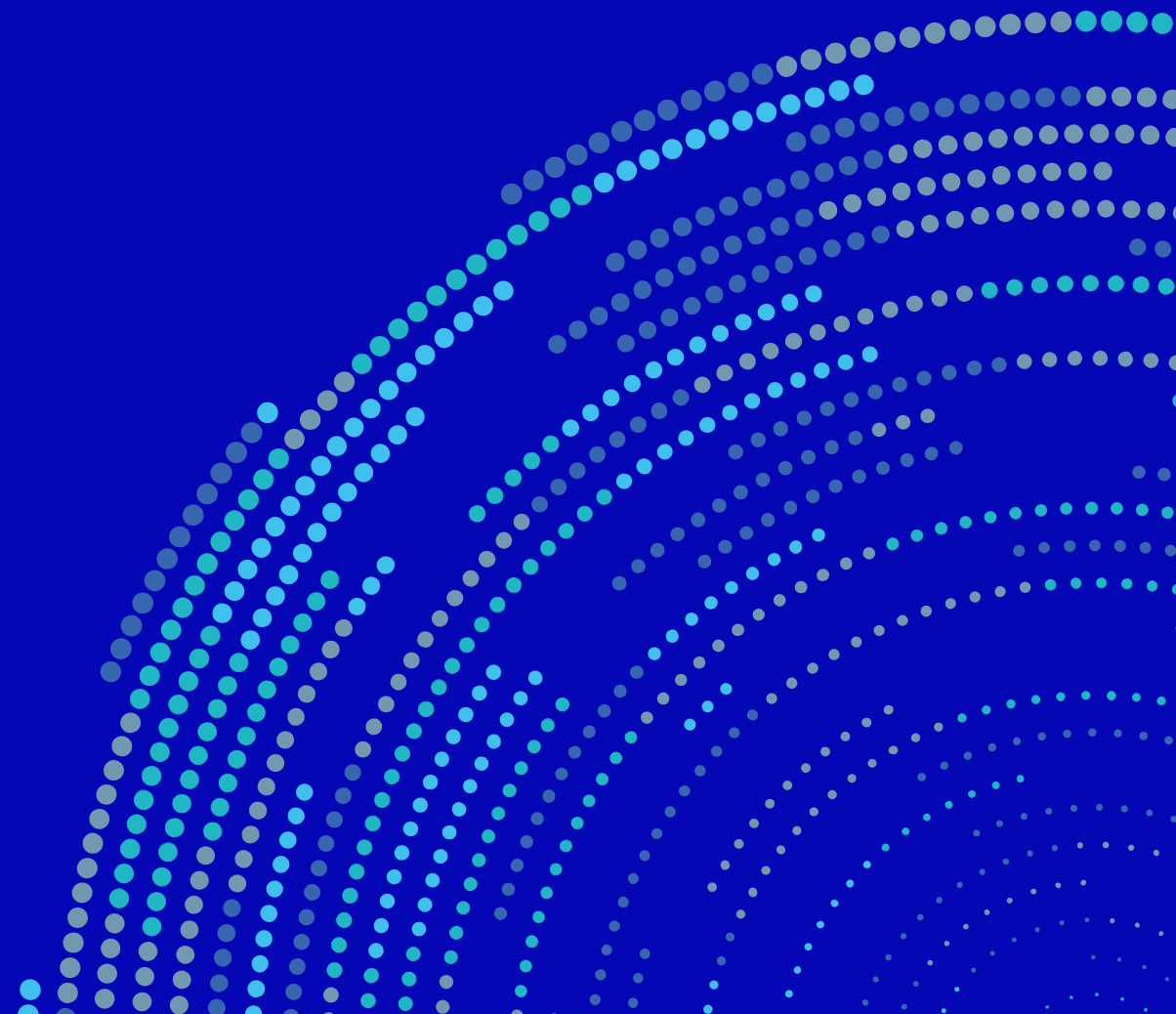


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This presentation also contains statistical data, estimates and forecasts that are based on independent industry publications or other publicly available information, as well as other information based on our internal sources. This information involves many assumptions and limitations, and you are cautioned not to give undue weight to such information. We have not independently verified the accuracy or completeness of the information contained in the industry publications and other publicly available information. Accordingly, we make no representations as to the accuracy or completeness of that information nor do we undertake to update such information after the date of this presentation.

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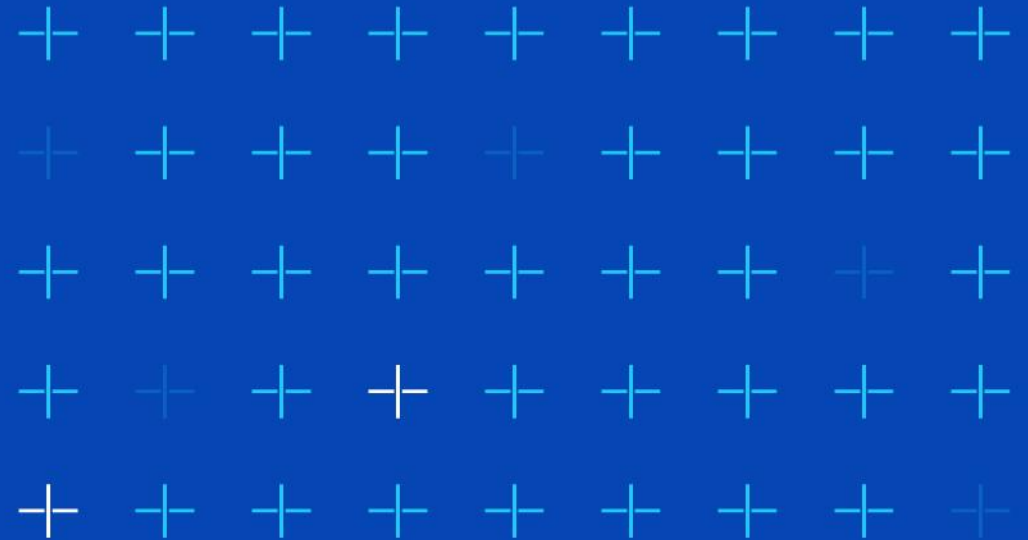






# OUR MISSION

To transform lives by delivering  
the therapeutic power of  
acoustic energy.

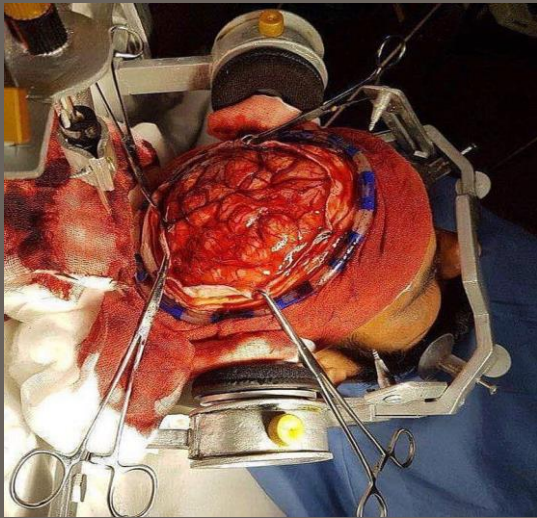




# THE EVOLUTION TO THERAPEUTIC ULTRASOUND

## TRANSFORMING NEUROSURGERY

**OPEN SURGERY**



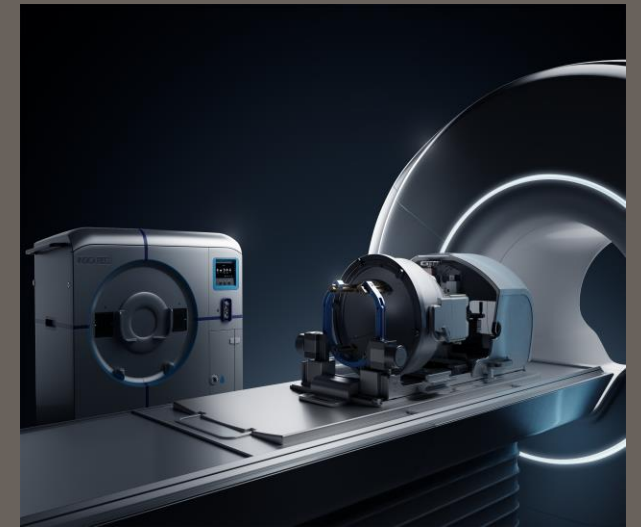
**MINIMALLY INVASIVE**



**ROBOTIC SURGERY**



**FOCUSED ULTRASOUND –  
Incisionless surgery**



**TODAY**





# OUR TECHNOLOGY | HOW IT WORKS





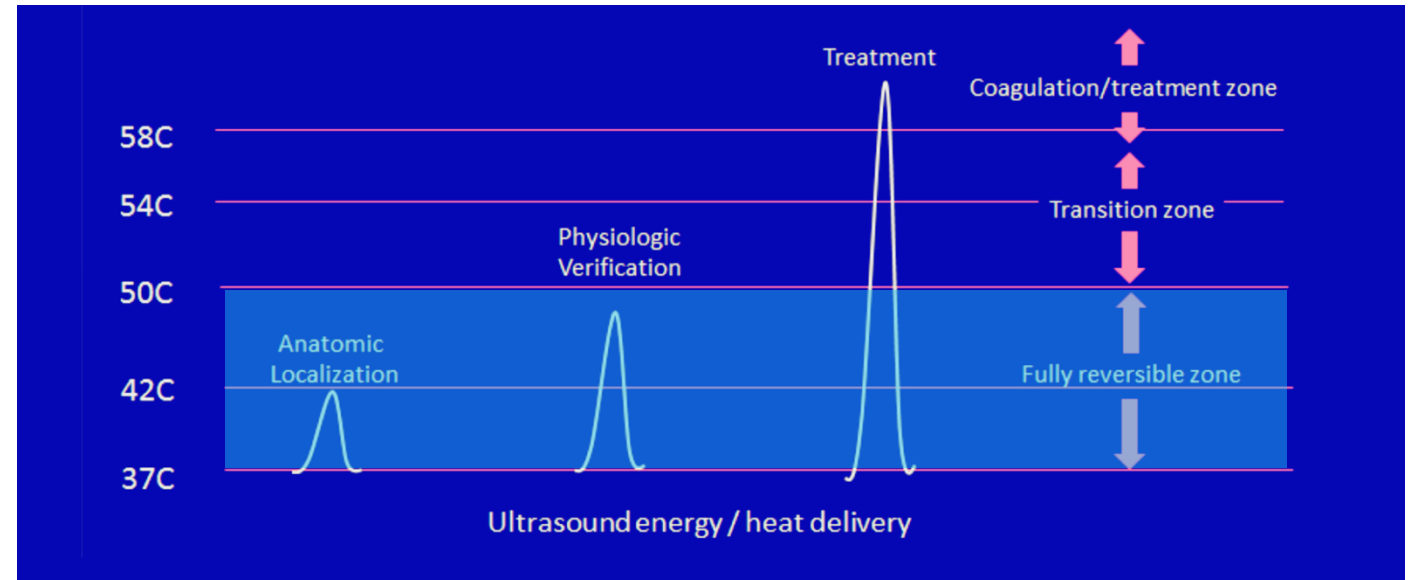
## OUR TECHNOLOGY | ADVANTAGES

### INCISIONLESS NEUROSURGERY PLATFORM

Insightec's Magnetic Resonance  
guided Focused Ultrasound

## Overview\*

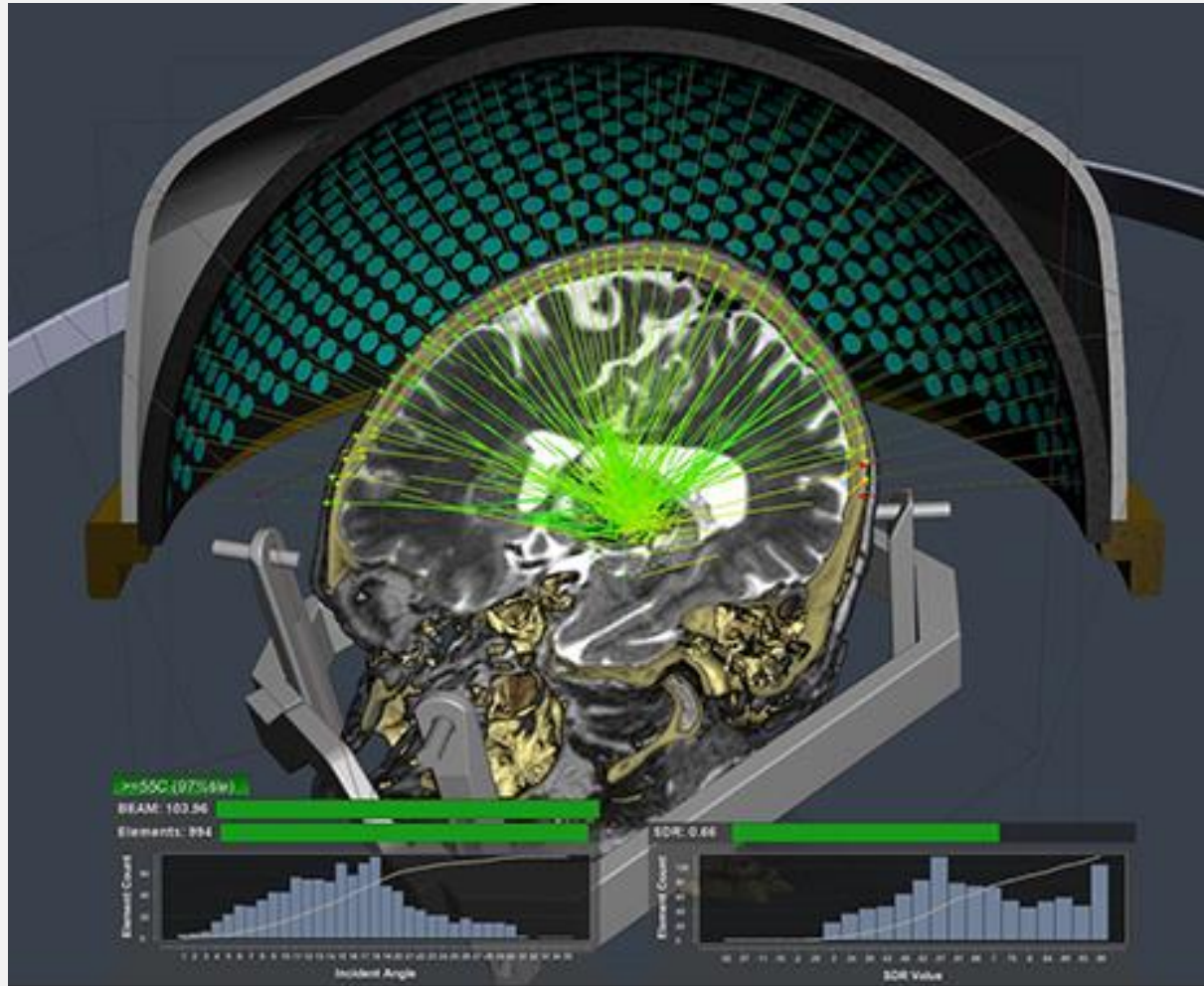
- Safely transverse the skull with no incisions and therefore no risk of infection
- Precise sub-millimetric control
- Real-time assessment of side effects and benefit\*
- Precise adjustments before final ablation
- Immediate outcomes
- Quick recovery-Outpatient procedure



\*Majority of side effects from the pivotal trial were mild or moderate and progressively resolved over time. [Pre-Market Approval \(PMA\) P150038/S015](#). Based on data from 76-patients enrolled in randomized controlled trial.



# OUR TECHNOLOGY | ESSENTIAL TREMOR PATIENT EXPERIENCE



## PERSONALIZED PRECISION

Hemispheric Ultrasound Array + Thermometry



## PATIENT RESULTS\*

Before + After Exablate Neuro

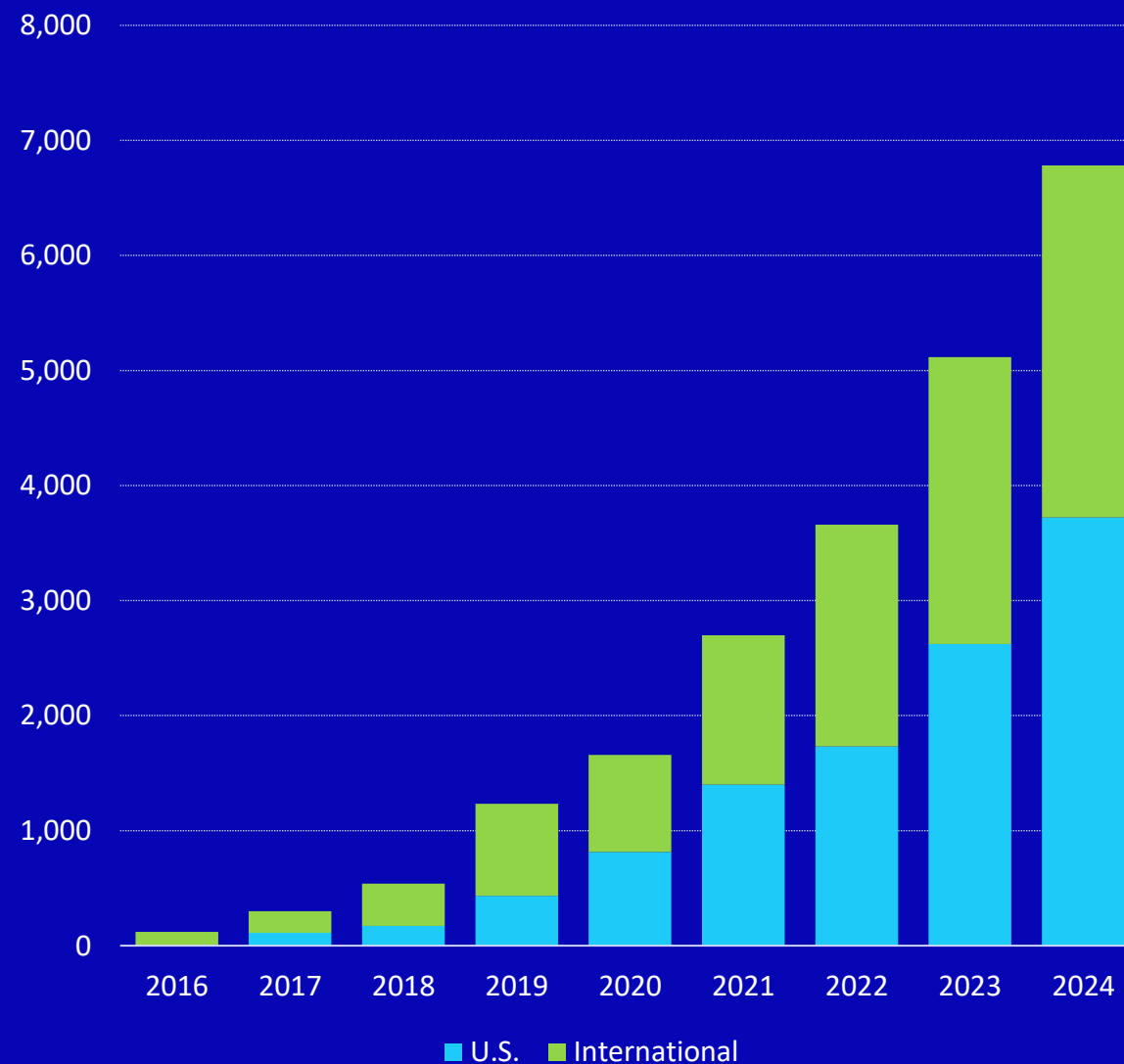


# MOVEMENT DISORDERS | GLOBAL COMMERCIAL PROCEDURES

PROCEDURES

> 22,000

Commercial treatments to date\*



# MOVEMENT DISORDERS | COMMERCIAL INSTALLED BASE





# MOVEMENT DISORDERS | AN UNDERSERVED POPULATION

**97%\***

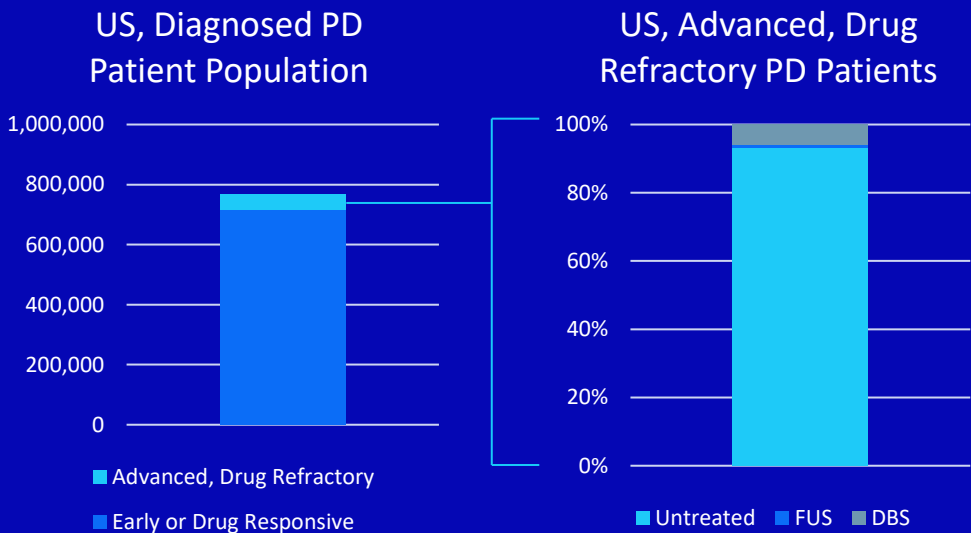
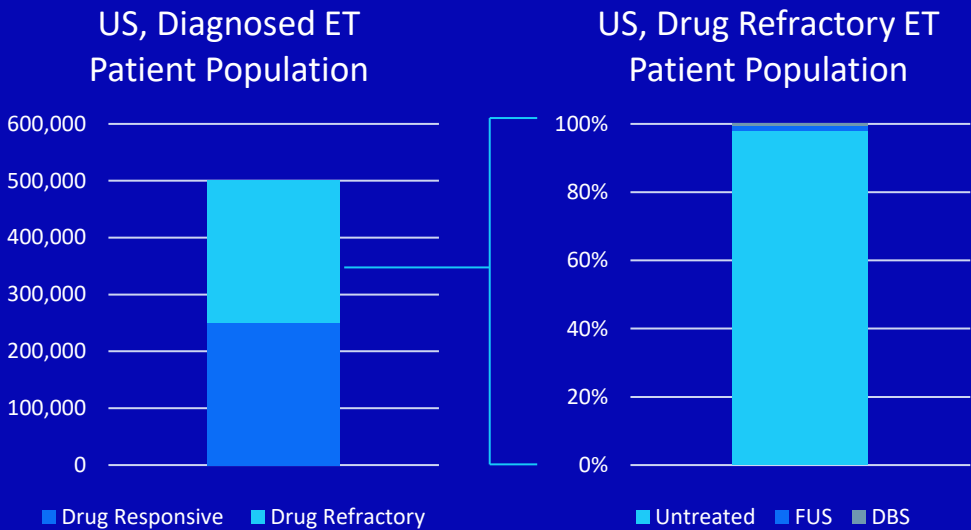
Of movement disorder patients eligible  
for advanced therapies remain  
untreated







# MOVEMENT DISORDERS | LARGE, UNTAPPED MARKET



## U.S. Recurring Kit Revenue TAM

	Essential Tremor	Parkinson's Disease
Eligible Patients	250,000	50,000
Bilateral Patients	125,000	50,000
Total Procedures	375,000	100,000
x Premium Kit ASP	\$4,300	\$4,300

**\$2B**

U.S. Recurring Kit Revenue Opportunity

\*Based on 2023 MedScout claims data on patient population and DBS volumes combined with Insightec treatment data on file (ET & PD)



# MOVEMENT DISORDERS\* | FDA STATUS

## MOVEMENT DISORDERS

Essential Tremor  
**UNILATERAL**



Essential Tremor  
**BILATERAL**



TDPD VIM  
**UNILATERAL**



PD GPi  
**UNILATERAL**



PD PTT  
**BILATERAL**



Submitted Q4 2024

\*FUS treats some of the motor symptoms of ET and PD. For a full list of indications and warnings please refer to the FDA website: [Pre-Market Approval \(PMA\) P150038](#) or [Indications for Use Summary](#)



# ESSENTIAL TREMOR | PUBLICATIONS AND SOCIETY SUPPORT

  
The NEW ENGLAND  
JOURNAL of MEDICINE

ORIGINAL ARTICLE

## A Randomized Trial of Focused Ultrasound Thalamotomy for Essential Tremor

W. Jeffrey Elias, M.D., Nir Lipsman, M.D., Ph.D., William G. Ondo, M.D.,  
Pejman Ghanouni, M.D., Ph.D., Young G. Kim, M.D., Ph.D., Wonhee Lee, M.D., Ph.D.,  
Michael Schwartz, M.D., Kullervo Hynnen, Ph.D., Andres M. Lozano, M.D.,  
Binit B. Shah, M.D., Diane Huss, D.P.T., N.C.S., Robert F. Dallapiazza, M.D., Ph.D.,  
Ryder Gwinn, M.D., Jennifer Witt, M.D., Susie Ro, M.D.,  
Howard M. Eisenberg, M.D., Ph.D., Paul S. Fishman, M.D., Ph.D.,  
Dheeraj Gandhi, M.D., M.B., B.S., Casey H. Halpern, M.D.,  
Rosalind Chuang, M.D., Kim Butts Pauly, Ph.D., Travis S. Tierney, M.D., Ph.D.,  
Michael T. Hayes, M.D., G. Rees Cosgrove, M.D., Toshio Yamaguchi, M.D., Ph.D.,  
Keiichi Abe, M.D., Takaomi Taira, M.D., Ph.D., and Jin W. Chang, M.D., Ph.D.

Annals of  
NEUROLOGY

## A Prospective Trial of Magnetic Resonance–Guided Focused Ultrasound Thalamotomy for Essential Tremor: Results at the 2-Year Follow-up

Jin Woo Chang, MD, PhD,<sup>1\*</sup> Chang Kyu Park, MD,<sup>1\*</sup> Nir Lipsman, MD, PhD,<sup>2</sup>  
Michael L. Schwartz, MD,<sup>2</sup> Pejman Ghanouni, MD, PhD,<sup>3</sup>  
Jaimie M. Henderson, MD,<sup>4</sup> Ryder Gwinn, MD,<sup>5</sup> Jennifer Witt, MD,<sup>6</sup>  
Travis S. Tierney, MD, PhD,<sup>7</sup> G. Rees Cosgrove, MD,<sup>8</sup> Binit B. Shah, MD,<sup>9</sup>  
Keiichi Abe, MD,<sup>10</sup> Takaomi Taira, MD, PhD,<sup>10</sup> Andres M. Lozano, MD,<sup>11</sup>  
Howard M. Eisenberg, MD,<sup>12</sup> Paul S. Fishman, MD, PhD,<sup>13</sup> and  
W. Jeffrey Elias, MD<sup>14</sup>

JNS JOURNAL OF  
NEUROSURGERY  
OFFICIAL JOURNALS OF THE AANS SINCE 1944

## Magnetic resonance imaging–guided focused ultrasound thalamotomy for essential tremor: 5-year follow-up results

G. Rees Cosgrove, MD,<sup>1</sup> Nir Lipsman, MD, PhD,<sup>2</sup> Andres M. Lozano, MD, PhD,<sup>3</sup>  
Jin Woo Chang, MD, PhD,<sup>4</sup> Casey Halpern, MD,<sup>5</sup> Pejman Ghanouni, MD, PhD,<sup>6</sup>  
Howard Eisenberg, MD,<sup>7</sup> Paul Fishman, MD, PhD,<sup>8</sup> Takaomi Taira, MD, PhD,<sup>9</sup>  
Michael L. Schwartz, MD, MSc,<sup>2</sup> Nathan McDannold, PhD,<sup>10</sup> Michael Hayes, MD,<sup>11</sup>  
Susie Ro, MD,<sup>12</sup> Binit Shah, MD,<sup>13</sup> Ryder Gwinn, MD,<sup>14</sup> Veronica E. Santini, MD, MA,<sup>15</sup>  
Kullervo Hynnen, PhD,<sup>16</sup> and W. Jeff Elias, MD<sup>17</sup>

Neurology®

## Three-year follow-up of prospective trial of focused ultrasound thalamotomy for essential tremor

Casey H. Halpern, MD, Veronica Santini, MD, Nir Lipsman, MD, PhD, Andres M. Lozano, MD, PhD,  
Michael L. Schwartz, MD, Binit B. Shah, MD, W. Jeff Elias, MD, Garth R. Cosgrove, MD, Michael T. Hayes, MD,  
Nathan McDannold, PhD, Christina Aldrich, RN, MSN, Howard M. Eisenberg, MD, Dheeraj Gandhi, MD,  
Takaomi Taira, MD, PhD, Ryder Gwinn, MD, Susie Ro, MD, Jennifer Witt, MD, Na Young Jung, MD,  
Jin Woo Chang, MD, Jarrett Rosenberg, PhD, and Pejman Ghanouni, MD, PhD

Correspondence  
Dr. Halpern  
chalpern@stanford.edu  
or Dr. Ghanouni  
ghanouni@stanford.edu

Neurology® 2019;93:e1-e10. doi:10.1212/WNL.00000000000008561

JAMA The Journal of the  
American Medical Association

## Safety and Efficacy of Staged, Bilateral Focused Ultrasound Thalamotomy in Essential Tremor An Open-Label Clinical Trial

Michael G. Kaplitt, MD, PhD; Vibhor Krishna, MD; Howard M. Eisenberg, MD; W. Jeffrey Elias, MD;  
Pejman Ghanouni, MD, PhD; Gordon H. Baltuch, MD; Ali Rezaei, MD; Casey H. Halpern, MD; Brian Dalim, MD;  
Paul S. Fishman, MD, PhD; Vivek P. Buch, MD; Shayan Moosa, MD; Harini Sarva, MD; Ann Marie Murray, MD

 ASSFN  
American Society for Stereotactic  
and Functional Neurosurgery

## ASSFN Position Statement on

## MR-guided Focused Ultrasound for the Management of Essential Tremor





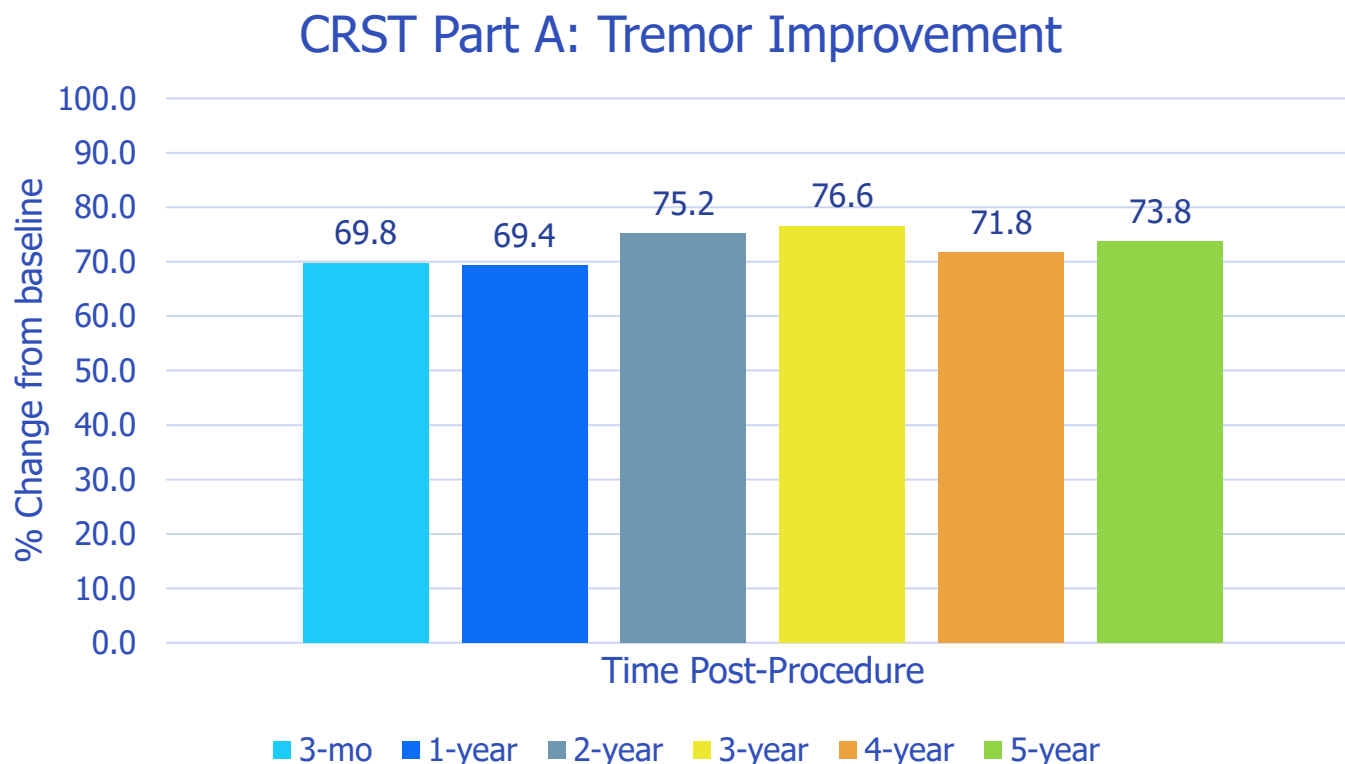
# ESSENTIAL TREMOR | CLINICAL EVIDENCE

## 73.8%

Tremor improvement  
at five-year follow-up.<sup>1</sup>

## 44.5%

Sustained improvement  
in QoL at 5 years.<sup>2</sup>



For complete safety and indication information please visit our website [Safety, Precautions, and Warning Information | Insightec](#)

1. Pre-Market Approval (PMA) P150038/S015. Based on data from 76-patients enrolled in randomized controlled trial.  
2. CRST Part C: Activities of Daily Living/Quality of Life functional, PMA P1150038/S015



# ESSENTIAL TREMOR | ESTABLISHED REIMBURSEMENT

Billable Event Description	Stage	CPT Code	APC Code	2025 CMS Reimbursement
Pre-Op Brain MRI w/o Contrast*	Pre-Op	70557	5524	\$508
Pre-Op CT MRI w/o Contrast*	Pre-Op	70450	5525	\$106
3D Treatment Planning	Intra-op	77295	5613	\$1,368
QA Machine Consult	Intra-op	77370	5611	\$133
Teletherapy isodose plan; complex includes basic dosimetry calculation(s)	Intra-op	77370	5612	\$366
Focused Ultrasound Delivery for Essential Tremor*	Intra-op	0398T	5463	\$12,470
Post-Op MRI w/o contrast (treatment effect)*	Post-Op	70557	5524	\$508
Total				\$15,459*

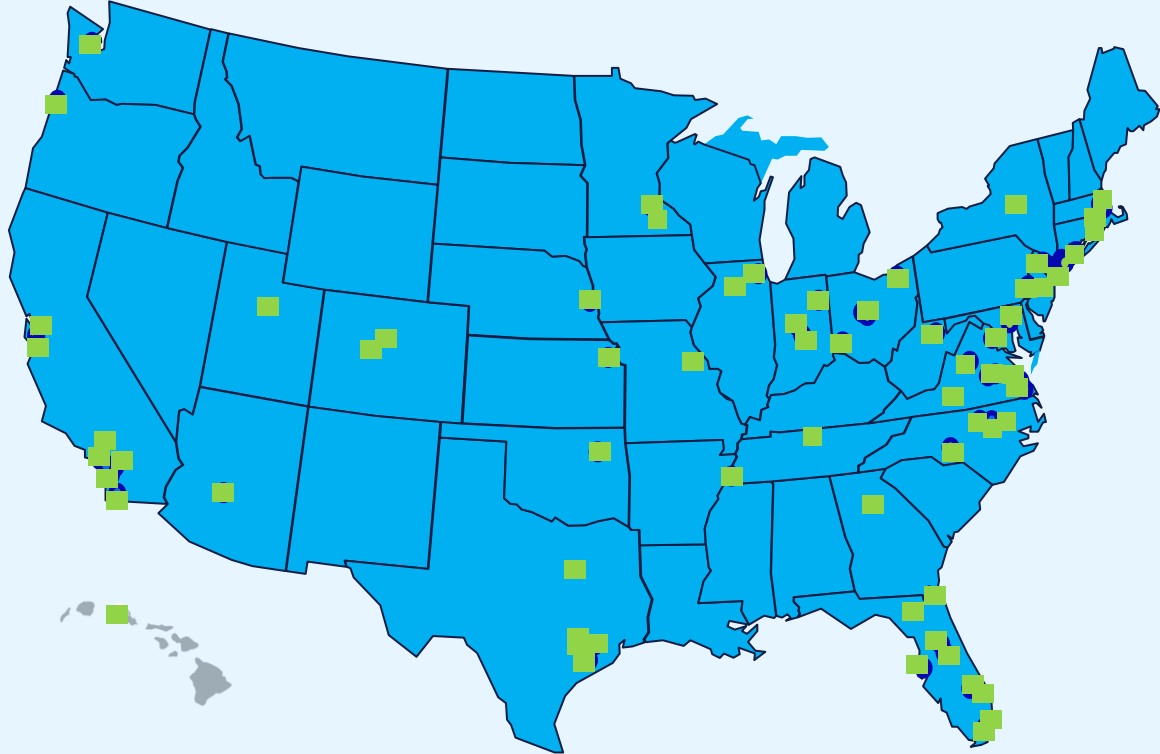
CMS Hospital Outpatient Prospective Payments for fiscal 2025

 **235M**  
**Lives covered**

\*Billable events covered by Medicare. Total stack typically covered by private payors.



## US Treatment Sites



■ Treatment Center

- Medicare coverage in all 50 States
- Favorable coverage by majority of private payors in the US
- CPT 1 code established for routine physician payment in 2025



# ESSENTIAL TREMOR | U.S. ADDRESSABLE MARKET

ET population<sup>1</sup>

7M

Annually Treated<sup>2</sup>

500K

Drug Refractory ET<sup>3</sup>

250K

SDR Eligible<sup>4</sup>

210K

Severe Disease<sup>5</sup>

60K

1,565 DBS<sup>2</sup>

~3,000 Exablate<sup>7</sup>

92%  
Untreated Patients

TAM

Unilateral Procedures  
Staged Bilateral<sup>6</sup>

60K Annual Procedures  
30K Annual Procedures

90K Annual  
Procedures

## Treatment Kit Addressable Revenue Opportunity

210,000 Eligible x 1.5 Treatments = 315,000 patients  
315,000 Treatments x \$4,300 = \$1.4B

60,000 Severe x 1.5 Treatments = 90,000 patients  
90,000 Treatments x \$4,300 = \$400M

**\$400M - \$1.4B**

1. U.S., which represents ~1/3 of worldwide opportunity

2. Medscount 2023 reported DBS procedures for ET

3. Louis *NEJM* 2001 | Diaz *Parkinsonism Related Disorders* 2010

4. Skull density ratio <0.4

5. Patient-reported severity (N>40,000) data on file with Insightec

6. Requires a second procedure

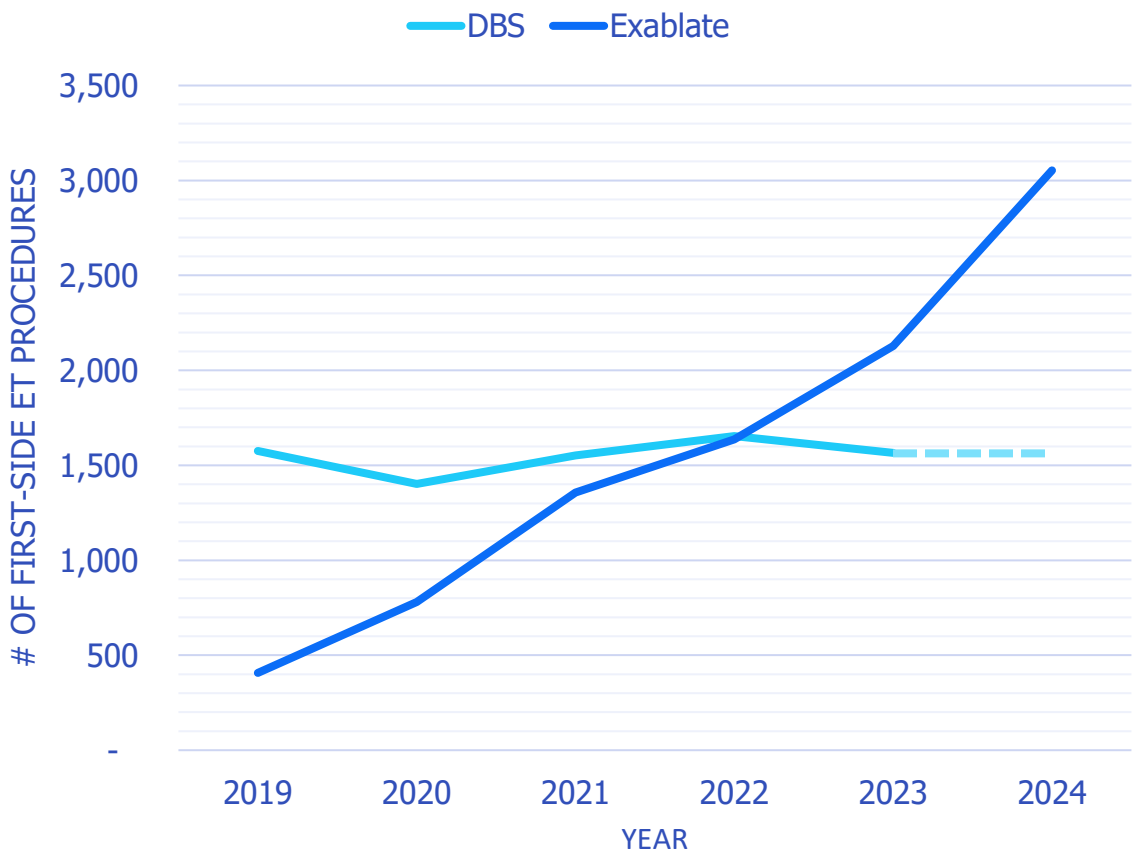
7. First side ET procedures estimated in 2024





# ESSENTIAL TREMOR | EXPANDING PATIENT TREATMENT

## U.S. Essential Tremor Patients



Source: Medscout, Insightec Data

Market	ET Patients <sup>1</sup>	Target Patient Market <sup>2</sup>	DBS Adoption <sup>2</sup>	Exablate Adoption <sup>3</sup>	Exablate Adoption if all Severe <sup>3</sup>
Houston	6,822	1,624	1.6%	7%	24%
Oklahoma City	2,600	1,105	1.0%	7%	23%
Charlotte	3,820	1,910	0.9%	6%	21%
Durham	4,488	2,244	0.6%	5%	17%
Portland, OR	7,292	3,099	0.5%	4%	15%
Boston	13,290	5,648	0.4%	2%	8%
New York	23,398	9,944	0.2%	2%	8%

1. Diagnosed ET patients living in market. Medscout 2023 data accessed Jan 2025  
2. Estimated at 50% of diagnosed population with SDR <0.4...out of eligible U.S. patient population of 210,000  
3. 2024 Exablate adoption out of 2023 MedScout target patient market  
4. 2024 Exablate adoption out of 2023 MedScout target patient market adjusted to severe disease population



# PARKINSON'S DISEASE

## Meet Kimberly Key Patient Details

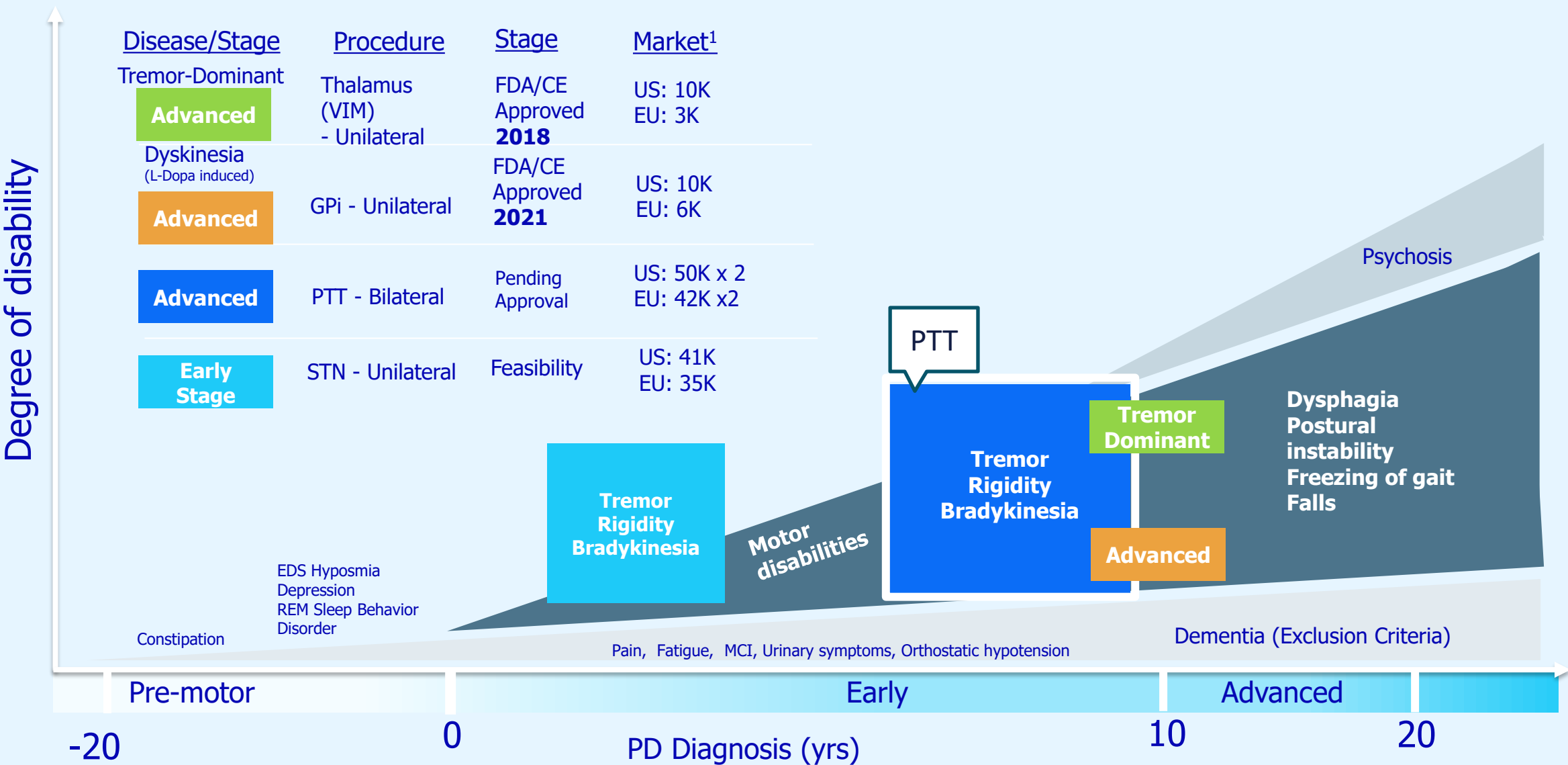
- + **Age:** 48 year-old
- + **Symptoms:** dystonia, numbness, tremors, stiffness, loss of muscle control
- + **Medication:** levodopa with serious side effects
- + **Procedure Time:** two hours
- + **Recovery time:** running one day after treatment
- + **Side effects:** mild headaches resolved days after treatment



Testimonial may not be representative of all treatment outcomes.



# PARKINSON'S DISEASE | THROUGH PROGRESSION

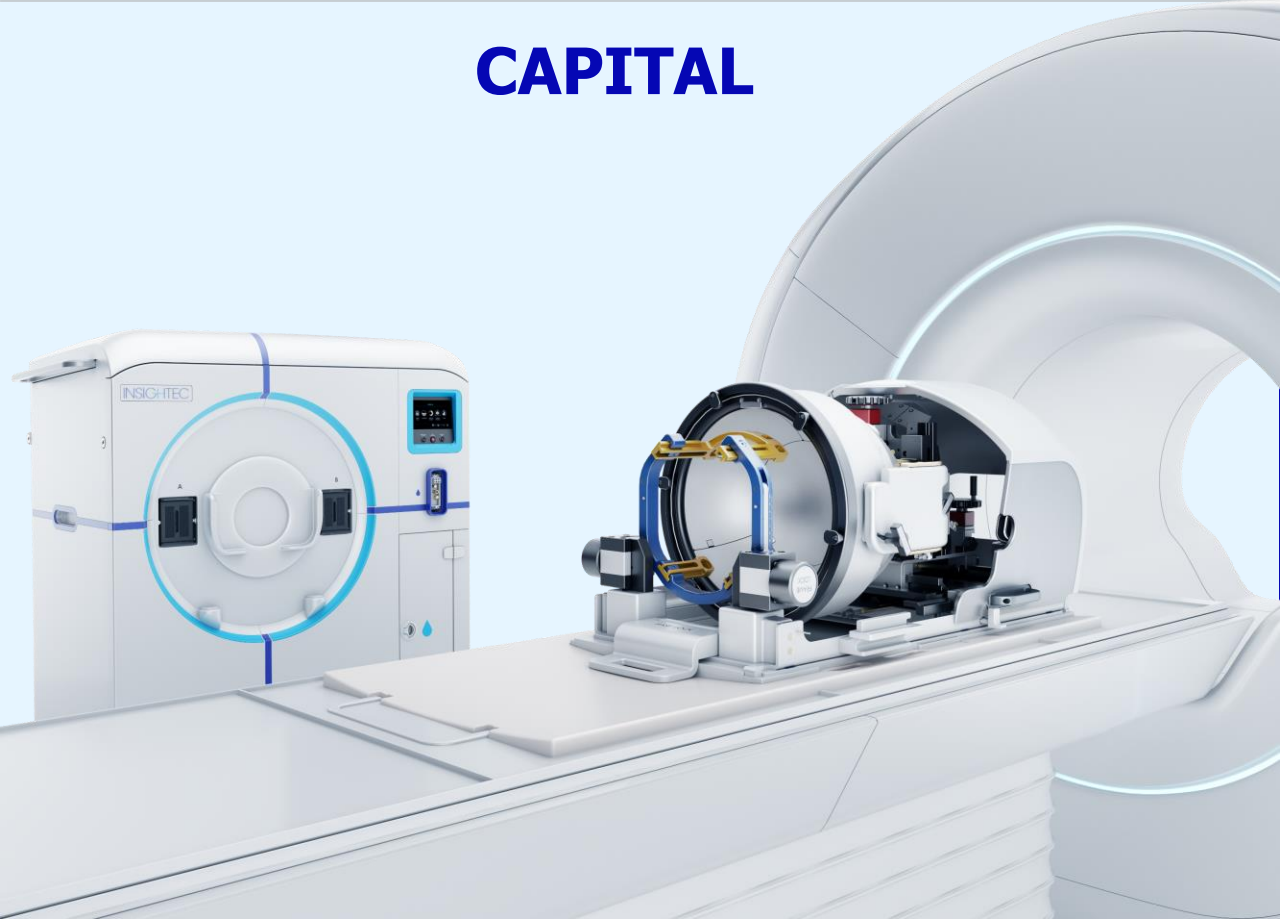


1. Data on file at Insightec



# ROBUST BUSINESS MODEL

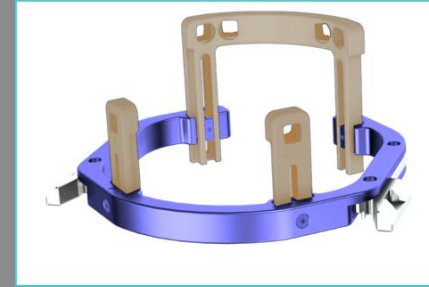
## CAPITAL



**Exablate Prime System: \$2.5M**

(Includes first year warranty)

## RECURRING



## Ablation Programs:

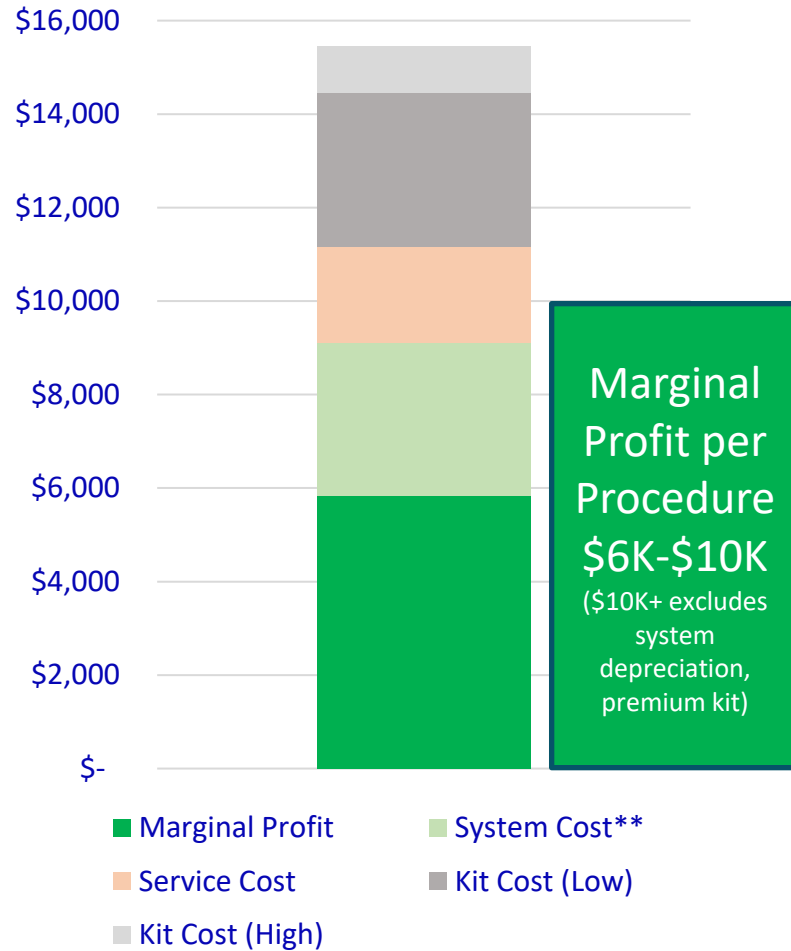
- Treatment Kit: \$3,300 or \$4,300 per procedure
- Annual Service Contract: \$205,000 per system



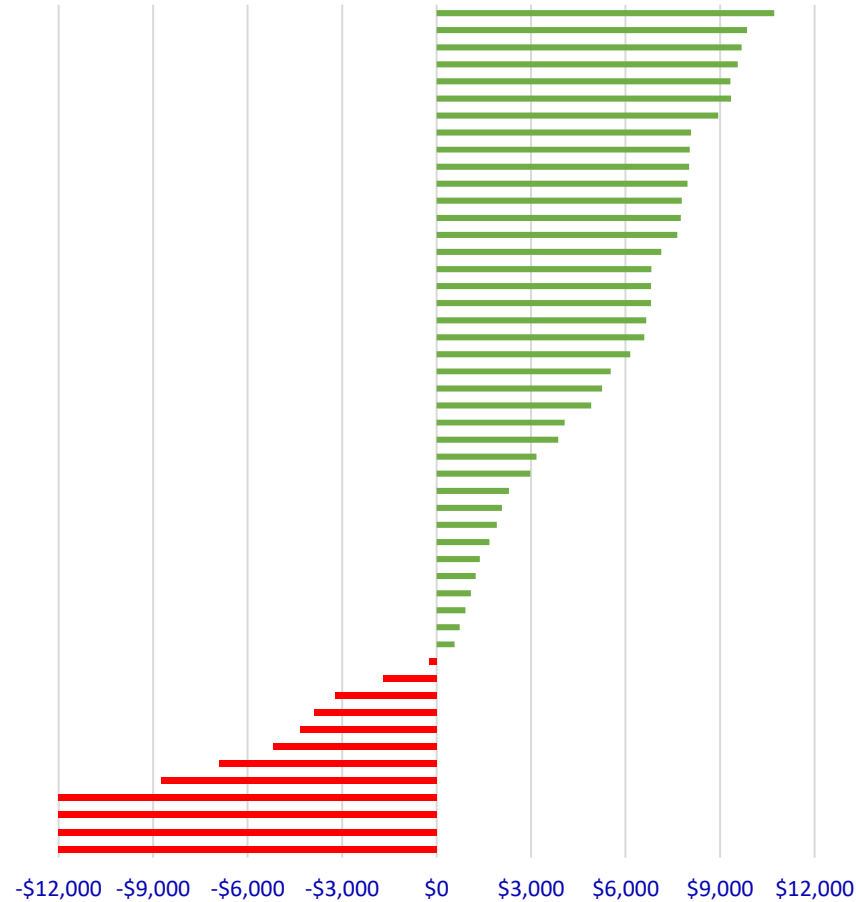


# EXABLATE | PROFITABLE CUSTOMER ECONOMICS

## Procedural Economics\*



## 2024 Marginal Profit Per Procedure by Active U.S. Customer



- Does not require dedicated MRI
- Most customers utilize MRI a single day per week (diagnostic MRI).
- Mature commercial customers perform 3-5 procedures per day; most profitable MRI day
- ROI driven by utilization
- With 7-year amortization, customers typically break-even at 40-50 annual procedures
- Exablate Prime enables incremental procedures per day

\*Reimbursement from slide 16, U.S. list prices, 2 procedures per week and 7-year system amortization  
\*\*Excludes first-year warranty at equivalent of annual service cost

Modeled based on actual price for system and service, \$3,300 kit price, 7-year system depreciation and 2024 procedures  
\* Excludes customers in initial 12-month ramp-up following installation



# EXABLATE PRIME | LATEST INNOVATION LAUNCHED 2024

Efficiency meets elegance

## Exablate® Prime

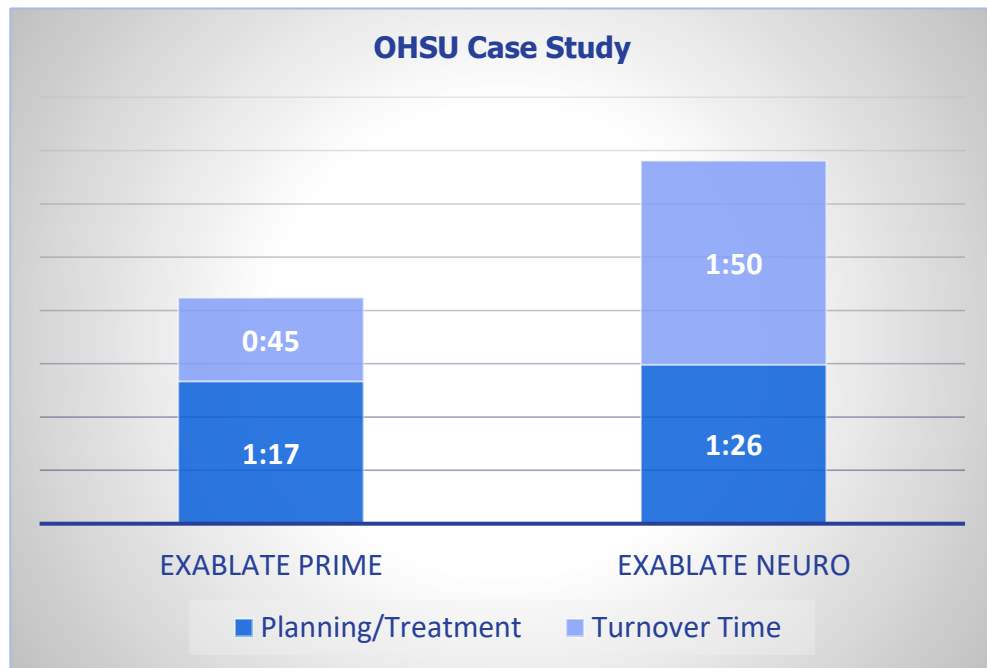
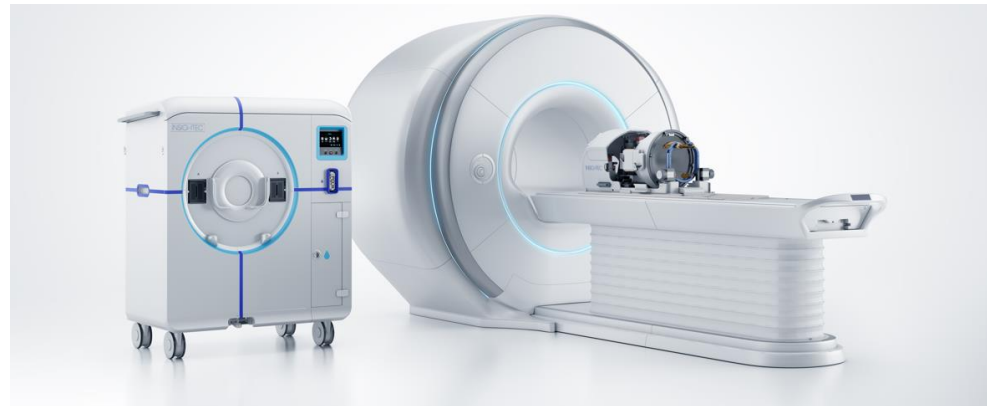
Streamlined workflows and powerful decision-making tools enables more cases per treatment day in less time.

### Key features

- Improved turnover/efficient cleaning cycle
- Automated workflows and smart algorithms, temperature driven control
- Faster, better imaging enabled by integrated head coil

### Real benefit (OHSU Case Study, N=100)

- 64% reduction in total treatment and turn over time
- 25% increase in treatments YoY (135→185)
- 3→4 cases per treatment day, often ending by 2PM
- 4x more cases completed in under an hour vs previous platform



As reported by Oregon Health & Sciences University Hospital over first 100 procedures.  
Results may vary by customer.



# COMPATIBLE WITH LEADING MRI VENDORS

**GE Healthcare**



**Siemens Healthineers**



**Royal Philips**





# PLATFORM POTENTIAL | U.S. TAM OPPORTUNITY

- Neuroablation
- BBB Disruption
- Neuromodulation

**\$2B+**

Essential Tremor  
Parkinson's Disease

NEAR TERM  
**Commercialization**

**\$20B+**

Addiction, Migraine, Obesity

ALS  
Other Brain Mets  
Brain Mets Lung, Brain Mets Breast  
GBM, Liquid Biopsy  
Alzheimer's, Parkinson's

Stroke  
Depression, OCD, Tumors  
Epilepsy, Neuropathic Pain  
Essential Tremor  
Parkinson's Disease

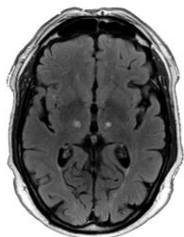
LONG-TERM\*  
**Changing Medical Therapy**

*\* Based on Recurring Kit Revenue Potential. Most investigational – not approved.*

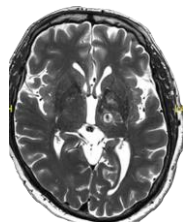


# PLATFORM POTENTIAL | AREAS OF CLINICAL EXPLORATION

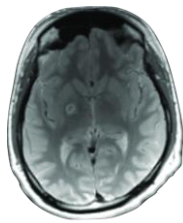
## Neurosurgery Opportunities



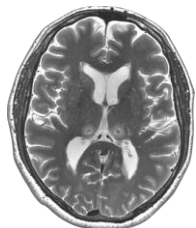
Bilateral ET



Essential Tremor (ET)



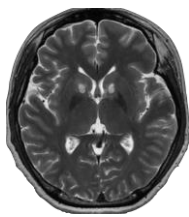
Unilateral PD



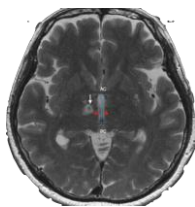
Neuropathic Pain\*\*



Bilateral PD\*



OCD/MDD\*

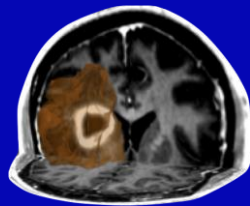


Dystonia\*

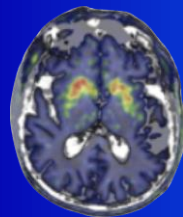


Epilepsy\*

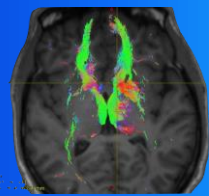
## Neuromodulation, BBB opening Opportunities



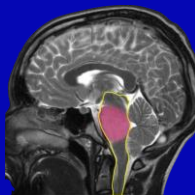
Glioblastoma\*



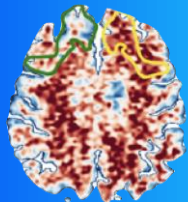
Parkinson's Disease (PD)\*



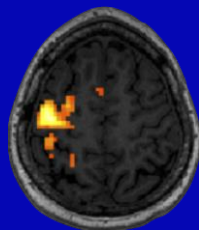
Addiction\*



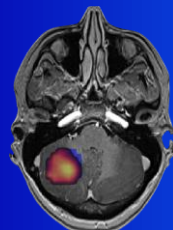
Pediatric DIPG\*



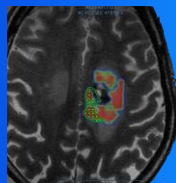
Alzheimer's Disease\*



ALS\*



Brain Metastases\*



Liquid Biopsy\*

\*Investigational – not approved  
\*\*CE Marked





# GLOBAL PRESENCE

## INSIGHTTEC

**US OFFICE**  
Dallas, Texas



**US HEADQUARTERS**  
Miami, Florida



**EUROPEAN HEADQUARTERS**  
Munich, Germany



**GLOBAL OFFICE CHINA**  
Jingan District, Shanghai



**GLOBAL OFFICE JAPAN**  
Hachioji-shi, Tokyo



**GLOBAL HEADQUARTERS  
AND PRODUCTION**  
Tirat Carmel, Israel





## 2024 FINANCIAL SUMMARY

**\$100M-\$102M Revenue**

**33% Procedure Growth**

**\$43M Recurring Revenue**

**25% Installed Base Growth**

**\$35M System Backlog**

*as of 12/31/2024*

**\$156M Cash Position**

*as of 12/31/2024*

# INSIGHTEC SUMMARY



Transform invasive procedures to incisionless



Address unmet medical need in neuroscience



Develop high-growth, recurring revenue business



Visionary management team with track record of excellence



First-to-market innovation creates IP and regulatory leadership



Funded to drive significant growth



# Transforming tomorrows, today.

Thank you – Insightec

