

INSIGHTEC

# INCISIONLESS. SAFE. **LIFE-CHANGING.\***

MR guided Focused Ultrasound for Essential Tremor.

## CLINICAL RESULTS SUMMARY

\* Life-changing refers to significant improvement in quality of life.

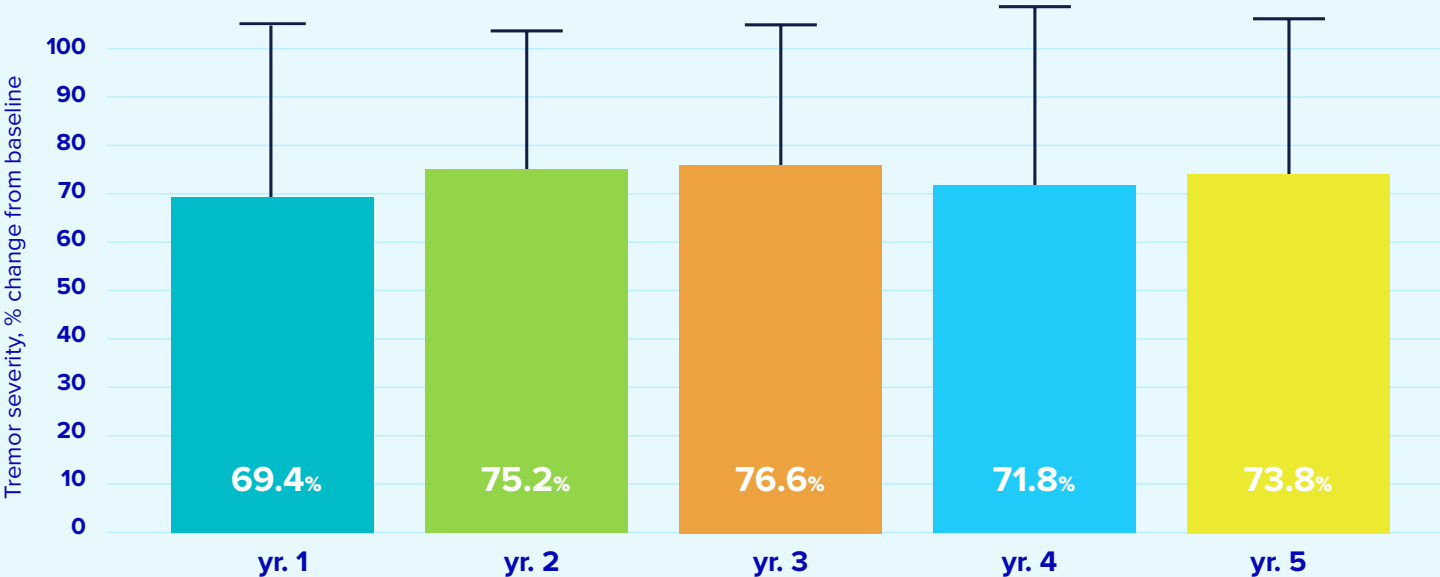
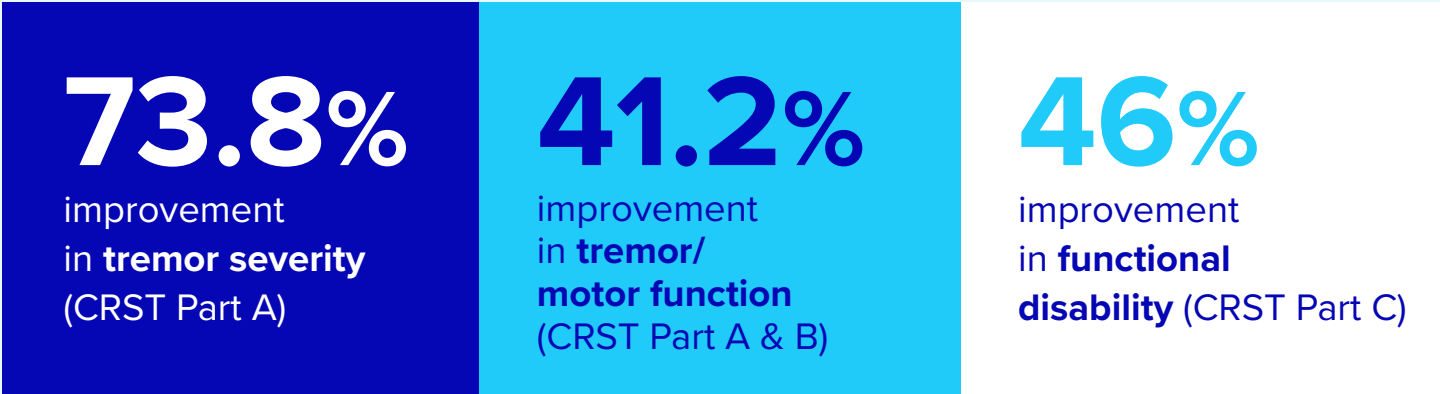


# UNILATERAL MR GUIDED FOCUSED ULTRASOUND

5-YEAR STUDY RESULTS.<sup>1</sup>



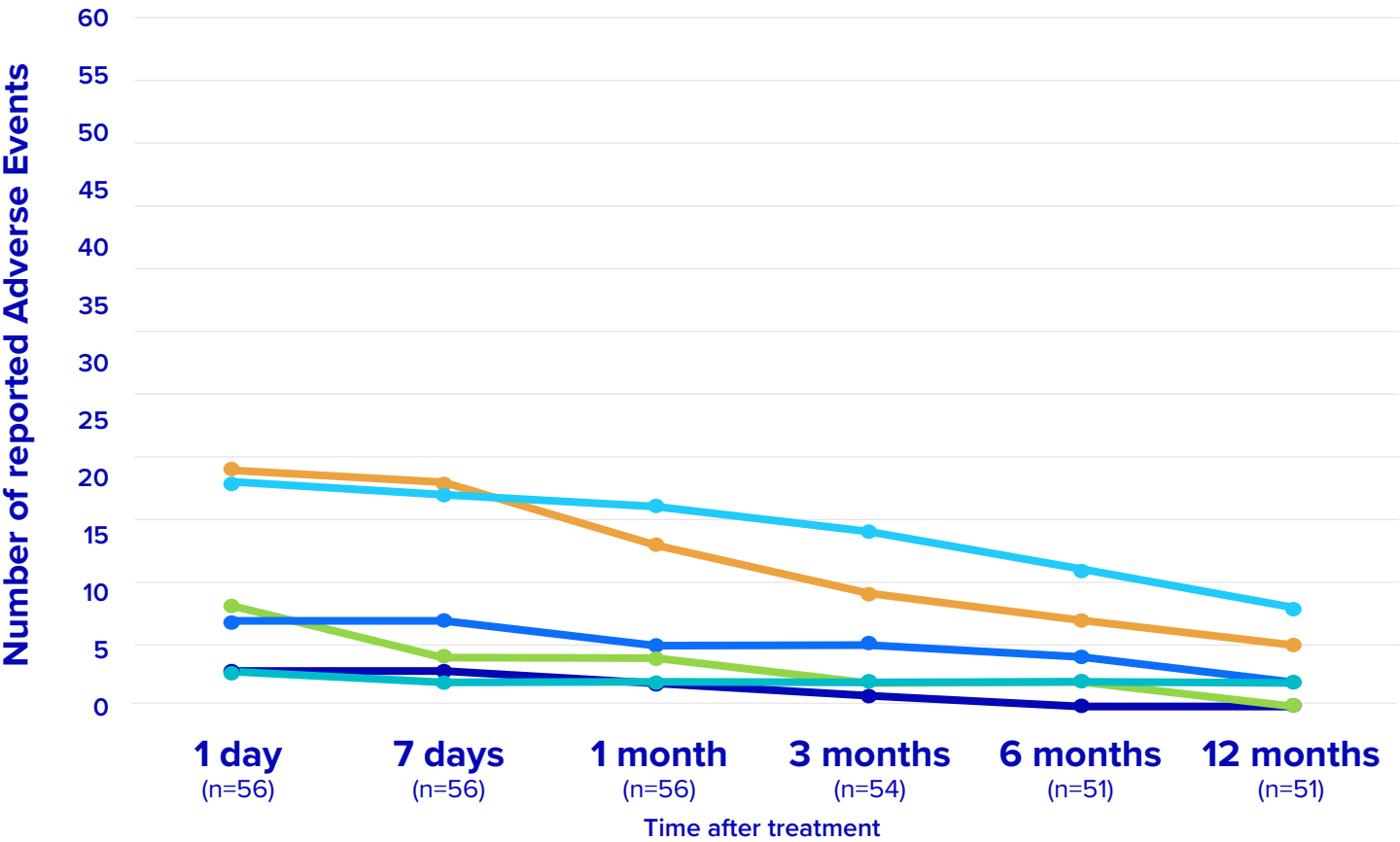
## EFFICACY & SUSTAINED IMPROVEMENT AFTER 5 YEARS.



1. Pre-Market Approval (PMA) P150038/S015

# SAFETY SUMMARY

REPORTED ADVERSE EVENTS (AEs) FOLLOWING  
UNILATERAL MRgFUS FOR ESSENTIAL TREMOR.



### Adverse Events\*

- Paresthesia or numbness in any region
- Taste disturbance
- Gait disturbance\*\* (Any, objective or subjective)
- Dysmetria, limb
- Headache lasting >1 day
- Fatigue

n = number of patients  
at time of follow up

\*All adverse events with more than 5 reported cases at day 1 are presented in the graph.

\*\*Five patients with gait disturbances were prescribed physical therapy, and one patient with persistent ataxia required a walker for ambulation.



# STAGED BILATERAL MR GUIDED FOCUSED ULTRASOUND

6-MOS FOLLOW-UP<sup>1</sup>



**EFFICACY:**  
**SECOND SIDE.** Minimum 9 months between treatments.

**80.2%**

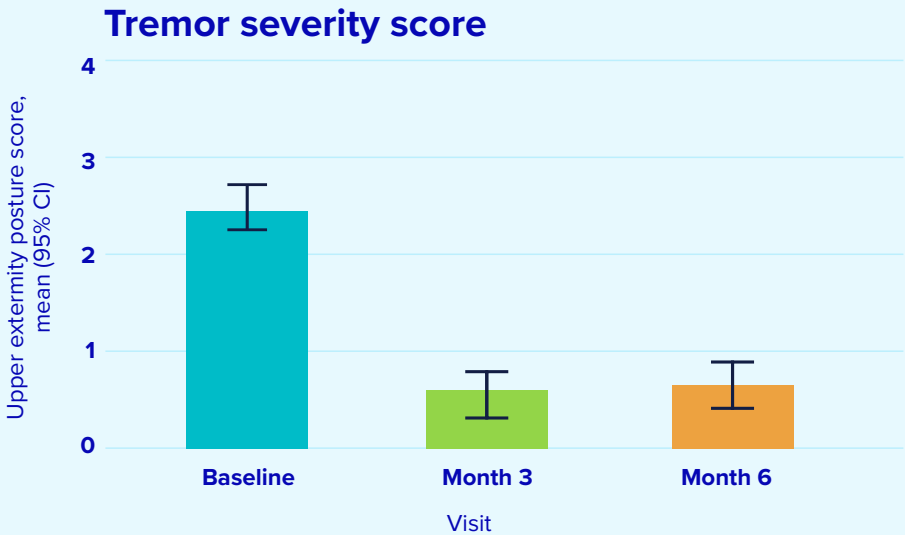
improvement in **tremor severity** (CRST PART A)

**64.3%**

improvement in **tremor/ motor function** (CRST Part A + B)

**74.3%**

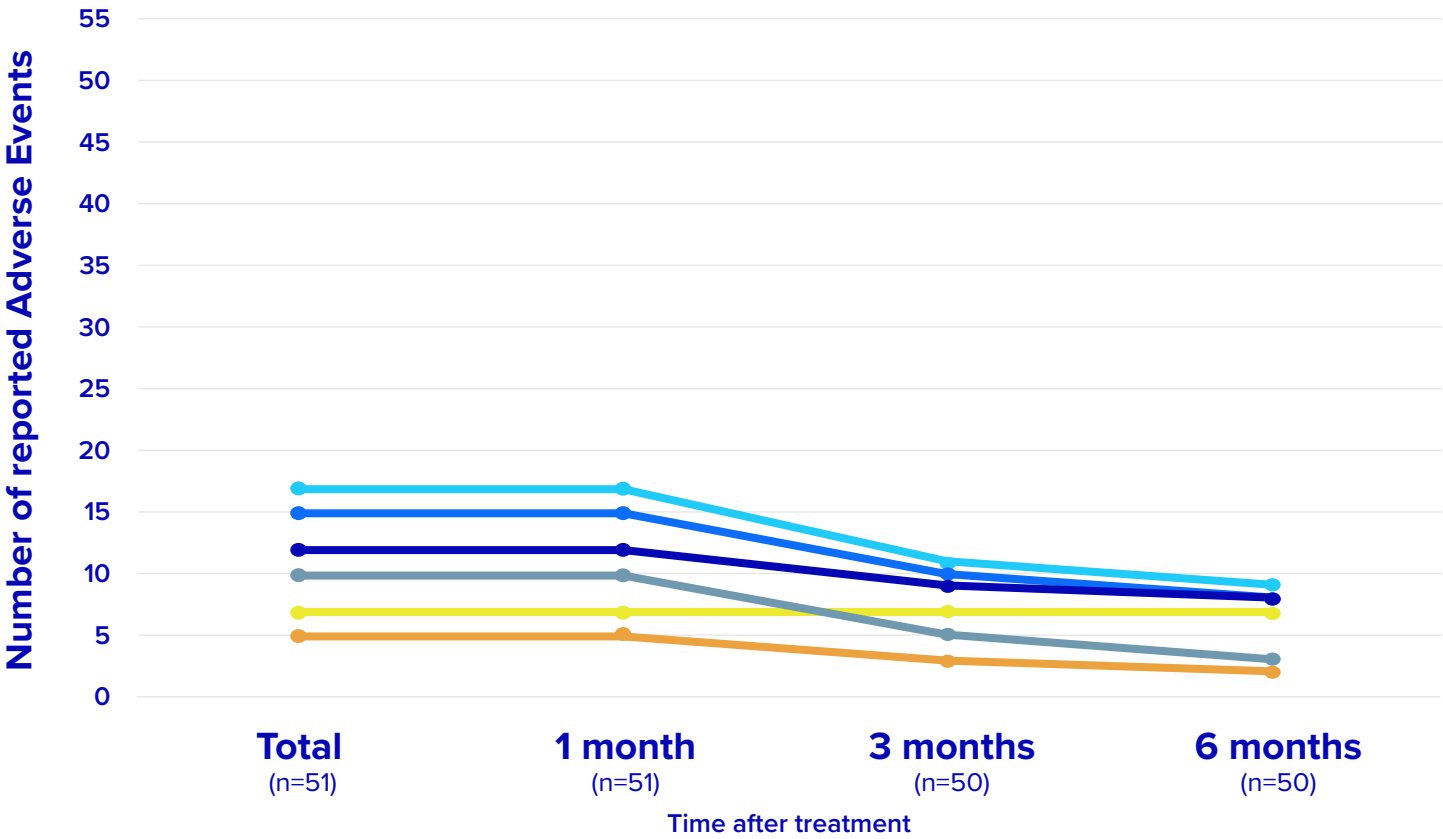
improvement in **functional disability** (CRST Part C)



1. Pre-Market Approval (PMA) P150038/S015

# SAFETY SUMMARY

REPORTED ADVERSE EVENTS (AEs) FOLLOWING STAGED, BILATERAL MRgFUS FOR ESSENTIAL TREMOR.



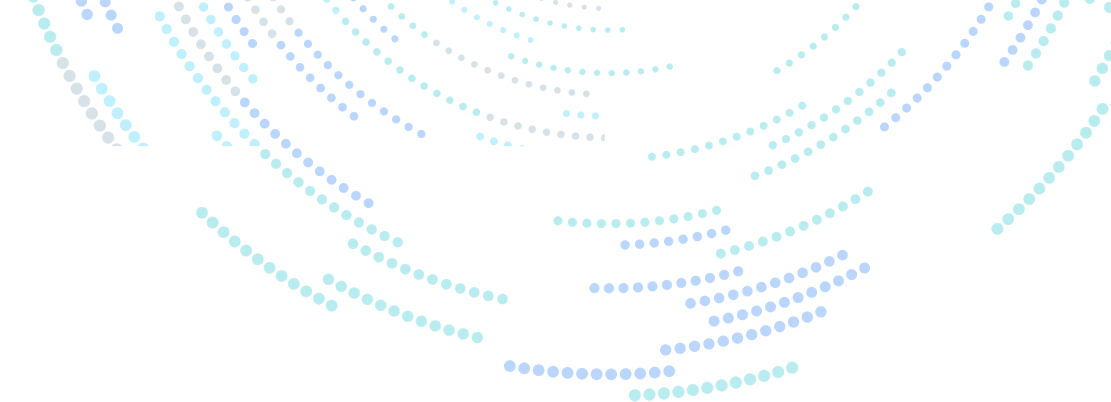
### Adverse Events\*

- Numbness/tingling
- Speech
- Ataxia
- Unsteadiness/imbalance
- Dysgeusia
- Gait disturbance

n = number of patients at time of follow up

There was one related, severe adverse event, a urinary tract infection resulting from use of a catheter during procedure.

\*All adverse events with more than 5 reported cases at day 1 are presented in the graph.



## This image shows a single sheet of white paper with horizontal blue ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.



# INSIGHT+TEC

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**SAFETY INFORMATION:** Focused ultrasound treatment has been shown to be safe for treating essential tremor and Parkinson's Disease certain indications, but as with any medical procedure, there are risks. For safety information, please visit: <https://insightec.com/safety-information/>. For detailed approved indications please visit: <https://insightec.com/regulatory-approvals/>

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