iota
hearing, advanced.®

iotaSOFT® Insertion System

World's first FDA-cleared robotic-assisted electrode array insertion technology

iotaSOFT® provides robotic-assisted control that **slows electrode array insertion speed beyond human capability** (0.1mm/s to 1.0 mm/s)

- A slow and consistent electrode array insertion speed reduces insertion forces.
- Reduced insertion speed and force reduces intracochlear trauma.

Robotic-Assisted Insertion **Reduces Insertion Force Variation** by up to

78%

when compared to manual insertion.[3]

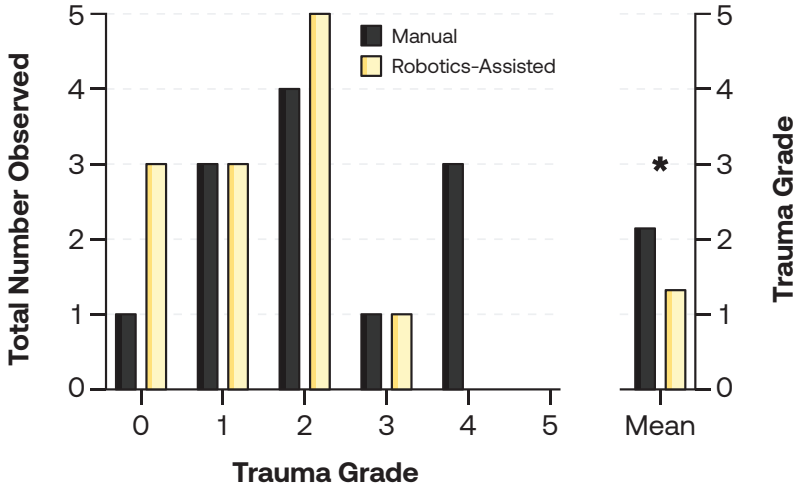
Robotic-Assisted Insertion **Reduces Maximum Insertion Forces** by up to

51%

when compared to manual insertion.[3]

Evidence shows that **robotic-assisted insertions result in less trauma to the cochlea** than manual insertions.[1]

**Denotes significant differences ($p < 0.05$)*



"Not only are robotic-assisted insertion devices able to control electrode array insertion with greater precision and less trauma than highly experienced surgeons can achieve using manual methods, but these results can be replicated by surgeons of varying levels of experience."[2]

Thumb-sized bone mounted drive unit and a reusable console with foot pedal control

The iotaSOFT® Advantage

Standardize Surgical Technique and Outcomes

- Minimal changes to surgical workflow with hands-free stabilization & control
- Multi-electrode lateral wall array compatibility
- Consistency in electrode insertion technique

Center of Excellence Promotion

- Competitive advantage opportunity to provide first and only robotic technology in region for cochlear implantation
- Expands robotic offering of center to otology applications

Influence Patient Barriers and Increase Access

- Reduces fear and provides confidence in patients considering CI surgery
- Builds awareness and interest in center and cochlear implants through robotic differentiation

Interested in learning more?

Please contact iotaMotion at info@iotamotion.com

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INNOVATOR OF THE YEAR 2022

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ADVANCING CI SURGERY

BEYOND HUMAN CAPABILITY.

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References:

1. Claussen AD, Shibata SB, Kaufmann CR, Henslee A, Hansen MR. Comparative Analysis of Robotics-Assisted and Manual Insertions of Cochlear Implant Electrode Arrays. Otol Neurotol. 2022;43(10):1155-1161. doi:10.1097/MAO.0000000000003707
2. Gantz JA, Gantz BJ, Kaufmann CR, et al. A Steadier Hand: The First Human Clinical Trial of a Single-Use Robotic-Assisted Surgical Device for Cochlear Implant Electrode Array Insertion. Otol Neurotol. 2023;44(1):34-39. doi:10.1097/MAO.0000000000003749
3. iotaMotion Data on File: Benchtop testing completed with the iotaSOFT Drive Unit at 0/1mm/s.

The iotaSOFT Insertion System is intended to aid the surgeon in placement of cochlear implant electrode arrays into a radiographically normal cochlea by controlling the speed of implant insertion. The iotaSOFT Insertion System is intended for use in cochlear implant patients ages 4 years and older during cochlear implant procedures using either a round window or cochleostomy approach.

Innovation • **Precision** • **Trust** • **Standarization**