ClearPoint® Neuro Navigation System

Integrated Software for Real-Time, MRI Guided, Minimally Invasive Neurosurgical Procedures

**Visualize**
- Accurately locate target & define safe trajectories
- Account for shifts in anatomy

**Verify**
- Observe progression of the device in real time
- Adjust and react to changes as they occur

**Confirm**
- Confirm precise placement of device and therapy
- Achieve sub-millimetric accuracy

One Procedure – One Room
Plus Integrated MRI Safe, Minimally Invasive Neurosurgical Disposable Components

MRI Safe Disposable Components:

SmartGrid® and SmartFrame® – Integrated ClearPoint Targeting and Trajectory Precision with Hand-Controller

ClearPoint® Drape provides sterile procedural field in any diagnostic or intraoperative MRI scanner
ClearPoint® Neuro Navigation

Expanding Variety of Neurosurgical Procedures

Placement of Electrodes

Depth and location...

Placement of Laser Ablation Catheters

For hippocampal ablation, ablation of tumor, ablation of radiation necrosis...

Placement of Biopsy Needles

Small, deep tumors, brain stem gliomas...

Placement of Drug Delivery Catheters

Clinical trials, research...
ClearPoint® Neuro Navigation

Expanding Your Neurosurgical Practice

### US Patient Populations

<table>
<thead>
<tr>
<th>Neuro Disorder</th>
<th>Patient Population</th>
<th>Treatment Resistant Patient Population</th>
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<tbody>
<tr>
<td>Epilepsy</td>
<td>2,300,000</td>
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<tr>
<td>Brain Tumor</td>
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<td>Parkinson’s Disease</td>
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<td>Dystonia</td>
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<tr>
<td>Huntington's</td>
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</tbody>
</table>

= Massive unmet patient need

### Therapeutic Approaches

- Electrode Placement
- Focal Ablation
- Biopsy
- Direct Drug Delivery

ClearPoint Platform Supports All of These Current and Emerging Therapeutic Approaches
ClearPoint® Neuro Navigation System

1.5T or 3T MR Scanners, also works in intraop MRI Suites

- University of Pittsburgh Medical Center
- Emory University Hospital
- UCSF Medical Center
- Brigham and Women’s Hospital*

*Image courtesy of IMRIS, Inc.

Integrates with All Major Scanner Platforms:

- SIEMENS
- PHILIPS
- GE Healthcare
- IMRIS
- BrainSUITE
Growing the ClearPoint Footprint

Installed Base of 39 sites in the US

September, 2015
The ClearPoint system has a variety of sterile drape configurations designed to be compatible with the most widely used MRI scanners.

The ClearPoint sterile drape system received 510(k) clearance for use during surgical procedures conducted under MRI imaging.

The ClearPoint drape provides a sterile covering between incision and MRI scanner.
ClearPoint® Neuro Navigation System

For Electrode Placement

“Real-Time” Image Control

Frame-less anatomic targeting under real-time MRI Visualization enables:

- Patient to be under general anesthesia
- Corrections of intra-procedural Brain-Shift*
- Often single pass electrode placement
- Monitoring of hemorrhage
- Adjustments without the need re-register to historic images

*Pre-Op images cannot account for intra-procedural anatomic changes due to air or CSF leakage
ClearPoint® Neuro Navigation System

For Laser Ablation

One procedure, One Room:

- Eliminate patient transport from the OR to the MR
- Reduce the risk of movement of the catheter in situ
- Reduce the risk of infection during transportation
- Reduce the risk of hemorrhage with real-time imaging control
- Reduce procedure time and laser catheter usage when multiple trajectories are required
- Combine biopsy and laser tumor ablation in the same setting
- Minimally Invasive
ClearPoint® Neuro Navigation System

*For Biopsy*

*Images courtesy of Dr. Clark Chen, UCSD*
ClearPoint® Neuro Navigation System

For Research including Drug Delivery

Clinical Research

ClearPoint is being used in Six Phase I Investigational Drug Clinical Trials*

Preclinical Research

Preclinical research at UCSF, Emory, Colorado State, Oregon, UPMC and Northern Biomed

Fixation frames available for multiple large animal models (non-human primates, pigs, dogs, sheep)

Seeing is Believing

*SmartFlow Cannula is approved for injection of Cyterabine or removal of CSF from the ventricles during intracranial procedures. Uses other than the approved indication are limited by Federal law to investigational use.
Appendix
ClearPoint® Neuro Navigation Software

- Intuitive, menu-driven software for surgical planning, navigation to target and device delivery.
- Streamlined workflows and user flexibility simplify frameless stereotactic procedure.
- Using intraprocedure MR images and coordinates, the software provides navigational instruction to reach the target with a high degree of precision.
Interventional MRI-Guided DBS
A Practical Atlas
Paul Larson and Others

This book is available for download with iBooks on your Mac or iOS device.

Description

This is a micro-textbook geared toward functional neurosurgeons, imaging scientists and others interested in MRI-guided DBS implantation using the ClearPoint system. Full of figures, animations and intraoperative videos, this hands-on surgical atlas is designed to teach both new and experienced teams who are looking to expand their expertise with ClearPoint. Detailed step-by-step descriptions of the procedure, MRI imaging protocols and numerous tips and pearls are provided by the group at the University of California, San Francisco, the originators of this technique.

What's New in Version 2.1
Version 2.1 has updated figures and a new MR Safety Checklist included in the supplemental materials.
Brain shift during bur hole–based procedures using interventional MRI

Clinical article


Fig. 1. Comparison of unique structures using ROIs. A T2-weighted axial MR image is obtained at 2 separate time points during surgery. The left is the pre-electrode placement image used for targeting. On the right is the post-bilateral electrode placement image. Each red outline is a specific ROI identifying a structure used to calculate shifted. Obvious shift can be noted in the left frontal lobe surface (circled).

Bibliography

MRI Interventions ClearPoint Indications for Use (K142505):
The ClearPoint® System is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures within the MRI environment and in conjunction with MR imaging. The ClearPoint® System is intended as an integral part of procedures that have traditionally used stereotactic methodology. These procedures include biopsies, catheter and electrode insertion. The System is intended for use only with 1.5 and 3.0 Tesla MRI scanners.


• Paul Larson and Others, *Interventional MRI-Guided DBS A Practical Atlas*; This book is available for download with iBooks on your Mac or iOS device.

Bibliography – Electrode Placement


Bibliography – Drug Delivery


