



Drug Delivery: *(For scientific information purposes only; Therapies discussed may not be approved in all geographies or may be investigational and used only in pre-clinical and clinical studies.)*

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**The ClearPoint Navigation System enables intraprocedural MRI guidance for a number of neurological therapies and approved clinical trials.*

ClearPoint Neuro, Inc. 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 including deep brain stimulation (DBS) lead placement. The System is intended for use only with 1.5 and 3.0 Tesla MRI scanners and MR Conditional implants and devices. The user should consult the “Navigational Accuracy” section of the User’s Guide to assess if the accuracy of the system is suitable for their needs.*

The SmartFlow® Neuro Cannula *has received 510(k) clearance from the FDA for use in the US for the aspiration of CSF, injection of the chemotherapy drug Cytarabine into the ventricles, or delivery of the gene therapy KEBILIDI to the brain parenchyma. It has also been CE marked for use in Europe for the delivery of approved fluids into the brain during intracranial procedures, or aspiration of CSF with the 14ga cannulas. The device is not intended for implant and is single patient use.*

The ClearPoint Prism® Neuro Laser Therapy System *is compatible with the following 1.5T and 3.0T MR scanner systems: Siemens MRI Magnetom and GE MRI Signa. When interpreted by a trained physician, this device provides information that may be useful in the determination or assessment of thermal therapy. Patient management decisions should not be made solely on the basis of analysis using the ClearPoint Prism® Neuro Laser Therapy System.*