PoleStar Surgical MRI System

Polestar N10

Polestar N20

Polestar N30

Intended Use

The PoleStar Surgical MRI System is intended for use as an intraoperative imaging device to produce MRI images of sections of the head selected by the physician. The images produced by the PoleStar reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR (nuclear magnetic resonance) properties that determine image structure are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and T2*. When interpreted by trained physicians, these images provide information that can be useful in determining a diagnosis.

The PoleStar Surgical MRI System and its associated applications are intended as an aid for precisely locating anatomical structures in open and percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure such as the skull, can be identified relative to a CT- or MR-based model of the anatomy.

Warning: This device may be used only as ordered by a physician. Use of this device for indications not specified in the Intended Use statement is limited to investigational purposes only.

Contraindications

Medical conditions which contraindicate the use of the PoleStar Surgical MRI system and its associated applications include any medical conditions which may contraindicate the medical procedure itself.

Although MRI does not use ionizing radiation to produce images, some important safety considerations should still be observed. These concern the use of magnetic fields, radio frequency energy, time-varying magnetic fields, and magnetic field gradients.

The use of the MRI system is contraindicated for patients with electrically, magnetically, or mechanically activated devices such as, but not limited to:

Cardiac pacemakers Bio/neuro stimulators The use of the MRI system is contraindicated for patients with passive devices such as, but not limited to:

Intracranial aneurysm clips Artificial valves unless the physician is certain that the implants are not magnetically active and cannot cause any damage.

The use of the MRI system is contraindicated for patients with embedded metallic fragments or shrapnel resulting from accidents or military service.

General Warnings and Precautions

Refer to the User Manual for MR-specific warnings and cautions, safety guidelines, patient and personnel screening procedures, and patient emergency procedures.

Warnings

The system and its associated applications should be used only by qualified medical professionals who are thoroughly trained and experienced in performing surgery with Medtronic computer-assisted surgery systems.

The system and its associated applications should be used only as an adjunct for surgical guidance. They are not a replacement for the surgeon's knowledge, expertise, or judgment.

Visually inspect scanner covers integrity before use. Don't use the system if the covers appear broken or damaged.

If system navigation seems inaccurate and recommended steps to restore accuracy are not successful, abort use of the system.

Accessory equipment connected to the analog and digital interfaces of the Medtronic computer-assisted surgery system must be certified according to the applicable IEC standards (e.g., IEC 60601-1 for medical equipment, UL60601-1, and CSA C22.2 No. 601-1-M90). Furthermore all configurations shall comply with the system standard IEC 60601-1-1 or the system requirements of Clause 16 IEC 60601-1: 3rd Edition. Any person who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC 60601-1-1 or the system requirements of Clause 16 IEC 60601-1: 3rd Edition. If in doubt, contact technical support or your local Medtronic Navigation, Inc. representative.

The system is not suitable for use in the presence of a flammable, anesthetic mixture with air or oxygen or nitrous oxide.

Some system components may contain batteries. Do not recharge or disassemble batteries. Do not dispose of batteries in fire. Observe local regulations concerning battery disposal.

Discard before use any pre-sterilized component whose sterile packaging appears to be compromised.

Do not re-process, re-sterilize, or re-use single-use devices. Attempts to re-process or re-sterilize these devices may be ineffective and may compromise their structural integrity. Any re-use creates a risk of contamination which could result in patient and hospital staff injury, illness, or death.

There is currently no effective sterilization method for components that are tainted with the infectious agent that causes Creutzfeld-Jakob Disease (CJD). Therefore, you must discard immediately after surgery any components that come into contact with biologic material from patients who carry or are suspected to carry this infectious agent. As a precaution, drape all non-disposable components that could otherwise come into contact with such material.

Precautions

Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

The system has been successfully tested against the requirements of IEC 60601-1-2. However, RF interference could hamper its operation or the operation of other nearby electrical devices. If you

suspect either of these conditions, move the conflicting equipment farther apart, separate the equipment with an RF barrier, or discontinue use of the system.

Do not exceed the recommended electrical ratings for the system. Exceeding the ratings could damage the system.

The system and its associated applications contain no user-repairable parts. This system must be installed, maintained, and serviced only by certified personnel. For repair or replacement of any part of the system or application, contact a technical support representative.

Do not modify the system in whole or in part without written approval from the manufacturer.

The system should undergo regular Planned Maintenance by certified service personnel. The frequency of the maintenance and its contents will be defined by Technical Support.

Do not connect any third-party equipment to the system without written approval from a technical support representative.

Before moving the system cart(s), shut down all components and remove any loose items from the top of the cart(s). To avoid contaminating the inside of the cart(s), clean the power cord(s) before retracting or coiling.

The system mouse is not designed for sterilization, and may be damaged if sterilization is attempted.

Cart storage drawers have a maximum load capacity of 3.8kg (8lb) each.

System components are fragile. Use care when handling system components.

Do not step on the black cables retractor. This may damage the scanner.

In case system disposal is required, contact Technical Support.