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(REV. B)

AQRATE™ INSTRUMENTS

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IMPORTANT INFORMATION ON AQRATE™ INSTRUMENTS



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MEDICAL

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WITHIN THE UNITED STATES ONLY

ENGLISH

**IMPORTANT INFORMATION
ON AQRATE™ INSTRUMENTS**

DESCRIPTION

AQRate™ instruments consist of the Universal Instrument Guides (UIG), assembly instruments, registration instruments and surgical instruments. UIGs are guide tubes that attach to the distal end of the robotic arm and provide a rigid structure for insertion of surgical instruments. Assembly instruments are used to attach the UIG to the robotic arm and to the AQRate™ Steering Handle. Registration instruments incorporate arrays of reflective markers, and are used to track surgical instruments. Surgical instruments are used to prepare the implant site or implant the device, and include k-wires, drills, drivers, and taps. AQRate™ surgical instruments are used with Globus screws.

INDICATIONS

The AQRate™ Robotic Assistance System is intended to be used for spatial positioning and orientation of an instrument holder or instrument guide to be used by surgeons to guide instruments during surgery in either open or percutaneous procedures. The instruments and instrument guides are designed for use with the Medtronic StealthStation® System, which 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 a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. The system is indicated for the placement of spinal screws.

COMPLICATIONS AND POSSIBLE ADVERSE EVENTS

Prior to surgery, patients should be made aware of the following possible adverse effects:

- Revision surgery
- Inaccuracy resulting in misplacement of the implant or screw could lead to neural or vascular structure injury, spinal canal violation, or nerve root compression.

PACKAGING

These instruments may be supplied pre-packaged and sterile. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. All components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

Instruments provided nonsterile are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments and instrument trays and cases must be cleaned, as described in the CLEANING section below.

HANDLING

All instruments, instrument trays, and cases should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion (i.e. rust, pitting), discoloration, excessive scratches, notches, debris, residue, flaking, wear, cracks, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

CLEANING

Instruments should be cleaned separately from instrument trays and cases. Lids should be removed from cases for the cleaning process, if applicable. All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The products should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments and instrument trays and cases after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzo® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzo® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.

- Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
- Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
- Dry instruments using a clean soft cloth and filtered pressurized air.
- Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). An AQRate™ User Manual may be obtained by contacting Globus Medical.

STERILIZATION

The High Speed Drill and Steering Handle are only provided sterile and are single use. The Anti-Skiving Drill is single use only and is available non-sterile. All other instruments may be available sterile or non-sterile.

All sterile instruments are sterilized by gamma radiation except for the Steering Handle which is sterilized by exposure to Ethylene Oxide. Sterile instruments have been validated to ensure a Sterility Assurance Level (SAL) of 10^{-6} . Sterile products are packaged in a heat sealed, double package or double blister. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged.

Nonsterile instruments have been validated to ensure an SAL of 10^{-6} . The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:




















- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in² total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 minutes	30 minutes

Do not stack trays during sterilization. These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (U.S.A.) Law Restricts this Device to Sale by or on the Order of a Physician.

SYMBOL TRANSLATION			
	CATALOGUE NUMBER		STERILIZED BY ETHYLENE OXIDE
	LOT NUMBER		STERILIZED BY IRRADIATION
	USE BY (YYYY-MM-DD)		STERILE BARRIER SYSTEM
	CAUTION		CONSULT INSTRUCTIONS FOR USE
	SINGLE USE ONLY		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	DO NOT RESTERILIZE		AUTHORISED REPRESENTATIVE IN SWITZERLAND
	DO NOT USE IF PACKAGE IS DAMAGED		MANUFACTURER
	PRODUCT QUANTITY		NON-STERILE
	MEDICAL DEVICE		DATE OF MANUFACTURE (YYYY-MM-DD)
	PRESCRIPTION ONLY		