DI222A-EN (Rev A)	ALLEGIANCE™ RETRACTOR SYSTEM
09/2024	**IMPORTANT INFORMATION ON THE ALLEGIANCE™ RETRACTOR SYSTEM**

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For symbols glossary, please refer to www.globusmedical.com/eIFU

English

FOR INSIDE THE UNITED STATES ONLY

IMPORTANT INFORMATION ON THE ALLEGIANCE™ RETRACTOR SYSTEM

DESCRIPTION

The ALLEGIANCE™ Retractor System is an anterior retractor and instrument system that provides efficient access to the spine. ALLEGIANCE™ Retractor System consists of arms, handles, blades and associated manual surgical instruments. The blades are available in several designs to accommodate individual patient anatomy.

ALLEGIANCE™ Retractor System is to be used with the NuVasive MaXcess™ Light Cable. For information on the NuVasive MaXcess™ Light Cable (MaXcess™ and NTS Sterile Light Cable IFU) please refer to https://www.nuvasive.com/eifu.

ALLEGIANCE™ Retractor System instruments are made from aluminum or stainless steel as specified in ASTM B221 and F899.

CLEANING

Cleaning instructions by hand, when properly carried out, causes less damage than mechanical cleaning. When cleaning instruments by hand, the following should be observed:

1. Clear any corners or recesses of all debris. (Note: extra care should be taken to clean out any cannulated areas by using an appropriate cleaning stylet and rinsing immediately.)
2. Remove all traces of blood and other such residues immediately. Do not allow these to dry.
3. The instruments should be submerged (if applicable) and cleaned with a commercially available manual cleaner (i.e. Instraclean from Calgon or Medline High Suds Detergent) prepared according to the manufacturer's recommendation.
4. A soft nylon bristled brush is then used to manually clean the devices while immersed in the cleaning solution. Never use steel brushes or abrasive pads, as these rupture the passive layer of the instrument surface which can lead to corrosion.
5. The instruments should be thoroughly rinsed after cleaning. Distilled water should be used.
6. Dry instruments immediately after cleaning.

STERILIZATION

Instruments that are provided STERILE should be considered sterile unless the packaging has been opened or damaged.

For instruments that are supplied NONSTERILE, sterilization is recommended as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Gravity (Wrapped)	132°C (270°F)	25 minutes	50 minutes
Steam	Pre-vacuum (Wrapped) Preconditioning Pulses: 3	132°C (270°F)	15 minutes	30 minutes

Cycles should be performed on tray with devices opened for maximum steam penetration.

These parameters are validated to sterilize only these instruments. 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 autoclave 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.