

Fiber Optic Retractors & Instruments

Instructions for Use

Rx ONLY



Description

Anthony Products stainless steel and silicon molded retractors & instruments are used in surgery for creating and maintaining working space required for the surgical operation in question. The fiber optic light carriers are employed for the illumination of operating field

Contraindications

No contraindications relating directly to the product are currently known. The use of the product is contraindicated if, in the opinion of the responsible physician, such an application could cause danger to the patient, e.g., due to the general condition of the patient, or if the method as such is contraindicated.

Warnings

- **Risk of injury:** A risk of injury to the patient /user and/ or damage to the products exists if the instruction manuals and warning symbols on the products are not observed. Observe the instruction manual and warnings.
- **Risk of infection:** Risk of infection: These instruments are not sterile when delivered and must therefore be cleaned, disinfection and/ or sterilized prior to initial use and each subsequent reuse.

Manual Preparation

Remove light carrier from the device. This is done by sliding the light carrier out of the guide laterally. Clean the surfaces carefully with a disinfected sponge or a disinfected soft brush. Brush any Lumina well and /or rinse through

Caution:

Parts with an integrated light cable must not be cleaned using ultrasound, as this may damage them. Parts without integrated light cable may be cleaned in an ultrasound bath (maximum five minutes). Finally, rinse with water, so that all cleaning residue is removed.

Immerse all the parts in a disinfectant solution making sure that all air bubbles have been removed and that the parts are completely covered, and taking into account the instructions provided by the chemical manufacturer on concentration and exposure times.

Rinse thoroughly with microbiologically pure/sterile water and dry with a lint free disposable cloth or sterile compressed air.

Cleaning, Disinfection, and Sterilization

All instruments should be cleaned and disinfected immediately after use. Do not allow blood or tissue to dry on instruments. Clean with soft brushes only, never use stiff brushes or abrasives to clean instruments. Use only neutral pH solutions for cleaning. If using an approved cleaning solution, make sure to follow all manufacturer instructions with regard to concentration of solution and duration. Do not leave instruments in disinfecting solutions overnight. As this may destroy the instrument. Never soak instruments in bleach. Flush instruments with distilled water after disinfecting.

Gravity Autoclave Sterilization:

Packaging: Package the device in an appropriately sized single pouch or in a wrap labeled as appropriate for the steam autoclave exposure parameters outlined below; package the device per facility practice in preparation for autoclave.

Gravity autoclave sterilization: Follow equipment manufacturer and facility procedures in the set-up and operation of autoclave equipment.

Gravity autoclave settings are as follows:

- Temperature: 132 °C (270 °F)
- Exposure time: 15 minutes (wrapped)
- Minimum dry time: 30 minutes

Pre-vacuum Autoclave Sterilization:

Packaging: Package the device in an appropriately sized single pouch or in a wrap labeled as appropriate for the pre-vacuum autoclave exposure parameters outlined below; package the device per facility practice in preparation for autoclave.

Pre-vacuum autoclave sterilization: Follow equipment manufacturer and facility procedures in the set-up and operation of autoclave equipment. Pre-vacuum autoclave settings are as follows:

- Temperature: 132 °C (270 °F)
- Exposure time: 4 minutes (wrapped)
- Minimum dry time: 20 minutes

Caution: Autoclave temperatures should not exceed 280°F or handles, Insulation or other nonmetallic parts may be damaged.

Application / Storage conditions

| | Temperature | Rel. humidity |
|-------------|-----------------|---------------|
| Storage | -20 °C...+60 °C | 10%...90% |
| Application | +10 °C... 40 °C | 30%...100% |

Disposal

To dispose of this medical device, no special measures are necessary. National laws and regulations must be observed.

Symbols

Symbols may be used on some package labeling fo easy indentification.



Manufacturer¹



Catalog number



Lot number



Latex free



Caution see warnings or precautions

Rx ONLY

Federal (USA) law restricts this device to sale by or on the order of physician or practitioner



Consult IFU
www.swantimedical.com

Consult instructions for use and website address

¹Company responsible for a device marketed under its own name regardless of whether "manufactured for" or "manufactured by" the company

