



Cleaning and Sterilization Instructions for the TiREX® Retractor System

With this shipment you are receiving a high-quality surgical retractor system. To ensure that the function and safety as well as quality requirements will be maintained for a long period, the parts, which are delivered in a non-sterile state, should be prepared **before first use and after each subsequent use** in the following manner:

1. General notes for processing

The valid statutory provisions for the processing of medical products must be observed (see for example: www.rki.de).

Please observe the directions and instructions for use of the manufacturer of the cleaning-disinfection devices (RDG-E) and cleaning-disinfection agents.

2. Storage after use and transfer to the processing location

Immediately after use on patients, place the TiREX® Retractor System in an instrument tray filled with a suitable cleaning-disinfection agent (alkaline, listed by the DGHN [Deutsche Gesellschaft für Hygiene und Mikrobiologie = German Society for Hygiene and Microbiology]). Placement in the agent prevents drying of residues. Processing of the retractor system should be performed no later than one hour after use. Transfer of the retractor to the processing location must be carried out in a closed instrument tray.

After the use of re-usable instruments, care should be taken that they are not damaged in transfer. Prior to cleaning, the instruments should be disassembled as much as possible. The frame, the table post and the clamps cannot be further disassembled. Care should be taken that the joints are open.

3. Cleaning and disinfection

In accordance with the recommendations of the Robert Koch Institute (RKI), processing should preferably be carried out automatically. Therefore, in the following, automatic processing will be described first, followed by the alternative manual processing.

3.1 Cleaning and disinfection in automatic machines

Commercially available alkaline cleaning and disinfection agents (e.g.: the ECOLAB alkaline cleaner "Sekumatic FR") should be used in accordance with the manufacturers' direction for use (use the correct dosage!). If an alkaline cleaner is used, a neutralizing step with a suitable process chemical (e.g.: ECOLAB "Sekumatic FNZ" neutralizer) must be included in the washing process. In loading the wash sieve, avoid areas that the cleaning jets can't reach. Place the frame with the open cartridge face down.

A typical cycle should include the following steps:

- Prewash, 3 min. at 15 °C / 59 °F
- Main wash, 10 min. below the protein coagulation temperature, < 60 °C / 140 °F
- Rinse/Neutralization in order to remove the cleaning agent, 2 min. with neutralizing agent
- Thermal disinfection (max. 93 °C / 199,4 °F)
- Final rinse with purified water (demineralized water)
- Drying cycle, max. 134 °C / 273,2 °F

After removal of all parts, examine for visible contamination (particularly in tubing and blind holes). If necessary, repeat the cycle or clean manually.

After cleaning all jointed parts must be dried with a clean air jet.

After processing a visual check for damages should be made. In the case of mechanical damages and other signs of wear, the TiREX[®] retractor system must be replaced by a new one.

After cleaning and cooling of the parts, the jointed and movable parts of the clamps and the table post must be treated with suitable maintenance products based on white oil or special instrument oil (silicone-free).

Die ball joints of the frame are maintenance-free and should not be oiled.

3.2 Cleaning by hand

Soak contaminated parts using a blood-dissolving cleaning agent, according to instructions of the cleaning agent manufacturer.

Submerge the parts and clean with an alkaline cleaning agent. In doing this, clean with a soft brush and take care that all surfaces are reached. Treat tubing and blind holes separately with a suitable brush.

Thoroughly rinse under running water. The water must flow through the tubing and blind holes must be repeatedly filled and emptied.
Carefully dry with a clean air jet.

After processing a visual check for damages should be made.

In the case of mechanical damages and other signs of wear, the TiREX[®] retractor system must be replaced by a new one.

After cleaning the jointed and movable parts of the clamps and the table post must be treated with a suitable maintenance product based on white oil or special instrument oil (silicone-free).
The joints of the frame are maintenance-free and should not be oiled.

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4. Sterilization

The parts can be sterilized, individually packed (in standard polyethylene or Tyvek pouches), in container systems intended for this purpose or in all-purpose sterilization containers.

Sterilization should take place via steam with fractionated vacuum, at a stylization temperature of 134 °C (273,2 °F) and a holding time of 5 minutes.

All joints and eccentric levers or closures must be opened during the sterilization

5. Transfers and Storage

During transfer and storage, the surgical retractor system should be protected from dust, moisture and recontamination.

6. Product life span

The TiREX[®] retractor system is made of high-quality materials.

The End of the product life span is fundamentally determined by wear and damage during use. Frequent reprocessing has no effects on the performance of the retractor system.

7. Final Considerations

MBP GmbH ensures that the above-described processes are suitable for the processing of the TiREX[®] retractor system. Responsibility lies with the processor that the processing actually performed with the equipment, materials and personnel in the processing facility achieves the desired results. Normally for this purpose, validation and routine monitoring of the process are necessary. In the same manner, the processor for its effectiveness and possible adverse consequences should carefully evaluate every deviation from the instructions provided.

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