

Issued by: Otto Leibinger GmbH, Griesweg 27, 78570 Muehlheim / Germany

Important

Before initial use, before all further use and before being sent to the manufacturer for repair, the instruments must be prepared according to our care and cleaning instructions.

Caution

The instruments may only be used for their intended purpose in the surgical specialties by educated and qualified personal. The surgeon, the buyer or user shall be responsible for the proper selection on the instruments for each application, for obtaining the appropriate training, knowledge and experience as well as for their operative use. Otto Leibinger GmbH as manufacturer and seller cannot accept any liability for immediate or consequential damages caused by inappropriate application and use or by inappropriate sterilization and maintenance of the instruments. If instruments are repaired by any companies or persons not authorized by Otto Leibinger GmbH to do so, all warranties are becoming null and void. Carefully examine each surgical instrument for breaks, cracks, deformations and malfunctions before use. It is especially essential to check areas such as blades, points, locks, ratchet and snaps as well as movables parts.

Instruments that are worn out, corroded, deformed, porous or damaged in any other way must be sorted out.

Storage

Instruments should be stored in a clean, dry, moisture free area. Instruments should be stored individually in their shipping carton or in a protective tray with partitions. Protect tips, edges etc. with tubing, protecting caps, gauze or fabric. Make sure that no chemicals are close to or in the storage area.

Steel instruments

The high-grade steels (rustproof, stainless) that are used for manufacturing surgical instruments create due to the chemical composition specific passive layers as protective surfaces. Those steels however are only to a certain extent resistant against attacks of chloride ions and aggressive mediums and liquids! Chloride ions mainly cause pitting, but can also cause stress corrosion cracking. The greatest danger is water in which considerable quantities of common salts (sodium chloride) are dissolved.

We recommend the following methods and procedures for the preparation of our reusable surgical instruments:

Manual cleaning

The instruments must be disinfected and cleaned according to our reprocessing brochure, immediately after use. Contaminations on the instrument must not get dry or encrusted, as this could cause difficulties in cleaning and disinfecting.

The following points are to be observed:

- Solutions used for the mechanical cleaning must be prepared strictly following the instructions given by the manufacturer.
- For the cleaning of cannulas, dead-end holes and cavities a suitable brush must be used so any area can be reached.
- Remove blood and all contaminations with a soft brush and a mild neutral or alkaline (except for aluminium!) detergent. Never use metal brushes or metal sponges for cleaning.
- To ensure proper function of the instrument, make sure that all movable parts are thoroughly cleaned.
- Clean instruments with hinges and box-locks in open as well as in closed position.
- Detach instruments for cleaning of slots, gaps, ratchets, box-locks, cannulations and dead-end holes.
- Surgical instruments should be placed in proper carriers, such as perforated trays, wire baskets etc.

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Ultrasonic treatment

For ultrasonic treatment instruments should be placed in open condition on proper perforated trays or wire baskets. Please ensure to avoid any "wave shadows" or covering surfaces caused by wire baskets or perforated trays or by large or bulky instruments.

Warm water without any additives does not have a satisfactory cleaning result and therefore a suitable cleaning agent should be added. Follow strictly the instructions given by the manufacturers regarding concentration and the temperature of the detergents in the ultrasonic basin. A too dirty solution in the ultrasonic basin decreases the cleaning effect. Therefore, the solution should be renewed at intervals according to the instructions given by the manufacturer. Ultrasonic wave times must be used according to the instructions given by manufacturer of the cleaning agent.

After ultrasonic treatment all instruments must be rinsed and checked for loose parts (e.g. screws etc.). For rinsing fully demineralized or distilled water must be used to avoid water spots.

Chemical disinfection

- The temperature of soaking solutions used for chemical disinfection must be used according to the instructions given by the manufacturer.
- Thinnings have to be made using fully demineralized or distilled pure water only. Detergent or cleaning agent must not be added. Follow precisely the instructions given by the manufacturer of the solution regarding dosage and induction time.
- The disinfection solutions must be refreshed daily. Reusing them can cause an increase of the dosage through evaporation (-> corrosion risk) or a too high contamination level (-> corrosion risk and reduced efficiency).
- After chemical disinfection all instruments must be rinsed with pure flowing water. To avoid water spots only fully demineralized or distilled water must be used.
- Dry surgical instruments immediately after each cleaning, disinfection and rinsing cycle.

Machine cleaning and disinfecting

- Machine cleaning and disinfection is always a preferable method compared to manual cleaning since machine procedures can be standardized.
- Follow the operating and loading instructions provided by the manufacturer of the washing machine. Use only the detergents and cleaning agents recommended by the manufacturer for the specific purpose.
- Hinged and box-lock instruments must be loaded and cleaned in open condition. Place instruments into the machine in a way that allows the water to flow out of cannulations, dead-end holes and cavities.
- Take instruments apart as much as possible for cleaning.
- Machine cleaning and disinfection is only suitable for instruments with long or thin cannulations if the hot disinfection solution can actually flow through them.
- When removing instruments from the washing machine, pay ratchets, box-locks, cannulations and dead-end holes. Check for any visible remaining contaminations. If necessary clean manually and/or repeat cycle.

Steam sterilization / Autoclaving

- Sterilize all instruments before use.
- Recommended sterilization methods steam sterilization with fractionated vacuum according to DIN EN ISO 17664.
- Recommended temperature 273°F (134°C).
- Recommended pressure 3 bar.
- Leave on time > 5 min.
- When using autoclaves for sterilization of surgical instruments, it has to be strictly ensured that the steam used is absolutely free of foreign subsequent corrosion or dirt (scum) deposit.
- Please observe strictly the instructions for use given by the manufacturers of autoclaves.
- Do not use any damaged instruments.

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Equipment and methods used for cleaning, disinfection and sterilization have to be in accordance with the following standards and recommendations:

- DIN EN ISO 17664 sterilization of medical devices – information to be provided by the manufacturer for the processing of resterilizable devices.
- EN 285 sterilization – steam-sterilizers – large sterilizers.
- EN 554 sterilization of medical devices – validation and routine control of sterilization by moist heat.
- DIN EN 556-2 sterilization of medical devices – requirements for medical devices to be designated “sterile” – part 1: Requirements for terminally sterilized medical devices.
- DIN 58946-7 sterilization; steam-sterilizers; architectural claims for large sterilizers.
- Proper maintenance of instruments, working group instruments preparation <http://www.a-k-i.org>



Limit of the preparation of instruments

Repeat instrument preparation has no significant influence on the lifetime of the surgical instruments. The lifetime of the instruments is usually determined by wear and tear or mutual damage during use.

Maintenance of instruments

Maintenance of surgical instruments means lubrication with physiologically save instrument oil (acc. To DAB 8 or Ph.Eur. or Usp) or cleaning milk (emulsion of hydrocarbons in water) particular of the joints. Make it basic rule to thoroughly lubricate surgical instruments prior to checking for function. All movable parts (joints) and cutting blades of scissors have to be lubricated. This avoids metal abrasion when checking for function. Lubricants used must guarantee, that even after frequently repeated use a “sticking” of joints through a multiplying effect is avoided.

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