



Directions for the Use

Surgical Instruments

First use of new Surgical Instruments

Every instrument *must* be cleaned and sterilised before it is used.

Caution

The instruments may only be used for their intended purpose in the surgical specialties by educated and qualified personal. The surgeon shall be responsible for the proper selection of the instruments for each application, for obtaining the appropriate training, knowledge and experience, and for their operative use.

Geister Medizintechnik GmbH as manufacturer and seller cannot accept any liability for immediate or consequential damages caused by inappropriate application and use or by inappropriate sterilisation and maintenance of the instruments.

If instruments are repaired by any companies or persons not authorized by Geister Medizintechnik 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, ends, stops and snaps as well as movable 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.

Used materials

Stainless steel as per DIN EN ISO 7153-1

Pure titanium as per DIN ISO 5832-2

Titanium alloys as per DIN ISO 5832-3

Light metal (Aluminium) as per DIN EN 573-3

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 waters! 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.

Titanium instruments

Instruments made from pure titanium or titanium alloy can be handled and treated like steel instruments and no special precautions have to be taken. Some titanium instruments are completely or partially anodised in blue color for identification purpose.

Aluminium instruments

Only non-alkaline, neutral cleaning agents in combination with fully demineralized water must be used. Otherwise damages to the anodized surface are possible. Alkaline cleaning causes marks and color fading on the surface particularly of colored instruments already after just a few cycles.

In addition to the endeavours undertaken by the manufacturer with regards to the selection of the proper materials and its careful processing, the user has to ensure continuous and proper care of the surgical instruments as well as proper preparation, cleaning and sterilisation.

Procedure:	Automated Cleaning Process
Products:	Instruments for Cardiovascular Surgery Microsurgical Instruments Tissue Forceps Bulldog Clamps Atraumatic Clamps Hemostatic and Dissecting Forceps Needle Holders Tourniquets, Suture Catchers, Vein Strippers Scissors Suction Tubes and Needles Self-retaining Retractors Hand-held Retractors Bone Instruments and Rongeurs Bronchoscopes, Mediastinoscopes Care and Maintenance
ADVICE:	Reprocessing procedures have only limited implications to a surgical instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. In case of damage the device should be reprocessed before sending back to the manufacturer for repair.
Reprocessing Instructions	
Preparation at the Point of Use:	Remove gross soiling by submerge the instrument into cold water (<40°C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residua which may influence the result of the reprocessing process.
Transportation:	Safe storage and transportation in a closed container to the reprocessing area to avoid any damage and contamination to the environment.
Preparation for Decontamination:	The devices must be reprocessed in an opened or disassembled state.
Pre-Cleaning:	Immerse the instrument into cold tap water for at least 5 minutes. Dismantle the instruments if possible and brush under cold tap water until all visible residues are removed. Inner lumens, threads and holes are flushed each with a water jet pistol for minimum 10 seconds in the pulsed mode Immerse the instrument into an ultrasonic bath with alkaline (enzymatic) detergent (0,5%) and treat with ultrasonic for 15 minutes at 40°C. The instrument is taken out of the bath and rinsed with cold tap water again.
Automated Cleaning:	A: Put the instruments opened and or, if possible, in a disassembled state on an instrument tray. Put the tray on an instrument rack in the washer disinfectant and start the cycle: B: Keyhole Surgery Instruments: Put the instruments opened and or, if possible, in a disassembled state on a special key hole surgery rack. Not suitable instruments are placed on an instrument tray below and start the cycle: 1. 1 min. pre-cleaning with cold water 2. draining 3. 3 min. pre-cleaning with cold water 4. draining 5. 5 min cleaning at 55°C, 45°C with 0,5 % alkaline, enzymatic detergent (if enzymatic detergent is used the cleaning temperature is 45°C). 6. draining 7. 3 min neutralisation with warm water (>40°C) and neutralizer 8. draining 9. 2 min rinse with warm water (>40°C) 10. draining
Disinfection:	Automated Thermal Disinfection in washer/disinfectant under consideration of national requirements in regards to A0-Value (see ISO 15883)

Drying:	Drying of outside of instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.
Functional Testing, Maintenance:	Visual inspection for cleanliness, assembling and functional testing according to instructions of use. If necessary perform reprocessing process again until the instruments are visibly clean.
Packaging:	Appropriate packaging for sterilization according ISO 11607 and EN 868
Sterilization:	Sterilization of instruments by applying a fractionated pre-vacuum process (according. ISO 13060 / ISO17665) under consideration of the respective country requirements. Parameters for the pre-vacuum cycle: 3 prevacuum phases with at least 60 milli bar Heat up to a minimum sterilization temperature of 132°; maximum temperature 137°C Minimum Holding time: 3 min Drying time: minimum 10 min
Storage:	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures of 5°C to 40°C.
Reprocessing validation study information	The following testing test devices, materials & machines have been used in this validation study; Detergent: Neodisher FA; Dr. Weigert; Hamburg Endozime, Fa. Ruhof (Enzymatic) Neutralizer: Neodisher Z; Dr. Weigert, Hamburg Washer / Disinfector: Miele 7735 CD Instrument Rack: Miele E 327-06 Key Hole Surgery Rack: Miele E 450 Details: Cleaning: Project No 01707011901-2 Sterilization: Project No 13308022609
Additional Instructions:	If the described chemistry and machines are not available, it is the duty of the user to validate his process
	It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.

When using autoclaves for sterilization of surgical instruments, it has to be strictly ensured that the steam used is absolutely free of foreign substances such as corrosive particles or dirt to avoid 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.

Hints for the sterilization of the instruments with sterilization container systems

- Use 1 or 2 layer of the OT cloth inside of the sterilization container as a wrap around the basket to absorb the humidity at the bottom in particular.
- Do not wrap the sterilization container on the outside with paper or textile filters during the sterilization cycle. This would cover the holes, press the filter inside and does not allow for the steam to move in and out properly. Also drying is not possible in proper manner.
- Replace single use paper filters after each and textile filters after 60 cycles.
- A drying cycle time of 20 minutes after autoclave cycles must be observed by all means! It's not allowed to skip this dry time, because it's crucial! After this the sterilization container and the goods should be quite dry inside. This should be tested.
- Remaining humidity in sterilization container and subsequent storage in this way can cause brownish discoloration or rust on instruments.
- IMPORTANT! Loading weight of 1/1 sterilization containers shall be not more than 10 kgs! The loading weight of the smaller sterilization containers shall be appropriate less than the 1/1 sterilization containers.

- For Crutchfield-Jacob contaminated instruments sometimes the holding time at the sterilization cycle will be increase to a higher time of 30 min. This is known to cause problems on many instruments. It's better to use a proper disinfectant before and use common holding time for instruments.

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

EN ISO 17664	Sterilization of medical devices – Information to be provided by the manufacturer for thr processing of reesterilizable devices
EN ISO 17665-1	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 14937	Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process
EN 285	Sterilization – Steam-sterilizers – Large Sterilizers
EN 13060	Small steam sterilizers
ISO 15883	Washer-disinfectors
DEN 556-1	Sterilization of medical devices – Requirements for medical devices to be designated “STERILE” – Part 1: Requirements for terminally sterilized medical devices
EN ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN 868	Packaging materials for terminally sterilized medical devices
DIN EN ISO 11737-1	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
DIN EN ISO 11737-2	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the validation of a sterilization process
DIN 58946-7	Sterilisation; Dampf-Sterilisatoren; Bauliche Anforderungen bei Groß-Sterilisatoren

Proper Maintenance of Instruments, Working group instrument preparation

<http://www.a-k-i.org>

Maintenance of instruments

Maintenance of surgical instruments means lubrication with physiologically inert instrument oil (acc. to DAB 8 or Ph.Eur. or Usp) particularly of the joints. Make it a 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.