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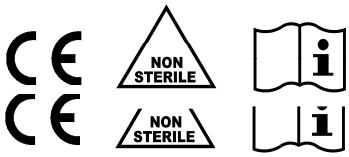
Instructions for the Use



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 propper 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	EN ISO 7153-1
Pure titanium	ISO 5832-2
Titanium alloys	ISO 5832-3
Light metal (Aluminium	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 gave 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 tab water again.
Automated Cleaning:	For instrument cleaning/disinfection special equipment (cleaning and disinfection devices) must be used. According to the RKI instructions "Hygiene requirements to medical devices for handling medical products", manual cleaning/disinfection is not recommended due to its much lower efficiency. 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 disinfector 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. By application of flushing systems please note separate instruction. 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 % alcaline, 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
Automated Disinfection:	For instrument cleaning/disinfection special equipment (cleaning and disinfection devices) must be used. According to the RKI instructions “Hygiene requirements for medical devices for handling medical products”, manual cleaning/desianfection is not recommended due to its much lower efficiency (when chemical disinfection is used, there is the danger of remaining of chemical disinfectants on the instruments). Automated thermal disinfection must be carried out in accordance with national regulations in relation to value A_o (see ISO 15883). When choosing cleaning/disinfection equipment, it is important to make sure that the efficiency of this equipment is properly certified (for example, approved by DGHM or FDA, or has a CE certificate according to DIN EN ISO 15883). The suitability of the procudure used for efficient automated disinfection is validated by the following working operations: • The use of Miele G 7736 CD sterilizer for cleaning and disinfection; • Rinsing with sterile debacterized (max. 10 microorganisms per ml), endotoxin-free (max. 0,25 endotoxins per ml) water; • Temperature 94° C, for at least 5 minutes. The above-described procedure allows to reach the A_o value of 3000. **<u>The sequence of operations:</u>** 1. Place the instruments into the cleaning/disinfection equipment. Make sure that the instruments do not touch each other. 2. Start the program. 3. When the program ends, remove the instruments from the cleaning/disinfection equipment. 4. Visually inspect the instruments and pack them as soon as possible after the removal (see **Functional Testing, Maintenance** and **Packaging** paragraphs) or after the additional drying (if needed) in a clean place. The process results must comply with the correspondent national requirements. The described procedure must be validated by the user. A final rinse should be carried out thoroughly with distilled or de□ionized water. It has a pH of 6.7 to 7.2 and leaves a neutral surface pH as the alkaline wash water residue is rinsed away. Alkaline earth deposits (calcium, magnesium, phosphate) and metals (iron, copper, cadmium) will not deposit themselves on the surface to promote corrosion. Distilled water also contains no dissolved or undissolved solids to adhere to the instrument surface. The instrument must then be dried completely, especially if it is to be stored for a period of time prior to sterilization. The heat of hot rinse water may aid the drying process. Inadequate drying will result in rusting during storage.
Drying:	Drying of outside of instrument through drying cycle of washer/disinfector. The air used for drying must be filtrated. 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:	Standartized packaging for the sterilized instruments in sterile bags acc. to ISO 11607-1. Any divergences from the recommended packaging must be validated.
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: 5 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 above-described chemicals and machines are not available, the user must validate his own process. The user must ensure that the biocompatibility of the devices could be assured through the selection of appropriate cleaning chemicals and re-processing procedures. The user is responsible for the removal of the cleaning chemicals after the used cleaning process. The complete removal of the cleaning chemicals for the used process must be specified and made valid.	
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 singel 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 smaler sterilization containers shall be appropriate less than the 1/1 sterilization containers.
- For Crutchfield-Jacob contaminationed 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, desinfection 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 resterilizable 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. The used lubrication with physiologically inert instrument oil must be eligible for the using with surgical instruments.

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 the “sticking” of joints through a multiplying effect is avoided.