Instruction Manual – Surgical Instruments

Thank you for the purchase of surgical instruments from Honer Medizin-Technik.
Please read this instruction manual carefully and completely before using the product.

1. Common Note
Important prior to first use and before returning for repair, the instruments must be cleaned and sterilized according to our treatment guide.

2. Intended Use
The instruments may be used exclusively for its intended use in medical fields by suitably trained and qualified personnel. Responsible for the selection of instruments for particular applications or operational use, the appropriate training and information, and the lack of experience for the handling of the instruments, is the attending physician, the buyer or user. Honer Medizin-Technik as the manufacturer and seller of the products shall not be liable for any direct or consequential damages resulting from improper use, handling or improper treatment, sterilization and maintenance.

3. Reusability
The instruments can - with proper care and if they are undamaged and fully functional - be reprocessed and reused. The lifetime is limited by damage and normal wear and tear; these products must be rejected after treatment. Please note, however, the limitation of Creutzfeldt-Jacob Disease (CJD) and then only for a presumption that the products do not have to be used and destroyed.
Honer Medizin-Technik does not specify the maximum number of applications and processing cycles of reusable instruments. The lifetime depends on many factors including the type and duration of application, as well as handling, storage and transportation of instruments. Thorough checks and functional tests before the next use is the best way to recognize a no longer viable tool and sort it out.
We point out that by enriching detergents the biological compatibility of the tools can not be given. This is the surveillance duty of the user.

4. Repair
Honer Medizin-Technik offers a repair service for your products. If the instruments are repaired by companies or individuals who have not been authorized by Honer Medizin-Technik for the repair the warranty is deletd. An inspection before and after each use, for breaks, cracks, bends, damage and functioning should be examined. Special care areas such as blades, points, locks, ratchets, and all moving parts have to be considered. Worn, corroded, deformed, porous, stress corrosion cracking or damaged instruments must be sorted out.

5. Treatment / Sterilization
5.1 General
The stainless steel used for the production of surgical instruments form the basis of their specific alloy passive layers as protective coatings. These steels are only partially resistant to be attacked by chloride ions and aggressive liquids!
In addition to the efforts being undertaken by the manufacturer in selecting the right materials and the meticulous craftsmanship, the user must pay attention to ongoing care and proper treatment of the surgical instruments by a professional. We recommend the following procedure for the reprocessing of our reusable surgical instruments:
Mechanical cleaning. The instrument cleaning and disinfection in cleaning machines is always the preferable method because mechanical processes can be standardized.
The operating and loading regulations of the manufacturers have to be followed. Only the recommended detergent for the specific application purpose from the manufacturer of the cleaning machines can be used.
Each instrument has to be placed in the cleaning machine in completely open state so that water can drain from cannulae, blind holes and hollow bodies.
Disassemble instruments as much as possible. Also the existing product protection has to be removed.
For instruments with long and narrow cavities, the methods are only suitable if these cavities can be traversed by the hot disinfectant media when removing the instruments. When removing the instruments check cannulations, blind holes, etc. to investigate visual pollution. If necessary, repeat the cycle or clean manually. Use only appropriate cleaning and disinfection agents.
An inspection before and after each use, for breaks, cracks, bends, damage and functioning should be undertaken. Special care areas such as blades, points, locks, ratchets, ratchets and all moving parts have to be considered. Worn, corroded, deformed, porous, stress corrosion cracking or damaged instruments must be sorted out.

5.2 Sonication
For ultrasonic cleaning surgical instruments must be stored in open state on cleaning / sterilizing baskets. Since warm water without additives brings no satisfied cleaning results, a suitable cleaning agent can be added to the water. The manufacturer's instructions regarding the concentration must be considered. The temperature of the cleaning solution in the ultrasonic tank must be followed according to the manufacturer of the applied detergent. Too much dirt loading affects the cleaning result. Therefore, the cleaning solution has to be replaced in intervals according to the manufacturer. The irradiation times must be used according to the manufacturer of the applied detergent.
Basically, ultrasonic cleaned instruments must then be subjected to a wash. After ultrasonic treatment, the instruments have to be checked for loose parts (screws, etc.). The flushing is carried out with distilled water to avoid water spots.

5.3 Manual Cleaning
The instruments should be cleaned and disinfected if possible immediately after use in accordance with our guidelines for preparation and sterilization of surgical instruments. The contamination should not dry on the objects to not discourage disinfection and purification processes.
The following points should be noted:
The solution for manual cleaning must be set according to the manufacturer. For cleaning needles, blind holes and hollow bodies a suitable soft brush can be used and a water pistol to flush (pulsed method), so that every part is reached. Remove blood and other debris with a soft brush and a mild neutral or alkaline cleaner. For manual cleaning never use metal brushes or metal sponges. To ensure the function of the instrument, make sure that all moving parts are thoroughly cleaned. Clean jointed instruments in closed open state. Disassemble instruments as much as possible. During cleaning special attention should be paid to slots, locks, close cannulations, blind holes and other difficult to reach areas. Suitable for cleaning surgical instruments are for example, sterilizing baskets. Honer Medizin-Technik offers suitable containers to you.

5.4 Chemical Disinfection

1. The solution during chemical disinfection must be used according to the manufacturer of the applied solvent.
2. The use dilutions of the chemical agent are produced with pure water. An addition of cleaning agent is not allowed. When using chemicals, the manufacturer's data (reaction time concentration) must be strictly observed.
3. The disinfectants must be used daily. Multi-use can cause the following problems: increasing the concentration by evaporation (corrosion) or high dirt protection (corrosion decrease the effect).
4. After disinfection the instruments must always be adequately rinsed with clean, running water. To avoid water spots demineralized water is used.
5. Surgical instruments must be sufficiently dried immediately after completion of the cleaning and rinse cycles.

5.5 Steam - Sterilization
Sterilize all instruments before use.
Recommended sterilization method: steam sterilization with fractionated vacuum EN 554
Recommended temperature: 134°C (max. 137°C, holding period: min. 5 to max. 18 minutes.
It is essential to excluded stresses of the steam by foreign substances, e.g. rust or other impurities. This can avoid the corrosion or dirt (formation of surface) of the surgical instruments. Steam for sterilization purposes must match DIN 58946. The manufacturer's instructions for steam sterilizers should be observed to avoid disadvantages. During the cleaning, disinfection and sterilization particularly the following sources are considered:
DIN EN ISO 17664 information provided by the manufacturer for the reprocessing of re-sterilisable devices. EN sterilization 285 - Steam sterilizers - Large sterilizers EN 554 Sterilization of medical devices, validation and routine control of sterilization by moist heat DIN EN 556-1 Sterilization of medical devices - Requirements for terminally sterilized medical devices that are marked as sterile - Part 1: requirements for medical devices, which were sterilized in the final:
DIN 58946-7 Sterilization, Steam - sterilizers, Structural requirements in large steam sterilizers
Proper Maintenance of Instruments made AK instrument preparation http://www.aki.org recommendations for validation and routine control of a sterilization process for medical devices with moist heat, the recommendation DGKH http://www.dgkh.de
Hygiene requirements for the reprocessing of medical devices, the recommendation of the Commission for Hospital Hygiene Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs Medical Devices (BfArM) to the standards of hygiene in the reprocessing of medical devices http://www.rki.de

6. Limitation and Information Processing
Honer Medizin-Technik offers the appropriate accessories for the reprocessing of surgical instruments.
Frequent reprocessing has little effect on these surgical instruments. The lifetime of the product is usually determined by wear and damage from use. After the end of the product lifetime, take care of proper disposal of the surgical instruments or recycle them.
It is up to the user to validate its corresponding method. It is the duty of the user to ensure that the reprocessing processes, including resources, materials and personnel, is suitable to achieve the required results The state of the art national law requiring the follow of validated processes.

7. Care
Honer Medizin-Technik provides cleaning product for the proper care of surgical instruments.
Maintenance means to put instrument oil (physiologically liquid paraffin to DAB and Ph. Eur.) or instrument milk (emulsion of hydrocarbon white oil in water) on the surface, particularly on moving parts / joints of the surgical instruments. In principle, surgical instruments are of sufficient care and that undergo prior to functional testing. Care products must guarantee that even with constant use the sticking the joint parts are excluded due to the summation effect. Dry the outside of the instruments by drying cycle of the cleaning / disinfection unit. If needed, additional manual drying can be done by using a lint free towel. Cavities of instruments should be dried with sterile compressed air.
Store the products in a dry, clean, dust-free environment away from direct sunlight at moderate temperatures from 5 ° to 40 °C. Transport and storage should not negatively affect the characteristics of the medical device.

8. Product protection
Instruments which by their nature have sharp ends will be delivered by a protective tube. Hereby, staff and the instrument itself are protected. To avoid injury, be careful when the protection is attached or detached.
The product protection is supplied non-sterile. The protective tube can be sterilized in accordance with these instructions. Defective or otherwise not suitable protection must be disposed immediately. Newly required protective tubes can be ordered at Honer Medizin-Technik.

9. Disposal
For disposal, the country-specific laws and regulations have to be considered.

10. Warranty
We provide full guarantee in the event of production or quality issues. In case of damage due to improper handling as for example mechanical action, camber, congestion, etc. the warranty is excluded. The normal wear and tear through the use of products is not covered by the warranty. Repairs should only be conducted by us or an authorized company.

11. Labelling
Products comply with the European directive 93/42/EC.
Not listed or missing information can be requested from the manufacturer. Valid is always the German version.

LOT	The batch number used for tracking. The batch number has to be mentioned in case of complaints.
	An instruction manual is available.
NON STERILE	The product is non sterile. All products, product protection and packaging, etc. are supplied non sterile!
CE	Class I products are CE marked.
CE 0086	Class II products are additionally marked with the identification number of the notified body CE 0086. BSI UK.