» REUSABLE SURGICAL INSTRUMENTS «

Surgical instruments are high-quality products whose proper handling and use will be described in the following.
In order to minimize hazards for patients and users these directions must be closely obeyed. Application, maintenance and test of the instruments may only be carried out by specially skilled staff. Reusable surgical instruments from Tekno-Medical are, if not stated otherwise, supplied not sterile and need to undergo a complete cleaning/disinfection cycle before the first and each following use.

INTENDED USE

This manual, if not stated otherwise, is valid for all Tekno-Medical reusable surgical instruments of risk class I, with article numbers starting with:
4xxx-xx; 5xxx-xx; 6xxx-xx; 7xxx-xx; 8xxx-xx; 9xxx-xx; 10xxx-xx; 11xxx-xx; 12xxx-xx; 13xxx-xx; 14xxx-xx; 15xxx xx; 16xxx-xx; 17xxx-xx; 18xxx-xx; 19xxx-xx; 20xxx-xx; 21xxx-xx;22xxx-xx; 23xxx-xx; 24xxx-xx; 25xxx-xx; 26xxx-xx; 28xxx-xx; 29xxx-xx; 30xxx-xx; 31xxx-xx,32xxx-xx; 34xxx-xx; 35xxx-xx; 36xxx-xx; 37xxx-xx; 38xxx-xx; 39xxx-xx; 40xxx-xx; 48xxx-xx; 49xxx-xx; 50xxx-xx; 51xxx-xx; 52xxx-xx; 53xxx-xx; 55xxx-xx; 54xxx-xx; 55xxx-xx; 56xxx-xx; 70xxx-xx; 71xxx-xx; 72xxx-xx; 73xxx-xx; 75xxx-xx; 79xxx-xx; 83xxx-xx; 6xx-xxx; 7xx-xxx; 8xx-xxx; Z0000xxxxxx.

These instructions for use are valid for surgical instruments made of stainless steel, such as dental instruments, extracting forceps, instruments for bone surgery, scalpels, knifes, scissors, forceps, clamps, retractors, probes, spatulas, suture instruments a s o.
Dismantable instruments or instruments made of other materials will be distributed with special instructions.
Instruments made of titanium or titanium alloys are to be treated exactly as stainless steel instruments. No special advice need to be observed.
Instruments made of aluminium need to be cleaned/disinfected with non-alkaline, neutral cleaning/disinfection detergents and fully desalinated water, in order to avoid damages to anodized surfaces. Alkaline cleaning procedures will very quick have negative effects on colour anodized surfaces.

TESTS

Prior to each use, the instruments must tested to their correct working order.
Surface damage such as scratches, cracks, nicks, dents as well as bent parts indicate that the instrument must not be used. Defective products should be repaired or disposed of as specified by the hospital.
Damaged products may not be used!

HANDLING

The instruments must not be overstressed by twisting or levering as this may lead to damages or cracking of the instruments.

PURPOSE / FIELD OF APPLICATION

These operating instructions are valid for standard surgical instruments of the production of Tekno-Medical. The user decides according to his specialized knowledge whether the instrument may suitable for the intended purpose.

CAUTION: USE OF SELF-RETAINING RETRACTORS MUST NOT EXCEED 60 MINUTES CUMULATIVELY.

CAUTION: SUCTION AND IRRIGATION CANNULAS ARE NOT SUITABLE FOR CONNECTION TO AN ACTIVE MEDICAL DEVICE.

DISPOSAL

Instruments that cannot be repaired or reprocessed should be disposed in accordance with the respective disposal guidelines of the hospital.

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MATERIALS

The materials used, if not otherwise stated, are stainless steels according to DIN EN ISO 7153-1.

REPROCESSING DIRECTIONS

Surgical instruments may in general only be processed by specially skilled staff possessing the specific knowledge for this kind of work.
Detailed information to the maintenance of instruments are available in the "Red Brochure" of the AKI. Under www.a-k-i.org links to laws, norms and specialized maintenance committees can be found.

ADVICE

- Instruments made of stainless steel must not be put in physiological saline solutions (NaCl), as longer contact may lead to corrosion damages.
- Instruments may only be sterilized after a previous cleaning and disinfection.

INSTRUCTION

Due to the design of surgical instruments and the used materials, it is not possible to determine a limited number of reprocessing cycles. The lifetime of surgical instruments is therefore determined by the function / wear of the device.
In case of damage the device must be reprocessed before sending back to the manufacturer for repair.

REPROCESSING INSTRUCTIONS

Preparation at the point of use:
Remove gross soiling by submerging 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 residuals 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. Instruments must be placed on adequate supports or trays. The nature of the supports or trays must not have any negative influence on the result of the following cleaning and disinfection by rinsing or ultrasonic treatment.

Manual precleaning:
Immerse the instrument into cold demineralised 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 an alkaline or enzymatic detergent (0,5%) and treat with ultrasound for 15 minutes at 40°C.
Remove the instruments from the bath and rinse again with cold tab water.
The cleaning bath must be changed at least once a day, or if required. Any pollution may influence the result of cleaning / disinfection and may favour corrosion.

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Automated cleaning:
Put the instruments opened on an instrument tray. Dismantable instruments must be taken apart as far as possible. Put the tray on an instrument rack in the washer disinfector 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 with 0,5 % alkaline; or at 45°C with an enzymatic detergent.
6. draining
7. 3 min. neutralisation with warm water (>40°C) and neutralizer
8. draining
9. 2 min. rinsing with warm demineralised water (>40°C)
10. draining

Disinfection:
Automated Disinfection:
Automated Thermal Disinfection with demineralised water in washer/disinfector under consideration of national requirements in regards to A_0-Value (see ISO 15883).

Drying:
Automated Drying:
Drying of the outer sides of the instruments by the drying cycle of washer/disinfector.
If necessary, additional manual drying can be performed with a lint free towel. Insufflate cavities of instruments by using sterile compressed air.

Manual cleaning:
In case of manual cleaning, the cleaning process needs to be adapted to the pre-treatment. The used detergents must be compatible, in order to avoid any negative influence on the cleaning/disinfection result.

- The detergent must be suitable for the treatment of surgical instruments.
- The manufacturer's instructions regarding concentration and reaction time must be strictly obeyed.
- Use only soft brushes, no metal brushes.
- Channels and hollow parts must be rinsed thoroughly. If necessary, a high pressure hose must be used.
- Rinse the instruments with running clear water.
- Dry the instruments thoroughly.
- The cleaning bath must be changed at least once a day, or if required.

Chemical disinfection:
The chemical disinfection follows the manual cleaning. A detergent, suitable for surgical instruments made of stainless steel must be used.

Drying:
Manual drying might be performed with a lint free towel. Insufflate cavities of instruments by using sterile compressed air.

Functional testing, maintenance:
Visual inspection for cleanness, assembling and functional testing according to instructions of use.
If necessary reprocess again until the instruments are visibly clean. Instruments with movable parts must be treated with a special instrument oil, e.g. TK95100-00. Instruments with ratchet must be closed in the first position.
Defective or damaged instruments must be immediately sorted out.

Packaging:
Appropriate packaging for sterilization according ISO 11607 and EN 868.

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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 millibar
- Heat up to a minimum sterilization temperature of 132°-134°C; maximum temperature 137°C
- Minimum Holding time: at least 5 min at 134°C
- Drying time: minimum 10 min
- A SAL(Sterility Assurance Level) of 10^{-6} must be achieved.
- Any change of the sterilization process is beyond our responsibility.

Storage:
Storage of sterilized instruments in appropriate packaging in a dry, clean and dust free environment at modest temperatures of 5°C to 40°C, and at a constant humidity. The distance between shelf and floor should be at least 30cm.
Storage duration time is to be determined by the user.

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:	01707011901-2 SMP GMBH
		Sterilization:

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.

WARRANTY

The products are made of high grade medical steel and are controlled prior to sale. In case of any error or inconvenience, please feel free to contact our service.
Tekno-Medical cannot provide any guarantee weather the instruments are suitable for the respective intervention. This has to be determined by the user.
Tekno-Medical does not provide any liability for any damages arising from pure chance.
Tekno-Medical does not provide any liability for any damages deriving from contravening against this manual.
In case of using the instruments on patients with CJD, Tekno-Medical does not provide any liability for the reprocessing of the instruments.

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