

Instruction of use

Detachable KERRISON
laminectomy punches



REF

40-014-01 Z - 40-016-26 ZE



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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.

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 (static pressure at least 3,7 bar) for minimum 10 seconds in the pulsed mode.

Automated cleaning

Put the instruments in a disassembled state on an instrument tray. Put the tray on an instrument rack in the washer disinfectant and start the cycle:

- Step 1 1 minute pre-cleaning with cold water
- Step 2 3 minutes pre-cleaning with cold water
- Step 3 5 min cleaning at 55°C with 0,5 % alkaline or enzymatic detergent (if enzymatic detergent is used the cleaning temperature is 45°C).
- Step 4 3 minutes neutralisation with warm water (> 40°C) and neutraliser
- Step 5 2 minutes rinse with warm water (> 40°C)
- Step 6 Draining

Disinfection

Automated Disinfection: Automated Thermal Disinfection in washer/disinfectant under consideration of national requirements in regards to A0-Value. (see ISO 15883)

Drying

Automated Drying: Drying of outside of instrument through drying cycle of washer/disinfectant. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.

Functional Testing and Maintenance

Visual inspection for cleanliness, assembling, loose screws and functional testing according to instructions of use. If necessary perform reprocessing process again until the instruments are visibly clean. Joints and Shaft guides must be lubricated with medical instrument oil to avoid fretting corrosion. Distribute the lubricant uniformly in the joint by opening and closing the instrument several times. Use only instrument oils, which are approved for sterilization and taking into account the maximum sterilization temperature applied, on which have proven biocompatibility.

Packaging

Appropriate packaging for sterilization according to ISO 11607 and EN 868.

Sterilization

Sterilization of instruments by applying a fractionated pre-vacuum process (according to DIN EN 13060/ISO 17665) 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: 4 Minutes
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.

Validation information of the cleaning process

The following devices, materials & machines have been used in this validation study:

Detergent: Neodisher FA; Dr. Weigert Hamburg (alkaline) Endozime, Fa. Ruhof (enzymatic)
Neutraliser: Neodisher Z; Dr. Weigert Hamburg
Washer / Disinfectant: Miele G 7736 CD
MIC Instrument Rack: E 327-06

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Additional instructions

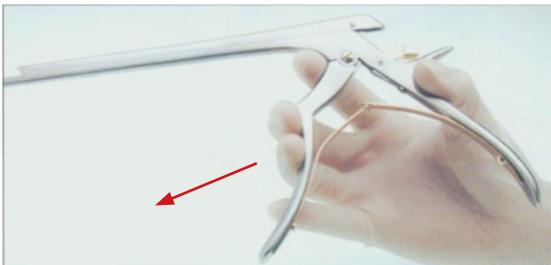
If the described chemistry and machines are not available, it is the duty of the user to validate his process. It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable of reaching the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.

AS MEDIZINTECHNIK GMBH DOES NOT ACCEPT RESPONSIBILITY IF THIS CUSTOMER INFORMATION HAS BEEN VIOLATED PROVABLY.

Disassembly



1. First close the handle.



3. Now open the handle.

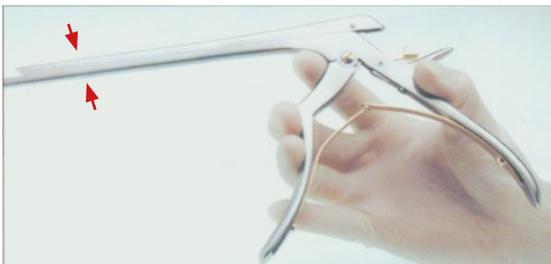


2. Then push the lever downwards.



4. And push downwards at the end of the shaft. Ready!

Assembly



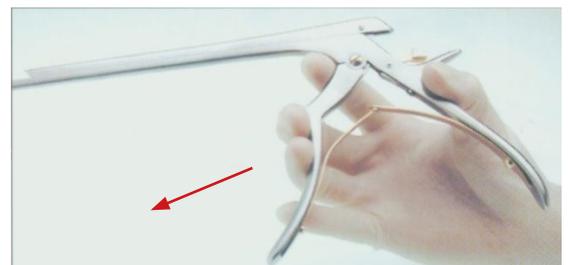
1. First push shaft parts into one other.



3. Now push the lever upwards.



2. Then close the handle.



4. And finally open the handle. Ready!