

Instruction of use

Detachable KERRISON
laminectomy punches



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Detachable Kerrison Laminectomy punches: Art. No. 40-014-01 Z - 40-016-26 Z

Procedure: Automated Cleaning Process
Products: AS Medizintechnik Kerrison Laminectomy punches, detachable

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.

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:

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 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 Disinfection: Automated Thermal Disinfection in washer/disinfector 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/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.

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Functional Testing, 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 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°-134°C; maximum temperature 137°C

Minimum Holding time: 4 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 / Disinfectant:	Miele 7735 CD
Instrument Rack:	Miele E 327-06

Additional Instructions:

If the described chemistry and devices 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.

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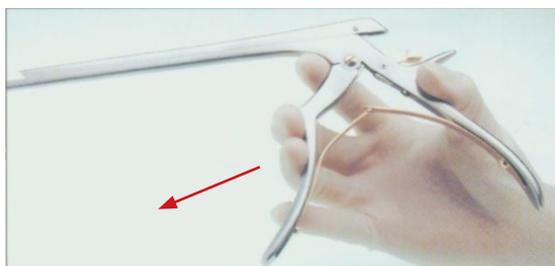
Disassembly



1. First close the handle.



2. Than push the lever downwards.



3. Now open the handle.



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

Assembly



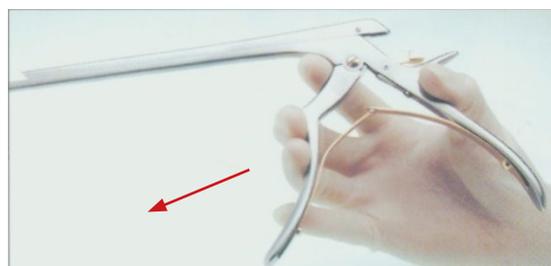
1. First push shaft parts into one other.



2. Than close the handle.



3. Now push the lever upwards.



4. And finally open the handle. Ready!

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