Maxer
GERMANY

USER MANUAL

Surgical Instruments

Instructions for reprocessing

Intended use

Please read the information for the usage carefully before the use. This application does not replace the instructions for use of other instruments as well as the related equipment. Improper handling and cleaning as well as use for purposes other than intended can lead to early wear or perilous risks for patients and users.

In order to ensure this, the below instructions for use and safety must be followed and complied with. By purchasing this instrument, you are receiving a high-quality product, proper handling and use of which is illustrated in the following. In order to minimize the risks and unnecessary charges for the patients, we request you to carefully look through and store the instructions for use.

Medical devices may be only used by the persons, who are specially trained or instructed for that. The attending physician is responsible for the selection of instruments for certain applications or the operative use, appropriate training and information on others and sufficient experience for handling the instruments. The literature provided to the physician contains specifications regarding the specific application areas.

Warnings / Preventive measures

Non-compliance with these warnings and preventive measures can have severe consequences.

Warnings

- The devices have only a limited stability. Too high / too large application of force can damage the product and influence the function.
- Brittle or cracked sealings must be immediately replaced.
- The devices delivered are NON-STERILE.

Preventive measures

- The devices must be checked for integrity and function as well as the identity and completeness upon receipt and before you provide the devices for reprocessing.
- These must be examined before every use of the devices for: cracks, ruptures, deformations, damages, discolourations and operational reliability. In particular, the areas such as blades, needles, locks, latches, frames and movable parts must be taken into account. Deformed, corroded, porous and worn-out as well as otherwise damaged devices must be rejected.
- For avoiding condensate, the devices must be taken out from the polyethylene bags and must be stored open to air, dry (at max. humidity of 75% RH) in protective container until the first reprocessing at room temperature.

Materials

The devices are manufactured from high-quality materials and are subject to a quality check before delivery. Should defects arise even after that, then kindly contact us.

Maintenance / lubrication

- Clean the sealing surfaces thoroughly. Do not remove the sealing ring for cleaning.
- Please only use the appropriate grease. Use sparingly! (Grease based on paraffin oil/white oil and silicon-free, approved for steam-sterilization and bio-compatible)

Caution Risk of damage:
Do not use any needles or sharp objects for inserting the sealing ring. The washers can be thereby damaged!

Guideline for inserting the sealing ring: Moisten the ring with water before inserting.
Otherwise, it is difficult to insert the sealing ring correctly in the slot. Incorrectly inserted Sealing rings are the reason for a dripping shaft.

- Replace damaged sealing rings by compatible sealing rings and ensure thereby that the sealing ring is correctly inserted in the slot.

General information on hygiene and reprocessing
Information:

- Brand-new devices must be reprocessed before their first use. The transport packaging, protective covers, etc. are not suitable for sterilization.
- Only the approved media (RKI, DGHN, VHA, etc.) must be used
- Alkaline as well as Ph-neutral cleansing agents can be used.
- Water quality according to DIN EN 285 appendix B
- Only the processed for cleaning/disinfection/sterilization sufficiently validated specific to the equipment and device must be used
- Manufacturer’s specifications and recommendations must be followed
- Defined limit of max. executable reprocessing cycles cannot be determined due to the product design and the materials used. The service life of the medical devices is determined by their function and the conservative handling.
- Cannulas less than 1 mm make high demands on reprocessing. Cannulas under 0.5 mm should be no longer reprocessed since an easy cleaning cannot be ensured.
- The instruments should not come in contact with each other at the time of cleaning/disinfection → risk of damages
- Defective devices must be passed through the complete preprocessing procedure before repairs.

Creutzfeldt-Jakob (CJK)

- The respectively applicable national ordinances regarding reprocessing of the instruments must be applied in case of patients with Creutzfeldt-Jakob disease, suspicion or possible variants of this disease.
- We refuse any responsibility for the reuse after the use on patients with Creutzfeldt-Jakob disease or its variants. We recommend the disposal of the instruments. A reprocessing and reuse of even according to the RKI² guideline is carried out completely on one's own responsibility.

Reprocessing / preparation at the location of use

STEP 1. Conserve moisture

The instruments must be placed in a sieve/container and cover them with a cloth, which is moistened with sterile, distilled water. Do not use any fixing material or hot water (<40°C) since this can lead to fixing of residuals and can affect the result of cleaning.

STEP 2. Soak

Immerse the instruments in an approved alkaline solution as per recommendations of the manufacturer of the solution. Ensure by turning and tilting that all the bubbles from all cavities are soaked.

STEP 3. Rinse

Remove the alkaline solution after the time recommended by the manufacturer and rinse the instruments with tap water.

STEP 4. Clean the instruments

Use a small, soft, clean brush to clean the instruments while these are still immersed in the cleansing solution.

STEP 5. Rinse

Rinse the instrument by immersing in the demineralized water and wipe with a clean, soft cloth.

STEP 6. Visual inspection

Carry out a visual inspection of the instrument for cleanliness.

STEP 7. Dry

The instruments must be thoroughly dried. Residual moisture can lead to corrosion.

Preparation before cleaning

Devices must be separated as far as possible and must be cleaned and sterilized individually according to the below preparation steps:

Cleaning

Manual cleaning

- Devices must be rinsed under running cold municipal water (>40°C) until all the visible contaminations are removed.
- If required, a soft brush should be used, in order to removed the visible contaminations
- Immerse the instruments in an alkaline cleansing medium (if an ultrasonic bath is used, then the ultrasonic processes of 3 minutes and ultrasonic frequency of 35 KHz are effective).
- Follow the instructions of the manufacturer of the cleansing medium
- Rinse the instrument under running cold municipal water (>40°C)

Automatic cleaning

Place the devices in a sieve tray on the slide-in trolley and start the cleaning process.

- 4 minutes pre-rinsing with cold water
- Drain
- 5 minutes washing at 55°C with 0.5% alkaline cleanser
- Drain
- 3 minutes of neutralization with warm water tap water (<40°C) and neutralizing agent
- Drain
- 2 minutes intermediate rinsing with warm tap water (<40°C)
- Drain

Special requirements of the manufacturer of the cleaning machine must be taken into account.

Disinfection

Manual disinfection

Transfer devices in cold water for at least 5 min. Clean the devices under cold water with a soft brush until residues are no longer visible. Flush at least for 10 sec. with a water pistol

in case of threads (pulse process). Place the devices for 15 min. in an ultrasonic bath at 40°C with 0.5% alkaline cleanser and treat with ultrasound.

After the chemical disinfection and cleaning, the devices must be thoroughly rinsed with clear, flowing water. Any residues of dirt still adhering to the devices are removed hereby **(Do not use any metal brushes and any abrasive cleansers!)** Final rinsing with demineralized water is recommended for avoiding stains due to water spotting. Subsequently, the instruments must be immediately dried.

Follow the manufacturer's instructions for disinfection cleansers. Ensure that the cleanser can reach all the internal and external parts. The lumen must be filled with cleanser for instruments with lumen.

Clean the device and the lumen after the contact time with distilled water, in order to remove the cleanser.

Automatic disinfection

Carry out automatic thermal disinfection under consideration of national requirements concerning A0 value (see DIN EN ISO 15883).

Drying

Manual drying with lint-free cloth.

Drying the outer side of the devices using drying cycle of the cleaning/disinfection equipment. If necessary, manual drying can be achieved additionally with the help of lint-free cloth.

Dry the cavities of devices with sterile compressed air.

Checking, maintenance and test

The devices must be examined before their use for discolourations, notches, cracks and other damage,
which could be caused due to improper sterilization and/or storage.

If one of the above mentioned features can be identified in the device, then it may not be used or applied in any case before a re-inspection from our side.

Execute optical assessment for cleanliness, maintenance, functions.

If necessary, repeat the reprocessing procedure until the instrument is visibly clean.

Before sterilization

Plug valves and valve plungers must be greased before sterilization (grease based on paraffin oil/white oil and silicon-free, approved for
steam sterilization and bio-compatible) and movable parts must be oiled.

Sterilization

- A fore-vacuum procedure is recommended for sterilization
- Other sterilization procedures and the flash sterilization procedures are not allowed.
- Sterilization of the devices with fractional fore-vacuum procedure (as per ISO 13060 / ISO 17665) under consideration of respective national requirements.

3 fore-vacuum pumps with at least 60 millibar pressure

Heating up to sterilization temperature of at least 132°C; max. 137°C

Shortest dwell time: 4 min

Drying time: at least 10 min

The devices are suitable for re-sterilization with the said procedure.

- Automatic cleaning/thermal disinfection must be preferably applied
- Proper handling and storage appropriate for the instruments
- A0 – value (duration/temperature) corresponding to grading of the devices on the basis of RKI2 guidelines
- Only the appropriate chemicals in right metering can be used as per specifications of the cleansing medium manufacturer.
- The material can be damaged due to unsuitable water, inappropriate cleansing medium or methods.

Cleaning and sterilization must be carried out only by the trained staff. Similarly, there is a risk due to improper reprocessing that the instrument is damaged and thus may no longer be used.

Contact with hydrogen peroxide (H_2O_2) must be avoided.

After the sterilization

All the plastic parts must be checked after the sterilization that these are not cracked, brittle or worn out. If necessary, these parts must be replaced by new original parts.

Disposal

The defective or explanted devices must be properly disposed.

Packaging

Packaging of instruments for sterilization conforming to standard as per ISO 11607

Storage

Storage of the sterilized instruments iin a dry, clean and dust-free environment at moderate temperatures.

Transport

Secure storage in a closed container and transport of the instruments to the location of reprocessing, in order to avoid the damages of the instruments and contamination towards environment

Safety and liability

- The user is obliged to test the device for the suitability and range of applications for the planned purposed at his own responsibility before its use. The application of the instruments is subject to the responsibility of the user.
- If the chemicals and machines mentioned above are not available, then it is the responsibility of the user to validate the procedure correspondingly.
- It is the duty of the user to ensure that the reprocessing procedure including resources, material and staff is suitable for achieving the required results.
- We do not assume any liability for the consequences of improper handling and reprocessing. The user decides whether the instrument is suitable for the planned application.

Repairs

- The medical devices sent for repairs must be cleaned beforehand (free from any residues), disinfected and sterilized.
- Service and repairs may be only carried out only by us as manufacturer or by the person determined by us.
- The medical devices show more or less heavy wear and tear even upon intended use depending on intensity of application, for which it is technically conditioned and unavoidable.

Warranty

The devices are manufactured from high-quality materials and are subject to a quality check before delivery. Should defects arise even after that, then kindly contact our service. However, we cannot provide any warranty whether the devices are suitable for the respective intervention. This must be determined by the user.

Guarantee

The company Maxer Medizintechnik GmbH does not provide any guarantee if using third-party equipment.

Identification

The symbols shown on the product or product label, who in accordance with DIN EN ISO 15223-1 following Importance:

	Lot Number
	Symbol for "Contents not sterile"
	Attention! Failure to observe the warnings and precautions can result in death or serious Injury.
	Symbol for "Instructions for use"
	Symbol for "Manufacturer"
	CE mark with identification number of the Notified Body mdc

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