Instruction manual

For reusable surgical instruments CE

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Manufacturer

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Products

This instruction manual is valid for all reusable surgical instruments, which

- are one-piece instruments
- optionally have simple joints or
- include simple moving parts
- are optionally composed of multiple replaceable parts (e.g. handle and multiple attachments)

Important Information

Read this instruction manual carefully before every application and keep it easily accessible for all users or the respective specialist staff.

Carefully read the warnings marked with this symbol. Improper use of the products may result in serious injuries to the patient, the users or third parties.

1 Scope

The instruments must be used according to their intended use in the medical fields and by respectively trained and qualified staff only. The treating physician and/or user is responsible for choosing the equipment for specific applications and/or operative use, for the appropriate training and information, and for the sufficient experience regarding the handling of the equipment.

The instruments intended application duration is 60 minutes. The product must be replaced after 60 minutes.

2 Contraindication

The instruments must be used according to their intended use in the medical fields and by respectively trained and qualified staff only. The instruments of CM GmbH may not be used in the areas of cardiothoracic surgery and neurosurgery.

3 Precautions and Warnings

Attention!

The instruments are only designed for surgical use and must not be used for any other purpose. Improper handling and maintenance as well as misappropriated use may result in the premature wear and tear of the instruments.

Material intolerance

Under no circumstances must the instruments be used if the user or specialist staff become aware of the patient being intolerant to the material.

Functional Impairment

Surgical instruments corrode and become impaired in their functionality if they come into contact with aggressive substances. It is therefore necessary to observe the storage and sterilisation instructions.

Operating Conditions

The aforementioned products require correct maintenance and care in order to guarantee that the products operate safely. In addition to this, functionality testing and a visual check should be performed prior to each application. For this reason, please pay attention to the respective chapters in this instruction manual.

Combination with other products

Should the products be reassembled after disassembly, individual parts must not be replaced with parts from other manufacturers! If the intended purpose of the product entails certain parts being exchanged (e.g. different attachments), no parts from different manufacturers must be used! We recommend to also purchase other accessories (e.g. detergents) at CM Instrumente GmbH.

Storage

There are no specific storage requirements concerning the products. Nevertheless, we recommend storing medical products in a clean and dry environment.

Creutzfeldt Jakob Disease

With regard to the reprocessing of medical devices that have been used on patients or suspected patients suffering from or suspected of suffering from Creutzfeldt-Jacob disease (CJD) or its variant (vCJD), the requirements specified in the corresponding appendix of the guidelines for hospital hygiene and infection prevention and the requirements specified by publications in the Federal Health Gazette must be adhered to. The medical devices that were used on this group of patients must be disposed of by incineration (European Waste Catalogue EAK 18 01 03) without risk. Dry heat, ethanol, formaldehyde and glutaraldehyde have a fixing but no inactivating effect on TSE pathogens. Of the sterilization methods available, only steam sterilization (especially 134°C, 18 minutes) has been shown to have a limited effect.

4 Liability and Warranty

As a manufacturer, CM Instrumente GmbH is not liable for consequential damage resulting from improper use or handling. This particularly applies to use which is not compliant with the defined intended use, or non-compliance with the instructions on preparation and sterilisation. This also applies to repairs or changes to the product which are not carried out by authorized staff of the manufacturer. These disclaimers also apply to warranty services.

5 Sterility

State upon Delivery

Medical products are delivered in a non-sterile condition and need to be prepared and sterilised by the user prior to the first application and any subsequent application according to the following instructions.

6 Reprocessing

Warnings

- Frequent reprocessing impairs the quality of the products.
- Any tap water to be used must comply with COUNCIL DIRECTIVE 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.
- The detergents and disinfectants used in order to maintain validation are listed in this instruction for reprocessing. Should an alternative detergent or disinfectant (listed at the RKI or VAH) be used, the responsibility lies with the reprocessor.
- Reassemble disassembled products prior to sterilisation.
- The preparation may only be carried out by qualified medical personnel. Machine reprocessing must be qualified and validated by the user. The washer-disinfectors must fully comply with the requirements of DIN EN ISO 15883.

Use Site

The first steps of a proper reprocessing take place in the operating theatre. Coarse contaminations must be removed prior to storing the instruments if possible. For this purpose, the instruments should be rinsed under cold tap water (<40°C). If this procedure is not sufficient to remove the obvious soiling, a soft plastic brush can be used to remove soiling.
Whenever possible, dry removal (moistened, closed system) should be the method of choice. A drying of any residues should be avoided! Wherever possible, dry disposal is to be preferred, since with wet disposal the prolonged lying of the medical devices in solutions can lead to material damage (e.g. corrosion). Long periods of waiting until the reprocessing, for instance overnight or over the weekend, must be avoided with both types of removal (<60 minutes).

Transport

The products must be disposed of in a dry state immediately (<60 min) after use, if possible. This means that the products have to be transported in a closed container from

the place of application to the purification, so that the products do not dry up.

Preparing the Decontamination

The products must be disassembled prior to the following reprocessing steps and/or must be exposed to the following reprocessing steps in an open condition, where possible. Rinse residue must be avoided. The products must be reprocessed in appropriate screen baskets or rinsing shields (choose size according to product). The products must be positioned in the cleaning basket at a minimum clearance from one another. Avoid overlapping so that the damaging of the products during the cleaning process can be excluded.

Pre-cleaning

Rinse the products under cold tap water suitable for use as drinking water (<40°C) until all visible contaminations are removed. Remove persistent dirt with a soft brush. Movable parts on the instrument need to be moved. Cavities, lumen, gaps and slits need to be rinsed intensively (>60 sec) with cold tap water suitable for use as drinking water (<40°C) using a water pistol (or similar). Insertion of the products into an ultrasonic bath (<40°C) with an alkaline cleaner (0.5% Neodisher® MediClean forte, Dr. Weigert), time of treatment 5 min. at a frequency of about 35 kHz. For this please observe the instructions of the cleaning agent manufacturer. Rinse instruments briefly (<15 sec) under cold water. Movable parts must be moved. Respectively rinse cavities, lumen, gaps and slits again (>30 sec.) with cold city water (<40°C) using a water pistol (or similar).

Cleaning/disinfection

Automated cleaning and/or disinfection process

(Miele Disinfector G7835 CD as per ISO 15883):

- Pre-clean for 1 minute
- Drain water
- Pre-clean for 4 minutes
- Drain water
- Clean for 6 minutes at 58°C +/- 1°C using 0.5 % alkaline detergent (0,5 % Neodisher Mediclean forte)
- Drain water
- Neutralize for 3 minutes (0.1% 0,1 % NeodisherZ) with cold tap water suitable for use as drinking water <40°C
- Drain water
- Clean for 2 minutes with FD water <40°C

Please observe the special instructions of the manufacturer of the automatic cleaning machine.

Automated Disinfection

Automated thermal disinfection in a cleaning and disinfection device taking into consideration the national requirements for the A_0 value; for instance, A_0 value 3000:

>5 minutes at >95°C.

Automated Drying

Automated drying in accordance with the drying operation of the cleaning and disinfection device for at least 30 minutes at 92°C +/- 2°C.

Sterilisation

(Typ B Autoklav by Tuttmauer as per DIN EN 13060)

Sterilisation of products with a fractionated pre-vacuum method (according to DIN EN ISO 17665-1) taking into consideration the respective national requirements. The sterilisation of the products must be conducted in suitable sterilisation packaging according to DIN EN ISO 11607-1 and EN 868

The sterilisation must be completed using a fractionated pre-vacuum method with the following parameters:

134°C,

5 minutes hold time,

3 pre-vacuum cycles

Drying in vacuum for at least 20 minutes

The instruction manual of the manufacturer of the autoclave and the recommended directions for maximum loading with goods to be sterilised must be observed. The autoclave must be installed, maintained, validated and calibrated in accordance with requirements.

⚠ **Additional Information**

The reprocessor is responsible for ensuring that the actual reprocessing, including the used equipment, materials and the staff involved in the reprocessing facility, achieves the desired results. This typically requires the validation and routine monitoring of the method and the equipment used.

7 Lifespan of the Products

Frequent reprocessing has little effect on the surgical instruments. Product life is limited by wear due to proper use and damage to the instrument. The product may no longer be used under the following conditions, among others:

Corrosion, damage, fractures, cracks, deformation, porosity, functional limitations, products with unrecognizable or missing marking. For this reason, the conditioner must comply with the relevant instructions for functional testing (section 8).

8 Functional testing

Check products after reprocessing and before sterilization with regard to the following aspects:

- Cleanliness
- Damage, including but not limited to signs of corrosion (rust, pitting), discoloration, deep scratches, flaking, cracking and wear.
- Proper function
- Missing or removed (ground off) part numbers.
- Do not use improperly functioning or defective and excessively worn products, products with unrecognizable markings, missing or removed (ground) part numbers.
- Check products for perfect surfaces, correct assembly and functionality. Do not use severely damaged products.
- Reassemble dismantled products before sterilization.

9 Service and Repair

⚠ **Service and Repair**

Do not carry out any repairs or changes to the product yourself. Authorized staff of the manufacturer are solely responsible for such work. Should you wish to make complaints or queries, or offer us any advice regarding our products, please feel free to contact us.

⚠ **Returns**

Defective or non-compliant products must go through the entire reprocessing process before being sent back for repairs/service.

10 Packaging, Storage and Disposal

Standard packaging of the products for sterilisation according to ISO 11607 and EN 868.

Store sterile products in a dry, clean, and dust-free environment, secured against damage, at moderate temperatures.

The medical products of the manufacturer should be stored and kept in single packaging, boxes or protective containers. Please handle the instruments with care during transportation, storage and reprocessing. The user and/or specialist staff intended for this is responsible for ensuring that the sterile state is maintained after the sterilisation.

The disposal of the products, packaging as well as the accessories must be performed in accordance with current rules and laws. No specific instruction regarding this matter is provided by the manufacturer.

11 Description of Symbols Used

⚠	Attention!
	Observe the instruction manual
REF	Item number
LOT	Lot designation
CE	CE labelling
NON STERILE	Indication of a non-sterile product
	Name and address of the manufacturer