Instruction for Use

Sterile goods, Storage

Valid from:	09.02.2023	Version:	2

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1 Important Information

Read these instructions for use carefully before each use and keep them easily accessible for the user or the relevant specialist staff.

Read the warnings marked by this symbol carefully. Improper use of the products can lead to serious injuries to the patient, the user or third parties.

2 Scope

The instruments may only be used for their intended use in the medical fields by appropriately trained and qualified personnel. The attending physician or the user is responsible for the selection of the instruments for specific applications or operative use, appropriate training and information, and sufficient experience for handling the instruments.

3 Products / Intended use

The products are intended for non-invasive treatments in various medical specialties. They correspond to risk class I.

Product family Bowl	
(Basic UDI-DI)	**Intended use**
General-purpose bowl 4049216428939B	For absorbing liquids, carrying or storing instruments before or during a treatment, collecting organic waste or other substances.
Sponge bowl, 40492161369285	A receptacle specifically designed to store and/or collect sponges; it may be used to collect sponges during a surgical procedure.
Emesis bowl 4049216115226V	Product in the form of a container for vomit or sputum, typically from a non-ambulatory patient
Dental amalgam cup 4049216358679L	Small bowl for holding mixed amalgam before it is picked up with an amalgam carrier or an amalgam syringe.
Product family Sterilization container	
(Basic UDI-DI)	**Intended use**
Sterilization/disinfection container 4049216137307L	Containers for holding surgical instruments during sterilization and subsequent storage.
Product family Accessories Sterilization container	
(Basic UDI-DI)	**Intended use**
Sterilization container filter 40492166090999	A non-sterile product intended to act as a microbial barrier in steam sterilization containers.
Sterilization container mat 4049216633769F	A non-sterile, soft polymer film that is placed in a container/tray used for instrument sterilization to protect the underside of the instruments.
Sterilization packaging, reusable 4049216405177W	Product for receiving medical devices for sterilization.
Product family Instrument storage	
(Basic UDI-DI)	**Intended use**
Instrument tray 4049216121436Q	A suitable platform to accommodate multiple medical, mostly surgical, instruments and items.
Instrument transport trolley system 4049216163498A	Containers for safely storing, handling and transporting reusable surgical instruments.
Forceps jar 4049216117998A	Vessel for holding various types of tongs
Product family Instrument storage	
(Basic UDI-DI)	**Intended use**
Hand-held urinal 4042796405049T	Urination vessel for patients.
Bedpan 404279634867BK	Collection vessel for urine and/or stool.

4 Contraindications

The products are contraindicated for all other uses other than the techniques mentioned in the intended purpose/indication(s).

Product specific contraindications

- No contraindications known

5 Complications / Side effect

⚠ **General**

Cut injuries from sharp edges

⚠ **Treatment related**

As the products are aids and have no direct contact with the patient, treatment-related complications / side effects and risks are not expected.

⚠ **Product related complications / side effects / risks**

In the course of market observation, further potential complications / side effects were identified:

Sterile container

- Leakage of the containers
- Sterile barrier not given

Filter:

- Sterile barrier not given

Urinal

- Cuts on the genitals
- Bruising, swelling and persistent bleeding
- Recontamination in processing
- Contamination of fresh dressings and thus possible infection of the wounds

Bedpan

- Risk of breakage if the mechanical load is too high
- Contamination of fresh dressings and thus possible infection of the wounds

6 Precautions and Warnings

⚠ Do not use steel wool or cleaning agents with an abrasive effect.

⚠ Do not use cleaning solutions with iodine or high chlorine content.

⚠ Do not place contaminated or used medical products in a case for cleaning in the cleaning/disinfection device. Contaminated products must be processed separately from the screens and cases. Cases are designed as organizational containers for steam sterilization, as storage containers for medical devices, and as organizational containers during surgery.

⚠ Machine cleaning is preferable, as this leads to a more effective result. With machine cleaning and disinfection, there is greater safety in the process.

⚠ Alkaline cleaning agents (pH >10) are not suitable for all materials. The Robert Koch Institute points out potential problems increased wear on aluminum, silicone elastomers, adhesive bonds, Silver and tin solder joints, sealing materials,

Plastic coatings, fiber optic light guides and optical surfaces with anti-reflective coatings.

⚠ Defective products must go through the entire remanufacturing process before being returned for repair or complaint to have. Proof of decontamination must be enclosed with the return. The sterilization parameters only apply to adequately pre-cleaned components.

⚠ The parameters listed apply only to properly installed, maintained and calibrated purification systems that meet the requirements of ISO 15883 and ISO 17665 standards.

⚠ Patients considered at risk for Creutzfeldt-Jakob disease (CJD) and associated infections operate with single-use instruments. Dispose of instruments used in surgery on a patient with suspected CJD or established disease after surgery and/or follow current national recommendations.

⚠ For more information, see applicable national laws and regulations. The clinic's internal policies and procedures, as well as the recommendations and instructions of the manufacturers of cleaning and disinfecting agents and clinical reprocessing systems must also be followed.

7 Combination products

The sterile container systems consist of sterile containers, perforated baskets and filters. In addition, accessories can be used for the container systems will. A screen basket of the right size should be used for the respective container size. The possible combinations are described below of the various container designs. A detailed overview of combinable products can be found in the next section.

Standard Container

Filter holders are located below/above the perforations in the lid and, if applicable, the tray. Before sterilization, disposable
Paper filter or permanent filter can be inserted.
A safety lid can also be placed on the lid of the standard container in sizes 1/1, ½ and ¾, as required. This protects against
Contamination during storage or transport of the sterile container.

Wire baskets

For every container size there is the right sieve basket in different heights, with the corresponding lid and matching feet.

Security seal

Security seals are applied to the outside of the closures by passing the seal through the opening of the spring closure system and the seal is then locked. The seal breaks when the locks are opened/folded up.

Silicone mats

The screen baskets are placed in the container and can be equipped with a silicone mat if required.

Indicator labels

The indicator contained changes color when steam sterilized at 134° C.
Please note the durability of the labels according to the manufacturer's information.
The indicator labels may only be used for the intended purpose. If the specifications are not observed, the result be falsified.

⚠ **Notes on the use of paper filters**

- Paper filters are intended for single use only.
- Paper filters are manufactured according to DIN EN ISO 11607-1.
- Paper filters must not be glued (e.g. to document the runs), as the glue can contain harmful substances. In addition, through
- Gluing destroys the germ barrier.
- The paper filters must be dimensioned in such a way that the perforation in the container lid is completely covered.

⚠ **Notes on the use of permanent filters**

- PTFE filters are designed for multiple use.
- Permanent filters must not be glued (e.g. to document the runs), as the glue may contain harmful substances. In addition, through
- Gluing destroys the germ barrier.
- If the filter is very dirty, it must be removed and cleaned.

- The permanent filters must be dimensioned in such a way that the perforation in the container lid is completely covered.

8 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 sterilization. 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.

9 Sterility

⚠ State upon Delivery

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

10 Reprocessing

⚠ Warnings

- The sterilization containers consist of an aluminum alloy whose surface is anodized to protect against corrosion. Aggressive cleaning agents, Metal brushes or scouring pads can permanently damage this surface and must therefore not be used. Will this statement not followed, the warranty will be excluded.
- The sterilization containers may only be handled by instructed or trained personnel in order to prevent damage to the containers, closures, seals and sterile filters/cassettes.
- The sterilization containers are also offered with colored lids to facilitate allocation to the individual disciplines and departments.
- Sterilization indicator and colored identification labels provide information about the content, place of use and condition.
- It must be ensured by appropriate measures (e.g. sealing, process indicators) in accordance with the normative specifications and recommendations that sterilized and non-sterilized sterilization containers cannot be mixed up. Only intact seals ensure that the sterilization container has not been opened without permission.

⚠Preparation for cleaning

- Separating the container tub and lid
- Remove the contents of the container (wire basket, instruments, etc.)
- Removing the filter holders/cassette from the inside of the lid and if applicable from the pan part (for containers with perforated bottom)
- For disposable paper filters: Dispose of disposable filters.
- Remove the one-time seals and the indicator labels.

⚠ Additional information

- Frequent reprocessing impairs the quality of the products.
- City 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.
- This treatment instruction specifies the detergents and disinfectants used for validation. If an alternative detergent and disinfectant (RKI or VAH listed) is used, the responsibility rests with the reprocessor.
- Reassemble disassembled products before sterilization.
- Reprocessing may only be performed 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

1. Pre-clean products completely under cold water (city water drinking water quality <40°C) with a soft brush.
2. Flush cavities and hard-to-reach areas, gaps and slots on the instrument with cold water (city water drinking water quality <40°C) for 60 sec using a water pressure gun.
3. Soak products in an alkaline cleaner (0.5 % Neodisher Mediclean forte) in an ultrasonic bath at 35 kHz for 5 min.
4. Rinse products under cold water (city water drinking water quality <40°C) for 15 sec.
5. Flush cavities and hard-to-reach areas, gaps and slots on the instrument with cold water (city water drinking water quality <40°C) for 30 sec using a water pressure gun.

Cleaning/disinfection

Automated cleaning and/or disinfection process

(Miele Disinfector G7835 CD as per ISO 15883):

- 1 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
- 3 minutes Neutralization (0.1 % NeodisherZ) with cold water
- Drain water
- Clean for 2 minutes with FD water <40°C.

Automated Disinfection

Automated thermal disinfection in a cleaning and disinfection device taking into consideration the national requirements for the A0 value; for instance, A0 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.

11 Filter change

After changing the filter, the filter holder must be brought into the correct position by pressing until it audibly engages. CM lids may only be used with CM filter holders can be used.

- Disposable paper sterile filters must be re-inserted before each new sterilization.
- The suitability and accuracy of fit is only guaranteed when using the CM filters.
- Warranty services can only be accepted if the original CM filters are used exclusively.

⚠Attention

Combine only original CM components such as lids, trays, filters, gaskets, cassettes and filter holders to ensure tightness and germ barrier. Otherwise CM does not assume any warranty.

12 Sterilization

(Typ B Autoclave by Tuttmauer as per DIN EN 13060

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

The sterilization 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 least 20 minutes

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

⚠Container loading

The total weight of the loading of the containers should not exceed the following amounts, otherwise satisfactory sterilization cannot be guaranteed.

Model	Max. load
1/1 (full) size container	9.0 kg
¾ size container	7.0 kg
½ size container	5.0 kg
flat container	1.5 kg
mini container	1.0 kg
dental container	1.8 kg

⚠Placement in the sterilizer

The containers are constructed in such a way that they can be used in any commercially available large sterilizer for sterilization with moist heat. Note Note that heavy containers are positioned at the bottom of the sterilization chamber.
Due to their construction, the containers can be stacked on top of each other safely and without problems during sterilization without slipping. Stacking is only recommended for sterilization cycles that use fractional vacuum processes. The stack height should not exceed 46 cm to achieve effective air removal and vapor penetration. The sterilizer manufacturer's instructions must be observed.

⚠Attention

Observe the following during sterilization:
Never pack the container in another outer packaging. Never cover the perforation areas in the lid and base any foil packaging or similar, as this will impede the flow of air and vapor into the container. The result is one vacuum-related deformation of the container due to insufficient pressure equalization and the sterility of the contents of the container will not guaranteed.
When loading and unloading the sterilizer and during transport, the sterile container is always held

by the carrying handles and never by the lid to wear.

⚠ Flow control

- Operate the loaded sterilizer according to the specifications of the sterilizer manufacturer for the selected sterilization cycle (related to temperature and sterilization time). The validation results must be taken into account.
- In order to avoid condensation in the container, the container should cool down completely on the sterilization trolley.
- After each sterilization, the sterile goods must be assessed and released in accordance with the internal instructions and the validation results. This is consequently done by employees with specialist qualification 1.

⚠ 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.

13 Maintenance-Control-Inspection

Cool down the products to room temperature!

Visual inspection (before assembly):

Check the surface of the instruments or the individual components before assembly. Pay particular attention to checking joints (final part), profiles, grooves and other structures that are difficult to access:

- Is there any residual soiling or residue?

If so, manual re-cleaning and renewed complete mechanical cleaning and disinfection.

- Are traces of corrosion (rust, pitting) visible?
- Is the surface damaged by cracks (including hairline cracks) or other signs of wear?
- Is the labeling no longer legible?

If so, the instrument in question must be marked and immediately sorted out and replaced.

Assembly and maintenance

- Assemble the disassembled instruments in a functionally correct manner.
- Treat moving parts, such as joints, threads and sliding surfaces, manually with suitable, medically approved instrument oil (steam-sterilizable care product based on paraffin/white oil, biocompatible according to EU standard). EU standard).
- Distribute the oil in the joint by opening and closing several times, remove excess care product with a clean, lint-free cloth.

Do not use mineral oil or silicone lubricant! Do not immerse instruments completely in the care product!

Function test

During the functional check, pay particular attention to the following aspects and possible malfunctions:

- No damage, such as broken tips, bent or loose parts (screws).
- No damage to the caps, seals, filter holders, filters, cassettes and bent and dented parts.

If defects are found during the functional test, the instruments must be marked and excluded from further use without fail.

14 Lifespan of the Products

The service life of the products results from their function, gentle reprocessing in accordance with these instructions and careful handling when handling the instruments. Therefore, a limit to the number of reprocessing cycles cannot be set across the board. Nevertheless, 100 reprocessing cycles were simulated, which showed no impairment of functionality, biocompatibility and identification of the products. The user recognizes the end of the usage cycle by the possible defects and limiting properties of the products indicated under maintenance, inspection and testing.

15 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.

16 Storage, Transport and Disposal

⚠ Storage

Please refer to DIN 58953-9 (Application technology for sterilization containers) for the storage period for medical products in sterilization containers. Usually the storage time depends on the storage conditions and has to be determined by the responsible hygiene personnel. In the case of a particularly high requirement for asepsis or in the event of deviations from the specified storage conditions, shorter storage periods apply or to use additional packaging

⚠ Storage Conditions

- Temperature: 15 - 26° C
- Humidity: 30 - 50%
- Air pressure: normal atmospheric pressure

Different container loads, storage times and storage conditions are subject to determination by the responsible hygiene staff.
The CM sterile containers were tested for a storage time of 6 months by applying Bacillus subtilis spore suspension. Based on this, a storage period of 6 months can be promised. The containers must be stored under protected conditions (e.g. in closed cupboards), protected from dust, clean, dry and free from vermin.

⚠ Transport

The sterile containers should only be transported using the carrying handles provided.

⚠ Disposal

The disposal of the products, the packaging material and the accessories must be carried out in accordance with the applicable national regulations and laws. The manufacturer does not provide any specific instructions for this.

17 Reporting obligations

Product defects which have occurred during proper use of our products should be reported directly to us as the manufacturer or to your supervising specialist dealer.
Defects in which patients, users or third parties have been harmed by the products (so-called reportable incidents) must be reported immediately to the manufacturer and, if necessary, to your competent, responsible authority. This reporting of incidents must take place immediately after they occur so that important reporting deadlines can be met.
The affected products must be discarded, reprocessed and sent to the manufacturer for examination. Your servicing dealer will be pleased to help you with this.
After receipt of your notification, we will inform you within a reasonable time frame about the further measures required.

18 Additional information

If the chemicals and machines described here are not available, and if the reprocessing process cannot be carried out as described, it is the user's responsibility to validate his process accordingly.

Further information on the reprocessing of medical devices:

- Internet: http://www.rki.de
- Internet: http://www.a-k-i.org
- Hygiene requirements for the reprocessing of medical devices Recommendation of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene requirements for the reprocessing of medical devices“
- DIN 96298-4 Functional control in the reprocessing process

19 Other applicable documents

Instructions for the proper disassembly of the listed products can be found on our homepage:

www.cm-instrumente.de/ifu

- Disassembly instructions for instruments

20 Description of symbols used

⚠	Attention!
	Observe the Instruction fo Use
REF	Item number
LOT	Lot designation
CE xxxx	CE labeling, if necessary m identification number of the notified body.
	Indication of a non-sterile product
	Name and address of the manufacturer
	Manufacturing date
MD	Medical device
UDI	Unique Device Identification, code for identifying a product
SRN	Registration number of the manufacturer in the EUDAMED database