

Instructions for use

Sterile goods, storage

dimededa[®]
SURGICAL INSTRUMENTS

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1 Important note



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



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

2 Area of application

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

Bowl product family	
(Basic UDI-DI)	Intended use
Bowl, general, reusable: 404279642893BH CE	For holding liquids, carrying or storing instruments before or during treatment, collecting organic waste or other substances.
Dab bowl 404279613692AB CE	Vessel specially designed to hold swabs and/or sponges; can be used to collect swabs during a surgical procedure.
Crushing bowl 40427961152293 CE	Product in the form of a container for vomit or sputum, usually from a non-ambulatory patient
Dental amalgam bowl 404279635867BS CE	Small bowl for holding mixed amalgam before it is taken up with an amalgam carrier or an amalgam syringe.
Product family Sterilization containers	
(Basic UDI-DI)	Intended use
Sterile container 4042796137309S CE	Container for holding surgical instruments during sterilization and subsequent storage.
Product family Accessories Sterilization containers	
(Basic UDI-DI)	Intended use
Sterilization container mat 404279663376BM CE	A non-sterile, soft polymer film that is placed in a container/tray used for sterilizing instruments to protect the underside of the instruments.
Sterilization packaging, reusable 404279640517A4 CE	Product for holding medical devices for sterilization.
Product family Instrument storage	
(Basic UDI-DI)	Intended use
Instrument tray 4042796121438W CE	A suitable platform for holding several medical, mostly surgical, instruments and articles.

Container systems for surgical instruments 404279616349AG CE	Containers for the safe storage, handling and transportation of reusable surgical instruments.
Stand for pliers 404279611799AG CE	Container for holding various types of pliers
Urinal product family	
(Basic UDI-DI)	Intended use
Urine collection bottle 4042796405049T CE	Urination vessel for patients.
Bedpan 404279634867BK CE	Collection container for urine and/or stool.

4 Contraindications

The products are contraindicated for all applications other than the techniques specified in the intended use / indication(s).

Product-specific contraindications

- No known contraindications.

5 Undesirable side effects / complications / Risks

General

- Cuts due to sharp edges

Treatment-related complications / side effects / risks

- As the products are aids and do not come into direct contact with the patient, treatment-related complications / side effects and risks are not expected.

Product-related complications / side effects / risks

Further potential complications / side effects were identified in the course of market monitoring:

Sterile container

- Leakage of the containers
- Sterile barrier not given

Urinal

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

Bedpan

- Risk of breakage due to excessive mechanical load
- Contamination of fresh dressings and therefore possible infection of wounds in the event of breakage or leakage

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 devices in a case for cleaning in the washer/disinfecter. Contaminated products must be reprocessed separately from the trays and cases. Cases are designed as organizational containers for steam sterilization, as storage containers for medical devices and as organizational containers during surgery.

⚠ Mechanical cleaning is preferable as it leads to a more effective result. There is greater safety in the process with automated cleaning and disinfection.

⚠ Alkaline cleaning agents (pH >10) are not suitable for all materials. The Robert Koch Institute points out potential problems caused by

increased wear on aluminum, silicone elastomers, adhesive joints, silver and tin soldered joints, sealing materials, plastic coatings, fiber optic light guides and optical surfaces with anti-reflective coating.

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

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

⚠ Operate on patients who are considered at risk of Creutzfeldt-Jakob disease (CJD) and the associated infections using disposable instruments. Dispose of instruments used to operate on a patient with suspected or confirmed CJD after surgery and / or follow current national recommendations.

⚠ For further information, see the applicable national laws and guidelines. The clinic's internal guidelines and procedural instructions as well as the recommendations and instructions of the manufacturers of cleaning agents, disinfectants and clinical reprocessing systems must also be followed.

7 Combination products & accessories

The sterile container systems consist of sterile containers, sieve baskets and filters. Accessories can also be used for the container systems. be used. A strainer basket of the appropriate size should be used for the respective container size. The possible combinations of the various container designs are described below. A detailed overview of combinable products can be found in the section below.

Standard container

There are filter holders below/above the perforations in the lid and, if applicable, the tray. Disposable paper filters or permanent filters must be inserted into these filter holders before sterilization. A safety lid can also be placed on the lid of the standard container sizes 1/1, 1/2 and 3/4 as required. This protects against contamination during storage or transportation of the sterile container.

Strainer baskets

For every container size, there are matching sieve baskets in various heights, with matching lids and feet.

Security seal

Security seals are attached to the outside of the locks by inserting the seal through the opening of the spring lock system and then locking the seal. The seal breaks when the latches are opened/folded up.

Silicone mats

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

Indicator labels

The indicator contained discolours during steam sterilization at 134° C. Please note the shelf life of the labels according to the manufacturer's instructions. The indicator labels may only be used for their intended purpose. If the instructions are not followed, the result be falsified.

8 Liability and warranty

Dimededa Instrumente GmbH, as the manufacturer, is not liable for consequential damage resulting from improper use or handling. This applies in particular to non-compliant use for the defined purpose or disregard of the reprocessing and sterilization instructions. This also applies to repairs or modifications to the product carried out by unauthorized personnel of the manufacturer. These

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exclusions of liability also apply to warranty services.

9 Sterility

⚠ Delivery condition

The medical devices are supplied in a non-sterile condition and must be prepared and sterilized by the user in accordance with the following instructions before the first and each subsequent use.

10 Preparation

⚠ Warnings

- Frequent reprocessing impairs the quality of the products.
- Urban water to be used must comply with Directive (EU) 2020/2184 on the quality of water intended for human consumption.
- The cleaning agents and disinfectants used for validation are specified in these reprocessing instructions. If an alternative cleaning agent and disinfectant (RKI or VAH listed) is used, the responsibility lies with the reprocessor.
- Reassemble disassembled products before sterilization.
- Reprocessing may only be carried out by qualified medical personnel. Automated reprocessing must be qualified and validated by the user. The washer-disinfectors must fully comply with the requirements of DIN EN ISO 15883.
- Sterilization must be qualified and validated by the user. The autoclaves must fully comply with the requirements of DIN EN ISO 17665.

⚠ Place of use

The first steps of proper reprocessing begin in the operating room. If possible, coarse soiling and residues should be removed before the instruments are put away. To do this, 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. Wherever possible, dry disposal is preferable, as prolonged immersion of medical devices in solutions can lead to material damage (e.g. corrosion). Drying of residues must be avoided! Long waiting times before reprocessing, e.g. overnight or over the weekend, should be avoided with both disposal methods (<60 minutes).

⚠ Transportation

If possible, the products must be disposed of dry immediately (<60 min) after use. This means that the products must be transported in a closed container from the place of application to the processing facility so that the products do not dry out.

Preparation for decontamination

If possible, the products must be disassembled before the subsequent reprocessing steps or fed to the subsequent reprocessing steps in an open state. Avoid rinsing shadows. The products must be processed in suitable sieve baskets or rinsing trays (select size according to product). The products should be placed at a minimum distance from each other in the cleaning basket. Avoid overlapping in order to prevent damage to the products during the cleaning process.

Pre-cleaning

1. pre-clean products completely under cold water (city water drinking water quality <40°C) using a soft brush.
2. rinse cavities and hard-to-reach areas, gaps and slits on the instrument with cold water (city water drinking water quality <40°C) for 60 seconds using a water pressure gun.

3. soak the 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. rinse cavities and hard-to-reach areas, gaps and slits on the instrument with cold water (city water drinking water quality <40°C) for 30 seconds using a water pressure gun.

Preparation

Automatic preparation

(Miele Disinfector G7835 CD according to ISO 15883):

- 1 minute pre-cleaning
- Water drainage
- 4 minutes pre-cleaning
- Water drainage
- 6 minutes cleaning with an alkaline cleaner (0.5 % Neodisher Mediclean) at 58°C +/- 1°C
- Water drainage
- 3 minutes neutralization (0.1 % NeodisherZ) with cold water
- Water drainage
- 2 minutes cleaning with cold water low in germs and endotoxins (max. 10 germs/ml and max. 0.25 endotoxin units/ml)

Automatic disinfection

Automatic thermal disinfection in washer-disinfector, taking into account the national requirements for the A₀ value; e.g. A₀ value >3000: With 5 minutes at >92°C

Automatic drying

Automatic drying according to the automatic drying process of the washer-disinfector for 30 minutes at 92°C +/- 2°C.

11 Sterilization

(Type B autoclave from Tuttnauer in accordance with DIN EN 13060)

Sterilization of the products using the fractionated pre-vacuum process (in accordance with DIN EN ISO 17665-1/ DIN EN 285), taking into account the respective national requirements. The products must be sterilized in suitable sterilization packaging in accordance with DIN EN ISO 11607-1 and EN 868.

Please observe chapter 12 before packing!

Sterilization must be carried out using a fractionated pre-vacuum process with the following parameters:

- 134°C,
- At least 5 minutes holding time
- 3 pre-vacuum cycles
- Drying in a vacuum for at least 20 minutes

The autoclave manufacturer's instructions for use and the recommended guidelines for the maximum load of sterilization items must be observed. The autoclave must be installed, maintained, validated and calibrated in accordance with the regulations.

⚠ Container loading

The total weight of the container load should not exceed the following quantities, otherwise satisfactory sterilization cannot be guaranteed.

Model	Max. Loading
1/1 (full) size container	9.0 kg
¾ Size container	7.0 kg
½ Size container	5.0 kg
Flat containers	1.5 kg
Mini container	1.0 kg
Dental container	1.8 kg

⚠ Placement in the sterilizer

The containers are designed so that they can be used in any commercially available large sterilizer for sterilization with moist heat. Please note that

heavy containers are positioned at the bottom of the sterilization chamber.

Thanks to their design, the containers can be stacked safely and easily during sterilization without slipping.

Stacking is only recommended for sterilization cycles using the fractionated vacuum method. The stack height should not exceed 46 cm to achieve effective air removal and steam penetration. Follow the sterilizer manufacturer's instructions.

⚠ Caution

Please note the following during sterilization: Never pack the container in additional outer packaging. Never cover the perforation fields in the lid and base with any film packaging or similar, as this impedes the flow of air and vapor into the container. The result is a vacuum-related deformation of the container due to insufficient pressure equalization and the sterility of the contents of the container is not guaranteed. During loading and unloading of the sterilizer and during transport, the sterile container must always be carried by the carrying handles and never by the lid.

⚠ Sequence control

- Operate the loaded sterilizer in accordance with the sterilizer manufacturer's specifications for the selected sterilization cycle (in terms of temperature and sterilization time). The validation results must be taken into account.
- 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 carried out consistently by employees with specialist knowledge 1.

⚠ Additional information

The reprocessor is responsible for ensuring that the reprocessing actually carried out with the equipment, materials and personnel used in the reprocessing facility achieves the desired results. This generally requires validation and routine monitoring of the process and the equipment used.

12 Maintenance-inspection-testing

Cool the products to room temperature!

Visual inspection (before assembly):

Check the surface of the instruments or individual components before assembly. Particular attention must be paid to checking joints (end piece), profiles, grooves and other structures that are difficult to access:

- Is there any residual dirt or residue? If yes, manual post-cleaning and complete mechanical cleaning and disinfection again.
- Are traces of corrosion (rust, pitting) visible?
- Is the surface damaged by cracks (including hairline cracks) or other signs of wear?
- Is the lettering no longer legible?

If so, the instrument in question must be labeled and immediately discarded and replaced.

Assembly and maintenance

- Assemble the disassembled products in a functional manner.
- Manually treat moving parts such as joints, threads and sliding surfaces with suitable, medically approved instrument oil (steam-sterilizable care product based on paraffin/white oil, biocompatible according to EU standard). EU standard) manually.
- Distribute the oil in the joint by opening and closing it 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

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During the functional test, 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 or bent and dented parts

If defects are found during the functional test, the instruments must be labeled and absolutely excluded from further use.

13 Service life of the products

The useful life of the products depends on their function, careful reprocessing in accordance with these instructions and careful handling of the instruments. It is therefore not possible to set a general limit on the number of reprocessing cycles. The user can recognize the end of the service life with regard to the functionality or identity of the products by the possible faults and limiting properties of the products specified under maintenance, inspection and testing, and biocompatibility can only be guaranteed up to 350 reprocessing cycles. After that, the products should be disposed of.

14 Service and repair

⚠ Service and repair

Do not carry out any repairs or modifications to the product yourself. Only authorized personnel of the manufacturer are responsible and intended for this. If you have any complaints, claims or comments regarding our products, please contact us.

⚠ Return transportation

Defective or non-compliant products must have gone through the entire reconditioning process before being returned for repair/service.

15 Storage, transportation and disposal

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

The manufacturer's medical devices should be stored and kept in individual packaging, boxes or protective containers. Please handle the instruments with the utmost care during transportation, storage and reprocessing. The maintenance of the sterile condition after the sterilization process must be ensured by the user or the specialist personnel designated for this purpose.

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

16 Reporting obligations

Product defects that have occurred during proper use of our products should be reported directly to us as the manufacturer or to your 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 applicable, to your competent authority. Incidents must be reported immediately after they occur so that important reporting deadlines can be met.

The affected products must be discarded, reconditioned and sent to the manufacturer for examination. Your specialist dealer will be happy to help you with this.

After receiving your notification, we will inform you within a reasonable period of time about the further measures required.

17 Additional information

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 check in the preparation process

18 Applicable documents

You can find instructions on how to properly dismantle the listed products on our homepage. <https://www.dimedada.de/demontageanleitungen/>

- Disassembly instructions for instruments

19 Symbol description

	Attention!
	Follow the instructions for use
	Item number
	Batch designation
	CE mark, if applicable with identification number of the notified body.
	Indication for non-sterile product
	Name and address of the manufacturer
	Date of manufacture
	Medical device
	Unique Device Identification, code for identifying a product
	Registration number of the manufacturer in the EUDAMED database