Instructions for use

sterile goods and storage CE

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Products

This instruction manual is valid for all sterile container systems and accessories from VeHu-Medical GmbH:

Important note

Read these instructions carefully before each application and keep them easily accessible to the user or the appropriate qualified personnel.

Read the warnings indicated by this symbol carefully. Improper use of the products can lead to serious injury to the patient, users or third parties.

1 Scope of application

The products listed above may only be used by appropriately trained and qualified personnel. The products may only be used in sterile environments.

2 Precautions and warnings

– Do not use steel wool or detergents with an abrasive effect.

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

– Do not place contaminated or used VeHu-Medical medical devices in a case for cleaning in the washer/disinfection device. Contaminated VeHu-Medical products must be processed separately from the sieves and cases. Cases are designed as an organizational container for steam sterilization, as storage containers for medical devices and as an organization container during surgery.

– Machine cleaning is preferable, as this leads to a more effective result. In the case of machine cleaning and disinfection, there is greater safety in the process.

– Alkaline detergents (pH >10) are not suitable for all materials. The Robert Koch Institute points out potential problems caused by
increased wear on aluminium, silicone elastomers, adhesive joints, silver and tin solder joints, sealing materials,

plastic coatings, fiber optic fibers and optical surfaces with anti-reflective coatings.

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

– The listed parameters apply only to properly installed, maintained and calibrated treatment systems that meet the requirements of the ISO 15883 and ISO 17665-1 standards.

– Patients who are considered high-risk patients with regard to Creutzfeldt-Jakob disease (CJD) and the associated infections operate with single-use instruments. Dispose of instruments used to operate on a patient with suspected CJD or proven disease after surgery and/or follow current national recommendations.

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

3 Limits of clinical preparation

– Repeated/frequent reprocessing in accordance with this instruction has little impact on the life of the containers.

– The service life of a sterilization container is essentially determined by wear and damage caused by the application.

– With proper use of an average of 4 times a week, it has a lifespan of at least 10 years.

4 Application area

– VEHU-MEDICAL sterile container systems combine proven filter technologies, tested materials and design properties to create a reliable container system.
They are reusable container systems that offer a wide range of dimensions and features to ensure effective packaging,
storage and transport of the instruments to be sterilized. The container systems are ideally suited for fractional vacuum processes.

Purpose

Product Group Sterile Goods and Storage	
(Basis UDI DI)	**Purpose**
Bowl 405937500000162 C5	To hold liquids, to carry or store instruments before or during a treatment, to collect organic waste or other substances.
Washing bowl 405937500000163 C7	Bowl for personal hygiene.
Dab bowl 405937500000164 C9	Vessel specially designed for the reception of swabs and/or sponges; can be used to collect swabs during a surgical procedure.
Crushing bowl 405937500000165 CB	Product in the form of a container for vomit or sputum, usually from a non-ambulatory patient
Dental amalgam bowl 405937500000166 CD	Small bowl for absorbing mixed amalgam before it is absorbed with an amalgam carrier or an amalgam syringe.
Sterile containers 405937500000167 CF	Containers for holding surgical instruments during sterilization and subsequent storage.
Filters for sterilization containers 405937500000168 CH 405937500000169 CK	A non-sterile product that serves as a microbial barrier in containers for steam sterilization.
Silicone mats 405937500000170 C4	A non-sterile, soft polymer film that is placed in a container/tray used for instrument sterilization to protect the underside of the instruments.
Container system for surgical instruments 405937500000171 C6	Product for receiving medical devices for sterilization.
Wire basket 405937500000172 C8	A suitable platform for holding multiple medical, mostly surgical, instruments and items.
Container systems for surgical instruments 405937500000173 CA	containers for the safe storage, handling and transport of reusable surgical instruments.
Stand for pliers 405937500000174 CC	Vessel for holding different types of pliers
Urine collection 405937500000175 CE	Urination vessel for patients.
Bedpan 405937500000176 CG	Collection vessel for urine and/or stool.

Contraindications

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

5 Complications / Side Effects

General:

- Cuts caused by sharp-edged edges

Treatment-related:

- Since the products are aids and do not have 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 the market observation, further potential complications / side effects could be identified:

Sterile containers:

- Leakage of containers
- Sterile barrier not given

Filters:

- Sterile barrier not given

Urinal:

- Genital
- Bruising, swelling and persistent bleeding
- Recontamination in treatment
- Contamination of fresh dressings and thus possible infections of the wounds

Bedpan:

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

Combination products

VEHU-MEDICAL sterile container systems consist of sterile containers, sieve baskets and filters. In addition, accessories can be used for the container systems
. A screen basket of the appropriate size should be used for the respective container size. In the following, the possible combinations are discussed

of the various container designs. A detailed overview of combinable products can be found in section

COMBINATION PRODUCTS

– Standard containers

In the lid and if necessary. In the tub, filter holders are located underneath/above the perforations. These filter holders must be fitted with disposable Paper filter or permanent filter can be inserted.
A safety lid can also be placed on the lid of the standard container of sizes 1/1, 1/2 and 3/4 as required. This protects against

Contamination during storage or transport of the sterile container.

– Strainer baskets

For every container size, there are suitable screen baskets in different heights, matching lids and 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. When opening/folding up the closures, the seal breaks.

– Silicone mats

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

– Indicator labels

The included indicator changes color 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 specifications are not observed, the result may be
be falsified.

⚠ Notes on the use of paper filters

– Paper filters are for single use only.

– Paper filters are manufactured in accordance with DIN EN ISO 11607-1.

– Paper filters must not be glued on (e.g. to document the runs), as the adhesive may contain harmful substances. In addition,

Sticking destroys the germ barrier.

The paper filters must be sized 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 uses.

– Permanent filters must not be glued on (e.g. to document the runs), as the adhesive may contain harmful substances. In addition,

Sticking destroys the germ barrier.

– In case of coarse soiling, the filter must be removed and then cleaned.

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

6 Handling and reprocessing

⚠ General

The VEHU-MEDICAL sterilization containers are made of an aluminum alloy whose surface is anodized for corrosion protection. Aggressive cleaning agents,
Metal brushes or scouring cloths can permanently damage this surface and must therefore not be used. If this instruction is
is not complied with, the warranty is excluded.

⚠ **The sterilization containers must only be handled by instructed or trained personnel to prevent damage to the containers, closures, seals and sterile filters/cassettes.**

The sterilization containers are also offered with colored lids to make it easier to assign them to the individual disciplines and departments.
Sterilization indicator and colored identification signs provide information about the contents, place of use and condition.
It must be ensured in accordance with the normative specifications and recommendations by suitable measures (e.g. sealing, process indicators) sterilized and unsterilized sterilization containers cannot be confused. Only intact seals ensure that the
sterilization container has not been opened without permission.

⚠ Preparation for cleaning

– Separation of container tray and lid

– Remove the contents of the container (screen basket, instruments, etc.)

– Remove the filter holders/cassette from the inside of the lid and, if applicable, from the tray part (for containers with bottom perforations)

– For disposable paper filters: Dispose of the disposable filter.

– Removal of single-use seals and indicator signs

Note: All paper filters are single-use filters and must be replaced after each use of the container.

⚠ Commissioning of a new container

– Before the first use, the container must be thoroughly cleaned.

– The container must be prepared in a validated, mechanical cleaning and disinfection process.

– For this purpose, a neutral cleaning agent should be used in the machine.

– After reprocessing in the mechanical cleaning and disinfection process, steam sterilization of the products in the fractional
steam sterilization process at 134°C.

– In addition, all moving parts on the container must be regularly maintained with an approved instrument care oil.

– After cleaning, suitable new filters must be inserted (see filter change).

7 Preparation

⚠ Additional information

- Urban 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 preparation instruction specifies the cleaning agents and disinfectants used for validation. If an alternative cleaning agent and disinfectant is used (RKI or VAH listed), the responsibility lies with the conditioner.
- Reassemble disassembled products before sterilization.

Manual pre-cleaning

• For aluminium containers and lids, mild, neutral cleaning agents or chemical products should be used wherever possible
which have also been expressly approved by manufacturing companies for the treatment of aluminium products. If applicable, the products are available on
suitability in the appropriate procedure. A soft, suitable sponge should be used for manual cleaning. Scouring Sponges
are not to be used, as they destroy the surfaces and thus the passivation and lead to the loss of warranty.

• After cleaning, careful rinsing with appropriate low-salt water (e.g., demineralized water) and sufficient drying
required.
• Do not use metal brushes or abrasives.

• Finally, disinfection must be carried out in accordance with the respective hygiene requirements.

• Ultaschall

If the pre-cleaning by the sponge and rinsing with a water jet gun has left visually visible impurities, a pre-cleaning by ultrasound must be carried out.

Immerse containers and sieves in an ultrasonic bath filled with water <40°C, 0.5 % alkaline detergent (Neodisher FA, Dr. Weigert) for 5 minutes and clean for 10 minutes. Rinse IContainer and sieves with a water jet gun (4 bar) > 10 sec.

Cleaning / disinfection

Automatic cleaning/disinfection process:

(*Washing machine, washer - Disinfector G 7735 CD (Miele*):

Step 1: 1 minute pre-cleaning with cold city water drinking water quality <40°C

Step 2: Water drainage

Step 3: 3 minutes of pre-cleaning with cold city water Drinking water quality <40°C

Step 4: Water drain

Step 5: 5 minutes clean at 55°C±5°C with 0.5% alkaline cleaner (Neodisher FA, Dr. Weigert).

Step 6: Water drain

Step 7: 3 minutes neutralization with cold city water Drinking water quality <40°C

Step 8: Water drainage

Step 9: Rinse for 2 minutes with cold city water Drinking water quality <40°C

The special instructions of the manufacturer of the cleaning machine must be observed.

Automatic disinfection

Automatic thermal disinfection in washer and disinfection device, taking into account the national requirements for the sanitizer. A0 value 3000:

>5 minutes at 92°C±2°C

with VE water.

Automatic drying

Automatic drying according to the automatic drying process of the washer-disinfector for at least 30 minutes (at 60°C±5°C in the sink chamber). If necessary, subsequent manual drying with a lint-free cloth and blowing out the corners using sterile, oil-free compressed air.

Filter Replacement

After changing the filter, the filter holder must be brought into the correct position by pressing until it audibly clicks into place. VEHU-MEDICAL lids may only be used with
VEHU-MEDICAL filter brackets.
• Disposable paper sterile filters must be reinserted before each re-sterilization.
• Only when using the VEHU MEDICAL filters is the suitability and accuracy of fit guaranteed.
• Warranty services can only be assumed if the original VEHU MEDICAL filters are used exclusively.

• PTFE filters have been tested for a service life of 1200 cycles and must be replaced afterwards.

⚠ Caution

Combine only original VEHU-MEDICAL individual parts such as lids, trays, filters, seals, cassettes and filter holders with each other so that the tightness and germ barrier are not jeopardized.

Otherwise, VEHU-MEDICAL does not assume any warranty.

Sterilization

Sterilization of container systems using fractional pre-vacuum process (in accordance with DIN EN ISO 17665-1) taking into account the respective national requirements. The sterilisation of the products must be carried out in suitable sterilisation packaging in accordance with EN ISO 11607 and DIN EN 868.

EU standard

Sterilization is to be carried out using a fractional pre-vacuum process, with the following parameters:

134°C

≥5 minutes holding time,

3 pre-vacuum cycles

Vacuum drying for at least 20 minutes

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

⚠ Container loading

The total weight of the loading of the containers should not exceed the following quantities, otherwise satisfactory sterilization will not be ensured

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Model	Max. load in kg
1/1 (Full-) Size Container	10.0 kg
3/4 Size Container	7.0 kg
1/2 Size Container	5.0 kg
Flat containers	1.5 kg
Mini containers	1.0 kg
Dental Containers	1.8 kg

⚠ Placement in the sterilizer

The containers are designed in such a way that they can be used in any commercially available large-scale sterilizer for sterilization with moist heat.
Notice
Heavy containers are positioned at the bottom of the sterilization chamber.
Due to their design, the containers can be stacked on top of each other easily and safely during sterilization without slipping.
Stacking is only recommended for sterilization cycles that use the fractional vacuum process. The stacking height should not exceed 46 cm to achieve effective air removal and steam penetration. The instructions of the sterilizer manufacturers must be observed.

⚠ CAUTION!

During sterilization, keep the following in mind:
Never pack the container in another outer packaging. Never cover the perforation panels in the lid and bottom with
of any film packaging or similar, because this obstructs the flow of air and steam into the container. The result is a
Vacuum-related deformation of the container due to insufficient pressure equalization and sterility of the contents of the container is not
guaranteed.
During loading and unloading of the sterilizer as well as during transport, the sterile container is always on the carrying handles and never on the lid
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⚠ Sequence control

- According to the steriliser manufacturer's specifications, operate the loaded steriliser for the selected sterilisation cycle (in terms of temperature and sterilisation time) taking into account the validation results.
- To avoid condensate accumulation in the container, the container should cool down completely on the sterilizing trolley.
- After each sterilization, the sterile goods must be assessed and released according to internal instructions and validation results. This is consistently done by employees with specialist knowledge 1.

⚠ Additional information

It is the responsibility of the reprocessor to ensure that the actual reprocessing carried out with the equipment, materials and personnel used in the reprocessing facility achieves the desired results. This usually requires validation and routine monitoring of the procedure and equipment used.

8 Exam

The sterilization containers must be checked for functionality before each use.
Damage to the closures, seals, filter holders, filters, cassettes, and bent and dented parts means that the sterilization containers
must be repaired and must not be used.
Do not use damaged sterilization containers.

• All moving parts on the container must be cared for with an approved instrument care oil.

• If damage is found to the seals, they must be replaced immediately.

• The seals should not be treated with spray, oil or solvent. For cleaning and care, an occasional wipe is sufficient
with a damp cloth.

• If damage is found on the sterilization containers, they must be checked, repaired or replaced.

• Spare parts can be obtained from VEHU-MEDICAL

⚠ Service and repair

Do not carry out any repairs or modifications to the product on your own. Only authorized personnel of the manufacturer are responsible and provided for this. If you have any complaints, complaints or information regarding our products, please contact us.

⚠ Return transport

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

9 Storage, transport and disposal

⚠ Storage

For the storage period for medical devices in sterilization containers, please refer to DIN 58953-9 (Application technology of sterilization containers).
Usually, the storage time depends on the storage conditions and must be determined by the responsible hygiene personnel.
In the case of a particularly high demand on asepsis or in the event of deviations from the specified storage conditions, shorter storage periods are required.
or 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 specialists.
The VEHU-MEDICAL sterile containers were tested for a storage period of 6 months by applying Bacillus subtilis spore suspension. Due to this, a storage period of 6 months can be promised. The containers must be stored under protected conditions (e.g. in closed cupboards) dust-protected, clean, dry and free of vermin.

⚠ Transport

The sterile containers should only be transported on the carrying handles provided for this purpose.

⚠ Disposal

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

10 Liability and warranty

VEHU-MEDICAL -Instrumente GmbH, as the manufacturer, is not liable for consequential damages resulting from improper use or handling. This also applies to repairs or modifications to the product made by unauthorized personnel of the manufacturer. These disclaimers also apply to warranty services.

11 Symbol description

⚠	Attention!
	Follow the instructions for use
REF	Article number
LOT	Batch designation
CE	CE mark
NON STERILE	Indication for non-sterile product
	Name and address of the manufacturer
	Date of manufacture
SRN	Manufacturer's registration number in the EUDAMED database
MD	Medical device
UDI	Unique Device Identification, a code used to identify a product
	Store in a dry place
	Temperature limitation
	Protect from sunlight
℞ ONLY	USA professionals only

12 Applied standards

In order to ensure the safety of the sterilization containers during production and handling, the following standards have been taken into account:

DIN EN 868-2
Packaging materials and systems for medical devices to be sterilised – Part 2: Sterilisation packaging; Requirements and test methods

DIN EN 868-8
Packaging Materials and Systems for Medical Devices to Be Sterilized – Part 8: Reusable Sterilizing Containers for Steam Sterilizers according to EN 285; Requirements and test methods

DIN EN ISO 11607-1
Packaging for medical devices to be sterilised in the final packaging – Part 1: Requirements for materials, sterile barrier systems and packaging systems

DIN 58952-2
sterilization; Packaging materials for sterilized goods, metal sterilization baskets

DIN 58952-3
sterilization; Packaging material for sterilized goods, sterilizing sieve trays made of metal

DIN 58953-9
sterilization; Sterile Supply – Part 9: Application Technology of Sterilization Containers

DIN EN ISO 14937
Sterilization of healthcare products – General requirements for the characterization of a sterilizer and for the development, validation and routine monitoring of a sterilization process for medical devices

DIN EN ISO 17665-1
Sterilization of healthcare products - Moist heat - Part 1: Requirements for the development, validation and control of the application of a sterilization process for medical devices

DIN EN 285

Sterilization - Steam Sterilizers - Large Sterilizers

To ensure sterility safety, tests have been carried out by an independent and accredited testing laboratory. The purpose of this
The purpose of the research was to validate a sterilization process with moist heat for the reusable VEHU-MEDICAL sterile container systems.

Based on the results, we therefore prescribe the sterilization procedure indicated on page 3 of this instruction manual.

13 Materials

Our sterilization containers are made of an anodized aluminum alloy and the accessories are made of stainless instrument steel.

14 Delivery condition

The VEHU-MEDICAL sterile container systems are delivered in a non-sterile condition and must be prepared and sterilized by the user in accordance with the following instructions before the first and any subsequent use.

VEHU-MEDICAL GMBH ASSUMES NO LIABILITY IF IT IS PROVEN THAT THIS CUSTOMER INFORMATION HAS BEEN VIOLATED.
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15 Reporting obligations

Product defects that have occurred during the proper use of our products should be reported directly to us as the manufacturer or your supervising specialist dealer.
Defects in which patients, users or third parties have been harmed by the products (so-called reportable events) must be reported immediately to the manufacturer and, if necessary, to the manufacturer. competent authority. This reporting of incidents must be made immediately after the occurrence in order to meet important reporting deadlines.

The affected products must be sorted out, processed and sent to the manufacturer for examination. Your specialist dealer will be happy to help you with this. After receiving your report, we will inform you of the further necessary measures within a reasonable timeframe.

16 Applicable documents

Information on the proper disassembly of the listed products can be found on our homepage.
www.vehu.com

- Disassembly instructions instruments