By purchasing this sterile container system, you are acquiring a high-quality product. Proper handling and use are described in these instructions for use.

To minimise risks and unnecessary strain on patients, users and third parties, please read these instructions for use carefully before use and keep them for future reference.

CONTENTS

Manufacturer in accordance with EU MDR 2017/745

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1 General information

- The applicable national regulations and standards for the reprocessing of medical devices must be observed.
- For patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants of this disease, the applicable national regulations on reprocessing must be followed.

2 Warnings and precautions

- Only containers and lids in perfect condition, with undamaged seals and undamaged filter systems or filters in place, may be used for sterilisation. Only one filter may be inserted per filter holder.
- Disposable paper filters are to be preferred over reusable filters.
- Only clean and low-germ sterilisation containers ensure successful sterilisation.
- Machine cleaning is preferable, as it is a more effective and safer method.
- Metal brushes, metal sponges or abrasive cleaning agents must not be used for manual cleaning.
- Alkaline cleaning agents (pH > 10) are not suitable for all materials. The Robert Koch Institute points out the risk of damage due to increased wear, particularly in the case of aluminium, silicone elastomers, adhesive and soldered joints (e.g. silver, tin), sealing materials, plastic coatings, glass fibre optical fibres and optical surfaces with anti-reflective coatings.
- Cleaning solutions containing bleaching agents (e.g. sodium hypochlorite) must not be used, as they can cause severe corrosion.
- The lid must not be loaded individually or used as a storage surface to prevent deformation.
- If sterilisation containers become deformed during the sterilisation process, there is a risk of non-sterility. In this case, the entire batch must not be used. The cause must be identified immediately (e.g. by checking the sterilisation process, the steriliser and other sterile packaging, and by testing the functionality of the affected container).
- Defective products must be fully reprocessed before being returned for repair or as a complaint. Proof of decontamination must be enclosed with the return.
- In cases of existing sensitivity to silicone or aluminium, direct contact may cause allergic reactions.
- Modifications to the product after manufacture are not permitted.

3 Intended use

The sterile container system is intended for holding reusable medical devices that are to be sterilised. Use outside this intended purpose is not permitted. It serves as a sterile barrier system for the sterilisation, storage and transport of the medical devices it contains until they are used.
Depending on the model, the containers are available with a perforated or solid base and a perforated lid. Certain container sizes may also be fitted with a safety lid.

4 Container system

The sterile containers form a system comprising several functionally coordinated components, in particular the container tray, lid, filter system (disposable or reusable filters), seals and optional accessories such as sieve baskets or filter cassettes.
The system's function as a sterile barrier system is only guaranteed if all components are used correctly and are compatible with one another.

Only components intended and approved for the sterile container system may be combined with one another.

The use of incompatible or non-approved components may:
- compromise the system's integrity
- compromise the sterile barrier
- lead to contamination of the sterile goods

The performance of the sterile barrier system is only guaranteed when the combinations described are used.

Standard containers

Suitable filters must be inserted before each sterilisation:
- Disposable paper filters or
- PTFE permanent filters

The filters must be inserted correctly and completely cover the perforations. For this purpose, there are filter holders in the lid and, where applicable, in the tray, positioned above or below the perforations.

Depending on the container size, a safety lid may be used as an option. This serves to protect against contamination during storage and transport.

The safety lid:
- must not be used during the reprocessing process
- must be removed before processing

Flex container
The lid features an integrated filter system, which may consist of the following types:
- Barrier filter system
- Valve system
- PTFE filter system

The filter systems are integrated into cassettes and must be fitted correctly.

Strainer baskets
Suitable strainer baskets in various designs are available for every container size (e.g. wire strainer baskets or perforated stainless steel strainer baskets).
The sieve baskets must be selected so that:
- the container can be closed properly
- the required clearances to the filter systems are maintained

Sealing seals
Disposable sealing seals must be applied to both closures prior to each sterilisation. The seals break when the container is opened. If a seal is damaged or opened after sterilisation, the sterility of the contents is no longer guaranteed and the container must be reprocessed.

Silicone mats
Silicone mats may be used optionally in sieve baskets. Before first use, these must be prepared in accordance with these instructions for use.

Indicator labels (steam sterilisation)
Indicator labels are used for visual verification of the sterilisation parameters achieved.
The indicator changes colour when the specified conditions are met.
If the indicator has not changed colour completely, the sterilisation must be repeated. The manufacturer’s instructions, particularly regarding shelf life, must be observed.

Paper filters
- Paper filters are intended for single use only and should be preferred over reusable filters.
- Paper filters must not be stuck to or labelled (e.g. for documenting cycles), as this may impair the function of the microbial barrier.
- After sterilisation, the used filter must be removed before the reprocessed instruments are taken out. The filter must then be checked to ensure it is in perfect condition before disposal.
- If the filter shows visible damage, the sterility of the products cannot be guaranteed. In this case, re-sterilisation is required.

Paper filters must be sized so that the perforations in the container lid and/or container tray are completely covered.
The shelf life of the filters must be observed in accordance with the manufacturer’s instructions.

PTFE permanent filters
- PTFE filters are designed for repeated use and can be used for up to 1,200 reprocessing cycles.
- Permanent filters must not be stuck with labels or written on (e.g. to document runs), as this may impair the function of the germ barrier.
- In the event of heavy soiling, the filter must be removed and then machine-cleaned in accordance with the instructions in this user manual.
- PTFE permanent filters must be sized so that the perforations in the container lid and/or container tray are completely covered.

5 Use and handling

The sterilisation containers are made of an aluminium alloy with an anodised surface for corrosion protection.
Aggressive cleaning agents, metal brushes or abrasive cleaning utensils must not be used, as they can cause permanent damage to the surface.

The sterilisation containers must only be handled by trained or qualified personnel to prevent damage to the containers, lids, seals, filters and cassettes.

The sterilisation containers are optionally available with coloured lids to facilitate allocation to specialist departments or areas of application.
Sterilisation indicator labels and coloured identification elements are used to identify the contents, location of use and reprocessing status.
Appropriate measures must be taken to ensure that sterilised and non-sterilised sterilisation containers can be clearly distinguished from one another (e.g. by sealing or process indicators).
Only undamaged and intact seals guarantee that the sterilisation container has not been opened without authorisation.

6 Cleaning, disinfection and sterilisation

6.1 Preparation for decontamination

1. Separate the container tray from the lid.
2. Remove the contents of the container (e.g. sieve baskets, instruments).
3. Remove the filter holders or cassettes from the inside of the lid.

   For containers with perforated bases, the relevant components must also be removed from the container tray.
4. Dismantle the filter systems according to the model:
   - For barrier cassettes: remove the barrier disc
   - For disposable paper filters: Remove and dispose of the filter (unless this has already been done after opening the container)
   - If valve or PTFE cassettes are heavily soiled: remove the cassettes as well
5. Remove disposable seals and indicator labels.

Notes

- Paper filters are single-use filters and must be replaced after each use of the container.
- For Flex containers, if cassettes are heavily soiled, they must be unscrewed for thorough cleaning to remove all residues.
- The lid must not be subjected to individual loads or used as a storage surface (e.g. by placing the container tray on top) to prevent deformation.

6.2 Commissioning a brand-new container

Before first use, the container must be cleaned, prepared and fitted with suitable filters in accordance with these instructions for use.

- The container must be machine-cleaned and disinfected before first use.
- Steam sterilisation must be carried out after cleaning and disinfection.
- All moving parts (e.g. closures) must be maintained with a suitable instrument care oil as required.
- Suitable, new filters must be fitted before use.

6.3 Cleaning and disinfection

Improper cleaning and disinfection can lead to corrosion and stress fractures. Therefore, the instructions provided by the manufacturers of the cleaning and disinfecting agents used must be followed.
The cleaning agents must be sodium- and carbonate-free, have a neutral pH value or be expressly approved by the manufacturer of the solutions used for the reprocessing of anodised aluminium.
The water used must meet at least the quality standards recommended by the manufacturer of the cleaning and disinfection unit (CDU) for the proper operation of the unit.

The following basic requirements must be observed when reprocessing sterile container systems:

The sterile container systems must be cleaned and disinfected before first use and after each subsequent use.

6.3.1 Machine cleaning

Contaminants that cannot be removed during the standard cleaning process, regardless of the method used (e.g. adhesive labels, indicator strips, markings), can be removed using a cleaner suitable for anodised aluminium. Following this additional treatment, the products must be reprocessed as described below.

- Neutral or other suitable cleaning and disinfecting agents that are expressly approved for the reprocessing of aluminium products must be used. The exact dosage should be taken from the manufacturer's instructions. With an optimised programme, these products may also be suitable for cleaning surgical instruments. Where necessary, the products must be tested for suitability in the relevant process.
- When using neutralising agents, the suitability of the products for aluminium must be checked.
- Low-salt water (e.g. fully demineralised water / deionised water) must be used for the final rinse.
- The cleaning equipment and inserts must be suitable for the reprocessing of containers, lids and cassettes. This applies in particular to proper placement within the loading inserts to ensure that rinsing, drainage of the media used and drying of the containers, lids and cassettes can take place unhindered and to a sufficient extent.
- As with all medical devices, the use of rinse aids is not recommended for plastic parts.
- Containers, lids and cassettes must not be cleaned and disinfected whilst closed.
- When loading the machines, ensure that the media can drain away sufficiently during the process.
- The container tray must be placed in the washer with the opening facing downwards to prevent water accumulation and ensure adequate drainage of the cleaning agents used.
- The container lid must be cleaned with the inside facing downwards and with the fasteners folded inwards.
- Once the machine cleaning and disinfection process is complete, the containers and their accessories must be removed without any visible residues of media.
- For Flex containers, the cassettes must be separated from the lid before cleaning. Barrier discs must be cleaned with the barrier side facing downwards. The remaining cassette parts can be cleaned vertically as individual components.
- If cleaning is carried out with the filter removed, care must be taken to ensure that the filter is cleaned outside the container. Damage to PTFE filters, particularly to sensitive structures such as central perforations, must be avoided.

If residues are nevertheless found, the position of the containers and accessories within the unit must be checked and adjusted if necessary. Closed cassettes must be opened so that residues can be removed.

A validated cleaning procedure can, for example, be carried out as follows:

- 1 minute of pre-cleaning with cold water (< 40 °C)
- Drain water
- 3 minutes of cleaning with a suitable cleaning agent at 45 °C
- Water drainage
- Neutralisation with fully demineralised water (deionised water), using a suitable neutralising agent if necessary
- Drain

The cleaning agent used must be expressly approved by the manufacturer for anodised aluminium. The manufacturer's instructions must be followed.

The cleaning and disinfection units (CDU) used must or should comply with the DIN EN ISO 15883 series of standards.

Water quality in accordance with validation:
For the final rinse, low-germ (<10 CFU/ml) and low-endotoxin water (<0.25 EU/ml) was used as part of the validation.
In practice, deionised water is usually used, which meets the technical requirements for RDG processing. Ensuring water quality is the responsibility of the operator in accordance with the specifications of the RDG and the facility.

Thermal disinfection:
Thermal disinfection is carried out in accordance with the A_0 concept as per DIN EN ISO 15883-1. Minimum requirement:
– A_0 = 3000, e.g. 90 °C for 5 minutes, deionised water

Responsibility for achieving the required A_0 value lies with the operator.

Drying
Complete drying of the containers and all components must be ensured.
Drying should preferably be carried out mechanically in the RDG.
It must be ensured that no residual moisture remains in the container, particularly in sealing areas and on contact surfaces.
If necessary, additional drying, e.g. using compressed air, may be carried out.

6.3.2 Manual cleaning

- For aluminium containers and lids, mild, neutral cleaning agents or chemical products that have been expressly approved by the manufacturer for use on aluminium products should be used where possible. Where necessary, the suitability of the products for the relevant process must be checked.
- After cleaning, thorough rinsing with low-salt water (e.g. deionised water) and adequate drying are required.
- A soft, suitable sponge must be used for manual cleaning.
- Scouring pads, metal brushes or abrasive cleaners must not be used, as these can damage the surfaces.
- For PTFE filters, manual cleaning is only carried out in the event of heavy soiling of the filter; otherwise, reprocessing is carried out mechanically.
- The filter must be removed from the container and cleaned carefully. Only cleaning agents suitable for containers and, where applicable, surgical instruments, and approved by the operator, must be used. Information on concentration, temperature and contact time can be found in the cleaning agent manufacturer's instructions.
- Finally, disinfection must be carried out in accordance with the relevant hygiene requirements.

6.4 Check / Inspection

All components of the sterile container systems must undergo a visual and functional check before each use.

It must be ensured that:
- all parts are undamaged and free from deformation
- all components are clean and completely dry
- the container tray and lid lie flat against each other

Seals:
- Seals in the lid and on the filter mountings must be present, correctly fitted and undamaged
- Seals must not show any cracks, deformation or brittleness
- Seals must be checked before each use

Filters:
- Paper and reusable filters must be undamaged
- Disposable filters must be replaced before each use
- Filters must be fitted correctly

Filter holders:
- must be properly secured
- must be in working order

Closure systems:
- must function perfectly
- must close securely

Other components:
- Brackets and fasteners must be securely fitted
- all components must be correctly fitted

If any damage, deformation or impairment of function is detected, the affected components must not be used further. Damaged components must be replaced or professionally repaired. The inspection must be carried out before each subsequent use.

6.5 Maintenance

Maintenance and repair work must only be carried out by qualified personnel.
Improper tampering, particularly with seals or fasteners, can impair the function and safety of the sterile container system and must be avoided.

Before carrying out any maintenance or repair work, ensure that the product has been reprocessed and decontaminated.

Seals:
- The maximum service life of the seals is 500 reprocessing cycles.
- Once this number has been reached, the seals must be replaced without fail, regardless of their visible condition.
- If damage is detected on a seal, it must be replaced immediately.

Seals must not be treated with oils, sprays or solvents.
For cleaning and maintenance, simply wipe them down occasionally with a damp cloth.

Moving parts:
- Moving components (e.g. closure systems and lid mechanisms) must be treated regularly and as required with a suitable maintenance oil approved for medical devices.

Operator's responsibility:
- The operator is responsible for establishing appropriate measures to monitor the reprocessing cycles carried out.

Repair and return:
- For maintenance or repair work, a suitable decontamination certificate must be provided with the product.
- Maintenance and repair work must be carried out in accordance with the manufacturer's specifications.

6.5.1 Filter replacement

After inserting the filter, press the filter holder into the designated position until it audibly clicks into place.

Only filters and filter holders designed for and compatible with the system may be used.
- Disposable paper filters must be replaced before each new sterilisation cycle.
- The use of unsuitable or incompatible filters may compromise the integrity and function of the sterilisation barrier.
- PTFE filters in standard containers are designed for a maximum service life of 1200 reprocessing cycles and must be replaced thereafter.

6.5.2 Cassette replacement

After cleaning, turn the lower part of the cassette into the correct position until it clicks into place.

Only compatible cassettes intended for use with the system must be used.
- The use of unsuitable cassettes may impair the function of the filter system.

6.6 Packaging

The sterile container systems constitute a sterile barrier system and serve as packaging for the sterilisation, storage and transport of medical devices.
Before sterilisation, ensure that:
- all components are fully assembled
- suitable and undamaged filters have been inserted
- disposable filters have been replaced
- reusable filters have been properly reprocessed and are undamaged
- seals are correctly fitted and undamaged
- the container is properly sealed

The container must be loaded in such a way that:
- the sterilisation media can reach all surfaces
- the filter surfaces are not blocked
- the container can be closed without any tension

The use of suitable sieve baskets and inserts is recommended.

To ensure integrity and for identification purposes, a seal or a suitable indicator system may be used. The container must only be sterilised, stored and transported whilst closed.

6.7 Sterilisation

The sterile container system has been validated for steam sterilisation using the fractionated vacuum method (pre-vacuum method).
Validated parameters:
- Method: fractionated pre-vacuum steam sterilisation (3 pre-vacuum phases)
- Temperature: 134 °C
- Half-cycle: 2.5 minutes
- Hold time: 5 minutes
- Drying time: 20 minutes

Validated load:
- Standard medical instruments (e.g. scissors, clamps, forceps)
- Textiles

6.7.1 Container load

The total weight of the load must not exceed the values specified below in accordance with DIN EN 868-8, as otherwise proper sterilisation cannot be guaranteed.

Model	Max. load in kg
Basic models	
1/1 container	10
3/4 container	7.0
1/2 container	5.0
Small set container	
Dental container	1.8
Mini container	1.0
Maxi 1/2 Dental	1.2
1/2 Dental Container	0.7
Flat container	1.5

Note:
National regulations may differ from the loading limits stated above and must be taken into account accordingly.

Loading with textiles
When loading textiles, please note the following:
- Laundry items or folded textiles should be placed as vertically as possible.
- Even at maximum load, there must be sufficient space for steam to penetrate.

As a guide:
It must be possible to slide a flat hand between the textiles.

Warnings regarding loading and preparation
- Loading configurations and sterilisation parameters must be determined by the qualified personnel responsible for this.
- Endoscopes, instruments with lumens, compressed air or mains-powered units, and instruments with cannulas must be prepared for sterilisation in accordance with the manufacturer's instructions.
- Small baskets, inserts or other accessories (particularly those with lids or flaps) may only be used if the sterilisation container system is designed and validated for this purpose.

Loading limits (filling height)
In addition to the weight limits, the following maximum loading heights must be observed:
- Basic models: maximum 10 mm below the top edge of the tray
- **Small set containers (e.g. mini, dental containers):** maximum 3 mm below the top edge of the tray

Further safety-related information
- The use of water-repellent inserts (e.g. plastic trays) can lead to the formation of residual condensation in the container and should be avoided. Instead, suitable, permeable mats or holders should be used.
- Before sterilisation, check that the filters are intact and that the filter holders are correctly seated. For Flex containers, also check that the cassettes are correctly seated and in good condition.
- The container lid and tray must be completely closed using the designated locking mechanism prior to sterilisation. It must be ensured that the closures are correctly locked and sufficiently tight.
- To prevent accidental opening and to ensure the integrity of the contents, sealing seals must be applied at the designated points.

6.7.2 Loading the steriliser

The containers are designed for steam sterilisation using the fractionated vacuum method and can be used in standard large-capacity sterilisers. Heavy containers must be placed at the bottom of the sterilisation chamber. Due to their design, the containers can be safely stacked on top of one another during sterilisation without slipping.
Stacking is intended exclusively for sterilisation cycles using the fractionated vacuum method. The maximum stacking height must not exceed 46 cm to ensure adequate air removal and steam penetration. To prevent condensation build-up and resulting drying problems, the containers must be positioned horizontally in the steriliser. The steriliser manufacturer's instructions must be followed.

Precautions for sterilisation
- The following must be observed during sterilisation:
- The container must not be enclosed in any additional outer packaging.
- The perforated areas in the lid and, where applicable, the tray must not be covered either inside or outside (e.g. with film or similar materials), as this impedes the passage of air and steam.
- This can lead to insufficient pressure equalisation, deformation of the container and loss of sterility of the contents.
- Disposal containers must not be sterilised whilst closed, as insufficient pressure equalisation can also lead to deformation in this case.
- During loading and unloading of the steriliser and during transport, the container must only be handled using the designated carrying handles.
- Carrying the container by the lid is not permitted.

6.7.3 Carrying out and following up on sterilisation

- The steriliser must be operated in accordance with the manufacturer's instructions for the selected sterilisation cycle (particularly with regard to temperature and sterilisation time). The validation results specified for the sterile container system must be taken into account.
- To prevent condensation, the container must be allowed to cool completely on the sterilisation trolley after sterilisation.
- After each sterilisation, the sterilised items must be assessed and released in accordance with internal guidelines and taking into account the validation results. Release may only be carried out by appropriately qualified specialist staff (e.g. Level I qualification).

6.8 Information on the validation of reprocessing

The cleaning, disinfection and sterilisation procedures described in these instructions for use have been validated.

Validation was carried out using suitable methods and taking into account the material and design characteristics of the sterilisation container systems. Reprocessing must be carried out using suitable, validated processes. Responsibility for the validation and implementation of the specific reprocessing processes lies with the operator.

Scope of validation
The validation covered the following containers:
- 1/1 container
- 3/4 container
- 1/2 container
- Flat container
- Dental container
- Mini container
- Maxi-1/2 Dental
- 1/2 Dental container
- Endo container

The validation applies to all sterilisation container systems listed in the declaration of conformity.

The sterilisation containers have been tested and validated for steam sterilisation using the fractionated vacuum method.

6.9 Restriction on reprocessing

- Repeated reprocessing in accordance with these instructions for use has only a minor effect on the service life of the containers.
- The service life of a sterilisation container is essentially determined by application-related wear and tear as well as possible damage.

7 Service life

When used correctly, with an average of around four processing cycles per week, both the containers and the sieve baskets have a service life of up to 10 years.

8 Storage, transport and disposal

8.1 Storage

The storage period for sterilised medical devices in sterilisation containers is governed by the requirements of DIN 58953-9.
It depends on the specific storage conditions and must be determined by the responsible hygiene specialist. This also includes determining loading configurations and suitable storage conditions.
Where there are increased requirements for aseptic conditions or deviations from the recommended storage conditions, correspondingly shorter storage periods must be specified or additional protective measures (e.g. additional packaging after sterilisation) must be taken.

Storage conditions
The following storage conditions must be observed:
- Environment: dry and low in dust
- Humidity: 30–50%
- Protection from light: no direct sunlight or UV exposure
- Mechanical stress: avoid
- Air pressure: 500–1060 hPa

The containers must be stored under protected conditions (e.g. in closed cabinets) in a clean, dry, dust-free environment and free from pest infestation.

Storage period (performance verification)
The Steril container system has been tested under microbiological test conditions (including with *Bacillus subtilis*, *Aspergillus brasiliensis* and *Candida albicans*) to ensure the maintenance of the sterile barrier. Provided the described storage conditions are adhered to, a storage period of up to 12 months can be achieved.

8.2 Transport

The sterilisation containers must only be transported using the designated carrying handles.
To prevent damage and the resulting contamination of container components or the contents, the container must be kept closed during transport. If available, a safety lid may also be used.
Filters must be protected from damage during transport, in particular from perforations.

8.3 Disposal

Before disposal, the products must be free of potentially contaminated material. To this end, the products must be prepared in accordance with these instructions for use, where applicable.
If there are any sharp edges or damage, disposal must be carried out in such a way as to prevent any risk to persons.

8.4 Materials

The sterilisation containers are made of anodised aluminium alloy; the sieve baskets are made of stainless steel.

9 Service

For service and repairs, please contact your local MEDICON eG representative.

10 Liability

Note for the USA

Under US federal law, this product may only be purchased in the USA by a doctor or on a doctor's prescription.

Validity of the instructions for use
Always use the latest version of these instructions for use. Due to technical developments, the instructions for use are updated regularly. The version date and revision number are indicated on the document.

Disclaimer
MEDICON eG accepts no liability for damage resulting from:

- improper use
- use not in accordance with the intended purpose
- incorrect handling, care or maintenance
- failure to comply with these instructions for use
- modifications or repairs carried out without the consent of MEDICON eG
- Repairs carried out by unauthorised persons or organisations

Furthermore, any modifications or unauthorised repairs will invalidate the warranty.

11 Accessories / Spare parts

Accessories / Spare parts	Item number
Filter holder S, M, L for ONE System	81.50.01
Disposable paper filters with steam indicator S, M, L for ONE System	81.50.02
Textile filters S, M, L for ONE System	81.50.03
PTFE filters S, M, L for ONE System	81.50.04
Filter holder XS for ONE System	81.50.05
Disposable paper filter with steam indicator XS for ONE System	81.50.06
Textile filter XS for ONE System	81.50.07
PTFE filter XS for ONE System	81.50.08

12 Explanation of symbols and images

	Manufacturer		MRI uncertain
	Date of manufacture		CE marking
	Production batch number, batch		Medical device
	Item number		Quantity
	Non-sterile		LDPE (Low-Density Polyethylene)
	Caution	Rx only	Prescription only
	Follow the instructions for use		