Instruction for use

Sterile container system

Important information

You receive a high-quality product by purchasing this sterile container system. Its proper handling and use will be described in the following.
Please read this user manual thoroughly and keep it in a safe place in order to minimise risks and unnecessary burdens for the patients, the users and third parties.
Please read carefully the warning notices identified by this symbol. Improper use of the products can lead to serious injuries to the patients, the users or third parties.

Products

This instruction applies to all sterile container systems supplied by **Berger Surgical Medical Products GmbH**.

⚠ NOTICE

- The processing of medical devices must be complied with the national regulations and standards.
- In case of patients who have or are suspected of having Creutzfeldt-Jakob disease (CJD) or any kind of variations of this disease, the currently relevant national regulations must be applied concerning the processing.

⚠ WARNING NOTICES AND PRECAUTIONARY MEASURES

- For sterilisation, only faultless container bottoms and lids with an undamaged seal and with an undamaged filter system and / or inserted filter may be used!
  Only one filter should be used per filter holder.
- Disposable paper filters are preferable to reusable filters.
- Only clean and low microbiological contaminated sterilisation containers allow a successful sterilisation.
- A washing and cleaning by a machine is preferable as it performs a more effective result. Using a machine obtains a greater safety by the cleaning and disinfection process.
- Never use metal brushes, metal scouring pads or abrasive cleaning agents for manual cleaning.
- Alkaline cleaning agents (pH >10) are not suitable for all materials. The Robert Koch Institute points out some potential problems caused by increased abrasion by aluminium, silicone elastomers, adhesive connections, solder connections of silver and stannic, sealing materials, plastic coatings, glass fibre light guides and visual surfaces with antireflection features.
- Never use cleaning solutions containing bleach, e. g. sodium hypochlorite, as these can cause severe corrosion.
- The lid should not be loaded without the bottom or used as storage area, to avoid deformation of the lid.
- If sterilisation containers are deformed in any way during the sterilisation process, there is generally a risk of non-sterility. In this case, the entire batch must not be used and the cause must be determined immediately (check the sterilisation protocol; check the steriliser as well as the other sterile material containers; find the cause by checking the function of the damaged sterilisation container).
- Defective products must run through the entire sterilisation reprocessing before returning them for repair or reclamation. The proof of decontamination must be enclosed with the return shipment.

RESTRICTION ON REPROCESSING

- Repeated / frequent processing as per this instruction has only minor effects on the service life of the containers.
- The service life of a sterilisation container is mainly determined by wear and damage through usage.
- Proper use on an average of 4 times a week, results in a service life of both containers and screen baskets of up to 10 years.

1 AREA OF USE

Berger Surgical sterile container systems combine approved filter technologies, tested materials and design properties into a reliable container system. These are reusable container systems which offer a wide selection of dimensions and equipment in order to provide an effective packaging, sterilisation, storage and transportation of the surgical instruments for sterilising. The container systems are optimally suitable for the fractionated vacuum procedure.

The premium systems (3-in-one) can be equipped with 3 different filter systems in the form of cassettes.

Sterilisation containers are intended for use by adequately instructed and / or trained personnel. Direct patient contact is not intended.

1.1 INTENDED PURPOSE

Berger Surgical sterile container systems are intended to be loaded with medical devices for sterilisation. The sterilisation and storage of the encased products are enabled and ensured until they are used.

Depending on the model, the containers are available with perforated and non-perforated bottoms and perforated lids. The 1/1, 3/4 and 1/2 E standard containers are also available with safety lids.

1.2 COMBINATION PRODUCTS

Berger Surgical container systems consist of sterile containers, screen baskets and filters. Accessories can also be used for the container systems. A screen basket in the suitable size must be used for each container size. The possible combinations of various container designs are shown under point 10.

⚠ CAUTION!

Combine only original Berger Surgical component parts such as lids, bottoms, filters, gaskets, cassettes, and filter holders with each other in order to avoid putting at risk the leak tightness and germ barrier. Otherwise, Berger Surgical does not assume any warranty.

Standard container

The lids and if applicable, the bottoms are equipped with filter holders below / above the perforations. Before sterilisation, disposable paper filters or PTFE permanent filters must be inserted into the filter holders.

A safety lid can also be placed on the lid of the E standard containers of the sizes 1/1, 3/4 and 1/2 as required.
This protects the sterile container from contamination during storage or transport.

3-in-one container (premium system)

The lid is equipped with either a barrier, valve or PTFE system. The different filter systems are fitted in “cassettes”.

Screen baskets

There are suitable wire screen baskets in various heights with compatible lids as well as stainless steel screen baskets made of perforated sheet with compatible lids and feet for each container size.

The screen baskets must be selected in such a way that the container can be closed without any problems and the specified distances to the filters are complied with.

Security seals

Security seals must be attached to the closures outside before each sterilisation by guiding the seal through the opening of the spring lock system and afterwards sealing it. The seal will break by opening / flipping the closures. Security seals are intended for single use.

Silicone mats

The screen baskets are placed into the container and if necessary, it can be equipped with a silicone mat. They should be washed and disinfected before first use.

Indicator labels for steam sterilisation

The supplied indicator changes its colour during steam sterilisation at 134°C.

The indicator labels may only be used for their intended purpose. The result can be falsified if the specifications are disregarded.

Please pay attention to the shelf life of the labels as specified by the manufacturer.

Information for the use of paper filters

- Paper filters are intended for single use only and are preferable to filters that are to be used several times.
- Paper filters must not be glued or labelled (e. g. to document the cycles), as this can disturb the germ barrier.
- The used filter must be removed before removing the reprocessed instruments and must then be checked for proper condition before being disposed of. In the event of visible damage, the sterility of the products cannot be guaranteed, so they must be re-sterilised.

The paper filters must have the correct measurements to cover the perforation completely in the container lid / bottom.

Please pay attention to the shelf life of the filters as specified by the manufacturer, if necessary.

Information for the use of PTFE permanent filters

- PTFE filters are intended for multiple uses (up to 1200 cycles).
- PTFE filters in 3-in-one cassettes can be used up to 5200 cycles.
- Permanent filters must not be glued or labelled (e. g. to document the cycles), as this can disturb the germ barrier.
- In case of extreme contamination, the filter must be removed and then machine-cleaned according to the instructions in this manual (see also point 2.4.1).

The PTFE permanent filters must have the correct measurements to cover the perforation completely in the container lid / bottom.

2 HANDLING

2.1 GENERAL

Berger Surgical sterilisation containers are made of an aluminium alloy and its surface is anodised to protect against corrosion. Aggressive cleaning products, metal brushes or scouring pads can permanently damage this surface and therefore may not be used. If this instruction is not followed, the warranty will be voided.

⚠ **The sterilisation containers may only be handled by trained and / or instructed personnel in order to prevent damage to the containers, closures, gaskets and sterile filters / cassettes.**

The sterilisation containers are also offered with coloured lids for the easier classification of the containers of the individual disciplines and special departments.
Sterilisation indicator labels and coloured identification labels provide information about the content, place of use and state.
Suitable measures (e. g. sealing, process indicators) must be taken according to normative requirements and recommendations to ensure that sterilised and unsterilised sterilisation containers cannot be mistaken for one another. Only intact sealing ensures that the sterilisation container has not been opened without permission.

2.2 PREPARATION FOR CLEANING

1. Separate container bottom and lid
2. Remove the contents of the container (screen basket, instruments, etc.)
3. Remove the filter holders / cassettes from the inside of the lid and if applicable also from the bottom part (in the case of containers with perforated bottom)
4. In the case of barrier cassette: Remove barrier disc
   In case of disposable paper filter: dispose the disposable filter
   If the valve or PTFE cassettes are strongly contaminated than these cassettes must be removed as well.
5. Remove disposable seals as well as indicator labels.

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

Note for 3-in-one containers: If the cassettes are strongly contaminated than they must be taken apart for a more effective cleaning to remove residues easier.

Note: The lid should not be loaded alone, e. g. with the container bottom or used as storage area, to avoid deformation of the lid.

IMPLEMENTING OF A BRAND-NEW CONTAINER

⚠ **Before the first use, the container must be thoroughly cleaned according to the instructions in this manual.**

- The container must be pre-processed in a validated cleaning and disinfection process.
- A neutral cleaning agent which is suited for reprocessing medical devices should be used for this purpose in the machine.
- Once the pre-processing in the cleaning and disinfection process is completed, the products must be steam-sterilised at 134°C in a fractionated steam sterilisation process.
- Furthermore, all parts of the sealing at the lid and the bottom must be treated regularly and if necessary, with approved instrument maintenance oil.
- Suitable new filters will have to be inserted after the cleaning process (see 2.6 Filter change).

2.3 CLEANING AND DISINFECTION

Note: Improper cleaning and disinfection may lead to corrosion and stress fractures. For that reason, the specifications of the manufacturer of cleaning and disinfection products must be observed. The cleaning agents must be free of sodium and carbonate, must have a neutral pH value and / or must be approved for the treatment of anodised aluminium by manufacturer of the solutions which are used for the processing. The water used for this purpose must be in conformity at least with the quality recommendation of the manufacturer of the CDD for the proper operation of the equipment. The following essential specifications must be followed during processing the containers:

⚠ **The container must be washed and disinfected before the first use and after each further use.**

2.3.1 MECHANICAL CLEANING

Contamination which cannot be removed in the usual washing procedure, (adhesive labels, indicator strips, markings) can be removed with an eloxal cleaning agent. After this special treatment, the products must be processed as described in the following:

- Neutral or other suitable cleaning and disinfection agents are to be used which are explicitly approved for the processing of aluminium products. For the proper dosing please refer to the manufacturer’s specifications. These products can also be suitable for cleaning surgical instruments by optimising the programme. If necessary, the products must be checked for the suitability for the relevant procedure.
- When using neutralisation agents then the products must be checked for the suitability for aluminium.
- Low-salt water (e. g. deionised water) should necessarily be used for the final rinsing.
- The cleaning devices and inserts must be suitable for the processing of containers, lids and cassettes. This applies particularly for the correct positioning in the loading inserts to ensure an adequate and unobstructed rinsing, draining of the applied media flow and the drying of the containers, lids and cassettes.
- For the 3-in-one container and other plastic parts, as with all medical devices, the use of rinse agents is not recommended.
- Containers, lids and cassettes may not be cleaned and disinfected in a closed state.
- Attention must be paid when loading the machine to ensure a sufficient media flow during the process.

- The container bottom must be placed into the washing machine with the opening downward in order to prevent the accumulation of water and to ensure that the used media flow off adequately.
- The container lid must be cleaned with the inside facing downward and the closures folded inward.
- After completing the mechanical cleaning and disinfection process, the containers and their accessories will be removed from the media without any visible residues.
- For 3-in-one containers: The cassettes must be detached from the lid before cleaning. Barrier discs are cleaned with the barrier-side facing downward. The other cassette parts can be cleaned positioned vertically as separate parts.

Should there be still any residues detected then the position of the containers and accessories in the device should be checked and changed, if necessary. In the case of closed cassettes these must be opened so that the remaining residue can be removed.

The following cleaning procedure has been validated in a suitable cleaning and disinfection device by Berger Surgical and can be used for the cleaning:

- 1 minute pre-cleaning with cold (<40°C) water (drinking water quality according to EC Directive 98/83/EG)
- 3 minutes cleaning with a suitable cleaning agent according to this IFU at 45°C
- Neutralisation with deionised water

The above recommendation is not binding.
Its observance is no guarantee for the material compatibility of an agent.

The cleaning agent must be approved for anodised aluminium by the manufacturer of the cleaning agent, the manufacturer's instructions must be observed.

The cleaning and disinfection devices (CDD) used should comply with the DIN EN ISO 15883 series of standards.

2.3.2 MANUAL CLEANING / DISINFECTION

- As far as possible mild, neutral cleaning agents should be used for aluminium containers and lids or chemical products which are specifically approved also for the treatment of aluminium products by the manufacturer. If necessary, the products must be checked for the suitability for the relevant procedure.
- After cleaning, a thorough rinsing with suitable low-salt water (e. g. deionised water) and sufficient drying is necessary.
- A suitable soft sponge should be used for manual cleaning.
- Do not use scouring pads, metal brushes or abrasive cleanser, because they can destroy the surfaces and lead to the loss of the warranty rights.
- In the case of the PTFE filters, manual cleaning is only carried out in the event of heavy contamination of the filter, otherwise mechanical cleaning is carried out together with the container.
  The filter is removed from the container and carefully cleaned. Only hospital-approved cleaning agents for containers and surgical instruments are used. Information on concentration, temperature and contact time can be found in the instructions of the cleaning agent manufacturer.
- Finally, disinfection must be performed according to the respective hygiene requirements.

2.4 INSPECTION, MAINTENANCE AND TESTING

The sterilisation containers must be inspected for their functionality before each use.

If there are any damages detected on the sterilisation containers then they have to be inspected, repaired and / or replaced, if necessary. Do not use defective sterilisation containers!

- All parts of the sealing at the lid and the bottom must be treated regularly and if necessary, with approved instrument maintenance oil.
- The durability of the gaskets is up to 500 sterilisation cycles. Afterwards the seals must be checked particularly carefully and replaced, if necessary.
- The operator is responsible that the amount of the preformed cycles for the products can be checked at any time.
- The sealing has to be checked before every use.
- If damage is found on a gasket, it must be replaced immediately. To protect the person carrying out the repair, the product must be processed before replacement.
- The gaskets should not be treated with spray, oil or solvents. It is enough for cleaning and maintenance to wipe occasionally with a moist cloth.
- The sterilisation containers may be maintained and repaired only by qualified persons. Do not try to repair the gaskets or attachments yourself in order not to compromise the safe use of the containers, unless this applies to containers which have a special replaceable silicone gasket (BS standard container).
- The sterilisation containers may be returned for maintenance or repair to Berger Surgical or to an authorised repair service. The proof of decontamination must be enclosed with the return shipment.

2.5 CHANGING OF FILTER

After changing the filter, the filter holder has to be placed by pressing into its correct position with an audible snap. Berger Surgical lids may only be used with Berger Surgical filter holders.

- Disposable paper filters must be reinserted before every re-sterilisation.
- Suitability and proper fit are only guaranteed if Berger Surgical filters are used.
- Warranty services can only be accepted if original Berger surgical filters are exclusively used.
- PTFE filters in BS standard containers have been tested for usage duration of 1200 cycles and must be replaced afterwards.

⚠ CAUTION!

Combine only original Berger Surgical component parts such as lids, bottoms, filters, gaskets, cassettes and filter holders with each other in order to avoid putting at risk the leak tightness and germ barrier. Otherwise, Berger Surgical does not assume any warranty.

2.6 CHANGING OF THE CASSETTES (for 3-in-one containers)

After cleaning, the lower part of the cassette must be rotated into the correct position until it clicks into place. Berger Surgical lids may only be used with Berger Surgical replacement parts.

- Suitability and proper fit are only guaranteed if Berger Surgical cassettes are used.
- Warranty services can only be accepted if original Berger Surgical parts are exclusively used.
- The PTFE filters for 3-in-one containers used for 3-in-one containers have been tested for usage duration of 5200 cycles and must be replaced afterwards.
  The operator is responsible that the amount of the preformed cycles for the products can be checked at any time.

3 STERILISATION

Berger Surgical sterilisation container systems have been validated with the following sterilisation parameters:

Method:	3 x pre-vacuum steam sterilisation
Temperature:	134°C
Half cycle	2.5 minutes
Holding time:	5 minutes
Drying time:	20 minutes
Loading:	Standard medical instruments (scissors, clamps, forceps, retractors) and textiles

The validation covered the following containers of the Berger Surgical sterile container system:

- XL container
- 1/1 container
- Wide body container
- 3/4 container
- 1/2 container
- Flat container
- Dental container
- Mini container
- Maxi 1/2 dental
- 1/2 dental container
- Endo container
- Baskets

⚠ **CAUTION!**

Berger Surgical sterilisation containers and baskets have been tested and validated for steam sterilisation with moist heat in a fractionated vacuum procedure.

3.1 LOADING OF THE CONTAINER

The total weight of the load of a container should not exceed the following weight according to DIN EN 868-8, since otherwise no satisfactory sterilisation can be guaranteed:

Model	Max. loading in kg
Basic models	
1/1 container	10
3/4 container	7.0
1/2 container	5.0
XL & wide body container	12
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

In accordance with national legislation the loading limit can differ from the details listed above.

In case of loading with textiles, please pay attention that the pieces of laundry and / or folded textiles are in vertical position. It should still be easily possible to slide an open hand between the pieces of laundry in the case of a fully loaded container.

The sterilisation containers were validated for instruments with a lumen from a diameter of 1.2 mm and up to a length of 23.5 mm.

⚠ CAUTION!

The sterilisation of various container loadings and the configurations must be determined by the responsible personnel.

Endoscopes, instruments with lumen, compressed air or mains-powered units and instruments with cannulas must be prepared for the sterilisation according to the specifications of the manufacturer.

Small baskets, trays or other accessories, especially the ones with lids or flaps, should only be used together with sterilisation container systems, if the sterilisation container was specifically designed and tested for this purpose.

Loading limits: For containers of the basic models, a loading limit of 10 mm from the bottom top edge must be observed.

For small set containers (e. g. mini, dental, ...) a loading limit of 3 mm from the bottom top edge applies.

⚠ CAUTION!

Using water-resistant inserts (e. g. plastic) may cause remaining condensate inside of the container. Instead, use other suitable mats or holders.

Check the integrity of the inserted filter and the proper attachment of the filter holder. In the case of 3-in-one containers, check the integrity of the equipped cassettes.

Always use the locking mechanism to close the container lid and bottom. Ensure that the closures are sealed properly before taking the container for sterilisation.

3.1 POSITION IN THE STERILISER

The containers are designed so that they can be used in any commercially available large steriliser for the sterilisation with moist heat. Keep in mind that heavy containers are to be positioned at the bottom of the sterilisation chamber.

The containers can be stacked easily and safely on top of each other due to their design, without slipping during the sterilisation procedure. Stacking is only recommended for sterilisation cycles operating with a fractionated vacuum system. The maximum stacking height should not exceed 46 cm in order to ensure an effective air removal and steam penetration.

To avoid one-sided accumulation of condensate (and thus drying problems), the containers in the steriliser should stand horizontally.

The instructions of the manufacturer of the steriliser must be followed.

⚠ **CAUTION!**

Pay attention to the followings during sterilisation:

- Never wrap the container in an additional outer packaging.
- Never cover the perforation fields in the lid and bottom (neither inside nor outside) with any kind of foil packaging or something similar because this prevents the air and steam flow in the container. As a result, there would be a container deformation caused by vacuum due to insufficient pressure compensation so that the sterility of the content of the container cannot be guaranteed.
- Disposal containers may not be sterilised in closed condition. The result is a deformation of the container due to the insufficient pressure compensation.
- Always carry the sterilisation container by the carrying handles and never by the lid during loading and unloading the steriliser as well as during transport.

3.2 SEQUENCE CONTROL

- Operate the loaded steriliser for the selected steriliser cycle according to the specifications of the steriliser manufacturer (referring to temperature and sterilisation time). The validation results must be taken into consideration.
- The container should cool down completely on the sterilisation cart in order to avoid condensation in the container.
- The sterile goods must be evaluated and approved after each sterilisation according to internal directives and validation results. This is consequently conducted by employees with special knowledge, qualification level 1.

4 STORAGE, TRANSPORT AND DISPOSAL

4.1 STORAGE 

Please refer to DIN 58953-9 (Use of sterilisation containers) for the storage period of medical devices in sterilisation containers. The storage time depends on the storage conditions and must be determined by the responsible hygiene specialists, as well as various container loads and the storage conditions themselves.
In case of extremely high requirements for asepsis or deviations on the specified storage conditions shorter storage periods or additional packaging after sterilisation must be used.

Storage conditions:

- Temperature: 15 – 26 °C
- Humidity: 30 – 50%
- Air pressure: 500 – 1060 hPa

Berger Surgical sterilisation containers have been tested for a storage period of 12 months by applying Bacillus subtilis, Aspergillus brasiliensis and Candida albicans. Therefore, depending on the storage conditions a storage period of up to 12 months can be assured. Thereby the containers have to be stored under protected conditions (e. g. in closed cabinets), protected from dust, clean, dry and free of vermin.

4.2 TRANSPORT

The sterilisation container should be transported only by the intended carrying handles.

To avoid damage and resulting contamination of container parts or the cargo, we recommend that containers are always transported with a closed lid and / or safety lid.

4.3 DISPOSAL

For disposal, the products must be free of potentially contaminated material. For this purpose, the product may have to be subjected to treatment.

If sharp edges are produced, disposal must be carried out in such a way as to avoid endangering people.

5 MATERIALS

The sterilisation containers are made of anodised aluminium alloy and the screen baskets are made of stainless steel.

6 STANDARDS APPLIED

The following standards were considered to ensure the safety of the sterilisation containers during handling:

DIN EN 868-2	Packaging for terminally sterilised medical devices – Part 2: Sterilisation wrap - Requirements and test methods
DIN EN 868-8	Packaging for terminally sterilised medical devices - Part 8: Re-usable sterilisation containers for steam sterilisers conforming to EN 285; requirements and test methods
DIN EN ISO 11607-1	Packaging for terminally sterilised medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
DIN 58952-2	Sterilisation - Transport baskets for sterile barrier systems - Part 2: Sterilising baskets made of metal
DIN 58952-3	Sterilisation - Transport baskets for sterile barrier systems - Part 3: Instrument trays for sterilising goods made of metal
DIN 58953-9	Sterilisation; Sterile supply – Part 9: Use of sterilisation containers
DIN EN ISO 14937	Sterilisation of health care products – General requirements for characterisation of a sterilising agent and the development, validation and routine control of a sterilisation process for medical devices
DIN EN ISO 17665-1	Sterilisation of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilisation process for medical devices

An independent and accredited testing laboratory performed tests in order to ensure the reliability of the sterility. The purpose of these tests was the validation of a sterilisation procedure using moist heat by reusable Berger Surgical sterile container systems.

Based on the results, we therefore recommend the specified sterilisation procedure under chapter 3 of this user manual.

7 WARRANTY

The sterilisation containers are manufactured of high-quality materials and subjected to quality control before delivery. Should any defects still occur, then please contact the manufacturer.

In case of repairs by companies, which are not authorised for repairs by Berger Surgical, the warranty is inapplicable.

If a serious incident occurs in connection with a product of the company Berger Surgical, the manufacturer must be notified immediately. After consultation with the latter, a notification is sent to the competent authority of the member state in which the user is established.

8 BERGER SURGICAL STAINLESS STEEL DISPOSAL CONTAINER

Berger Surgical stainless steel disposal containers are ideally to be processed by machine. The validated cleaning process guarantees an effective cleaning and thereafter a reliable disinfection.
Usable chemical cleaning agents may be mildly alkaline (pH 10-11) or alkaline (pH >12). Please observe the neutralisation of the cleaning agent after the cleaning step. This is accomplished by rinsing and, if necessary, using a neutraliser with citric or phosphoric acid base.

Berger Surgical stainless steel removal container without filter units may not be sterilised in closed condition. The result is a deformation of the container due to the vacuum.

9 SYMBOLS USED IN THE USER MANUAL AND ON THE LABEL

	Attention, observe the accompanying documents
	Observe user manual
	Manufacturer
CE	The device complies with the requirements of European Directive 93/42/EEC for medical devices. Therefore it is marked with CE label.
	Keep in a dry place
REF	Order number / catalogue number
LOT	Batch designation
	Non-sterile
	Temperature limitation
	Keep away from sunlight

THE COMPANY BERGER SURGICAL MEDICAL PRODUCTS GmbH ASSUMES NO LIABILITY, IF THIS CUSTOMER INFORMATION IS DEMONSTRABLY VIOLATED.

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