# IFU_100
# Container


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## Products

*These instructions for use are valid for all sterile container systems and accessories from erbrich instrumente GmbH with the article number range:*

REF ***19E-0XX.XX – 19E-6XX.XX***

## Important note

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

*Carefully read the warnings marked by this symbol. Improper use of the products may result in 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 a sterile environment.*

## 2 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 erbrich medical devices in a case for cleaning in the washer/disinfector. Contaminated erbrich 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.*

*– Eine maschinelle Reinigung ist zu bevorzugen, da diese zu einem effektiveren Ergebnis führt. Bei der maschinellen Reinigung und Desinfektion besteht eine größere Sicherheit im Verfahren.*

*– Alkaline cleaning agents (pH >10) are not suitable for all materials. The Robert Koch Institute points out potential problems due to increased wear on aluminum, silicone elastomers, adhesive joints, soldered joints made of silver and tin, sealing materials, plastic coatings, fiber optic light guides and optical surfaces with anti-reflective coating.*

*– Defective products must have gone through the entire remanufacturing process before being returned for repair or reclamation.*
*process before being returned for repair or complaint. A decontamination certificate 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 preparation systems that meet the requirements of ISO 15883 and ISO 17665 standards.*

*– Operate on patients who are considered at risk for Creutzfeldt-Jakob disease (CJD) and associated infections using disposable instruments. Dispose of instruments used to operate on a patient with suspected or proven 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 the cleaning and disinfection agents and the systems for clinical reprocessing must also be followed.*

## 3 Limits of clinical reprocessing

*– Repeated/frequent reprocessing according to this instruction has little effect on the service life of the containers.*

*– The service life of a sterilization container is essentially determined by wear and damage from use.*

*– Proper application of an average of 4 times a week results in a service life of at least 10 years.*

## 4 Application area

*– erbrich sterile container systems combine proven filter technologies, tested materials and design features to create a reliable container system.*
*They are reusable container systems that offer a wide range of dimensions and equipment to provide effective packaging, storage and transport of instruments to be sterilized. The container systems are ideally suited for fractionated vacuum processes.*

***Purpose***

*The erbrich sterile container systems are intended for loading with medical devices that are sterilized. Sterilization and storage of the enclosed products is*
*sterilization and storage of the enclosed products until they are used.*
*Depending on the model, the containers are available with perforated and non-perforated tray bottoms and perforated lids. The 1/1, ¾- and ½ - containers are*
*also available with safety lid.*

***Combination products***

*erbrich sterile container systems consist of sterile containers, sieve baskets and filters. Accessories can also be used for the container systems.*
*can be used. A sieve basket of the appropriate size should be used for the respective container size. The following section describes the possible combinations of the different container designs. A detailed overview of combinable products can be found in section*
*COMBINATION PRODUCTS*

***– Standard container***

*Filter holders are located below/above the perforations in the lid and, if applicable, in the tank. Disposable paper filters or permanent filters must be inserted in these filter holders before*
*paper filters or permanent filters before sterilization.*
*A safety lid can be placed on the lid of the standard container of sizes 1/1, ½ and ¾ as required. This protects against contamination during storage or transport of the sterile container.*

***– Screen baskets***

*For each container size, there are matching screen baskets in different heights, matching lids and matching feet.*

***– Security seal***

*Security seals are attached to the outside of the closures by inserting the seal through the opening of the spring closure system and then locking the seal.*
*then locking the seal. When opening/flipping up the closures, the seal breaks.*

***– Silicone mats***

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

***– Indicator labels***

*The indicator contained discolors during steam sterilization at 134° C.*
*Please observe the shelf life of the labels according to the manufacturer's instructions. The indicator labels may only be used for their intended purpose. Failure to comply with the specifications may falsify the*
*be falsified.*

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

*– Paper filters are intended for single use only.*

*– Paper filters are manufactured according to EN ISO 11607-1.*

*– Paper filters must not be glued (e.g. for documenting the runs), as the glue may contain pollutants. In addition, the germ barrier*
*also destroys the germ barrier.*

*The paper filters must be sized so that the perforation in the container lid is completely covered.*

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

*– PTFE filters are designed for multiple use.*

*– Permanent filters must not be glued (e.g. for documenting the runs), as the glue may contain pollutants. In addition, the germ barrier*
*also destroys the germ barrier.*

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

*The permanent filters must be sized so that the perforation in the container lid is completely covered.*

## 5 Handling and preparation

⚠ ***General***

*The erbrich sterilization containers are made of an aluminum alloy whose surface is anodized for corrosion protection. Aggressive cleaning agents, metal brushes or scouring pads can permanently damage this surface and must therefore not be used. If this instruction is not followed, the warranty will be excluded.*

⚠ ***The sterilization containers may 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 facilitate assignment to the individual disciplines and departments. Sterilization indicator and colored identification labels provide information about the contents, place of use and condition. In accordance with the normative requirements and recommendations, suitable measures (e.g. sealing, process indicators) must be taken to ensure that sterilized and that sterilized and unsterilized sterilization containers cannot be confused. Only intact sealing ensures that the*
*sterilization container has not been opened without authorization.*

⚠ ***Preparation for cleaning***

- *Separation of container tray and lid*
- *Remove the contents of the container (sieve basket, instruments, etc.)*
- *Removal of the filter holders/cassette from the inside of the lid and, if applicable, from the tray part (for containers with bottom perforation).*
- *For disposable paper filters: Dispose of disposable filters.*
- *Removal of the disposable seals as well as the indicator plates*

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

⚠ ***Icommissioning of a new container***

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

*– The container must be reprocessed in a validated, automated cleaning and disinfection process.*

*– A neutral cleaning agent should be used in the machine for this purpose.*

*– After reprocessing in the automated cleaning and disinfection process, the products must be steam sterilized in the fractionated steam sterilization process at 134°C.*
*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).*

## 6 Preparation

⚠ ***Additional information***

- *City water to be used must comply with COUNCIL DIRECTIVE 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.*
- *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 reprocessor is responsible.*
- *Reassemble disassembled products before sterilization.*

***Manual pre-cleaning***

*• If possible, mild, neutral cleaning agents or chemical products should be used for aluminum containers and lids.*
*which have been expressly approved by the manufacturers for the treatment of aluminum products. If necessary, the products should be suitability in the appropriate process. A soft, suitable sponge should be used for manual cleaning. Scouring sponges should not be used, as these destroy the surfaces and thus the passivation and lead to loss of warranty.*
*• After cleaning, careful rinsing with appropriate low-salt water (e.g., deionized water) and sufficient drying is required.*
*• Do not use metal brushes or abrasive cleaners.*

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

*• Ultra sonic*

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

*Immerse container and sieves in ultrasonic bath filled with water <40°C, 0.5 % alkaline detergent (Neodisher FA, Dr. Weigert) for 5 minutes and clean for 10 minutes. Rinse container 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 drain*

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

*Step 4: Water drain*

*Step 5: 5 minutes cleaning 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 drain*

*Step 9: 2 minutes rinsing with cold city water Drinking water quality <40°C*

*Follow the specific instructions of the manufacturer of the automatic cleaning machine.*

*Automatic disinfection*

*Automatic thermal disinfection in washer-disinfector, taking into account the national requirements for the. A0- value 3000:*

*>5 minutes at 92°C±2°C*

*with deionized 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 rinsing chamber). If necessary, subsequent manual drying with a lint-free cloth and blowing out the corners using sterile, oil-free compressed air.*

***Filter change***

*After changing the filter, the filter holder must be brought into the correct position by pressing it until it audibly engages. erbrich lids may only be used with*
*erbrich filter holders.*
*- Disposable paper sterile filters must be reinserted before each new sterilization.*
*- Suitability and accuracy of fit can only be guaranteed if erbrich filters are used.*
*- Warranty claims can only be accepted if original erbrich filters are used exclusively.*
*- PTFE filters have been tested for a service life of 1200 cycles and must then be replaced.*

⚠ ***Attention***

*Only combine original erbrich individual parts such as lids, trays, filters, seals, cassettes and filter holders with each other so that the tightness and germ barrier are not compromised. Otherwise erbrich will not assume any warranty.*

***Sterilization***

*Sterilization of the container systems using the fractionated pre-vacuum process*

(according to DIN EN ISO 17665-1), taking into account the respective national requirements. The products must be sterilized in suitable sterilization packaging in accordance with EN ISO 11607 and DIN EN 868.

**EU standard**

Sterilization is to be performed using a fractionated pre-vacuum process, with the following parameters:

134°C

≥5 minutes holding time,

3 pre-vacuum cycles

Drying in vacuum for at least 20 minutes

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

**⚠ Container loading**

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

| Model | Max. Load in kg |
|---|---|
| 1/1 (Full-) Size Container | 9,0 Kg |
| ¾ Size-Container | 7,0 Kg |
| ½ Size-Container | 5,0 Kg |
| Flach-Container | 1,5 Kg |
| Mini-Container | 1,0 Kg |
| Dental-Container | 1,8 Kg |

**⚠ Placement in sterilizer**

The containers are designed to be used in any commercial large sterilizer for moist heat sterilization. Note
that heavy containers are positioned at the bottom of the sterilization chamber.
Due to their design, the containers can be easily and safely stacked on top of each other during sterilization without slipping. Stacking is recommended only for sterilization cycles using fractionated vacuum method. Stacking height should not exceed 46 cm to achieve effective air removal and steam penetration. The sterilizer manufacturer's instructions must be followed.

**⚠ CAUTION!**

Observe the following during sterilization:
Never pack the container in any other outer packaging. Never cover the perforation fields in the lid and base with any foil packaging or similar
any foil packaging or similar, because this will obstruct the flow of air and steam into the container. The result is
vacuum-induced deformation of the container due to insufficient pressure equalization and the sterility of the container contents is not guaranteed.
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.
the lid.

**⚠ Flow control**

- Operate the loaded sterilizer according to 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.
- In order to avoid the accumulation of condensate in the container, the container should cool down completely on the sterilization cart.
- After each sterilization, the sterilized items must be assessed and released in accordance with the internal instructions and the validation results released. This is consistently carried out 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 usually requires validation and routine monitoring of the process and equipment used.

## 7 Testing

The sterilization containers must be checked for proper functioning before each use. Damage to the caps, seals, filter holders, filters, cassettes as well as bent and dented parts mean that the sterilization containers must be repaired and must not be used.
must be repaired and must not be used.
Do not use damaged sterilization containers.

- All moving parts on the container must be maintained with an approved instrument care oil.
- If any damage is found on the seals, they must be replaced immediately.
- The seals should not be treated with spray, oil or solvent. Occasional wiping with a damp cloth is sufficient for cleaning and care with a damp cloth.
- If any damage is found on the sterilization containers, they must be checked, repaired or replaced.
- Spare parts can be obtained from erbrich

**⚠ Service and repair**

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

**⚠ Return transport**

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

## 8 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 hygienist.
In the case of particularly high asepsis requirements or deviations from the specified storage conditions, shorter storage periods or additional packaging should be used.
or additional packaging should be used.

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

Different container loadings, storage times and storage conditions are subject to determination by the responsible hygienic personnel.
The erbrich sterile containers have been tested for a storage period of 6 months by applying Bacillus subtilis spore suspension. Based on this, a storage period of 6 months can be guaranteed. The containers must be stored under protected conditions (e.g. in closed cabinets), protected from dust, clean, dry and free from vermin.

**⚠ Transportation**

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

**⚠ Disposal**

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

## 9 Liability and warranty

erbrich-Instrumente GmbH, as the manufacturer, is not liable for consequential damage resulting from improper use or handling. This also applies to repairs or modifications to the product carried out by non-authorized personnel of the manufacturer. These exclusions of liability also apply to warranty services.

## 10 Symbol description


*Attention!*


*Observe operating instructions*

REF *Item number*

LOT *Batch designation*

CE *CE marking*

*Not sterile*


*Manufacturer*


*Store dry*


*Temperature limit*


*Protect from sunlight*

MD *Medical device*

## 11 Applied standards

*To ensure the safety of the sterilization containers during production and handling, the following standards were taken into account:*

***DIN EN 868-2***
*Packaging materials and systems for medical devices to be sterilized - Part 2: Sterilization packaging; requirements and test methods*

***DIN EN 868-8***
*Packaging materials and systems for medical devices requiring sterilization - Part 8: Reusable sterilization containers for steam sterilizers*
*according to EN 285; requirements and test methods*

***EN ISO 11607-1***
*Packaging for terminally sterilized medical devices - 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 materials for sterilization goods, metal sterilization trays*

***DIN 58953-9***
*Sterilization; sterile supply - Part 9: Application technology of sterilization containers*

***EN ISO 14937***
*Sterilization of health care products - General requirements for characterization of a sterilant and development,*
*Validation and routine monitoring of a sterilization process for medical devices.*

***EN ISO 17665-1***
*Sterilization of health care products - Moist heat - Part 1: Requirements for development, validation and control of the use*
*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 these*

*was to validate a moist heat sterilization process for the reusable erbrich sterile container systems.*

*Based on the results, we therefore prescribe the sterilization procedure specified on page 3 of these instructions for use.*

## 12 Materials

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

## 13 Delivery condition

*The erbrich sterile container systems are shipped in a non-sterile state and must be prepared and sterilized by the user in accordance with the following instructions before the first and each subsequent use.*

***erbrich instrumente GmbH (Georg B. Erbrich) ASSUMES NO LIABILITY IF THERE IS EVIDENCE THAT THIS CUSTOMER INFORMATION HAS BEEN VIOLATED.***
***WERE.***