

# Instructions for Use

## Sterile Container Systems



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With the purchase of this sterilisation container you have chosen a high quality product. The correct handling and use are described in the following.

In order to keep risks and unnecessary burdening as low as possible for the patient, the user and third parties, we request that you carefully look through these instructions for use and keep them for further reference.

### 1 Field of application

The ERMIS Sterilization Container System is a sterile packaging system for medical instruments and textiles that utilizes an established filter technology. It is a reusable device and features an assortment of sizes and configurations that provide an effective packaging method for sterilization, storage and transportation of surgical instrument by healthcare providers. This container system is intended for use in pre-vacuum Steam Sterilizers.

It is intended to allow sterilisation of the enclosed device and also maintain sterility of the enclosed device until used.

All Containers are available with perforated and non-perforated bottom and perforated lids. The Full-size,  $\frac{3}{4}$ -size and  $\frac{1}{2}$ -size containers are available with safety lid.

All containers use suitable disposable paper filters, which must be replaced before each sterilisation.

#### 1.1 Sterilisation method

The ERMIS Container System was validated with the following sterilisation parameters (Zwisler Report 1510.2743, 2015).

Each facility may need to run internal testing to determine if adjustments are necessary for their facility:

method:	three times pre-vacuum steam sterilization
temperature:	134 °C (273 °F)
holding time:	5 minutes
Drying time:	10 minutes
loading:	standard surgical instruments (scissors, clamps, forceps) and textiles

The validation considered the following Containers of the ERMIS Container System:

- Full-size container,
- $\frac{3}{4}$ -size container,
- $\frac{1}{2}$ -size container,
- Dental container,
- Mini container.

The validation applies to all sterilization containers with the following references:

ER000.010 - ER561.130E



#### Important:

A mechanical cleaning is needed to achieve a more effective result.



#### Attention:

Please note that ERMIS sterilisation containers were tested and validated for steam sterilisation procedure only!

### 2 Handling

#### 2.1 General

The ERMIS container is made of aluminum alloy with an anodised oxide surface which prevents corrosion. Abrasive cleaners, metal brushes or abrasive cleaning pads can cause permanent damage to the container surface and therefore must not be used. Warranty exclusions will be the result in case these instructions are not followed.

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The product and accessories must be used only by qualified or trained and experienced personnel, in order to prevent damage to the containers, closing devices, seals and sterile filters.

The sterilisation containers are also available with coloured lids. Allocation to various medical disciplines and specialist departments can thus be simplified using different colours. Coloured identification tags provide information about the content and location for their use.

The closing device can be provided with a security seal, which has to be broken when opening. Only an intact security seal ensures that the sterilisation container has not been opened without permission.

When using the double lid system, it is possible to disassemble the two lids and clean them separately. For that purpose the combined lid needs to get dismounted from the bottom. The locking mechanism that connects the inner and outer lid is to be found on the inside of the lower lid. It needs to get pushed to separate the two lids from each other.

The safety lids should be used during the transport and storage.

#### 2.2 Preparation before cleaning

1. separate lid and bottom
2. Remove the devices from the inside of the container (baskets, instruments,...)
3. take off the filter holders inside the lid and, if existent, in the bottom (in case of perforated bottom containers)
4. throw away the disposable filter(s)
5. remove disposable locks and indicators

Note: all paper-filters are for single use only and should be thrown away after each processing-cycle

#### 2.3 First use

- The new container needs proper cleaning before first use.
- The container has come to terms with a validated, automated cleaning and disinfecting program.
- In the machine to use there should be a neutral detergent (pH 7).
- After processing in the cleaning and disinfection equipment, Sterilize the parts in 121 °C or 134°C
- Maintain of all moving parts on the container with instrument oil.
- After cleaning, a new filter must be inserted (see 2.6 filter change)

#### 2.4 Cleaning and disinfection

Note: Improper cleaning and disinfection can lead to corrosion and stress cracks. Therefore follow the specifications of the manufacturer of cleaning and disinfecting agent.

Detergents must be alkaline-, sodium- and carbonate-free, of neutral pH (7) and mild. Only fully deionised water (quality according to EN 285 Annex B) is recommended for reprocessing the product.

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- Before every use, the container has to be cleaned and disinfected.
- Removal containers have to be cleaned and disinfected each time after use.

### 2.4.1 Manual cleaning

- Mild detergents or neutral cleansers that are specially recommended for anodised aluminium by the manufacturer are to be used in combination with a soft sponge and water..
- After cleaning, careful rinsing and sufficient drying is necessary.
- Do not use metal brushes or scouring agents.

### 2.4.2 Mechanical cleaning

- Mechanical cleaning of the containers is only recommended if the washer/disinfector has a special programme for aluminum containers. When mechanically cleaning the containers, it is absolutely essential to observe the specifications of the washer/disinfector manufacturers and their instructions for the cleaning of containers.
- Use only neutral cleaners and disinfectants for cleaning. Do not use any cleaning solutions containing soda or caustic soda
- No additional use of acidic neutralizers
- Use neutral cleaners only with aluminium containers, which have been expressly approved by the manufacturer for the cleaning of aluminium containers. The exact dose of the cleaner is to be used as specified by the manufacturing company. With an optimisation of the program these products are also suitable for cleaning surgical instruments
- Fully demineralised water has to be used for final rinsing, as the salts in the water during the subsequent sterilisation can also lead to spotting
- The container lid and bottom need to be cleaned separated from each other.
- The container bottom needs to be placed upside down in the washer/disinfector to avoid the collection of water.
- The inside of the container lid should face the machine-bottom with the latching mechanism folded into the inner part of the lid.
- All component parts of the container (bottom, lid, filter-holders...) should be disassembled and placed in the washer/disinfector baskets that are specially designed for containers and accessories.
- After the washing/disinfection program is finished, the container and accessories need to be dried with a soft dry cloth or by air.
- Contaminations that cannot be removed in a normal cleaning cycle independent of the process (sticky labels, indicator strips, writing), can be removed with Eloxal cleaner. After this special treatment, the containers should be cleaned as usual.

### 2.4.3. Cleaning process

The following cleaning process was validated by Ermis in a suitable cleaning- and disinfecting device (Miele PG 8528):

- 1 min pre-wash with cold water
- 3 min cleaning with Mediclean 0,5%(Dr. Weigert) by 45°C
- Neutralisation with purified water

### 2.5 Testing

The sterilisation containers have to be checked every time before use to ensure their correct functionality.

If any damage of closing device, seals, filter holders, filters or any bent and dented parts occur, the container needs to be taken out of circulation and must be repaired. Do not use any damaged sterilisation containers.

### 2.6 Filter change

After placing the filters over the perforated areas on the inside of the lid and (if applicable) on the bottom of the container, the filter holders have to be pressed into place until they snap into position. ERMIS lids should only be assembled with ERMIS filter holders.

- The disposable paper filters have to be exchanged before every new sterilisation cycle.
- Only ERMIS filters can ensure suitability and exactness of fit.
- Guarantee can only be accepted when original ERMIS filters have been used.
- PTFE filters are tested for the application of 1200 cycles, afterwards they have to be changed.



### WARNING!

Only original ERMIS component parts such as lids, bottoms, seals, filters and filter holders should be combined with each other so that the container sealing and function as a germ barrier is not compromised.

Otherwise warranty exclusion will be the result.

## 3 Loading

The overall weight for loading containers should not exceed the following loads, as otherwise satisfactory sterilisation of sterile materials cannot be ensured.

Model	Dimension	Maximum Load in kg	
		Instruments	Textiles
1/1 (Full-) Size Container	580x280x100	3,8	3
	580x280x135	5,2	4,1
	580x280x150	5,8	4,6
	580x280x200	7,7	6,1
	580x280x260	10	8
Wide Body	600x400x120	10	8
	600x400x180	10	8
¾ Size Container	465x280x100	3,1	2,5
	465x280x135	4,2	3,3
	465x280x150	4,6	3,7
½ Size Container	285x280x100	1,9	1,5
	285x280x135	2,6	2
	285x280x150	2,8	2,2
	285x280x200	3,8	3
	285x280x260	4,9	3,9
Flat Contai- ner	285x280x55	1,3	1,0
	285x280x85	1,5	1,2

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Mini Container	300x140x40	0,4	0,3
	300x140x70	0,7	0,5
	300x140x100	1	0,8
Dental Container	310x190x40	0,6	0,5
	310x190x65	0,9	0,7
	310x190x80	1,2	0,9
	310x19x100	1,5	1,2
	310x190x130	1,8	1,4

When loading with textiles, pay attention that the folded textile or laundry articles are positioned vertically. In the case of a full container, it should be possible to push an outstretched hand without effort between the pieces of laundry.

### **PRECAUTION!**

The sterilisation of various container loads and packaging configurations has to be validated by the responsible specialist hygiene personnel.

Complex instruments like Endoscopes, instruments with a lumen, compressed air-driven instruments or power systems and instruments with cannulae are to be prepared for the sterilisation according to the manufacturers' instructions.

Small baskets, trays, other types of accessories, especially with cover or lids, should only be used with the sterilisation container, if the sterilisation container has been specifically designed and tested for that purpose.  
Please see details about ERMIS frames, baskets, and metal sterilising trays in our product catalogue.



### **WARNING!**

When using non-absorbent tray liners (e.g., plastic/silicone-fingered organising mats) for the containers this can cause condensate to pool. Instead of this use moisture absorbing mats if necessary.

Always check the integrity of the inserted filter and correct positioning of filter holder.  
Attach the lid to the bottom via the latching mechanism and make sure of a sealing of both closures before placing the container in the steriliser.

## **4 Placement in the steriliser**

The sterilisation containers are constructed so that they can be used in any conventional large steam steriliser.  
Pay attention that heavy containers are placed at the bottom of the sterilisation chamber.  
Thanks to the way they are constructed, the sterilisation containers can be stacked safely and without a problem on top of one another during sterilisation without slipping out of place.  
Only stack containers in high-vacuum cycles and do not stack them higher than 40-46 cm (16-18") to allow an effective air removal and steam penetration. Please pay attention to the loading instruction of the manufacturer of sterilizer/autoclave.

### **PRECAUTION!**

Never wrap the container in any kind of outer packaging.  
Never cover the perforated area of the container with any kind

of foil packaging or similar during sterilisation, because this will block the air and steam flow through the perforation. The result will be a vacuum damage due to insufficient pressure venting and the container content will not be sterilised.

During loading and unloading of the steriliser and during transport, the sterile container must always be carried by the handles and never by the lid.

## **5 Processing**

- Follow the time and temperature specifications of the steriliser manufacturer for every chosen sterilisation cycle.
- To minimize condensate inside the container, leave container on container carts until cool enough to handle.
- After each sterilization, the sterilization performance have to be stated according to internal instructions and the validation results. The container lid and bottom, closures and sealing must be checked for damages before release. The sealing of the container must be closed and undamaged.

## **6 Storage**

Please refer to DIN 58953-9: recommendation about the storage of sterile material in a container. Usually the storage period depends on the storage conditions and must be defined by the responsible specialist hygiene personnel.

In the case of particularly high demands on sterility, for example, shorter storage times or additional packaging should be used.

Storage conditions:

- Temperature 15 – 26 ° C
- Air humidity 30 – 50%
- Air pressure, normal atmospheric pressure

Various container loads, storage periods and storage conditions have to be validated by the responsible specialist hygiene personnel.

The ERMIS sterilisation containers were tested for a storage period of 6 months by spraying *Bacillus subtilis* – Spore suspension in an unventilated room.

Therefore, we advise a storage period of 6 weeks in open racks and 6 months when stored under protected conditions (e.g. in closed cabinets).

## **7 Maintenance / Repair**

- The useful life of undamaged cover seals is at least 500 sterilisation cycles. Afterwards the cover seals have to be checked and when necessary to be replaced.
- Cover seals have to be exchanged if they show signs of damage.
- Cover seals should not be treated with spray, oil or solvents. For cleaning and maintenance simply wipe off occasionally with a damp cloth.
- If any damage on the container or its parts is noticed the container needs to be taken out of circulation immediately and returned for repair.

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- Qualified persons only may carry out maintenance and repair of sterilisation containers. Do not attempt to carry out repairs on the cover seals or closing devices yourself, in order not to jeopardise the safe function of the container.
- Sterilisation containers can be sent to ERMIS or one of the authorised repair services for maintenance and repairs.
- Replacement parts can be obtained from ERMIS:
  - Paper filter holders ER 809.090
  - Lid cover seals ER 999.010
  - Disposable paper filters (100's) for 1/1 containers, 3/4 containers, 1/2 containers and flat containers ER 800.000
  - Disposable paper filters (100's) for dental and mini-containers ER 802.000
  - Identification labels ER 820.010 to ER 820.060
  - Plastic Security seal (100's) ER 819.000

### 8 Materials

Sterilisation containers are made of anodised aluminium alloy and their accessories of surgical stainless steel.

### 9 Container design and applied standards

The following international and German standards were taken into consideration in order to ensure the safety of sterilisation containers in manufacturing and handling:

EN 868-2	Packaging materials and systems for medical devices which are to be sterilized - Part 2: Sterilization wrap; requirements and test methods
EN 868-8	Packaging materials and systems for medical devices which are to be sterilized - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285; requirements and test methods
ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
DIN 58952-2	Sterilization; packing materials for sterilizing goods, sterilizing baskets made of metal
DIN 58952-3	Sterilization; packing materials for sterilizing goods, instrument trays made of metal
DIN 58953-9	Sterilization - Sterile supply - Part 9: Handling of sterilization container
ISO 14937	Sterilization of health care products - General criteria for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
ISO 11134	Sterilization of health care products; requirements for validation and routine control; industrial moist heat sterilization
ISO 17665	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

In order to ensure sterile safety, tests were carried out by an independent and accredited test laboratory. The purpose of these trials was to validate a sterilisation process for the reusable ERMIS sterilisation container with steam.

On the basis of the results, we would strongly advise the sterilization process from page 1 of this instruction.

### 10 Warranty

These sterilisation containers have been manufactured from high quality materials and have been subjected to quality control checks before release to the market. Nevertheless, revert to the above-mentioned address in case any errors should arise.

The warranty shall lapse if companies who are not authorised for repairs by ERMIS carry out repairs.

### 11 ERMIS Stainless steel Removal Container

#### 11.1 Handling

Stainless steel removal container are ideally cleaned automated. The validated cleaning process guarantees an effective cleaning and safe disinfection. Suitable chemical cleaners can be mildly alkaline (pH 10-11) and alkaline (pH>12). The cleaner has to be neutralized after the cleaning process. This is achieved by rinsing and if necessary, by using a neutralizer based on citric or phosphoric acid.

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