Trade Name: Sterile Container Systems

REF 85.327.00 / 85.327.10 / 85.327.15 / 85.327.20 / 85.327.30

Dear Customer!

With the purchase of this sterilization container you have chosen a high quality product, the correct handling and use of which are described in the following.
In order to keep risks and unnecessary burdening of the patient, the user and third parties as low as possible, we request that you carefully look through these instructions for use and keep them for further reference.

1 FIELD OF APPLICATION

The Helmut Zepf 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 sterilization 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, ¾-size and ½-size containers are available with safety lid.
All containers use suitable disposable paper filters, which must be replaced before each sterilization.

1.1 RECOMMENDED STERILIZATION METHOD

The Helmut Zepf Container System was validated with the following sterilization parameters. 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:	3 minutes
Drying time:	10 minutes
Loading:	standard surgical instruments (scissors, clamps, forceps) and textiles

The validation considered the following containers of the Helmut Zepf Container System:

- Full-size container, size 1/1
- ¾-size container
- ½-size container
- Dental container
- Mini container

2 HANDLING

2.1 GENERAL

The Helmut Zepf container is made of aluminum alloy with an anodized 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.
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 sterilization containers are also available with colored lids. Allocation to various medical disciplines and specialist departments can thus be simplified using different colors.
Colored 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 sterilization 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.

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.
- After cleaning, a new filter must be inserted (see 2.6 filter change).

2.4 CLEANING AND DISINFECTION

Note: Improper cleaning and desinfection can lead to corrosion and stress cracks. Therefore follow the specifications the cleaning and disinfecting agent's manufacturer recommends. Detergents must be alcaline-, sodium- and carbonate-free, of neutral pH (7) and mild. Only fully deionized water (quality according to EN 285 Annex B) is recommended for reprocessing the product.

- 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 anodized aluminium by the manufacturer are to be used in combination with a soft sponge and water.
- After cleaning, careful rinsing and manual 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/desinfector has a special programme for aluminum containers. When mechanically cleaning the containers, it is absolutely essential to observe the specifications of the washer/desinfector manufacturers and their instructions for the cleaning of containers.
- Only use neutral cleaners or neutral cleaners and disinfectants for cleaning. Do not use any cleaning solutions containing soda or caustic soda.
- No additional use of acidic neutralizers.

78606 Seitingen-Oberflacht, Germany | Tel.: +49 (0) 74 64 / 98 88 -0 | Fax: +49 (0) 74 64 / 98 88 -88 | info@zepf-dental.com | **www.zepf-dental.com**

HELMUT ZEPF MEDIZINTECHNIK GMBH

CE All medical devices indicated here bear the CE mark according to the Medical Device Directive 93/42/EEC.

Trade Name: Sterile Container Systems
REF 85.327.00 / 85.327.10 / 85.327.15 / 85.327.20 / 85.327.30

- 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 optimization of the program these products are also suitable for cleaning surgical instruments.
- Fully demineralized water has to be used for final rinsing, as the salts in the water during the subsequent sterilization 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/desinfector 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, filterholders…) should be disassembled and placed in the washer/desinfector baskets that are specially designed for containers and accessories.
- After the washing/desinfection 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 anodic cleaners. After this special treatment, the containers should be cleaned as usual.

2.4.3 RECOMMENDED CLEANING PROCESS

We recommend the following cleaning process which was validated by HELMUT ZEPF in an appropriate cleaning and disinfection unit (Miele PG 8528) with the following settings:

- 1 minute pre-washing in cold water
- 3 min cleaning with Mediclean 0.5 % (Dr. Weigert) at 45° C (122° F)
- Neutralization with demineralized water

2.5 TESTING

The sterilization 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, these container parts need to be taken out of circulation and must be returned for repair. Do not use any damaged sterilization 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. Helmut Zepf lids should only be assembled with Helmut Zepf filter holders.

- The disposable paper filters have to be exchanged before every new sterilization cycle.
- Only Helmut Zepf filters can ensure suitability and exactness of fit.
- Guarantee can only be accepted when original Helmut Zepf filters have been used.

WARNING!
Only original Helmut Zepf component parts such as lids, bottoms, filters, seals and filter holders should be combined with each other so that the container sealing and function as a germ barrier is not compromised. All filters or seals made by other manufacturers must be approved by Helmut Zepf before used with the Helmut Zepf Container System. Otherwise warranty exclusion will be the result.

Model	Dimension [mm]	Max. Recommended Load	
		Instruments	Textiles
1/1 (Full-) Size Container	580x280x100	3,8 kg	3 kg
	580x280x135	5,2 kg	4,1 kg
	580x280x150	5,8 kg	4,6 kg
	580x280x200	7,7 kg	6,1 kg
	580x280x260	10 kg	8 kg
¾ Size Container	465x280x100	3,1 kg	2,5 kg
	465x280x135	4,2 kg	3,3 kg
	465x280x150	4,6 kg	3,7 kg
½ Size Container	285x280x100	1,9 kg	1,5 kg
	285x280x135	2,6 kg	2 kg
	285x280x150	2,8 kg	2,2 kg
	285x280x200	3,8 kg	3 kg
	285x280x260	4,9 kg	3,9 kg
Mini Container	300x140x40	0,4 kg	0,3 kg
	300x140x70	0,7 kg	0,5 kg
	300x140x100	1 kg	0,8 kg
Dental Container	310x190x40	0,6 kg	0,5 kg
	310x190x65	0,9 kg	0,7 kg
	310x190x130	1,8 kg	1,4 kg

3 LOADING

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

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 between the pieces of laundry without effort.

PRECAUTION!
The sterilization of various container loads and packaging configurations has to be validated by the responsible specialist hygiene personnel according to ISO 11134.
Complex instruments like endoscopes, instruments with a lumen, compressed air-driven instruments or power systems and instruments with cannulae are to be prepared according to the manufacturers' instructions for sterilization and to be sterilized accordingly.
Small baskets, trays, other types of accessories, especially with cover or lids, should only be used with the sterilization container, if the sterilization container has been specifically designed and tested for that purpose.

78606 Seitingen-Oberflacht, Germany | Tel.: +49 (0) 74 64 / 98 88 -0 | Fax: +49 (0) 74 64 / 98 88 -88 | info@zepf-dental.com | **www.zepf-dental.com**

HELMUT ZEPF MEDIZINTECHNIK GMBH

Trade Name: Sterile Container Systems

REF 85.327.00 / 85.327.10 / 85.327.15 / 85.327.20 / 85.327.30

Please see details about Helmut Zepf frames, baskets, and metal sterilizing trays in our product catalogue.
Always attach the lid to the bottom via the latching mechanism before placing the container in the sterilizer. Otherwise the content of the container will become unsterile as soon as the sterilizer door will be open.

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

4 PLACEMENT IN THE STERILIZER

The sterilization containers are constructed so that they can be used in any conventional large steam sterilizer.
Pay attention that heavy containers are placed at the bottom of the sterilization chamber.
Thanks to the way they are constructed, the sterilization containers can be stacked safely and without a problem on top of one another during sterilization without slipping out of place.
Only stack containers in hight-vacuum cycles and do not stack them higher than 16-18” to allow an effective air removal and steam penetration. The loading instructions of the sterilizer manufacturer should be observed.

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 sterilization, 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 sterilized.
During loading and unloading of the sterilizer 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 recommendations of the sterilizer manufacturer for every chosen sterilization cycle.
- After sterilization leave sterilizer door open at 6” for approximately 15 minutes to aid drying (see recommendation of sterilizer manufacturer).
- To minimize condensate inside the container, leave container on container carts until cool enough to handle.
- Always check if the sterilization has been successful by observing indicators and the container latch (must be closed).

6 STORAGE

Sterile material maintains its sterility from several weeks to up to 6 months under normal aseptic conditions, in unopened sterilization containers and with undamaged sterile filters. 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.
Recommended storage conditions:

- Temperature: 15 - 26°C (59 - 79°F)
- 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 Helmut Zepf sterilization containers were tested for a storage period of 3 months by spraying bacillus subtilis – spore suspension in an unventilated room.

We therefore recommend a storage period of 6 weeks in open racks and 3 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 sterilization 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.
- Qualified persons only may carry out maintenance and repair of sterilization containers. Do not attempt to carry out repairs on the cover seals or closing devices yourself, in order not to jeopardize the safe function of the container.
- Sterilization containers can be sent to Helmut Zepf or one of the authorized repair services for maintenance and repairs.
- We recommend the use of our medical white oil **25.950.10** for the care of all moving parts on the container. Also available in the practical oil pen **24.950.12**.
- Following replacement parts can be obtained from Helmut Zepf:

- Disposable paper filters (100’s) for 1/1-,¾-, ½- and mini containers	**85.299.05**
- Disposable paper filters (100’s) for dental containers	**85.320.01**
- Colored Identification Labels	
brown	**85.312.00**
blue	**85.312.01**
yellow	**85.312.02**
green	**85.312.03**
purple	**85.312.04**
orange	**85.312.05**
red	**85.312.07**
black	**85.312.08**
silver	**85.312.09**
- Plastic Security Seals (100’s)	**85.327.70**

8 MATERIALS

Sterilization containers are made of anodized aluminium alloy and their accessories of surgical stainless steel.

78606 Seitingen-Oberflacht, Germany | Tel.: +49 (0) 74 64 / 98 88 -0 | Fax: +49 (0) 74 64 / 98 88 -88 | info@zepf-dental.com | **www.zepf-dental.com**

HELMUT ZEPF
MEDIZINTECHNIK GMBH

Trade Name: Sterile Container Systems
REF 85.327.00 / 85.327.10 / 85.327.15 / 85.327.20 / 85.327.30

9 CONTAINER DESIGN AND APPLIED STANDARDS
The following international and German standards were taken into consideration in order to ensure the safety of sterilization containers in manufacturing and handling:

DIN EN 868-2
Packaging materials and systems for medical devices which are to be sterilized – Part 2: Sterilization wrap; requirements and test methods

DIN 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

DIN 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; 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

DIN EN 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

DIN EN 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 were to validate a sterilization process for the reusable Helmut Zepf sterilization container with steam.
On the basis of the results, we therefore recommend the sterilization process from page 1 of this instruction.

10 WARRANTY
These sterilization 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 authorized for repairs by Helmut Zepf carry out repairs.

THE HELMUT ZEPF COMPANY ACCEPTS NO LIABILITY IN DEMONSTRABLE CASES OF VIOLATION OF THIS CUSTOMER INFORMATION.

78606 Seitingen-Oberflacht, Germany | Tel.: +49 (0) 74 64 / 98 88 -0 | Fax: +49 (0) 74 64 / 98 88 -88 | info@zepf-dental.com | **www.zepf-dental.com**