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MELAG
competence in hygiene

Operating Manual

Sterilization container



EN

Dear doctor,

We thank you for your confidence demonstrated by the purchase of this product.

As an owner-run and operated family concern founded in 1951, we have a long history of successful specialization in hygiene products for practice-based use. Our focus on innovation, quality and the highest standards of operational reliability has established MELAG as the world's leading manufacturer in the instrument treatment and hygiene field.

You, our customer are justified in your demand for the best products, quality and reliability. Providing **"competence in hygiene"** and **"Quality – made in Germany"**, we guarantee that these demands will be met. Our certified quality management system is subject to close monitoring: one instrument to this end is our annual multi-day audit conducted in accordance with ISO 13485. The effective application ensures that all MELAG products are manufactured and tested in accordance with strict quality criteria.

The MELAG management and team.

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General notes

Please read this operating manual carefully before commissioning the sterilization container. The long-term functionality and value-retention of this sterilization container depends on the care accorded to it.

Store this operating manual carefully and in close proximity to the sterilization container. They represent a component of the product.

Validity

The application advice applies exclusively to the sterilization described in this document, which are used exclusively in steam sterilizers.

About this document

Symbols used

Symbol	Explanation
	Indicates a dangerous situation, which if not avoided, could entail slight to life-threatening injuries.
	Draws your attention to a situation, which if not avoided, could result in damage to the instruments, the practice fittings or the sterilization container.
	Draws your attention to important information.
	Indicates manufacturer

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⚠ Safety

When operating the steam sterilizer, please observe the following safety instructions as well as those contained in subsequent sections.

Accessories/spare parts

- Use only original accessories and spare parts (see page 13).
- Use only original single-use paper filters (see page 13).

Load

- Comply with pre-determined loading patterns established within the scope of the validation procedure. The load must be arranged so that steam can penetrate to the sterilization material without difficulty. Only then correct sterilization can be guaranteed.

Storage

- Store the sterilization container in accordance with the specifications provided in DIN 58953-9. Always store the sterilization container dry and protected against corrosive objects.

Disposal

- Should the sterilization container present considerable signs of wear (e.g. abrasion, cracks or other wear) which prevent further use, it must be disposed of in the correct manner.

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1 – Performance specifications and application

Intended use

This accessory is a sterilization container for holding instruments and/or textiles during a vacuum steam sterilization procedure and the maintenance of sterility under the requisite conditions. The sterilization container is not to be used as a transport or disposal container.

The sterilization container consists of a perforated anodized aluminium base and a perforated stainless steel lid. The sterilization container is equipped with single-use paper filters to protect against contamination. These require changing after every sterilization procedure.

The sterilization container is suited exclusively to use in steam sterilizers with a fractionated pre-vacuum or a fractionated flow procedure.

PLEASE NOTE

The sterilization container may not be used for:

- Hot air sterilization
- Gravitation or flow procedures
- Formaldehyde or ethylene oxide sterilization
- Plasma or peroxide sterilization
- Transport or disposal

NOTICE

Never insert the sterilization container in the steam sterilizer with additional exterior packaging. Increased flow resistance could hinder the sterilization process or destroy the container.

Loading instructions

The sterilization container must be arranged in the steam sterilizer in such a way that the steam can penetrate to the sterilization material without difficulty.

- Comply with the maximum specified load quantity of the steam sterilizer. Otherwise, the sterilization performance could be compromised.
- Sterilization material packaged in the sterilization wrapping may only be allowed to come into mutual contact on the paper sides.
- Observe the information provided in the steam sterilizer user manual regarding special instruments (dental transfer instruments, ophthalmological instruments, instruments with interior lumina). When using accessories from a different manufacturer, check their general suitability for use in this procedure.

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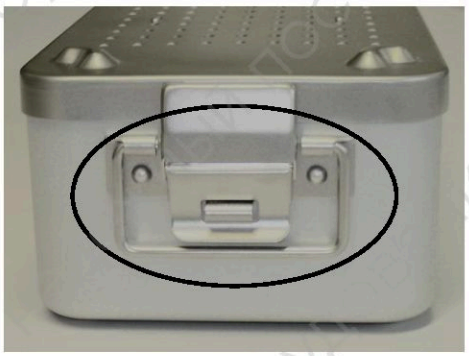
Closing the sterilization container

WARNING

Failure to close the lid correctly brings the danger of insterility.

Close the sterilization container by placing the lid flush on the container with the locking lug open. The lid must seal onto the container without pressure.

Lock the sterilization container with the lateral seals to prevent inadvertent opening.



PLEASE NOTE

Ensure that no material protrudes when using interior packaging. This could compromise the seal.

Following sterilization

CAUTION

Danger of burns from hot sterilization container.

- Wear suitable gloves when removing the sterilization container from the steam sterilizer.

Over-fast cooling of the sterilization container can result in the unpropitious formation of a high volume of condensate.

- Allow the sterilization container to cool slowly after the end of the sterilization procedure.
- Do not place the sterilization container on cold surfaces.

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Storage

Comply with the guidelines for the storage period of sterile medical products in accordance with DIN 58953-8:2010. External influences during storage, transport and handling can impair the sterility of the sterilized material. An ideal storage time can not generally be specified. Storage length for sterile medical products represent recommendations only.

PLEASE NOTE

Responsibility for compliance with the specified storage requirements and period lies with the operator of the institution.

The following requirements apply to the storage of sterile medical products:

- Ensure that no more than a maximum of four identical sterilization containers are stacked on each other. The total weight (load + container) may not exceed 15 kg.
- The storage rooms must be dry, cool and easy to clean.
- The storage rooms must not be accessible to everyday activity.
- We recommend protected storage in cupboards or drawers.

Storage period for sterile medical products

Packaging type	Storage period	
Sterile barrier system	***Unprotected storage****	***Protected storage***
Sterilization paper bag in accordance with DIN EN 868-4 and heatable, self-sealing transparent bags and tubing made of paper and plastic composite film in accordance with DIN EN 868-5, or other equivalent packaging.	Serves provision for immediate use.**) Should be avoided as a method of storage.	6 months But not longer than the expiry date.
Packaging system (a combination of a sterile barrier system and protective packaging).	5 years, as far as the manufacturer has not determined an alternative expiry date.	

*) On shelves in rooms which do not correspond with room class II as defined by DIN 1946-4:2008-12.
**) Immediate use means application / use of the product within a maximum of 2 days / 48 hours.

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2 – Maintenance

Routine checks

Before every application:

- Check the seals in the lid and change if damaged.
- Sterilization container, surfaces and lid are undamaged.
- The lid closes correctly.
- Damaged parts such as the grip plate or the locking lug are secure.
- The seal in the lid is completely inserted and undamaged.
- The filter bracket cover is not deformed. The filter covers the lid perforations completely.

WARNING

Replace a damaged sterilization container or seal. Such damage brings the risk of contamination of the sterilization material. Should no damage be visible, the sterilization container may remain in use.

Cleaning and maintenance

Comply with the manufacturer's specifications of the cleaning fluid and disinfectants when cleaning and disinfecting the sterilization container. Clean the sterilization container regularly and thoroughly both inside and out. The cleaning fluid used for this purpose must be pH-neutral (pH value 6-8). It is not recommended automatic treatment in a washer-disinfector, as this could place the material of the sterilization container under even greater strain. Under certain circumstances, this could lead to a reduction in its life-expectancy. We always recommend that you use manual cleaning and disinfection with suitable resources.

NOTICE

Do not use tap water or softened water in the washer-disinfector. Hot, softened water can attack the aluminium, resulting in white deposits.

Manual cleaning (recommended)

- ✓ *Do not use an abrasive cleaning fluid, metal brushes or similar to clean.*
- ✓ *Remove all cleaning fluid residue by thorough rinsing with demineralized water.*
- ✓ *Allow all parts of the sterilization container to dry completely following cleaning and/or disinfection.*

Automatic cleaning

- ✓ *The sterilization container may only be treated in the washer-disinfector under the use of demineralized water.*
- ✓ *The sterilization container can be cleaned with demineralized water up to 95 °C.*
- ✓ *Use a pH-neutral enzymatic cleaning fluid (pH value 6-8) for automatic cleaning and/or disinfection and washing.*
- ✓ *Place the sterilization container and lid in the machine basket separately and at an angle. The opening of the sterilization container should point downwards.*
- ✓ *The sterilization container is made of anodized aluminium and the more chemically-resistant stainless steel. The anodized protective layer may not be allowed to suffer damage from pointed or sharp-edged objects. Ensure that you select a cleaning fluid and disinfectant, which is aluminium compatible.*

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Changing the paper filter

MELAG provides paper filters as single-use papers (1 PU[2] = 100 pieces). Only use undamaged paper filters of the foreseen size. The paper filters must be changed after every sterilization procedure.

PLEASE NOTE
Sterilization containers, which originally used cotton filters cannot be converted to enable use of the paper filters.

NOTICE
Do not swap the paper filter and perforated plates from the lid and container.

Proceed as follows to change the paper filter:

1. Release the locking lugs from the sterilization container on both sides and remove the lid.



2. Press the perforated plate downwards lightly and then to the side.
The slides should be located in the larger opening.



3. Lift the perforated plate from the lid using the slides and remove the old paper filter.



4. The paper filters have pre-made holes.
Lay the new paper filters over the lugs and on the lid in alignment with the holes.



5. Place the perforated plate on the paper filter. Press the perforated plate downwards lightly and then to the side.



[2] PU = Packaging unit

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Changing the seal

Check the seal in the lid for wear, deformation or decolouration before every application
Replace a damaged seal.

Proceed as follows to change the seal:

1. Release the locking lugs from the sterilization container on both sides and remove the lid.



2. Use a small object (e.g. a screwdriver) to remove the seal from the lid groove and slide out the seal.

   Make sure not to damage the lid!



Check the old seal after removal as to whether the seal face of the lid is damaged or soiled. If necessary, clean the lid before inserting the new seal.

Inserting the seal:

Start with the side edges.

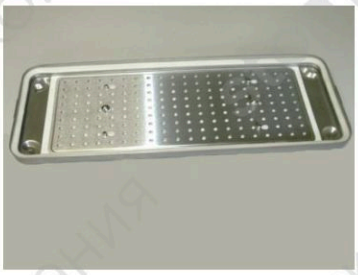
3. Then gradually press the seal into the entire lid groove.

   Make sure not to twist the seal when inserting it!



PLEASE NOTE
The seal is longer than apparently necessary, as it shrinks during the sterilization process. Press the seal into the lid groove when inserting.

4. Insert the seal completely in the lid groove.



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Accessories and spare parts

Accessories

Single-use paper filter (100 pcs.)	Dimensions (length x width)	Art. no.
For sterilization container 15 K	11.5 x 10.5 cm	27325
For sterilization container 15 M/15G	29.5 x 10.5 cm	27335
For sterilization container 17 K	13.0 x 12.0 cm	27345
For sterilization container 17M/17G	35.5 x 12.5 cm	27355
For sterilization container 23M/23G	35.2 x 13.2 cm	26515
For sterilization container 28M/28G	24.2 x 14.0 cm	27365

Spare parts

Cover seal	Dimensions	Art. no.
For sterilization container 15 K	56 cm	15611
For sterilization container 15 M/15G	96 cm	15612
For sterilization container 17 K	64 cm	15613
For sterilization container 17M/17G	110 cm	15614
For sterilization container 23M/23G	118 cm	15615
For sterilization container 28M/28G	95 cm	15616

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We reserve the right to technical alterations

Your stockist

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