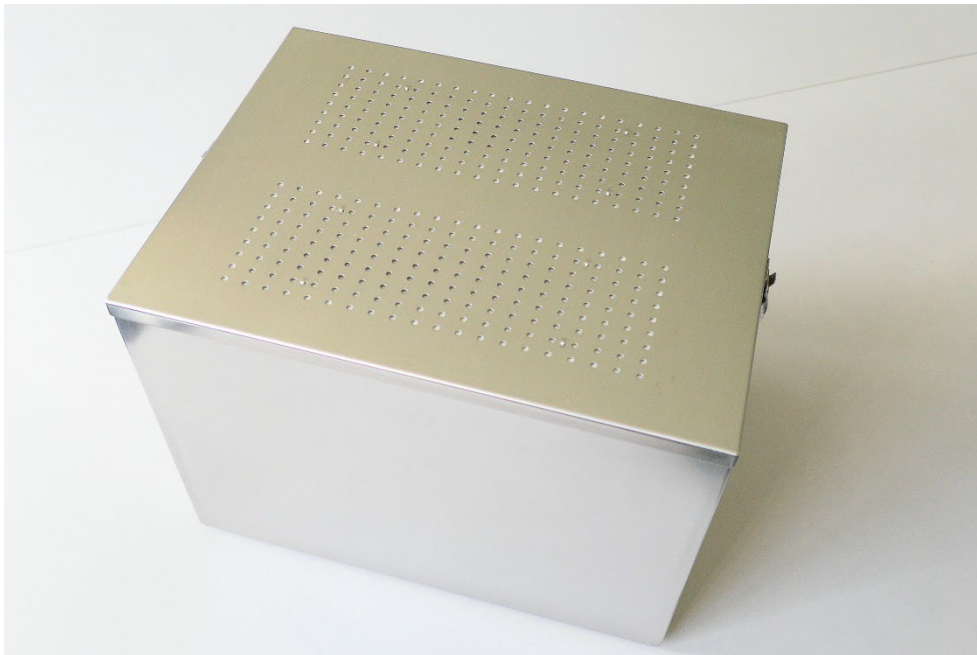


Operating Manual

Micro instruments- sterilization container



EN

Dear Ladies and Gentlemen,

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

As an owner-run and operated family concern founded in 1947, we build sterilization container and laboratory accessories- **Made in Germany.**

Our certified quality management system, is applied effectively and monitoring in our annual multi-day audit conducted in accordance with ISO 13485.

Our products leave our house in impeccable, consistently high and tested quality. This is an essential foundation stone of your and our success.

The Schöndorf management and team.

Basic-UDI: 4260736210005TQ

SRN: DE-MF-000011418



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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



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 12).

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.

Notification requirement

- All serious incidents occurring in connection with the product must be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

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

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 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 put the sterilization container into the steam sterilizer with additional outer packaging. The 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 result 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 user manual of the steam sterilizer regarding special instruments (dental transfer instruments, ophthalmological instruments, instruments with interior lumen). When using accessories from a different manufacturer, check their general suitability for use in this procedure.

Closing the sterilization container



WARNING

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

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.

Storage

The maximum storage period depends on the packaging and storage conditions. 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.

Comply with the guidelines for the storage period of sterile medical products in accordance with (e.g. DIN 58953-8:2010 or DGSV-guidelines) and following requirements:



PLEASE NOTE

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

- ▶ Observe the maximum storage period depending on the type of packaging.
- ▶ 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.
- ▶ Only stack containers with a stacking device. Containers without a stacking device are not suitable for stacking due to their size.
- ▶ 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.

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.

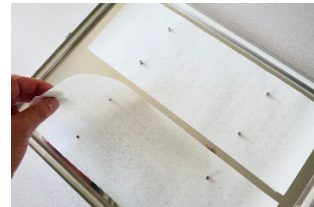
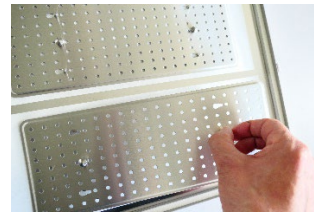
Changing the filter

Schöndorf provides paper filters as single-use papers (1 PU¹ = 100 pieces). Only use undamaged paper filters of the foreseen size. The paper filters must be changed after every sterilization procedure.

Use only undamaged filters of the correct size. Pay attention to the correct use of lid and bottom filters as they have different sizes for most container sizes.

Proceed as follows to change the filter:

- 1.** Loosen the locking lugs from the sterilization container on both sides and remove the lid.
- 2.** Press the sieve plate down slightly and push it to the side. The slides should be located in the larger opening.
- 3.** Lift the sieve plate from the lid using the slides and remove the old filter.
- 4.** The paper filters have pre-made holes. Place the new filters over the lugs and on the lid in alignment with the holes.
- 5.** Place the sieve plate on the filter. Press the sieve plate down slightly and push it to the side.



¹ PU = Packaging unit

Changing the seal

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

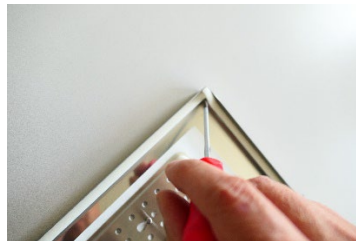
Proceed as follows to change the seal:

1. Loosen 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!



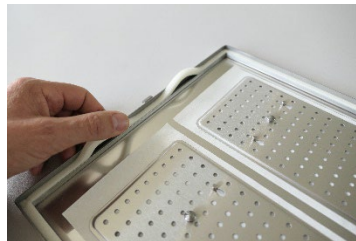
Check the old seal after removal as to whether the seal face of the lid is damaged or soiled. If necessary, clean the lid before inserting the new seal.

Inserting the seal:

Start with the side edges.

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

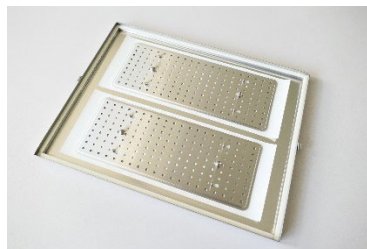
Make sure not to twist the seal when inserting it!



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



Spare parts

Single-use paper filter (100 pcs.)	Dimensions (width x length)	Art. no.
For sterilization container M282006p	13,6 x 24,0 cm	TS3216FP
For sterilization container M371906p	13,6 x 35,8 cm	TS4216FP
For sterilization container M382606p	13,6 x 35,8 cm	TS4216FP
For sterilization container 423231FL	13,6 x 35,8 cm	TS4216FP
For sterilization container M601507p	13,6 x 35,8 cm	TS4216FP

Cover seal	Dimensions	Art. no.
For sterilization container M282006p	2x 32 cm + 2x 23 cm	
For sterilization container M371906p	2x 41 cm + 2x 22 cm	
For sterilization container M382606p	2x 42 cm + 2x 29 cm	
For sterilization container 423231FL	2x 46 cm + 2x 36 cm	
For sterilization container M601507p	2x 64 cm + 2x 18 cm	

Manufacturer



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We reserve the right to technical alterations

Your stockist

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