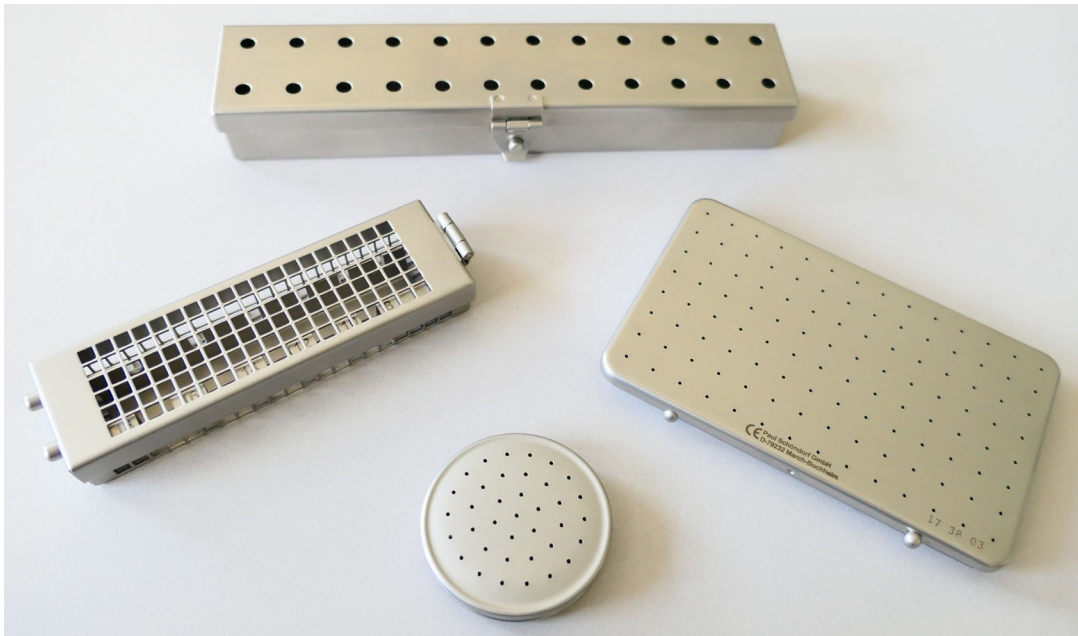


Operating Manual

Sterilization box



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 box. The long-term functionality and value-retention of this sterilization box depends on the care accorded to it.





Store this operating manual carefully and in close proximity to the sterilization box. 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 box dry and protected against corrosive objects.

Disposal

- Should the sterilization box 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 box for holding instruments, needles during vacuum steam sterilization procedure and the maintenance of sterility under the requisite conditions. The sterilization box consists of a perforated base and a perforated lid made of stainless steel. The sterilization box 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

Loading instructions

The sterilization box 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 box

It must be possible to close the lid without putting pressure on the box. For boxes with a locking system, lock the sterilization box with the side lock to prevent accidental opening.

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 box can result in the unpropitious formation of a high volume of condensate.

- ▶ Allow the sterilization box to cool slowly after the end of the sterilization procedure.
- ▶ Do not place the sterilization box 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:

- ▶ Sterilization box, surfaces and lid are undamaged.
- ▶ The lid closes correctly.
- ▶ Der Deckel schließt korrekt.
- ▶ Fittings are stuck.



WARNING

Replace a damaged sterilization container.

Cleaning and maintenance

Comply with the manufacturer's specifications of the cleaning fluid and disinfectants when cleaning and disinfecting the sterilization box. Clean the sterilization box 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 box 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.

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 box to dry completely following cleaning and/or disinfection.

Automatic cleaning

- ✓ The sterilization box may only be treated in the washer-disinfector under the use of demineralized water.
- ✓ The sterilization box 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.

Manufacturer



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We reserve the right to technical alterations

Your stockist

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