



polySteribox®

SH, M, L, XL

The polySteribox® is a reusable **sterilization, transport and storage container** and was manufactured with great attention to detail. In order to retain the function of this sterilization container for as long as possible, please read the instructions for use carefully prior to first use!

Instructions for Use

Safe handling and functionality of the polySteribox® are only guaranteed by following these instructions for use.

By following this instruction manual, the expiration dates stamped on the lid or bottom part of all polySteriboxes still in use and in a usable condition cease to be effective. The functionality is assessed by visual inspection performed before each new use.

Visual Inspection:

Before each new use, the polySteribox® must be inspected and assessed by qualified and trained staff.

The following aspects must be checked:

1. Expiration date of the filter
2. Correct positioning of the filter support and filter
3. Undamaged loop of Henle (Figure 1) in the lid and bottom part
4. Integrity of the components relevant to tight interlocking

If necessary, any damaged locks or other components must be replaced by qualified and trained personnel, or if a repair is not possible, these components must be sent to Ritter company for repair or be disposed of.

Cleaning Instructions:

For cleaning purposes, only open the polySteribox® in order to be able to clean the lid and bottom part separately. The filter supports and filters remain mounted on the bottom part!

Cleaning and disinfection must be performed in accordance with currently applicable requirements of KRINKO (Commission for Hospital Hygiene and Infection Prevention), BfArM (German Federal Institute for Drugs and Medical Devices) and the recommendations published by the RKI (Robert Koch Institute). With regard to material compatibility, only tested and approved process chemicals may be used for this purpose (e.g. RKI, VAH (German Association for Applied Hygiene) or DGHM (German Society for Hygiene and Microbiology)). All application specifications of the chemicals manufacturer must be observed.

- Metal brushes, scouring agents or other substances which could damage the surface may not be used for cleaning.
- In the case of coarse contaminants, in particular contaminants visible on the filter, the polySteribox® must be cleaned in an ultrasonic bath and subsequently rinsed thoroughly with water.

Due to the high-performance plastic used, the polySteribox® is suitable for mechanical cleaning and disinfection with acidic, neutral and alkaline chemicals in an automatic decontamination machine at a maximum cleaning temperature of 60 °C. In accordance with currently applicable requirements of KRINKO, BfArM and the recommendations published by the RKI, the polySteribox® is also suitable for subsequent thermal disinfection at max. 93 °C or chemical disinfection at max. 60 °C. Excessive stress cracks can only be avoided through adequate rinsing with deionized water for the complete removal of chemical residues, as well as compliance with the specified parameters. **The use of drying aids, in particular "neodisher MediKlar" from the company Chemische Fabrik Dr. Weigert, is strongly discouraged!**

Non-compliance with the temperature specifications and inadequate rinsing of chemical residues or surface-active chemicals can cause stress cracks in the polySteribox®. Any leaks or brittleness in the polySteribox® must therefore be addressed in accordance with the methods specified under "Visual Inspection".

The reliable and safe use of the polySteribox® is only guaranteed by adhering to the handling procedures specified in the instructions for use!

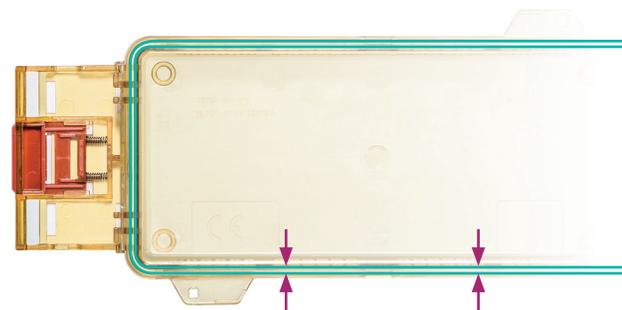


Fig. 1: The parallel borders highlighted in color in the sketch form the loop of Henle in the lid and the bottom part. They should not exhibit any damage, e.g. cracks or jags!

Opening the polySteribox®

The Ritter GmbH locking system for the polySteribox® provides security. This locking system precludes inadvertent or accidental opening.

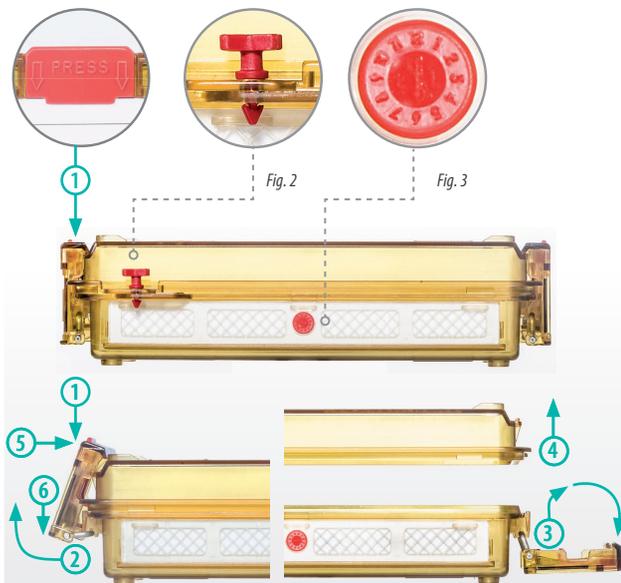
- Press down the red "PRESS" button (Step 1).
- At the same time, fold out the lock on the bottom part (Step 2).
- Push the lock upwards and to the side (Step 3).
- Lift the lid up to remove (Step 4).

Locking the polySteribox®

- Place the lid on top
- Push the lock upwards.
- Fasten the lock on top (Step 5).
- Press the lower lock side down until it snaps into place (Step 6).

Seals:

The use of seals is recommended to ascertain the unopened condition of the polySteribox® and to prevent unauthorized opening (Fig. 2).



Filters:

There are two types of filters for the polySteribox®:

1. Annual filters, which must be replaced annually as per the date stamp (Fig. 3) according to the instructions set out below.
2. Permanent filters, which must be replaced every five years as per the date stamp (Fig. 3) according to the instructions set out below.

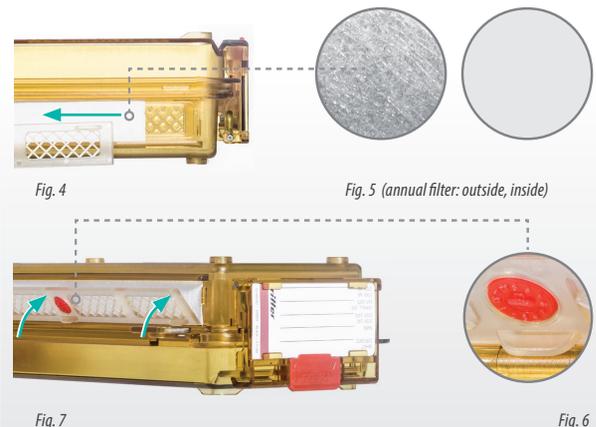
The filters are protected from puncture by the honeycomb structure of the filter support. During cleaning of the polySteribox®, the filter support and filter remain mounted on the bottom part!

Filter Change:

- Release the filter support from the holder with a pointed object and remove and destroy the used filter (Fig. 4).
- Insert a new date stamp (Fig. 3) into the filter support.
- Insert annual filter with the smooth side toward the inside and the rough side toward the outside (Fig. 5).
- The permanent filter can be inserted both ways, as both sides have the same texture.
- Reinsert the filter support into the designated recesses. The lugs must be on the outside (Fig. 6). Fix the filter support firmly in place until a click is heard.
- **Tip:** Place the polySteribox® on its lid and insert the filter support into the recesses. Push the filter support upwards to the filter and press it firmly from one side to the other into the rail (Fig. 7).

After changing the filter, recheck the following:

1. No air slot must be visible between the filter support and the polySteribox®.
2. The date stamp must be in place.
3. There must be no visible mechanical damage.



Storage:

The hygiene personnel responsible must define reasonable storage periods, having regard to DIN 58953 – 8+9. The polySteribox® can be stacked for storage purposes.

Recommended storage duration for sterile medical devices:

Type of packaging	Unprotected storage	Protected Storage ^a
Primary packaging	Used for delivery and for prompt use ^b and must be avoided as storage method!	6 months but no longer than the expiration date.
Storage packaging	5 years, provided no other expiration date is specified by the manufacturer	

^a On shelves in rooms that do not correspond to Room Class II according to DIN 1946-4:2008-12.

^b Prompt use means the application or use of the product within a maximum of 48 hours.

Sterilization Procedures:

The polySteribox® is validated and approved for steam sterilization in accordance with EN 285.

The polySteribox® is suitable both for plasma sterilization (STERRAD®) and gas sterilization with formaldehyde/ethylene oxide at max. 65 °C.

The polySteribox® meets the current requirements of MDD 93/42/EEC, EN ISO 13485 as well as the current relevant standards:

- DIN EN ISO 11607 – 1 + 2
- DIN EN 868 – 8
- DIN 58953 – 8 + 9

Spare parts and other accessories are available for the polySteribox®. More detailed information can be found at www.ritter-medical.de or contact us directly by phone: +49 8232 5003-45.