WAGNER

steriset®

Gebrauchsanweisung
Instructions for use
Notice d’utilisation
Instrucciones de Manejo
Indicazioni per l’utilizzazione

steriset

Deutsch
English
Français
Español
Italiano

www.wagner-steriset.de

www.wagner-steriset.de

steriset®

CE

SteriSet® Container erfüllen die zutreffenden Anforderungen:

- der Europäischen Medical Device Directive (CE-Kennzeichnung in den Begleitpapieren)
- der Normen EN 868-1:1997-05 (ersetzt durch: EN ISO 11607-1:2006-07) sowie EN 868-8
- der Deutschen Normen DIN 58952/1 und DIN 58953/9
- der Vertriebszulassung in USA (FDA 510K Premarketing Notification)

SteriSet® Container werden unter einem TÜV-zertifizierten Qualitäts-Management-System gemäß EN ISO 13485:2003 gefertigt.

Viele Designmerkmale sind international patentgeschützt.

SteriSet® Containers meet the following requirements:

- European Medical Device Directive (CE-mark declared)
- European Standards EN 868-1:1997-05 (replaced by: EN ISO 11607-1:2006-07) and EN 868-8
- German Standards (former DIN 58952/1 and actual DIN 58953/9)
- FDA 510K Premarketing Notification for USA

SteriSet® Containers are manufactured in Germany, covered by a TÜV-certified Quality-Management-System acc. EN ISO 13485:2003

The design is protected by multiple international patents.

TÜV SÜD

WAGNER


1

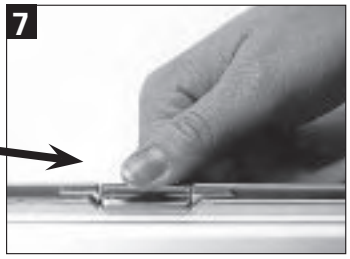

2


3


4


5


6


7


8


9


10


11


12


13


14


15


16


17

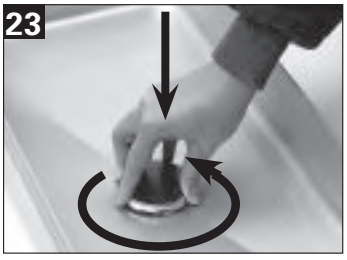

18


19


20

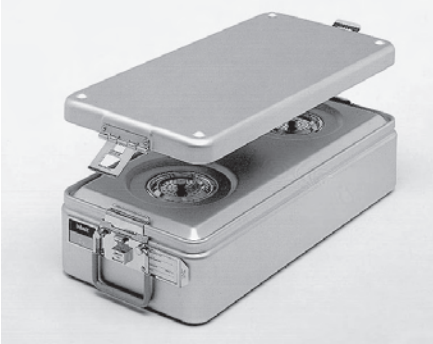

21


22


23


24

The SteriSet System



SteriSet-Containers are reusable, metal, sterilization containers. They are used for holding operating room instruments and/or textiles during vacuum-steam sterilization procedures and for maintaining sterility during storage and transport under proper hospital conditions.

The containers are intended for use by specialist trained professionals and their assistants working in the fields of hospital hygiene and sterilization technology.

This user manual describes important instructions on the proper use and care of SteriSet containers, and – without claiming to be comprehensive – outlines a number of possible hazards that could result from failure to observe the instructions.

⚠ Compatibility warning!

If the SteriSet-Containers are used in combination with components or articles (filters, seals, etc.) from another manufacturer, then sterility and/or the functioning of the anti-bacteria barrier, etc. is no longer guaranteed!

Only combine WAGNER sterile container products!

Filter or Valve System

SteriSet filter containers are containers with a closed (unperforated) base and perforated filter lid (covered by a protective lid). They are intended to be used with single use (disposable) filters made from sterilization paper.

In case of use of filters which are not supplied by WAGNER, the user must validate the permeability and barrier properties himself.

SteriSet valve containers are containers with a closed (unperforated) base and a permanent stainless-steel pressure-sensitive valve in the inner lid. These sterilization valves react to the change in pressure within the sterilizer.

- during the vacuum phase, the valve opens upwards, and the air/steam mixture flows out of the container
- during the pressurization phase, the valve opens downwards and thus allows steam to flow in. The system is automatically flushed and sterilised by the steam rushing through the valve during every sterilization cycle
- when not in the sterilizer (i.e. during storage and transport under specified conditions; see section on „Storage"), the sterilizing valve is closed and a barrier to microorganisms.

SteriSet containers are suitable for use in validated steam sterilizers using vacuum processes (e.g. DIN 58946 /EN 285 / ANSI/AAMI/ISO 11134-1993, ST46-1993) and are evaluated for suitability in accordance with EN 868-8.

⚠ Validation

The latest technical standards require the user to validate the sterilization procedure (e.g. in accordance with EN 554/ISO 13863) even when the sterilizer being used has been built in accordance with one of the above standards, as it may otherwise not be possible to guarantee the attainment of sterility.

⚠ Caution

With loads comprising solely instruments (i.e. containing no porous items such as textile packs, etc.), then (simple) prevacuum procedures may also be suitable (validation!).

Hot-air sterilization, gravity or circulation procedures and also formaldehyde or ethylene oxide sterilization or other substitute procedures for the sterilization of thermolabile products such as plasma sterilization or peroxide sterilization may not be used.

⚠ Misuse

Careless handling or the use of inappropriate chemicals can cause damage to the sterilization containers, thereby putting at risk the ability to attain and preserve sterility. Example: Never use disinfection solutions containing halogen or chloride – there is a danger of corrosion even for stainless steel containers. SteriSet containers therefore require regular visual and, if necessary, functional checks.

Servicable Life

After 5000 cycles of accelerated aging in accordance with EN 868-8 Annex G, the tested (seal/gasket function and barrier properties) SteriSet Containers showed no functional changes .
The end of serviceable life tends to be determined by mechanical wear and tear and damage rather than frequent use of the container for its intended purpose and can be identified by the required control of function before reuse.

Maintenance

During storage, sterilization containers are better than disposable soft packages at protecting sterile goods from recontamination caused by, for example, mechanical load / damage.

Like all reusable equipment, however, the SteriSet container although robust also needs to be treated with care in order to ensure that its protective qualities are preserved.

- Only use Steriset containers following the instructions in this user manual.
- Relevant personnel must therefore be familiar with the correct handling practices.
- Make sure the user manual is easily accessible for relevant personnel.
- Observe current standards.
- Carefully follow the general guidelines and hygiene principles on handing contaminated products, products awaiting sterilization and products which have been sterilized.

Before using the sterile container, or after any accident (such as being dropped on the ground), it is essential that the sterile container undergoes a thorough visual and functional check for damage.

Never use a damaged or defective sterile container!

Control of Function

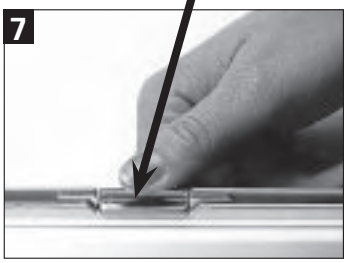
Undamaged shape
The seating of the seals on the upper rim of the container base tray and on the inner lid must be free of dents and visible deformations. Neither the lid nor filter plate nor the tray may show noticeable buckling or holes.

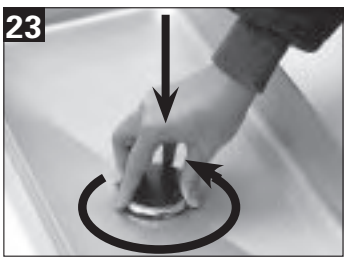
Seal
The seal in the inner lid (and filter plate button, filter plate and condensate drain if applicable) must be completely inserted and undamaged.

Handles and clasps
Handles, closure clasps and similar fittings must not be loose (no „wobble"). The closure clasps must lock the lid firmly to the bottom of the container.

Filters or valves
Neither filters / valves nor filterplates or valve covers (see pic. 8 - the perforated disc sections) may show visible malformations.
The seals on the filter plates, the lock pin on the lid must not be damaged and filters must fully cover the visible perforations in the lid. The filters are to be subjected to visual and mechanical inspections (see pics 6-8 and 20–22) .

Containers with condensate drain valves
The condensate valve must be screwed in correctly with the attached seal and be spring-tensioned (check the spring tension by thumb pressure with the valve screwed in position. To screw in the valve, press vertically downwards whilst at the same time turning clockwise until it clicks into place. See pics. 23, 24).





Tamper-Proof Sealing

Sealing

It is recommended and required by the latest technical standards (DIN EN ISO 11607-1 5.1 10c) that containers are sealed in such a way as to prevent inadvertent opening of containers and to ensure that it is evident whether or not a container has been opened. SteriSet containers offer two alternative methods for this:

1. Disposable plastic seals which, once attached, can be opened only by breaking. They are inserted through the horizontal hole in the closure before sterilization, and fastened between thumb and index finger (press fully together, but do not snap off!).
To unseal /open: Insert, for example, an index finger and TWIST (do not pull – see diagram 1–3).

If seals purchased from a company other than Wagner are to be used, the user has to make sure that containers are sealed in such a way as to prevent inadvertent opening of containers and to ensure that it is evident whether or not a container has been opened.

2. The „automatic sealing" option (ThermoLoc): Containers with this type of closure indicate sealing automatically as a result of the heat during sterilization procedure. In the sealed condition, a diagonal red block appears below the closure. To unseal, push the block vertically upwards until the red block has disappeared into the housing. Only then can the clasp be released (see diagram 12–14).

Safety note
The sealing function of ThermoLoc may only be reset after cool down (app. 10 minutes after removal from the sterilizer). Resetting the seal before cool down would require application of force and gloves to be worn (hot!) and might cause the (still hot) latch to reappear after the lid latch was opened. After cool down the seal can be reset without dropping down again. Such the first opening since cool down is clearly indicated.

Sterilization

Because of their safety-cover design, SteriSet containers can also be sterilized whilst stacked.

Stack height: <= 60 cm.

To prevent accidents or mechanical damage, do not handle stacked containers jerkily.

To prevent condensation collecting on one side (and thus causing drying problems), the containers should be placed horizontally in the sterilizer.

Internal packaging

Use of simple internal packaging (e.g. cloth wrap) can assist the final drying stage and good aseptic presentation of the sterile goods.

The size of the internal packaging should be calculated so that when its is unfolded all the external walls of the container can be covered.

As an alternative to reusable cloths, easily wrapable (non-woven) disposable materials can also be used. Because non-woven materials have a higher flow resistance than cloths, we recommend that in such cases the perforated tray be placed in the arch and fixed with adhesive tape before the load is placed into the container. The package cannot then open during sterilization and block the inlets and outlets of the container (the resulting raised flow pressure could damage the container).

Because of the problem associated with folding stiff paper, the use of **sterilization paper is expressly not recommended.**

In order to prevent colours leaching and thereby staining the containers, colour-fast internal packaging or pre-washed materials should be used.

⚠ Close the lid properly

improperly-sealed lids can jeopardize sterility.

⚠ Risk of non-sterility

For example, there is a risk of non-sterility if the container is over-loaded or protruding cloth corners prevent the container from closing properly.

⚠ Deformation of containers

If the sterilization procedure causes sterilization containers to become deformed in any way, then there is no guarantee of sterility. In such cases, the entire batch must not be used, and an investigation started to determine the cause (analysis of the sterilization record; examination of the sterilizer as well as the other sterile packs; investi-gation into the cause involving functional tests on the damaged sterilizing container).

Special linen for drain type bottoms

Inner linen

⚠ No additional external packaging

Never use additional external packing or wrap during sterilization as the resulting increase in flow resistance may affect sterilization (non-sterilization) or damage the container (implosion).

Sterilization operational limits

- In order to ensure that the lid can close properly, sterilization containers must not be filled above the level of the lower ridge of the edge indentation on the container tray. The lid must lie flat on the lower section without being forced and so that it does not wobble even when the clasps are open. It must also be possible to close the clasps without additional pressure on the lid and after closing the lid must sit tightly against the rim.
- In the case of instrument sterilization, the load weight (including perforated tray) should not exceed 10 kg, as residual moisture may otherwise remain even despite the use of materials to assist drying.
- With cloth loads (or similar), the load weight should not exceed 6.5 –7 kg.
- In order to prevent damage to the parts of the container or its load, we recommend that the container be transported with its lid closed whenever possible.
- As a general rule, contains should only be handled after cool down (DIN 58953/9 recommends 30 minutes in still air).

Security

Data cards / indicators

We recommend the use of documentation cards with chemical process indicators in the outer holding frame of the container (see also DIN 58953/9). These cards help substantiate that the containers were treated correctly, and facilitate performance documentation.

The additional use of chemical sterilization indicators inside the containers is not absolutely necessary. Such indicators are basically able to prove that a sterilization procedure has been performed, but are just as unable as an external card to indicate whether the contents of the container actually attained sterility (they indicate only that the contents at the location of indicator were sterile). If they are used, we recommend that they are placed in the middle of the load as this is usually the most critical point.

The use of, for example, a single chemical indicator in a specific „worst case" test receptacle is considered to be a sensible alternative to batch documentation obtained by placing chemical in-, dicators in every single sterile pack. If such a „worst case pack" signals „sterile", then there is a much smaller probability of the procedure having failed (for example as a result of spontaneous changes such as insufficient air circulation caused by faulty door seals) than if indicators are place in a normal container.

Note
The batch documentation does not replace regular checking and documentation of the sterilizers (ventilation tests; sterilization tests with chemical and biological indicators; vacuum-leak tests, etc.).

Caution

If procedure indicators are not used, then other organizational measures should ensure that no unsterilized – and thus non-sterile – containers are inadvertently released.

Condensation valve

Some drying problems with instruments (such as overloaded instrument sets) can be solved only by using a container fitted with a condensate drain valve in the base. Such containers are equipped with a sump with a central outlet, which is tightly closed by a temperature-controlled valve. The valve opens in 134 °C programmes when the temperature rises above 130 °C, thereby allowing condensate to drain out during sterilization.

During the drying phase, the condensate valve closes while still inside the sterilizer when the temperature first drops below 110 °C. It re-opens only when the temperature again rises above 130 °C, which means that this option is associated with absolutely no risks at typical removal temperatures of 75 – 80 °C.

121 °C program

Standard condensation valves do not open during the 121°C sterilization programme for the above reasons (a condensation valve for 121 sterilization is optionally available)

Note:
For containers with condensate drain valves in the base, the condensate should be able to drip to the base unimpeded. This can be achieved by using cloth wraps with a central hole. The recommended dimensions for the hole in the cloth are 40x20 cm (or 20x20 cm for half-size containers).

No prolonged exposure

Containers shall be removed from the sterilizer at program end, latest within 1 hour after program end: if left for a prolonged period in the closed, heated chamber, the drain's switch temperature could be reached again, such re-open the drain valve and introduce the risk of non sterility when taking out!
Specifically in the case of small load sterilization (<2 kg), the container must be removed from the sterilizer promptly at program end.
The condensate valve with seal attachment must always be properly screwed in and be spring-tensioned (press with thumb to check spring tension, see pics. 23, 24).

After Sterilization

After Sterilization

To safeguard against accidents (burns, dropping, etc.), containers that are still hot should never be handled with bare hands, even despite the thermally insulated handles (silicon coating).

After removal from the sterilizer, the containers should not be cooled to room temperature too rapidly (e.g. do not place on cold surfaces or expose to a cold draught), as excessively rapid external cooling can lead to recondensa-tion of the water vapour inside the container with an unwanted accumulation of condensate.

- A cooling time of 30 minutes should be allowed before handling containers (as detailed in DIN 5895379;2000)!

Storage / Transport

Sterility can be maintained inside proper packaging during clean hospital storage for a practically unlimited period. Depending upon storage duration and conditions, however, external contamination occurs, and this represents a potential risk during subsequent use, transport and aseptic presentation. According to scientific research (see also DIN 58953/9;2000) this risk factor can be reduced by the following measures:

- The use of internal packaging
- Storage under (dust)-protected conditions
- Limitation of the storage period

DIN 58953 part 9: Sep 2000 (table 2) recommends, – without claim to be comprehensive, – to limit storage duration to 6 months (dust protected and dry storage provided – with or without internal packaging), but also references to the responsibility of the medical director to lay down the acceptable storage duration individually.

Other important points are

- Dry storage under controlled conditions (low air-contamination, constant humidity, etc.)
- Handling as vibration-free as possible
- Packaging mechanically undamaged

If these points are followed, then the risk of recontamination will be essentially restricted to the effects of external contamination accumulated during storage. Unlike other types of packaging, the protective cover concept of the SteriSet containers is a simple method of eliminating this potential risk (e.g. by swab disinfection of the protective lid or using the S-model). We nevertheless recommend following DIN 58953/9; 2000 –"Operation procedures for sterilization containers."

Special cases

When storing or transporting sterile containers under non-standard hospital conditions (e.g. house-external transport; strong vibration, extreme changes in temperature, when there is a danger of contact with fluids, high humidity, or rapid pressure changes due to transportation in aeroplanes or trucks), then internal packaging and transport packaging to protect against dust contamination should be used to reduce the associated risks.

Aseptic presentation

The contents of a container can only be considered sterile if the container has been correctly sterilized and at the time of opening its lock has not been tampered with. If containers are to be opened after a long period of storage or after storage under non-ideal conditions, then we recommend either using the S model (protective cover removable separately as a first stage, see figs. 16–19) or wiping the unperforated cover with a disinfectant before handling.

Caution

In general containers should be handled in such a way that mechanical damage is minimized. Both lid latches of the container must opened to allow to lift the lid up completely. Opening only one side (latch) with the other side still closed will very likely damage the still closed latch or closure and as such hamper the integrity of the container.

Cleaning and Disinfection

In the operating room SteriSet containers are normally protected from direct contamination with blood or protein, as they are covered with sheets or are removed from the room before the operation starts.

Experience has shown that optically „clean" containers are therefore not microbiologically burdened (bioburden) to such an extent that this can influence the effectiveness of sterilization. However, if this cannot be excluded (inspection by hygiene control personnel, for example by surface contact trials),containers should be cleaned/disinfected before the next use.

Compatibility with materials

Container bases (trays), inner lids and outer lids are made of anodized aluminium. The fittings, and valves (and also the protective cover if this option is chosen) are made of electrolytically polished, chemically resistant stainless steel 1.4301. When selecting cleaning and disinfection agents and methods, particular attention must be paid to tolerance by aluminium as well as the following points:

- Do not use lathering cleaning substances (powder) or abrasive metal brushes or similar.
- Do not use substances containing halogen or chloride, there is a danger of corrosion, even on stainless steel!
- Thorough rinsing must remove all cleaning agent residues.
- The individual parts must be thoroughly dried and stored in a dry place following cleaning/disinfection,
- The selected cleaning agents must be appropriate for the quality of the available water: For thermal cleaning and disinfection (first choice) we recommend:
- **in case of fully desalinated water:** cleaning with i.e. the pH-neutral enzymatic cleaner NEODISHER MEDIZYM at app. 55 °C or MediClean up to 60°C or Medi Clean Forte at max. 45°C and subsequent thermodisinfection during final rinsing by use of fully desalinated water.
- **Cleaning in case of only softened water:** use of mild alkaline, non-chlorous substances (such as NEODISHER SeptoClean/liquid or NEODISHER MA/powder) at appr. 55 oC followed by thermodisinfection with fully desalinated water

Note
NEODISHER is a registered trademark of „Chemische Fabrik Dr. Weigert", Hamburg, Germany

For **chemical** cleaning and disinfection (2nd choice) we recommend:

Use of pH-neutral or weak acidic substances such as NEODISHER Dekonta (a combined cleaning & disinfection product) and:

- **in case of fully desalinated water:** Use of a neutral final rinse aid such as neodisher TN.
- **in case of only softened water:** Use of a mild alkaline, soft water compatible final rinse aid such as neodisher TS.

⚠ Waterquality

Please note:

a) **Regular tap water** can only be used cold,and thus is unsuitable for washing.

b) **Softened water** should only be used up to max. 60 °C :
- Rinsing: only << 60 °C
- Washing: up to max. 65 °C – when suitable cleaner selected (see recommendations)
- Thermodisinfection: NOT applicable ! (hot softened water may degrade aluminum-white deposit !)

c) **Desalinated water** (EN 285 quality, appendix B)
- Rinsing: suitable up to 95 °C
- Washing: in combination with a suitable cleaner (see recommendations)
- Thermodisinfection: suitable up to 95 °C

The brochure „Proper maintenance of instruments" of the German working group "Instrument preparation now" gives further valuable guidance for re-processing of reusable medical devices: See i.e. PDF-brochure under **www.a-k-i.org**

Suitable cleaners / disinfection solutions are i.e. offered by:

- Chemische Fabrik Dr. Weigert: the MediClean - Medizym - Neodisher family: **www.drweigert.de**
- Henkel-Ecolab : the Sekumatic family: **www.ecolab.com**
- Instructions for the preparation of re-useable medical products in accordance with EN 17664:2004 are available on **www.wagner-steriset.de/Catalogs**

⚠ Caution

Recommendations are not mandatory. Adherence to the recommendations is no guarantee that the material can tolerate the cleaning agent. When such substances are applied manually, the instructions for use should be followed exactly to ensure that inadequate effect and damage to the material are avoided. Specific attention should be paid to ensuring that the substances selected are tolerated by the materials, as well as to the concentration, mixing ratio, water quality, exposure time, temperature and effect of mixing various different cleaning agents.

In case of doubt ask the manufacturer of the cleaning agent whether the agent is tolerated by aluminium under the selected conditions of use.

Cleaning machines

Internal and external lids should be separated (see diagram 5 – 8), and placed diagonally in the washing basket. The lower section should be inverted and face downwards.

Disinfectants

Disinfectants should be checked not just for chemical tolerance to aluminium (see above) but also for effectiveness. We therefore recommend selecting a disinfectant with proven material tolerance from List VII issued by the „Deutsche Gesellschaft für Hygiene und Mikrobiologie" / DGHM (= German Society for Hygiene and Microbiology).

- As there are generally no chemically-resistant anodized" colours, we recommend that coloured anodized aluminium sections be cleaned preferably manually using neutral cleaning and disinfection substances and fully desalinated water.

⚠ Caution

When such substances are applied manually, the instructions for use should be followed exactly to ensure that inadequate effect and damage to the material are avoided. Specific attention should be paid to ensuring that the substances selected are tolerated by the materials, as well as to the mixing ratio, exposure time and effect of mixing various different cleaning agents.

steriset®

Wagner GmbH
Fabrik für medizinische Geräte
Schulstraße 16 a
D-80634 München/Germany

Telefon +49 (89) 12 11 01-0
Fax +49 (89) 13 30 99
info@wagner-sterilsysteme.de
www.wagner-steriset.de

WAGNER