INSTRUCTIONS FOR USE for Sterisafe DURO, Toolsafe and Accessories

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MD CE

Sterisafe® Toolsafe®

Sterilization Containers | Grid Baskets and Trays | Silicon Parts | Holding Devices | Filters | Accessories

Product | Article-Group | Basis-UDI-DI

- **Sterisafe DURO** | 21 0… | 4260734022106K [A3, A3plus, A4, A4plus, A6, A8, E42]
- **Toolsafe Grid Uses** | 22 0… | 4260734022206N
- **Toolsafe Cushion Mats** | 22 1… | 4260734022216Q
- **Toolsafe Fixation Strips** | 22 3… | 4260734022236U
- **Toolsafe Holding Devices** | 22 4… | 4260734022246W
- **Toolsafe Instrument Brackets** | 24 1… | 4260734022416W
- **Toolsafe Grid Baskets, -Trays** | 25 0… | 4260734022506X

Product | Article-Group | Basis-UDI-DI

- **Accessories for the Sterilization Container**
  - Date Stamps | 21 101… | 42607340221101G9
  - Security Seals | 21 102… | 42607340221102GB
  - Inscription Seals | 21 71… | 42607340221711HA
  - Sliding Locks and Filter Grids | 21 8… | 42607340221873
  - Bent-Lever-Closures, Label Holders | 21 9… | 42607340221975
- **Disposable Filters | 21 2… | 4260734022123SU**
- **Long-term Filters | 21 1… | 4260734022110SK**

The Sterisafe DURO sterilization containers, made of high-performance polymer (anthracite, translucent), and their accessories as well as the Toolsafe product-group are sterile barrier and packaging systems for sterile processing. These systems are especially suitable for the protective and safe reprocessing, transport, and storage of sensitive instruments such as thermolabile endoscopes.

According to the EU Regulation 2017/745 (MDR), the products of the Sterisafe DURO group are classified as medical devices of class I, container accessories and the products of the Toolsafe group are classified as accessories to the medical device and comply with the essential safety and performance requirements of the above-mentioned regulation.

Sterilization Methods

Sterisafe DURO containers and their accessories are suitable for steam sterilization processes under vacuum (121°C and 134°C), for low-temperature sterilization with gas (FORM and EO) and H2O2 / H2O2 plasma (VH_2O_2).
Only products which are suitable for multiple sterilizations and the respective sterilization process are permitted for sterilization in Sterisafe DURO containers.

Thermolabile Flexible Endoscopes

Sterisafe DURO A3 is validated and approved with the respective reference instruments of the manufacturers K. STORZ, OLYMPUS and R. WOLF in STERRAD® NX and 100NX for thermolabile flexible endoscopes within the lumen claims of ASP. For instruments from R. WOLF this applies additionally for the STERRAD 100S.

Loading variants for the Sterisafe DURO A3 with Toolsafe Bottom and Top Grids A3 can be requested from SAVUNA or the instruments and sterilizers manufacturers.

Attention

These containers and their accessories are approved for use by trained personnel only.
Users are obliged to validate their method according to DIN EN ISO 17664.

Initial Commissioning

NON STERILE

Containers and accessories are shipped non-sterile. They must undergo a complete reprocessing cycle before initial loading and sterilization.

Delivery Status

Sterisafe DURO containers are delivered without Filters, Date Stamps, and Security Seals. These must be ordered separately and inserted according to the IFU. Only Sterisafe DURO A3 containers have Filter Grids and Sliding Locks installed, all other containers are supplied with Filter Grids for self-assembly during initial use. Complete pre-assembly with Long-term Filters is possible for an additional charge. In this case, the Date Stamps are factory set to the insertion date of the Long-term Filters. Disposable Filters must always be inserted by the user at the time of use. → *see Filter Change*

Cleaning

Sterisafe DURO can be cleaned manually and mechanically (with thermal or chemothermal disinfection).
The following products are recommended:

Manufacturer	Manual Cleaning rinse	do not rinse	Machine Cleaning chemothermal	thermal
Dr. Weigert	neoform Classic neoform MED FF	neoform MED rapid neoform Rapid	neodisher Septo DN	neodisher MediClean forte neodisher MediKlar neodisher MediClean advanced
Ecolab	Aniosyme X3 Aniosyme XL3 Anios Clean Excel D Aniosyme Synergy 5 Sekusept Aktiv Sekusept Plus Sekusept Multi/Enzyme Sekusept PureClean		Sekumatic NDT Sekumatic LDI Sekumatic FDR	Aniosyme Synergy 5 Aniosyme Synergy WD Aniosyme Synergy WD Plus Aniosyme Synergy WD Ultra
Hartmann (Bode)	Bacillol 30 Sensitive Foam Bacillol 30 Sensitive Tissues Mikrobac Tissues Mikrobac forte Kohrsolin FF/-Tissues Dismozon plus	Bacillol AF Bacillol Tissues Bacillol AF Tissues Bacillol Wipes	Korsolex Endo-Cleaner in combination with Korsolex Endo-Disinfectant	
Schuelke (Merz)	mikrozid AF wipes mikrozid AF liquid mikrozid sensitive wipes mikrozid sensitive liquid mikrozid universal wipes *premium* mikrozid universal liquid		thermosept NDR	thermosept NKZ thermosept RKF thermosept alka clean forte thermosept X.tra thermosept X.tra enzymatic cleaner

Cleaning generally

All Sterisafe DURO must be cleaned according to the currently valid requirements of the KRINKO, BfArm as well as the RKI and can be reprocessed alkaline according to the RKI guideline, up to pH 14. Please note that alkaline cleaning agents (pH >10) are not suitable for all materials and potential problems may occur due to increased wear.

INSTRUCTIONS FOR USE for Sterisafe DURO, Toolsafe and Accessories

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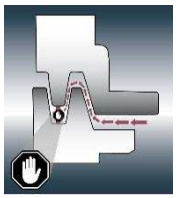
Cleaning and Tensides

Rinsing aids containing tensides should always be avoided. Residues affect the reprocessing process and could damage the Sterisafe DURO, especially in VH_2O_2 processes. The rinsing aid **neodisher Mediklar** approved by us is harmless in combination with steam sterilization.
Due to the higher effectiveness, machine processes are preferable for cleaning and disinfection. In the case of manual cleaning, rinsing **must** be carried out with demineralized water to avoid residues of the cleaning agents on the containers. Non-observance may impair the sterilization process and result in damage to the container. Improper cleaning and disinfection can lead to embrittlement, corrosion, and breakage.

Cleaning and Filters

- **Long-term Filters** made of ePTFE remain inserted in the base of the container during the washing process.
- **Disposable Filters** must be removed before the washing process.
- Also comply with the instrument manufacturer's instructions for the release of cleaning agents and disinfectants.

Visual Inspection and Function Control



Visual Inspection of the Containers, Filters and Accessories is routinely necessary before each cleaning and disinfection, during each packing process, batch release and sterilization to detect damage and initiate measures.
- The sterilization containers may not have any deformations or breaks that impair their function.
- All Bent-Lever-Closures, Filter Grids, Sliding Locks and Long-term Filters must be functional.
- The Pasteur's Loop between the Lid and Base of the container is a germ barrier and does not require a gasket. Therefore, the Lid and Base must fit together so that the Pasteur Loop can be easily joined, the Bent-Lever-Closures can be closed with moderate pressure and audibly engage.
- On the Sterisafe DURO A3 and A3plus, the Filter Grids must fit tightly onto the Base, and all four Sliding Locks must be pushed outwards and engaged, so that the Lid can be positioned without any resistance. → *see Filter Change*
- Long-term Filters must be visually inspected before each new use.
- Defective parts and filters must be replaced immediately, defective and/or not fully functional containers must be taken out of service and, if necessary, sent for qualified repair.

Packing Sterile Goods

Both the container and load must be clean and dry at the time of loading. → *see Handling*

Drying Measures

- The sterilization container and load must be at least at room temperature when placed in the sterilizer.
- Sterilization containers must stand horizontal.
- Drying times according to the sterilizer validation for steam sterilization must be complied with.

Avoiding Condensation after Sterilization

- Cooling phase of 30 minutes outside the sterilizer.
- Avoid draught during the cooling phase.
- Do not place a container on a cold surface during the cooling phase.

Container Lifetime

The containers (**not the Filters!**) can be reprocessed more than 2,000 times if used properly.
The durability is determined by mechanical wear and damage during use.

Method	**Lifetime**	(not applicable when using tensides)
Steam Sterilization (STEAM)	~ 2,000 cycles	
Gas Sterilization (FORM/EO)	~ 1,000 cycles	(1 cycle = cleaning +
H_2O_2 / H_2O_2-Plasma Sterilization (VH_2O_2)	~ 500 cycles	disinfection + sterilization)

Labeling

The Sterisafe DURO sterilization containers can be labeled with marking lasers, P-Touch and with labels approved for the reprocessing process. Unapproved engraving will void the warranty.

Consumables

Tested and validated are only the filters and accessories offered through the SAVUNA-product-catalog.
Using third-party materials voids conformity and warranty claims.

- Only for Sterisafe DURO A3 and A3plus:
  - Disposable Filter with one indicator point VH_2O_2
  - Disposable Filter with 3 indicator points STEAM-EO-FORM
- For all Sterisafe DURO containers:
  - Long-term Filters for STEAM-Sterilization
  - Inscription Seals for STEAM-Sterilization
  - Inscription Seals for VH_2O_2-Sterilization
  - Security Seals, Date Stamps

Spare Parts / Accessories

Sterisafe DURO Lid and Base are available individually, Filter Grids, Sliding Locks, Bent-Lever-Closures, Universal Label Holder are available in packaging units and as sets.

Long-term Filter

Long-term Filters made of ePTFE for steam sterilization must be replaced after **100 cycles** or **after 12 months** at the latest from the time of insertion – whichever comes first!
Mark the time of insertion with a Date Stamp and/or write it on the filter (outside) with a suitable marking pen and enter it in the documentation.

Disposable Filter

Disposable Filters (only available for A3 / A3plus) for STEAM-EO-FORM or VH_2O_2
Disposable filters must be inserted after cleaning and disinfection of the container, but before sterilization.
The color change of the indicator dot (for VH_2O_2 according to the reference card) exclusively indicates the performance of the respective sterilization process. → *see also Inscription Seals*
A reference card is enclosed with each Disposable Filter packaging unit for checking and archiving purposes.
For proof of the sterilization process, suitable validation is also required.

Disposal of the Filters

Long-term Filters and Disposable Filters can be disposed of with regular hospital waste after completed reprocessing – PTFE filters are suitable for recycling.
Contaminated Disposable Filters must be disposed of in accordance with the LAGA directive.

Attention:

Sterilization of thermolabile lumen instruments such as flexible endoscopes is only authorized and validated using the Disposable Filters suitable for the respective procedures and approved for the Sterisafe DURO.

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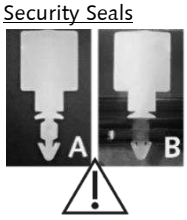
Filter Change for Sterisafe DURO A4, A4plus, A6, A8 and E42

1. Open the Filter Grid
   Lift Filter Grid from Base using a flat object (such as a small screwdriver) around the lower recess.
2. Filter replacement (both sides / for A8 only one filter)
   Remove used filter and insert a new filter.
   - → For **ePTFE Long-term Filter**, plain side shall face inward;
   - → mark the time of insertion with Date Stamp and/or mark on filter (outside) with suitable marking pen and enter in documentation;
   - → do not use damaged filters;
   - → do not bend or puncture the filter;
   - → do not stick labels on the filter - this reduces the filter quality and filtering effect.
3. Date Stamp (only when using **Long-term Filters**)
   Press the Date Stamp into the Filter Grid from behind.
   Set the Date Stamp to indicate the filter insertion or change, to the arrow on the Filter Grid (month/year).
   Recommendation: "Insertion date of the filter"
4. Close the Filter Grid
   Insert the Filter Grid into the available slots with the catch lugs (top) and press the Grid tightly against the Base (plain side facing inwards) until the Filter Grid can be heard to engage and lies flush.
5. The reprocessors are responsible for the documentation and completion of the filter change. The **date of insertion** resp. the **date of change** shall be specified in the reprocessing instructions.

Filter Change for Sterisafe DURO A3, A3plus

1. Unlocking the Filter Grid (without tools)
   After lifting off the Lid, push the two Sliding Locks inwards to the middle of the container until they are heard to engage.
2. Filter replacement (perform on both sides)
   Flip down the Filter Grid and remove the old filter.
   Insert the new filter so that it lies exactly between the lateral stop ribs.
   Then flip the Filter Grid back onto the Base.
   - → For **ePTFE Long-term Filters**, the plain side shall face inwards.
   - → Mark the time of insertion with a Date Stamp (month/year) and/or write it on the outside of the filter with a suitable marking pen and enter it in the documentation;
   - → for **Disposable Filters**, the labeled side with the indicator point shall face outwards – Date Stamps will be not used;
   - → do not use damaged filters;
   - → do not bend or puncture the filter;
   - → do not stick labels on the filter - this reduces the filter quality and filtering effect.
3. Date Stamp (only when using Long-term Filters)
   Press the Date Stamp into the Filter Grid from behind.
   Set the Date Stamp to indicate the filter insertion or change, to the arrow on the Filter Grid. *Recommendation: "Insertion date of the filter"*
4. Locking the Filter Grid
   Push out both Sliding Locks towards the Bent-Lever-Closures until they clearly engage. The Lid shall be able to be placed on without resistance, otherwise the Sliding Locks are not properly engaged.
   CAUTION: If the Sliding Locks are stiff, we recommend the economical use of Lubrinol Maintenance Oil before cleaning in the WD.
   Please refer to the application instructions for Lubrinol in combination with VH_2O_2 sterilization!
5. The reprocessors are responsible for the documentation and completion of the filter change. The **date of insertion** resp. the **date of change** shall be specified in the reprocessing instructions.

Security Seals



Security Seals (A) are provided for securing purposes. These are inserted from above into the slots provided for this purpose on the top and bottom parts of the containers when they are closed. When the two blades at the tip of the inserted Security Seal **(B)** fully engage, both container parts are securely connected to each other with it. This ensures that the sterilization container has not been opened after sterilization until the sterilized items are used, if the Seals are intact. To open the container, the Security Seals must be destroyed by snapping them off to the side. **For a sealed Sterisafe DURO container, the integrity of the Security Seals ensures the preservation of sterility within the container after the successful sterilization process, even if one or more Bent-Lever-Closures have been accidentally opened, e.g., during transport.**

Inscription Seal

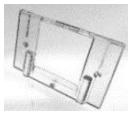
Inscription Seals are used as sterilization seals. After closing the Sterisafe DURO, they are inserted from above into the locking latch of the Bent-Lever-Closure or sticked onto it. When the Bent-Lever-Closure is opened, the label will be destroyed and thus the seal broken.

Important: Use the Inscription Seal which is in accordance with the specific sterilization process and marked correspondingly!
STEAM (steam sterilization process) - The indicator dot printed on the paper label changes color **from pink to black** during the sterilization process.
PLASMA (VH_2O_2 plasma sterilization) - The indicator dot printed on cellulose-free material for VH_2O_2 sterilization changes color analogously to the disposable filters. → *Reference card is enclosed with Inscription Seals*
Both indicators are class 1 process indicators according to ISO 11140-1 (= treatment indicator). They are used exclusively to avoid confusion between treated and untreated sterile goods and do not provide any information on the sterility of the container contents. The successful sterilization process must be ensured by additional indicators and the prescribed validation (device and process).

Bent-Lever-Closures

All Sterisafe DURO are equipped with the same **Bent-Lever-Closures**. To open, the Bent-Lever-Closures are unlocked without tools **by pulling on the lower side** and folded away from the container. For mechanical cleaning, the closures can optionally also be removed from the metal pin of the Base and rinsed separately in the **small parts grid basket**. The Bent-Lever-Closures are attached by placing them with the open eyelets on the metal pin of the Base and clicking them on.

Universal Label Holder



The **Universal Label Holder** can be used for our entire container program, except for the Sterisafe DURO A8, and is clicked onto one of the Bent-Lever-Closures. The Universal Label Holder is suitable for all documentation or log labels with a width of more than 50 mm.
In addition to the Inscription Seal for STEAM- or VH_2O_2-sterilization, you can also mark the Sterisafe DURO sterilization containers with your own standard labels.

INSTRUCTIONS FOR USE for
Sterisafe DURO, Toolsafe and Accessories

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Toolsafe Product Group

Container accessories with Bottom- and Top Grid, Cushion Mats, Fixation Strips, Grid Baskets/-Trays, and Instrument Racks to protect and securely fix sensitive instruments in the reprocessing circuit, during transport and storage. Toolsafe products are made of silicone, metal, or hybrid.
The materials and manufacturing processes used comply with the special standards of medical devices.
All Toolsafe products are approved for validated sterilization processes with STEAM, EO, FORM and VH_2O_2. In addition to these instructions for use, comply with the manufacturer's instructions for the release of cleaning agents and disinfectants.

Handling and Loading

The loading of the Sterisafe DURO containers and configuration of the Toolsafe Grid Baskets and Trays must be determined for reprocessing by the responsible hygienist to avoid overloading.
Endoscopes, instruments with lumens, compressed air or mains-operated units, and instruments with cannulas must be prepared for sterilization according to the manufacturer's instructions.
Only products from the Toolsafe Group and accessories that have been approved by SAVUNA are allowed to be used in the Sterisafe DURO containers.
For configuration options, examples, and loading instructions, as well as further details on the various systems, please refer to the product list. Individual loading recommendations can be provided upon request

Operating Conditions
Storage and Transport

+10 to +40 °C, Humidity 30 - 75 %, Standard Pressure
-20 to +60 °C, Humidity 10 - 90 %, Air Pressure 500 - 1060 hPa (pressure compensation via the filter areas)

Storage

- Protect from heat, sunlight, light sources, and store in a dry place.
- Sterisafe DURO containers can be reprocessed and stored in stacks.
- Correctly processed and sealed (Security Seals!) Sterisafe DURO containers keep sterile goods sterile for at least 6 months under normal clinical conditions and correct storage.
- The storage time generally depends on the storage conditions and must be determined by the responsible hygienic personnel considering DIN 58953 -8, -9 - in the case of particularly high asepsis requirements, also with shorter storage periods or additional storage packaging.

Maintenance, Repair, and Disposal

Maintenance and repair of the sterilization containers may only be performed by qualified persons.
Containers, Grid Baskets and Grid Trays may be returned to SAVUNA for repair or disposal. These products must have undergone a complete reprocessing cycle before being returned. A reprocessing confirmation must be enclosed with each return shipment. Used or damaged products must be disposed of in accordance with the known national and international legal regulations.

Attention: The state of the art and national laws require following validated processes. It is the user's responsibility to use suitable and qualified personnel and material for the reprocessing process in order to achieve the required results. Only the products mentioned in this IFU are tested and validated; the use of third-party materials and process change invalidates conformity and warranty claims. In case of proven violation of these instructions for use, the company SAVUNA GmbH assumes no liability.

Applied Standards

DIN EN 285	DIN EN 868-2, -8	DIN EN ISO 11607-1, -2
DIN EN ISO 11135	DIN EN ISO 10993-7	DIN EN ISO 14180
DIN EN ISO 14937	DIN EN ISO 17665	DIN EN ISO 25424
DIN 58952-2	DIN 58952-3	DIN 58953-8, -9

In addition, national regulations, and standards for the reprocessing of medical devices must be fulfilled. For patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or HIV, and possible variants of these above-mentioned diseases, the applicable national regulations must be applied regarding reprocessing.

Used Symbols

- Attention, observe accompanying Documents
- Observe Instructions for Use
- Manufacturer
- Date of Manufacture
- According to MDR EU-2017/745
- Medical Device
- Order Number or Catalog Number
- Batch Designation
- Non-Sterile
- Store in a Dry Place
- Store away from Sunlight
- Temperature Limit
- Recyclable
- Do not reuse

Instructions for Use

The current version of these instructions for use, declarations of conformity and certificates can be found in our download area after registration. Hard copies can be requested from us by eMail.

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