Aesculap®

Aesculap Sterile Technology

en **Instructions for use/Technical description**
Sterile container system

USA Note for U.S. users
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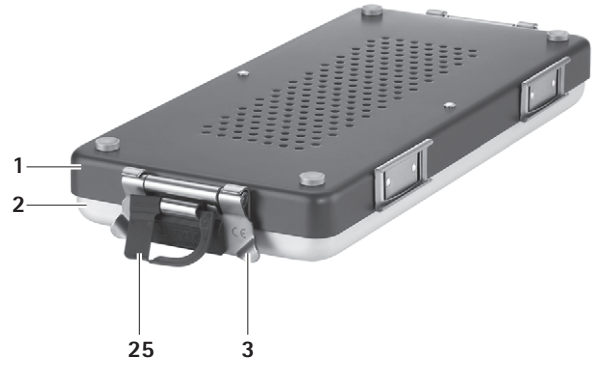
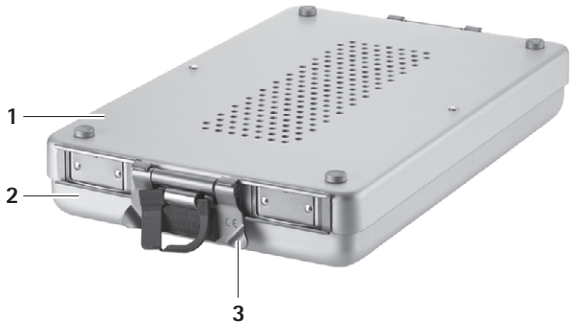
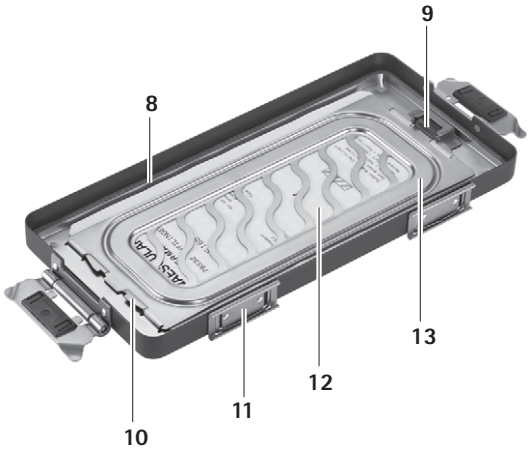
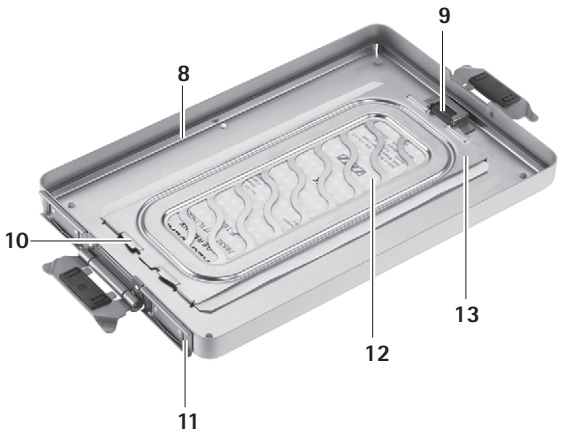
B BRAUN
SHARING EXPERTISE

Mini/dental container

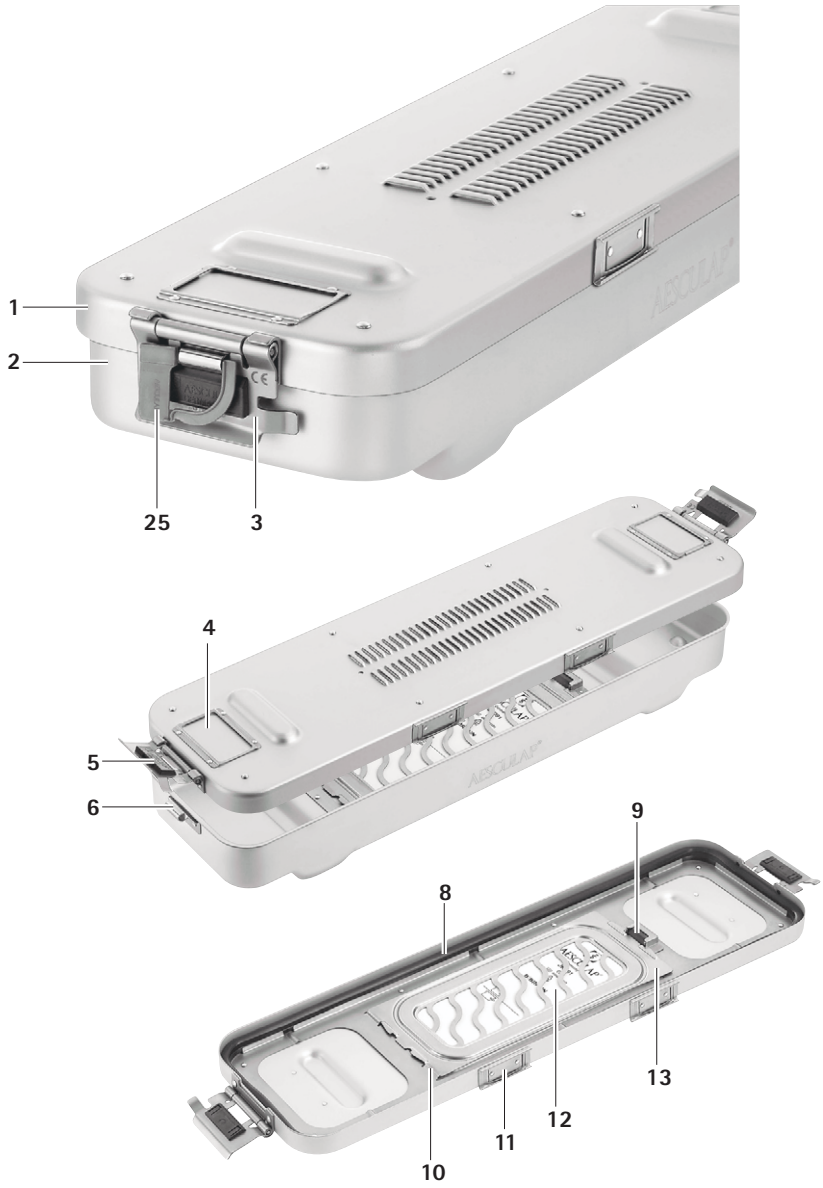




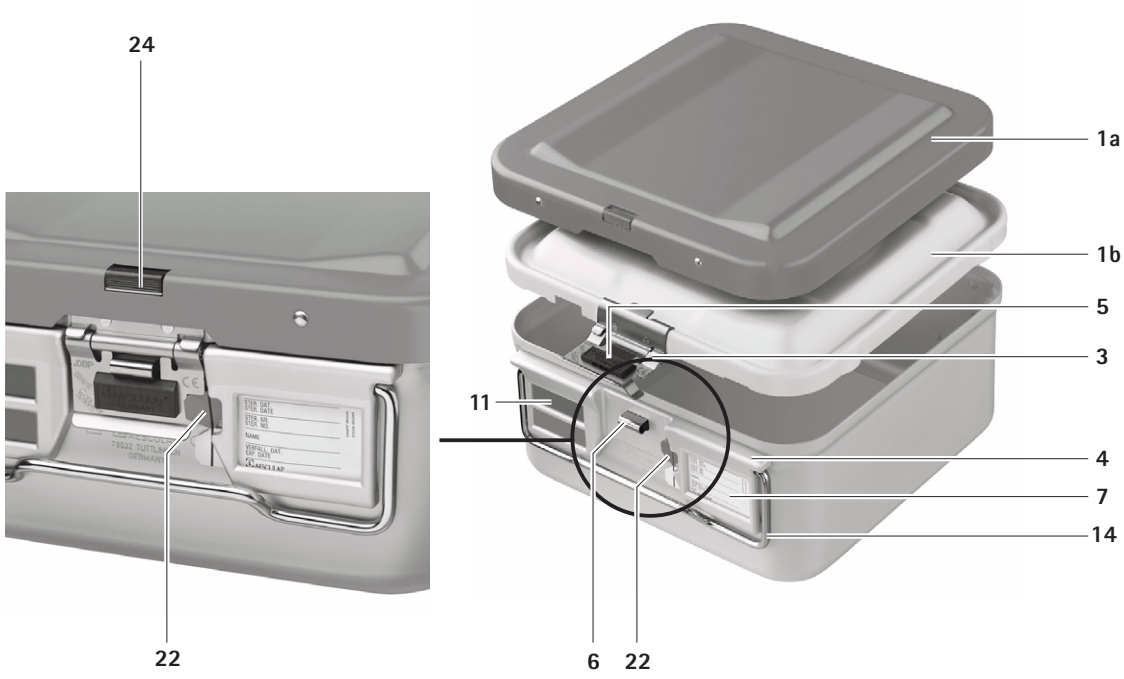


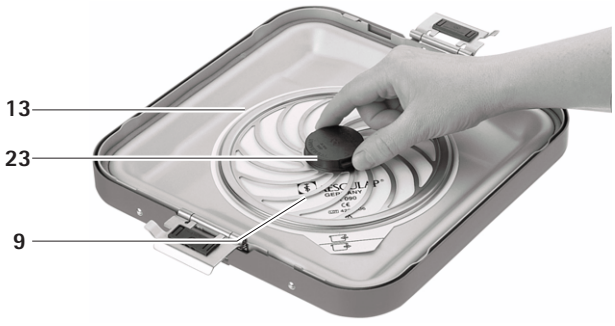


Optics container



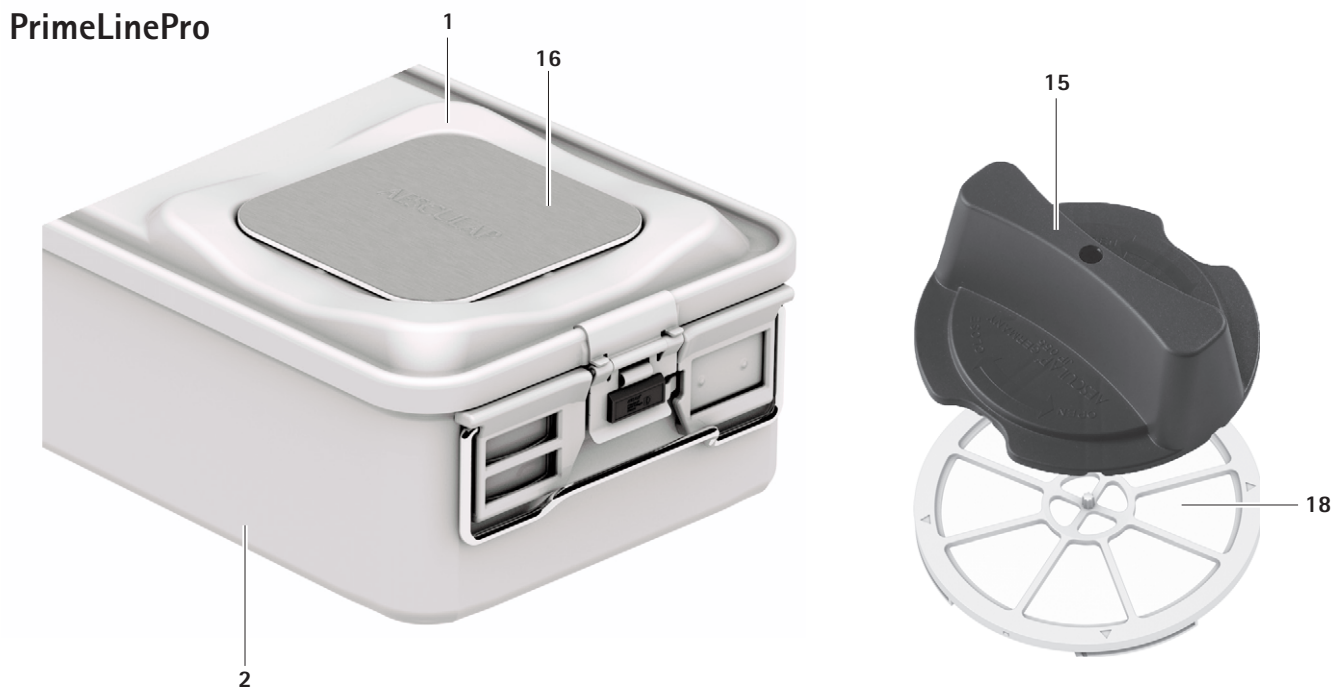
BASIS/VARIO container

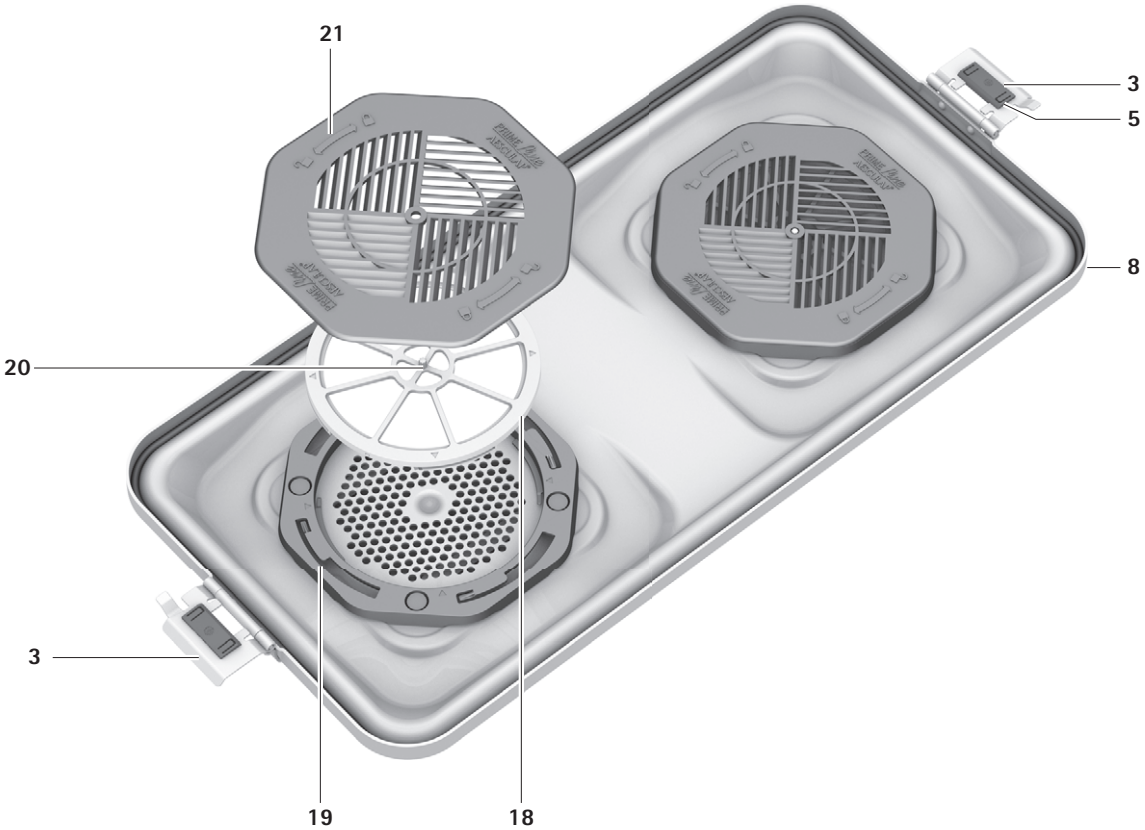




PrimeLine

PrimeLinePro





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Aesculap®

Sterile container system

Legend

1 Lid, **1a** Top lid, **1b** Lower lid
2 Bottom
3 (Lower) lid lock
4 Indicator sign retainer
5 Plastic detent part
6 Detent spring
7 Indicator seal
8 Lid seal
9 Push button
10 Latch nose
11 (ID) sign retainer
12 Disposable/permanent filter
13 (Universal) filter retainer
14 Screw handle
15 Mounting handle
16 Perforation field cover
17 Detent claw
18 Integrated germ retention system
19 Adapter frame
20 Handling pin
21 Ribbed cover grid
22 Tab
23 Cap
24 Cover latch
25 Plastic seal

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1. About this document

Note

General risk factors associated with surgical procedures are not described in these instructions for use.

1.1 Scope

These instructions for use apply to BASIS-, VARIO-, PrimeLine-, PrimeLine Pro, Mini, Dental and Optik containers.

► For article specific instructions for use and material compatibility and lifetime information, see B. Braun eIFU at eifu.bbraun.com

1.2 Safety messages

Safety messages make clear the dangers to patient, user and/or product that could arise during the use of the product. Safety messages are labeled as follows:

⚠ DANGER

Indicates a possible threat of danger. If not avoided, death or serious injury may result.

⚠ WARNING

Indicates a possible threat of danger. If not avoided, minor or moderate injury may result.

⚠ CAUTION

Indicates a possible threat of material damage. If not avoided, the product may be damaged.

2. Clinical use

2.1 Product description

The Aesculap sterile container system meets the requirements of EN ISO 11607 Part 1.

- Sterile containers with a perforated lid and a closed bottom have been validated for steam sterilization in a sterilizer as per EN 285 in a fractionated procedure.
- Sterile containers with a perforated lid and a perforated bottom are also suitable for steam sterilization in a sterilizer as per EN 285 in a gravitation procedure.
- Optik container with perforated lids and perforated container bottoms are also suitable for sterilization in
- Separately labeled sterile containers (Sterile Container S) with perforated lids and perforated container bottoms are also suitable for sterilization with hydrogen peroxide in a Sterrad® 100 S, Sterrad® 200, Sterrad® NX, Sterrad® 100NX, Steris® V-Pro®1 and Steris® V-Pro®1 Plus sterilizer.

Note

When using hydrogen peroxide in sterilization, use an appropriate JF167 filter for this sterilization process.

Note

The suitability of any specific process must be validated at the site of application.

Please contact your Aesculap sales representative on whether the Aesculap sterile container can be used in other sterilization procedures.

Note

Sterrad® 100 S, Sterrad® 200, Sterrad® NX and Sterrad® 100NX are registered trademarks of ASP.

Steris® V-Pro®1 and Steris® V-Pro®1 Plus are registered trademarks of Steris.

2.2 Areas of use and limitations of use

2.2.1 Intended use

The Aesculap sterile container systems is a multi-use sterilization container. It serves as a sterile goods package to hold sterile goods and/or textiles during sterilization and to maintain sterility during storage and transport under proper hospital conditions.

Users are trained experts in the area of hospital hygiene and preparation of medical devices or staff working under their instructions and supervision.

2.2.2 Indications

Note

The manufacturer is not responsible for any use of the product against the specified indications and/or the described applications.

For indications, see Intended use.

2.2.3 Contraindications

No known contraindications.

2.3 Safety information

2.3.1 Clinical user

General safety information

To prevent damage caused by improper setup or operation, and to not compromise the manufacturer warranty and liability:

► Use the product only according to these instructions for use.

► Follow the safety and maintenance instructions.

► Ensure that the product and its accessories are operated and used only by persons with the requisite training, knowledge and experience.

► Store any new or unused products in a dry, clean, and safe place.

► Prior to use, check that the product is in good working order.

► Keep the instructions for use accessible for the user.

Note

The user is obligated to report all severe events in connection with the product to the manufacturer and the responsible authorities of the state in which the user is located.

Notes on surgical procedures

The medical professional will make decisions on concrete applicability based on the warranted properties and technical data.

2.3.2 Product

Product-specific safety information

Risk of contamination of sterile materials from sterile containers that have not passed the function test.

The sealing of the sterile container and its germ barrier function will be compromised if the sterile container is combined with components from other manufacturers.

► Only combine Aesculap sterile container products with one another.

► Before use, check the product is in full working order and in good condition, see function check section and function check poster C63301.

► Follow general guidelines and aseptic principles when handling contaminated items that have undergone or are to undergo sterilization.

2.3.3 Sterility

The product is delivered in an unsterile condition.

► Clean the new product after removing its transport packaging and prior to its initial sterilization.

2.4 Preparation

► Thoroughly clean the new sterile container prior to first use.

► After cleaning, use a suitable filter, see System set-up.

PrimeLine and PrimeLine Pro sterile container system:

The permanent germ retention system **18** is integrated in the system.

2.5 System set-up

Note

A suitable filter must be used for the sterilization process.

2.5.1 Remove the BASISVARIO container lid

If an upper lid **1a** is used, it can be removed to clean the sterile container and, if it is soiled, it can be separated from the lower lid **1b**.

■ VARIOVARIO container (by default with lower and upper lid):

The upper lid can be separately removed with the VARIO container.

► Open lid latch **24** and remove outer lid **1a**.

► Press the lid latch **3** and remove lower lid **1b**.

■ BASIS container (with retrofitted lid):

► Remove the the combined upper lid **1a** and lower lid **1b** from the pan **2**.

► Loosen the lid latch **17** and remove upper lid **1a**.

2.5.2 Remove the Mini, Dental, Optik, PrimeLine- and Primeline Pro container lid

► Open lid lock **3**.

► Remove lid **1** from the bottom **2**.

2.5.3 Replace the filter in the lid and the tray

Replace the filter at the following intervals, depending upon the filter type:

- Replace single use filter before every sterilization
- Permanent filter (BASIS/VARIO): after a maximum of 1,000 sterilization cycles, see TA013138
- PrimeLine/PrimeLine Pro germ retention system: after a maximum of 5,000 sterilization cycles

■ VARIO container and BASIS container:

► Press simultaneously both push buttons **9** on the universal filter retainer **13**.

► Remove the universal filter retainer **13**.

► Insert a new filter and remount the universal filter retainer **13**.

► Push the cap **23** down on the universal filter retainer **13** until you hear it click into place.

■ PrimeLine and PrimeLine Pro sterile container system:

► Turn the ribbed cover grid **21** to the left until it is unlocked.

► Remove the ribbed cover grid **21** of the germ barrier system **18**.

► Turn the germ barrier system **18** with the mounting handle **15** to the left until it is unlocked from the adapter frame **19**.

► Lift the germ barrier system **18**, gripping it at the handling pin **20**, and remove it.

► Install the germ barrier system **18** in the reverse sequence of steps.

■ Mini, Dental and Optik container:

► Push back the release button **9**.

► Remove filter retainer **13** once it is unlocked.

► Replace filter and insert the filter retainer **13** under latch loops **10**.

► Push down filter retainer **13** so that it clicks into position.

2.6 Functional testing before use

► Visually inspect all components of the sterile container before each use to ensure correct function and that there is no damage, see also function check poster C63301:

- Metal parts are not deformed
- The aluminum lid and bottom are not warped
- Plastic parts are not damaged
- The plastic lid is intact on both sides (no cracks)
- Lid seals **8** are intact
- The seal at filter retainer **13** is intact (no cracks)
- The edges of the filter retainer **13** are seated in full-surface contact
- The filter retainer **9** latch functions properly (engages)
- The single use filter **12** has been changed
- The single use/permanent filter **12** is undamaged (no kinks, holes or cracks)
- The PrimeLine/PrimeLine Pro germ barrier system **18** is undamaged (no kinks, holes or cracks)
- The lock **3** functions properly (engages)

Note

For the PrimeLine/PrimeLine Pro sterile container system, the ribbed cover system **21** *must be removed.*

► Use sterile containers only if they have been visually inspected and are free from defects listed above. Replace any damaged components immediately with original spare parts, or have the damaged components repaired see Technical service.

2.7 Application

⚠ WARNING

Risk of contamination of sterile materials from sterile containers that have not passed the function test.

The sealing of the sterile container and its germ barrier function will be compromised if the sterile container is combined with components from other manufacturers.

► **Only combine Aesculap sterile container products with one another.**

⚠ CAUTION

Risk of non-sterility of container contents.

► **Always carry the sterile containers by their handles.**

► **Never carry or lift the sterile container by the lid.**

► **Transport the sterile container in such a way that mechanical damage will not occur.**

2.7.1 Loading the sterile containers

According to DIN EN 868-8 and DIN 58953-9, the following maximum load of the container (including the basket) must be adhered to:

- Loading weight
  - 1/1 container: 10.0 kg
  - 1/2 container: 5.0 kg
  - 3/4 container: 7.5 kg
  - Optik container: 3.0 kg
  - Dental container: 2.0 kg
  - Mini container: 1.5 kg
- Maximum loading height
  - BASIS/VARIO/PrimeLine/PrimeLine Pro: up to about 2 cm below the edge of the container.
  - Optik container: to the container edge
  - Dental and Mini container: up to about 0.5 cm below the edge of the container.

Note

Store sterile goods in baskets with suitable supports. When doing so, lay hollow materials, dishes, plates, etc with the opening facing downwards at a slant.

Note

Pack folded textiles in such a way that they fit vertically in the sterile container.

Make certain that when the sterile container is fully loaded, it is still possible to insert a flat hand between the individual items without difficulty.

Note

Load the sterile container in such a way that the filter retainer **13** *and the germ retention system* **18** *is not obstructed.*

► Lock the lid **1** with the lid lock **3** on the tray **2**.

► Ensure that the lid lock seal **3** audibly clicks. If not: have the sterile container repaired, see Technical service.

2.7.2 Label and seal the containers

- BASIS/VARIO/PrimeLine/PrimeLine Pro:

► After loading the sterile container, label the indicator seal **7** (e.g. contents, batch no., expiry date etc.).

► Slide the indicator seal **7** from the outside into the indicator sign retainer **4** to the stop, so that the red area of the indicator seal **7** covers the tab **22** of the lid lock and the lid lock **3** is sealed.

- or -

► After locking the sterile container, insert a plastic seal **25** (e.g. JG739) on the lock.

- Mini, Dental and Optik container:

► Slide the identification plate into the plate retainer **4** (optional).

► Pull the identification sign (paper, such as production ticket) onto the tab in the sign retainer **11**.

► Lock the sterile container, insert a plastic seal **25** (e.g. JG739) on the lock.

Note

A suitable indicator must be used for the sterilization process (type 1, as per EN ISO 11140-1).

2.7.3 Loading the sterilizer

Prepare the sterile container and the sterilizer the following way when loading the sterilizer:

⚠ WARNING

Risk of vacuum damage to the sterile container due to inadequate pressure equalization.

► **Do not use outer packaging for the sterile containers.**

► **Never obstruct air in the tray and lower lid/lid.**

► **Do not place foil packaging directly on the sterile container.**

Note

One can sterilize with the upper lid placed for VARIO containers as well as BASIS containers.

► Please observe the instructions issued by the sterilizer manufacturer.

► Always place heavy sterile containers at the bottom of the sterilizer.

Note

Sterile containers can be stacked in the sterilizer.

2.7.4 Sterilization

⚠ CAUTION

Risk of sterilization failure.

► **Sterilize the containers only by approved and validated sterilizing processes.**

► Sterilizing with steam: sterilization must be performed by means of a validated steam sterilization process (e.g. in a sterilizer according to EN 285 and validated according to ANSI/AAMI/ISO 17665-1).

► Sterilization with ethylene oxide (EtO): Only use Optik containers. Sterilization must be validated in accordance with EN 550/ISO 11135-1.

► Sterilization with hydrogen peroxide: only specially-marked sterile containers (sterile container S) may be used for Sterrad® 100 S, Sterrad® 200, Sterrad® NX, Sterrad® 100NX, Steris® V-Pro®1 and Steris® V-Pro®1 Plus.

► Ensure that the maximum load capacity of the steam sterilizer, as specified by the manufacturer, is not exceeded.

► Ensure that the sterilization medium can reach all products stored in the sterile container.

2.7.5 Unload the sterilizer and release the sterile goods

⚠ DANGER

Risk of contamination from improperly sterilized materials.

► **Before preparing the sterile materials, check to ensure that the sterilization was successful.**

⚠ WARNING

Risk of burns due to a hot sterile container after sterilization.

► **Always wear protective gloves.**

► Make certain that the color of the indicator point has changed.

► Ensure that the container seal **7/25** is intact.

2.7.6 Transporting the sterile container

⚠ CAUTION

Risk of non-sterility of container contents.

► **Never carry or lift the sterile container by the lid.**

► **Transport the sterile container in such a way that mechanical damage will not occur.**

2.7.7 Storing the sterile containers

Note

The sterile containers may be stored in stacks.

► Store sterile containers in a dry, clean and protected place.

The loss of sterility is normally event-based and not time-based. Loss of sterility is not so much connected to the storage periods as to outside influences and the effects of storage, transport and handling. Therefore, blanket statements cannot be made regarding appropriate storage periods; see EN ISO 11607-1, ANSI/AAMI ST79, DIN 58953-8.

Note

Storage duration (up to one year) for Aesculap sterile containers has been investigated in various long-term studies. Retention of sterility has been demonstrated over the entire period. The storage conditions used in the test therefore conform with ANSI/AAMI ST79.

2.7.8 Checking and commissioning the sterile materials

The contents of a sterile container can only be considered to be sterile if the sterile container is sterilized, stored and transported as specified.

► Verify that the indicator color has changed.

► Ensure the following components are intact:

- Container seals **7/25**
- All container components
- Plastic lid **1** on both sides (no cracks)
- Germ barrier system/permanent filter **18**
- Lid seal **8**

If this is not the case, the sterile materials must be processed again.

2.8 Troubleshooting

Malfunction	Cause	Remedy
Excessive amounts of condensate inside the sterile container	Temperature of sterile materials too low prior to sterilization	Allow sterile materials to reach room temperature (approx. 20 °C)
	Textiles too damp	Sterilize dry textiles only
	Sterile container too heavy	1/1 container: with instruments: max. load 10.0 kg with cloth: max. load 8.0 kg
		1/2 container: max. load 5.0 kg
		3/4 container: max. load 7.5 kg
		Optik container: max. load 3.0 kg
		Dental container: max. load 2.0 kg
		Mini container: max. load 1.5 kg
	Sterile materials improperly packed	Lay hollow materials, dishes, plates, etc with the opening facing downwards at a slant.
		Arrange textiles in loose vertical piles, do not press them together
	Sterile container incorrectly positioned in sterilizer	Always place heavy sterile containers at the bottom
	Sterile containers processed immediately after sterilization	Allow sterile containers to cool down to room temperature prior to processing
	Sterile containers improperly positioned during cooling phase	Do not store sterile containers on a floor or in a drafty place. Store sterile containers in air-conditioned areas with constant relative humidity and temperature.
	Sterilizer properties do not comply with DIN EN 285	Have sterilizer serviced regularly. Check drying vacuum. Check drying time.
		Check steam quality and upgrade if necessary.
	Empty-cycle and vacuum test not run daily before sterilization begins	Run empty-cycle and vacuum test daily before beginning sterilization.
	Unsuitable sterilizer cycle selected	Select cycle in accordance with load.
	Sterilizer door left open too long, sterilizer cooled down	Load and unload sterilizer quickly.
Condensate on the lid	Incorrect loading configuration	Loading configuration as per validation and loading instructions.
	Sterilizer properties do not comply with DIN EN 285	Have sterilizer serviced regularly. Check drying vacuum. Check drying time.
		Check steam quality and upgrade if necessary.
No clear indicator seal color change	Sterilization performed incorrectly Sterilizer faulty	Have sterilizer repaired by manufacturer.
	Indicator seals stored improperly	Observe storage conditions as specified on the packaging of the indicator seals
Sterile containers deformed	Perforations covered during sterilization	Do not cover the perforation field from the inside or outside.
	Allowable loading height exceeded	Note the loading heights, see Loading the sterile containers
Inner or outer lid cannot be positioned or locked on the bottom component	Container lid or bottom are deformed/damaged due to improper handling	Replace container lid or tray, or have components repaired by the manufacturer

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3. Validated reprocessing procedure

3.1 General safety information

Note

Adhere to national statutory regulations, national and international standards and directives, and local, clinical hygiene instructions for reprocessing.

Note

For patients with Creutzfeld-Jakob disease (CJD), suspected CJD, or possible variants of CJD, observe the relevant national regulations concerning the reprocessing of products.

Note

Mechanical reprocessing should be favored over manual cleaning as it gives better and more reliable results.

Note

It should be noted that successful reprocessing of this medical device can only be guaranteed following prior validation of the reprocessing method. The operator/reprocessor is responsible for this.

The recommended chemical was used for validation.

Due to process tolerances, the manufacturer's specifications can only serve as an approximate guide for assessing the processing procedures applied by the individual operator/processors.

Note

For the latest information on reprocessing and material compatibility see also the B. Braun eIFU at eifu.bbraun.com

3.2 General notes

Dried or affixed surgical residues can make cleaning more difficult or ineffective and lead to corrosion. Therefore, no more than 6 hours should pass between use and preparation, pre-clean temperatures >45 °C liable to fusing should not be employed and disinfectants liable to fusing (aldehyde or alcohol-based) should not be used.

Only process chemicals that have been tested and approved (e.g. VAH or FDA approval or CE mark) and which are compatible with the product's materials according to the chemical manufacturers' recommendations may be used for reprocessing the product. All of the chemical manufacturer's application specifications must be strictly observed. Failure to do so can result in the following problems:

- For aluminum, the application/process solution only needs to be pH >8 to cause visible surface changes.
- Material damage such as corrosion, cracks, fracturing, premature aging, or swelling.

► Do not use metal cleaning brushes or other abrasives that would damage the product surface and could cause corrosion.

► For more detailed information on hygienically safe reprocessing which is protective of materials and retains their value, please see www.a-k-i.org Heading "AKI-Brochures", "Red brochure".

3.3 Reusable products

Influences of the reprocessing which lead to damage to the product are not known.

A careful visual and functional inspection before the next use is the best opportunity to recognize a product that is no longer functional, see Inspection.

3.4 Preparing for cleaning

Note

For wet disposal of products, Aesculap recommends using disposal containers (e.g. JK060R).

3.5 Cleaning/Disinfection

3.5.1 Product-specific safety information on the reprocessing method

Damage to or destruction of the product due to inappropriate cleaning/disinfecting agents and/or excessive temperatures!

► Following the manufacturer's instructions, use cleaning and disinfecting agents,
  - that are approved for use on materials such as aluminum, plastics and stainless steel,
  - do not cause stress cracks in plastics (e.g., PPSU).
  - that do not attack softeners (e.g., in silicone) leading to brittleness.

► Observe specifications regarding concentration, temperature and exposure time.

► Do not exceed the maximum allowable disinfection temperature of 95 °C.

Note

If drying with pressurized air, avoid damage to the permanent filter.

3.6 Manual cleaning/disinfection

- ► Prior to manual disinfecting, allow water to drip off for a sufficient length of time to prevent dilution of the disinfecting solution.
- ► After manual cleaning/disinfection, check visible surfaces visually for residues.
- ► Repeat the cleaning/disinfection process if necessary.

3.6.1 Manual cleaning with disinfecting cleaning by wipe disinfection

Phase	Step	D [°C/°F]	t [min]	Conc. [%]	Water quality	Chemistry	
I	**Cleaning**	RT (cold)	-	-	D–W	-	
II	**Drying**	RT	-	-	-	-	
III	**Wipe disinfection**	-	>1	-	-	**a** Alcohol Denat. 70% (B. Braun ethanol)	**b** Aldehyde-free surface disinfectants (e.g. Melisptol® HBV cloths)
IV	**Final rinse**	RT (cold)	0.5	-	FD–W	not required	Rinse off cleaning chemicals; do not leave residues
V	**Drying**	RT	-	-	-	-	

DW: Drinking water
FD–W: Fully desalinated (demineralized) water
RT: Room temperature

Phase I

- ► Clean the product under running tap water, using a suitable cleaning brush until all visible residues have been removed from the surfaces.
- ► Mobilize non-rigid components, such as set screws and hinges, during cleaning.

Phase II

- ► Dry the product in the drying phase with suitable equipment (e.g. cloth, compressed air).

Phase III

Note

Only use denat. alcohol for Primeline. 70% (e.g. B. Braun ethanol).

- ► Wipe all surfaces of the product with a single-use disinfecting wipe.

Phase IV

- ► Rinse disinfected surfaces under running demineralized water after the specified contact time has elapsed (at least 1 min).
- ► Drain any remaining water fully.

Phase V

- ► Dry the product in the drying phase with suitable equipment (e.g. cloth, compressed air).

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3.7 Mechanical cleaning/disinfection

3.7.1 Mechanical neutral or mild-alkaline cleaning and thermal disinfection

Machine type: single-chamber cleaning/disinfecting machine without ultrasound

Phase	Step	D [°C/°F]	t [min]	Water quality	Chemistry
I	**Pre-rinse**	<25/77	3	D–W	-
II	**Cleaning**	55/131	10	FD–W	**Neutral**: ■ B. Braun Helimatic Cleaner neutral – pH neutral – Working solution 0.5% **Mildly alkaline**: ■ Concentrate: – pH = 9.5 – <5 % anionic surfactant – Working solution 0.5 % **Alkaline**: Reprocessing is possible up to pH 10.5, provided the cleaning agent is manufacturer-approved for cleaning aluminum or plastic sterile containers. **Note**: If using mild alkaline or alkaline cleaning agents colored anodized aluminum may discolor. This does not, however, affect functionality.
III	**Intermediate rinse**	> 10/50	1	FD–W	Especially forPrimeLine, ensure that the surface is rinsed without leaving any residues.
IV	**Thermal disinfection**	90/194	5	FD–W	Other process parameters may be feasible with agreement by the hospital hygienist.
V	**Drying**	-	-	-	According to mechanical cleaning program Do not use rinsing agent for PrimeLine.

DW: Drinking water
FD–W: Fully desalinated (demineralized) water

► Check visible surfaces for residues after mechanical cleaning/disinfecting.
► Repeat the cleaning/disinfection process if necessary.

Note

Temperatures of up to 120 °C are permitted for machine drying with hot air.

Note

When cleaning or disinfecting non-anodized sterile containers (specially marked sterile containers: Sterile container S), there can be changes (such as spots) on the aluminum surfaces. Such changes do not affect the functionality of the product.

3.8 Inspection

► Allow the product to cool down to room temperature.

► Dry the product if it is wet or damp.

3.8.1 Visual inspection

► Make certain that all soiling has been removed. In particular, pay attention to mating surfaces, hinges, shafts, recessed areas, drill grooves and the sides of the teeth on rasps.

► If the product is dirty: repeat the cleaning and disinfection process.

► Check the product for damage, e.g. insulation or corroded, loose, bent, broken, cracked, worn or severely scratched and fractured components.

► Check the product for missing or faded labels.

► Check the surfaces for rough spots.

► Check the product for burrs that could damage tissue or surgical gloves.

► Check the product for loose or missing parts.

► Immediately put aside damaged or inoperative products and send them to Aesculap Technical Service, see Technical service.

3.8.2 Functional test

► If necessary, lightly lubricate moving metal parts (such as locking hinges) with suitable maintenance oil (e.g. Aesculap-STERILIT® I oil spray JG600 or maintenance oil JG598).

► Check that the product functions correctly see Functional testing before use.

► Check that all moving parts are working properly (e.g. hinges, locks/latches, sliding parts etc.).

► Check for compatibility with associated products.

► In case of visible damage, replace the seal immediately.

► Immediately put aside damaged or inoperative products and send them to Aesculap Technical Service, see Technical service.

Note

The sterile containers may be tested and repaired only by persons with the appropriate training, expertise or experience.

4. Technical service

⚠ CAUTION

Modifications carried out on medical technical equipment may result in loss of guarantee/warranty rights and forfeiture of applicable licenses.

► **Do not modify the product.**

► **For service and repairs, please contact your national B. Braun/Aesculap agency.**

Service addresses

Aesculap Technischer Service

Am Aesculap-Platz

78532 Tuttlingen / Germany

Phone: +49 7461 95-1601

Fax: +49 7461 16-2887

E-Mail: ats@aesculap.de

Other service addresses can be obtained from the address indicated above.

4.1 Accessories / spare parts

Accessories and supplies are listed in brochure no. C40402.

5. Disposal

⚠ WARNING

Risk of infection due to contaminated products!

► **Adhere to national regulations when disposing of or recycling the product, its components and its packaging.**

Note

The user institution is obliged to reprocess the product before its disposal, see Validated reprocessing procedure.

► Detailed information concerning the disposal of the product is available through your national B. Braun/Aesculap agency, see Technical service.

6. Technical data

The variants and sizes of sterile containers are listed in brochure no. C40402.

7. Norms

7.1 Standards cited

The following standards are cited in connection with the sterile containers:

- EN ISO 11607: Packaging for final packaging of medical devices - Part 1
- ANSI/AAMI/EN ISO 17665-1: Sterilization of health care products - moist heat - Part 1
- EN ISO 11135-1: Sterilization of health care products - ethylene oxide - Part 1
- EN 868-8: Packaging for final packaging of medical devices to be sterilized - Part 8
- EN 285: Large steam sterilizers
- DIN 58953-8: Sterilization - sterile goods care - Part 8: Logistics for sterile medical devices
- ANSI/AAMI ST46: Steam sterilization and sterility assurance in health care facilities
- ANSI/AAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities

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