

# Usage Advice

**MELAstore<sup>®</sup>-Box 100**

**MELAstore<sup>®</sup>-Box 200**

Sterile container



EN

---

Dear customer,

We thank you for your confidence demonstrated by the purchase of this MELAG product.

As an owner-run and operated family concern founded in 1951, we have a long history of successful specialization in hygiene products for practice-based use. Our focus on innovation, quality and the highest standards of operational reliability has established MELAG as the world's leading manufacturer in the instrument treatment and hygiene field.

You, our customer are justified in your demand for the best products, quality and reliability. Providing "**competence in hygiene**" and "**Quality – made in Germany**", we guarantee that these demands will be met. Our certified quality management system is subject to close monitoring: one instrument to this end is our annual multi-day audit conducted in accordance with ISO 13485. This guarantees that all MELAG products are manufactured and tested in accordance with strict quality criteria.

The MELAG management and team.



# Contents



General notes .....	4
About this manual .....	4
Safety .....	5
Chapter 1 - Product description .....	6
Intended use .....	6
Mode of operation .....	6
Views MELAstore-Box 100* .....	7
Chapter 2 – Working with the sterile container .....	8
First use .....	8
Set-up .....	8
Function checks .....	8
Operation .....	9
Chapter 3 – Cleaning and disinfection .....	12
Manual cleaning/disinfecting (recommended) .....	12
Mechanical cleaning/disinfecting .....	13
Chapter 4 – Maintenance and care .....	14
Maintenance .....	14
Care .....	14
Chapter 5 – Accessories .....	15

## General notes

Please read these instructions for the MELAstore-Box 100/200 carefully before commissioning the device. They include important safety information. The functionality and value-retention of this product depend primarily on the care accorded to it. Make sure to keep these instructions close to the product. They represent a component of the product.

## About this manual

### Symbols used

Symbol	Explanation
	Draws your attention to a situation, which if not avoided, can result in damage to the product.
	Draws your attention to important information.

### Formatting rules

Symbol	Explanation
see <a href="#">Chapter 2</a>	Reference to another text section or diagram within this manual.

# Safety

---



## WARNING

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

- Only combine MELAG products (e.g. MELAstore-Trays or MELAstore-Boxes) with each other.
- 

- ▶ Prior to use, check that the product is in good working order.
- ▶ To prevent damage caused by improper setup or operation, and in order not to compromise warranty and manufacturer liability:
  - Use the product only according to these instructions for use. Please observe the safety information and maintenance.
  - Never use damaged or faulty sterile containers. Replace any damaged components immediately with original spare parts.
  - If sterile container components are repaired in a way that could affect the sterile container's germproof qualities: Inspect the sterile container thoroughly before use.
- ▶ Ensure that only persons with the requisite training, expertise or experience will handle the sterile container and its accessories.
- ▶ Keep the instructions accessible for personnel.
- ▶ Follow general guidelines! Follow aseptic principles when handling contaminated items that have undergone or are to undergo sterilization.
- ▶ For more information please read the latest instructions for use by the sterile container manufacturer <http://www.bbraun.co.uk>.

# Chapter 1 - Product description

---

## Intended use

The sterile container is validated for steam sterilization in a sterilizer in accordance with DIN EN 13060, EN 285, ANSI/AAMI ST 46-2002 and ANSI/AAMI/ISO 17665-1. Medical devices can be sterilized, stored and transported in the sterile container. The sterile container can also be used for transporting medical devices back to the decontamination centre after use.

## Mode of operation

The sterile container is conform to DIN 58953-9 and EN ISO 11607-1 requirements. Sterile containers with perforated lids and closed container bottoms are validated for steam sterilization in a sterilizer in accordance with EN 285 and DIN EN 13060 in fractionated vacuum process.



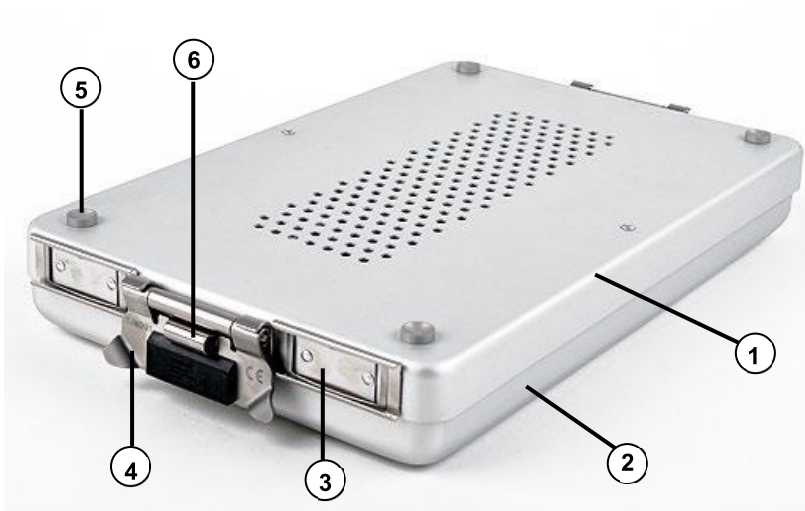
### PLEASE NOTE

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

---

## Views MELAstore-Box 100\*

### Front view



- (1) Lid
- (2) Bottom
- (3) Plate holder
- (4) Lid lock
- (5) stacking knobs
- (6) Indicator holder

Fig. 1: closed MELAstore-Box 100

### Interior view of the lid



- (7) Plastic latch
- (8) Filter holder
- (9) Filter housing
- (10) Latch nose
- (11) Lid seal

Fig. 2: Lid of the MELAstore-Box 100

\* Views are identical with MELAstore-Box 200

# Chapter 2 – Working with the sterile container

---

## First use

- ▶ Thoroughly clean the new sterile container prior to first use, see [Chapter 3 – Cleaning and disinfection](#) [page 12].
- ▶ After cleaning, use a suitable filter (see [Changing the filter in the lid](#) [page 8]).

## Set-up

### Removing the lid

- The lid can be removed for cleaning the sterile container.
- Open lid lock and remove the lid.

### Changing the filter in the lid

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

- Single-use paper filter: prior to each sterilization cycle
- PTFE permanent filter\*: after max. 1 000 sterilizations

\* For further information please consult the instructions for use of the permanent filter.

#### **Changing the filter**

1. To open filter holder press back plastic latch.
2. Remove filter holder once it is unlocked.
3. Replace filter and install filter holder under latch noses.
4. Push down filter holder so that it clicks into plastic latch.

## Function checks

Visually inspect all components of the sterile container before each use to ensure there is no damage, and check to ensure correct function:

- ▶ Metal parts are not deformed.
- ▶ Lid and bottom are not warped.
- ▶ Filter holder sits in full surface contact.
- ▶ Lid seals are fully intact (no cracks).
- ▶ Plastic parts are fully intact (no cracks).
- ▶ The permanent filter is undamaged.
- ▶ The disposable filter has been changed.
- ▶ The lock functions work properly (engages).
- ▶ The filter holder latch functions work properly (engages).
- ▶ The seal at filter holder is undamaged (no cracks).
- ▶ Use sterile containers only if they are in mint condition. Replace any damaged components immediately with original spare parts, or have the damaged components repaired.



## Operation

---



### WARNING

#### Risk of contamination of sterile materials!

- Never carry or lift the sterile container at the lid.
  - Transport the sterile container in such a way that mechanical damage will not occur.
- 

## Loading the sterile container

### *Please observe the maximum load:*

- Maximum loading: 2 kg per sterile container\*

\* Please note the loading instructions of sterilizer manufacturer.

### **Possible combinations of the sterile containers in MELAG steam sterilizers**

- 4x MELAstore-Box 100
- 2x MELAstore-Box 200 and 1x MELAstore-Tray 100
- and less

### **Permitted combinations of sterile container and Washing tray**

- 1x MELAstore-Box 100 and 1x MELAstore-Tray 100
- 1x MELAstore-Box 100 and 2x MELAstore-Tray 50
- 1x MELAstore-Box 200 and 1x MELAstore-Tray 100
- 1x MELAstore-Box 200 and 1x MELAstore-Tray 200
- 1x MELAstore-Box 200 and 2x MELAstore-Tray 50

### **Instruments**

- ▶ Store instruments in the washing tray with appropriate storage devices, with hollow items, dishes, plates, etc. placed at a downward angle.
- ▶ Load the sterile container in such a way that filter holders are not obstructed.
- ▶ Please observe the maximum loading height.
- ▶ Lock lid to bottom using lid lock.
- ▶ Ensure that lid lock clearly engages in detent spring.

## 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 airflow through the perforation fields in the bottom and lid.
  - Do not place foil packaging directly on the sterile container.
- 

- ▶ Follow the sterilizer manufacturer's recommendations.
- ▶ Always place heavy sterile containers at the bottom of the sterilizer.
- ▶ Always lift or transport the sterile container on the bottom.
- ▶ It is possible to staple the sterile container in the sterilizer on the stacking knobs.
- ▶ Transport stacks of sterile containers in such a way that the stacks do not topple over.

## Inserting the identification plate and lead seal

After loading the sterile container, include an identification plate if necessary.

- ▶ Slide the identification plate into the plate holder.

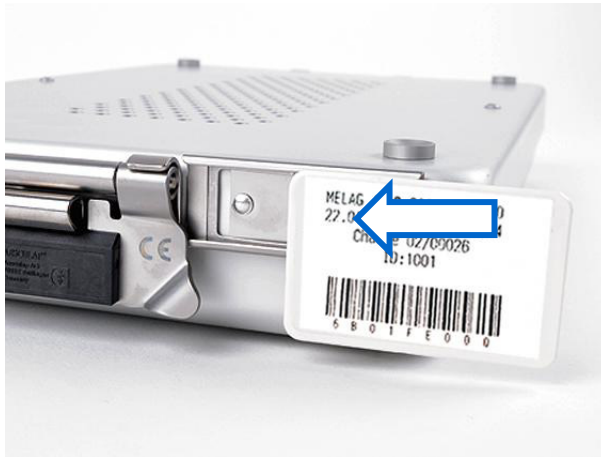


Fig. 3: Slide identification plate into the plate holder

- ▶ After sealing the sterile container, insert a lead seal at the indicator lock of the closed container.



Fig. 4: Insert a lead seal

## Sterilization



### WARNING

#### Risk of contamination!

- Sterilize the sterile container (anodized surface) only with approved and validated sterilization processes.
  - Sterilize expressly marked sterile container only with approved and validated sterilization processes.
- 
- ▶ Sterilize with steam, taking note of the following: Sterilization with steam must be carried out with a validated steam sterilization process (e.g. in a sterilizer in accordance with DIN EN 13060, EN 285, ANSI/AAMI ST 46-2002 and validated in accordance with ANSI/AAMI/ISO 17665-1).
  - ▶ If sterilizing several sterile containers: 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.

---

## Unloading the sterilizer

**CAUTION**

**Risk of burns due to a hot sterile container after sterilization!**

- Always wear protective gloves when unloading the sterilizer.
- 

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

**WARNING**

**Risk of contamination from improperly sterilized materials!**

- Prior to commissioning the sterile materials, check to ensure that the sterilization was successful.
- 

- ▶ Verify that the indicator color has changed (if available).
- ▶ Make sure that all parts of the sterile container, particularly the lid locks, are intact.
- ▶ Ensure that the sterile container lead seal on the sterile container is intact.

## Storing the sterile containers

**PLEASE NOTE**

**The sterile containers may be stored in stacks.**

- Store sterile containers in a dry, clean and protected place.
  - Observe the storage period and storage conditions as per DIN 58953-8 and DIN 58953-9, see Storage periods for sterile materials: extract from DIN 58953-9.
-

## Chapter 3 – Cleaning and disinfection



### WARNING

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

- Following the manufacturer's instructions, use cleaning and disinfecting agents which
  - ✓ ensure that cleaning and disinfecting agents are approved for use on aluminum, plastics and stainless steel and
  - ✓ do not attack softeners (e.g. in silicone).
- Observe specifications regarding concentration, temperature and exposure time.
- If drying with pressurized air, avoid damage to the permanent filter.

### Manual cleaning/disinfecting (recommended)

Comply with the manufacturer's specifications of the cleaning fluid and disinfectants when cleaning and disinfecting the sterilization container. Clean the sterilization container regularly and thoroughly both inside and out. The cleaning fluid used for this purpose must be pH-neutral (pH value 6-8). MELAG does not recommend automatic treatment in a washer-disinfector, as this could place the material of the sterilization container 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.

- ▶ 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.

**Table 2: Manual cleaning with disinfecting cleaning by wipe disinfection**

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Cleaning and disinfecting agents	
I	Cleaning	RT (cold)	-	-	D-W	-	
II	Drying	RT	-	-	-	-	
III	Wipe disinfection	-	>1	-	-	-	II Aldehyde-free surface disinfection
IV	Final rinse	RT (cold)	0.5	-	DI-W	not required	Remove cleaning and disinfecting agents without leaving any residue
V	Drying	RT	-	-	-	-	

D-W: Drinking water

DI-W: De-ionised (demineralized) water

RT: Room temperature

**Phase I**

- ▶ Wipe off gross debris prior to cleaning.

**Phase II**

- ▶ Dry the instrument with a lint-free cloth or medical compressed air.

**Phase III**

- ▶ Carry out wipe disinfection

**Phase IV**

- ▶ When using aldehyde-free disinfectants:
  - ✓ *After the specified exposure time (at least 1 min), rinse the disinfected surfaces under running DI water.*
- ▶ Drain any remaining water fully.

**Phase V**

- ▶ Dry the product with a lint-free cloth or in a heating cabinet.

## Mechanical cleaning/disinfecting

- ▶ The cleaning and disinfection device must be of tested and approved effectiveness. Follow the sterilizer manufacturer's recommendations.
- ▶ Do not use rinsing agents.
- ▶ Use appropriate insert racks for machine cleaning according to manufacturer's instructions.
- ▶ Final rinsing with the aid of de-ionised water (DI water).
- ▶ For more information please read the latest instructions for use by the sterile container manufacturer (<http://www.bbraun.co.uk>).

# Chapter 4 – Maintenance and care

---

## Maintenance

---



### PLEASE NOTE

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

---

- ▶ In case of visible damage, change the lid seal immediately.
- ▶ If the lid or bottom is damaged, send the sterile container to your stockist.

## Care

Lightly lubricate moving metal parts, e.g. latch or lock hinges, with appropriate maintenance oil for the respective sterilization process.

## Chapter 5 – Accessories

---

Article	Art. no.
MELAstore permanent filter 2 pcs.	01193
MELAstore single-use paper filters 100 pcs.	01194

Distributed by:

**MELAG Medizintechnik GmbH & Co. KG**

Geneststraße 6-10  
10829 Berlin  
Germany

Email: [info@melag.com](mailto:info@melag.com)

Web: [www.melag.com](http://www.melag.com)

**Manufacturer**

Aesculap AG  
Am Aesculap-Platz  
78532 Tuttlingen  
Germany

Subject to technical alterations

Your stockist

