

# KLS martin

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**MicroStop® – Sterilcontainer**

**MicroStop® – Sterile Container**

**MicroStop® – Contenedor Estéril**

**MicroStop® – Conteneur Stérile**

**MicroStop® – Contenitore Sterile**

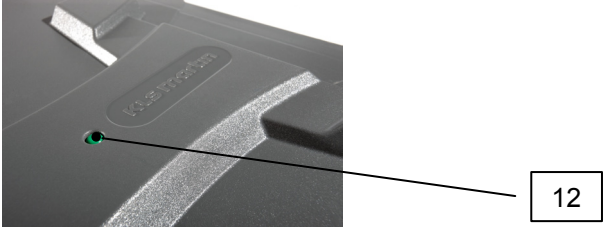
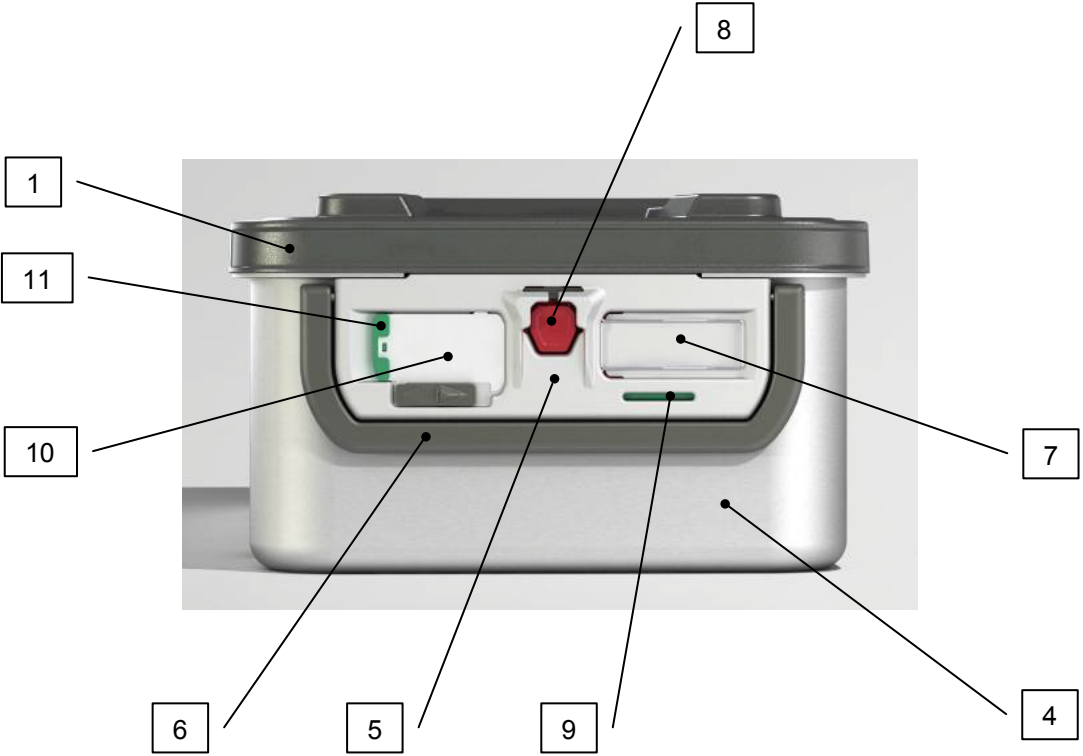
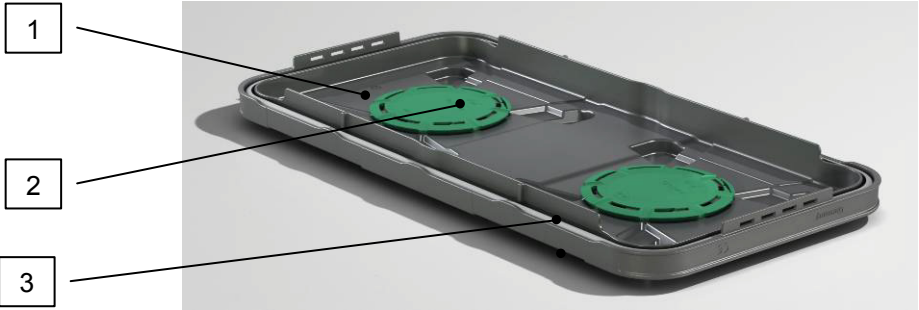
**MicroStop® – Sterilcontaineren**

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**MicroStop® – Steriele container**



## Legend relating to illustrations on fold-out page

### Ref.No. Description

- |    |  |
|----|--|
| 1  | Container cover                          |
| 2  | <i>MicroStop</i> ® microbial barrier     |
| 3  | Cover seal and centering elements        |
| 4  | Container box                            |
| 5  | Handle plate                             |
| 6  | Carrying handles                         |
| 7  | Log label accommodation field            |
| 8  | Opening button with integrated seal slot |
| 9  | Red/green tamper evident indicator       |
| 10 | Coding label                             |
| 11 | Color tab                                |
| 12 | <i>Greencheck</i> ® pin                  |

## 1 Product Liability and Warranty

### 1.1 General Information

We are pleased that you decided to buy a KLS Martin product. This product bears the CE-mark, which means that it satisfies the essential requirements set out in the EU Directive 93/42/EEC relating to medical devices.

Here is the detailed manufacturer's information:

Correspondence (for US and Canadian markets only):

KLS Martin L.P.

P.O. Box 50249

Jacksonville, Florida 32250-0249

Shipping:

KLS Martin L.P.

11239 St. Johns Industrial Parkway

Jacksonville, Florida 32246

E-mail: [info@klsmartin.com](mailto:info@klsmartin.com) • Web site: [www.klsmartin.com](http://www.klsmartin.com)

Correspondence for all other markets:

Gebrüder Martin GmbH & Co. KG,  
a company of the KLS Martin Group  
Ludwigstaler Straße 132  
78532 Tuttlingen  
Germany

### 1.2 Warranty

Our Standard Terms and Conditions of Sale effective at the time shall apply. Agreements diverging from these Standard Terms and Conditions do not restrict the legal rights of the buyer. Any warranty exceeding the above provisions shall require a contractual form and shall exclude component-related vandalism and consumables. Improper interventions or alterations performed by third parties during the period of limitation shall void any and all warranty claims. Unauthorized actions performed on the product shall invalidate any liability claims against Gebrüder Martin.

## 2 Product Overview

The product is illustrated on the fold-out page (cover page) of these Instructions for Use. For a description of the various features, see opposite page.

## 3 Intended Purpose

The KLS Martin *MicroStop*® Sterile Container is to be used for storing, sterilizing and transporting sterile supplies and placing them ready for use under sterile conditions. All models and their components fully meet the requirements of the relevant international and national standards, specifically ISO 11607-1:2009 and ISO 11607-2:2006, EN 868-8:2009 and DIN 58953-9:2010.

### 3.1 Sterilization

The containers are suitable for steam sterilization in Pulsing Vacuum (Pre-Vac) sterilizers only. It is essential, however, to use a validated steam sterilization process (e.g. a sterilizer complying with EN 285:2009, validated in accordance with ISO 17665-1:2006 requirements). The use of other sterilization methods requires approval from Gebrüder Martin.

**Warning:** The *MicroStop*® Sterile Container is not designed to be used in hot air, gravity, circulation, formaldehyde, ethylene, oxide, plasma, STERRAD (Hydrogen Peroxide Gas Plasma) or peroxide sterilization systems.

## 4 Container Design and Functions

### 4.1 *MicroStop*® microbial barrier

The *MicroStop*® microbial barrier consists of the system integrated on the underside of the cover (1) and one or two *MicroStop*® disks (2). The *MicroStop*® disk (2) is locked in position before sterilization by rotating it clockwise as far as the stop (bayonet catch) on the underside of the cover (1). Rotating it counterclockwise (unlocking the bayonet catch) allows the disk (2) to be removed for routine cleaning and checks.

### 4.2 Visual inspection of the microbial barrier from outside

Once the cover has been locked in place, the *Greencheck*® pin (12) attached to the green *MicroStop*® disk allows users to verify and recognize at any time whether the microbial barrier has been properly installed or not.

### 4.3 Cover seal

The inner edge of the cover features an all-around silicone gasket (3) with two centering elements. This ensures a tight fit and total impermeability to germs. If required, the gasket (3) with its centering elements can be easily replaced, thanks to the positive fit. To do this correctly, please observe the special "Instructions for Replacing the Container Seal" supplied with the product! The gasket has been installed in such a way that it is easily accessible for cleaning.

### 4.4 Locking & unlocking the container

**Closing the container:** Place the cover (1) onto the container (4) and press in place until you can feel and hear the cover lock in place. To ease the process, we recommend placing the container (4) on a solid level surface.

**Opening the container:** To open the container, simultaneously press the red opening buttons provided on the front sides of the container. If seals were attached in addition, these must be removed first. To remove the cover, always operate both buttons together, then lift it off horizontally. The locking mechanism is maintenance-free.

**Opening the container:** By pressing both of the blue opening buttons (8) or (8a) at the same time – after removing the tamper seals first in the case of (8a) –, the cover will release from the container. The locking mechanism is designed to be maintenance-free.

### 4.5 Tamper evident indicator (9)

The container's handle plate (5) features an integrated **tamper evident indicator** (9) which alerts the user (in accordance with EN 868-8:2009, 4.2.3) if the container has been accidentally or willfully opened after it has cooled down.

The pertinent standard requires a cooling down phase of 30 minutes outside of the sterilizer (see DIN 58953-9:2010, "Sterilization – Sterile supply – Part 9: Handling of sterilization containers", Section 5.3).

Provided that the cover has been applied correctly, the tamper evident indicator (9) turns from red to green during the sterilization process as a result of the heat generated. As soon as the container is opened after the cooling down phase, however, the tamper evident indicator (9) turns red again.

### 4.6 Seal slot

Slots are provided in the upper area of the opening buttons. This allows users to install seals (item no. 55-996-82-04 or 55-996-83-04) in addition to the tamper evident indicator.

Note:

As the tamper evident indicator has been designed to visualize any unauthorized opening of the container after sterilization, the additional use of seals is not mandatory.

**4.7 Carrying handles (6)**

The container features two wide carrying handles (6) whose carrying capacity complies with the requirements set out in the European standard EN 868-8:2009, Appendix C.

**4.8 Coding labels and color tabs**

A panel designed for attaching a coding label is integrated into the handle plate on both front sides of the container. Laser-lettered coding labels with customized information concerning tray contents and destination are available from Gebrüder Martin on request. To fix the coding label in place, simply insert the pin provided on the upper right of the label into the corresponding cutout of the handle plate. Thereafter, operate the spring mechanism on the handle plate once in full to lock the label securely in place. Removing the label is also done by operating the spring mechanism. Tabs are available in nine different colors to allocate labels to specific medical fields. These tabs are simply clicked into the coding labels.

**4.9 Log cards or labels**

In addition, the handle plates (5) feature a section (7) with a retaining spring intended for accommodating universal log labels.

**5 Initial Use**

**The container must be thoroughly cleaned before loading it for the first sterilization cycle and must be cleaned prior to loading and reuse (see Section 10, "Disinfecting, Cleaning and Care").** Note, however, that the cover (1) should never come in contact with ACETONE/BENZINE! To assemble the container, follow the instructions given in Section 4, "Container Design and Functions", then carry out a functional check in accordance with Section 6.1, "Functional check prior to charging the container".

**6 Loading the Container**

When loading the container, always maintain a clearance of at least 10 mm between the container load and the *MicroStop*® barrier (2) to ensure a uniform distribution of the in-flowing steam.

**6.1 Functional check prior to charging the container**

Prior to using the container, all container components must be visually inspected for potential defects. Any damaged components found must be repaired or replaced. The tamper evident indicator must be red at this stage. The cover seal must be free from visible defects or must be replaced. Only clean container components and assemblies may be used.

**6.2 Loading the container with linen or other textiles**

When loading the container with textiles, be sure to pile the folded items (max. 6 kg) upright into the container. Do not overfill! It should always be easily possible to slide the stretched hand into the pile. In accordance with the German standard DIN 58953-9:2010, we also recommend wrapping the items to be sterilized with a suitable, adequately sized cloth inside the container. This ensures easy handling of the sterile supplies and contamination-free provision for use later.

**6.3 Loading the container with instruments**

We recommend using sterilization trays (as per DIN 58952-3:1977) when sterilizing instruments in the container.

**Note:** Thanks to the design and shape of the KLS Martin container box, **no additional internal wrapping** is required for the sterile removal of the instrument tray after opening the container in the OR.

**Note:** For ergonomic reasons and in order to avoid excessive condensation, the container load should not exceed 10 kg.

**7 Loading and Unloading the Sterilizer**

The loading instructions provided by the manufacturer of the sterilizer must always be duly observed. We recommend a "mixed load" that includes both textiles and instruments. Heavy containers should always be placed in the bottom of the sterilizing chamber. *MicroStop*® containers can be stacked both during sterilization and storage. During the sterilization process, however, a clearance of at least 10 mm must be maintained all around each of the containers (vis-à-vis other containers as well as sterilizer walls or equipment). When moving containers in the course of loading or unloading the sterilizer, always use the carrying handles (6). **Do not use the cover for lifting or carrying the container!**

**Warning:** Never wrap or cover the container inside the sterilizer!

**8 Storing Sterile-Supply Containers**

The containers must be stored so that they are protected against dust, moisture and damage. The storage life depends on local storage conditions and cannot be specified universally. Therefore, the Hygiene Board must determine the acceptable storage period. The responsibility for storage conditions and periods always lies with the hospital management or the medical director. Sterile containers must be kept separate from any goods that represent a potential danger. Therefore, it is advisable to store them in a separate room (i.e. physical and/or organizational separation).

*MicroStop*® sterile containers were tested under worst case conditions for a storage life of 6 months. The report can be requested from the manufacturer.

**Note:** Loss of the quality of seal on the sterile packaging is generally event-related and not time-related.

**9 Placing the Sterile Supplies Ready for Use**

Prior to opening the container and removing sterilized items, visually check the color of the tamper evident indicators, which show GREEN after proper sterilization. A RED indicator signals that the container has been opened in violation of safety rules. It must therefore be considered unsterile. Similarly, ensure that the *Greencheck*® pins (12) of the *MicroStop*® disks are visible in the corresponding openings in the cover from the outside. If this is not the case, the *MicroStop*® disks have not been installed correctly and the container contents must be considered unsterile. If sealed containers are used, verify that the seals are still correctly in place and fully intact. Before opening the container, destroy and remove the seals according to instructions. Only then can the opening buttons be used as intended.

**Note:** As the tamper evident indicator has been designed to visualize any unauthorized opening of the container after sterilization, the additional use of seals is not mandatory.

**10 Disinfecting, Cleaning and Care****10.1 General information**

The parameters for cleaning and disinfecting the container are to be determined by the operator/user (e.g. as part of the hygiene plan). The chosen treatment agents must be compatible with the container component materials and also effective both hygienically and microbiologically. A thorough final rinse must ensure that no cleaning and care agent residues are left on any of the components of the container.

The following sections provide information on manual and mechanical cleaning and disinfecting options, focusing on material compatibility and value retention.

**Note:** The cover (1) and container box (4) must be separated for cleaning. The *MicroStop*® disk (2) can be removed easily for a regular visual check.

**10.2 Materials used**

Container box (4) and handle plate (5):

The container box (4) and handle plate (5) are made of aluminum and feature a protective anodized coating that makes the surface more abrasion-resistant, thus enhancing its resistance to wear. However, while anodized surfaces are resistant to neutral-pH cleaners, they are susceptible to destruction by chemical attack, particularly when alkaline agents and acid neutralizers are used in machine based processing. Therefore, the container (4) may only be treated with neutral-pH agents or with alkaline agents explicitly permitted for cleaning anodized aluminum surfaces. Be sure to observe the manufacturers' instructions relating to both your automatic cleaning apparatus and the cleaning agents used.

**Container cover (1) and carrying handles (6):**

The container cover (1), including the *MicroStop*® disk (2), and the carrying handles (6) are made of a special high-performance plastic suitable for sterilization. The cover (1) can be treated with any program that is generally suitable for cleaning aluminum products. Thermal disinfection up to 95°C (203°F) is possible as well, posing no problem.

**WARNING:** The container cover and the *MicroStop*® disk should never be treated with ACETONE/BENZINE! In addition, be sure to use cleaning agents only in concentrations that do not exceed the maximum specified by the manufacturer in each case (this applies to both manual and machine cleaning processes). Note that ACETONE/BENZINE as well as excessive cleaner concentrations cause stress corrosion cracking, thus destroying the material! For the same reason, no disinfectants containing glucoprotamine should be used for disinfecting the *MicroStop*® container cover because such agents would attack the silicone gasket, thus reducing its life or even destroying it completely.

**10.3 Manual cleaning and disinfection**

All accessible components can be cleaned with neutral, surfactant-based cleaning agents (mild dishwashing liquids; neutral cleaning agents). For disinfecting, pH-neutral disinfectants may be used. The final rinsing may only be carried out using demineralized water. The use of additional drying agents (rinsing agents) is not permitted. Do not use metal brushes or scouring agents for cleaning.

**10.4 Machine cleaning and disinfection**

For machine-based cleaning processes, use only pH-neutral cleaning agents which the respective manufacturer has expressly declared suitable for cleaning aluminium products. To keep the aluminium surfaces protected from damage, no acid neutralizers should be added. The final rinsing may only be carried out using demineralized water. The use of additional drying agents (rinsing agents) is not permitted. Be sure to observe also the instructions provided by the manufacturer of your automatic cleaning apparatus (W/D) as well as those provided by the manufacturer of the products used. Moreover, it is essential to use only cleaning plants that are suitable for cleaning containers, allowing safe container storage inside the washing baskets and providing adequately arranged spray nozzles or arms.

**10.5 Removing residues**

Stubborn container residues or dirt that cannot be removed during the usual cleaning process (such as adhesive labels, indicator strips, lettering) can be treated either with KLS Martin's special cleaner for anodized surfaces (item/order number 55-999-89-04) or with similar commercial products that may be used for this purpose. Residues found on the cover or handle plates must be removed with commercially available cleaners such as rinsing liquids (mild dishwashing liquids), neutral cleaning agents or alcohol. Following this special treatment, both the container and the cover should either be thoroughly rinsed or subjected to routine cleaning.

**11 Maintenance and Repair**

The manufacturer will only assume responsibility for the safety and reliability of the Sterile Containers if repairs or modifications are carried out by authorized persons and if the containers are used as intended and in accordance with these Instructions for Use. Whenever parts affecting germ impermeability are repaired, a careful visual inspection must be carried out before putting the container back in service. Note that only genuine KLS Martin spare parts may be used for repair. Use of third-party spare parts shall void the warranty.

**NOTE:** The container may be repaired only by KLS Martin or by a person or firm that has been specially authorized by KLS Martin to carry out such work. If the repair is carried out by a person or firm duly authorized by KLS Martin, the operator of the container is required to obtain from the repairer a certificate with details on the nature and scope of the work done. This certificate must show the name and address of the firm and must be dated and signed. Moreover, the repaired container or container parts must be marked with the repairer's ID label in such a case (i.e. when-ever the repair has not been performed by the manufacturer itself).

**11.1 Replacing the cover seal**

The gasket with the two centering elements can be replaced by the user if required. In such a case, proceed as described in the "Instructions for Replacing the Container Seal" supplied with the product.

**11.2 Maintenance schedule**

Depending on the specific conditions of use, and following EN 868-8:2009 requirements, we recommend taking the following maintenance steps, either on a yearly basis or at least after 500 sterilization cycles:

Component	Check for	How?	Remedy
Seal (gasket)	Elasticity	Following maximum compression, the gasket must recover its original shape and position	Replace gasket (re-install centering elements)
	Integrity	Visual inspection for sealing lip damage	Replace gasket (re-install centering elements)
Cover	Integrity	Visual inspection for damage	Replace cover
<i>MicroStop</i> ® receptacle	Integrity	Visual inspection of shape and lock	Replace cover
<i>MicroStop</i> ® disk	Integrity	Visual inspection of shape and lock	Replace
Container	Integrity	Visual inspection of shape and cover fit/interlock	Repair or replace
Sealing face	Integrity	Visual inspection for smoothness and potential damage	Replace