KLS martin GROUP

Implementation of a Container System

Prearrangements and handling in the process

How to?!

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Index

1. Cleaning and Disinfection

1.1 Introduction

CSSD – Central Sterile Supply Department

This recommendation paper is aimed at CSSD leader, sales persons, product specialists and distributor as well. In this manual the most important points are described and explained concerning an implementation, to ensure proper long-term functionality of the container system.

When using sterilization containers as a packaging system, they must be cleaned and disinfected before reuse. The type of cleaning and disinfection is treated differently in different countries. So here general hints are given that can be implemented country-specific in a modified way or just in part.

Before thinking about introducing a container system, it is to clarify the advantages of such a procedure:

- Easy inventory due to stackability contrary to flexible packaging
- Stable and resistant
- Good logistical coding possibilities
- Using colors to be assigned to various disciplines
- Secure closure
- Low space requirement for packing

1.2 Chemicals used in the process

WD – Washers & Disinfectors

It should be noted that containers cannot be processed in the regular instrument programs. This is mainly due to the aluminum components of modern container systems. It is therefore necessary to ensure that a separate container washing program is implemented by the manufacturer of the WD. The following points for process chemicals must be observed.

Mildly alkaline solution
up to max. pH = 10.5.

The process chemicals are primarily to verify for the availability or compatibility with anodized aluminum and plastics. The cleaning can only be performed in a mildly alkaline solution up to max. pH = 10.5. Optimal is a neutral pH. An exemplary list of suitable chemical products for processing of containers can be found in Table 1.

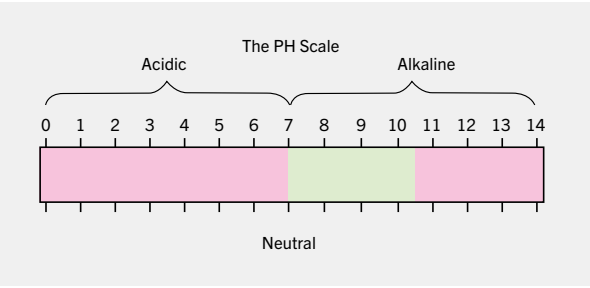


Fig. 1: pH scale for reprocessing of containers

	Suitable for container (anodized aluminum)
Dr. Weigert	
Neodisher FA	o
Neodisher Mediclean Forte	x
Neodisher Septoclean	x
Neodisher DuoClean	o
Neodisher MediClean	x
Neodisher Alka 300	o
Neodisher MA	(x)
Neodisher Oxivario	o
Neodisher Orthovario	o
Schülke & Mayer	
Thermosept RKF	o
Thermosept RKN –Zym-	x
Thermosept Alka Clean	x
Thermosept Alka Clean Forte	x
Ecolab	
Sekumatic MultiClean	x
Sekumatic FRE	x
Sekumatic ProClean	(x)
Sekumatic PR	o
Sekumatic FR	o
Anios Laboratoires	
Actanios LDI	o
Anyosme DLM Maxi	x
Anios DLH	(x)
Anios NDT	x

x = suitable o = not suitable (x) = to be tested

Table 1: Usability of well-known chemicals

Demineralized water (free of ingredients)

Fleet carrying effects – Carryover of cleaning residues in various cleaning steps

Basically it should be done a sufficient final rinse with deionized water in all procedures. In case of non-thermal but chemical disinfection (usually in the manual process) it is essential to carry out a final rinse after disinfection to avoid both deposits and a fleet carrying effect to the WD and/or sterilizer, preventing possible damage to the container. It is also prohibited to use any rinsing agents in the process. In addition, any media, such as acetone, benzene and/or acid neutralizing agents for the reprocessing shall (primarily mechanical) not be applied. These chemicals can lead to functional impairment and permanent damage to the container systems.

1.3 Manual cleaning and disinfection

Lid and bottom are reprocessed separately.

All accessible components can be cleaned with neutral 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. Do not use metal brushes or scouring agents for cleaning. After this procedure, all parts should be checked for visible dirt. If there is any residual dirt, repeat the process.

Phase	Step	Temperature	Water quality	Chemicals		Note
1	**Cleaning**	Room temperature (cold)	Drinking water	--		Remove gross contamination
2	**Drying**	Room temperature	--	--		Lint-free cloth or medical-grade compressed air
3	**Wiping Disinfection**	--	--	Alcohol 70%	Aldehyde-free surface disinfectant	
4	**Final Rinsing**	Room temperature (cold)	Fully demineralized water	Not required	Fully remove all chemicals	Remove chemicals using demineralized water
5	**Drying**	Room temperature	--	--		Lint-free cloth

Picture 2: recommendation for manual cleaning and disinfection

1.4 Mechanical cleaning and disinfection

Lid and bottom are processed separately. An automatic treatment is always preferable to the manual, as it is validatable and correspondingly easier to control and reproduce.

For machine-based cleaning processes, use only pH-neutral cleaning agents which the respective manufacturer has expressly declared suitable for cleaning aluminum products.* To protect the aluminum surfaces from damage, no acidic neutralizers should be added. The final rinsing may be carried out using demineralized water only. Be sure to observe also the instructions provided by the manufacturer of your automatic cleaning machine as well as those provided by the manufacturer of the products used. Moreover, it is essential to use only cleaning machines that are suitable for cleaning containers (WD/CW), allowing safe placement inside the washing baskets and providing adequately arranged spray nozzles or arms.

* see table 5

CW – Cart Washer

Picture 3: Loading with MicroStop®

Picture 4: loading example

For more information visit http://kls-martin.com/phnet/

The critical sizes when reprocessing automatically are the dimensions of the container lid.

1.5 Requirements for loading carrier WD / CW

As mentioned in Section 1.4 a proper loading of the machines is the basic requirement of successful cleaning and disinfection. It is crucial that a sufficient flow of fluids is ensured by the proper placement. The critical sizes when reprocessing automatically are the dimen-s-ions of the container lid. Table 2 shows the dimensions of the lid of each container variation. Table 3 illustrates the suitability of common loading carrier for both container series.

	Length	Width	Height
MicroStop®			
60 x 30 cm	57.66 cm	29.06 cm	4.9 cm
47 x 30 cm	45.96 cm	29.06 cm	4.9 cm
30 x 30 cm	27.69 cm	29.06 cm	4.9 cm
marSafe®			
60 x 30 cm	57.66 cm	29.06 cm	2.8 cm
47 x 30 cm	45.96 cm	29.06 cm	2.8 cm
30 x 30 cm	27.69 cm	29.06 cm	2.8 cm

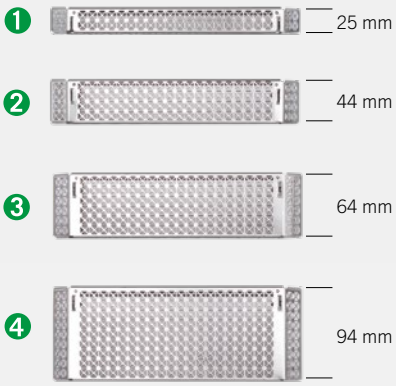
	MicroStop®	marSafe®
Miele		
910/4	x	x
913/3	x	x
E 912/2	x	x
E 911/3	x	x
Getinge		
46-Serie	only partially	x
Belimed		
870030	x	x
870008	x	x
870006	x	x
870010	x	x
870004	x	x

Table 3: Usability of common loading carrier

1.6 Capacity with automatic cleaning and disinfection

This point is particularly important to consider when a general introduction of container packaging is done. Should so far only flexible packaging have been used, a cleaning and disinfection of packaging material was not previously required. With the introduction of containers it is important to note that this is to undergo a processing after each use. Given that automatic methods are to be preferred, it is critically to verify whether the requested amount of containers can be mechanically processed with the available capacities.

If this is not possible with the existing capacity, a capacity expansion in the form of additional WD or a CW is required. Alternatively, the option of manual processing in accordance with 1.3 shall be checked.



The container may be loaded to a maximum of 5 mm below the rim of the bottom.

Packaging system is the combination of sterile barrier system and protective packaging.

The prescribed loading maximum according to DIN EN 868:8 must be observed.

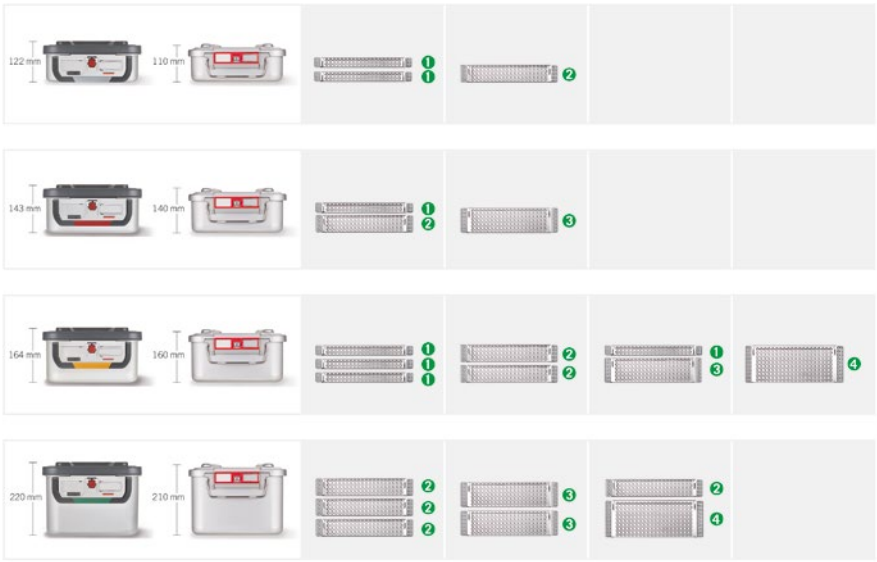
2. Packing area

2.1 Requirements for packaging procedures

2.1.1 Redesign

When changing from soft wrapped instrument sets to container packaging as the primary packaging a reorganization of the packaging lists usually is necessary. This is mainly due to the loading measurements, which defines a container. In contrast to flexible packaging, it is crucial for the success of sterilization to comply with these loads. Appropriate loading configurations are provided in each product brochure.

marSafe® **microStop®**



Picture 5: Loading configurations of marSafe® and MicroStop®

Basically, the container may be loaded to a maximum of 5 mm below the rim of the bottom. An additional placing of towels is not allowed. This leads to considerable drying difficulties and possibly deformations of the container bottoms.

With the introduction of a container system, it is not necessary from a legal point of view to work with an inner wrapping for instrument sets, since a container system is already a packaging system by definition according to ISO 11607:1, i.e. the combination of sterile barrier system and protective packaging.

In addition, the prescribed loading maximum according to DIN EN 868:8 (see Table 4) must be observed. This limitation is primarily to the employee protection. Secondly, it prevents excessive condensate. Heavy loadings have to be packed in 2 sets/containers.

Size of container	Maximum loading weight
60 x 30 (1/1)	10 kg
47 x 30 (3/4)	7.5 kg
30 x 30 (1/2)	5 kg

Table 4: loading maximum according to EN 868:8

To increase security, it is recommended to use additional storage aids of silicone.

It is recommended a hanging storage of packaging material.

2.1.2 Adaption

With the introduction of MicroStop® containers a correct loading height must be maintained (see 2.1.1). Furthermore, it is recommended to refrain from inner wrapping, since this is considerably more difficult in drying by the high proportion of plastics.

In addition, paragraph 2.1.1 should be noted.

2.1.3 Mesh trays/instrument baskets

If at the time of changing from flexible packaging to container packaging no baskets or mesh trays were used for the storage of instruments, so this is definitely recommended. In the best case, the trays are from the same manufacturer as the container system. This is due to the perfect composition and conception of each other.

Baskets are designed to protect the instruments and in addition they facilitate the aseptic removal of the products from the container interior. To increase security, it is recommended to use additional storage aids of silicone. These provide a secure holding of the instruments in the basket and contribute to their longevity. In particular, the protection against damage is a major advantage.

2.2 Changed storing capacities in packing area

When changing from soft packaging to the container, it should be noted that this increases the storage capacity in the packing area significantly. Before the introduction of containers the soft packaging had only to be stored temporarily. Since this for bulky goods usually remains partially intact, altered space for the temporary storage of cleaned and disinfected containers is necessary. The following figures show examples of situations in the packing areas of CSSD. The changing of space requirements must be observed and must not be neglected. Therefore the hanging storage of packaging material is recommended, as shown in Figure 7.

Picture 6: table storing of wrapping materials

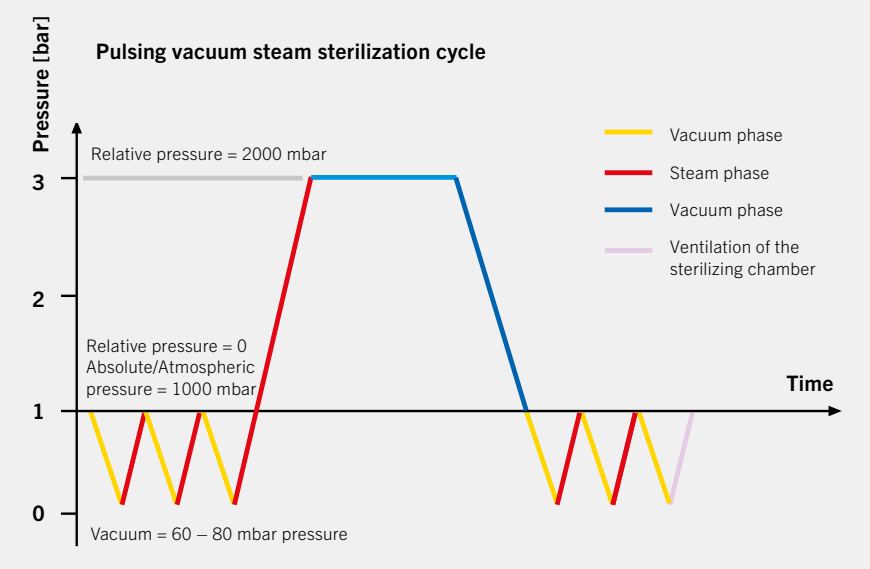
Picture 7: hanging storage of wrapping materials

3. Sterilization

3.1 Testing the suitability of sterilization procedures

The sterilization has to take place in a validated steam sterilization procedure.

Both container systems are only suitable for steam sterilization. The following should be noted: The sterilization has to take place in a validated steam sterilization procedure (e.g. in a sterilizer according to EN 285:2009 and validated according to ISO 17665-1:2006). This process is called pre-vacuum cycle. The following figure shows the schematic flow with fractionated drying.



Picture 8: process flow of a pre-vacuum steam sterilization

Special marSafe®:

Sterilization containers with perforated lid and perforated bottom are also suitable for steam sterilization in a sterilizer according to EN 285 with gravity cycle.

The steam sterilization according to EN 285 has established itself as a very safe and reliable sterilization method worldwide and is therefore the method of choice in relation to temperature and moisture insensitive sterilizing materials. Therefore, there is no need to steam-sterilizable medical devices being sterilized with alternative sterilization methods, such as low-temperature plasma sterilization (H_2O_2), formaldehyde and ethylene oxide. Since the plasma sterilization is discussed in terms of efficacy in lumens and cavities in professional circles controversial, the KLS Martin Group does not perform validation of sterilization by steam-sterilizable medical devices in this procedure. However, every operator of a CSSD is free to check a sterilization validation with the items to be sterilized for an alternative sterilization procedure, including the packaging itself.

3.2 Requirements of measurements needed for implementation

3.2.1 Thermal measurements

With the launch of a container system or when switching to a different system, a so-called OQ (operational qualification) is required:

"A method for obtaining and recording the evidence that the equipment, as it is installed and if it is used as intended, works properly according to given criteria, and thus supplying products that meet their specifications."

This means that it is checked whether the necessary temperature requirements according to EN ISO 17665 are achieved or not.

The container interior and the sterilization chambers are equipped with data loggers. The aim of this measure is to carry out a thermoelectric review of the loading. This means that it is checked whether the necessary temperature requirements according to EN ISO 17665 are achieved or not. The so-called reference load (full load sterilization chamber) and the partial load is tested. This measurement, validation of containers in the process, is mandatory in accordance with the above standard. Usually this can be done by sterilizer manufacturers or independent third parties and must be made for each used packaging system. If the test results are within the tolerance ranges, a proper functionality of the container in this process can be assumed. The following table shows an example of a measurement in a CSSD.

Criteria	Set points	Measured values	Review
Sterilization temperature belt < 3 °C	≤ 3 K	≤ 3 K	ok
Temperature fluctuation	± 1 K	0,30 K	ok
Temperature deviation	≤ 2 K	0,72 K	ok
Compensation time	≤ 15s	10 s	ok
Sterilizing time	≥ 300s	313 s	ok

Table 5: example measurement according to EN ISO 17665

In principle, all types of packaging must be recorded for OQ. The table below shows this for an example CSSD:

No.	Description of used packaging systems	Manufacturer	Conformity to standards
1	Aluminum container with plastic lid, lifetime filter (MicroStop®), inner packaging	KLS Martin Group	yes
2	Aluminum container with plastic lid, lifetime filter (MicroStop®), small set, inner packaging	KLS Martin Group	yes
3	Aluminum container with aluminum lid, single use paper filter, inner packaging – marSafe®	KLS Martin Group	yes
4	Aluminum container with aluminum lid, single use paper filter, inner packaging	KLS Martin Group	yes
5	Aluminum container with aluminum lid, single use paper filter, inner packaging	Aesculap	yes
6	wrapped, 2-times	VP	yes
7	Paper/film pouches 1-time	VP	yes
8	Paper/film pouches 2-times	VP	yes

Table 6: example listing of different packaging materials in a CSSD

According to EN 285 the maximum change in pressure of 10 bar/min is allowed.

Still cool down for 30 minutes outside of the sterilizing chamber.

3.2.2 Measurement of pressure gradients

For the implementation of sterilization containers a pressure measuring of the sterilizers is also recommended. This may be conducted in the same course with the electrothermal investigation. Furthermore, it is also possible to have this done by the manufacturer of the container system.

In this measurement, the so-called pressure gradients are examined. These describe the relative pressure change in a fixed time. According to EN 285 the maximum change in pressure of 10 bar/min is allowed. For this measurement, data logger (see 3.2.1) are introduced into an empty lot and a full load.

This measurement is not required for an implementation, but it is highly recommended, as these forces can lead to deformation of container bottoms. If the pressure gradients are considerably greater than the allowable value, it is possible that the bottom will bend inwards.

3.2.3 Testing the dryness of loadings

Especially in the change to hybrid containers with plastic lids, a review of the dryness of the load is required. This should be carried out by two different methods. It is important that in principle the sterile goods can still cool down for 30 minutes outside of the sterilizing chamber before the batch will be released and stored.

Firstly, a visual inspection of the sterilization batch is required, whereas it can be determined whether the loading is dry or not. Secondly, the batch can be weighed before and after. According to ISO 17665, a maximum raise of 0.2% of the initial weight is permitted.

Basically, the more plastics in a sterilization batch, the more residual moisture. This applies plastic lids, storage trays, instrument handles made of plastic (orthopedic sets) and non-woven packaging (including in the container).

In order to ensure the dryness of the load already in the implementation of the container system, there are different recommendations:

- Observe the maximum load (see 2.1.1)
- Prolonging the general drying time in the sterilizing program
- Minimum 30 minutes to cool down outside of the sterilizer
- Reduction of the plastic content in the loading
- Avoiding nonwoven packaging in containers
- Avoidance of cold shock, by deposition on cold surfaces after sterilization
- Introduction of fractionated drying in the sterilizer
- 100% saturated steam quality

Those recommendations are to be used mainly for hybrid containers with plastic lid.
If there are no efforts in the dryness of the sterilized items, even after having checked all recommendations above, we recommend to use the container system with aluminum lid marSafe®.

3.3 Transportation

3.3.1 Storage capacities in CSSD/OR

With the introduction of containers a different type of storage is necessary in contrast to flexible packaging. As a rule, less storage capacity is linked with the introduction of containers in the process because they can be stacked.

When switching to other types of containers, it has to be checked whether the new container systems fit into the respective storage systems based on other dimensions. This should be considered especially when changing from aluminum containers on hybrid container with plastic lid. In addition, the storing conditions have to be checked. The maximum permitted stacking height is 55 cm. It is not allowed to mix between wrapped items/flexible packagings and container systems. Flexible packagings have to be stored separately to the container systems.

3.3.2 Transporting systems to OR/CSSD

The transport to / from the OR should take place in closed trolleys. These protect the sterilized goods additionally from external influences. In addition, it provides optimum disposal.

3.3.3 Disposal to CSSD

By a maximum of 6 hours after application.

When disposing used medical devices, the return to the CSSD, there are two types of procedures. It must be noted that the return should take place as soon as possible after application. In practice, it is also spoken by a maximum of 6 hours after application. This is mainly due to the increased risk of corrosion of the instruments through to long-term reaction of proteins and other waste materials.

The now common variant is the dry disposal.

The now common variant is the **dry disposal.** This is recommended especially in the presence of automatic cleaning equipment. The instruments are supplied at no extra pre- and / or disinfection in the CSSD. This protects the instruments and significantly simplifies the handling of the employees on the unclean area. Because using so-called Natrium-chloride solutions or disinfectants proteins and proteins are fixed on the surfaces. This complicates the cleaning and disinfection afterwards and significantly increases the risk of corrosion. Such an approach is also called a **wet disposal.** However, it should be avoided in any case. An exception is the washing of rough contamination, e.g. in minimally invasive instruments or orthopedic sets (e.g. acetabular milling).

The coarse dirt must still be removed before disposal in the operating room.

4. Requirements for training

With the introduction of container packaging or when switching to other types of containers a user training is necessary. It is important to mention that both the CSSD staff as well as the surgical staff must be trained on the proper use of containers.

The minimum requirements for the training contents are given in the Appendix 5.2. This applies as a template and own points can be added.

5. Appendix lists

5.1 Guidance

	Met	Not met	Remark	signature
Compatibility of process chemicals				
Manual cleaning and disinfection				
Automated cleaning and disinfection				
Compatibility of loading carriers WD/CW				
Capacities for automated reprocessing				
Packaging structures checked and adapted if necessary				
Storage capacity in the packing area				
Suitability of sterilization methods checked				
Performed thermal measurements				
Measurement of pressure gradients performed				
Dryness of loadings				
Storage capacity in CSSD/OR				
Disposal				
Necessary documents (e.g. mannuals) available?				

5.2 Training matrix

5.2.1 Training matrix CSSD

	Trained	Not trained	Signature
Opening and closing of container			
Removal and insertion of the filter unit/microbial barrier			
Manual cleaning and disinfection			
Storing on loading carrier WD/CW			
Cleaning program			
Visual checks			
Compliance of loading heights			
Compliance of loading sterilizer			
Compliance of stacking conditions			
Use of seals			

5.2.2 Training matrix OR

	Trained	Not trained	Signature
Destroy of seals			
Greencheck® system			
Opening of container			
Removal of the filter unit/microbial barrier			
Manual cleaning and disinfection			
Compliance of stacking heights			

Training done:

Signature (MPB)	
Date	
Company	
Address	

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