

| Störung | Grund | Lösung |
|---|---|--|
| Verriegelung des Deckels Ausfall | Die Schösser wurden anstelle von Griffen zum Tragen des Sterilisations Containersystem | Bitte kontaktieren Sie Dewimed Medizintechnik GmbH. Ein Container mit einem gebrochenen Schloss ist nicht geeignet für Sterilisation geeignet. |
| | Das Sterilisationscontainersystem hatte einen physischen Einfluss auf die Deckelverschluss. | |
| B3 Biostop Bestandteile sind nicht auf dem Deckel montiert | B3 Biostop Komponenten oder Deckel verformt. | Bitte kontaktieren Sie das Dewimed Medizintechnik GmbH |
| Während der Sterilisation Prozess wird der B3 Bio-stop Barriere Komponenten wurden demontiert aus der Kammer. | B3 Bio-Stop Bestandteile sind nicht ordnungsgemäß verschlossen | Bitte kontaktieren Sie das Dewimed Medizintechnik GmbH |

Weitere Informationen

Für die Aufbereitung von Medizinprodukten dürfen ausschließlich validierte Prozesse verwendet werden

Erklärung der Symbole

| | | | | | |
|--|---|--|--------------------|--|-----------------------------|
| | Achtung | | Hersteller | | Herstellungsdatum |
| | Medizinprodukt | | Unsteril | | Stückzahl in der Verpackung |
| | Artikelnummer | | Chargenbezeichnung | | Gebrauchsanweisung beachten |
| | CE-Zeichen der Benannten Stelle mdc medical device certification GmbH, Stuttgart, Deutschland | | | Verschreibungs-pflichtiges Medizinprodukt (USA) | |



IFU-V9-003 | 16.02.2024

ENGLISH

INSTRUCTIONS FOR USE STERILIZATION CONTAINER SYSTEM

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IMPORTANT INFORMATION PLEASE READ BEFORE USE

Products

These instructions for use apply to the DEWIMED sterilization container system of risk class 1: Article no.: 88.XXX.XX

Important information

The instructions for the correct use of Sterilization containers are described below.

It is recommended to read the Instruction Manual prior to the usage in order to avoid the risks, as much as possible, that may occur from improper usage of the container.

Intended Use

Sterilization container systems are systems that provide sterile storage of surgical hand tools. The system, which is suitable for reuse, is an effective packaging method that ensures sterilization, storage and transportation of surgical and orthopedic instruments. Various sizes and configurations are available. The sterilization container system is designed in accordance with Vacuum Steam Sterilization (If different sterilization method is to be applied, please contact the manufacturer or authorized distributor). The sterilization container system provides the opportunity to store the instruments, devices, etc., in a sterile form, until they are used again after the sterilization process. According to the sterility and stability test results, if the lid of sterilization container systems is not opened, they are kept sterile for 6 months

Sterilization container models

Standard-Plus-Model

This model is suitable for usage with filters;

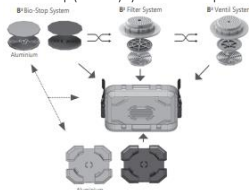
- Paper Filter
- Textile filter
- PTFE (Teflon) Filter
- PP (Polypropylene) Filter

Window Model

The Window Model Sterilization container provides the opportunity to control the condition of both product and sterilization via the transparent PPSU window system on the lid. The requirements of the sterilization process are provided by the filter, valve system or B3 in the box. Since this model has no perforation on the lid, it should be used with perforated boxes.

Modell B3-Barrier

The system, which consists of a combination of 3 different modules in one cover, allows to be used as PTFE Filter, Valve or Bio-Stop (Pasteur) system with the preferred model.



Maintenance

Proper cleaning methods shall be used for the cleaning of the sterilization container system prior to the usage. Sterilization container systems are suitable for automatic washing. Neutral enzymatic solutions should be used during the washing process. The preferred filters for filtered models, shall be checked after each cleaning and before each sterilization. In case of any kind of damages on the filters such as cracks, scratches etc. or if the filters are wet etc. the filters shall never be used.

Sterilization Container Systems shall only be used with the components that are approved by our company. Our company shall not be responsible for the damages that may occur due to the usage of components unapproved or inappropriate. Ensure that all the components of the Sterilization Container System work properly before each usage.

Unacceptable situations

- Damaged lock mechanism
 - Deformation or rupture of the internal lid gasket
- Use given values in the table for the replacement of the gasket.

Control and replacement of the gasket

- Clean the lid groove with the help of acetone in order not to have any gasket residues in the groove.
- Apply the silicone adhesive (Henkel-Sista® is recommended) to the gasket groove, which is cleaned properly.
- Cut the gasket related with the dimensions given in Table-1 and place it into the groove (flat surface facing up) and wait 12 hours to have the gasket dried.

| Lid | X long | X Large | (1/1) | (3/4) | Flak (1/2) | Dental | Dental 1/2 | Large Dental | Mini | Endo-Modell |
|-------------------|--------|---------|--------|--------|------------|--------|------------|--------------|-------|-------------|
| Gasket Dimensions | 185 cm | 180 cm | 158 cm | 136 cm | 101 cm | 89 cm | 72 cm | 118 cm | 77 cm | 130 cm |

Table 1 Gasket Dimensions

- Check the gaskets in the filter holders.
- Ensure that the filter holders have been fitted exactly.
- The filter holders must fit via the "click" sound.
- Do not use the damaged, torn or wet filters.
- Check the flexibility of valve springs in B3 Model Valve System.
- Check the flexibility of the valves by pushing the valve shaft on the module by pressing with finger.
- Do not use the mechanisms that have lost their flexibility.

The model conveniences of the filters and their usage periods are given in the table below:

| | Model | PP Filter ¹ | PTFE Filter | Paper Filter | Textile filter | Valve-system | Bio-Stop-system |
|------------------------------|---------------------|-------------------------|----------------------|-------------------------|----------------|--------------|-----------------|
| Sterilization Container Type | Standard-Plus-Model | ✓ | ✓ | ✓ | ✓ | - | - |
| | Window-Model | ✓ ¹ | ✓ ² | ✓ ¹ | ✓ ² | - | - |
| | Model B3-Barrier | ✓ | ✓ | - | - | ✓ | ✓ |
| | Plasma-Model | ✓ | - | - | - | - | - |
| | Dental-Model | ✓ | - | - | - | - | - |
| | ½-Dental-Model | ✓ | ✓ | ✓ | ✓ | - | - |
| | Endo-Model | ✓ | ✓ | ✓ | ✓ | - | - |
| | Mini-Model | ✓ | ✓ | ✓ | ✓ | - | - |
| Flat-Model | ✓ | ✓ | ✓ | ✓ | - | - | |
| Filter by time | | Single use ³ | 2000 SC ⁴ | Single use ³ | 50 SC | | 5000 SC |

Table 2 Filter Usage Times

¹ The filters are placed in the box in Window Model System

² PP: Polypropylene Filter

³ Single-Use: Needs to be replaced after each use.

⁴ Sterilization Cycle: It increases by 1 after each sterilization process.

SC: Sterilization Cycle

Cleaning and disinfection

Incorrect cleaning and disinfection may cause corrosion and erosion on the surface.

Use alkaline-free, caustic-free (NaOH) and carbonate-free neutral enzymatic detergents for washing.

The final rinsing water to be used before sterilization shall be de-ionised (in accordance with EN 285 Appendix –B). Before washing, remove all the removable parts of Sterilization container. Remove the filter holder and the filter for the filtered model; filter module, Bio Stop Module and valve module for B3-Barrier Model. Remove the paper labels and aluminium labels.

Manual washing

Wash using cold water for at least 2 minutes. While rinsing use a soft brush and a lint-free cloth to ensure that the sterilization container is cleaned from dirt and dust etc. Immerse the container in neutral enzymatic detergent and soak for 5 minutes at least. Then apply the detergent on the container with a soft brush and a lint-free cloth.

In order to use the neutral enzymatic cleaning solutions properly, it is recommended to follow-up the manufacturer's instructions while preparing the solution (Proper Temperature, Concentration etc.).

Mechanical Washing

Mechanical washing of Sterilization Container is only recommended if the disinfectors has a special program for the aluminium boxes. The used program of the washers and the disinfectors for stainless steel surgical instruments, Cannot be applied to the Sterilization Containers.

Do not wash the container with Alkaline and Acidic solutions in automatic washers.

| Process Sequence | Time (min)/ Temperature | Water Quality | Detergent Features |
|-------------------|-------------------------|-----------------|------------------------|
| Pre-Wash Rinse | 1/Cold | Tap water | n/a |
| Wash 1 (Manual) | 2/ Cold | Tap water | Neutral pH 7 |
| Wash 2 (Mechanic) | 5/ 40°C | Tap water | Neutral pH 7 Enzymatic |
| Final Rinse | 2/ 40°C | Distilled Water | n/a |
| Drying | 40 min/ 93°C | n/a | n/a |

Table 3 Mechanical Washing Process Parameters

Distilled water should be used in the final rinsing process of the Sterilization Containers due to the fact that the mineral salts in mains-water may cause spots and erosion over time during sterilization.

- Remove the Sterilization Container's box from the lid prior to washing.
- Place the box vertically and upside down into the disinfectant in order to prevent the water accumulation.
- The inside of the container lid should be positioned at the bottom of the machine with the locking mechanism folded into the lid.
- Remove all the components of the container and clean them separately by placing into the basket (if applicable).

Loading the equipments

- Place the equipments/materials to be sterilized in the container by leaving at least 2 inches (approx. 5 cm) gap between the lid holes and the load so that these don't prevent the function of the filters.
- If the perforations are clogged while the container is being loaded before sterilization, the vacuum in the pre-vacuum steam sterilization causes the deformation of the container.
- It is recommended to use a basket when loading the container. Baskets are used for the grouping and stacking of surgical and orthopedic equipments (organising) in Sterilization container and also for washing these equipments.



Loading should be done according to the values given in the table below. When the values in the table are exceeded, the materials are likely to remain wet. The Sterilization process will not be complete.

| Material | Container Type | Maximal Total Weight ¹ | Relevant Standard |
|---------------------|-------------------------------|-----------------------------------|-------------------|
| Surgical Instrument | 1/1 | 10 kg | EN 868-8 |
| Surgical Instrument | 3/4 | 7 kg | EN 868-8 |
| Surgical Instrument | 1/2 | 5 kg | EN 868-8 |
| Surgical Instrument | Mini, Dental & Special Models | 3 kg | EN 868-8 |
| Textile | All models | 8kg ² | EN 285 |

Table 4 Equipment Loading & Maximum Total Weights

¹ Maximum total weight : Container weight + basket or drape weight + Material weight.

² Ensure that the container perforations do not close when the textile materials are loaded. When light pressure is applied on it, it should be positioned so as to maintain its flexural stiffness. Otherwise, the steam cannot penetrate into the container and there won't be any sterilization.

Sterilization

- Ensure that the lid is fully closed after the equipments are loaded. Ensure that the lock system works correctly.
- Place the lid parallel on the box and lock the lid. Otherwise, the box will not be locked properly, thus there will be an unbalanced force to be applied and the locking system won't be functioning. As the result of this there shall not be a proper sterilization.

Do not wrap the sterilization container in any kind of packages. In case the perforations are clogged during the sterilization, vapour and steam won't be discharged. Thus the container will be damaged and there shall not be a proper sterilization.

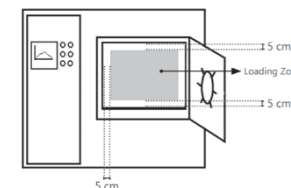
It is recommended to use either security seal or automatic lock system to ensure the sterility.



| Sterilization Type | Time 121°C | Time 134°C | Drying Time |
|--------------------------------|------------|------------|---------------|
| Gravity Sterilization | 30 Minutes | 15 Minutes | 15-30 Minutes |
| Pre-Vacuum Steam Sterilization | - | 5 Minutes | 15-20 Minutes |

Table 5 Parameters of Sterilization

- Prevent the products to face big temperature differences in the environment after sterilization process.
- Wait until the container cools down to the room temperature before unloading the autoclave. In case of sudden temperature changes sweating on interior surfaces of the container will occur.
- If the loading weights given in Table 4 are not followed, the sterilizer may not fully perform the drying function. In this case the equipment and materials will not be considered as sterile.
- Place the containers having larger volumes to the bottom and the ones with smaller volumes to the top, in case more than one container is to be put into the sterilizer. Do not exceed the maximum allowed height of 45cm.



If the equipments are still humid or wet although all of these instructions are followed, contact immediately with the manufacturer of the sterilizer machine.

Transportation

- Always hold from the handles of the container during loading, unloading and transportation.
- Do not carry the container holding from the lock mechanism.

Carrying the container holding from the locking mechanism may cause a defect on the locking system and as the result of this there may be air leakage, which will lead to the loss of sterilization.

Safe carrying weights of Sterilization Container System is given the table below.

| Size | Height | Safe Carrying Weight | Stack Capacity (Up to 45 cm) |
|----------------|--------|----------------------|------------------------------|
| 1/1 - 3/4 -1/2 | 100 mm | 20 kg | 4 Stück |
| XL | 120 mm | 22 kg | 4 Stück |
| 1/1 - 3/4 -1/2 | 135 mm | 23,5 kg | 4 Stück |
| 1/1 - 3/4 -1/2 | 150 mm | 25 kg | 4 Stück |
| XL | 180 mm | 28 kg | 4 Stück |
| 1/1 - 1/2 | 200 mm | 30 kg | 4 Stück |
| 1/1 - 1/2 | 260 mm | 36 kg | 4 Stück |

Table 6 Container Loading Capacity

Storage

Recommended proper storage conditions of Sterilization container system are as follows.

- Temperature: (-20) - 60°C
- Humidity: % 10 – 70 Rh
- Pressure: Normal Atmospheric Pressure (Refer to: DIN 58953-9)

Storage times of sterilization container systems depend on ambient conditions. Storage conditions and times must be approved by qualified personnel.

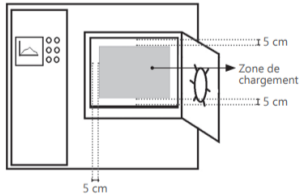
Troubleshooting table

| Fault | Reason | Solution |
|---|--|---|
| Sterilization Excessive moisture from inside the container. | The temperature of the materials before sterilization is too low | Sterilize materials at 20°C sterilization at minimum initial room Temperature |
| | The drapes are very damp | The drapes to be placed in the sterilization container should be dry |
| | Containers to be sterilized are not properly placed in the sterilization unit. | The total height should be 45 cm, with the heavier containers at the box. It should be preferred that the polymer lid container are at the top. |
| | Improper cooling | Select the appropriate sterilization |

| Type de stérilisation | Temps 121°C | Temps 134°C | Temps de séchage |
|------------------------------------|---------------------|---------------------|------------------------|
| Stérilisation par gravité | 30 Procès-verbal | 15 Procès-verbal | 15-30 Procès-verbal |
| Vapeur de pré-vacuum Stérilisation | - | 5 Procès-verbal | 15-20 Procès-verbal |

Tableau 5 Paramètres de la stérilisation

- Empêcher les produits d'être confrontés à de grandes différences de température dans l'environnement après le processus de stérilisation.
- Attendez que le conteneur refroidisse à la température ambiante avant de décharger l'autoclave. En cas de changements soudains de température, il se produira une transpiration sur les surfaces intérieures du conteneur.
- Si les poids de chargement indiqués dans le tableau 4 ne sont pas respectés, le stérilisateur peut ne pas assurer pleinement la fonction de séchage. Dans ce cas, les équipements et les matériaux ne seront pas considérés comme stériles.
- Placez les récipients ayant les plus grands volumes au en bas et les plus petits en haut. Plus petits vers le haut, au cas où plus d'un récipient doit être mis dans le stérilisateur. Ne dépassez pas la hauteur maximale hauteur maximale autorisée de 45 cm.



⚠ Si les équipements sont toujours humides ou mouillés bien que toutes ces instructions aient été suivies, contactez immédiatement le fabricant de la machine de stérilisation.

Transport

Toujours tenir par les poignées du conteneur pendant le chargement, le déchargement et le transport.

- Ne transportez pas le conteneur en le tenant par le mécanisme de verrouillage mécanisme de verrouillage

⚠ Le transport du récipient à partir du mécanisme de verrouillage peut provoquer un défaut sur le système de fermeture et, par conséquent, il peut y avoir une fuite d'air, ce qui entraînera la perte de la stérilisation.

Les poids de portage sûrs du système de conteneur de stérilisation est indiqué dans le tableau ci-dessous.

| Taille | Hauteur | Transport en toute sécurité Poids | Capacité d'empilage (Jusqu'à 45 cm) |
|-----------------|---------|-----------------------------------|-------------------------------------|
| 1/1 - 3/4 - 1/2 | 100 mm | 20 kg | 4 pièce |
| XL | 120 mm | 22 kg | 4 pièce |
| 1/1 - 3/4 - 1/2 | 135 mm | 23,5 kg | 4 pièce |
| 1/1 - 3/4 - 1/2 | 150 mm | 25 kg | 4 pièce |
| XL | 180 mm | 28 kg | 4 pièce |
| 1/1 - 1/2 | 200 mm | 30 kg | 4 pièce |
| 1/1 - 1/2 | 260 mm | 36 kg | 4 pièce |

Tableau 6 Capacité de chargement des conteneurs

Stockage

Les conditions de stockage correctes recommandées pour le système de conteneur de stérilisation sont les suivantes.

- Température: (-20) - 60° C
- Humidité: % 10 – 70 Rh
- Pression: Pression atmosphérique normale (Se référer à : DIN 58953-9)

⚠ Les temps de stockage des systèmes de conteneurs de stérilisation dépendent des conditions ambiantes. Le stockage conditions et durées de stockage doivent être approuvées par personnel qualifié.

Tableau de dépannage

| Défauts | Raison | Solution |
|---|--|---|
| Stérilisation Excès de humidité de l'intérieur le récipient. | La température des matériaux avant la stérilisation est trop basse | Stériliser les matériaux à 20°C stérilisation à température ambiante initiale minimale température initiale minimale. |
| | Les rideaux sont très humides | Les rideaux à être placés dans le conteneur de stérilisation doivent être secs |
| | Les récipients à stériliser ne sont pas placés correctement dans l'unité de stérilisation. | La hauteur totale devrait être de 45 cm, avec les plus lourds les conteneurs les plus lourds au niveau de la boîte. Il est préférable que les récipients à couvercle en polymère se trouvent au haut. |
| | Refroidissement incorrect après la stérilisation. | Sélectionnez la méthode de stérilisation appropriés. |
| | Les spécifications de l'autoclave ne répondent pas à la norme DIN EN 285 | Lorsque vous utilisez l'autoclave, tenez compte des recommandations du fabricant. |

| Défauts | Raison | Solution |
|---|--|--|
| | | Vérifiez le temps de séchage et la qualité de la vapeur. Calibrez si nécessaire. (Voir tableau 4) |
| | Le récipient stérile stérile est surchargé | vérifier le poids approprié poids. |
| | La boucle de ralenti et le test de vide ne sont pas effectués quotidiennement avant de commencer la stérilisation | Effectuez des tests de cycle à vide et de vide avant la stérilisation. Assurez-vous que votre stérilisateur fonctionne correctement. |
| Verrouillage du couvercle panne | Les serrures ont été utilisées à la place des poignées pour transporter le système de stérilisation système de conteneur | Veillez contacter le représentant de l'entreprise. Un conteneur avec une serrure cassée ne convient pas à la stérilisation. |
| | Le système de stérilisation des conteneurs a eu un impact physique sur le couvercle serrures. | |
| B3 Biostop composants ne sont pas montés sur le couvercle. | B3 Biostop composants ou couvercle déformé | Veillez contacter le Dewimed Medizintechnik GmbH |
| Pendant la stérilisation de stérilisation, le B3 Bio-stop barrière composants ont été démontés de la chambre. | B3 Les composants du bio-arrêt ne sont pas correctement verrouillés. | Veillez contacter l'entreprise représentant |

Plus d'informations

Seuls des processus validés peuvent être utilisés pour le retraitement des dispositifs médicaux.

Explication des symboles

| | | |
|---|---|---|
| ⚠ Attention | 🏭 Fabricant | 📅 Date de fabrication |
| MD Dispositif médical | ⚠ Non stérile | QTY Quantité dans l'emballage |
| REF Numéro d'article | LOT Numéro de lot | 📖 Suivre les instructions d'utilisation |
| CE Marque CE de l'organisme notifié mdc medical device certification GmbH, Stuttgart, Allemagne | R _{only} Dispositif médical de prescription (États-Unis) | |