

STERILIZATION CONTAINER SYSTEM USER MANUAL



ORSAMTIP

ORTHOPAEDIC & SURGICAL DEVICES TRADE CO.



1.0 STERILIZATION CONTAINER SYSTEM MODELS

1 Standard Model

Standard model container systems are designed for providing perfect steam flow and penetration for suitable loads according to the standards and can be used with single use paper filter or reusable PTFE Teflon filters.

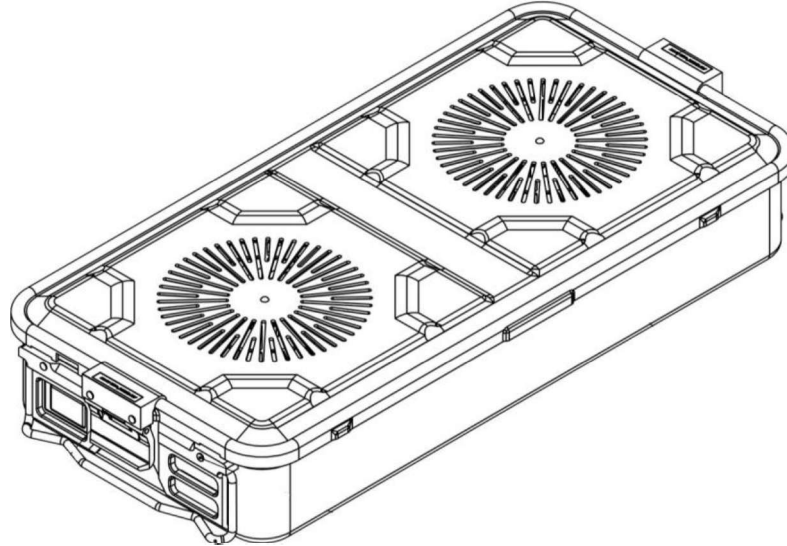


Figure - 1

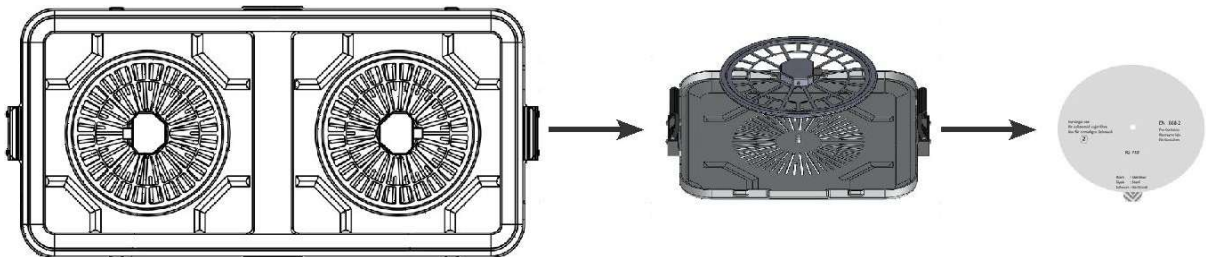


Figure - 2

1.2 Bio-Barrier Model

Bio-Barrier model sterilization container systems are designed with mechanical valves that do not require the use of any single-use filter in both the lid and the box.

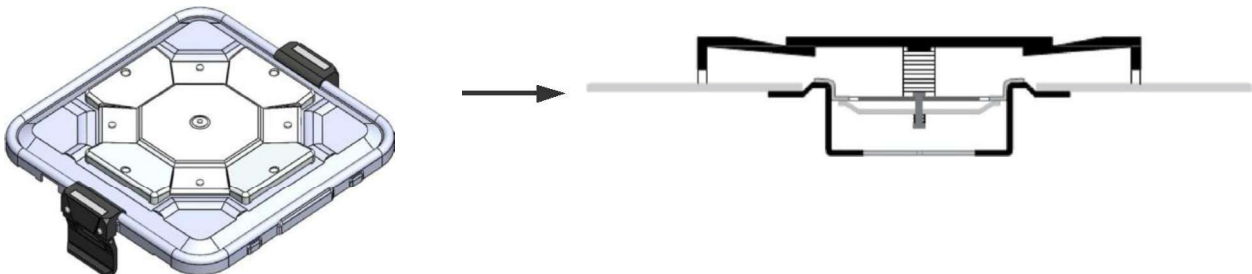


Figure 3

View of valve mechanism before Sterilization process. (See. Figure-3) (Rest status,+ / - no pressure and valves closed.)

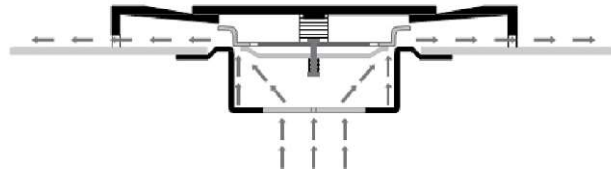


Figure 4

During sterilization, the valves are opened by the effect of pre-vacuum. Thus, dry air comes out of the container. (See. Figure-4)

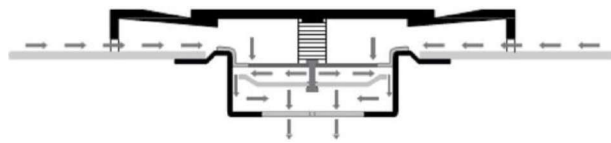


Figure 5

During sterilization the valves are opened in the opposite direction by the pressure effect .View of the introduction of hot steam into the container for sterilization (See. Figure-)

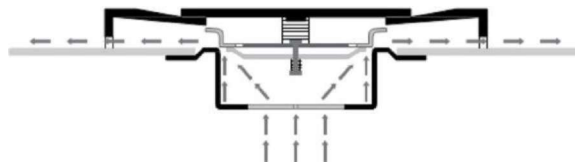


Figure 6

The re-opening of the valves with vacuum effect during the sterilization process .View of hot steam flowing out of the container (see figure

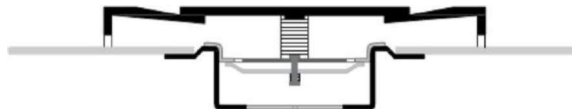
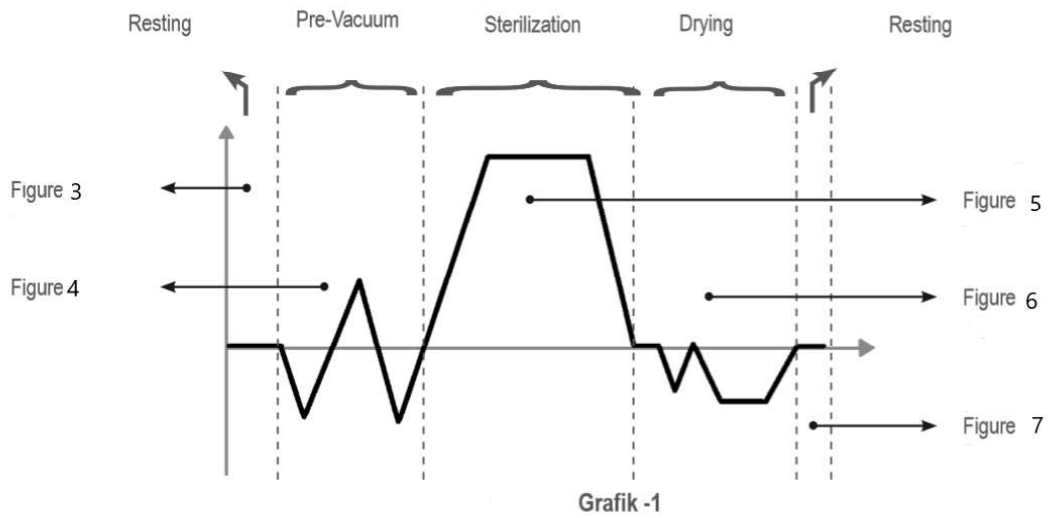


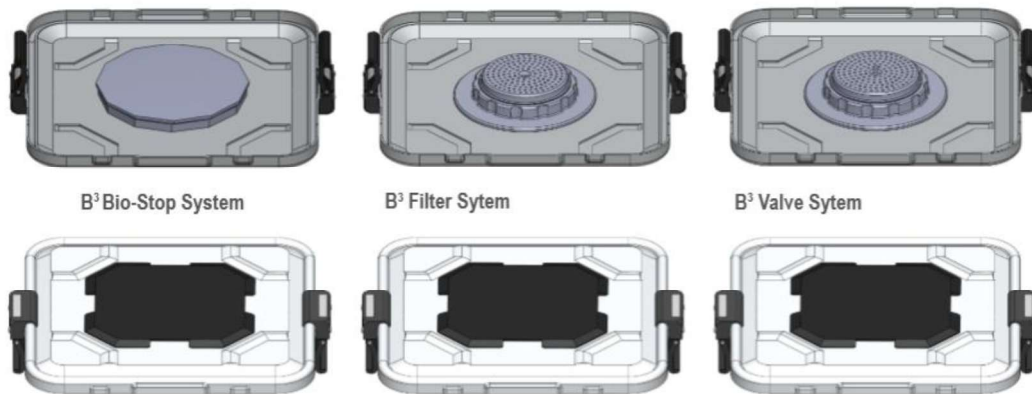
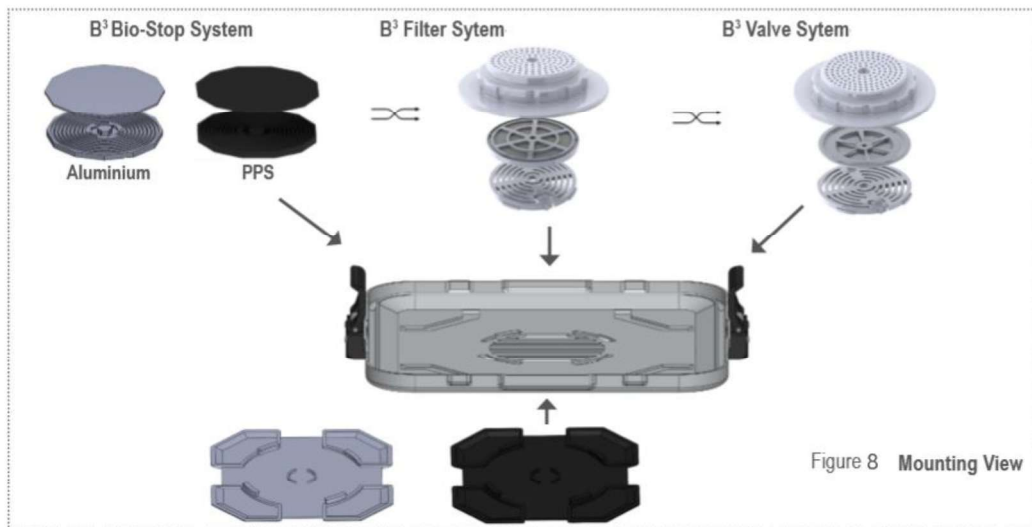
Figure 7

Closure of the valve mechanism after the completion of sterilization (resting position) see figure 7



1.3 B3 BARRIER MODEL

B3 model Sterilization containers are designed to provide filtering mechanisms in a single B3 model container lid according to user. B3 model sterilization container can be used with 3 different filtering mechanisms. (See. Figure-8)



1.3.1 B³ Filter System (PTFE)

B3 Model filtering mechanism is used with PTFE Teflon Filter which can be changed by the user easily like in standard model filter-based Sterilization containers. (See. Figure- 9)

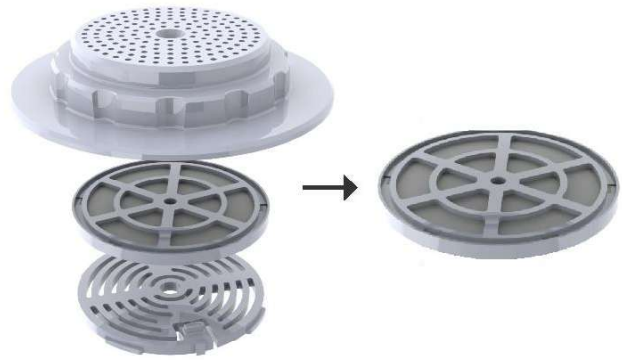


Figure 9

1.3.2 B³ Valve System

B3 Model valve system is a modernized new model of Bio- Barrier systems and has the same working principal.

This system is based on the principle of operation of valves with the effect of pressure and vacuum during sterilization in the autoclave. (See. Figure-10)

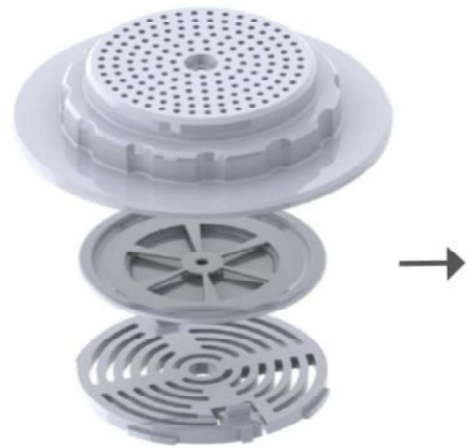


Figure 10

1.3.3 B3 Bio-Stop System

B3 Model Bio-Stop system is a flow inhibition system based on a principle discovered by Louis Pasteur. With a separation efficiency of 99.99 %, it offers significantly better protection against microbes and particles. (See. Figure-11)

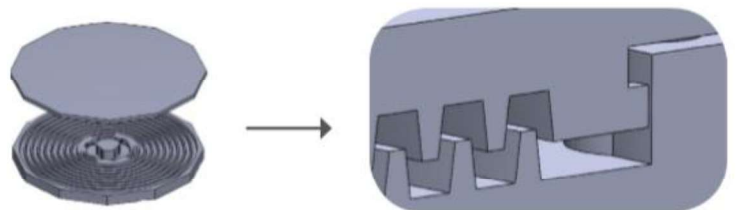


Figure 11

1.4 Standard Plus Model

Standard Plus model container systems are designed for providing perfect steam flow and penetration for suitable loads according to the standards and can be used with single use paper filter or reusable PTFE Teflon filters.

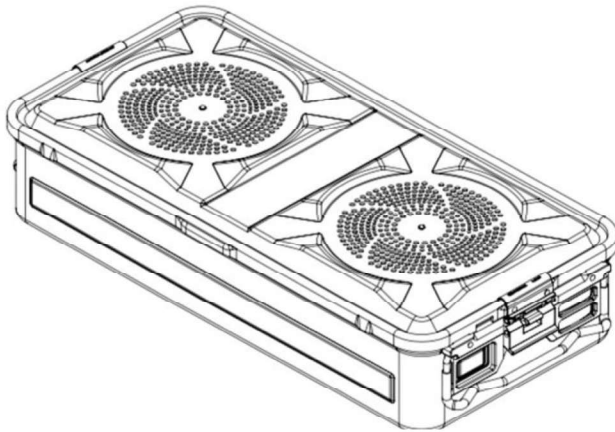


Figure 12

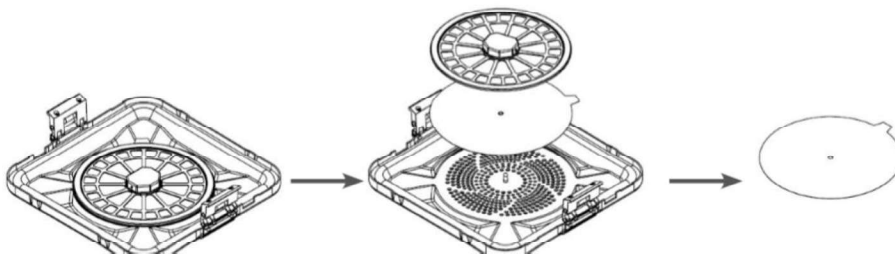
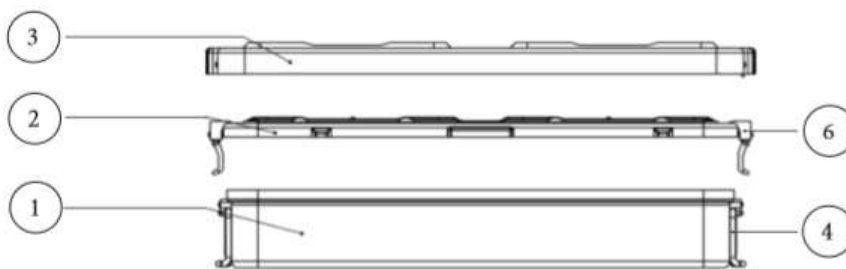
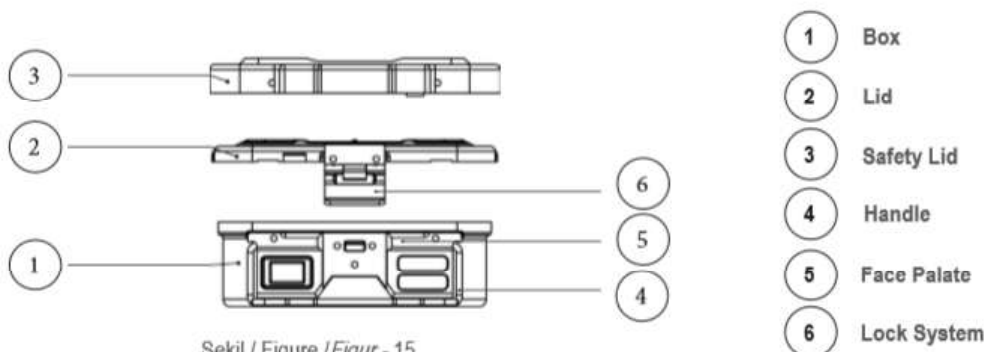


Figure 13

2-COMPONENTS OF STERILIZATION CONTAINER



Şekil / Figure / Figur - 14



Şekil / Figure / Figur - 15

- 1 Box
- 2 Lid
- 3 Safety Lid
- 4 Handle
- 5 Face Palate
- 6 Lock System

2.1 Boxes

2.1.1 Non-Perforated Box

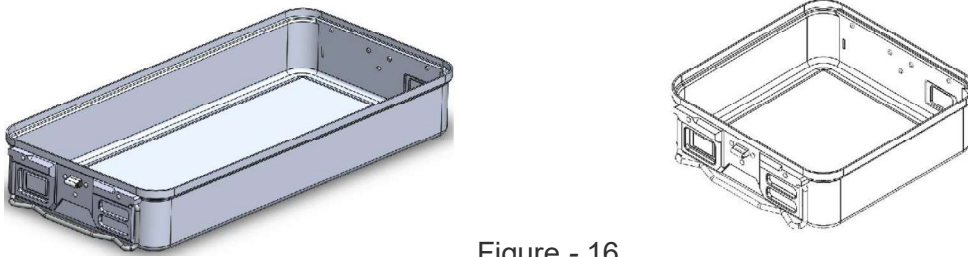


Figure - 16

Surface: Anodized

Color: Grey

NOTE :

Non-Perforated boxes should be used with perforated Lids for sterilization. The non-perforated box, together with the non-perforated lid, is only used for transport purposes.

2.1.2 Perforated Box

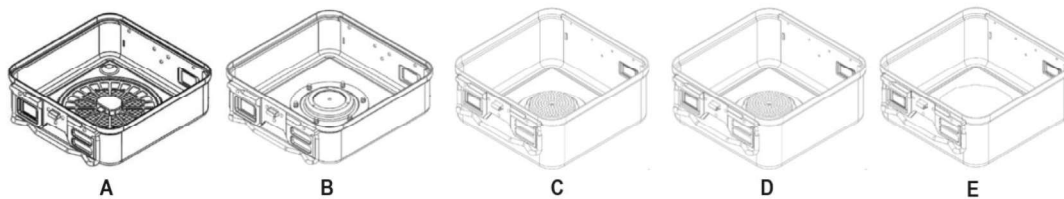


Figure 17

Surface : Anodized
Color: Grey
Hole Type:
A-Standard / Standard Plus Filter Mechanism
B-Bio-Barrier Valve System
C-B3 PTFE Filter Mechanism
D-B3 Valve Mechanism
E-B3 Bio-Stop System

Sizes	Mechanism				
	A	B	C	D	E
1/1 Full Size	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
3/4 Quarter Size	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
1/2 Half Size	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Extra Large Size	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Extra Long Size	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Large Dental	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Dental Size	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1/2 Dental Size	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mini Size	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Flat Size	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Endo Size	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Implant & Mini Implant ¹	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Scopy Size ¹	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

¹ Used only for transport purposes. They can be used organizer in containers suitable for sterilization.

Mevcut / Available / Verfügbar

Mevcut Değil / Not Available / Nicht Verfügbar

2.2 Lids

2.2.1 Non-Perforated Lid

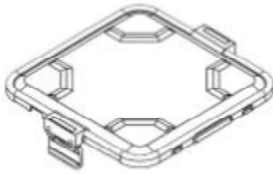


Figure - 18

Material : Aluminum

Surface : Anodized

- Color:
- Gray
 - Yellow
 - Green
 - Blue
 - Red
 - Black

Material : PPSU Polymer

Surface :-

- Color:
- Gray
 - Yellow
 - Green
 - Blue
 - Red
 - Black
 - Transparent



NOTE

Non-Perforated lids should be used with perforated boxes for sterilization. The non-perforated lid, together with the non-perforated box, is only used for transport purposes. (See 2.4)

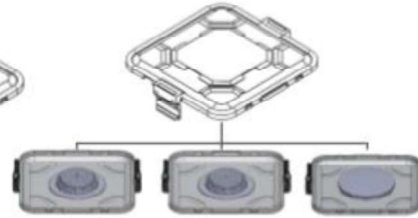
2.2.2 Perforated Lid



A



B



C

D

E

Figure - 19

Material-1: Anodized Aluminum	Color: - Gray - Yellow - Green - Blue - Red - Black
Material-2 PPSU Polymer	Color: - Gray - Yellow - Green - Blue - Red - Black - Transparent
Hole Type: A-Standard Filter Mechanism B-Bio-Barrier Valve System C-B3 PTFE Filter Mechanism D-B3 Valve Mechanism E-B3 Bio-Stop System	

Size	Mechanism				
	A	B	C	D	E
1/1 Full Size	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
3/4 Quarter Size	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
1/2 Half Size	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Extra Large Size	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Extra Long Size	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Large Dental	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Dental Size	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
1/2 Dental Size	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Mini Size	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Flat Size	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Endo Size	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Implant & Mini Implant ¹	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Scopy Size ¹	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

¹ Used only for transport purposes. They can be used as organizer in containers suitable for sterilization.

- Available
- Material-1 and Material-2 options are available

2.3 Safety Lid

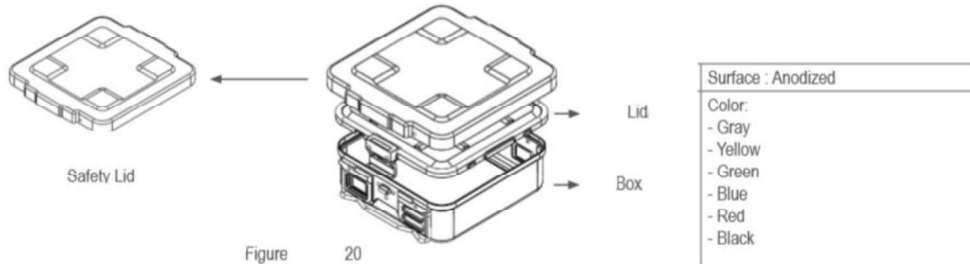
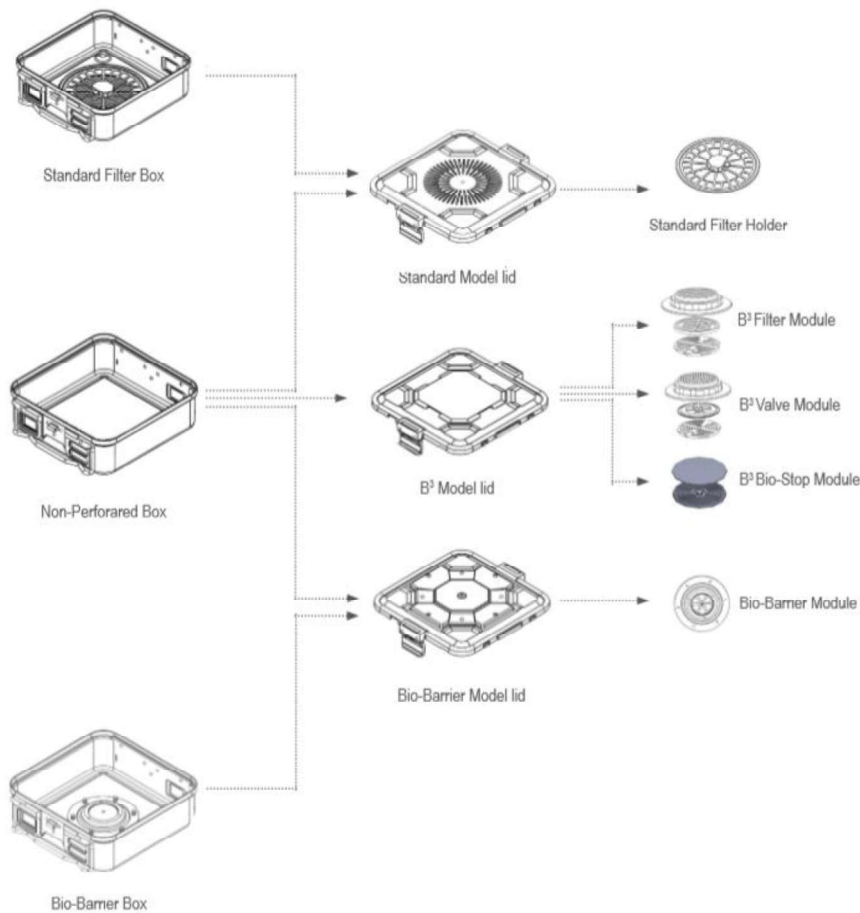


Figure 20

Boyut / Sizes/Größe:	Safety Lid	
1/1 Full Size	<input checked="" type="checkbox"/>	Available
3/4 Quarter Size	<input checked="" type="checkbox"/>	
1/2 Half Size	<input checked="" type="checkbox"/>	
Extra Large Size	<input type="checkbox"/>	Not Available
Extra Long Size	<input type="checkbox"/>	
Large Dental	<input type="checkbox"/>	
Dental Size	<input type="checkbox"/>	
1/2 Dental Size	<input type="checkbox"/>	
Mini Size	<input type="checkbox"/>	
Flat Size	<input type="checkbox"/>	
Endo Size	<input type="checkbox"/>	
Implant & Mini Implant	<input type="checkbox"/>	
Scopy Size	<input type="checkbox"/>	

Tablo / Table / Tabelle -3

2.4 Box, Lid and Mechanism Compliance Scheme



2.5 Baskets



Wire Mesh Basket



Wire Mesh-Sheet Basket



Perforated Sheet Basket

There are 3 kinds of basket system: Wire Basket, Sheet Metal Basket and Wire-Metal Basket. Baskets are used for the grouping of medical hand tools (set-up), washing and stacking in sterilization container.

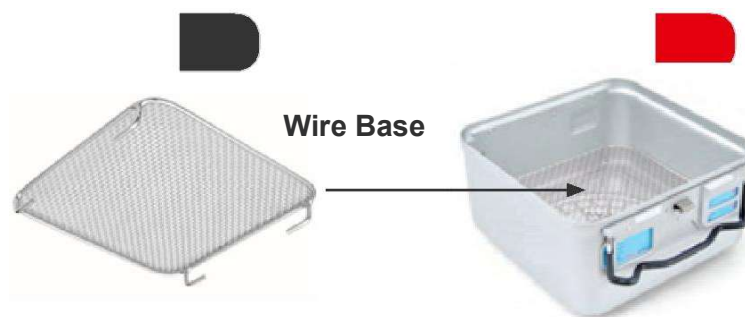
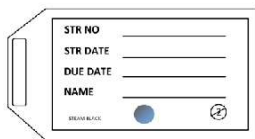


Figure - 22

2.6 Single Use Components:

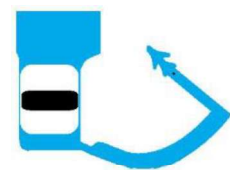
The disposable components are paper labels with indicator, paper label without indicator, disposable paper filter, safety lock with indicator and safety lock without indicator (For more information see. 5.6)



Paper labels with Indicator



Paper Filter



Security Seal



WARNING

Disposable components should be replaced before each sterilization cycle

2.7 Reusable Components

2.7.1 Reusable Filters

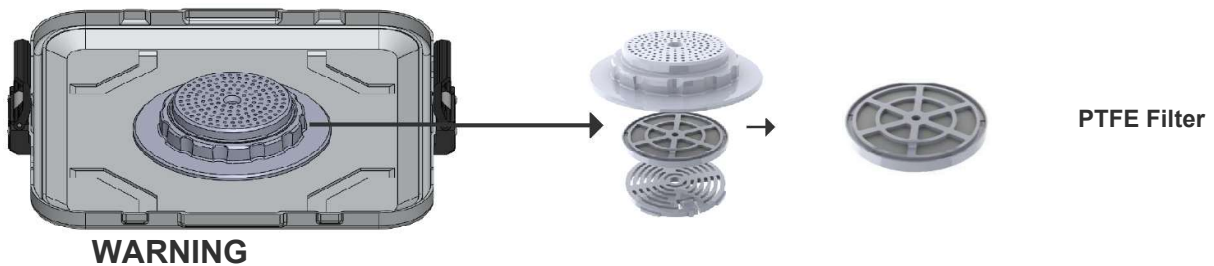
Standard Filter system container models have 3 different reusable filters

Types of Filter	Filter Usage Time
Textile Filter	50 Sterilization Cycles
PTFE Filter	2000 Sterilization Cycles

Table -4

2.7.2 Reusable Filters-B₃ Barrier Model

B₃ Barrier the filter module used in the model system has a reusable PTFE Filter



The service life of the B₃ Barrier model filter module is 2000 sterilization cycles

2.8 Automatic Lock System

The automatic locking system, which can be used instead of the safety seal in the sterilization container systems, is mounted on the nameplate so that it is positioned next to the lid lock on the container faceplate. In the system which works with thermal sensitivity, the lock tongue is located on the inside-position before sterilization. During the sterilization, the tongue of the automatic locking system is positioned outwardly by the help of the heat applied to the container, thus preventing the opening of the container lid.

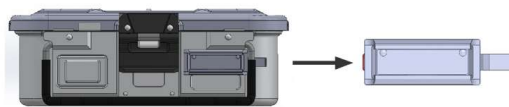
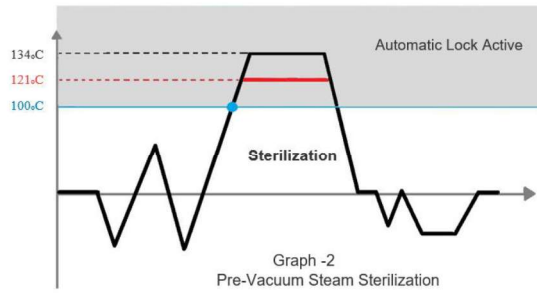


Figure - 25
View of automatic lock before sterilization



Figure- 26
View of automatic lock after sterilization





The users need to push the latch inside as shown in the figure in order to open the lid after sterilization (Figure-27). This must be done when the container cools down till room temperature

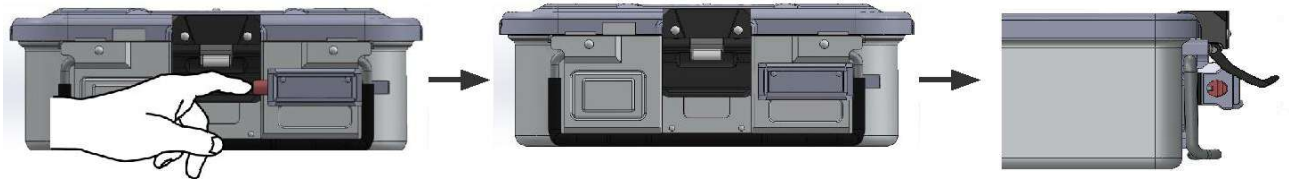


Figure – 27

WARNING

Do not unlock the automatic lock before the container reaches room temperature after sterilization. Otherwise, the automatic lock loses its function.

Product Shelf Life

Product Name	Shelf Life
Container (Box)	10 YEARS
Container (Lid)	
Wire Basket	
Plate Basket	
Aluminum Basket	
Auto-Lock Mechanism	
Disposal Stamp	
Label Holder	
Filter Dispenser	
Silicone Mat	
Paper Filter	
Polypropylen Filter	
Teflon Filter	
Silicone Mesh Mat	
Emulating Indicator Card	
Security Seal	
Silicone Handle	

3-MAINTENANCE AND CONTROLS: 3.0 Maintenance Instructions


For sterilization container systems, check the following points before each use

Lids Checkpoint	• Standart Model • A1 Model	Bio Barrier Model	B ³ Barrier PTFE Filter system	B ³ Barrier Valve system	B ³ Barrier Bio-Stop System
Lid Gaskets control	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	See				
Container Lock System	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	See				
Filter Holder control	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	See				
Filters control	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	See				
Valve System control	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	See				
<input checked="" type="checkbox"/> Check	<input type="checkbox"/> Not Applicable				

Table -5

Box Checkpoint	IMAGE
Lock latch Control	
	See

Table -6

 **NOTE**

The mechanism controls in the perforated boxes are the same as the mechanism controls on the lid.

3.1 Lid Gaskets control

Before each sterilization the sealing gaskets on the edge of the lid should be visually inspected. In the case of cracks or tears on the sealing gasket before use, the container loses its ability to sterilize. Replace the sealing gasket. The lid should not be used if the sealing gasket is removed. Maintenance and repair are necessary. Replace the sealing gasket. See. 3.1.1

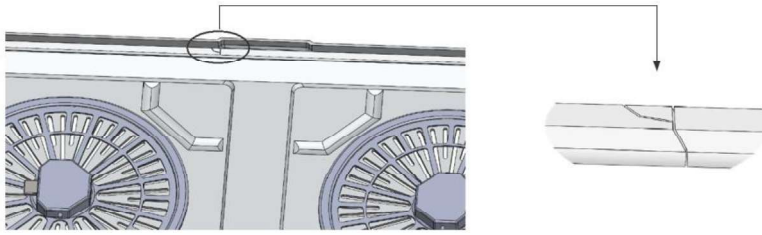


Figure – 28

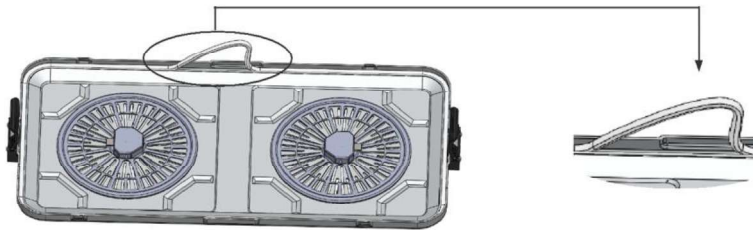


Figure- 29

3.1.1 Replacement of the lid gaskets

Choose the convenient cutting dimensions for the gaskets of the lids from the table below

Container Lid Sizes	Gasket Cut Size
1/1 Size	158 cm
3/4 Size	136 cm
1/2 Size	101 cm
Extra Large (XL) Size	180 cm
Extra Long Size	185 cm
Dental Size	89 cm
1/2 Dental Size	72 cm
Large Dental Size	118 cm
Mini Model Size	77 cm
Endo Model Size	130 cm

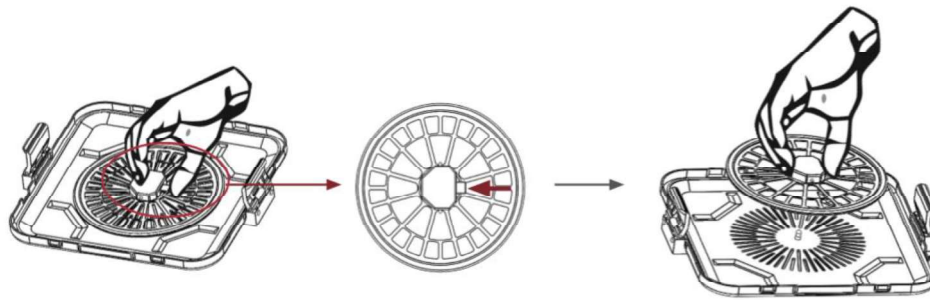
- Remove the gasket to be replaced from the lid.
- Make sure that the surface is cleaned using alcohol so that the adhesive silicone residue does not remain.
- Make sure that the new seal is cleaned from the residues on the contact surface.
- Apply silicone adhesive to the gasket channel.
- It should be left for 12 hours for drying.
- When it is dried, the replacement is completed.

3.2 Lock System Control

Check the function of the locking system. Place the lid on the box. Close the locks. Make sure the lid is tightly closed so that it does not move over the box. Otherwise, the lock function is not fully fulfilled, and the seal cannot be secured. It will not be suitable for sterilization.

3.3 Filter Holder Control

Check that the Filter Holders of the Sterilization Container Systems with Filter Mechanism are Functioning Correctly before Use



As show in Figure 30, remove the filter holder from the lid by pressing the latch on it

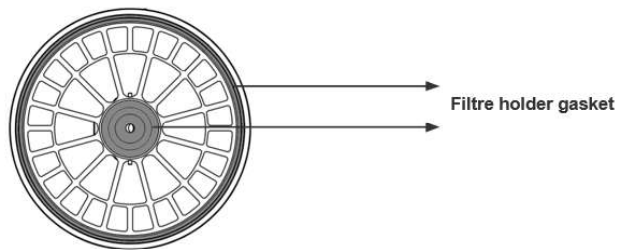


Figure- 31
Check the gaskets on the inside edges of the filter holder. Do not use torn or deformed gaskets on the filter holders.

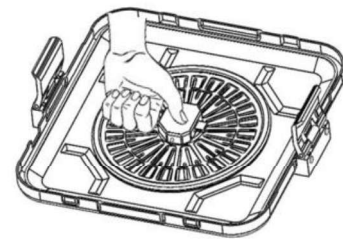


Figure- 32
Press your finger on the button until you hear the "click" sound. Try to rotate the filter holder by hand. If the filter holder does not rotate, the mechanism is seated.

3.4 Filter Control

3.4.1 Standard Model Filter Control

Disposable filters (Paper Filter) must be replaced after each use. Check before use if the reusable filters (Textile filter, PTFE and Non-woven PP filter) are available. Do not use the filters if wet. Reusable filters should not use if tears, cracks and other damage noticed . For filter usage time see. Table-4

3.4.2 B3 Barrier Model Filter control

For the B3 Barrier Model filter maintenance, unscrew the module as shown in Figure-33

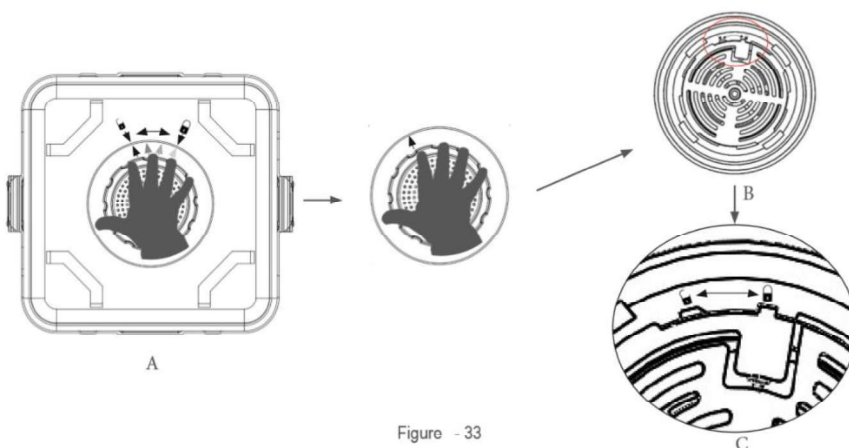


Figure - 33

Flip the lid over. Remove the module by turning the mechanism to the left. (Figure 33-A)

Turn the module over. (Figure 33-B)

Open the rear lid by turning the latch in the direction of the arrow as shown in Fig. 33-C)

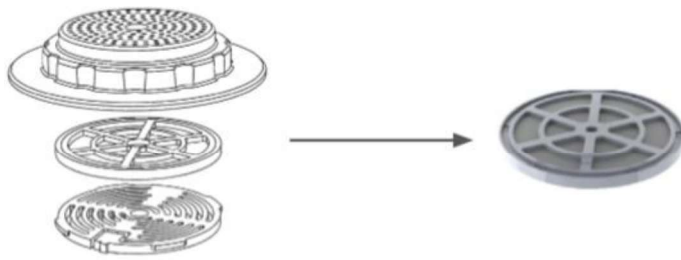


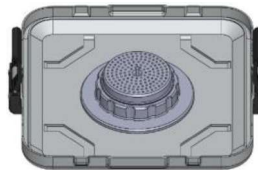
Figure - 34

Check the filters before each usage. Do not use the filters as damp or wet. The filters should not have any tensions, tears, cracks and other damage markings. For filter usage time. (See Table-4)

3.5 Valve System Control



Bio-Barrier Model



B3 Barrier Model-Valve Model

3.5.1 Bio-Barrier Model-Valve System Control

To check the Bio-Barrier model valve mechanism, press with a pointed material as shown in figure-35. If the mechanism is moving, it means that the system is running.

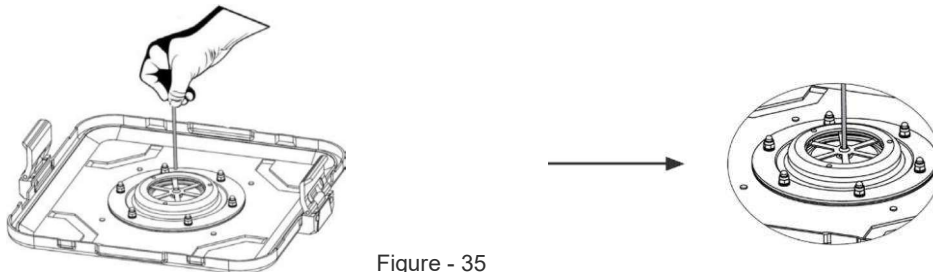


Figure - 35

3.5.2 B3 Barrier Model Valve Module Control

The control of the mechanism can be done while on the lid. Turn the lid over and press with the finger on the pin located in the middle of the mechanism. If the mechanism is moving, it is working.

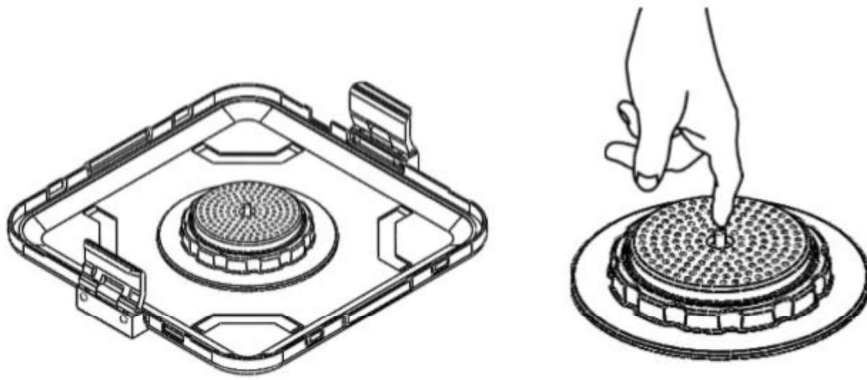
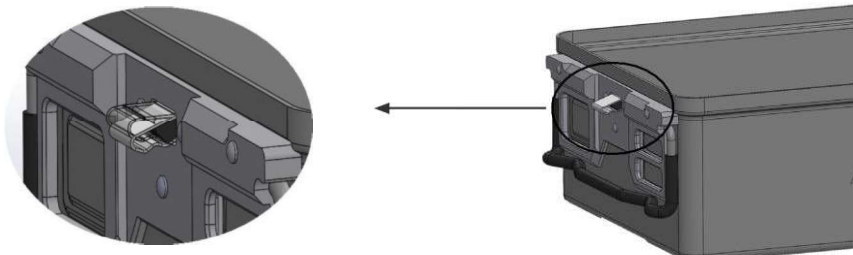


Figure - 36

3.6 Box Lock latch Control

Check the lock latch in the box. The lid will not fit properly fit to boxes, where the latches are bent or broken. In this case the sealing cannot be fully achieved.



WARNING
 After the lid is correctly positioned on the box, the locking operation should be performed. The lid will cause unbalanced force to be applied when it is not fully seated on the box. For this reason, if the lock system fails, the seal will not function properly and there will be a risk of sterilization

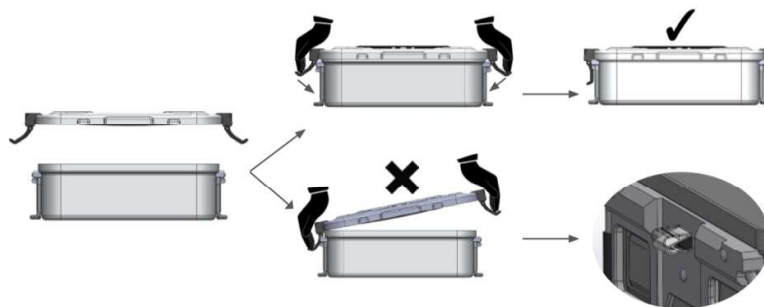


Figure - 38

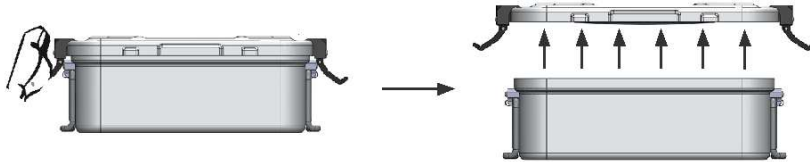
4.0 Cleaning

The users of the sterilization container system should apply their preparations for reuse, the solutions to be used during the cleaning process and the way they are applied to the products should be in accordance with the instructions given by the manufacturer

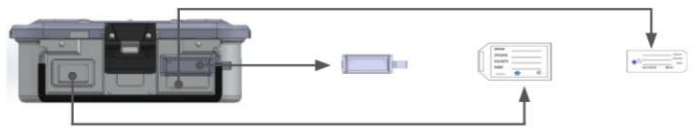
4.1 De-assembly of components prior to cleaning

Remove all the detachable parts of the container prior to cleaning

Remove the lid from the box

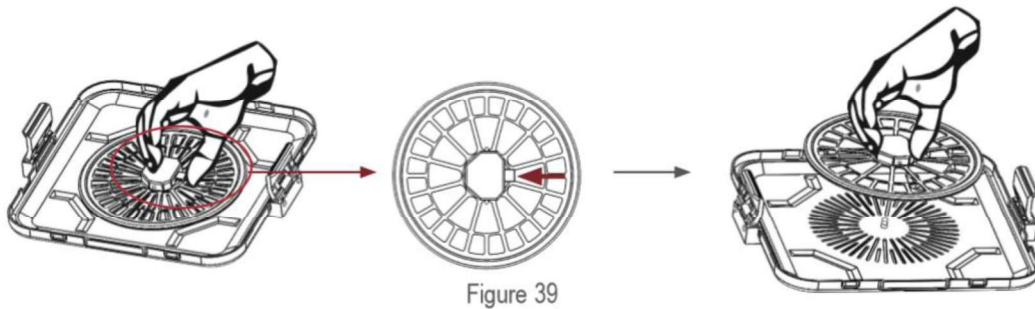


Remove paper labels, metal badges and auto lock components (if available) on the box

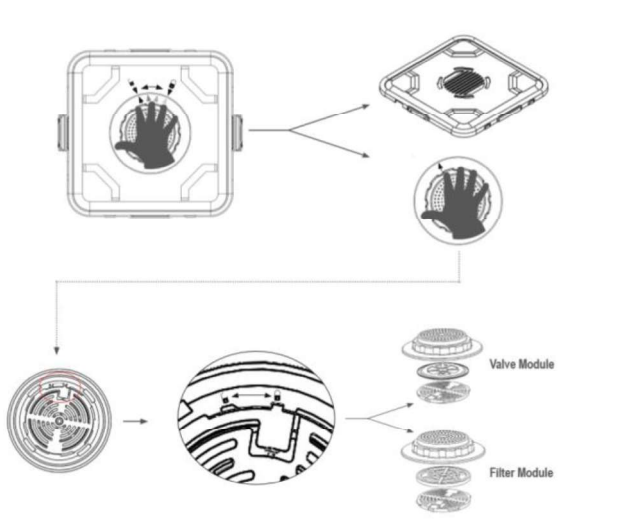


For models with standard filter mechanism.

Remove the filter holders and filters from the standard box and lids with filter



For B3 Barrier Model Filter or Valve module; Remove the valve or filter module as shown below



For B3 Barrier Model Bio-Stop module

Remove the Bio-Stop module as shown below.

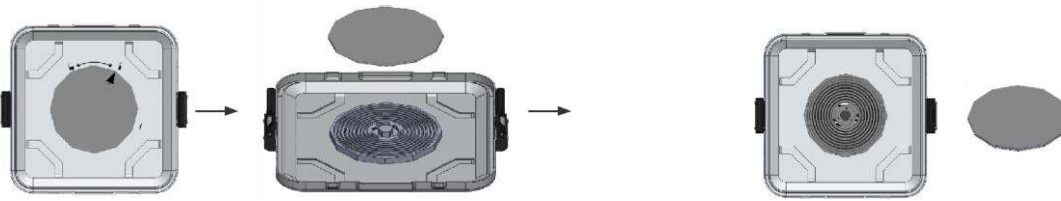


Figure - 40-a

a- Turn the Bio-Stop module in the direction of the “unlock” sign. Remove the module top component.

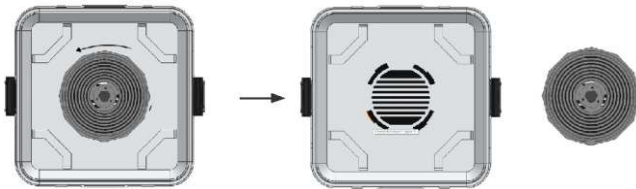
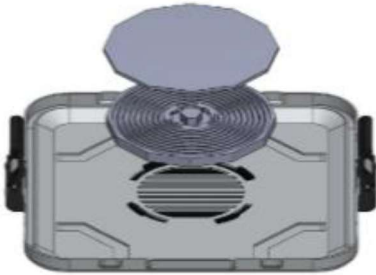


Figure - 40-b

b- Remove the module subcomponent by turning left. Disconnect the components.




WARNING

Do not expose the B3 model to temperatures above 90 °C when disassembled. Otherwise, the PPS components will undergo deformation. If thermal disinfection is to be carried out, first install the components in the main product.

4.2 Washing Process

4.2.1 Pre-Cleaning

Sterilization containers should be rinsed without waiting for intensive medical tissue and blood stains on the after use. Pre-cleaning can be achieved with a cloth or soft bristle brush.

**WARNING**

In order to remove coarse dirt in the prewash it is absolutely not necessary to use cleaning devices which may cause scratching and hard surface, except soft bristle brushes. Scratches that occur on the surface of the container will cause the loss of antiseptic properties.

4.2.2 Washing water quality

Tap water: It should be used for first wash (soaking) and for rinsing in process stages.

Critical water: It is obtained by removing microorganisms, inorganic and organic materials from water. It must be used in the mechanical washing process as machine water, in steam sterilization as steam water and in the last rinsing process.

Water use condition	Unit	Tap Water	Critical Water
Hardness (mg/L = ppm CaCO ₃)	mg/L	<150	<1
pH	n/a	6-9	<5-7
Chlorides	mg/L	<250	<1
Silica	mg/L	<150	<1

Table -7

If the recommended water is not used.

- Containers are coated with anodizing to obtain antiseptic properties and resistance to corrosion. Anodized surface will suffer damage over time.

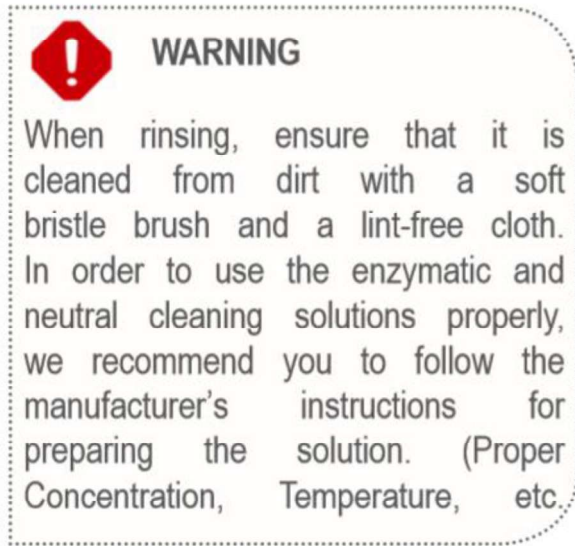
- Sterilizers consume too much water during the cycle. The harder the water, the more the valves and injectors become clogged. The possibility of deterioration of the clogged injectors becomes high and the sterilization process becomes risky.

4.2.3 Washing Process - Manuel washing

Firstly, dismantle all detachable parts of the container as described in section 4.1.

Wash with cold water for at least 2 minutes. (Tap water see 4.2.2). When rinsing, ensure that it is cleaned from dirt with a soft bristle brush and a lint-free cloth. Submerge container in Neutral pH enzymatic detergent and soak for 5 minutes least

- Then rinse for at least 2minutes



4.2.4 Washing Process - Mechanical washing

The containers after each use, should be washed with a properly diluted, enzymatic/ Neutral pH detergent solution recommended for use on anodized aluminum.

- Firstly, dismantle all detachable parts of the container as described in section 4.1.
- Wash with cold water for at least 1 minutes. (Tap water see 4.2.2). When rinsing, ensure that it is cleaned from dirt with a soft bristle brush and a lint-free cloth.

Process Steps	Time (min) / Temperature	Water Quality	Detergent Properties
Pre-Cleaning	1 min - Cold	Tap Water	N/A
Washing-1	2 min -Cold	Tap Water	Neutral Enzymatic Detergent pH:7
Washing-2	5 min/ 40 ^o C	Tap Water	Neutral Enzymatic Detergent pH:7
Final Rinse	2 min/ 40 ^o C	Critical Water ₁	N/A
Drying	40-90 °C	N/A	N/A

4.2.5 Cleaning of reusable filters

- Reusable filters can be hand-washed with neutral enzymatic detergent using a soft sponge or soft bristle brush.



WARNING

Clean the filters in such a way that they do not cause damage. Reusable filters should not use existing tensions, such as tears, cracks and other damage markings. Reusable filters should thoroughly dry after cleaning. Do not use wet or damp filters.

4.2.6 Washing Process - Points to be taken into consideration

- Do not use alkaline and acidic detergent for washing sterilization container.
- Do not use caustic (NaOH) solutions.
- Apply the detergents to be used in accordance with the instructions given by the manufacturer. (Concentration, temperature etc.)



NOTE

In washing process applied for surgical instruments in automatic washing devices, neutralizing (acidic) detergents are used with alkaline detergent. Do not wash the containers with the surgical instrument wash program.

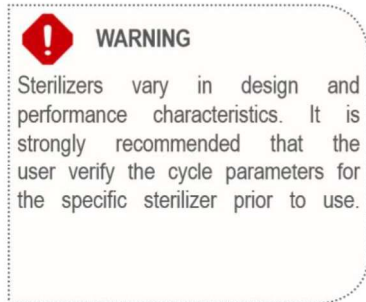
5 STERILISATION:

5.0 Sterilization Process

5.1 control before sterilization:

Before sterilization, ensure that the cleaning of the sterilization container systems is complete and correct.

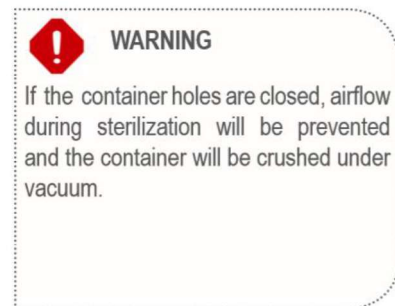
Make sure that the maintenance and controls specified in Section 3 are fully performed.



5.2 Material loading for sterilization

- Do not load inside the container in such a way as to cause the container holes to close when loading the materials to be sterilized.

Keep a distance of at least 2 inches (about 5 cm) between the lid holes and the load



Container Size		Maximum Loading Weight			Related Standard
External Dimensions L*W (mm)		Height	Metal Loads	Textile Loads	
Mini Model	315*142	45 mm	0,45 Kg	0,3 Kg	For metal loads DIN EN 868-8
		70 mm	0,70 Kg	0,5 Kg	
		100 mm	1,0 Kg	0,7 Kg	
Flat Model	297*280	75 mm	1,3 Kg	1,0 Kg	For Textile loads EN 285
		90 mm	1,55 Kg	1,2 Kg	
Endo Model	535*160	75 mm	1,35 Kg	1,0 Kg	
		90 mm	1,65 Kg	1,2 Kg	
Maximum loading weight = Wire basket or Drape + Material weight					

Do not load more than 10 kg according to DIN EN 868-8 and DIN 58953-9 standards for sterilization.

Container Size		Maximum Loading Weight		Related Standard	
External Dimensions L*W mm		Height	Metal Loads		Textile Loads
1/1	600*285	110 mm	4,5 Kg	3 Kg	For metal loads DIN EN 868-8 For Textile loads EN 285
		135 mm	5,0 Kg	3,7 Kg	
		155 mm	5,5 Kg	4,3 Kg	
		205 mm	7,5 Kg	5,6 Kg	
		255 mm	10 Kg (max)	7,0 Kg	
3/4	475*285	110 mm	3,2 Kg	2,41 Kg	
		135 mm	4,0 Kg	3,0 Kg	
		155 mm	4,5 Kg	3,4 Kg	
1/2	310*285	110 mm	2,1 Kg	2,2 Kg	
		135 mm	2,6 Kg	2,7 Kg	
		155 mm	3,0 Kg	3,1 Kg	
		205 mm	4,0 Kg	4,0 Kg	
		255 mm	5,0 Kg	5,0 Kg	
Extra Long	725*285	140 mm	10 Kg (max)	4,6 Kg	
		205 mm	10 Kg (max)	6 Kg	
Extra Large	600*372	120 mm	10 Kg (max)	4,3 Kg	
		185 mm	10 Kg (max)	6,7 Kg	
Large Dental	380*255	110 mm	2,5 Kg	1,7 Kg	
		130 mm	2,7 Kg	2,0 Kg	
		150 mm	3,0 Kg	2,3 Kg	
Dental	325*190	55 mm	0,7 Kg	0,5 Kg	
		70 mm	0,9 Kg	0,7 Kg	
		135 mm	1,75 Kg	1,35 Kg	
1/2 Dental	232*174	63 mm	0,5 Kg	0,4 Kg	
		100 mm	0,85 Kg	0,65 Kg	
		130 mm	1,2 Kg	0,85 Kg	

Table: 9



WARNING

After sterilization, pay attention to the given loading weights to avoid excessive condensation on the materials.

Place the textile products in the container in the upright position with the fold. When the container is full, it should be in position where a flat hand can enter easily between the textile products.

Load textile products so they do not lid the container holes. Otherwise, the steam will not penetrate the container and the sterilization




Figure – 41

5.3 Loading containers into sterilizer

For steam sterilizers.

Do not use other packaging for the steam sterilization container system

- If more than one container system is subject to sterilization at the same time, large volumes should be placed at the box, small volumes being at the top.

 **WARNING**

On the sterilizer, do not stack the fabric packaged set on top of the sterilization container.

If the container and fabric package are to be sterilized together, stack the container on the fabric packages.

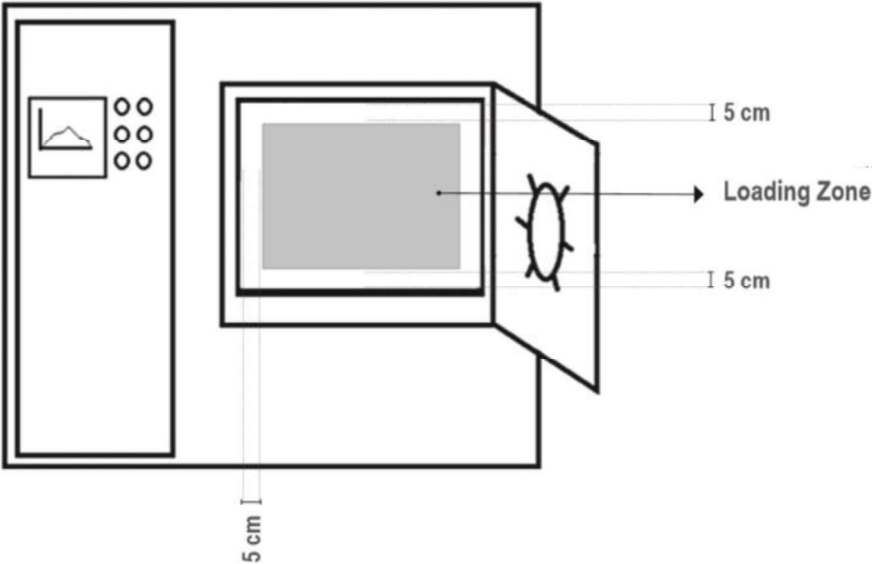

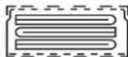


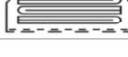
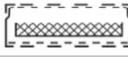










Figure - 42

When loading containers into sterilizers, allow at least 5 cm of space at the inner edges of the sterilizer to ensure a good air flow .

5.4 Suitability for steam sterilization procedures

Sterilization Container	EN 868-8'e göre paketlenme Packaging according to EN 868-8 Verpackung gemäß EN 868-8		EN 285'e göre buhar sterilizasyon prosedürü Steam sterilization procedure according to EN 285 Dampfsterilisationsverfahren nach EN 285				
	Açıklama Explanation Erläuterung	Sembolik Paketleme Symbolic Packaging Symbolische Verpackung	Graviti Gravitational Schwerkraft	Ön Vakum Pre-Vacuum Vorvakuum	Fraksiyonel Vakum Fractionate Vacuum Fraktioniertes Vakuum	Ön Fraksiyonel Enjeksiyon Preliminary Fractionated injection Vorläufige fraktionierte Injektion	Buhar Enjeksiyon Steam injection Dampfeinspritzung
Filtreli / with Filters / mit Filte	Kutu ve Kapak Filtreli, Tekstil ürünler için. Textiles in container with filter in lid and box Textilien in Container mit filter in Deckel und box		+	+	+	+	+
	Kutu deliksiz, kapak filtreli, tekstil ürünler için. Textiles in container with filter in lid, non perforated box Textilien in Container mit filter in Deckel, nicht perforierter box		○	○	+	+	+
	Kutu filtreli, kapak deliksiz, tekstil ürünler için. Textiles in container with filter in box, non perforated lid Textilien in Container mit filter in box, nicht perforierter Deckel		-	-	+	+	+
	Kutu filtreli, kapak deliksiz, tekstil ürünler için. Textiles in container with filter in box, non perforated lid Textilien in Container mit filter in box, nicht perforierter Deckel		-	-	+	+	○
	Tel sepet içinde alet sterilizasyonu için, Kutu ve kapak filtreli. Instruments in wire basket, in sterilization filter in lid and box Instrumente im Drahtkorb, im SterilisierContainer mit Filter im Deckel und Box		+	+	+	+	+
	Tel sepet içinde alet sterilizasyonu için, kapak filtreli, kutu deliksiz Instruments in wire basket, in sterilization container filter in lid and non-perforated box Instrumente im Drahtkorb, im SterilisierContainer mit Filter im Deckel und nicht-perforiert Box		-	+	+	+	+
	Tel sepet içinde alet sterilizasyonu için, kutu filtreli, kapak deliksiz. Instruments in wire basket, in sterilization container filter in box and non-perforated lid Instrumente im Drahtkorb, im SterilisierContainer mit Filter im box und nicht-perforiert Deckel		○	+	+	+	+
	Tel sepet içinde alet sterilizasyonu için, kapak valfli, kutu deliksiz. Instruments in wire basket, in sterilization container with valve in lid and non-perforated box Instrumente im Drahtkorb, im SterilisierContainer mit Ventile im Deckel und nicht perforiertem Box		-	+	+	+	+
Valfli / with Valves / mit Ventilen	Tekstil ürünler için, kutu ve kapak valfli Textiles in sterilization container with valves in lid and box Textilien im SterilisierContainer mit Ventilen in Deckel und Box		-	○	+	+	○
	Tekstil ürünler için, Kutu deliksiz, kapak valfli Textiles in sterilization container with valves in lid and no valves on the box Textilien im SterilisierContainer mit Ventilen im Deckel, keine ventile auf der Box		-	-	+	+	○
	Tel sepet içinde alet sterilizasyonu için, Kutu ve kapak valfli. Instruments in wire basket in sterilization container with valve in lid and box Instrumente im Drahtkorb, im SterilisierContainer mit Ventile im Deckel und Box		-	-	+	+	-
	Tel sepet içinde alet sterilizasyonu için, kapak valfli, kutu deliksiz. Instruments in wire basket, in sterilization container with valve in lid and non-perforated box Instrumente im Drahtkorb, im SterilisierContainer mit Ventile im Deckel und nicht perforiertem Box		-	-	+	+	-
	Tel sepet içinde alet sterilizasyonu için, kutu filtreli, kapak deliksiz. Instruments in wire basket, in sterilization container filter in box and non-perforated lid Instrumente im Drahtkorb, im SterilisierContainer mit Filter im box und nicht-perforiert Deckel		-	+	+	+	+
	Tel sepet içinde alet sterilizasyonu için, kapak valfli, kutu deliksiz. Instruments in wire basket, in sterilization container with valve in lid and non-perforated box Instrumente im Drahtkorb, im SterilisierContainer mit Ventile im Deckel und nicht perforiertem Box		-	+	+	+	+
	Tel sepet içinde alet sterilizasyonu için, kutu filtreli, kapak deliksiz. Instruments in wire basket, in sterilization container filter in lid and non-perforated box Instrumente im Drahtkorb, im SterilisierContainer mit Filter im lid und nicht-perforiert Box		-	+	+	+	+
	Tel sepet içinde alet sterilizasyonu için, kutu valfli, kapak deliksiz. Instruments in wire basket, in sterilization container with valve in box and non-perforated lid Instrumente im Drahtkorb, im SterilisierContainer mit Ventile im box und nicht-perforiert Deckel		-	+	+	+	+

(+) Uygulanabilir / Applicable / Arwendbar (-) Uygulanamaz / Not Applicable / Nicht Arwendbar (○) Sınırlı / Limited / Begrenzt

Tablo / Table / Tabelle -10

¹ In order to avoid mistakes with regards to service, operation and/or when loading the sterilizer, please refer table 10 for correct or wrong combination of sterilization containers for standardized steam sterilization procedures.


² Only sterilization containers guaranteed evaporation or discharge of condensate are suitable above. ³ Gravitation procedures having no drying process do not guarantee of sterility a sufficient after-drying effect

5.5 Sterilization Process Parameters

Application parameters of steam sterilization

Sterilization Type	Time/ 121°C	Time/ 134°C	Drying Time	Description
Gravity Sterilization	30 Minutes	15 Minutes	15-30 Minutes	Check the proper packing method from Table 10.
Pre-Vacuum Steam Sterilization	-	4 Minutes	15-20 Minutes	Drying times are given according to the loading weights indicated in table 9.

Table -11

 **WARNING**

In the sterilization of container models with valve mechanism, the working pressure of the autoclave is 2 bar and the vacuum time is 15-20 minutes.

5.6 Controls after Sterilization Process

 **WARNING**

Always wear protective gloves when emptying containers from the sterilizer.

Products should not undergo a change of environment with large temperature differences after sterilization process.

It should be expected to cool down to room temperature. Sweating will come to the fore in sudden temperature changes.

Make sure the chemical indicator color on the paper labels have changed. (For paper labels see. 2.5)

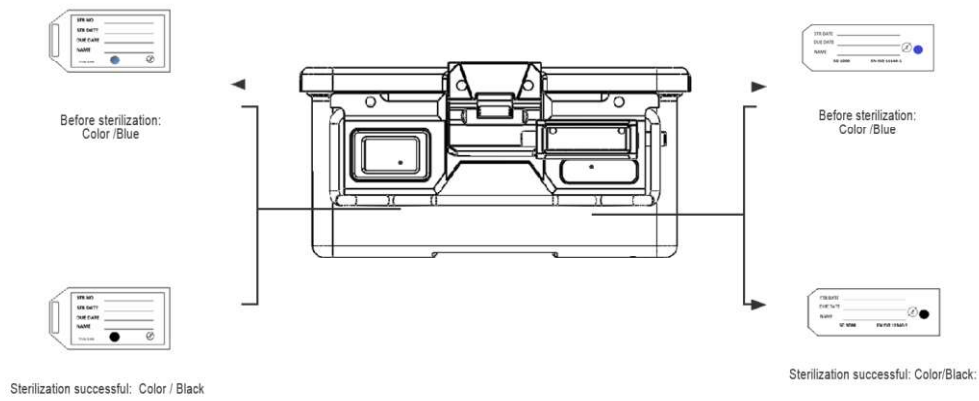


Figure - 43

If a chemical-indicative safety seal is used prior to sterilization, the sterilization control can also be provided via the security seal.



Figure - 44

In the paper filter models of sterilization containers, there are chemical indicators on the disposable filters. Internal control can be provided with disposable filters.



Figure - 45

The color conversion of the indicator color on the chemical



Figure - 46

5.7 Transport and storage after sterilization

- Always carry the sterilization containers by their handles.
- Never carry sterilization container holding from the lid or lock system.
- Transport the sterilization container in such a way that mechanical damage will not occur.

Sterilization container storage room condition:

Temperature	15-26 °C
Humidity	30-50 %
Air Pressure	Normal atmospheric pressure

Table -12



NOTE

The sterilization container systems have been validated as sterile for 1 year and 1 day under the appropriate storage conditions specified in table 12.

References:

- **93/42/EEC**
- **EN 285 in combination with EN ISO 17665**
- **EN ISO 11607**
- **EN 868-8**
- **DIN 58953-9**
- **DIN 58946-7**
- **CDC (Center for disease control and prevention)**
- **DAS (Disinfection Antiseptic Sterilization Association)**



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