




STERILIZATION CONTAINER TECHNICAL FILE

Product Description

Prepared by;

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1.MANUFACTURER INFORMATION

1.1. Manufacturer

Company name: Medster Tıbbi Cihaz ve Saęlık Hizmetleri Ltd. Őti.
Address: Malıköy Bařkent OSB Mah. 19.Cad No:51 Sincan / Ankara / Türkiye
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Web: www.medster.com.tr
Presentation: MEDSTER; With its 40 years of experience based on printing technologies, it produces its patented products in domestic production facilities and in completely sterile conditions, and offers them to the service of Turkish and World Medical Authorities.

With its innovative structure and sterile solutions that provide strategic and global cooperation, MEDSTER is a corporate company that has proven its competence and reliability on the international platform. It has managed to have a say in the international arena with its technology-oriented sterilization products and services in projects that require knowledge, experience and professional competence.

Established in 1968, the company expanded its expertise in sterilization services to "MEDSTER Medical Devices and Health Services Ltd. Sti." has taken its title to a new dimension. It continues to serve as a corporate company that steers the sector by strengthening its corporate structure day by day.

MEDSTER is a company that has undertaken the product distributorship of 17 countries and exports to 35 countries and is a member of the Turkish Exporters Assembly. It participates in the world's leading fairs such as Germany - Medica Fair, Dubai - Arap Health and Miami USA - Fime International Medical Exposition and follows the innovations on site.

With its development-oriented visionary structure, MEDSTER continues to invest in machinery and renews itself every year and continues to be the indispensable choice of public and private hospitals both in Turkey and abroad. By supplying products to many manufacturers in the sector, it stands out as the solution partner of the sector with its versatile structure and a wide product range that can meet all the needs of the sector from a single point.

MEDSTER, which combines the advantages of sterile and domestic production, the measurements given and the supply of special products that can be prepared according to demand, has proven its success with its quality certificates.

Sterile Container systems manufactured by Medster Medical Devices are designed and manufactured in a number of different types and sizes in order to meet the requirements of several applications available in sterile healthcare institutions. These containers are designed in order to ensure the sterile condition of medical devices used in surgical operations, subcutaneous medical devices, surgical tools and electro-surgery tools and are equipped with a number of accessories such as wire basket, silicon strip, textile products, filters and labels.

Designed for medical purposes, Medster Sterile Container Systems are commonly used in clinical applications and medical field in general. The product is manufactured under ten general groups with a large number of variations. A total number of 4 types of filters, namely, paper filter, cloth filters, teflon and barrier filter, were mainly used for containers with different models. Medster Sterile Container System is manufactured for transportation of surgical tools and sterile products, their packaging, sterilization and sterile storage after sterilization.

Medster Sterile Container System consists of different size lids and boxes manufactured in accordance with customer needs and standards, filter systems with different operating techniques, filter holders, indicators and other necessary accessories. Following the sterilization process conducted in compliance with aseptic techniques, it is possible to store any devices and tools in the container for 6 months in a sterile manner.

1.1.3 Product Warehouse Address:

Address: Malıköy Başkent OSB Mah. 19.Cad No:51 Sincan / Ankara / Türkiye

1.1.4 Production Address of Sterile Container Systems:

Company name: Medster Tıbbi Cihaz ve Sağlık Hizmetleri Ltd. Şti.

Address: Malıköy Başkent OSB Mah. 19.Cad No:51 Sincan / Ankara / Türkiye

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2. CLASSIFICATION, GENERAL AND SPECIAL DEFINITION

Sterile Container Systems manufactured by Medster Surgical Instruments Inc. are classified under Class I medical devices according to the Article #1 of the Council Directive Appendix 9 numbered 93/42/EEC (accepted 2007/47/EEC) issued on June 14, 1993.

(Article 1. All non-refractive devices are classified under Class 1 unless one of the articles below applies.)

3. VERIFICATION DEVICE

Medster Sterilization Sterile Container System each part of the technical file has a separate document number and a revision number in conjunction with this number. Revisions are monitored and recorded by the Medster Quality Assurance Department.

4. PURPOSE OF USAGE

Our products are used to provide sterile barrier properties. It is designed to maintain its sterile feature during the period from sterilization to use of a properly packaged medical device. They are single use products.

Detailed information is in the user manual.

5. PRODUCT MODEL

No	Model Name	Sterile Storage	Intended Use
1	Classic Model	Suitable	Transportation, Storage, Sterilization and Sterile Storage
2	Bio-Barrier Model	Suitable	Transportation, Storage, Sterilization and Sterile Storage
3	Window Model	Suitable	Transportation, Storage, Sterilization and Sterile Storage
4	PPSU Model	Suitable	Transportation, Storage, Sterilization and Sterile Storage
5	Dental Model	Suitable	Transportation, Storage, Sterilization and Sterile Storage
6	Scopy Model	Not Suitable	Transportation, Storage and Sterilization
7	Flat Model	Suitable	Transportation, Storage, Sterilization and Sterile Storage
8	Implant Model	Not Suitable	Transportation, Storage and Sterilization
9	Mini Model	Suitable	Transportation, Storage, Sterilization and Sterile Storage
10	B3 Model	Suitable	Transportation, Storage, Sterilization and Sterile Storage
11	Endo Model	Suitable	Transportation, Storage, Sterilization and Sterile Storage
12	A1 Model	Suitable	Transportation, Storage, Sterilization and Sterile Storage
13	Standard Plus Model	Suitable	Transportation, Storage, Sterilization and Sterile Storage

There are 13 different sterilization container system.

No	Model Name	Sterile Storage	Intended Use
1	Wire Basket	Not Suitable	Transportation, Storage and Cleaning
2	Stainless Steel Sheet Basket	Not Suitable	Transportation, Storage and Cleaning



Classic Model

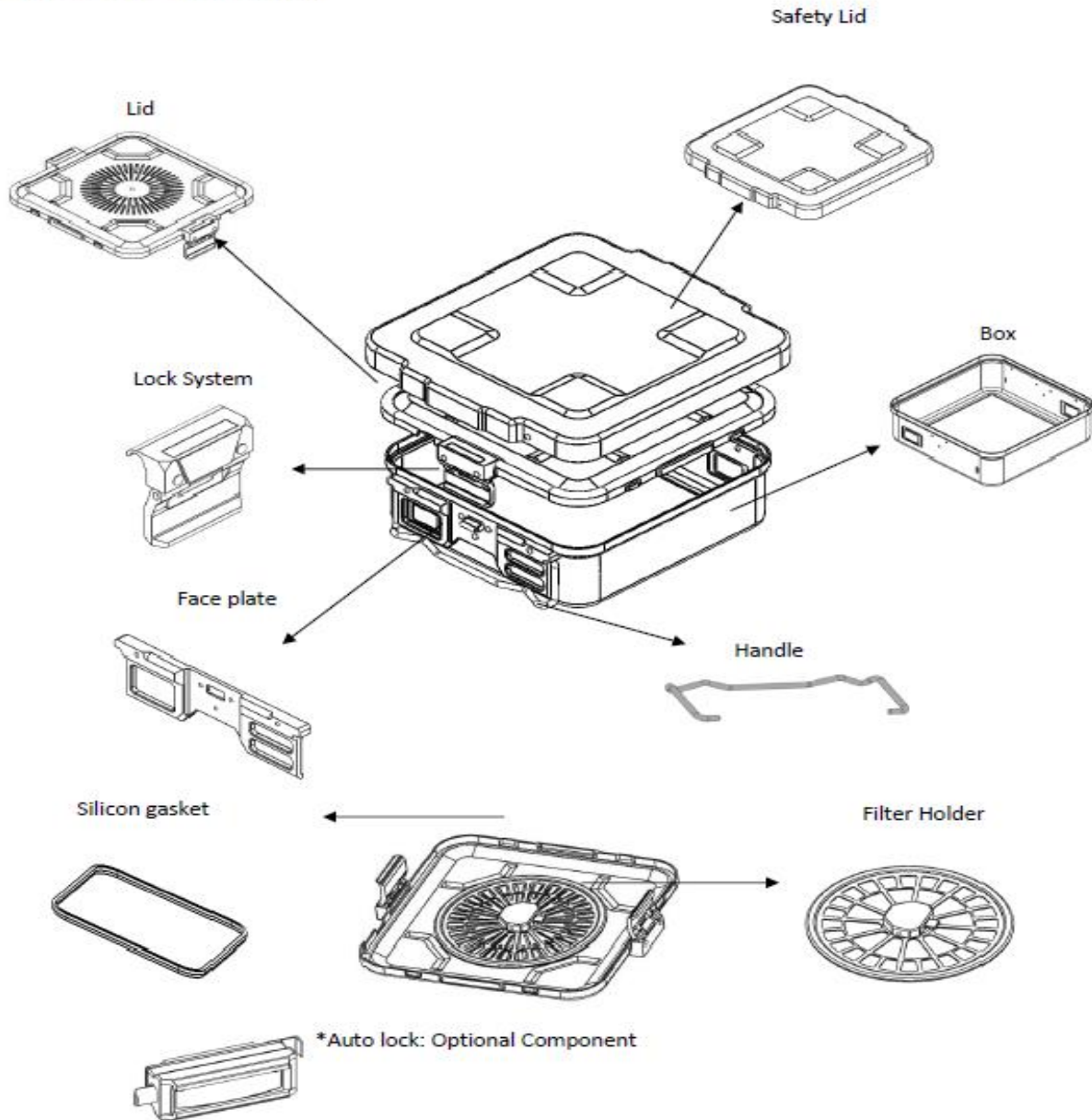


Wire Basket

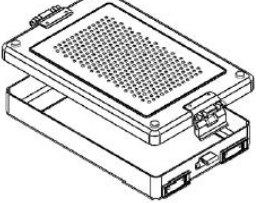
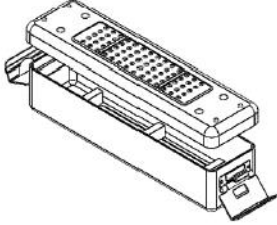
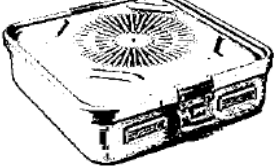
Figure-1 Product Image

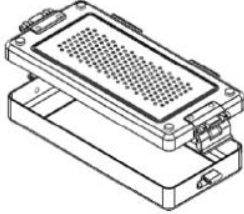
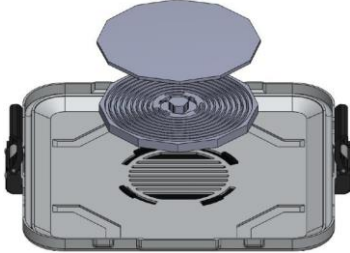
5.1 Components of a Standard Container

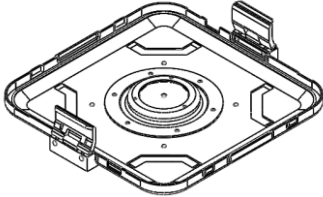
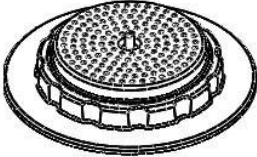
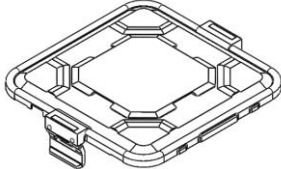

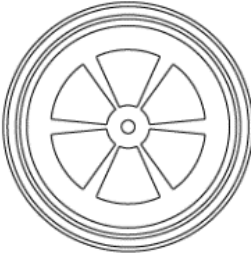
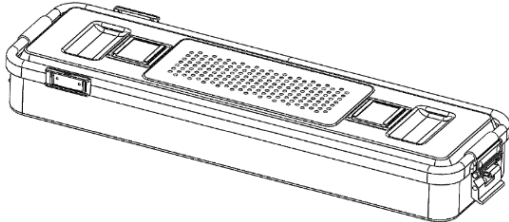
Components of a Standard Container,







5.2 Properties of Sterilization Container Systems

No	Model Name	Properties	
1	Classical Model	Classical container model manufactured for transportation and sterile storage of Surgical instruments and products that should be sterilized. The classical model will be filter system and can be usable with paper, textile and teflon filter to according to preference.	
2	Bio-Barrier Model	Bio-Barrier model is a system that does not require a filter system and provides sterile storage with a special valve mechanism. There will be no filter in this system. Other components are the same.	
3	Window Model	There is a window system in window model system lids to see inside the container. The system can be usable with filter or valve mechanism. Valve or filter mechanism will be on the box.	
4	PPSU Model	The Working Mechanism of PPSU Model Container and components are similar with the classical model container. The only difference is the raw material of the Lid is PPSU instead of Aluminum.	
5	Dental Model		The intended use of the Dental model container system is the same as the classic model, differences are dimensions and components. The system becomes suitable with filter and valve mechanism with purpose. There is no holder for transportation and faceplate.
6	Scopy Model		Scopy model container does not have sterile storage property. Designed for storage and transportation of instruments. There is different design with lock mechanism and without lock mechanisms.
7	Flat Model		The intended use of the flat model container system is the same as the classic model, differences are dimensions and components. The system becomes suitable with filter and valve mechanism with purpose. There is no holder for transportation and faceplate.

8	Implant Model	The implant container model does not have sterile storage property. Designed for storage and transportation of instruments.	
9	Mini Model		The intended use of the mini model container system is same as classic model, differences are dimensions and components. System becomes suitable with filter and valve mechanism with purpose. There is no holder for transportation and faceplate.
10	A1 Model	A1 container model will be grown sterile after extensive training and sterilization, intended for instrument and sterile use. It is a Filtered System, optionally supplied with paper, textile and Teflon filters. The difference from the standard model is the filter temperature from the sample to the candidate. It has been saved from being economical	
11	Standard Plus	The Standard Plus Container model is produced for the transport, packaging, sterilization and sterilization of surgical instruments and products for sterile use after sterilization. It is a Filtered System and optionally, it can be used with paper, textile and Teflon filters.	
12	B3 Model	<p>B3- Bio Stop Model</p> 	<p>B3 Model sterilization container has advantages when compared with standard model. B3 model designed for here different sterilization container groups. 3 properties can be applied without any different lid. Mechanism that used in B3 Model container can be usable as valve system and standard filter system.</p> <p>Valve Component</p>

13	Endo Model	<p>B3 Valve System</p> 	 <p>Bio-Stop Component</p>
		<p>B3 Filter System</p> 	  <p>Filter Component</p>
			<p>Endo Model Container System has the same intended use with Classic Model, the differences are dimensions and components of Systems. With the filter mechanism, it becomes suitable for intended use. There is no handle for transporting and faceplate.</p>

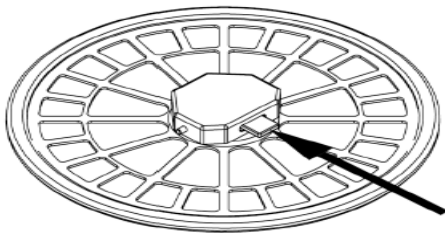
5.2.1 Sterilization Container System Dimension Table

Type	Classic Model	PPSU Model	Bio-Barrier Model	Window Model	Dental Model	Scopy Model	Flat Model	Implant Model	Mini model	B3 Model	Endo Model	A1 Model	Standard Plus Model
 Non-perforated Box Lid Perforated	√	√	-	-	√	√	-	√	√	-	√	√	√
 Box Perforated Lid Perforated	√	√	-	-	√	√	√	√	√	-	√	√	√
 Box Perforated Lid Perforated With Safety Lid	√	-	-	-	-	-	√	-	-	-	-	√	√
 Box Perforated Lid Perforated With Safety Lid	√	-	-	-	-	-	√	-	-	-	-	√	√

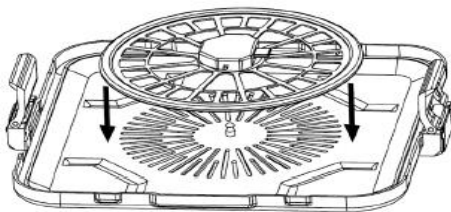
5.2.2 Types of Sterilization Container System

Height	Classic Model				PPSU Model				Bio-Barrier Model				Window Model				Dental Model	Scopy Model	Flat Model	Implant Model			Mini model	B3 Model				Endo Model	A1 Model								
	1/1	3/4	1/2	XL	1/1	3/4	1/2	XL	1/1	3/4	1/2	XL	1/1	3/4	1/2	XL	320X190	250X60	450X70	285X280	300X149	500X169	160X70	200X145	315X135	1/1	3/4	1/2	XL	535X160	1/1	3/4	1/2	XL			
40 mm	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	
50 mm	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
55 mm	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
60 mm	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	
65 mm	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
70 mm	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
85 mm	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
100 mm	+	+	+	-	+	+	+	-	+	+	+	-	+	+	+	-	-	-	-	-	-	-	-	-	-	+	+	+	+	-	+	+	+	+	+	+	-
120 mm	-	-	-	+	-	-	-	+	-	-	-	+	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	+
130 mm	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
135 mm	+	+	+	-	+	+	+	-	+	+	+	-	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	-	-	+	+	+	-	-
150 mm	+	+	+	-	+	+	+	-	+	+	+	-	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	-	-	+	+	+	-	-
180 mm	-	-	-	+	-	-	-	+	-	-	-	+	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	+
200 mm	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	+	-	+	-	-	+	-	+	-	-

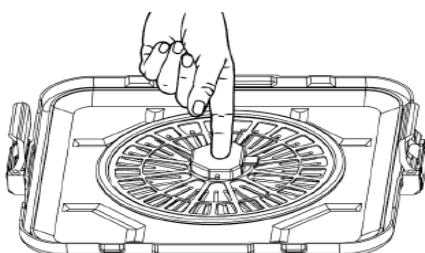
5.3 WORKING PRINCIPLE AND EFFECT MECHANISM



1. The filter holder is separated from the cover by pressing the mandrel on it. Check the gaskets on the inside edges of the filter retainer

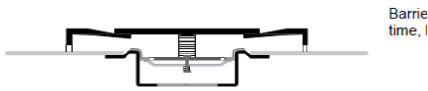


2. The filter retainer lid is placed in the direction of the arrow to seat on the pin

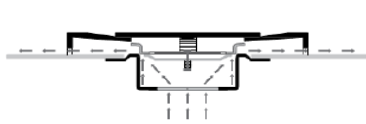


3. Press your finger on the button until you hear the "click" sound. If sound comes out then the mechanism is working.

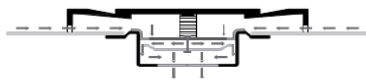
5.4 BARRIER MODEL VALVE SYSTEM WORKING MECHANISM AND MAINTENANCE



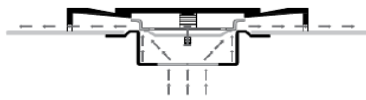
Barrier model system valves work in 3 different positions during rest time, before sterilization and after sterilization.



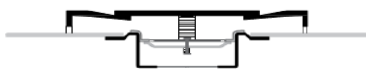
Before sterilization, the valves are at rest position



After sterilization, the valves are opened in the opposite direction by pressure effect and the sterilization of the container is ensured.

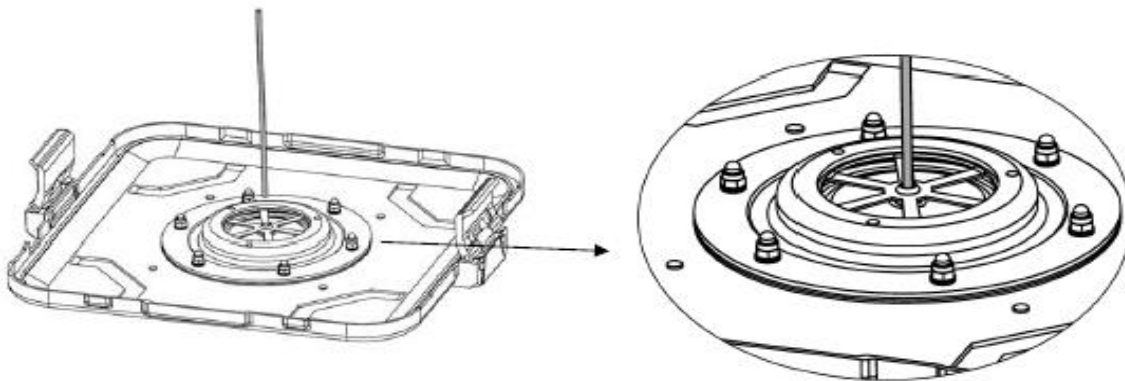


During the sterilization, the valves are fully opened by vacuum effect, so that dry air leaves the container.



During the sterilization, the valves are fully opened by vacuum effect, so that dry air leaves the container.

After sterilization, the valves are in the resting phase.



Before the sterilization container is filled with tools, remove the cap and ensure that the valve functions are correct. To make sure that the function work properly, it is pressed inward as shown with a pointed bar. The movement of the valve mechanism is controlled.

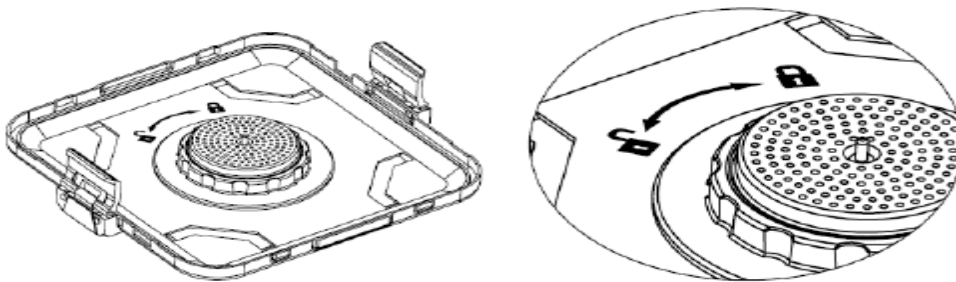
5.4.1 B3 Model Working Mechanism and Maintenance

The B3 Model is designed for 3 different sterilization container groups. It can be applied to 3 different features on a single lid without the need for different lid systems.

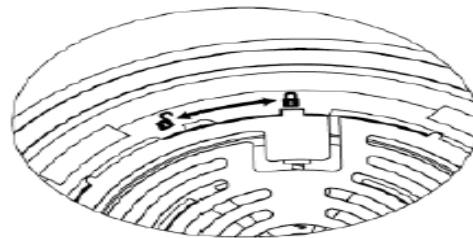
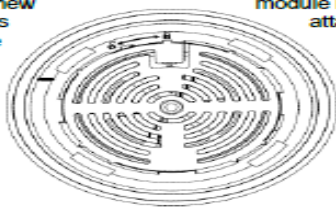
Thanks to the mechanism used in the B3 model, the container can be used both as a valve system, as a standard filter system and as a bio-stop system.

5.4.2 B3 Filter System Working Mechanism

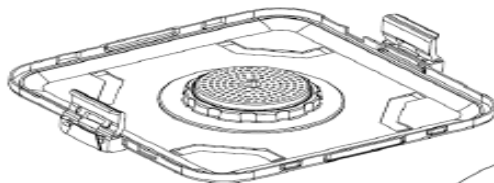
B3 Model Filter module replacement



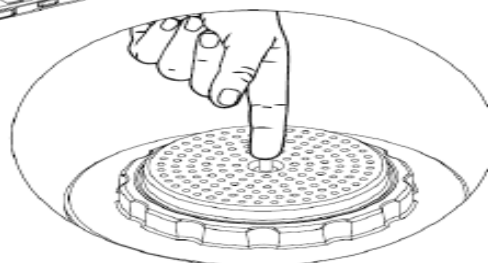
- 1-For the B3 filter module, the lid is turned upside down and the mechanism is turned to the left to remove the mechanism.
- 2- The lid behind the mechanism is removed by turning it in the direction of the arrow as seen
- 3- Once the mechanism lid is removed, the filter module is changed.
- 4- After the new module is installed, the mechanism is attached to the lid by reversing the process.



1.6.2 B3 Module

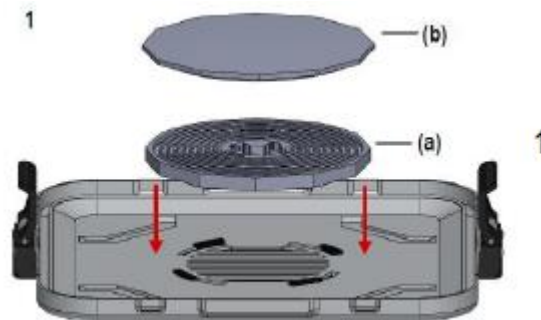


Model Valve Mechanism Maintenance

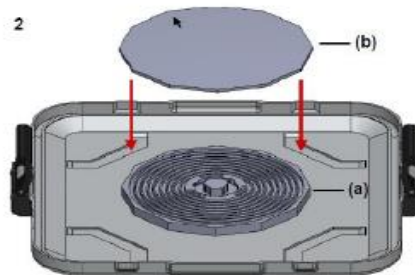


B3 Model Valve module operating mechanism is the same with barrier model. The control of the mechanism can be done on the cover.

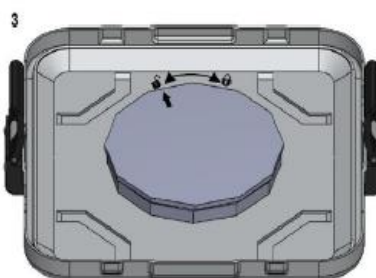
The cover is turned upside down and the pressure is applied with the finger to the pin in the middle of the mechanism. It is checked whether the mechanism is moving or not. Make sure the spring system in the mechanism works



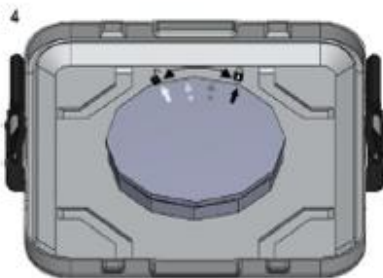
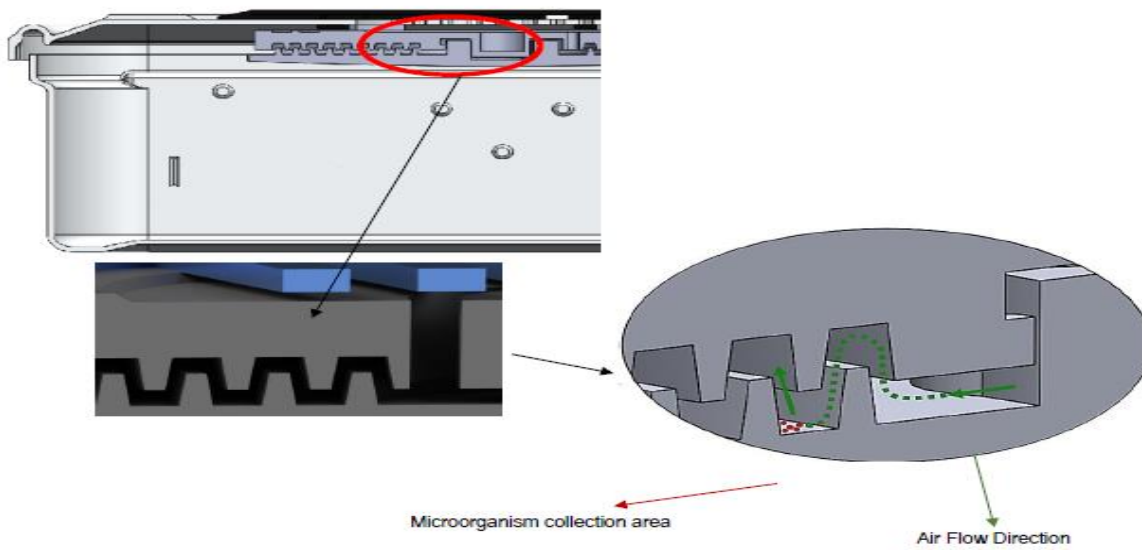
In Figure-1, the lower component of the barrier system (a) is located in order to fit into the slots available on the cover and the lower component (a) is moved to the 'Lock' location from 'Unlock'



In Figure 2, the upper barrier component of the barrier system (b) is fitted on the lower barrier component (a) as shown in the figure.



In Figure 3, when the barrier components are fitted the symbol available on the cover must be pointing at the 'Unlock' symbol.



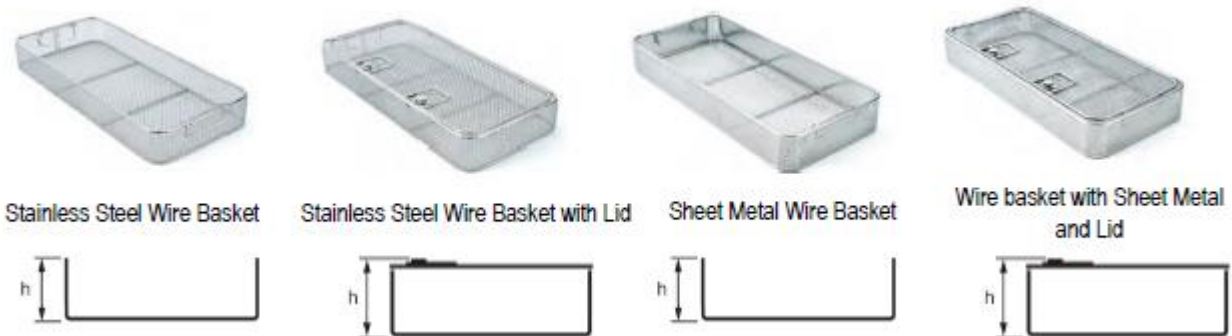
In Figure 4, the assembly is completed when the barrier components are moved to point at the 'Lock' symbol.

Designed based on the Pasteur Flow Inhibition system, the custom geometric features of this product offers a technology which eliminates microorganisms in the air flow.

Thanks to the barriers available in the mechanism, it prevents the microorganisms floating with the air flow to be introduced in the system having ensured they are trapped in the barriers also making use of the gravitational force.

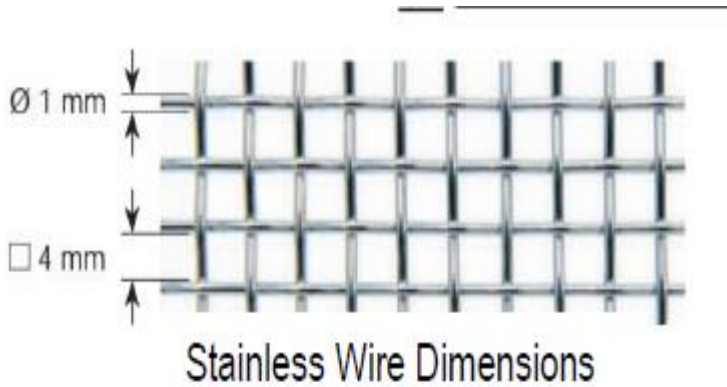
The system is designed to collect microorganisms in the tubes located between barriers. While EN 868 approved filter systems collect microorganisms in on the filter itself, B3 Bio-stop model collects microorganisms in the tubes located between barriers.

5.4.3 Surgical Baskets

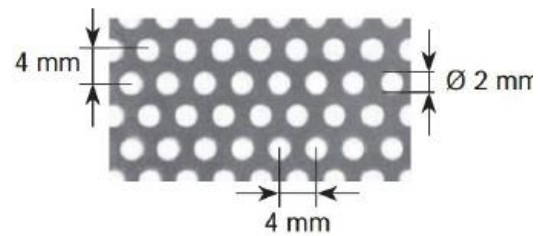


Baskets are the main supplementary components of container systems, and they are necessary for a full set container. Medster has focused on 3 main models in basket production. Two of these models are wire basket and perforated sheet basket. The third model is a combination of these two models with perforated metal plates on sides and with wire mesh on bottom. MEDSTER has the model and sizes of baskets in its standard production appealing to all container model and sizes. Also, it ensures basket production in demanded sizes besides standard production.

Height (h)	1/1											
	Wire Basket		Wire Basket with Lid		Wire Basket with Sheet Metal		Wire Basket with Sheet Metal and Lid		Sheet Metal Basket		Sheet Metal Basket with Lid	
	540x250	480x250	540x250	480x250	540x250	480x250	540x250	480x250	540x253	485x253	540x253	485x253
30 mm	+	+	-	-	-	-	-	-				
35 mm	-	-	+	+	-	-	-	-				
40 mm	-	-	-	-	-	-	-	-	+	+		
43 mm	-	-	-	-	-	-	-	-			+	+
50 mm	+	+	-	-	+	+	-	-				
55 mm	-	-	+	+	-	-	+	+				
60 mm	-	-	-	-	-	-	-	-	+	+		
63 mm	-	-	-	-	-	-	-	-			+	+
70 mm	+	+	-	-	+	+	-	-				
75 mm	-	-	+	+	-	-	+	+				
80 mm	-	-	-	-	-	-	-	-	+	+		
83 mm	-	-	-	-	-	-	-	-			+	+
100 mm	+	+	-	-	+	+	-	-				
105 mm	-	-	+	+	-	-	+	+				
110 mm	-	-	-	-	-	-	-	-	+	+		
113 mm	-	-	-	-	-	-	-	-			+	+



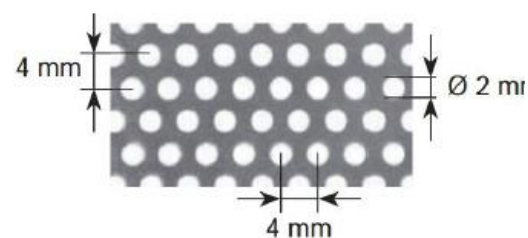
The standard diameter of the wire used in basket production is 1 mm and mesh distance is 4 mm. But this distance can also be arranged according to the special demands. Besides, Medster manufactures fine mesh baskets for small instruments, laundry baskets and endoscopic baskets. These baskets can also be produced in demanded sizes and mesh distances.



Perforated Sheet Metal Dimensions

Height (h)	3/4					
	Wire Basket	Wire Basket with Lid	Wire Basket with Sheet with Metal	Wire Basket with Sheet with Metal and Lid	Sheet Metal Basket	Sheet Metal Basket with Lid
	405x250	405x250	405x250	405x250	540x253	485x253
30 mm	+	-	-	-	-	-
35 mm	-	+	-	-	-	-
40 mm	-	-	-	-	+	-
43 mm	-	-	-	-	-	+
50 mm	+	-	+	-	-	-
55 mm	-	+	-	+	-	-
60 mm	-	-	-	-	+	-
63 mm	-	-	-	-	-	+
70 mm	+	-	+	-	-	-
75 mm	-	+	-	+	-	-
80 mm	-	-	-	-	+	-
83 mm	-	-	-	-	-	+
100 mm	+	-	+	-	-	-
105 mm	-	+	-	+	-	-
110 mm	-	-	-	-	+	-
113 mm	-	-	-	-	-	+

The standard diameter of the wire used in basket production is 1 mm and mesh distance is 4 mm. But this distance can also be arranged according to the special demands. Besides, Medster manufactures fine mesh baskets for small instruments, laundry baskets and endoscopic baskets. These baskets can also be produced in demanded sizes and mesh distances.

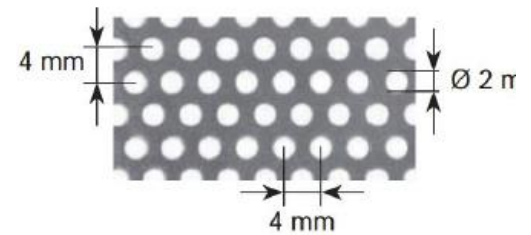


Perforated Sheet Metal Dimensions



Height (h))	1/2					
	Wire Basket	Wire Basket with Lid	Wire Basket with Sheet Metal	Wire Basket with Sheet Metal and Lid	Sheet Metal Basket	Sheet Metal Basket with Lid
	255x250	255x250	255x250	255x250	255x253	255x253
30 mm	+	-	-	-	-	-
35 mm	-	+	-	-	-	-
40 mm	-	-	-	-	+	-
43 mm	-	-	-	-	-	+
50 mm	+	-	+	-	-	-
55 mm	-	+	-	+	-	-
60 mm	-	-	-	-	+	-
63 mm	-	-	-	-	-	+
70 mm	+	-	+	-	-	-
75 mm	-	+	-	+	-	-
80 mm	-	-	-	-	+	-
83 mm	-	-	-	-	-	+
100 mm	+	-	+	-	-	-
105 mm	-	+	-	+	-	-
110 mm	-	-	-	-	+	-
113 mm	-	-	-	-	-	+

The standard diameter of the wire used in basket production is 1 mm and mesh distance is 4 mm. But this distance can also be arranged according to the special demands. Besides, Medster manufactures fine mesh baskets for small instruments, laundry baskets and endoscopic baskets. These baskets can also be produced in demanded sizes and mesh distances.

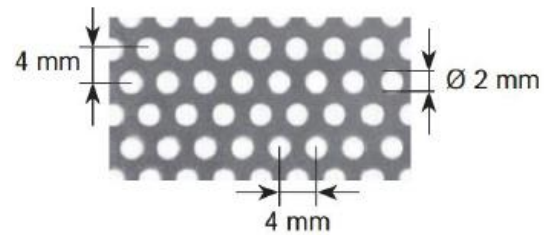


Perforated Sheet Metal Dimensions



Height (h)	Extra Large Model			
	Wire Basket	Wire Basket with Lid	Sheet Metal Basket	Sheet Metal Basket with Lid
	533x337	533x337	533x340	533x340
30 mm	-	-	-	-
35 mm	-	-	-	-
40 mm	-	-	+	-
43 mm	-	-	-	+
50 mm	+	-	-	-
55 mm	-	+	-	-
60 mm	-	-	+	-
63 mm	-	-	-	+
70 mm	+	-	-	-
75 mm	-	+	-	-
80 mm	-	-	+	-
83 mm	-	-	-	+
100 mm	+	-	-	-
105 mm	-	+	-	-
110 mm	-	-	+	-
113 mm	-	-	-	+

The standard diameter of the wire used in basket production is 1 mm and mesh distance is 4 mm. But this distance can also be arranged according to the special demands. Besides, Medster manufactures fine mesh baskets for small instruments, laundry baskets and endoscopic baskets. These baskets can also be produced in demanded sizes and mesh distances.



Perforated Sheet Metal Dimensions

6. INTENDED USE AND AREAS OF USAGE

Medster Sterile Container System is manufactured for transportation of surgical tools and sterile products, their packaging, sterilization and sterile storage after sterilization.

Medster Sterile Container System can be used by hospitals, surgical clinics and any other healthcare providers.

Medster Sterile Container System consists of different size lids and boxes manufactured in accordance with customer needs and standards, filter systems with different operating techniques, filter holders, indicators and other necessary accessories.

Following the sterilization process conducted in compliance with aseptic techniques, it is possible to store any devices and tools in the container for 6 months in a sterile manner.

Medster Sterile Container System is suitable for steam sterilization. (DIN 58946-1)

7. OPERATING METHOD OF STERILE CONTAINER SYSTEMS

- Clean the container manually and mechanically before initial sterilization.
- Proper filter must be fitted before the pre-sterilization cleaning process.
- When placing the tools in the wire basket for storage and sterilization, they can be wrapped using the green cloth.
- It is recommended to use silicon strip on the bottom for the storage of micro tools in the container.

- Storage in sterile container must be arranged in a way not to interrupt the functionality of the filter.
- A distance of at least 2 inches (approx. 5cm) must be available between container and its load to provide acceptable and suitable sterile container loading.
- Container may be secured using cloths to wrap it when it is positioned perpendicularly.
- After the loading of the sterile container is complete, sterilization indicator must be placed in the label holder for sterilization process and its details. The change in the color of the indicator must be observed. Sterilization is not properly done if there is no change in the color.
- Information such as 'sterilization date', 'sterilization number', 'expiration date', etc. must be filled on the label.

7.1 Loading a Tool

- The total weight of the container plus tools shall not exceed **10kg** (DIN 58953-9). Otherwise, sterilization may not fulfill its purpose fully.

The total weight of the container plus tools for $\frac{3}{4}$ container shall not exceed 7 kg while it shall not exceed 5kg for $\frac{1}{2}$ container.

7.2 Loading a textile

- Acceptable maximum loading weight is **8kg**. It should be ensured that folded textile products are placed in a horizontal manner. In order to allow for the steam to move in the container without interruption, the compactness of the textile products must allow one to be able to push them down without effort. (DIN 58952-9).

7.3 Sterilization and Container Stacking

- Sterile Container Systems by Medster are suitable for any moist heat sterilization.
- Make sure that you have stacked containers on top of each other, the heavy ones being stacked at the bottom. *It is preferable to stack containers with polymer lids on the top.*
- Comply with the loading instructions of the autoclave manufacturer.
- Container stacking on top of each other is only recommended for "high vacuum cycle".
- Do not pack the sterile container itself.
- As the container will be hot after the sterilization, be aware of the risk of burn when handling the container.
- After the sterilization process, let the sterilizer cool down to room temperature leaving its door ajar. Do not leave the hot sterile container in windy or cold places right after the sterilization process. This may lead to heterogeneous cooling of the surface which may prove harmful for the container.

7.4 Storage

- It is recommended to use dust-proof carts for the transportation of the sterile container system.
- Proper sterilization must be ensured before storing sterile materials.
- Make sure that the indicator color has changed before opening the sterilized containers.

-Store your sterile container in a clean, dry and safe place.

7.5 Human Blood And Tissue Of Animal Origin

Human blood or tissue of animal origin don't use in Sterilization Container System. Therefore, there is no need to take any prevention.

8. PRODUCT LIFETIME

Warranty of Sterilization Container System is 2, product lifetime is 5 years. The lifetime of the private products like the filter, on 3 year.

9. STERILIZATION VALIDATION DATAS

Any parts of Sterilization Container Medical Device System do not dispatch sterile.

10. PRODUCT LIST

The container product list is specified in TD.ECD.08 -Declaration of conformity.









11. PRODUCT WEIGHTS



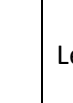


The container product weights are specified in Catalog in Medster.

12. PRODUCT DIMENSIONS

The container product dimensions are specified in Catalog Medster.

13. PRODUCT LABEL

SYMBOLS USED ON PART LABELS AND THEIR MEANINGS	
	Product Lot Information
	Reference Number
	Production Date (Month/Year)
	Expiration date
	Manufacturer Information
	Do not expose to sunlight
	Keep Dry
	Store between 0°C and 40°C.

	Max. 70% RH
	Metal Free
	Lead Free
	Medical Device
	CE Symbol

14. TRACEABILITY

Traceability of our products is done through Lot Number. The lot number will be determined as described below:

For Sterilization Container Systems

MSC + Order Number + Product Code

For example, MSC004SFCK-108 Example of lot number of the product with order number 0005 and product code 600X272

Product type codes are given in Table.1. In addition, the lot number assignment is specified separately for each product in the LS.15.03 Product Lot Table.

15. APPLIED STANDARDS AND DIRECTIVES

No	Standard / Directive No	Standard / Directive Name
1	2017/745/EC	Medical Device Regulation
2	EN ISO 14971:2019	Medical devices – Applying risk management to medical devices
3	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
4	EN ISO 15223-1:2016	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
5	EN ISO 17665:2024	Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices
6	TS EN 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices
7	TS EN 868-8	Packaging for terminally sterilized medical devices - Part

		8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods
8	TS EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
9	TS EN ISO 17664-1	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices

16. REVISION TRACKING

REV.NO	REV. DATE	REV. PERFORMING	REASON FOR REVISION
00	24.04.2024	Ebru İÇMEN	New Release