

## INSTRUCTION FOR USE

### Product Name: Container Label Steam

#### Product Description:

MEDSTER SafeCheck Container Label for Steam is designed to ensure that sterilized materials are accurately recorded. When exposed to steam sterilization conditions, the indicator ink will turn reference color.




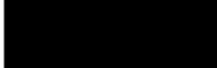
LOT and expiry date information can be found on the product label.

The shelf life of our product is 3 years.

Our product meets the performance specifications of ISO 11140-1 "Sterilization of health care products - Chemical indicators - Part 1: General specifications" for Class 1 Process Indicators.

#### Instruction:

- Place the materials to be sterilized in the appropriate sterilization tray.
- Place the Container Label suitable for the sterilization type to be used on the container.
- Record the information required for sterilization monitoring on the label.
- Check the indicator conversion after sterilization. If the indicator conversion is not the specified color, repeat the process.

Color Conversion Chart	
Before Sterilization	After Sterilization
	
	
















#### Warnings and Precautions:

- The medical device is for single use only, do not reuse.
- Check the product before using it. Do not use the product that is deformed or has a color change in the indicator color.
- Do not use expired products.

#### Storage, Storing and Disposal Information:

- Do not expose to direct sunlight and keep it dry.
- Between 0°C and 40°C and Max. Store at 70% RH humidity.
- Store in its original packaging.
- Dispose of in accordance with the place of use and local regulations.

#### Symbols and their meanings on the product label and user manual:

Symbols	Meaning	Symbols	Meaning	Symbols	Meaning
	Manufacturer Information		Production Date (Month/Year)		Single Use Only
	Product Lot Information		Expiration date		CE Symbol
	Reference No		Unique Device ID		Medical Device
	Do not expose to sunlight		Keep Dry		Store between 0°C and 40°C
	Max. 70% RH		Metal free		Lead free



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<b>STEAM</b>	Suitable for steam sterilization	
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### Packaging and Product Information:

Product Code	Product Description	Package Contents	Inner Box Quantity
80.100	Container Label Steam	100 pcs	50 packs



## INSTRUCTIONS FOR USE

### Product Name: Paper Container Filter Steam

#### Product Description

Medster Paper Container Filter Steam is a single-use cellulosic paper filter which contains steam and heat sensitive indicator printed on. Our product is designed to use on the containers during steam sterilization. The indicator on the filter shows accurate and reliable information about the cycle. Due to changes on the sterilization parameters, indicator color change maybe darker.



LOT and expiry date information can be found on the product label.

The shelf life of our product is 3 years.

Our products meet the performance specifications stated in EN 868-8 "Packaging for terminally sterilized medical devices - Part 8: Re-usable sterilization containers for steam sterilizers" for Class 1 Process Indicators.

#### Instructions:

- Place the Medster Paper Container Filter inside the designated filter housing.
- Lock the container to prevent opening during the sterilization cycle.
- Start the steam sterilization cycle according to the sterilizer instructions.
- At the end of the cycle, the indicator will change color to the reference color.
- If the indicator does not change to the reference color, the sterilization cycle is unsuccessful and must be repeated.

Color Change Table	
Before Sterilization	After Sterilization
	

















#### Warnings and Precautions:

- Product is for single use only
- Control the filter before use. Never use wet, deformed or torn filters.
- Control the initial color of the indicator on the filter. Never use filters those indicators have changed its color.
- Never use expired products
- Keep the filter away from sterilant, alkali chemicals and acids.

#### Storage, Storage and Disposal Information:

- Do not expose to direct sunlight and keep it dry.
- Between 0°C and 40°C and Max. Store at 70% RH humidity.
- Store in its original packaging.
- Dispose in accordance with the place of use and local regulations.

#### Symbols and their meanings on the product label and user manual:

Symbols	Meaning	Symbols	Meaning	Symbols	Meaning	Symbols	Meaning
	Manufacturer Information		Suitable for steam sterilization		Production Date (Month/Year)		Single Use Only
	Product Lot Information		Max. 70% RH		Expiration date		CE Symbol
	Reference No		Metal free		Unique Device ID		Medical Device
	Do not expose to sunlight		Keep Dry		Lead free		Store between 0°C and 40°C



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## **INSTRUCTIONS FOR USE**

### **Packaging and Product Information:**

<b>Product Code</b>	<b>Product Description</b>	<b>Package Contents</b>	<b>Inner Box Quantity</b>
80.300	Paper Container Filter Steam	100	-



## INSTRUCTIONS FOR USE

### Product Name: PTFE Container Filter Steam

#### Product Description

Medster PTFE Container Filter Steam is a reusable PTFE filter which contains steam and heat sensitive indicator printed on. PTFE filters are porous membranes used in steam sterilization reusable rigid containers as sterile barrier against the penetration of microorganisms. Our product is designed to use on the containers during steam sterilization. The indicator on the filter shows accurate and reliable information about the cycle. Due to changes on the sterilization parameters, indicator color change maybe darker.



LOT and expiry date information can be found on the product label.

The shelf life of our product is 3 years.

Our products meet the performance specifications stated in EN 868-8 "Packaging for terminally sterilized medical devices - Part 8: Re-usable sterilization containers for steam sterilizers" for Class 1 Process Indicators.

#### Instructions:

- Place the Medster PTFE Container Filter inside the designated filter housing.
- Lock the container to prevent opening during the sterilization cycle.
- Start the steam sterilization cycle according to the sterilizer instructions.
- At the end of the cycle, the indicator will change color to the reference color.
- If the indicator does not change to the reference color, the sterilization cycle is unsuccessful and must be repeated.

Color Change Table	
Before Sterilization	After Sterilization
	
















#### Warnings and Precautions:

- Control the filter before use. Never use wet, deformed or torn filters.
- Control the initial color of the indicator on the filter. Never use filters, those indicators have changed its color.
- Never use expired products
- Keep the filter away from sterilant, alkali chemicals and acids.

#### Storage, Storage and Disposal Information:

- Do not expose to direct sunlight and keep it dry.
- Between 0°C and 40°C and Max. Store at 70% RH humidity.
- Store in its original packaging.
- Dispose in accordance with the place of use and local regulations.

#### Symbols and their meanings on the product label and user manual:

Symbols	Meaning	Symbols	Meaning	Symbols	Meaning	Symbols	Meaning
	Manufacturer Information		Suitable for steam sterilization		Production Date (Month/Year)		Store between 0°C and 40°C
	Product Lot Information		Max. 70% RH		Expiration date		CE Symbol
	Reference No		Metal free		Unique Device ID		Medical Device
	Do not expose to sunlight		Keep Dry		Lead free		



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## INSTRUCTIONS FOR USE

### Packaging and Product Information:

Product Code	Product Description	Package Contents	Inner Box Quantity
80.400	PTFE Container Filter Steam	1 pc	-



## INSTRUCTION FOR USE

### 1. PRODUCT DESCRIPTION:

#### Product Name : Sterilization Container System

Sterilization container systems are systems that allow surgical hand tools to be stored sterile. The system, which is suitable for reuse, is an effective packaging method that allows surgical hand tools to be sterilized, stored and transported. It is available in various sizes and configurations. The sterilization container system is designed for Vacuum Steam Sterilization (If a different sterilization method is to be applied, please contact the manufacturer or authorized distributor). The sterilization container system allows the products such as instruments, devices, etc. to be stored sterile until re-used after the sterilization process. According to the sterility and stability test results, the sterilization container systems can be kept sterile for 6 months if the lid is not opened.

### 2. CONTAINER MODELS

#### Standard Model;

1. Paper filter
2. Textile filter
3. PTFE (Teflon) filter
4. PP (Polypropylene) filter

#### Windowed Model;

With the PPSU window system on the lid, both the product and the control of sterilization can be seen with the naked eye. The requirements of the sterilization process are provided by the filter, valve system or B3 in the box. Since there is no pore on the lid of this model, it must be used with a porous box.

#### BIO-Barrier Model;

Thanks to the valve, it allows the sterilization process to be carried out without using a filter. In the vacuum steam sterilization process, dry air is released from the container as a result of the opening of the valves with pre-vacuum. During the sterilization phase, the valves are opened in the opposite direction and the hot air steam is allowed to enter. After sterilization, the hot air is released again with the vacuum and the valves are balanced so that there is no air inlet or outlet. Thus, the sterility of the interior of the container is preserved.

#### B3 model;

allows use as a PTFE Filter, valve or Bio -Stop (Pasteur) system with the preferred module .

### 3. 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.

#### Warning;

Sterilization container systems only with components deemed appropriate by our company should be used. Otherwise, problems may arise. Our company is not responsible. Each use of the sterilization container system Make sure your components are working properly beforehand. Be.

#### Unacceptable Situations;

- Damage to the locking mechanism
- Torn and deformed inner seals of the lid
- The cut for seal replacement is given in Table-1. dimensions use .

#### Control And Replacement Of The Gasket;

Clean the seal channel on the cover with old seal residue. Clean it with acetone until no residue remains. To the seal channel that you are sure is clean Apply silicone adhesive. (Recommended: Henkel Sista ®) Cut the gasket according to the dimensions in Table-1 . into the sealing groove on the lid (flat surface) above will look Place it as follows ) And dry up for 12 hours wait .

lid	X Long	X Large	(1/1)	(3/4)	Flat/(1/2)	Dental	Dental 1/2	Large Dental	Mini	Endo Model
Gasket Dimensions	185cm	180cm	158cm	136cm	101cm	89cm	72cm	118cm	77cm	130cm

Table-1 Gasket Dimensions

- The seals on the filter holders should be checked.



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- Make sure that the filter holders are fully seated.
- The filter holders should engage with a “click” sound.
- Do not use torn, wet or deformed filters.
- In the B3 Model valve system, the flexibility of the valve springs should be checked.
- Control of the valve shaft on the module is provided by pushing it with a finger.
- Bio- Barrier In the model whereas Check the spring of the valve mechanism with a thin -tipped material.
- Do not use mechanisms that have lost their flexibility.
- Model suitability and usage periods of the filters are as follows.

	MODEL	PP Filter <sup>2</sup>	PTFE Filter	Textile Filter	Paper Filter
STERILIZATION CONTAINER TYPES	STANDARD MODEL	✓	✓	✓	✓
	WINDOW MODEL	✓ <sup>1</sup>	✓ <sup>1</sup>	✓ <sup>1</sup>	✓ <sup>1</sup>
	BIO-BARRIER MODEL	-	-	-	-
	B3 MODEL	✓	✓	-	-
	PLASMA MODEL	✓	-	-	-
	DENTAL MODEL	✓	✓	-	✓
	1/2 DENTAL MODEL	✓	✓	✓	✓
	ENDO MODEL	✓	✓	✓	✓
	MINI MODEL	✓	✓	✓	✓
FLAT MODEL	✓	✓	✓	✓	
Filter Using Time		Single-use <sup>3</sup>	2000 SC <sup>4</sup>	50 SC <sup>4</sup>	Single-use <sup>3</sup>

Table-2 Filter Usage Times

<sup>1</sup> In windowed model systems, filters are located in the box is taking .

<sup>2</sup> PP: Polypropylene Filter

<sup>3</sup> Single Use: Must be replaced after each use .

<sup>4</sup> Sterilization Cycle: Increases by 1 with each sterilization cycle.

TK: Single Use SD: Sterilization The cycle

### 4. CLEANING AND DISINFECTION

Incorrect cleaning and disinfection practices may lead to corrosion and abrasion on the surface.

alkali, caustic (NaOH), or carbonate for washing . The final rinse in the cleaning process before sterilization should be deionized. This with (According to EN 285 Annex-B ). Before washing , remove all removable parts of the sterilization

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container. If it is a filtered model, filter holder and filters, Filter module for B3 Model containers, Valve module and the Bio-Stop module Remove the box, paper Labels and metal name tags disassemble .

### Manual Washing;

- Wash with cold tap water for at least 2 minutes. While rinsing, remove dirt with a soft-bristled brush and lint-free cloth.
- Immerse the container in Neutral Enzymatic detergent and soak for at least 5 minutes. Then apply thoroughly to the surface with a soft bristle brush or lint-free cloth.

### Mechanical Washing

Neutral Enzymatic solutions correctly in preparation of solution for use comply with the instructions given by the manufacturer recommendation ( Appropriate temperature , concentration etc. )

Process Sequence	Time (min)/ Temperature	Water Quality	Detergent Features
Pre-Wash-Rinse	1 / Cold	Tap water	n/a
Wash 1 (Manuel)	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**

Use distilled water in the final rinse step. Otherwise, the mineral salts in the tap water will cause staining during the sterilization phase and after whereas in time to wear and tear path will open . Washing pre- Sterilization container and box and cover from each other should be separated . In order to prevent water accumulation , the box base should be placed in the disinfectant in a vertical position. The inside of the container cover should be positioned at the bottom of the machine, with the locking mechanism folded into the cover. All removable

components of the container should be disassembled and placed separately (if any) in a wire basket. by positioning should be washed .

### 5. LOADING THE EQUIPMENTS

- When loading materials to be sterilized into the container, stack them in a way that will not prevent the filters from working. When loading the container, a distance of at least 2 inches (approximately 5 cm) should be left between the lid holes and the load.
- If the holes are blocked during loading before sterilization, the vacuum created during pre-vacuum steam sterilization will cause the container to deform.
- Loading instruments into sterilization containers when making the baskets. surgical and orthopedic hand instruments (Set arrangement), washing and sterilization container into stacking for is used .

Material	Container Type	Maximum Total Weight <sup>1</sup>	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	8 kg <sup>2</sup>	EN 285

**Table-4 Equipment Loading & Maximum Total Weights**

- 1 Maximum Total Weight: Container weight + Wire Basket or Green Cover weight + Material weight .
  - 2 When loading textile materials, the container your holes not to close attention It should not flex when light pressure is applied to it . should be positioned in a way that leaves room for it. Otherwise if steam penetrates into the container difficult will be And sterilization it will not happen
- In the table given to values according to loading should be done. When the values in the table above are exceeded, the

materials are likely to remain wet. Sterilization the process in full will not happen .

### 6. STERILIZATION

- Before sterilization, after loading the material, it must be ensured that the lid is completely closed. The locking system TRUE because it works sure should be .
  - placed on the body then the locking process must be performed. If the lid is not placed completely on the body, it will cause an unbalanced force to be applied. For this reason, if the locking system loses its function, the sealing will not be fully ensured and the sterilization process will not be carried out properly.
  - It is recommended to use a security seal or automatic lock system to ensure the sterile security of the container system prepared for sterilization .
  - sterilization container systems in any packaging. If the holes that provide air flow to the container are closed during sterilization, air and steam evacuation will not occur. In such cases, damage to the container may occur due to the vacuum effect . order sterilization process will not happen .
  - The products are large after the sterilization process environmental change where there are temperature differences should not be affected .
  - Cool down to room temperature on its own should be expected . Sweating will occur on the inner surfaces during sudden temperature changes.
  - The loading weights given in Table 4 are not complied with.
- in case The sterilizer will not be able to perform its drying function. Thus, the materials will not be considered sterile.
- Multiple container systems simultaneously sterilization , large volumes should be placed at the bottom and small volumes at the top, and the height should not exceed 45 cm maximum . If the materials remain damp despite following all these warnings, the sterilizer manufacturer with contact please pass .



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( See DIN 58953-9)

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



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

### 7. TRANSPORT

- Loading of sterilization container systems, It must always be held by the handles during unloading and carrying.
- Do not carry it by holding the locking mechanism during transportation.
- Moving the holding container by the locking mechanism may cause a malfunction in the locking system and result in loss of sterilization . will be weather fugitive may occur .

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

Table-6 Container Loading Capacity

### 8. STORAGE

Recommended sterilization container systems Suitable storage conditions are as follows.  
 Temperature: 0 - 40° C  
 Humidity: max 70% Rh  
 Pressure: Normal Atmospheric Pressure

### 9. 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 containers are at the top.
	Improper cooling after sterilization. Select	Select the appropriate Sterilization parameters.
	Autoclave specifications do not meet the DIN EN 285 standard	When using the autoclave, consider the manufacturer's recommendations. Check the drying time and the steam quality. Calibrate if necessary.
	The sterile container is overloaded	Check the appropriate weight.
Lid lock failure	The idle loop and vacuum test are not performed Daily before starting sterilization	Perform idle cycle and vacuum tests before sterilization. Make sure your sterilizer is working properly.
	Locks have been used instead of handles to carry the Sterilization container system	Please contact the company representative. Container with a broken lock is not suitable for sterilization
The Sterilization container system has had a physical impact on the lid locks		
B3 Biostop components are not mounted on the lid.	B3 Biostop components or lid deformed.	Please contact the company representative
During the Sterilization process, the B3 Bio-stop barrier components Were dismantled from the chamber.	B3 Bio-stop components are not properly locked.	Please contact the company representative



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