REF 53-110-10-01 - 53-330-01

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EN

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reddot design award
winner 2017

asipco®
Made in Germany

REF 53-110-10-01 - 53-330-01

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1. Product liability and warranty

1.1 General

We are pleased that you have decided for a product from our company. This product carries the CE mark. It therefore fulfils the basic requirements specified by the regulation (EU) 2017/745 (MDR).

1.2. Warranty

Our general terms of delivery and payment apply in the respective applicable version. Deviating agreements do not limit the rights of the purchaser. An extended warranty requires contractual form and excludes vandalism on components and consumables. Improper interventions or modifications by third parties during the limitation period shall void any warranty claims. AS Medizintechnik GmbH does not assume any liability for unauthorised actions carried out at the product.

1.3 Symbol legend

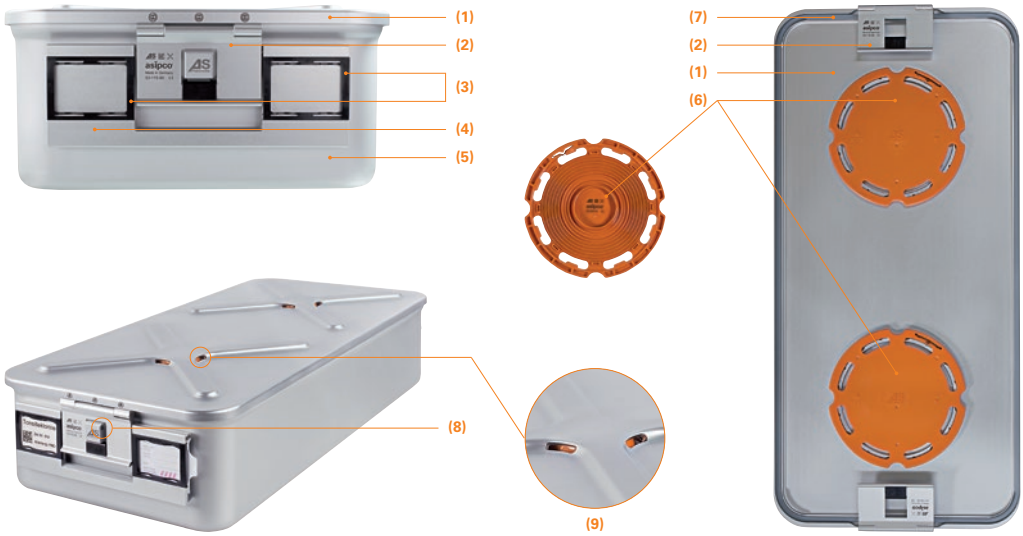
Symbol	Explanation
	Manufacturer
	Production date
REF	Order number
LOT	Batch number
SN	Serial number

Symbol	Explanation
	Observe user manual
	ATTENTION
NON STERILE	Non-Sterile
	Keep away from sunlight
	Protect from moisture

Symbol	Explanation
GS1	GS1 Germany
MD	Medical device
QTY	Quantity
UDI	Unique Device Identification
CE	CE Marking

2. Product overview

The product images can be found in the following image legend.



(1) asipco® container lid
(2) Catch fastener
(3) Logistic-frame left / right
(4) Handle
(5) asipco® container bottom
(6) asipco® microbial barrier disc
(7) Lid gasket (grey)
(8) Seal seating
(9) Visual check of the microbial barrier disc

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3. Intended purpose

The AS Medizintechnik asipco® Sterilizing-Container is used for packaging, sterilisation, transporting and for sterile provision of sterile materials, as well as for the recirculation of the contaminated sterile materials. The designs correspond in all, for the container applicable components, with the requirements of the international and national standards ISO 11607-1, ISO 11607-2, EN 868-8 and DIN 58953-9.

3.1 Sterilisation

The AS Medizintechnik asipco® Sterilizing-Container is suited for steam sterilisation. It must be ensured that the sterilisation is carried out in a validated steam sterilisation procedure (e.g. in a steriliser according to EN 285 and validated according to ISO 17665-1). The use of other sterilisation procedures must be agreed upon with AS Medizintechnik GmbH.

Information on the validation of the sterilisation

Sterilisation of the products 3-fold fractionated pre-vacuum procedure (e.g. steam steriliser: Tuttnauer EHS 3870) according to ISO 17665-1 under consideration of the respective national requirements.

Validated procedure:

Pre-vacuum:	3 x
Temperature:	134° C / 273° F
Pressure:	3 ± 0.5 bar
Holding time:	5 minutes
Drying time:	20 minutes

The instruction of use of the autoclave manufacturer and the recommended guidelines for the maximum load with sterilisation material must be observed. The autoclave must be installed, serviced, validated and calibrated appropriately.

Details see report: No. 1610.2161.1 (Zwisler Laboratorium GmbH)

4. Structure and function of the asipco® Sterilizing-Container

4.1 Microbial barrier with optimised Pasteur's loop (6)

The microbial barrier consists of an orange coloured plastic disc and the subsystem integrated on the inside of the lid. Disc and subsystem are simply locked by means of a bayonet locking mechanism. Prior to the steam sterilisation, the disc must be connected to the subsystem integrated on the lid. The system works permanently and does not require any consumables.

4.2 Visual check of the microbial barrier from the outside (9)

Even with the lid closed it can be seen and checked at any moment, if the system is used properly, e.g. during approval.

4.3 Lid gasket (7)

On the inside of the lid there is a firmly anchored silicone gasket, which ensures the germ-proof fit of the lid on the bottom after having put the lid on the bottom and after successful sterilisation. The gasket can easily be checked visually for any wear as a routine measure. Damaged gaskets must be replaced (see chapter 11.2 maintenance plan).

4.4 Container lock / lid locking mechanism (2)

Closing the container:

- The lid is placed onto the bottom and locked by means of noticeable locking (pressing on) of the catch fasteners at the end sides of the container.

Opening the container:

- This is done in reverse order. By lifting the catch fasteners the lock is released. The lid can now be removed easily. If seals were affixed, they will be forcibly destroyed and must then be removed.

4.5 Inclusion of seals (8)

The standard requires that the unintentional or unauthorised opening of the container after its sterilisation must be made visible. Therefore, the container must be sealed on both end sides prior to sterilisation. Due to the operating principle of the catch fasteners, the seal is forcibly destroyed when opening the container.

4.6 Handles (4)

On the end sides of the container the wide handle is integrated in the fitting part. After opening the closure, the lid can be removed easily and comfortably since the entire fitting part can be lifted "as a handle". The resilience of the handles complies with the requirements of EN 868-8, annex C.

4.7 Identification tags / document cards or labels (3)

On both end sides of the container there are 2 fields integrated in each of the handle plates, which serve in connection with the logistics frames to accommodate identification tags and document cards / labels. The identification tags can be marked by AS Medizintechnik GmbH with the text provided by the user (Set contents / destination). The fields integrated in the handle plate are equipped with a logistics frame. The logistics frames are available in

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7 different colours and can be used for logistics purposes.

5. Initial commissioning

The container must be cleaned prior its placement and the first sterilisation (see chapter 10 "Disinfection, cleaning and care"). The assembly of the container is done according to chapter 4 "Assembly and function of the container". The functional test must be carried out according to chapter 6.1 "Functional test prior to placement".

6. Container placement

The container must be loaded in such a way that there is a free space below the microbial barrier of at least 10 mm so that the uniform distribution of the steam flowing into the container is guaranteed.

Bottom height, inside
(Usable height minus 10 mm to ensure steam circulation)

6.1 Functional test prior to placement

All components at the container must undergo a visual check for possible damage before each use by trained professionals. If required, they must be replaced or repaired. The gasket in the lid must not show any visible damage, otherwise it must be replaced. Only cleaner container assemblies must be used. See page 9 - 10 „FUNCTION TEST".

6.2 Laundry placement

The container must be loaded with laundry in such a way that the folded pieces of laundry (max. 6 kg) are placed vertically in the container. The filling method must be calculated in such a way that it is still possible to insert an outstretched hand inbetween the laundry pieces when the container is fully packed. For purposes of easy handling and aseptic presentation of the sterile material, DIN 58953-9 recommends to wrap the laundry pieces in a suitable inner lining for sterile material of appropriate dimensions.

6.3 Instrument loading

We recommend to sterilise the instruments on sterilisation trays in the container according to DIN 58952-3.

Note:
The design shape of the asipco® Container bottom permits the removal of the instrument tray under sterile conditions after opening the container in the theatre also without additional inside packaging. This decision is the responsibility of the in-hospital hygiene commission.

ATTENTION:
The total weight of the container load must not exceed the following weight according to DIN EN 868-8, otherwise satisfactory sterilisation cannot be guaranteed:

Basic models	Max. loading
1/1 Container	10,0 KG
3/4 Container	7,5 KG
1/2 Container	5,0 KG

The loading limits may differ from the above in accordance with national law.

7. Loading and unloading the steriliser

The placement method of the steriliser manufacturer must be observed. It is recommended to position heavy containers at the bottom of the sterilisation chamber. The asipco® Sterilizing-Container can be stapled on top of each other during sterilisation and storage. Containers must be arranged in the steriliser in such a way that a clearance of at least 10 mm to all other containers or installations of the steriliser is guaranteed from all sides of the container. When loading and unloading, the container must always be carried at the handles and never at the lid.

ATTENTION:
In the steriliser, the container must not have any additional packaging or covered (risk of implosion).

8. Storage of the container with sterile material

During storage, the containers must be protected from dust, humidity and damage. The acceptable storage duration depends on the storage conditions and can therefore not be specified in a general manner. The specification of the acceptable storage duration is done by the hygiene

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commission. The hospital owner / the medical director is responsible for the storage conditions and duration. The sterile containers must be stored separated from other goods in terms of space and/or organisation, if those could be potentially hazardous.

asipco® Sterilizing-Containers were tested under worst case conditions for a storage duration of 6 months. The report can be requested from AS Medizintechnik GmbH.

Note:
The loss of integrity of the sterile packaging is usually event-related and not time-related.

8.1 Transport

The sterilisation containers may only be transported using the carrying handles provided. Both carrying handles must be held. It is not permissible to hold the sterilisation container by only one carrying handle, as otherwise the sterilisation container or the sterilised items may be damaged. Make sure that the sterilisation container is not tilted or held at an angle during transport.

9. Provision of the sterile material

Prior to opening the container and the removal of sterilised products, it has to be visually checked, if the seals were affixed properly and are undamaged. When opening the container the seals will get forcibly destroyed and must be removed afterwards.

10. Disinfection, cleaning and care

10.1 General

The parameters for cleaning and disinfection of the asipco® Sterilizing-Container systems are specified by the operator/user within the scope of the hygiene plan. The treatment agents must be selected in such a manner that the compatibility with the container components and the hygienic and microbiological effectiveness is guaranteed. It must be ensured by means of thorough rinsing that there are no cleaning agent or care product residues on the container components. In the following we will provide you with notes on the different possibilities of manual and mechanical disinfection and cleaning, which refer in particular to the material compatibility and value preservation of the container. Mechanical cleaning and thermal disinfection is preferred.
Separate the lid **(1)** and bottom **(5)** for the cleaning process. Remove the discs **(6)** of the microbial barrier.

10.2 Notes on the material

Container bottom **(5)**, container lid **(1)** and handles **(4)** are made from aluminium.
The surfaces are coated with a protective anodised layer. The anodised surface increases the abrasion resistance and resistance to wear. The anodised layer is resistant to pH-neutral treatment agents. Especially in case of mechanical treatment with alkaline detergents and acidic neutralisation agents, destruction of the anodised layer due to chemical attack must be taken into account. Aluminium components must therefore only be cleaned with pH-neutral / alkaline agents that are approved explicitly for the use on anodised aluminium components. The manufacturer details on the treatment agents and the automatic cleaning unit must be observed.

10.3 Manual cleaning and disinfection

All accessible parts can be cleaned with neutral tenside-based detergents (neutral detergent, dishwashing liquid). pH-neutral disinfectants can be used for disinfection. The final rinse must be carried out only with demineralised water. No metal brushes or scouring agents must be used for cleaning.

10.4 Mechanical cleaning and disinfection

For mechanical cleaning only pH-neutral or mildly alkaline process chemicals (pH value 8 - 10.5), which are approved by the manufacturer explicitly for the cleaning of aluminium, should be used. Adding acidic neutralisation agents must be avoided to prevent damage to the aluminium. We recommend disinfection/final rinse in an RDG at > 90° C with respective exposure time according to A_0 procedure, EN ISO 15883-1, annex B. The final inspection must be carried out only with demineralised water. The notes of the manufacturers of the automatic cleaning units as well as of the manufacturers of the treatment agents must be observed. The cleaning unit must be designed for cleaning the containers. Important is here in particular the secure placing in the washing baskets and the correct layout of the spray nozzles and spray arms.

ATTENTION:
Note on rinsing agent! Due to the plastic components (disc of the microbial barrier, logistics frame at the fitting parts) at the container, the use of rinsing agent is not recommended, since tenside residue on the surfaces leads to changes in the plastic structure and thus to the formation of cracks in the subsequent steam sterilisation.

Information on the validation of the sterilisation

We recommend the following cleaning procedure that was validated by AS Medizintechnik GmbH in as suitable cleaning and disinfection device with the following settings:

Manual pre-cleaning:
Separate the lid **(1)** and the bottom **(5)** for the cleaning process. Remove the discs **(6)** of the microbial barrier.

Rinse all parts under cold municipal water (< 40° C) until all visible contamination is removed. Persistent dirt is to be removed with a soft brush. Cavities, lumen are to be rinsed intensively (> 30 sec) with cold municipal water (< 40° C) using a water pressure gun.

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Special instructions of the manufacturers of the automatic cleaning unit must be observed.

Automatic cleaning:
- 1 minute pre-cleaning with cold municipal water < 40° C, water drain
- 3 minutes pre-cleaning with cold municipal water < 40° C, water drain
- 5 minutes cleaning at 55° C ± 5° C with 0.5 % alkaline detergent (neodisher® MediClean forte), water drain
- 2 minutes intermediate rinsing with cold demineralised water

Automatic disinfection (Miele G7835 CD):
Automatic thermal disinfection in cleaning and disinfection device, taking into consideration the national requirements to the A_0-3000 value, > 5 minutes at 92° C ± 2° C, demineralised water, water drain.

Automatic drying:
Automatic drying according to automatic drying process of the cleaning and disinfection device 30 minutes at 60° C ± 5° C if required subsequent manual drying with lint-free cloth and blowing out of lumen using sterile, oil-free compressed air.

The following inspection instructions, materials and machines are used for validation:

Cleaning disinfection device:	Miele G 7835 CD
Detergent (mechanical):	neodisher® MediClean forte; Dr. Weigert
Details see report:	No. 1612.0813.1 (Zwisler Laboratorium GmbH)

Should the previously described chemicals and machines not be available, it is for the user to validate its procedure accordingly.

10.5 Removal of residue from the material
Residues or contaminations on the container that cannot be removed in the normal cleaning process (indicator strips, adhesive labels, lettering) must be removed with the AS Medizintechnik Detergent for Anodised Surfaces, item no. 53-900-00 or other standard agents such as dishwashing liquid, neutral detergent or alcohol. After this special treatment, the container bottoms or lids must be rinsed again or undergo the usual cleaning routine.

ATTENTION
Due to an error in the reprocessing process (cleaning), a white powder (aluminum oxide Al_2O_3) may form on the surface. This is a sign of a damaged or already destroyed surface (protective layer, anodized layer). Since this white powder can come into contact with the instruments in the sterilization-container, appropriate measures must be taken, such as replacing the affected sterilization-containers. The cause must be identified and eliminated (e.g., an unsuitable highly alkaline cleaner).

11. Maintenance and repairs
The manufacturer considers himself responsible for the safety and reliability of the sterilisation containers only, if repairs or modifications are carried out by persons authorised by him and the sterilisation containers are used in accordance with the instruction of use. Only AS Medizintechnik GmbH original replacement parts must be used for repairs. Only then can guarantees be assumed.

The sterilisation container may only be repaired by us or by a person or company expressly authorised by us. If the repair is carried out by a person or company authorised by us, the operator of the sterilisation container shall be requested to demand a certificate from the repairer stating the type and scope of the repair. This certificate must show the date of execution and the company name with signature.

If the repair is not carried out by the container manufacturer himself, repaired containers and container parts must also bear the mark of the repairer.

11.1 Replacement of gaskets (7)
The replacement of gaskets can only be carried out by the manufacturer himself and by authorised persons.

11.2 Maintenance plan
Depending on the application conditions, we recommend, in conformity with EN 868-8, to carry out the following maintenance steps after 500 usage cycles or once yearly:

• Gasket:	(7)	Inspection for integrity. Visual check for damage. If required replace the seal as a measure.
• Container lid:	(1)	Check for integrity. Visual check for damage. If required replace the lid as a measure.
• Microbial barrier:	(6)	Check for integrity. Visual check of the contour and the locking mechanism. Replace if required.
• Container bottom:	(5)	Check for integrity. Visual check of the contour and the locking with the lid. If required, repair or replace.
• Movable parts:	(2 / 4 / 6)	Movable parts (screws on the flap closure and the carrying handles, closing spring of the microbial barrier disc) must be lightly oiled with sterilisable, steam-permeable maintenance oil AS no 56-920-10.

All maintenance, carried out by trained specialist personnel, CSSD clinic personnel, is limited to the daily routine tests in accordance with point 6.1 „Functional test prior to placement". If these are carried out with each cycle, a separate check after 500 cycles of use or once a year by the trained specialist personnel, CSSD clinic personnel is not necessary.

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12. Dimensions

The asipco® Sterilizing-Container comply in their dimensions with the recommendations of EN 868-8 (nominal dimensions). The dimensions can be found in the AS Medizintechnik brochure.

13. Safety regulations

The contents of a sterilisation container can only be regarded as sterile, if the disc(s) **(6)** were affixed properly, the lid **(1)** is closed, the container was sterilised, the seal is intact (visual check) and all container components are undamaged. The successful sterilisation exposure is recorded by the steriliser and documented.

The sterilisation container is hot after successful sterilisation!

WARNING: Risk of burns! Wear protective clothing!

To avoid hazards and material damage, containers must not be stacked higher than 550 mm (2 container units). Suitable installations are to be used for transport and storage that prevent falling over or falling down of containers. All product manufacturer's instructions must be adhered to.
The container is not suited for the sterilisation of medicinal products or biological products.

14. Replacement parts

- asipco® Microbial barrier disc, PPSU, orange, Ø 154 mm — REF: 53-325-00
- asipco® Logistic-frame, Unit = 4 pieces — REF: 53-320-01 - 53-320-07
- asipco® Coding tag, PPSU, white, 57 x 40 mm — REF: 53-321-00 - 53-321-02

Item numbers for the asipco® Container lids and bottoms can be found in the current asipco® Sterilizing-Container brochure.
Replacement parts are also available from AS Medizintechnik GmbH.

ATTENTION: Only approved AS Medizintechnik original parts may be combined.

15. General

The general guidelines and hygiene principles on the handling with contaminated, goods to be sterilised and already sterilised goods must be observed. To exclude possible recontamination risks, the above mentioned instruction of use must be adhered to. If when opening the sterilisation container deviations from the above mentioned desired state are detected, the contents of the sterilisation container must be regarded as non-sterile and the treatment process must be repeated.

Note:
The sterilisation containers must only be used by trained personnel.

16. Other applicable standards and literature

- DIN EN 285
- DIN EN ISO 17665-1
- DIN EN ISO 11607-1
- DIN EN ISO 11607-2
- DIN EN 868-8
- DIN 58953-9
- DIN 58952-3

17. Manufacturer information according to EN 868-8

- Specification of the essential components: see chapter 4 "Structure and function of the container" and chapter 2 "Product overview"
- Manner of inspection and maintenance and/or use: see chapter 5.11, .13 and .14
- Useful life of the sterilisation container (usage cycles) according to EN 868-8
- Useful life of the gaskets according to EN 868-8
- Cleaning procedure: see chapter 10 "Disinfection, cleaning and care"

18. Disposal container

18.1 Purpose

The disposal container is used for storage and the safe transport of contaminated materials until reprocessing.

ATTENTION:
The disposal container must not be sterilised with the lid in place! The bottom and the lid must be sterilised separately in the sterilisation chamber of the steriliser!

18.2 Material
Lid and bottom of the asipco® disposal container are made from anodised aluminium and can be treated according to chapter 10 "Disinfection, cleaning and care". The asipco® disposal container does not have a microbial barrier. With the exception of the notes on these systems, all notes of these instruction of use also apply to the lid of the asipco® disposal container.

18.3 Dimensions
The dimensions of the asipco® disposal containers comply with the recommendations of EN 868-8 (nominal dimensions). The dimensions can be found in the current AS Medizintechnik brochure.

19. Disposal

For disposal, the containers must be free of potentially contaminated material. For this purpose, the product must be subjected to validated reprocessing by the operator. In the case of sharp edges, disposal must be carried out in such a way that persons are not endangered.

The disposal of the products, the packaging material and the accessories must be carried out in accordance with the nationally applicable regulations and laws. The country-specific laws and regulations must be observed for disposal.

AS MEDIZINTECHNIK GMBH DOES NOT ACCEPT RESPONSIBILITY IF THIS CUSTOMER INFORMATION HAS BEEN VIOLATED PROVABLY.

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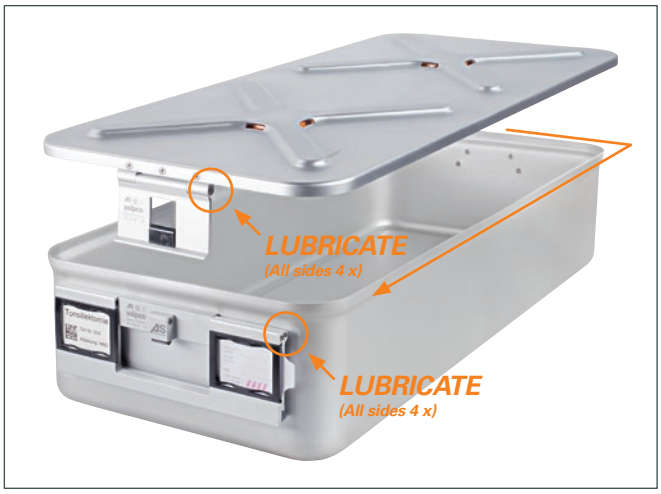
AS Medizintechnik – Technical Service

FUNCTION TEST

All components of the asipco® Sterilizing-Container must be visually inspected for damage and proper functionality before every use. The Instructions of use must be observed for your own safety!

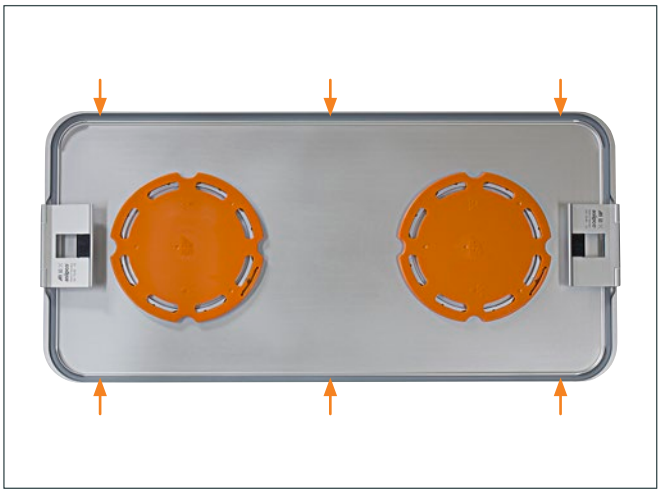
1. LID AND BOTTOM

The lid and bottom must be inspected for deformations and dents. Particular attention should be paid to the rim of the lid and bottom. Movable parts must be lubricated (instrument maintenance oil AS no 56-920-10)



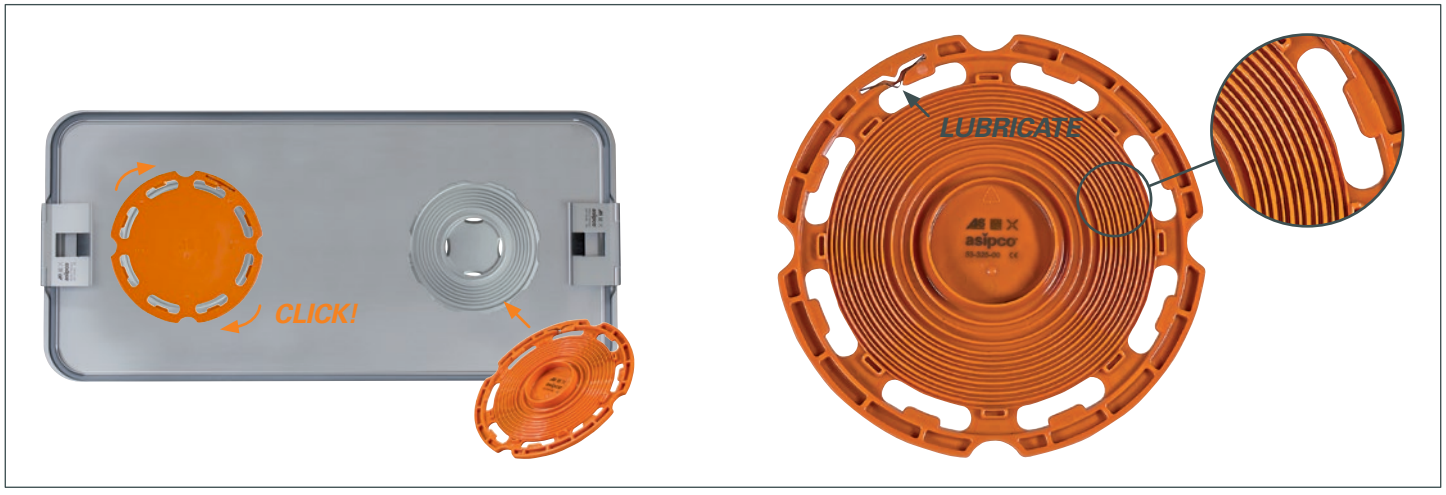
2. GASKET

The gasket must be in place and unbroken with no cracks or tears, etc.



3. MICROBIAL BARRIER

The microbial barrier disc (orange) and the docking and barrier part on the inside of the lid must be visually inspected for tears, breaks, cracks, damage and cleanliness. Special attention must be paid to ensure the surface structure is not damaged and there are no cracks along the loop edges. When screwing in the barrier disc, the full face of the disc must lie flat and audibly click into place. The closing spring must be lubricated at all points (instrument maintenance oil AS no 56-920-10).



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FUNCTION TEST

All components of the asipco® Sterilizing-Container must be visually inspected for damage and proper functionality before every use. The Instructions of use must be observed for your own safety!

4. PROPER LID FASTENING AND LOCKING

The fastener must be inspected for damage and functionality. The fastener must clearly and audibly click into the receiver on the bottom.

5.CARRYING MECHANISM (HANDLES)

Handles must be intact and undamaged.

6. UNDAMAGED CONTAINERS

Damaged or faulty components must be immediately repaired and/or replaced with original parts.

7. SEALING AND LABELLING

Closed containers must be provided with a seal. Place labels with content, coding and production data in the holder provided.