Instructions for Use
Sterilization Containers

The correct handling and use of the gSource sterilization containers are described in the following.

In order to keep risks and unnecessary burdens as low as possible for the patient, the user and third parties, we request that you carefully look through these instructions for use and keep them for future reference.

1. Field of application
The gSource sterilization container is a sterile packaging system for medical instruments and textiles. It utilizes an established filter technology, proven materials and design properties which make it reliable. It is a reusable device and features an assortment of sizes and configurations that provide an effective packaging method for sterilization, storage and transportation of surgical instruments by healthcare providers. This container is suitable for use in pre-vacuum steam sterilizers.

Containers are available with either a perforated or a non-perforated bottom, and a perforated lid. Large containers are available with and without a safety lid.

The containers must only be used with appropriate single-use paper filters provided by gSource.

2. Intended use
The gSource sterilization container is intended to allow sterilization of the enclosed medical devices and also maintain sterility during transport and storage for 30 days. The system consists of Mini and Large containers which vary in size and perforations. All models are available with a perforated green lid and either a perforated or non-perforated bottom. To enable proper organization of sterilized instruments, different wire or sleeve baskets adapted exactly to the specific container dimensions are available. All models are intended to be used with gSource single-use paper filters.

The containers are reusable devices designed to be used with the following sterilization cycle parameters:

Pre Vacuum cycle:

4 minutes
132°C (270°F)
Drying Time minimum 20 minutes

3 minutes
135°C (273°F)
Drying Time minimum 16 minutes

Loading: Metal surgical instruments (scissors, clamps, forceps) and textiles

2.1 Contraindications
This gSource sterilization container has not been validated for sterilization of instruments with channels or lumens, compressed air-driven instruments, or power systems.

The gSource sterilization containers are not made or suitable for gas sterilization procedures, besides those outlined in these Instructions for Use (IFU), especially procedures that utilize formaldehyde or ethylene oxide.

⚠️ **DO NOT EXTERNALLY STACK THE CONTAINERS!**

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3. Handling

3.1 General
This gSource sterilization container is made of aluminum alloy with an anodized oxide surface which resists corrosion. Abrasive cleaners, metal brushes or abrasive cleaning pads can cause permanent damage to the container surface and therefore must not be used.

The product and accessories must be used only by qualified or trained and experienced personnel, in order to prevent damage to the containers, closing devices, seals and sterile filters.

3.2 Preparation before cleaning
1. Separate lid and bottom.
2. Remove the devices from the inside of the container (baskets, instruments).
3. Take off the filter holders inside the lid. If bottom of container is perforated, take off the filter holders at the bottom of the container as well.
4. Discard the disposable filter(s).
5. Remove disposable locks and indicators.

Note: All paper filters are for single-use only and should be disposed after each processing cycle.

3.3 First use
- The new container needs proper cleaning before first use.
- Use the automated cleaning procedure prior to first use as described in section 3.4.2.
- A neutral detergent (pH of 7) should be used.
- After automated cleaning procedure is completed, we recommend sterilizing the container according to the sterilization parameters defined in this IFU document.
- We also recommend maintenance of all moving parts on this container by using instrument oil.
- After cleaning, a new filter must be inserted (see 3.6 Filter Change).

3.4 Cleaning
This device is only validated for the automated cleaning procedure described in section 3.4.2.

Note: Improper cleaning and disinfection can lead to corrosion and stress cracks. Therefore, follow the specifications the cleaning agent's manufacturer recommends. Detergents must be mild, alkaline-free, sodium-free, carbonate-free, and of neutral pH (7). Only fully deionised (DI) water is recommended for reprocessing the product.

- Before every use, the container must be cleaned.
- Removable containers must be cleaned each time after use.

3.4.1 Mechanical cleaning
- Mechanical cleaning of the containers is only recommended if the washer/disinfector has a special program for aluminum containers. When mechanically cleaning the containers, it is absolutely essential to observe the specifications for use of the washer/disinfector as dictated by the manufacturer, and their instructions for the cleaning of containers.
- Only use neutral cleaners for cleaning. Do not use any cleaning solutions containing sodium bicarbonate/soda or sodium hydroxide/caustic soda.
- Use only neutral cleaners that are approved by the manufacturer for the cleaning of aluminum containers. Use the exact amount of the cleaner as specified by the manufacturing company. These products are also suitable for cleaning surgical instruments.
- Do not use additional acidic neutralizers.
- Fully deionized water must be used for final rinsing, as the salts in the water during the subsequent sterilization can also lead to spotting.

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- The cleaning system must be constructed for the cleaning of sterilization containers and specifically indicate the safe placement of the washing baskets and the positioning of the spray nozzles or units.
- The container lid and bottom need to be cleaned separately from one another.
- The container bottom needs to be placed upside down in the washer/disinfector to avoid the collection of water.
- The inside of the container lid should face the machine bottom with the latching mechanism folded into the inner part of the lid.
- All component parts of the container (bottom, lid, filter holders) should be disassembled and placed in the washer/disinfector baskets that are specially designed for containers and accessories.
- After the washing/disinfection program is finished, the container and accessories need to be dried with a soft dry cloth or by medical grade compressed air.
- Contaminations that cannot be removed in a normal cleaning cycle independent of the process (sticky labels, indicator strips, writing), can be removed with an ELOXAL cleaning agent. After this special treatment, the containers should be cleaned as usual.

3.4.2 Recommended Cleaning Procedure
Based on validation studies, we recommend the following cleaning procedure by using qualified equipment for mechanical cleaning (Miele PG 8528):
- 1 minute prewash with cold DI water
- 3 minutes cleaning with Mediclean® 0.5% (Dr. Weigert) at 45° C
- Neutralization with DI water

3.5 Inspection
The sterilization containers must be checked each time before use to ensure their correct functionality. If the user detects any visible signs of wear, such as discoloration, cracking, peeling or flaking, the containers must be discontinued and prevented from being reused.

3.6 Filter Change
After placing the filters over the perforated areas on the inside of the lid and (if applicable) on the bottom of the container, the filter holders have to be pressed into place until they snap into position. gSource instrument container lids should only be assembled with gSource filter holders.
- The disposable paper filters must be changed before every new sterilization cycle.
- Only gSource filters can ensure suitability and an exact fit.

⚠ WARNING!
Only original gSource component parts such as lids, bottoms, filters, seals and filter holders should be used together so that the container sealing is not compromised and functions properly as a microbial barrier.

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4. Loading

The overall weight for loading containers should not exceed the following loads:

Model	Dimension (mm)	Maximum Recommended Load in lb (kg)	
		Instruments	Textiles
Mini Size Container	300x140x40	0.8 lb (0.4 kg)	0.6 lb (0.3 kg)
Mini Size Container	300x140x70	1.5 lb (0.7 kg)	1.1 lb (0.5 kg)
Large Size Container	580x280x100	8.3 lb (3.8 kg)	6.6 lb (3.0 kg)
Large Size Container	580x280x150	12.7 lb (5.8 kg)	10.1 lb (4.6 kg)

When loading with textiles, pay attention that the folded textile or laundry articles are positioned vertically. In the case of a full container, it should be possible to push an outstretched hand between the pieces of laundry without effort

⚠️ **PRECAUTION!**

Complex instruments like endoscopes, instruments with a lumen, compressed air-driven instruments or power systems and instruments with cannula are to be prepared according to the manufacturer's instructions for sterilization and are to be sterilized accordingly.

Lids, wire baskets and other types of accessories should only be used with the sterilization container if the sterilization container has been specifically designed and tested for that purpose.

Please see details about gSource sterilization containers and wire baskets on www.gSource.com.

⚠️ **WARNING!**

Using non-absorbent tray liners (e.g., plastic/silicone-fingered organizing mats) for the containers can cause condensation to pool. Use moisture absorbing mats if necessary instead.

Always attach the lid to the bottom by securing the latching mechanism before placing the container in the sterilizer. Otherwise the content of the container will become unsterile as soon as the sterilizer door is opened.

5. Placement in the Sterilizer

⚠️ **PRECAUTION!**

Never wrap the container in any kind of outer packaging. Never cover the perforated area of the container with any kind of foil packaging or similar during sterilization as this will block the air and steam flow through the perforation. The result will be vacuum damage due to insufficient pressure venting and the contents inside the container will not be sterilized.

During loading and unloading of the sterilizer, and during transport, the sterile container must always be carried by the handles and never by the lid.

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6. Processing

- Follow the time and temperature recommendations of the sterilizer manufacturer for every chosen sterilization cycle.
- To minimize condensation inside the container, leave container on container carts until cool enough to handle.
- Always check if the sterilization has been successful by observing indicators and the container latch (must be closed).
- Wet filters or visible moisture within a load may compromise the sterile barrier and contents should not be considered sterile when removed from the sterilizer.

7. Storage

Recommended storage conditions:
- Temperature 15 – 26 ° C
- Air humidity 30 – 50%
- Air pressure, normal atmospheric pressure

8. Maintenance

- Cover seals should not be treated with spray, oil or solvents. For cleaning and maintenance, simply wipe off occasionally with a damp cloth.
- If any damage on the container, or its parts, is noticed, the container must be discarded and prevented from being reused.
- Replacement parts can be obtained from gSource:

Instrument Containers - lid colors available: grey(1), yellow(2), red(3), blue(4), green(5), black(6)	
gS 98.9111-gS 98.9116	**Mini**, 300x140x40mm OD, **bottom perforated**, lid perforated, aluminum
gS 98.9131-gS 98.9136	**Mini**, 300x140x70mm OD, **bottom perforated**, lid perforated, aluminum
gS 98.9201-gS 98.9206	**Large** Standard, 580x280x100mm OD, **bottom non-perforated**, lid perforated, aluminum
gS 98.9211-gS 98.9216	**Large** Standard, 580x280x100mm OD, **bottom perforated**, lid perforated, aluminum
gS 98.9241-gS 98.9246	**Large** Standard, 580x280x150mm OD, **bottom non-perforated**, lid perforated, aluminum
gS 98.9251-gS 98.9256	**Large** Standard, 580x280x150mm OD, **bottom perforated**, lid perforated, aluminum
gS 98.9341-gS 98.9346	**Large** Standard Safety, 580x280x150mm OD, **bottom non-perforated**, lid perforated, aluminum
gS 98.9351-gS 98.9356	**Large** Standard Safety, 580x280x150mm OD, **bottom perforated**, lid perforated, aluminum
gS 98.9411-gS 98.9416	**Large Safety**, 580x280x100mm OD, **bottom perforated**, lid perforated, aluminum
gS 98.9441-gS 98.9446	**Large Safety,** 580x280x150mm OD, **bottom non-perforated**, lid perforated, aluminum
gS 98.9451-gS 98.9456	**Large Safety**, 580x280x150mm OD, **bottom perforated**, lid perforated, aluminum
Baskets for Instrument Containers	
gS 98.9191	Wire Basket, **Mini**, 265x120x45mm OD, stainless steel
gS 98.9192	Screen Basket, **Mini**, 271x117x40mm OD, stainless steel
gS 98.9501	Wire Basket, **Large**, 540x255x30mm OD, stainless steel
gS 98.9502	Wire Basket, **Large**, 540x255x50mm OD, stainless steel

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gS 98.9503	Wire Basket, **Large**, 540x255x70mm OD, stainless steel
gS 98.9504	Wire Basket, **Large**, 540x255x100mm OD, stainless steel
gS 98.9532	Screen Basket, **Large**, 545x255x50mm OD, stainless steel
gS 98.9533	Screen Basket, **Large**, 545x255x70mm OD, stainless steel
Single-Use Paper Filters for Instrument Containers	
gS 98.9900	**Mini**, Single-Use Paper Filters without steam indicators, 235x118mm, white, pkg 100
gS 98.9910	**Large**, Single-Use Paper Filters without steam indicators, round diameter 190mm, white, pkg 100
Security Seals for Instrument Containers	
gS 98.9920	Security Seals, blue plastic, package 100
Identification Tags for Instrument Containers - colors available: yellow(1), red(2), blue(3), green(4), black(5), violet(6), orange(7), brown(8)	
gS 99.9941-gS 99.9948	Identification Tag, 56x17mm, aluminum

9. Materials

Containers are made of anodized aluminum alloy and their accessories of surgical stainless steel.

In order to ensure sterile safety, tests were carried out by an independent and accredited test laboratory. The purpose of these trials was to validate a sterilization process for the reusable gSource sterilization container using steam.

On the basis of the results, we therefore recommend the sterilization process from page 1-2 of this instruction.

gSource does not accept any liability if these instructions for use have not been observed or followed.

Meaning of the Symbols

⚠ Attention, Observe Notes.

REF : Catalog or model number – Indicates the manufacturer's catalog number so the medical device can be identified (ISO 15223-1)

LOT : Batch code – Indicates the manufacturer's batch code so that the bath or lot can be identified (ISO 15223-1)

� : Date of manufacture - Indicates the date when the medical device was manufactured (ISO 15223-1)

EC REP : Authorized European representative - Indicates the Authorized representative in the European Community (ISO 15223-1)

▲▲ : Manufacturer - Indicates the medical device manufacturer (ISO 15223-1)

MD : Medical device – indicates that the device is a medical device (EU MDR 2017/745)

NON STERILE : Non sterile - Indicates a medical device that has not been subjected to a sterilization process (ISO 15223)

unit/X – X devices in unit – Indicates the number of devices in unit of labeled unit

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⬚ⓘ : Consult instructions for use - Indicates the need for the user to consult the instructions for use (ISO 15223)

www.gSource.com/IFU - online location for IFUs available for users

CE Manufacturer's declaration that products comply with requirements of the European Union Medical Device Regulation.

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