CONTAINER SYSTEM FLEX FAMI

1. Title
Container System Flex

2. Intended use
Suitable for preparing, sterilizing, storing and transporting medical devices (MD). FAMI brand.

3. Features and differentials
The Container System Flex is made of anodized aluminium, which provides corrosion resistance, lighter weight and excellent thermal conductivity. The lids of the Container System Flex have perforations that allow the sterilizing agent to circulate and are equipped with a silicone foam seal, guaranteeing the sterility of the contents up to the point of use.
The Container System Flex bases have silicone-coated handles, offering greater ergonomics when loading. In addition, they have supports for documentation and identification labels, facilitating process traceability, as well as stainless steel locking latches with supports for security seals, ensuring the sterile barrier system is inviolable.
The Container System Flex is designed to be used with single-use disposable filters, or with encapsulated PTFE cassettes, suitable for up to 1,200 processing cycles.
Container System Flex meets the requirements of international standards ISO 11607, EN 868, DIN 58953 and ISO 17665.

4. Precautions
Before use, visually inspect the container. Avoid overloading it to prevent damage to the physical structure. Check the handles before each use to ensure safe transportation. Avoid prolonged exposure of containers to corrosive chemicals, salt and chlorine solutions, as these substances can cause staining, pitting and corrosion.
Only use detergents regulated for hospital use, following the dilution, temperature and exposure time instructions recommended by the manufacturer. When stacking, only place other containers on top of the containers.

5. Contraindications
There are no contraindications and/or adverse effects.

6. Instructions for use
6.1. Reusable. Must be decontaminated, cleaned and inspected before each use according to the instructions below.
6.2. Manual cleaning: remove the safety overcap (if removable) and the container lid by separating them from the base, as well as the filter retainer by separating them from the lid (do not disassemble the cartridge); pre-clean by hand, with running water or pre-cleaning by flowing steam to remove coarse dirt; soak in a hospital detergent with a low alkaline content, ideally neutral (7-10.5 pH), which is compatible with anodized aluminium, prepared in accordance with the sanitizer manufacturer's Instructions for Use (IFU); use non-abrasive sponges or brushes on the internal and external surfaces; rinse in potable running water until the detergent residue is completely removed; visually inspect to ensure complete removal of dirt from the surfaces; to dry, use a clean, dry absorbent product that does not release particles or an automated dryer with hot air.

6.3. Automated cleaning: remove the safety overcap (if removable) and the container lid by separating them from the base, as well as the filter cartridge or retainer by separating them from the lid (do not disassemble the cartridge); pre-clean manually, with running water or pre-clean by flowing steam to remove coarse dirt; if necessary, carry out prior manual cleaning as described above; carry out automated cleaning - parameters according to validation/qualification of the cycle for cleaning instruments; visually inspect to ensure complete removal of dirt from surfaces; dry with a clean, dry absorbent product that does not release particles or in an automated hot air dryer. The container system is validated for automated cleaning programs provided that the equipment has specific programs and supports for cleaning and disinfecting aluminum containers and uses a hospital detergent with a low alkaline content, ideally neutral (7-10.5 pH), which is compatible with anodized aluminum. The lid, cartridge/retainer and base of the container should be disassembled and placed in the rack separately so that the water jets reach all parts equally and the base should be positioned in the disinfecting washer rack with the opening downwards to prevent water from accumulating inside.

6.4. Inspection and Preparation: check for damage or any deterioration of the structure, loss of functionality before use, if detected replacement is recommended; arrange the instruments in an organized manner inside the Processing Basket and accommodate the basket inside the Flex System Container; place the PTFE filter or cassette, seal and label in each required compartment of the container; the containers must be positioned horizontally on the sterilizer support/rack and can be stacked ONLY with other containers, and a maximum of 3 containers overlapping, so that there is NO sealing of the container lid perforations.

6.5. Sterilization: the container must remain in a horizontal position on the sterilizer support/rack during the cycle; container stacking can occur as described above; observe the sterilizer manufacturer's IFUs; it is recommended to validate the use of containers during the sterilizer performance qualification.

6.6. Storage and distribution: after sterilization, store the product in the sterile materials area until transport to the point of use.

6.7. After use: clean as soon as possible to prevent drying out and the build-up of surgical dirt. If necessary, use moisturizing solutions before cleaning.

7. Disposal

Reusable product. Dispose of in accordance with the institution's protocol.

8. Warning

Serious incidents involving this product should be reported to the manufacturer as soon as possible.

9. Technical sheet

- Made of anodized aluminum, silicone seals and AISI 304 stainless steel latches and locks. Ideal for medical and dental use.
- Not sterile.
- Reusable.
- Recyclable.
- In accordance with the requirements of DIN 58953-9 and ABNT NBR ISO 11607-1:2013.

10. Codes, dimensions and weight

Container Flex System			
Colors	**Codes**	**Dimensions**	**Weights**
graphite	Y 105.10M7	585 x 280 x 90 mm	1.965 kg
graphite	Y 105.13M7	585 x 280 x 120 mm	2,150 kg
graphite	Y 105.15M7	585 x 280 x 140 mm	2,200 kg
graphite	Y 105.20M7	585 x 280 x 190 mm	2,720 kg
graphite	Y 105.26M7	585 x 280 x 250 mm	3,420 kg
graphite	Y 205.10M7	465 x 280 x 90 mm	1,190 kg
graphite	Y 205.13M7	465 x 280 x 120 mm	1,470 kg
graphite	Y 205.15M7	465 x 280 x 140 mm	1,960 kg
graphite	Y 205.20M7	465 x 280 x 190 mm	2,450 kg
graphite	Y 205.26M7	465 x 280 x 250 mm	3,150 kg
graphite	Y 305.10M7	295 x 280 x 90 mm	1,300 kg
graphite	Y 305.13M7	295 x 280 x 120 mm	1,490 kg
graphite	Y 305.15M7	295 x 280 x 140 mm	1,540 kg
graphite	Y 305.20M7	295 x 280 x 190 mm	2,030 kg
graphite	Y 305.26M7	295 x 280 x 250 mm	2,060 kg

Flex System Container Cover			
Colors	**Codes**	**Dimensions**	**Weights**
silver	Y 103.01M	585 x 280 mm	1,110 kg
graphite	Y 103.07M	585 x 280 mm	1,110 kg
graphite	Y 203.07M	465 x 280 mm	0.870 kg
silver	Y 303.01M	295 x 280 mm	0.650 kg
graphite	Y 303.07M	295 x 280 mm	0.650 kg

***For other colors, visit the website or contact FAMI: www.fami.com.br.*

FREQUENTLY ASKED QUESTIONS:

- **How should I proceed before first use?**
  Use hospital-grade detergents, sponges or non-abrasive brushes on the internal and external surfaces, and rinse with clean running water until the detergent residue has been completely removed. To dry, use a clean, dry absorbent product that does not release particles or an automated hot air dryer.

- **What cleaning method do you recommend?**
  Manual and automated cleaning, as long as the equipment manufacturer's IFUs are followed.

- **What types of detergents are recommended?**
  Hospital detergents with a low alkaline content, ideally neutral (7-10.5 pH), can be used, following the sanitizer manufacturer's IFU.

- **Are there any water restrictions?**
  Use drinking water in accordance with ANVISA's RDC No. 15 of March 2012.

- **How should it be stored before use?**
  In the warehouse: pack in transparent plastic packaging, identify the product with a label containing: product code, product name, date of manufacture, expiry date, batch number and manufacturer's name. Store in a clean, dry place in closed cabinets protected from dust.
  In the CSSD of the Health Service before use: clean and disinfect and store in closed cabinets and after use follow the guidelines described above.

- **Are there any recommendations for maintaining the product's durability?**
  Do not use corrosive chemicals, saline or chlorinated solutions, as these substances can cause stains, *pitting* and corrosion.

- **What daily cleaning method do you recommend?**
  After each use, the container must be cleaned and disinfected; dirt and contamination that cannot be removed in a normal cleaning cycle such as: adhesive labels, indicator tapes or pen inks must be removed with cleaning agents such as ELOXAL CLEANER or a product with the same active ingredient.
  Manual cleaning: follow the IFU described above.
  Note: Do not use compressed air directly on silicone seals. Compressed air can only be used at a distance of at least 30 cm.
  Automated Cleaning and Disinfection: follow the IFU described above.
  Disinfecting washer: follow the IFU described above.

- **What are the steps for using Container System Flex?**
  The system must be clean and dry.

1. Place the filter(s) in the lid;
2. Arrange the instruments inside the basket (one or more baskets, depending on the number of instruments and the size of the container;
3. The instruments must be arranged inside the basket so that they do not extend beyond the edges of the basket;
4. The processing baskets, with or without the health products, must be positioned (individually or stacked) at least 2 cm lower than the total height of the System Flex container, leaving a free space between the filter and the health products as a safety measure;

5. Place the lid on the base and snap it into place in a single movement;
6. Lock the lid onto the base with the latch until it makes an audible sound;
7. Seal the container with a FAMI plastic container seal - on both latches;
8. Identify the container with a FAMI identification label containing the Type 1 chemical indicator (CI
9. Place the container's nameplate(s) on the specific side support;
10. Follow the manufacturer's instructions for use when loading the sterilizer.
11. The heaviest containers should occupy the bottom position of the autoclave rack;
12. Only containers can be stacked with containers, overlapping other products can obstruct the perforation and prevent the penetration of the sterilizing agent and damage the container.
13. A minimum distance must be respected between one container and another to allow the sterilization agent to circulate. Check AAMI, SOBECC or other recommendations;
14. Occupy 80% of the autoclave's internal chamber capacity. Check AAMI, SOBECC or other recommendations.

Note: Do not wrap or pack the container with any type of external packaging. Do not cover or obstruct the perforated area of the container with any type of foil or object during sterilization, as this will block the flow of air and steam. The result will be a vacuum deficiency due to insufficient pressure difference and the contents will not be sterilized.
Use the two handles of the container to load and unload the autoclave, and to transport it.

- **Does the Container replace the processing basket?**
  As protective packaging, yes, but the processing basket is used inside the container to accommodate the medical devices more securely and the container should not be used without a processing basket.

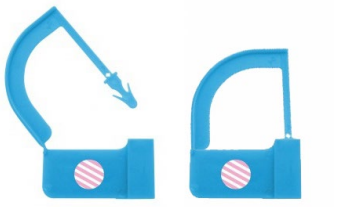
- **Can the Container be used without a filter**?
  No. Its use in the container is essential for the formation of a rigid sterile barrier system, which allows air to be removed and steam to penetrate and be removed during sterilization, maintaining sterility up to the point of use.

- **How should I position the filter in the Container System Flex?**
  On System Flex 1/1, 3/4 and 1/2 DIN containers, unlock the filter retainer from the lid (or lid and bottom, if present) of the container by pressing the lock located on the side of the center of the retainer, center the filter with the information facing out of the container and lock it again by pressing its center against the lid.

- **Should all perforated areas contain filters?**
  Yes. There are containers with two areas with retainers on the lid, and both must have the cassettes of the same system fitted.
  Note: Do not combine different systems in the same container.

- **Where should I put the seal?**
  The seals with or without indicator are inserted and positioned next to the side latches on the lids and bases, and when closed they guarantee the inviolability of the sterile barrier system.

- **How do I close the seal?**
  To close the seal, bring the arrow-shaped end to the base and snap it into place. See figure below.



- **How do I break the seal?**
  At the point of use, lift the container latches to break the FAMI seal and open the container.

- **How should I attach the identification label to the container?**
  The label must be inserted on both sides of the container in the given space/place, with traceability information previously filled in.
  The use of labels fitted in the appropriate places contributes to the preservation of the container and facilitates maintenance and upkeep, as it avoids the inappropriate use of adhesive labels or tapes on the surface of the container to identify the contents.

- **Does the container have thermal validation?**
  The Flex System Container is validated to be sterilized in steam autoclaves with a pre-vacuum system that meet at least the following parameters:

  Temperature: 134 °C
  Exposure time: 5 minutes
  Drying time: 20 minutes
  Vacuum pulses: 4 pulses
  Vacuum: 150 mbar
  Steam: 1,300 mbar

  ATTENTION: Each institution must validate its processes to determine the need for adjustments to their use. The validation considered FAMI container systems with the following dimensions: 1/1, 3/4 and 1/2 containers.
  FAMI sterilization containers have been tested and validated for steam sterilization processes.

- **What is the maximum load supported by each container?**
  According to DIN EN 868-8 and DIN 58953-9, the following maximum container loads are recommended:
  1/1 container: 10kg
  3/4 container: 7Kg
  Container 1/2: 5Kg
  To allow the sterilizing agent to penetrate the container and reach all the products inside, ensuring their sterilization, it is necessary to comply with the recommendation to occupy the floor space with the total load recommended in the standards. FAMI cannot guarantee the sterilization of the products if these recommendations described below are not met.

Model	Dimension (in mm)	Maximum load (in Kg)
1/1 container	580 x 280 x 100	3,8
	580 x 280 x 135	5,2
	580 x 280 x 150	5,8
	580 x 280 x 200	7,7
	580 x 280 x 260	10
3/4 container	465 x 280 x 100	3,1
	465 x 280 x 135	4,2
	465 x 280 x 150	4,6
Container 1/2	285 x 280 x 100	1,9
	285 x 280 x 135	2,6
	285 x 280 x 150	2,8
	285 x 280 x 200	3,8
	285 x 280 x 260	4,9

- **How should I organize container loads and packages in the autoclave?**
  The sterilization of cargo with mixed packaging of containers and packages must be validated by the service.

- **Can I use a container to sterilize complex instruments such as scopes?**
  Complex instruments, such as scopes, instruments with lumens or pneumatic and electrical equipment, must be prepared for sterilization according to the manufacturers' instructions.

- **Are there any water restrictions?**
  Use drinking water free of organic and inorganic residues.

- **Which sterilization processes can it be used for?**
  Validated for steam sterilization in an autoclave with vacuum pump.

- **How should it be stored?**
  General storage conditions must comply with the recommendations of ANVISA Resolution - RDC No. 15 of March 15, 2012.
  The shelf life of the sterilization process depends on the related events, and it is up to each institution to validate its process according to its structure and storage conditions.

- **Can containers be stacked?**
  Yes. The standardized measurements allow them to be stacked.

- **Are there any recommendations for maintaining the product's durability?**
  Do not use detergents with a high alkaline content, or that contain high concentrations of sodium and carbonate, always use treated water, ultrasonic cleaners can discolor or stain the product, do not use hot air drying temperatures above 120° C, do not use sprays, oils or solvents to clean or lubricate the lid seals.

- **What recommendations do you have for maintenance and repairs?**
  - The useful life of the lid seals is 500 sterilization cycles, and when this number is reached, replacement is recommended. If you notice any damage to the seals, we recommend replacing them immediately.
  - To maintain the seals on the lids, wipe them with a clean, damp cloth;
  - When the container or any component of the system is damaged, it must be taken out of use and sent for repair;
  - Only qualified persons may carry out maintenance and repair work on containers, otherwise the functionality and safety of the product may be compromised;
  - FAMI does not recommend and cannot be held responsible if containers are repaired by unqualified professionals;
  - Sterilization containers can be sent to FAMI or to one of the authorized repair services for maintenance and repairs;
  - We recommend lubricating all moving parts in the container with lubricants suitable for surgical instruments.
  - The cartridges are long-lasting systems. The PTFE system is valid for between 1,200 and 5,000 cycles, after which it must be replaced with a new one. The other systems only need to be replaced in the event of damage or a mechanical defect (valve).

  Note: *do not use compressed air directly on silicone seals*

- **Which standards and regulations do the containers meet?**
  The following international standards have been taken into account in order to guarantee the safety of sterilization containers in manufacturing and handling:

EN 868-2:2009	Packaging for terminally sterilized medical devices. Sterilization wrap. Requirements and test methods
EN 868-8:2009	Packaging for terminally sterilized medical devices. Re-usable sterilization containers for steam sterilizers conforming to EN 285. Requirements and test methods
ABNT NBR ISO 11607-1:2013	Final packaging for sterile health products - Part 1: Requirements for materials, sterile barrier systems and packaging systems.
DIN 58952-2:2012-04	Sterilization - Transport baskets for sterile barrier systems- Part 2: Sterilizing baskets made of metal
DIN 58952-3:2012-04	Sterilization - Transport baskets for sterile barrier systems - Part 3: Instrument trays for sterilizing goods made of metal
DIN 58953-9:2002-10	Sterilization - Sterile supply - Part 9: Use of sterilization container
ISO 14937:2009	Sterilization of health care products -- General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices
ISO 11134	Sterilization of health care products; requirements for validation and routine control; industrial moist heat sterilization
ABNT NBR ISO 17665-1:2010	Sterilization of health products - Steam - Part 1: Requirements for the development, validation and routine control of sterilization processes for health products.

- **Is it registered with ANVISA?**
  This product does not fall under the concept of Medical Devices (ANVISA), according to Technical Note 218/2020 ANVISA.