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## FAMI TRANSPORT BASKET



### 1. Title

FAMI Transport Basket

### 2. Intended use

Suitable for transporting Medical Devices (MD) packaged with a flexible sterile barrier system, such as SMS. Product developed and manufactured by FAMI Tecnologia Médica.

### 3. Features and differentials

The FAMI Transport Basket is used to accommodate and organize packages of materials during sterilization, storage and transport from the Materials and Sterilization Centres (CSSD) to the point of use in the Surgical Centres (SC). FAMI Transport Baskets reduce the risk of events related to the flexible sterile barrier system damaging the packages and consequently recontaminating the contents of the packages. FAMI Transport Baskets should be handled by ergonomic handles and can be stacked on the autoclave rack during load assembly and on shelves, cabinets or storage racks in the CSSD armoury, optimizing the use of physical spaces.

The FAMI Transport Basket is made from AISI 304 stainless steel (without the addition of other materials such as welds and rivets), has rounded corners and a smooth finish. It has been developed in accordance with international DIN standards. Made entirely from robust, lightweight, versatile and safe stainless steel wires, the spacing between the wires makes it easy for cleaning agents to access. In addition to being stackable during use, the FAMI Transport Baskets are nestable, allowing for a reduction in storage space when not in use.

### 4. Precautions


Inspect visually before use. Do not overload the basket to avoid damaging its physical structure. Check the handles before use to ensure safe transportation. Avoid prolonged exposure of the baskets to corrosive chemicals, saline and chlorinated solutions, as these substances can lead to stains, pitting and corrosion. Detergents: only use regulated products for hospital use (enzymatic, slightly alkaline or neutral), with dilution, temperature and exposure time in accordance with the product manufacturer's instructions for use. Do not stack other heavy products on top of the FAMI Transport Basket.

### 5. Contraindications

There are no contraindications and/or adverse effects.

### 6. Instructions for use

- 6.1. Reusable. It should be decontaminated, cleaned and inspected whenever necessary following the instructions below.
- 6.2. Manual cleaning: manual pre-cleaning, with running water or pre-cleaning by flowing steam to remove coarse dirt; immerse in a detergent for hospital use, prepared in accordance with the sanitizer manufacturer's Instructions for Use (IFU); use non-abrasive sponges or brushes on internal and external surfaces; rinse in clean running water until the detergent residue has been completely removed; visually inspect to ensure that the dirt on the surfaces has been completely removed; to dry, use a clean and dry absorbent product that does not release particles or an automated hot air dryer.
- 6.3. Automated cleaning: dispensable step, but if necessary, follow as described - manual pre-cleaning, with running water or pre-cleaning by flowing steam to remove coarse dirt; if

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necessary, carry out manual pre-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; proceed to drying with a clean, dry absorbent product that does not release particles or in an automated hot air dryer.

- 6.4. Inspection and preparation: check for damage or any deterioration of the structure, loss of functionality before use, if detected, replacement is recommended; the baskets should be positioned horizontally on the sterilizer support/rack.
- 6.5. Sterilization: the basket must remain in a horizontal position on the sterilizer support/rack during the cycle; the stacking of processing baskets inside the sterilization chamber can only be carried out with the use of a Transport Basket; observe the sterilizer manufacturer's IFU; it is recommended to validate the use of processing baskets 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: only when necessary and in the institutions' routines, following the Standard Operating Protocols (SOPs), and should be decontaminated, cleaned and inspected following the instructions above.

## 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 from AISI 304 stainless steel (stainless steel composed of iron, chromium and nickel), as it offers greater resistance to corrosion and oxidation. Ideal for medical and hospital use.
- Not sterile.
- Reusable.
- Recyclable.
- In accordance with technical standards ISO 11607-1 and DIN 868.

## 10. Codes, dimensions and weight

Codes	Descriptions	Weights
665.905	600 x 292 x 150 mm	1,495 kg
665.906	600 x 292 x 260 mm	1,770 kg

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## 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 types of detergents are recommended?**  
It can be used with all types of detergent, as long as the sanitizer manufacturer's Instructions for Use (IFU) are followed.
- Which sterilization processes can it be used for?**  
The baskets can be sterilized in all sterilization processes, however, when associated with medical devices it is recommended to follow the product manufacturer's Instructions for Use (IFU).
- How should it be stored?**

  - 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: after the cleaning and disinfection process, it can be packaged in transparent plastic packaging, sealed and identified with the date of processing, the method, limit date of use and identification of the professional, as determined by ANVISA's RDC n°15 of March 2012.
- Can they be stacked?**  
Yes, one of the main features of FAMI Transport Baskets is correct stacking, as it maintains the distance between packages, preventing damage to the packaging.
- Are there any recommendations for maintaining the product's durability?**  
Do not use corrosive chemicals, saline or chlorinated solutions; these substances can cause stains, pitting and corrosion.
- What cleaning method do you recommend?**  
Manual and automated cleaning, provided the equipment manufacturer's IFUs are followed.
- What types of detergents are recommended?**  
It can be used with all types of detergents for hospital use, as long as the sanitizer manufacturer's IFUs are followed.
- Are there any water restrictions?**  
Use drinking water in accordance with RDC 15.
- Is it registered with ANVISA?**  
This product does not fit the concept of Medical Device (ANVISA), according to Technical Note 218/2020 ANVISA.