

## FAMI BASKET FOR PROCESSING



### 1. Title

FAMI Basket for Processing

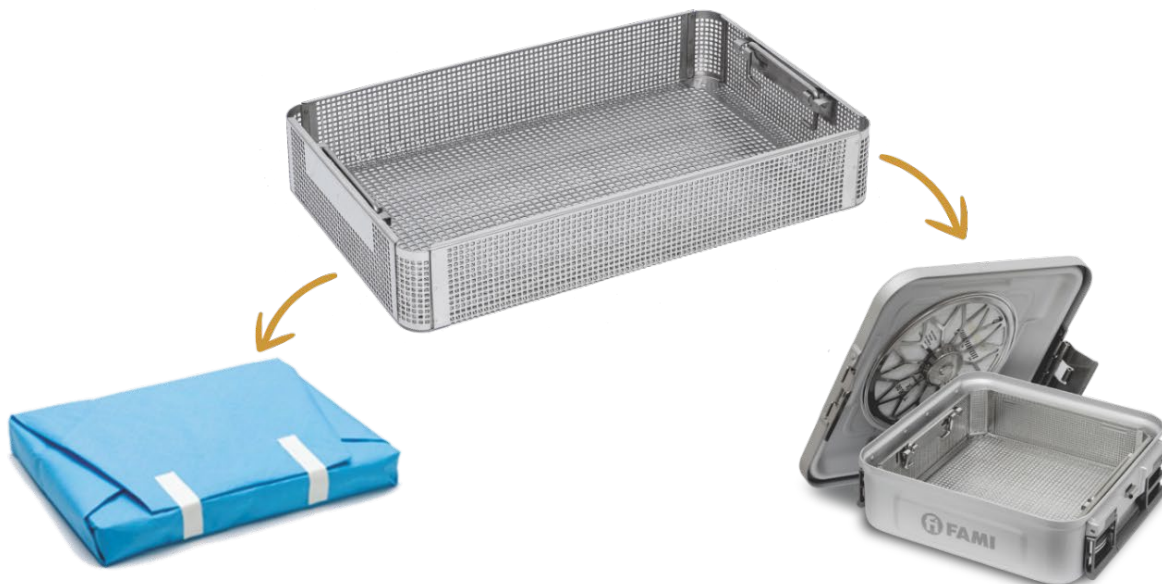
### 2. Intended use


Suitable for cleaning, packaging, sterilizing, storing and transporting MD. Product developed and manufactured by FAMI Tecnologia Médica.

### 3. Features and differentials

The Basket for Processing is protective packaging made from AISI 304 stainless steel (without the addition of other materials such as welds or rivets), has rounded corners and a smooth finish, and retractable handles for easy transportation and aseptic presentation. It has been developed in accordance with good international packaging practices. It is a resistant product because it is made entirely from perforated stainless steel sheets to guarantee the penetration of cleaning and sterilizing agents. The dimensions of the perforations are millimetrically designed to prevent instruments from escaping from the sides, avoiding occupational risk and protecting the Sterile Barrier System (SBS) from possible breaches.

Processing baskets are resistant and economical, as they optimize the manual and automated cleaning, drying and sterilization processes; they are versatile and can be used throughout the processing cycle, replacing perforated cases/boxes and wired baskets with numerous advantages. The baskets are a lighter product than the cases/boxes, as a result of the large perforated area, thus reducing the weight of the load to be sterilized and contributing to the good performance of the sterilization equipment. They must be packed in a flexible SBS (e.g. SMS) or used inside a rigid SBS (container), and their measurements follow international standards (DIN).



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#### 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, 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 Processing Basket.

#### 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: pre-clean manually, 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 under running drinking 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, dry absorbent product that does not release particles or an automated hot air dryer.
- 6.3. Automated cleaning: pre-clean manually with running water or pre-clean with flowing steam to remove coarse dirt; if necessary, 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; dry 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 we recommend replacement; arrange the instruments neatly inside the Processing Basket; pack baskets individually in a flexible or rigid SBS (container system); 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: clean as soon as possible 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 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 dental use
- Not sterile.
- Reusable.
- Recyclable.
- In accordance with technical standards ISO 11607-1 and DIN 868
- Perforation dimensions: Base 5 mm, sides 3 mm


## 10. Codes, dimensions and weight

PROCESSING BASKETS		
Codes	Dimensions	Weights
662.130	540 x 255 x 30 mm	0.880 kg
662.150	540 x 255 x 50 mm	1,035 kg
662.170	540 x 255 x 70 mm	1,170 kg
662.190	540 x 255 x 100 mm	1,430 kg
662.230	485 x 255 x 30 mm	0.800 kg
662.250	485 x 255 x 50 mm	0.960 kg
662.270	485 x 255 x 70 mm	1,085 kg
662.290	485 x 255 x 100 mm	1,300 kg
662.330	405 x 255 x 30 mm	0.720 kg
662.350	405 x 255 x 50 mm	0.850 kg
662.370	405 x 255 x 70 mm	0.980 kg
662.390	405 x 255 x 100 mm	1.205 kg
662.530	245 x 255 x 30 mm	0.520 kg
662.550	245 x 255 x 50 mm	0.620 kg
662.570	245 x 255 x 70 mm	0.750 kg
662.590	245 x 255 x 100 mm	0.875 kg
662.745*	265 x 120 x 45 mm	0.380 kg
662.845*	265 x 170 x 45 mm	0.510 kg

\*No lid

TAPES		
Codes	Dimensions	Weights
662.110**	540 x 255 mm	0.650 kg
662.210**	485 x 255 mm	0.600 kg
662.310**	405 x 255 mm	0.455 kg
662.410**	350 x 255 mm	0.370 kg
662.510**	245 x 255 mm	0.335 kg

\*\* Lids are sold separately

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## FREQUENTLY ASKED QUESTIONS:

- Does the Processing Basket replace the wire basket in disinfecting and ultrasonic washers?**  
Yes, with the advantage of being sturdier and safer, as wire baskets often come loose from the main structure, causing accidents at work and damage to instruments).
- Does the Processing Basket replace the instrument case?**  
Yes, with the advantage of being lighter, versatile, ergonomic and contributing to the good performance of sterilizers, making it possible to use them in the cleaning and sterilization stages.
- Does the Processing Basket have a lid**  
Yes, the Processing Basket is designed to be used with a lid (sold separately). It helps protect the MDs when packed with SBS (e.g. SMS).
- Can the Processing Basket be used without a lid**  
Yes, the Processing Basket has been designed with the top edges facing inwards, to help you pack with flexible SBS without risk of damage.
- 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, 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 ANVISA's RDC No. 15 of March 2012.
- What packaging and processes are recommended for sterilization?**  
Flexible (SMS or Pouch) or rigid (container) SBS. It can be used in all sterilization processes, as long as the IFUs of the SBS and equipment manufacturers are followed.

Protective packaging	Sterile barrier system (SBS)	Sterilization methods				
		Dry heat	Saturated steam under pressure	Ethylene oxide (ETO)	H2O2 vapor	VBT Formaldehyde
Baskets	Container	No	Yes	Yes	Yes	Yes
	Pouch		Yes	Yes	No	Yes
	Tyvek		No	Yes	Yes	Yes
	SMS		Yes	Yes	Yes	Yes
	Crepe paper		Yes	Yes	No	Yes
	Cotton fabric		Yes	No	No	No

Source: Adapted from APECIH, 2003

- **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.

- **Can they be stacked once packed?**

Good practice recommends that packaging systems (protective packaging + SBS) should not be stacked. Storage or transport baskets can be used to optimize storage.



- **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 accessories are available to extend its benefits?**

Lid, over-basket, small parts basket, silicone holders, silicone blankets, Pouch holder, stainless steel identification label and transport basket.

- **Is it registered with ANVISA?**

This product does not fit into ANVISA's concept of Medical Devices, according to Technical Note 218/2020 ANVISA .