	FAMI QUALITY MANAGEMENT SYSTEM Technical Description	DTec 001	Page 1 from :4
	Packaging system	REV: 02	DATE 21/02/2025

## FAMI BASKETS FOR SMALL ITEMS



### 1. Title

Basket for Small Items

### 2. Intended use

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

### 3. Features and differentials

Small Parts 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 wire baskets with numerous advantages. The Small Parts Basket is a protective container made of 304 stainless steel, with a lid attached to the base with a secure closure to keep small parts and accessories protected throughout the process. Produced entirely from stainless steel sheets, it is resistant and safe. The perforations measure 2.5x2.5 mm with a spacing of 0.65 mm between them, and are millimetrically designed to prevent instruments from exiting through the sides, base and lid, avoiding occupational risk and protecting the Sterile Barrier System (SBS) from possible violations, its perforations facilitate access for cleaning and sterilization agents, it is economical and versatile and can be used throughout the processing cycle, and accommodated in the processing baskets along with the other components of the surgical instrument kit. Small Parts Baskets are a lightweight product, as a result of the extensive perforated area, thus reducing the weight of the load to be sterilized and contributing to the good performance of the sterilization equipment. They should be packaged in a flexible SBS (SMS) or used inside a rigid SBS (container).

### 4. Precautions


Inspect visually before use. Do not overload the basket to avoid damaging the physical structure. Inspect 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 Small Parts 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-clean by flowing steam to remove coarse dirt; soak in a hospital-use detergent, 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.

	FAMI QUALITY MANAGEMENT SYSTEM Technical Description	DTec 001	Page 2 from :4
	Packaging system	REV: 02	DATE 21/02/2025

- 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), which offers greater resistance to corrosion and oxidation. Ideal for medical and dental use
- Not sterile.
- Reusable.
- Recyclable.
- In accordance with ISO 11607-1 technical standards.

## 10. Codes, dimensions and weight

Codes	Descriptions	Weights
134.117	80X50X40 mm	0.065 kg
134.120	80X80X40 mm	0.100 kg
134.133	150X140X40 mm	0.195 kg

## FREQUENTLY ASKED QUESTIONS:

- **Does the Small Parts Basket replace the wire basket in disinfectors and ultrasonic cleaners?**

	FAMI QUALITY MANAGEMENT SYSTEM Technical Description	DTec 001	Page 3 from :4
	Packaging system	REV: 02	DATE 21/02/2025

Yes, with the advantage of being sturdier and safer, as wire baskets often come loose from the main structure, causing accidents and damage to instruments.

- **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.

- **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.

	<b>FAMI QUALITY MANAGEMENT SYSTEM</b> Technical Description	DTec 001	Page <b>4</b> from : <b>4</b>
	Packaging system	REV: 02	DATE 21/02/2025

- **Is it registered with ANVISA?**

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