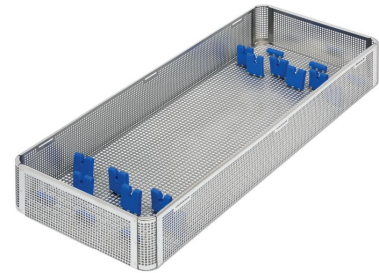
	FAMI QUALITY MANAGEMENT SYSTEM Technical Description	DTec 001	Page 1 from :4
	Packaging system	REV: 02	DATE 27/02/2025

## FAMI STEEL SHEET BASKETS FOR ROBOTIC SYSTEMS



### 1. Title

Steel Sheet Baskets for Robotic System

### 2. Intended use

Suitable for packaging, sterilizing, storing and transporting medical devices used in minimally invasive surgeries using the Da Vinci robotic system. Made of stainless steel with silicone supports. Product developed and manufactured by FAMI Tecnologia Médica.

### 3. Features and differentials

The Steel Sheet Baskets for Robotic System is protective packaging made from AISI 304 stainless steel (without the addition of other materials such as welds), with rounded corners and a smooth finish. It has been developed in accordance with good international packaging practices. It is a resistant product, as 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.

Steel Sheet Baskets for Robotic System are resistant and economical, as they optimize the drying and sterilization processes; 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. Baskets should be packaged in a flexible SBS (e.g. SMS).

### 4. Precautions


Inspect visually before use. Do not overload the basket to avoid damaging its physical structure. Check the silicones to ensure that the instrument is properly fixed. 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 Robotic System 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 27/02/2025

- 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 Robotic System Basket; pack the baskets individually in flexible SBS (e.g. SMS); 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 Robotic System 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 the 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 hospital use.
- With internal silicone support.
- 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

Codes	Dimensions	Weights
124.330	680 x 260 x 100 mm - for 6 clamps	2,760 kg
124.320	560 x 150 x 70 mm - for 1 optic	1,360 kg
124.310	690 x 90 x 100 mm - p/1 clamp	1,560 kg
124.410	680 x 260 x 100 mm - for 1 optic	2,550 kg

\*All models have a lid.

### FREQUENTLY ASKED QUESTIONS:

- Does the Steel Sheet Baskets for Robotic System replace the wire basket in disinfecting washers?**

Yes, with the advantage of being sturdier, safer (as in wired baskets the wires can detach from the main structure and cause adverse events for the professional and damage to the instruments), and having perforations in two sizes (the lower perforations facilitate access for cleaning and sterilization agents, while the side perforations prevent instruments from escaping, protecting the flexible sterile barrier system and reducing occupational risk). It also allows surgical kits to be prepared after cleaning and sterilization in a single product.
- Does the Steel Sheet Baskets for Robotic System replace the instrument case?**

Cases/boxes for cleaning robotic medical devices do not apply.
- Does the Steel Sheet Baskets for Robotic System have a lid?**

Yes, the Optical Basket is designed to be used with a lid. It helps protect medical devices and the flexible sterile barrier system (e.g. SMS).
- 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 SBS (SMS or Pouch). 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.

- **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?**

Basket for small parts, silicone holders, silicone blankets, holder for Pouch, stainless steel identification label and basket for transportation.

- **Is it registered with ANVISA?**

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