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FAMI SCOPE BASKET



1. Title

FAMI Scope Basket

2. Intended use

Suitable for packaging, sterilizing, storing and transporting scopes. Product developed and manufactured by FAMI Medical Technology.

3. Features and differentials

The Scope Basket 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 and prevent instruments from escaping from the sides, avoiding occupational risk and protecting the Sterile Barrier System (SBS) from possible breaches.

Optical baskets are resistant and economical, as they optimize the 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 should be packed 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 Optics 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 with flowing steam to remove coarse dirt; soak 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, carry out manual pre-cleaning as described above; carry out automated cleaning - parameters according to validation/qualification of the cycle for

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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 any damage or deterioration of the structure, loss of functionality before use, if detected, replacement is recommended; arrange the instruments in an organized manner inside the Optical Basket; pack the baskets individually in flexible SBS (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; stacking Optical Baskets inside the sterilization chamber can only be carried out using a Transport Basket; observe the sterilizer manufacturer's IFU; it is recommended to validate the use of Optical 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 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 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

| OPTICAL BASKETS | | |
|-----------------|---|----------|
| Codes | Dimensions | Weights |
| 124.211 | 290 x 80 50 mm - without support | 0.465 kg |
| 124.111 | 290 x 80 50 mm - 1 scope with holder | 0.480 kg |
| 124.212 | 460 x 80 50 mm - without support | 0.690 kg |
| 124.121 | 290 x 80 x 50 mm - 2 scope with stand | 0.565 kg |
| 124.112 | 460 x 80 50 mm - 1 scope with stand | 0.730 kg |
| 124.114 | 290 x 160 x 50 mm - 1 scope with stand | 0.765 kg |
| 124.122 | 460 x 80 x 50 mm - 2 scopes with stand | 0.765 kg |
| 124.113 | 670 x 80 x 50 mm - 1 scope with stand | 1,055 kg |
| 124.115 | 460 x 160 x 70 mm -1 scope with stand | 1,300 kg |
| 124.116 | 460 x 160 70 mm - CM - 1 scope with holder (Endoscopy) | 1,270 kg |
| 124.141 | 640 x 150 x 70 mm - 1 scope and cable (Rigid Ureteroscopy) | 1,600 kg |
| 124.131 | 540 x 250 x x70 mm - flexible scope and cable | 1,850 kg |
| 126.312 | 540 x 250 x 70 mm - flexible scope (Fiber Nasopharyngoscope) | 1,860 kg |

*All models have a lid.

FREQUENTLY ASKED QUESTIONS:

- Does the Optical 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 Optics Basket have a lid?**
Yes, the Optical Basket has been designed to be used with a lid. It helps protect MD when packed with SBS (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, as long as 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 (e.g. SMS) It can be used in all sterilization processes, as long as the SBS and equipment manufacturers' IFUs are followed.

| Protective packaging | Sterile barrier system (SBS) | Sterilization methods | | | | |
|----------------------|------------------------------|-----------------------|-------|---------------------|-------------------|--------------|
| | | Dry heat | Steam | Ethylene Oxide (EO) | Hydrogen Peroxyde | Formaldehyde |
| Scope Basket | Pouch | No | 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?**

Basket for small parts, silicone holders, silicone blankets, holder for surgical grade paper, stainless steel identification label and transport basket.

- **Is it registered with ANVISA?**

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