



TECHNICAL SPECIFICATIONS

Medical device for filtration

"F Filtration Set 60 ml" REF. FL0000013 – Liposmart®

Closed-circuit system for the processing of large volumes of autologous adipose tissue, equipped with 3 emulsifiers (Ø 1.2 – 1.4 – 2.4 mm) and LL syringes.

LATEX FREE

F Filtration Set 60 ml is a single-use, closed-circuit device designed to harvest, micro-fragment, and purify lipoaspirate for autologous implantation without the use of enzymes or centrifugation.

Through an advanced filtration and washing system, F Filtration® preserves the complete architecture of the vascular stromal niches of the lipoaspirate, enhancing bioavailability and the cells' ability to respond to regenerative stimuli.

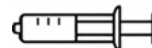
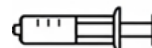
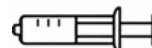
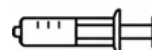
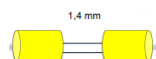
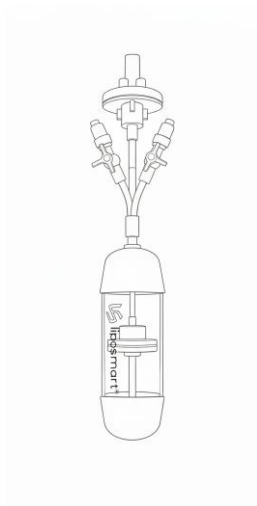
Adipose tissue processing occurs entirely within the device, with minimal manipulation, and is performed in a single surgical step in the operating room.

Closed-circuit system for the processing of autologous adipose tissue.

- Registration with the Ministry of Health: No. 9983, dated 28/02/1984.
- **CE Certification (Annex V) pursuant to Directive 93/42/EEC, issued by the Istituto Superiore di Sanità, Notified Body No. 0373. Certificate No. QPZ-1924-19 Add.01-20, issued on 20/12/2021, with extension until 31/12/2028 under EU Regulation 2023/607. Classification: Class IIa – CND B06 – RDM 2141255.**
- The material used for the manufacture of the tubing and its components consists of high polymers to which stabilizers and plasticizers permitted by law have been added (not plasticized with phthalates).
- They are chemically stable, transparent, flexible, and resistant to tensile stress and the internal pressure of the fluid circuit.
- The materials used, with regard to the potential release of substances into the administered solutions, comply with the requirements of the Official Pharmacopoeia.
- The materials used are compatible with the pharmaceutical products with which they may come into contact during normal use. They are also biocompatible and non-toxic, as required by the following standards: UNI EN ISO 10993-1 (current edition); UNI EN ISO 10993-4 (current edition); UNI EN ISO 10993-5 (current edition); UNI EN ISO 10993-10 (current edition).

Tests performed: allergic sensitization, irritation or intracutaneous reactivity, cytotoxicity, hemolysis, chemical validation, and LAL test.

- The inks used to mark measurement or reading indicators on parts in direct contact with the product are non-toxic. This compliance is also assessed for suppliers of medical bags and externally printed polyethylene bags.
- The device is single-use. Reuse carries serious risks of biological contamination.
- Sterilization method: ETO (ethylene oxide) – single-use (not re-sterilizable). ETO residue: less than 4 mg per unit.
- Recommended storage conditions: at room temperature (5–30°C) in a clean, dry place (humidity between 40–65%) in the original packaging.
- Product shelf life: packaging in medical-grade paper and polyethylene pouches ensures product stability and preservation for at least 5 years.
- Disposal: by means of a specialized hospital procedure.



Syringe 30 ml lock

Syringe 10 ml

Syringe 20 ml

Syringe 60 ml

CONSISTS OF:

- 1.** 60 ml housing/container
- 2.** Y-connectors
- 3.** Self-sealing needle-free valve
- 4.** Filter
- 5.** Tubing Ø 4.8 × 6.8 mm
- 6.** Tubes, 2 cm, Ø 1.2 – 1.4 – 2.4 mm emulsifiers
- 7.** Female Luer Lock caps
- 8.** 350 ml waste bag with 2 FLL inlets
- 9.** 0.2 µm filter
- 10.** One-way taps (on/off)
- 11.** Tray Ø 16 × 70 mm + spike
- 12.** Infusion set filter
- 13.** Air inlet with open/close function and antibacterial filter
- 14.** Tube clamp
- 15.** LL syringes 10 ml / 20 ml / 60 ml, Plastipak
- 16.** 30 ml Lock syringe
- 17.** Bag 25 × 35 cm
- 18.** Dispenser

Silicone, polycarbonate, ABS
ABS
Polycarbonate + silicone
DEHP-free PVC + PES 700 µm + green PE cap
DEHP-free PVC
DEHP-free PVC
PE (natural, green, yellow)
DEHP-free PVC
ABS + PES 0.2 µm
Polycarbonate
DEHP-free PVC
ABS + nylon 15 µm
Polyethylene + Pall 0.45 µm
ABS
Polypropylene
Polycarbonate
Polyethylene – medical-grade paper, paper

Our infusion device accessories/components undergo dimensional and quality control by our Company's Quality Control department. Physical tests on eluates, biocompatibility, pyrogenicity, sterility, and bacterial endotoxin testing are performed on the finished product according to validated internal protocols.

Quantity of devices per standard package:

- Number of units per carton: 1