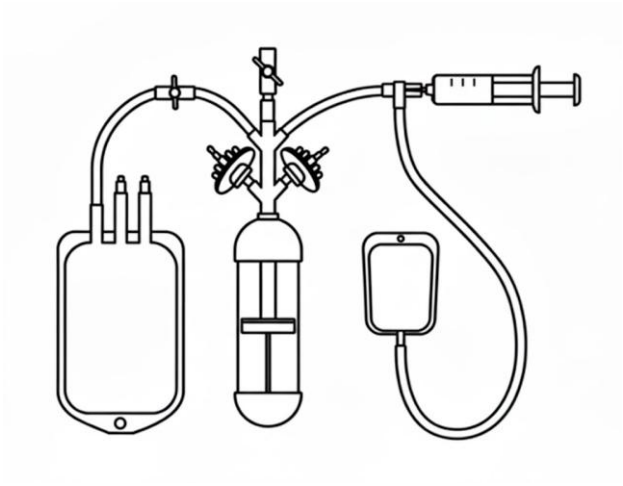
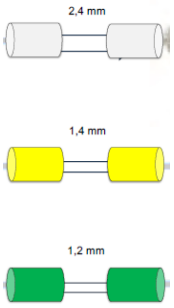
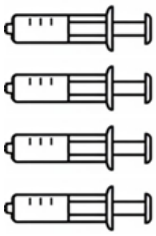
TECHNICAL SPECIFICATIONS
Medical device for filtration
"F Filtration Set 120 ml" REF. FL0000011 – Liposmart®
Closed-circuit system for the processing of large volumes of autologous adipose tissue, equipped with 3 emulsifiers (Ø 1.2 – 1.4 – 2.4 mm) and LL syringes.
LATEX FREE

F Filtration Set 120 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' capacity 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 – n.2
Syringe 10 ml – n.2
Syringe 20 ml – n.2
Syringe 60 ml – n.2

CONSISTS OF:

1.	120 ml housing/container	Silicone, polycarbonate, ABS
2.	0.2 µm filter	ABS + PES 0.2 µm
3.	Y-connectors	ABS
4.	Self-sealing needle-free valve	Polycarbonate + silicone
5.	Filter	DEHP-free PVC + PES 1200 µm + yellow PE cap
6.	Filter	DEHP-free PVC + PES 700 µm + green PE cap
7.	Tubing Ø 4.8 × 6.8 mm	DEHP-free PVC
8.	350 ml waste bag with 2 FLL inlets	DEHP-free PVC
9.	One-way taps (on/off)	Polycarbonate
10.	Tray Ø 16 × 70 mm + spike	DEHP-free PVC
11.	Infusion set filter	ABS + nylon 15 µm
12.	Air inlet with open/close function and antibacterial filter	Polyethylene + Pall 0.45 µm
13.	Tube clamp	ABS
14.	Tubes, 2 cm, Ø 1.2 – 1.4 – 2.4 mm emulsifiers	DEHP-free PVC
15.	Female Luer Lock caps	Natural PE, green, yellow
16.	Female Luer Lock	DEHP-free PVC
17.	Female Luer Lock caps	Polyethylene
18.	LL syringes 10 ml / 20 ml / 60 ml, Plastipak BD	Polypropylene, polycarbonate
19.	30 ml Lock syringe	Polyethylene – medical-grade
20.	Bag 25 × 35 cm	paper, paper
21.	Dispenser	

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 packaging:

- Number of units per carton: 1