Indications for Use – F Filtration Set (Liposmart)

System for Processing and Autologous Reimplantation of Adipose Tissue – F Filtration Set (Liposmart)

Liposmart is a sterile Class IIa medical device with a closed circuit for processing lipoaspirated adipose tissue, intended for autologous implantation.
The device can be used in various therapeutic areas such as plastic surgery, aesthetic surgery, orthopedic surgery, gastrointestinal surgery, urological surgery, general surgery, and gynecological surgery.

Device Description

CE certified (Annex V, Directive 93/42/EEC) by Istituto Superiore di Sanità, Notified Body 0373, Certificate QPZ-1924-19 ADD 01-20 (19/06/2020, extended to 31/12/2028 under EU Regulation 2023/607), Class IIa – CND B06 – RDM 2141255.

The device consists of:

- Processing unit with a graduated scale for continuous monitoring of the process from collection to processing and the final obtained volume.
- 1 washing line equipped with a flow regulator and a T-shaped one-way valve with Luer lock connection.
- 1 outlet for collecting the processed material, featuring a one-way blue Luer lock tap and a self-sealing valve.
- 1 drainage line connected to the processing unit, with a one-way white inline tap leading to a 350 ml waste collection bag for adipose tissue washing, featuring two attached outlet points with FLL fittings.
- 2 inlets with the adipose tissue micro-fragmentation device, featuring a green one-way valve and a yellow cap for the 1,200µ filter, and a green cap for the 700µ filter.

The materials used for the production of the device and its components are high-grade polymers, incorporating legally permitted stabilizers and plasticizers (phthalate-free – DEHP-free – latex-free).These materials, with regard to potential leaching into administered solutions, comply with the Official Pharmacopoeia and are also biocompatible and non-toxic, as required by the following standards: UNI EN ISO 10993-1, UNI EN ISO 10993-4, UNI EN ISO 10993-5, UNI EN ISO 10993-10 (current editions).
Tests performed: allergic sensitization, intracutaneous irritation or 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 evaluated for suppliers of medical bags and externally printed polyethylene bags.

The device is available in 3 versions, each featuring a processing unit of a different color according to the volume required for the specific clinical application:

- 60 ml (Liposmart Boost)
- 120 ml (Liposmart)
- 275 ml (Liposmart Augment)

Read the Instructions for Use carefully before using Liposmart. The device is intended for use by physicians only.

Packaging and Sterility

The device is sold in a single-use package.
Sterilization method: ETO (ethylene oxide) – single-use (not re-sterilizable). ETO residue: less than 4 mg per unit.
It is packaged in a double medical paper pouch.
Before use, carefully check the integrity of the double sterile pouch. Do not use if the package is open, damaged, or contaminated.
Use the device in a sterile environment, ensuring complete sterility of the product at all times.
The device is single-use only (cannot and must not be reused or re-sterilized). Reuse carries serious risks of biological contamination.

Usage Procedure

1. Check the sterility and integrity of the packaging.
2. Open the primary package and remove the device.
3. Infiltrate Klein solution into the adipose tissue harvest area according to the physician's instructions.
4. Allow the anesthetic to act for 8–10 minutes, or for the time specified by the manufacturer, before proceeding with liposuction.

Preparation and Processing Phase of the Liposmart Device

Liposmart must be placed on a sterile field to ensure its sterility.

- Pierce the saline solution bag with the tip of the flow regulator.
- Connect the flow regulator tubing to the T-valve (FLL upper connection perpendicular to the line) and attach a 60 ml Luer lock syringe to the FLL inlet, depending on the chosen Liposmart device.
- Draw the saline solution through the flow regulator tubing using the selected Luer lock syringe. Once filled, gently press the syringe plunger to prime the circuit and remove any air, ensuring better quality of the final product. Visually check that the circuit is completely filled during this step.
- After priming, fill the processing unit up to 50% of the device's maximum processable volume; the graduated scale on the device allows monitoring of this step.

Once the liposuction has been performed and the tissue is preloaded into the Luer lock syringe chosen by the physician, proceed with the following steps:

- Connect the Luer lock syringe to the end of the Liposmart device where the micro-fragmentation chamber with a green one-way valve is located. The 1,200µ filter is identified by a yellow cap, and the 700µ filter by a green cap.
- Press the plunger of the Luer lock syringe to introduce the adipose tissue through the filtration chamber until the processing unit is filled. The graduated scale on the device allows monitoring of the amount of processed adipose tissue.
- Gently shake the processing unit to allow the saline solution to wash the micro-fragmented tissue.
- Allow the adipose tissue to settle upward, holding the processing unit vertically with one hand.
- Remove the saline solution along with inflammatory and waste products from the processing unit by turning the one-way tap (white) connected to the waste collection bag.
- The processing unit will automatically purify the adipose tissue.
- Repeat the filling phase with saline solution if further washing of the adipose tissue is deemed necessary.
- To recover the washed adipose tissue from the device, connect a Luer lock syringe to the circuit outlet with a one-way blue tap and self-sealing valve. The syringe will automatically fill with the processed and washed tissue. The graduated scale on the device allows visualization of the amount of injectable tissue obtained.
- Repeat the previous procedure if additional tissue collection is desired.
- At the end, disconnect the device from the saline solution bag and dispose of all components appropriately.

Storage

The device must be stored in its intact original packaging, in a cool and dry place. Do not expose the device to extreme heat (not exceeding 50°C) or humidity, and avoid direct and prolonged exposure to sunlight.

Shelf Life, Sterility, and Disposal

The packaging ensures the stability and preservation of the product for at least 5 years.
The expiration date is indicated on the label of the primary container. Check the expiration date before use. Do not use the device after its expiration date.

Dispose of used, unusable, or damaged devices and expired packages according to the regulations and procedures applicable to this type of hospital special waste.

Contraindications

The device Liposmart (LD 60, LGD 120, LGD 240) must be used only by licensed and trained physicians who are aware of the potential side effects, complications, limitations and contraindications to harvesting procedures of subcutaneous adipose tissue, tissue processing and subsequent grafting. It is not recommended to perform the procedure on patients suffering from coagulation disorders or in patients under anticoagulant therapy.

Precautions

- This device is designed to remove localized deposits of excess fat through small incisions and subsequently transfer the tissue back to the patient.
- Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician.
- The amount of adipose tissue removed should be limited to that necessary to achieve the desired cosmetic effect.
- Results of this procedure may or may not be permanent.
- The use of the device is restricted to licensed physicians, trained to perform procedures for harvesting, processing and grafting subcutaneous adipose tissue.
- Single use device. Do not reuse. The device cannot and must not be re-sterilized or reused. This device has been designed and produced for a single use. Reuse may result in contamination, loss of mechanical integrity and malfunction leading to loss of mechanical functionality and harm to the patient.
- When loading, do not exceed the maximum volume of tissue, which is 15 ml at a time for LGD 60, 40 ml at a time for LGD 120 and 80ml at a time for LGD 240 for a maximum of 2 times in order to avoid sieve obstruction or other malfunctioning.
- Ensure all components of the device are present. The manufacturer assumes no responsibility for damages to persons or property if non original components are used.