N.L.F. System®

Instructions for use

Euromi

TABLE OF CONTENTS

1. Medical device presentation

1.1 General

These instructions for use describe the procedures for using the N.L.F. System®- Sterile fat cell collection and re-injection kit - safely. The device is only to be used by appropriately qualified health care professionals.

The N.L.F. System® is a class IIa short-term invasive medical device.
The N.L.F. System® is sold sterile following a sterilization with ethylene oxide. It is for single use and single patient. It must not be re-used or re-sterilized under any circumstances.

The N.L.F. System® is packaged in a single-use double package to ensure a double microbiological barrier and guarantee its sterility until use. The cardboard packaging provides additional mechanical protection to the double packaging.

The N.L.F. System® is CE certified since September 2015.

1.2 Composition

The N.L.F. System® (Reference 1118NLF2) is composed of:

- 1 canister with filter - Capacity: 1 liter
- 1 scraper with lid
- 1 aspiration tubing
- 1 sampling tubing
- 1 fat sampling tubing (luer connector)
- 2 elbows

An optional reusable stainless-steel support is available in option to provide stability to the N.L.F. System®.

1.3 Description

The N.L.F. System® is a device that **collects fat in a canister and is based on a completely closed, sterile and disposable circuit**. In addition, the N.L.F. System® **filters the collected fat** to remove residue and obtain purified fat.

1.4 Technical performances

The technical performance of the N.L.F. System® is as follows:

- Pressure : 2.8 to 3.5 bars
- Vacuum: -0 to -0.9 bars.

2. Intended purposes / Target population

2.1 Intended purposes

The NLF System® is intended for the collection and separation of fat during reconstructive surgery requiring a volume increase, such as lipofilling, fat grafting, or scar filling.

2.1 Target population

The device under evaluation does not have specific target population. Its target populations are those of the lipofilling / fat grafting procedure as follows : Adults over the age of 18 with no restriction on gender, or type of skin, ethnic origin, or number of medically justified lipofilling procedure.

3. Contraindications

The device under evaluation does not have specific contra-indications. Its contraindication are those of the lipofilling / fat grafting procedures as follows :

- Patients with diagnosis of cancer or tumours with active treatment
- Patients with family history of breast cancer
- Patients with pre-existing pathology, wound or radiotherapy-related skin damage in the area of the procedure
- Patients with generalized infection / active systemic infection or ongoing erysipelas in the area of the procedure
- Severely irradiated patients
- Patients who had previously undergone surgery to the gluteal region, and post bariatric patient
- Patients who smoke / patients with nicotine use
- Patients using antiplatelet or anticoagulant / Patients with previous thromboembolism, history of cardiovascular incidents or surgery / Patients with previous evidence of genetic predisposition to thromboembolism (such as Factor V Leiden disease, and thrombophilia) or bleeding (such as hemophilia and von Willebrand factor disease) / Patients with clotting disorders
- Exclusion criteria included American Society of Anesthesia score 3 or 4 (high risk for anaesthesia), and collagen vascular diseases / General medical comorbidities contraindicating a general anaesthesia
- Patients with chronic health problems (diabetes / diabetes mellitus, cardiovascular diseases, lung disease, circulatory system conditions, uncontrolled hypertension, renal insufficiency, obesity with a body mass index over 30, active autoimmune disease)
- Patients with neurologic, vascular, or connective tissue disorders of the upper extremities
- Patients with poor psychological and/or physiological condition / Patients with clinically significant medical or psychiatric illness / Patients not having the ability to understand the consequences, implications and risks related to the treatment
- Pregnant or lactating women or women trying to become pregnant
- Patients with very little fat to remove
- Patients with recent surgery (less than 6 weeks)
- Patients under 18 years of age
- Patients with > 5 kg weight change in past 2 months prior to treatment
- Patients with high body temperature (pyrexia)
- Patients with chronic antibiotics or systemic corticosteroids or oral steroids / Patients who use of oral or topical medication including over-the-counter and herbal medications for the treatment of hair loss / Patients with immunosuppressive medications
- Patients with dermatological condition in the treatment area or significant scar in the hair treatment area
- Patients with organ transplantation

4. Possible complications

Like any surgical procedure, liposculpture involves surgical and post-surgical risks. The practitioner is responsible for the pre-surgical evaluation of the patient. He/she must inform the patient of the risks associated with the procedure and potential post-surgical complications.
A difference must be made between the complications associated with anaesthesia and those related to the surgical procedure.

4.1 Possible complications due to anesthesia

During the consultation, the anaesthesiologist will personally inform the patient of the anaesthetic risks. Patients must be informed that anaesthesia sometimes induces unpredictable reactions in the body. Risk of lidocaine-induced cardiotoxicity or lidocaine-related drug interactions for tumescent liposuction. Using highly competent health professionals, working in a surgical context (recovery room, resuscitation facilities), means that the risks incurred are statistically very low.

4.2 Possible complications due to the surgical procedure

Complications are exceptional after a liposuction procedure which has been performed to a high standard. When this procedure is performed by a healthcare professional who is competent, qualified and trained to carry out this type of procedure, potential risks are limited, but not entirely eliminated.

The following complications may be observed:

• **Altered skin pigmentation:** excessive friction of the motion of the cannula movement during the liposuction process may cause pigment cells to form on the skin, resulting in hyperpigmented (brownish) or hypopigmented (whitish) scars.

• **Anaesthetic risks:** risks associated with anaesthesia

• **Analgesic poisoning (lidocaine, adrenaline, etc.):** a poisoning corresponds to the arisen of disorders of the body functions in reaction to the absorption of an analgesic, to toxic dose. The disorders can concern the whole body or an organ in particular.

• **Bleeding:** a bleed is a flow of blood outside the natural bloodstream.

• **Blister:** swelling of the skin, filled with serous fluid.

• **Bradycardia:** is an arrhythmia associated with an abnormally slow heart rate (less than 60 times per minute)

• **Burning sensation:** a burn is a lesion of the skin and mucous membranes (layer of cells covering the inside of the hollow organs in contact with air) caused by heat. This burning sensation can be caused by mechanical action (friction, skin erosion).

• **Cutaneous ptosis relapse due to partial fat reabsorption:** this risk means that the skin might sag again because some of the injected fat is reabsorbed by the body, reducing the desired effect.

• **Cystic mass / palpable mass:** abnormal growth filled with liquid or semi-solid substance

• **Decreased or increased of the sensitivity:** abnormal intensity of sensitivity.

• **Embolism (pulmonary, fat, arterial…) / thromboembolic events:** sudden obstruction of a blood vessel by a foreign body, a clot.

• **Erythema / irritation:** superficial reddening of the skin, usually in patches.

• **Extended or additional intervention / revision surgery:** increase of the duration of the initial intervention or the new intervention.

• **Fibrosis:** fibrosis is the formation of excess fibrous connective tissue in an organ or tissue as a reparative or reactive process, often in response to injury, inflammation, or surgery.

• **Haematoma / Ecchymosis:** a haematoma is defined as a collection of blood that has become encysted (isolated by a fairly thick membrane). It appears either in an organ or in a tissue (collection of cells) and generally follows a bleed. A bruise or ecchymosis is a collection of blood located under the skin that occurs after trauma; it forms what can be described as a stain visible to the naked eye.

• **Haemorrhage:** important flow of blood outside the natural bloodstream.

• **Hypovolemic shock:** is caused by a significant drop in blood volume. The decrease in venous return (preload) causes a decrease in ventricular filling and a reduction in stroke volume.

• **Imperfections (insufficient or excessive correction, residual asymmetry, surface irregularities, waves, healing problem…):** imperfections can be observed:

- **Insufficient or excessive results:** tissue reaction following surgery is always specific and remains partly unpredictable. For this reason, the results may be considered insufficient or excessive.
- **Asymmetry:** a lack of symmetry.
- **Waves/Contouring defects:** these are uneven surfaces on the skin.
- **Healing problem:** when the incision does not heal well this can result in unsightly, hypertrophic or keloid scarring. Delayed healing may also occur in the following cases: when doing certain sports, due to infection, or when the sutures are too close together. If the problem persists, the scars may have to be managed surgically.

A liposuction retouch or touch up can be performed simply under local anaesthesia from the sixth month after the initial surgery to correct these localised imperfections.

• **Infection (Streptococci, gas gangrene, sepsis, toxic shock syndrome, necrotizing fasciitis, cellulitis, surgical site infection):** the term infection refers to the invasion of a living organism by germs, specifically pathogenic microorganisms, such as bacteria, viruses, fungi or parasites. The term pathogen refers to anything able to cause a disease.

• **Inflammation:** body's defense reaction to infection or tissue damage.

• **Injury to the skin:** a skin injury after lipofilling can occur due to trauma, infection, or poor blood supply, leading to bruising, lumps, or necrosis.

• **Lidocaine-induced cardiotoxicity:** advent of cardiac muscle dysfunction induced by lidocaïne

• **Lidocaine-related drug interactions:** reaction between two (or more) drugs and lidocaïne

• **Mechanical injuries, including those caused by unintended cavitation, and corresponding side-effects:** mechanical injuries, including those caused by unintended cavitation (air bubbles or spaces forming in tissues), can lead to side effects such as bruising, swelling, or tissue damage.

• **Metabolic disorders (anaemia, hyperhydration, hypohydration):** metabolic disorders are disruptions affecting the way the body functions and related to conditions caused by the accumulation in the cells of abnormally high amounts of normal or pathological substances (lipids, carbohydrates, calcium, etc.):

- **Anaemia:** decrease in the amount of haemoglobin, contained in a unit of blood.
- **Hyperhydration, hypohydration:** imbalance of the aqueous ions.

• **Necrosis / Fat necrosis:** necrosis is the abnormal or unscheduled death of a cell or tissue.

• **Nerve compression**: nerve compression occurs when pressure is applied to a nerve, which can cause pain, numbness, tingling, or weakness in the affected area. This pressure can result from swelling, fluid accumulation, or scar tissue following surgery or injury.

• **Numbness:** a sensation that is either generalised or only affects one part of the body, consisting of decreased sensitivity and mobility.

• **Oedema/Swelling:** oedema is the swelling of a tissue as a result of an unusual accumulation of serous fluid, usually blood serum, within various tissues.

• **Pain / Aches:** pain is an abnormal and painful sensation experienced in a fairly defined area of the body. It results from the perception by the brain of stimuli transmitted by the peripheral nervous system. The soreness is muscle pain.

• **Panniculitis:** is an inflammation of the fatty layer under the skin. Panniculitis can develop in people with certain infections, lesions, and autoimmune diseases. Typically, symptoms include red, painful bumps under the skin.

• **Partial aerolar necrosis:** refers to the death of some areas of tissue in the areola, the pigmented area around the nipple, often due to compromised blood flow or injury. This condition can occur after surgeries like breast reductions or augmentations and may lead to localized skin damage or discoloration.

• **Perforation (abdominal and bowel, colon, superior epigastric artery, small intestine etc):** accidental opening or damage to an organ.

• **Phlebitis / Thrombophlebitis:** the main medical risk is phlebitis, which consists of the formation of clots in one of the deep veins of the leg.

• **Pneumothorax:** The Pneumothorax is a filling of the pleural cavity of the lungs with air. Because of the presence of air, the disorder causes the detachment and a retraction on itself of one or several lungs, leading to breathing difficulties.

• **Retracted nipple:** condition where the nipple is pulled inward or turned towards the chest instead of protruding outward. This can occur due to factors like scarring, infection, or complications from breast surgery.

• **Seizure:** a sudden, involuntary contraction of muscles that results in rhythmic contortions of the body, often accompanied by a loss of consciousness. Some of the incidents listed here above (analgesic poisoning and embolism) can result in seizure.

• **Seromas / Lymphatic effusion / Fluid accumulation:** accumulation, in surrounding tissues, of trauma or surgery, of serositis from injured blood vessels. Lymphatic effusion is the accumulation of lymphatic fluid in the interstitial spaces, especially in the subcutaneous fat, following a rupture of the lymphatic system.

• **Thermal injury:** refers to damage to the skin or underlying tissues caused by exposure to extreme heat or cold. This can include burns from hot surfaces, liquids, or flames, as well as frostbite from very cold temperatures. Thermal injuries can lead to pain, blistering, or tissue loss.

• **Tiredness:** decreased ability to function, resulting in the widespread weakness of the body.

• **Tissu injury:** Trauma or overuse occuring to muscles, tendons or ligaments

• **Wound dehiscence:** Wound dehiscence is when a surgical incision reopens.

5. Use of the medical device

5.1 Warnings

Competence and training

• The device under evaluation should be used by medically qualified and appropriately trained healthcare professionals
• Users must be trained in safe and effective use.
• The user must leave at least 6 weeks between two operations.

Usage and sterility

• The NLF System® is for single use only.
• The NLF System® is a sterile product : it must not be cleaned or sterilized by the surgeon.
• Any reuse of an the NLF System® is strictly forbidden because it may result in serious clinical

complications, including death. Similarly, any re-sterilization of the NLF System® is formally forbidden, as it may causes a significant deterioration in its properties.
• The NLF System® is to be used only once and for a single patient.
• The fat must be transferred to the patient directly after the collect.
• The expiration date of the NLF System® must be respected.
• The validated lifetime of the NLF System® is 3 hours.
• The NLF System® must be decontaminated before disposal.

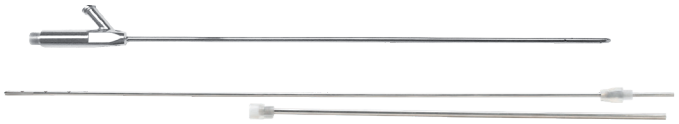
Handling and checks
• Do not use the NLF System® if the sterile packaging is damaged or unintentionally opened before use.
• NLF System® must be unpacked from its sterile packaging and handled under sterile conditions.
• NLF System® must be handled with care and caution.
• Do not use the NLF System® if has been dropped or knocked.
• The graduations on the NLF System® are given for informational purposes only.

Connectivity and accessories
• NLF System® must only be connected to another Euromi medical device.
• The user is responsible for the use of accessories other than those supplied by Euromi S.A.
• A maximum of 3 devices sterilized with ethylene oxide must be used at any one time.
it. With respect to tumescent liposuction, appropriate post-procedure monitoring shall be in place as lidocaine levels have been found to rise for up to 16 hours post-operation.

Restrictions and responsibilities
• NLF System® must not be modified.
• It is forbidden to resell a Euromi device for reasons of traceability.
• EUROMI S.A. is not responsible for the use of any air source that does not supply medical or compressed air.
• Euromi S.A. is not responsible for any use of the device other than the one foreseen in these instructions for use

5.2 Devices used in combination with the N.L.F. System®

Description	Photo	Class
Stainless steel support The 304 stainless steel support allows the canister to remain stable throughout the duration of the intervention. This accessory is re-sterilizable. It is sold separately from the kit.		NA
Evamatic® The evamatic® is a device (pneumatic) used to collect or reinject fat cell thanks to the technique N.I.L.® **Adipmaster®** The Adipmaster® is a device (mecanic) used to collect or reinject fat cell thanks to the technique N.I.L.® . The infiltration kit is an accessory for Adipmaster®.	 	IIb

Evasp® range / Adipcontrol® The evasp® / Adipcontrol® range is a complete range of devices to assist the practitioner during an intervention (Regulation of the supply of compressed air, aspiration, infiltration...).	 Evasp® 1 Evasp® 2 Evasp® 6 Evasp® 7 Adipcontrol®	IIb
Reusable cannula **Sterile single-use cannula and crossing-tube**		IIa

5.3 Surgical techniques

• Perform fat harvesting from the selected donor site.
• Separate the harvested fat to eliminate contaminants and prepare the viable fraction for reinjection.
• Use appropriate cannulas to inject the prepared fat into the targeted areas, ensuring a uniform and aesthetically pleasing fill.

The procedure lasts between 30 minutes and 3 hours depending on the intervention.

5.4 Installation and use of the N.L.F. System®

Installation of N.L.F. System® kit

• **Adjust the pressure.** The recommended air pressure is between 2.8 and 3.5 bar

• **Adjust the vacuum.** The recommended vacuum is between -0.3 and -0.4 bar
NB: Never be below -0.3 bar in order to limit the loss of watertightness of the canister and never exceed -0.5 bar in order to minimize the trauma suffered by the adipocytes during sampling.

• **Perform a tumescent liposuction / lipofilling.**

• **Tilt the canister regularly** to the right and then to the left with the support to prevent the filter from clogging (only if you use the NLF support with Eva SP).

• The liquids pass through the filter and are directly evacuated to the "garbage" canister.

• **Stop the evasp®/ Adipcontrol®**.
• **Connect the re-injection syringe** to the sampling tubing with luer lock to collect the adipocytes*.

• **Turn the rotary connector to remove the remaining fat cells** with the integrated scraper and collect the adipocytes with the syringe*.

• Re-inject the harvested fat.

* *Steps can be carried out throught the intervention*

CANISTER

Place the **canister on a flat surface in a stable manner** or use the support in stainless steel (available as option). If you are using an Adipcontrol®, place the canister on the support provided on the machine.

SAMPLING TUBING

Connect the **blue tip** of the sampling tubing **to the patient connector** and **the other end to the cannula** who crosses the Evamatic® or Adipmaster®.

Note: The tubings supplied are compatible with the evasp® / Adipcontrol® ranges. However, these can be cut and adapted if necessary.

ASPIRATION TUBING

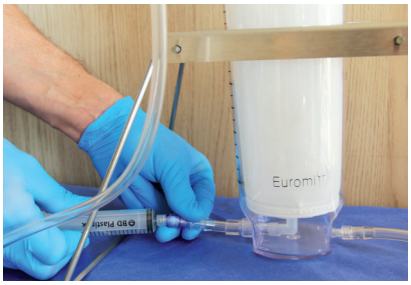
Connect the **white tip** of the aspiration tubing (with the red clamp) **to your aspiration system** and put elbows at the connectors. **The other end** of the aspiration tubing is screwed **to the Vaccum fitting of N.L.F. System®.**

SCRAPER

At any time, you can **turn the rotary connector** to remove the fat cells that have adhered to the walls of the filter t**hanks to the integrated scraper.**

FAT SAMPLING TUBING

Connect **the reinjection syringe to the fat sampling tubing** (luer lock) to collect the adipocytes for reinjection.



Disassembly

- Unscrew the cannula from its holder.
- The chuck key can be used to facilitate the disassembly.
- Remove the canister from its support.
- Dispose of the N.L.F. System® cf. §7.
- Clean and sterilise the evamatic® according to the procedure described in the iassociated nstructions for use.

6. Disposal

Dispose of each type of waste according to the appropriate channel:

- **Non-Infectious Clinical Waste:** such waste includes packaging, unused and noncontaminated medical devices.
- **Infectious and Medical Waste:** such waste includes tubing, contaminated devices. This waste is to be disposed of according to the appropriate channel to prevent any contamination.

The N.L.F. System® must not be disposed of with public or communal waste.

The device must be disposed of in accordance with current national legislation.

7. Transport and storage of the medical device

The N.L.F. System® must be transported and stored in its original double packaging, away from light, in a dry place, protected from dust and pests.

To prevent condensation from developing on the N.L.F. System®, large temperature fluctuations should be avoided during storage. The N.L.F. System® must be stored at a temperature between 0°C and 40°C.

To avoid any risk of chemical contamination, the storage of chemicals with the N.L.F. System® is prohibited.

The lifespan of the product is 3 years after sterilization. It is imperative to check the expiration date of the device on the traceability label before use.

Storage conditions:

8. Resterilization and reuse

The N.L.F. System® is supplied sterile and is for single use only. Any reuse of a N.L.F. System® is strictly forbidden.

Any reuse of a N.L.F. System® may result in serious clinical complications, including death. Similarly, any resterilization of a N.L.F. System® is formally forbidden, as it causes a significant deterioration in its mechanical properties.

9. Labels, patient card and surgeon's certificate

Each NLF System® is supplied with:
• Two traceability labels for the traceability made by the surgeon.

11. Materiovigilance case

Any incident or risk of a serious incident which has led or could lead to the death or serious deterioration of the state of health of a patient, a user or a third party involving N.L.F. System® must be reported without delay to the competent authorities and to Euromi S.A. at the email address **materiovigilance@euromi.com**.

12. Handling returns

Products that are the subject of a complaint or that have caused an incident or risk of a serious incident must be reported and returned to the local Euromi S.A. material vigilance representative. Before returning the product to the manufacturer, it must first be decontaminated and disinfected (according to the procedures in force at the health care facility). The product should not be returned to Euromi S.A. if the patient is infected with HIV, hepatitis or if he/she is a known or suspected carrier of another infectious agent.

13. Guarantees and limits of guarantees

Euromi S.A. guarantees all products for one year, as from the invoice date. Euromi S.A. guarantees that all products are supplied without any defects or malfunction.

If our product is defective, despite the meticulous manufacturing process, please contact the technical department.

The warranty applies if the defective product is presented during the guarantee period and if it is a defect coming directly from the manufacturer Euromi.

For more information, please contact the technical department at Euromi S.A. or consult our general sales conditions on our website.

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Medical device

Read the instructions for use carefully

Name and address of the manufacturer

Batch number

Commercial reference

Indication of notified body responsible

Warning

Single use product, do not use a second time

Do not sterilize a second time

Expiration. Do not use after the date indicated

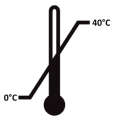
Date of manufacture

Product sterilized with ethylene oxide, in double sterile packaging

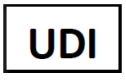
Keep away from light

Do not use if packaging is damaged

Keep in a dry place



The product must be stored between 0°C minimum and 40°C maximum



UDI code

Fragile, handle with care

Vertical orientation

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