Adipclean®

Instructions for use

Euromi

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1. Medical device presentation

1.1 General information

These instructions for use describe the procedures for using the Adipclean® - Sterile fat cell collection and re-injection kits, the cell divider and infiltration tubing safely. The Adipclean® is only to be used by appropriately qualified health care professionals.

The Adipclean®, cell divider and infiltration tubing are a class IIa short-term invasive medical device. The Adipclean®, cell divider, infiltration tubing are sold sterile and for single use and single patient. They must not be reused or re-sterilized under any circumstances.

The Adipclean®, cell divider and infiltration tubing are 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

1.2 Composition

The Adipclean® is composed of: *Polypropylène, VALOX, Polycarbonate, G-PAEK, PVC, Polyester*

- 1 canister with filter - Capacity: 1 liter
- 1 scraper
- 1 vacuum tubing
- 1 flexible shaft

The Celldivider® is composed of: *Inox and polycarbonate*

The Infiltration tubing is composed of: *Polycarbonate, PVC and silicone*

1.3 Description

The Euromi Adipclean® - Sterile fat cell collection and re-injection kit - Celldivider®, Infiltration tubing are devices that **collect fat in a canister and rely on a completely closed, sterile and disposable circuit**. In addition, the Adipclean® **filters the collected fat** to eliminate residues and obtain purified fat.

1.4 Technical performances

The performance characteristics of Adipclean® are as follows:

- The technical performances of the Adipclean® are as follows:
  - Motor Speed = 0 to 4000 rpm
  - Basket speed = 300 to 1333 rpm
  - Vacuum: -0 to -0.9 bars.

2. Intended purposes / Target population

2.1 Intended purposes

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

2.2 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).

• **Cystic mass:** Abnormal growth filled with liquid or semi-solid substance

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

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

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

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

• **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):** 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.

- **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**

- **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.

- **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.

- **Fluid accumulation**

- **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**

- **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**

• **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:** 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:** Injury to the underlying skin's structure

• **Skin injury**

• **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 Warning

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.

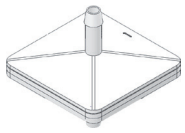
Usage and sterility
• The Adipclean® is for single use only.
• The Adipclean® is a sterile product : it must not be cleaned or sterilized by the surgeon.
• Any reuse of an the Adipclean ® is strictly forbidden because it may result in serious clinical complications, including death. Similarly, any re-sterilization of the Adipclean ® is formally forbidden, as it may causes a significant deterioration in its properties.
• The Adipclean® 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 Adipclean® must be respected.
• The validated lifetime of the Adipclean® is 3 hours.
• The Adipclean® must be decontaminated before disposal.

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

Connectivity and accessories
• Adipclean ® 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.

Restrictions and responsibilities
• Adipclean ® 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 Adipclean®, Celldivider® and Infiltration tubing

Description	Photo	Class
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
Adipcontrol® Adipcontrol® is a device to assist the practitioner during an intervention (Regulation of the supply of compressed air, aspiration, infiltration...).		IIb
Sterile single-use cannula and crossing-tube		IIa
Celldivider® The Cell divider is an accessory composed of a filter which allows fat cells to be divided depending on the desired size. There are several filter sizes: 100µm, 200µm, 400µm, 800µm, 1250µm and 1400µm.		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 Adipclean®, Celldivider® and Infiltration tubing

The Adipclean®, Celldivider® and Infiltration tubing can be connected to a:

- Non-sterile liposuction equipment Adipcontrol®
- Sterile Single-use cannula and crossing tube
- Adipmaster®
- Air and fat tubing

Setting up the Adipclean®

1. Place the Adipclean on the Adipcontrol support
2. Connect the flexible shaft (cable with white chain) to the Adipcontrol
3. Connect the other end of the cable to the Adipclean
4. Connect the vacuum tubing to the Adipclean
5. Connect the white Funnel of the vacuum tubing to the waste canister
6. Connect the fat tubing from the infiltration kit or Adipmaster to the Adipclean cap
7. Connect the blue connector on the underside of the Adipclean with the Luer connector on the infiltration kit.

The speed settings for Adipclean® operation are as follows:

Adipcontrol® Motor speed in %	25	50	75	100
Adipclean® Motor speed in (rpm)	1 000	2 000	3 000	4 000
Adipclean® Motor basket speed (rpm)	333,3	666,6	1000	1333,3

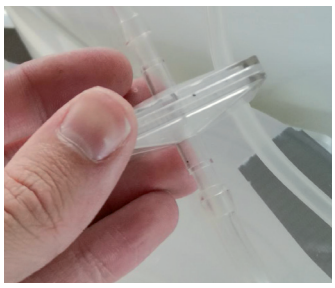
Setting up the Celldivider®

1. On the infiltration kit, locate the **duckbill** (non-return valves) at the outlet of the syringe pump (there's an arrow on the duckbill)

2. Cut the tubing after the duckbill.

3. Force the two pieces of tubing onto the Celldivider's splined connectors



4. Place a second Celldivider on the second syringe if you want to double the filtration capacity.

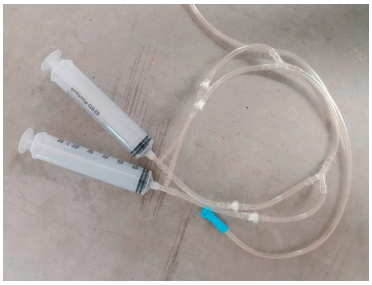
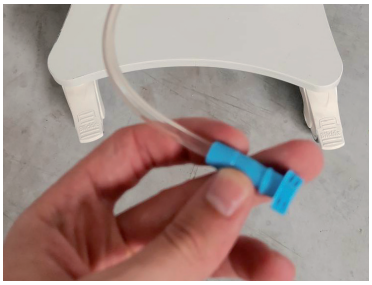
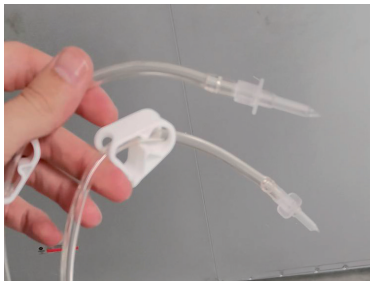
5. The Adipclean® and Adipcontrol® can then be used to pass fat through the filters.

Setting up the Infiltration tubing

1. Screw the **two T-pieces onto the syringes**.

2. Place **syringes on syringe plungers**.

3. Tear off the **diaphragm spike (blue part) and stick the debubbler into it**.
(Connect the debubbler to the infiltration cannula).
4. Connect the spikes to the saline bags. Close the white clamps to prevent the liquid from flowing down. Open the desired clamp according to the quantity remaining in bag one or two

Using accessories

• To use the Adipcontrol® system, follow the instructions provided in the corresponding instructions for use.
• To use the Adipmaster® system, follow the instructions provided in the corresponding instructions for use.
• To use the air and fat tubing, follow the instructions provided in the corresponding instructions for use.

Stopping the device

• Release the pedal of the Adipcontrol® system to stop the Adipclean®.
• To stop the aspiration machine: refer to the Adipcontrol® instructions 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 cannulas, contaminated devices. This waste is to be disposed of according to the appropriate channel to prevent any contamination.

The Adipclean® 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 Adipclean® - Sterile fat cell collection and re-injection kit - Celldivider® and infiltration tubing must be transported and stored in their original double packaging, away from light, in a dry place, protected from dust and pests.

To prevent condensation from developing on the Adipclean® - Sterile fat cell collection and re-injection kit - Celldivider® and infiltration tubing, large temperature fluctuations should be avoided during storage.

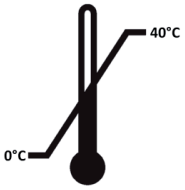
To avoid any risk of chemical contamination, the storage of chemicals with the Adipclean® - Sterile fat cell collection and re-injection kit - Celldivider® and infiltration tubing is prohibited.

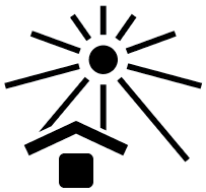
The Adipclean® must be stored at a temperature between 0°C and 40°C To avoid any risk of chemical contamination, the storage of chemicals with the Adipclean ® - Sterile fat cell collection

and re-injection kit, Cell divider and infiltration tubing are prohibited.

The lifespan of the products is 1 year 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 Adipclean® - Sterile fat cell collection and re-injection kit - Celldivider® and infiltration tubing are supplied sterile and is for single use only. Any reuse of an Adipclean® - Sterile fat cell collection and re-injection kit - Celldivider® and infiltration tubing - is strictly forbidden.

Any reuse of an Adipclean® - Sterile fat cell collection and re-injection kit - Celldivider® and infiltration tubing - may result in serious clinical complications, including death. Similarly, any resterilization of an Adipclean® - Sterile fat cell collection and re-injection kit - Celldivider® and infiltration tubing is formally forbidden, as it causes a significant deterioration in its mechanical properties.

9. Labels, patient card and surgeon's certificate

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

10. 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 Adipclean® - Sterile fat cell collection and re-injection kit - Celldivider® and infiltration tubing must be reported without delay to the competent authorities and to Euromi S.A. at the email address **materiovigilance@euromi.com**.

11. 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.

12. 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

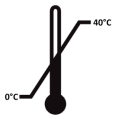
Date of manufacture

Product sterilized with dry heat, 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

Euromi

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