Adipmaster®

& Infiltration kit

Instructions for use

Euromi

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1. Medical device presentation MD

1.1 General information

These instructions apply to Adipmaster® sterile single-use handpiece (including infiltration kits) manufactured by Euromi S.A. These devices are only to be used by appropriately qualified health care professionals.

The Adipmaster® is a class IIb medical device sold in a sterile and single-use format. It is accompanied by an accessory – the infiltration kit, which is a class IIa medical devices and is also sold in a sterile and single-use format.

1.2 Composition

The Adipmaster® is composed of: PEEK; PEAK; VITON; PVC; VALOX; INOX; TPE.

The infiltration kit is composed of: POLYPROPYLENE; POLYCARBONATE; SILICONE; MAKROLON; PVC; PURELL.

1.3 Description

The Adipmaster® is sterile single-use medical devices used for liposuction, lipoinfiltration and lipofilling.

The infiltration kit is a medical device used for liposuction, lipoinfiltration and lipofilling.

1.4 Performance characteristics & Technical performances

The performance characteristics of Adipmaster® are as follows :

- The various components of the Euromi Adipmaster® (including infiltration kit) in contact with the patient are made of biocompatible materials.
- The Euromi Adipmaster® (including infiltration kit) is designed so as not to compromise the clinical state, safety and health of the patient when they are used in the intended conditions and for the intended purposes.
- The Adipmaster® (including the infiltration kit) by Euromi will be packaged in packaging designed to protect the device from damage during storage and transport and to preserve the sterility.
- The Adipmaster® (including the infiltration kit) is dry heat sterilized.
- The Adipmaster® functions thanks to the Euromi Adipcontrol®.
- The Adipmaster® has an adaptated bracket for Euromi cannula.
- The Adipmaster® has an adaptated bracket for fat tubing and cables supplied by Euromi.
- The Adipmaster® allows a move of the cannula and creates a nutation movement.
- The Adipmaster® is packaged in such a way as to be easy to transport.
- The Adipmaster® works during 3 hours minimum and the product is restistant and reliable during its lifetime.
- The disposal procedure of the Adipmaster® is available in this IFU.
- The Adipmaster® is easy to handle.

The technical performances of the Adipmaster® are as follows:
- Speed = 0 to 4000 rpm
- Elongation (cannula translation) = 6 to 10mm

2. Indications / Intended uses / Benefits

2.1 Indications

• **Medical indications** for use in treatment of conditions such as lymphedema and lipomatosis and for adipocyte grafting for re-injection during reconstructive surgery

• **Non-medical indications** in aesthetic and plastic surgery, including lipoplasty for the purpose of aesthetic body contouring

2.2 Intended uses

The Adipmaster® (including infiltration kit) is intended to be used for:

Medical intended purposes:

• **Lipoinfiltration:** Infiltration of tumescent solutions to facilitate the removal of tissue and/or fluid for the treatment of lipomatosis, lymphoedema or during breast reconstruction procedures.
• **Liposuction:** The removal of tissue and/or fluid from the body for the treatment of lipomatosis, lymphoedema or during breast reconstruction/reduction procedures.
• **Lipofilling:** Introduction of autologous adipose tissues during breast reconstruction procedures.

Non-medical intended purposes:

• **Lipoinfiltration:** Infiltration of tumescent solutions to facilitate the removal of tissue and/or fluid for the treatment of lipomatosis, lymphoedema or during breast reconstruction procedures.
• **Liposuction:** The removal of tissue and/or fluid from the body during aesthetic procedures.

This technique can be used on both men and women from the age of 18, for any type of skin/fat (Caucasian, Asian, African, etc.) and also for patients already treated (2nd liposuction).
It should be used by healthcare professionals with the relevant medical qualifications and who have received the suitable training for carrying out infiltration, liposuction and lipofilling procedures.

Fat removal is possible on the following parts of the body :

SITE NUMBER	SITE NAME
1	Cheeks
2	Chin
3	Neck
4	Buffalo hump
5	Back
6	Arms
7	Serratus anterior
8	Breasts
9	Chest

SITE NUMBER	SITE NAME
10	Abdomen
11	Waists
12	Buttocks
13	Pubis
14	Hips
15	Thighs
16	Knees
17	Calves
18	Ankles

2.3 Benefits

• Clinical benefits (medical indications):

• Aesthetic outcome: significant improvement of satisfaction score following liposuction
• Overall patient satisfaction: at least 80% of patients were satisfied with liposuction results
• Patient satisfaction: excellent satisfaction rate for patients having undergone breast reduction using liposuction (99.7%).
• Fasciotomy scarring patient-assessment: scars considered “minor” by 98.5% of patients at one-year post-operation, excellent satisfaction.

3. Contra-indications

Liposuction and lipofilling are contraindicated in the following cases:

- Active cancer or tumours
- Family history of breast cancer
- Pre-existing pathology, wound or radiotherapy-related skin damage in the area of the procedure
- Generalized 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
- Smokers/smoking
- Use of antiplatelets or anticoagulants, previous thromboembolism, history of cardiovascular incidents or surgery, previous evidence of genetic predisposition to thromboembolism (such as Factor V Leiden disease, and thrombophilia), or bleeding (such as haemophilia and von Willebrand factor disease)
- 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
- Patient with chronic health problems (diabetes / diabetes mellitus, heart disease, lung disease, circulatory system conditions, uncontrolled hypertension, obesity with a body mass index over 40)
- Patients with neurologic, vascular, or connective tissue disorders of the upper extremities
- Poor psychological and/or physiological condition
- Pregnancy
- Patient with very little fat to remove
- Recent surgery (less than 6 weeks)
- Patient under 18 years of age
- Patient not having the ability to understand the consequences, implications and risks related to the treatment
- High body temperature (pyrexia).

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 anaesthesia

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 high-quality liposculpture. Potential risks are limited with a qualified and competent health professional, trained to perform this type of procedure; however, such procedures are never completely risk free.

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 / Revision surgery:** increase of the duration of the initial intervention or the new intervention / A revision surgery is a follow-up surgical procedure performed to correct or improve the results of a previous 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):** 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 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**

- **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.

- **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. Aches are 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:** Injury to the underlying skin's structure

• **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. Information to give to patients

The surgeon must provide the patient with the information indicated in the appendix, at the end of the instructions.

6. Use of the medical device 

6.1 Warnings

Devices intended for invasive use should only be used in an appropriate medical environment, by suitably trained and qualified physicians or accredited in accordance with national legislation. The doctor who performs the act is assisted by at least one doctor or paramedical professional qualified or approved in accordance with national legislation.

All staff involved in the procedure shall be trained and shall keep their knowledge of basic cardiac life support and in the checking of equipment and emergency drugs used for resuscitation purposes up-to-date. Medical doctors performing the procedure shall also be trained in advanced cardiac life support.

The medical doctor or allied health professional responsible for anaesthetic management shall ensure appropriate monitoring of the consumer both during the procedure and after 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.

• Liposuction, lipolysis and lipoplasty are not reliable methods for losing weight. Exercise and diet, as well as lifestyle modification, should be taken into account, both as alternatives to liposuction and lipolysis and to maintain any reduction in fatty tissue that these procedures may cause. Our devices have not been validated for the treatment of clinically diagnosed obesity and should not be used for such purposes.

• The volume of blood loss and loss of endogenous body fluid may adversely affect intra and/or posterior haemodynamic stability and patient safety. The ability to ensure proper and timely fluid management is critical to patient safety. The volume of adipose tissue removed must be at the discretion of the surgeon, who must take into account the patient's morphology.

• Careful consideration shall be given to patient suitability with respect to medication which has the potential to cause bradycardia or hypotension as this has been reported as the cause of death in a number of patients undergoing tumescent liposuction. Patients taking drugs such as beta-adrenergic antagonists, non-dihydropyridine calcium-channel blockers, cardiac glycosides, and centrally acting

alpha-adrenergic agonists shall be subject to very careful consideration as deaths have been reported due to bradycardia and hypotension. The procedure has to be preceded by a medical consultation which has to be documented and during which chronic disease and drugs taken by patient need to be considered.

• Adipmaster® (including infiltration kit), is single-use.

• Adipmaster® (including infiltration kit), being sterile products, must not be cleaned or sterilised by the surgeon.

• The Adipmaster® (including infiltration kit) must be used only once, and for only one patient. (The instructions for use should only be used once time).

• Inspect the sterile components to ensure their packaging is not damaged. Do not use the device if package is damaged.

• The Euromi Adipmaster® and infiltration kit must be unpacked from its sterile packaging, under sterile conditions.

• Always visually inspect each Adipmaster® and infiltration kit before use. Discard the device if there are any signs of wear, cracking, corrosion or if the device is bent, broken or deformed.

• The Adipmaster® and infiltration kit should be handled carefully and with caution.

• Any device that has fallen to the ground or has been knocked should not be used.

• Do not exert excess pressure on the Adipmaster® (including infiltration kit).

• In extreme cases, the device may heat up excessively.

• Handle the Adipmaster® (including infiltration kit) under conditions of asepsis.

• The Adipmaster® (including infiltration kit) must only be connected to a device from the Euromi medical device range (cannula and Adipcontrol® provided by Euromi).

• The user shall be responsible for the use of any accessories other than those supplied by Euromi S.A. These accessories do not comply with the requirements of the Adipmaster® (including infiltration kit).

• Adipcontrol® system and cannula instructions for use must be examined prior to use for warnings and instructions for use.

• Liposuction is a surgical procedure that can only be performed by a competent and qualified user (refer to the legislation of the country where the procedure takes place).

• The users must be trained in safe and effective use.

• The user must leave at least 6 weeks between two operations.

• The use of a heated cover during the procedure or after the procedure is not recommended.

• Adipmaster® (including infiltration kit) must be decontaminated before they are discarded.

• The Adipmaster (including infiltration kit) mustn't be modified.

• The expiration date of the Adipmaster® (including infiltration kit) must be respected.

• It is forbidden to resell a Euromi device for traceability reasons.

Euromi S.A. shall not be held responsible for any use of the device that does not comply with these user instructions.

• The pressure must be adjusted according to the area and the medical procedure to be performed:

  • **For infiltration / injection:** the recommended air pressure is between 1.8 and 3 bar.

- **For aspiration / harvesting:** the recommended air pressure is between 3 and 5 bar.
    - **Deep liposuction in significant adipose tissue mass:** between 3.5 and 5 bar.
    - **Superficial liposuction:** between 3 and 4.5 bar.
- **For fat removal in the context of lipofilling:** between 2.8 and 3.5 bar.

- Depression should be adjusted according to the medical procedure to be performed:
    - **In the case of fat removal for lipofilling:** the recommended depression is between -0.5 bar and -0.7 bar.
    - **In the case of aspiration / harvesting:** the recommended depression is -0.9 bar maximum.

If all the instructions for use mentioned above are not respected by the surgeon, he is liable to cause complications affecting the health of the patient.

6.2 Surgical techniques

Tumescent liposuction takes place in two phases:

1) The healthcare professionnal makes small incisions through which he infiltrates with an infiltration / injection cannula a large amount of diluted anesthetic solution into the adipose tissue and subcutaneous fat, leaving the swollen treatment area.

During the procedure, the health professional will guide the infiltration / injection cannula by moving it under the skin. It's the **lipoinfiltration procedure**.

2) After, he can easily aspirate the fat thanks to the swelling of the fat cells with an aspiration / harvesting cannula connected to an aspiration / harvesting machine. It's the **liposuction procedure**.

In the context of a lipofilling, the fat must be purified in order to obtain a good fat quality (elimination of the blood and the fat cells destroyed during the sampling).

Once the fat is purified, it is injected into the dedicated area. By an incision, the injection cannula is introduced. The fat is then gradually deposited. This process is repeated until the desired volume is obtained.

The procedure lasts between 30 minutes and 3 hours depending on the extent of liposuction.

For tumescent liposuction, Euromi S.A. validated the following anesthetic solution:

Additive	Amount
Lidocaine 2 %	500 mg
Epinephrine	1 mg
Sodium bicarbonate	12 mEq (12.5 ml of an 8.4% $NaHCO_3$ solution)
Normal saline (0.9%)	1000 mL

The maximum safe dose of lidocaine with epinephrine in tumescent anaesthesia for liposuction is between 35 and 55 mg / kg. With epinephrine, maximum cumulative dose of lidocaine must not exceed 500 mg.
Lidocaine by itself and with epinephrine is highly acidic. The addition of bicarbonate alkalinizes the solution, increasing the percentage of local anaesthetic in the nonionized form, which promotes its transit into cells and speeds the onset of analgesia. Bicarbonate also reduces pain on injection. The epinephrine is added to prolong the duration of analgesia and reduce bleeding.

The use of other solutions has not been validated.

6.3 Installation of the Adipmaster®

The Adipmaster® can be connected to a:

- Non-sterile liposuction equipment **Adipcontrol®**
- **N.L.F. System®** (sterile kit for collection and re-injection of fat cells)
- **Infiltration kit**
- **Euromi** aspiration, infiltration and lipofilling **cannula**.

6.4 Use of the Adipmaster®

- Inspection of the condition of the various parts:

1. Check the functions of the Adipmaster® (including infiltration kit) before using the device. In the event of the slightest malfunction being found, contact Euromi S.A.'s customer services.

2. Inspect the handpiece, the Adipcontrol® system and the cannulas, to identify any damage, corrosion or any sign of excessive wear and tear.

3. Inspect the sterile components to make sure that their packaging is not damaged. Do not use the device if the package is damaged.

- Accessory installation:

1. Install the Adipcontrol® system following the instructions provided in the corresponding instructions for use.

2. Refer to the instructions for use of the N.L.F. System® kit to connect the N.L.F.® tubing.

- Setting up the Adipmaster® (including the infiltration kit):

- **Connection to the Adipcontrol® and to the infiltration kit**

1. Depending on the procedure performed, connect the large diameter fat tubing to:

- The Euromi infiltration kit via the large Y (Lipoinfiltration + Lipofilling);
- The NLF system® kit (Lipofilling)
- The waste garbage can (Liposuction).

2. Connect the Adipmaster® to the Adipcontrol® via the white cable and fuse to the Adipcontrol® connector.

3. Connect the circlip.

4. Connect the small diameter cooling tubing (small diameter) to Adipcontrol® via the quick coupling adjacent to motor connector.

- **Installation of the infiltration kit**

1. Connect 2 Terumo syringes to luer T-connectors.

2. Connect the large diameter fat tubing to Y.

3. Connect the white funnel to the lid of the NLF system® kit (if no NLF system® kit, connect white funnel to waste garbage can). Connect the third output of the 3-way valve to the bottom connection of the NLF® (on the jar).

4. Connect spikes to the serum bag.

5. Purge the syringe: To purge the syringes, check that the white and blue clamps are open, and the red clamp is closed. Purge air by filling 10mL of serum into the syringes.

6. Place syringes on syringe plungers.

7. Initialize Adipcontrol® so that syringes can be clipped on.

8. Place N.L.F system® kit on its base (Adipcontrol®).

9. Refer to the NLF system® kit and Adipcontrol® instructions for use to continue operation.

Additional informations :
• White and blue clamp open and red clamp closed > Infiltration via syringe pumps
• Red clamp open / blue clamp closed > Aspiration

• Connection of the cannula to Adipmaster®:

1. Inspect the handpiece, Adipcontrol® control box, cannulas for damage, corrosion, or signs of excessive wear.

2. Install the cannula: Manually screw the cannula onto the Adipmaster® without forcing it (it should screw on very easily).

• Start-up

1. Start up the Adipcontrol® according the instructions for use of the Adipcontrol®.

2. Set the motor speed by choosing wich speed pourcentage you want in the different modes. The recommended speed is 88% to 100% (3500 to 4000 rpm) in order to get the optimized work frequency. Below is a table showing the correspondence between Adipmaster® speed and Adipcontrol® setting:

Adipmaster® speed (+/-50 rpm)	Adipcontrol® settings
400 rpm	10%
800 rpm	20%
1200 rpm	30%
1600 rpm	40%
2000 rpm	50%
2400 rpm	60%
2800 rpm	70%
3200 rpm	80%
3500 rpm	88%
3600 rpm	90%
4000 rpm	100%

3. Set the depression depending on the procedure to be carried out:
- **Recommended depression for removal for lipofilling:** between -0.5 bar and -0.7 bar;
- **Recommended depression for suction:** -0.9 bar maximum.

4. Begin infiltration or aspiration using the control unit and by referring to the instructions for use of the Adipcontrol®.

6.5 Stopping the device

1. Release the pedal of the Adipcontrol® system to stop the Adipmaster®.

2. Stopping the suction machine. > *Refer to the* Adipcontrol® instructions for use.

7. Disposal

Dispose of each type of waste through the appropriate channel:

• **Non-Infectious Clinical Waste:** such waste includes packaging, medical devices not used and not contaminated.
• **Infectious and Medical Waste:** they include tubing, contaminated cannulas, contaminated devices. They are to be disposed of according to the appropriate channel to prevent any contamination. The device must be disposed of in accordance with current national legislation.

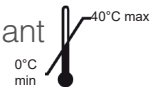
8. Transport and storage of the medical device

The Adipmaster® (including infiltration kit) must be transported **in its original packaging**.

The storage conditions are as follows:

• The Adipmaster® (including infiltration kit) must be kept in a dry place, away from sunlight, where cleanliness conditions are controlled (walls, floors, ceilings and storage area must be smooth and easy to clean and disinfect), and away from dust and pests.

• The Adipmaster® (including infiltration kit) must be kept in conditions which maintain the product's sterility.



• To prevent condensation from forming on the Adipmaster® (including infiltration kit), significant fluctuations in temperature should be avoided during storage. The Adipmaster® (including infiltration kit) must be stored at a temperature between 0°C and 40°C.

• To avoid any risk of chemical contamination, storing chemical products with the Adipmaster® (including infiltration kit) is prohibited.

• The Adipmaster® (including infiltration kit) shelf life is 1 year.

9. Resterilization and reuse

Adipmaster® (including infiltration kit), is for single use only. Any reuse of an Adipmaster® (including infiltration kit) is strictly forbidden. Any reuse of an Adipmaster® (including infiltration kit) may result in serious clinical complications, including death. Similarly, any re-sterilization of an Adipmaster® (including infiltration kit) is formally forbidden, as it causes a significant deterioration in its mechanical properties.

10. Medical device vigilance cases

Any incident or risk of a serious incident that has resulted in or is likely to result in the death or any serious deterioration in the condition of a patient, user or third party and involving an Adipmaster® (including infiltration kit) must be reported immediately to the competent authorities and to Euromi S.A. at the e-mail address: **materiovigilance@euromi.com**.

11. Handling returns

Products subject to a complaint or that have caused an incident or risk of a serious incident should be reported and returned to the local medical device vigilance representative of Euromi S.A.
Before returning the product to the manufacturer, it must first be decontaminated and disinfected (in accordance with the health facility's current procedures). The product must not be returned to Euromi S.A. if the patient is infected with HIV, with hepatitis or if it is suspected or confirmed they are infected with another infectious agent.

12. Guarantees & 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 Customer Services.

The warranty applies if the defective product is returned during the warranty period and the defect stems directly from the manufacturer, Euromi.

The warranty does not cover any of the following:

- **periodical maintenance and repairs or replacement of parts following normal wear and tear**;
- **any deterioration or change due to**:
  - incorrect use: handling resulting in deterioration;
  - any physical or aesthetic modification to the product;
  - product maintenance/servicing or cleaning that does not comply with the instructions supplied by Euromi;
  - repairs carried out or attempted by individuals other than Euromi technicians or the technicians used by approved suppliers or approved independent technicians who have undergone certified technical training at Euromi.
  - in the event of force majeure: natural catastrophe, accident (fire), war, etc.

For any queries, please contact the technical department at Euromi S.A., at the following address:

Euromi S.A.
Zoning Industriel des Plenesses
Rue des Nouvelles Technologies, 11
B-4821 Andrimont, Belgium

Email : info@euromi.com
Website: www.euromi.com

Tel : +32 (0) 87 29 22 22

13. Regulatory references

The main harmonized standards used by Euromi S.A. are:

- **BS EN ISO 13485:2016+A11:2021:** Medical devices. Quality management systems. Requirements for regulatory purposes.
- **BS EN ISO 14971:2019+A11:2021:** Medical devices. Application of risk management to medical devices.
- **BS EN 62366-1:2015+A1:2020:** Medical devices. Application of usability engineering to medical devices.

The exhaustive list of harmonized standards used by Euromi S.A. is available on request.

Additionally, because the Adipmaster® sterile single-use handpiece (including infiltration kits) have non-medical indications for use, the requirements of Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices have been taken into account as well.

Medical device

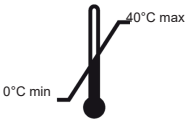
Consult the instructions for use

Indication of notified body responsible

Warning

Keep away from light

Keep dry



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

Single use product, do not use a second time

Do not sterilize a second time

Sterilised using dry heat - Double sterile barrier system

Do not use if package is damaged

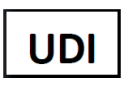
Commercial reference

Batch number

Expiration date. Do not use the product after the date indicated

Manufacturing date

Name and address of the manufacturer



UDI code

Annex: Information to be provided to patients

Please share the information below with your patients.

It is strongly recommended that all patients undergo a medical consultation, including a diagnostic examination, of the areas intended for the treatment, prior to undergoing any surgical intervention.

The Adipmaster® (including infiltration kit) is intended to be used for:

Medical intended purposes:

• **Lipoinfilration:** Infiltration of tumescent solutions to facilitate the removal of tissue and/or fluid for the treatment of lipomatosis, lymphoedema or during breast reconstruction procedures.
• **Liposuction:** The removal of tissue and/or fluid from the body for the treatment of lipomatosis, lymphoedema or during breast reconstruction/reduction procedures.
• **Lipofilling:** Introduction of autologous adipose tissues during breast reconstruction procedures.

Non-medical intended purposes:

• **Lipoinfilration:** Infiltration of tumescent solutions to facilitate the removal of tissue and/or fluid for the treatment of lipomatosis, lymphoedema or during breast reconstruction procedures.
• **Liposuction:** The removal of tissue and/or fluid from the body during aesthetic procedures.

This technique can be used on both men and women from the age of 18, for any type of skin/fat (Caucasian, Asian, African, etc.) and also for patients already treated (2nd liposuction).
It should be used by healthcare professionals with the relevant medical qualifications and who have received the suitable training for carrying out infiltration, liposuction and lipofilling procedures.

The users of Euromi devices have received appropriate training on the conditions to safely use these devices.

Any incident or risk of a serious incident that has resulted or is likely to result in the death or any serious deterioration in the condition of a patient, user or third party and involving an Adipmaster® (included infiltration kit) must be reported immediately to the competent authorities and to Euromi S.A. at the email address: materiovigilance@euromi.com.

Important information:

• **Liposuction, lipolysis and lipoplasty are not reliable methods for losing weight**. Exercise and diet, as well as lifestyle modification, should be taken into account, both as alternatives to liposuction and lipolysis and to maintain any reduction in fatty tissue that these procedures may cause. Our devices have not been validated for the treatment of clinically diagnosed obesity and should not be used for such purposes.

• Patients may need to **stop taking oral contraception**, particularly when associated risk factors are present (obesity, poor condition of veins, coagulation disorder).

• **No medicine containing aspirin** should be taken in the 10 days before the procedure.

• Depending on the type of anaesthesia, **the patient may be required to fast** (eating or drinking nothing) for 6 hours before the procedure.

• **Wearing an elastic compression garment is advised for a minimum of 2 to 4 weeks** after the procedure.

• **Sporting activities** may be resumed 3 weeks after the procedure.

• **Do not expose the areas that have been operated on to the sun or to UV** for at least 3 weeks.

• There will be **no marked change to the treated area in the first 2 to 3 weeks,** since at first postsurgical swelling (oedema) will be observed in the area of the procedure.

• In some cases, **localised imperfections may be observed,** although these may not be real complications: insufficient correction, residual asymmetry, surface irregularities. As a general rule, additional treatment may be available for such issues: a liposuction “retouch” is possible.

• The volume of blood loss and loss of endogenous body fluid may adversely affect intra and/or posterior **hemodynamic stability** and consumer safety. The ability to ensure proper and timely fluid management is critical to consumer safety. The volume of adipose tissue removed must be at the discretion of the surgeon, who must take into account the patient's morphology.

• **Drugs that may cause bradycardia or hypotension**, such as beta-adrenergic antagonists, calcium channel or dihydropyridine blockers, cardiac glycosides, and centrally acting alpha-adrenergic agonists, should be given special consideration. The treatment must be preceded by a medical consultation which must be documented and during which the chronic illnesses and the medications taken by the patient must be taken into account.

• **Results may vary according** to the age of the patient, the surgical site and the experience of the doctor.

The complication risk:

Complications are exceptional after high-quality liposculpture. Potential risks are limited with a qualified and competent health professional, trained to perform this type of procedure; however, such procedures are never completely risk free.

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 / Revision surgery:** increase of the duration of the initial intervention or the new intervention / A revision surgery is a follow-up surgical procedure performed to correct or improve the results of a previous 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):** 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 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**

• **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.

• **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. Aches are 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:** Injury to the underlying skin's structure

• **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.

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