INSTRUCTIONS FOR USE

EVAMATIC®

Euromi

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1. Medical device presentation MD

1.1 General information

These instructions apply to evamatic® and its accessories manufactured by Euromi S.A. They describe the procedures for safely using, cleaning, sterilising and maintaining the evamatic®. These devices are to be used only by qualified healthcare professionals.

The evamatic® is a Class IIb medical device.

The evamatic® is a reusable medical device, and is sold non-sterile.

The evamatic® has been CE certified since 2009. CE 2797

1.2 Composition

The evamatic® is shipped in a storage case containing:

DESCRIPTION	REF. NUMBER
evamatic® 5	1101EKL5
Maintenance oil	Codache 15 of Siprotec
Cleaning key	1201L-010
Tightening key	1201L-009
Cylindrical cleaning brush	1771GF-40
Manual handle	1311LMG-002
Infiltration cannula (optional)	1214L4INF-DIAMETRELONGUEUR
Aspiration cannula (optional)	1214LMODELE-RECOUVREMENT-DIAMETRELONGUEUR

The device does not include:

- medicinal or biological substances;
- measurement features.

1.3 Description

The evamatic® is a pneumatic handpiece for assistance to the realization of the Nutational Infrasonic Liposculpture®.
The evamatic® is suitable for infiltration, liposuction and lipofilling procedures.

1.4 Performance characteristics & Technical performances

The performance characteristics of evamatic® are as follows :

- The Euromi evamatic® 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 Euromi evamatic® is packaged in packaging designed to protect the device from damage during storage and transport.
- The evamatic® is not provide sterile but indications for sterilization are available in this IFU.
- The evamatic® functions thank to a device of a evasp® range.

• A black handle is available with the evamatic®.

• The evamatic® has an adaptated bracket for Euromi cannula.

• The evamatic® has an adaptated bracket for fat tubing supplied by Euromi.

• The evamatic® allows a move of the cannula and create a nutation movement.

• The evamatic® is packaged in such a way as to be easy to transport.

• The evamatic® works during 3 hours minimum and the product is restistant and reliable during its lifetime.

• The evamatic® weights less than 750g.

• The evamatic® is not provided sterile but indications for sterilization are available in this IFU.

• The evamatic® is easy to handle.

The technical performances of the evamatic® are as follows:
- Frequency: 15 to 25 Hz
- Elongation: 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 breast reconstructive surgery.
- **Non-medical indications** in aesthetic and plastic surgery, including lipoplasty for the purpose of aesthetic body contouring.

2.2 Intended uses

The evamatic® range is intended to be used for:

Non-medical intended purposes:

- **Lipoinfiltration:** Infiltration of tumescent solutions to facilitate the removal of tissue and/or fluid during aesthetic procedures
- **Liposuction:** The removal of tissue and/or fluid from the body during aesthetic procedures

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.

These techniques are possible for both men and women from the age of 18, for any type of skin/fat (Caucasian, Asian, African, etc.), and also for patients who have already been treated (2nd liposuction). They should be used by medically qualified and appropriately trained healthcare professionals to undertake infiltration/ injection, 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 bodytemperature (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 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 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 disruption (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 Warning

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.

Evamatic® non-sterile reusable handpieces are supplied in a non-sterile condition and must be cleaned and sterilised before they are used, including the first use, according to the method described in these instructions. After sterilisation, a cannula can be connected to the evamatic®, and the evamatic® can be connected to a device from the Euromi evasp® range.

• 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 hemodynamic stability and consumer 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 consumer 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 consumers 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.

• Evamatic® is multiple patient multiple use.

• Always visually inspect each handpiece before use. Discard the handpiece if there are any signs of wear, cracking, corrosion or if the handpiece is bent, broken or deformed.

• The evamatic® should be handled carefully and with caution.

• Do not use the evamatic®, if it is damaged.

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

• Do not exert excess pressure on the evamatic®.

• Handle the evamatic® under conditions of asepsis.

• The evamatic® must only be connected to a device from the Euromi medical device range.

• 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 evamatic®.

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

• Before any use combined with a cannula, it must be cleaned and sterilised according to the procedures describes in the user instructions of cannula. 

• Euromi S.A. will not be held responsible for use of an air source that does not supply medical air.

• 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 user must be trained in safe and effective use.

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

• The evamatic® is multiple patient ; multiple use (Multiple use requires cleaning and sterilisation between each use)

• Use a single-use handpiece if the patient is infected with HIV, with hepatitis or if it is suspected or confirmed they are infected with another infectious agent.

• The evamatic® mustn't be modified.

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

• Evamatic® must be decontaminated before they are discarded.

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

The life of the evamatic® is 5 years following its receipt, subject to annual maintenance.
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 and use

• Inspection of the condition of the various parts:

1. Check the functions of the evamatic® 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 evasp® 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.

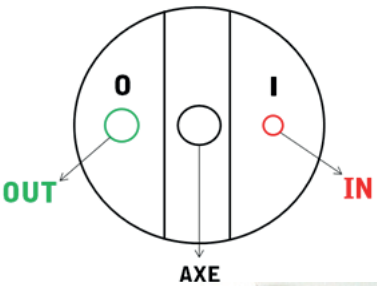
• Accessory installation:

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

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

• Connection:

1. Connect the **AIR SOURCE** plug, via the braided tube provided with the evasp® , to the compressed air supply, following the evasp® aspiration machine instructions.

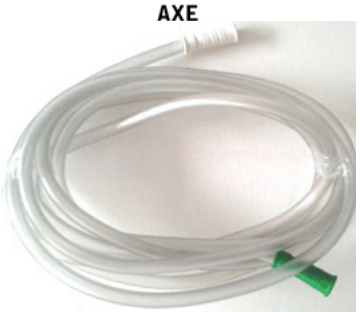


2. Connect the **small diameter air tubing** to the **(IN)** plug of the *eva*sp® and to the **I** connector of the evamatic®.

3. Connect the **larger diameter air tubing** to the **(OUT)** plug of the evasp® and to the **O** connector of the evamatic®.

4. Connect the **white** connector of the fat evacuation tubing to the **central connector of the evamatic®**.

5. Connect the **green** connector of the fat evacuation tubing to the **PATIENT** connector of the **fat decanting canister of the evasp®** system.



• Installing the cannula:

The cannula can be connected to:

• evamatic®;

• A handle (or manual handpiece).

• Connection of the cannula to evamatic®:

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

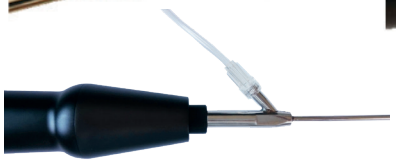
2. Remove the detachable connector (nozzle) from the evamatic®.

3. Install the cannula: Manually screw the cannula onto the evamatic® without forcing it (it should screw on very easily).(1) Then fasten the cannula using a gentle turn of check key to ensure a secure attachment.

- ***For the infiltration cannulas***: connect the intravenous line to the Luer connector. (2)
- ***For the N.L.F.®* cannulas:** Assemble both parts of the N.L.F cannula. Make sure that the tube and the N.L.F. ® cannula are aligned. Insert the tube into the evamatic®.(3) Screw the tube without forcing it and, if necessary, finish using a gentle turn of the tightening tool.

(1)

(2)



(3)

• Connection of the cannula to handle:

1. Manually screw the cannula on the handle. A chuck key can be used to ensure a secure attachment.

2. Then, connect the aspiration tubing (fat tubing) to the handle.

• Start-up:

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

2. Set the pressure in bar depending on the area to be operated on and the procedure to be carried out:

- **Recommended air pressure for infiltration:** between 1.8 and 3 bar;
- **Recommended air pressure for aspiration:** 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.
- **Recommended air pressure for removing fat for lipofilling**: between 2.8 and 3.5 bar.

3. Set the negative pression depending on the procedure to be carried out:

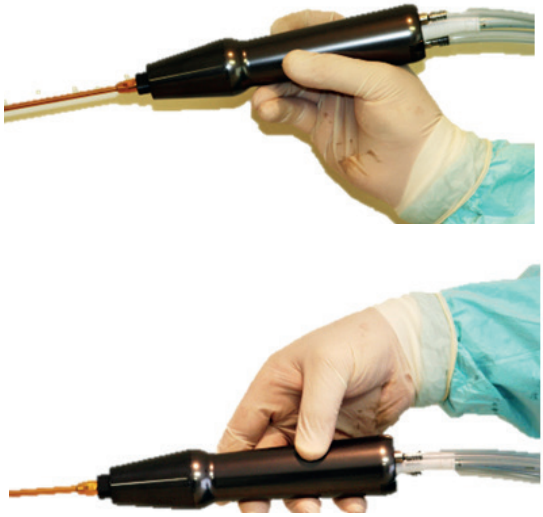
- **Recommended depression for removal for lipofilling:** between -0.5 bar and -0.7 bar;
- **Recommended depression for aspiration:** -0.9 bar maximum.

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

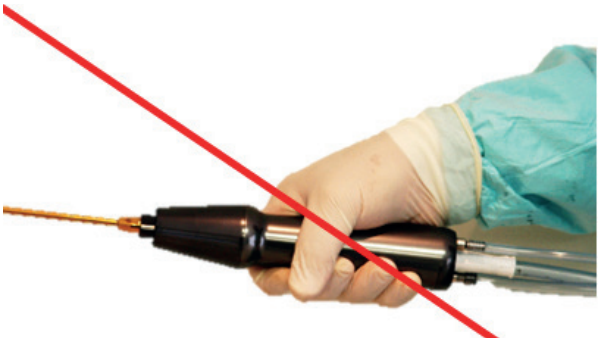
• Hand position:

The correct hand position is important when using the evamatic®:

Correct position:



Incorrect position:



6.4 Stopping the device

1. Release the pedal of the evasp® system to stop the evamatic®.

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

7. Maintenance

Preventative maintenance:

The evamatic® must be returned to the factory for a control and a routine revision at least once per year. Maintenance and repair operations must imperatively be carried out by Euromi S.A.'s technical department or by a technician approved by Euromi. Contact your retailer for further information. The spare parts of the device are available for 5 years from the date of installation, only if Euromi S.A. receives the warranty certificate duly completed and signed by the end customer or from the date of invoice.

Trouble shooting:

A manual hand piece (supplied with the evamatic®) is available in the event of unscheduled outage of the evasp® or the evamatic®.

• **Evamatic® safety mode:**

  • Manually move the cannula holder up and down once or twice, holding the cannula between your thumb and index finger and releasing the pedal. It will automatically start up again.

  • This action can also be carried out using the cleaning key.

8. Disposal

Dispose of each type of waste through the appropriate channel:

• **Non-Infectious Clinical Waste:** such waste includes packaging, unused and non-contaminated 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 device must be disposed of in accordance with current national legislation.

9. Transport and storage of the medical device

The evamatic® and its accessories should be **transported in its original packaging** (case).

Before cleaning and sterilization, the storage conditions are as follow:

- The evamatic® must be stored in a closed, dry, designated area, sheltered from dust and pests.
- To prevent condensation from forming on the evamatic®, significant fluctuations in temperature should be avoided during storage.
- If stored for longer than 4 years, the evamatic® device must be reviewed by the Euromi S.A. technical department prior to use.
- To avoid any risk of chemical contamination, storing chemical products with the evamatic® is prohibited.
- For a storage time exceeding 4 years, you must have the evamatic® revised by Euromi S.A.'s technical department prior to use.

After cleaning and sterilisation, the handpiece must be transported in its double packaging, in dry conditions, away from dust and pests.

The storage conditions are as follows:

- The sterile and packaged evamatic® 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 evamatic® must be kept in conditions which maintain the product's sterility.
- To prevent condensation from forming on the evamatic® significant fluctuations in temperature should be avoided during storage. The evamatic® must be stored at a temperature between 0°C and 40°C.
- To avoid any risk of chemical contamination, storing chemical products with the evamatic® is prohibited.
- The authorised storage time depends on the sterile barrier system used and the storage conditions. This storage time must be established by the competent authority of the hospital.

- For a storage time exceeding 4 years, you must have the evamatic® revised by Euromi S.A.'s technical department prior to use.

10. Resterilization et reuse

The evamatic® and its accessories are supplied non-sterile and therefore must be cleaned and sterilised before use.

The healthcare institution must ensure that the combination of cleaning and sterilisation used results in devices that present no risk for surgery.

Automatic cleaning is not recommended for the evamatic®.

1. At the site of the procedure *(this step is not carried out during the first cleaning):*

- Remove the tubing (disposable) and the cannula from the handpiece;
- Remove any excess dirt with a disposable, lint-free cloth;
- Rinse the device under cold running water;
- Cover the devices with a wet cloth;
- Keep the instruments hydrated until they are treated. Devices must be treated within 30 minutes following their last use in order to reduce the risk of the organic matter drying on the devices. The cleaning of the evamatic® cannot be guaranteed if the allocated time between the use and treatment of the device exceeds 30 minutes.
- Other devices must be covered and transported with the handpiece but must be cleaned and sterilised following the instructions stated in their respective instructions for use.
- Place soiled devices in a watertight bag or a confinement device for transporting them to the decontamination area.
- Take the necessary precautions to prevent damaging the device.

2. Preparation of the cleaning solution:

- Wear personal protection equipment as required during the cleaning process (as recommended by the supplier of the cleaning agent).
- Only use cleaning solutions with a neutral pH.
- The cleaning solution must not be flammable.
- Do not use a cleaning solution containing chlorine or chloride as the active ingredient is corrosive for stainless steel.
- Cleaning product performance must comply with the regulations in force.
- Do not use a cleaning solution containing aldehydes to avoid proteins adhering to the device.
- Prepare a cleaning solution using warm tap water, according to the instructions of the manufacturer of the cleaning agent). The temperature of the cleaning solution must be between 30 and 40°C (86-104°F).
- Fixing agents or hot water (>40°C) should not be used as it will result in the fixation of residues and may affect the cleaning results.

3. Decontamination:

• Completely immerse the handpiece in at least 3 L of cleaning solution which has been previously prepared (increase the volume of water used if the handpiece is not completely immersed), following the manufacturer's instructions regarding the contact time. If no contact time is specified, immerse the device for 15 minutes.

• Rinse the device carefully using running warm water at a temperature between 30 and 40°C (86-104°F) for at least 2 minutes.

4. External cleaning of the device:

• Fill a container or sink large enough to fully immerse the device with a minimum of 3 L of water at a temperature between 45°C and 55°C (113-131°F). Dilute the cleaning solution according to the manufacturer's instructions.(1)

• Use a lint-free cloth moistened with water to facilitate the removal of excess dirt and contaminants. Replace the cloth, as necessary, when it is dirty.

• Fully immerse the device in the cleaning solution for the contact time recommended by the manufacturer. If no contact time is specified, immerse the device for 15 minutes.

• Carry out external cleaning of the device in the cleaning solution; to do this, brush the external surfaces using a soft-bristled brush (such as brush reference 09478 by STERILMED®) for at least 2 minutes or until all traces of visible soiling have been eliminated from the exterior of the evamatic®.

5. Manual cleaning for the central axis:

• Brush the evamatic®'s central axis using a suitable cylindrical brush (such as the GF-40 cleaning brush from the brand Bontempi) under running water between 45°C and 55°C (113 -131°F) for at least 2 minutes.(2)

Never use brushes with metal bristles or metal wool, as these may damage the device.

• Rinse the central axis under running water at a temperature between 45°C and 55°C (113-131°F) for at least 2 minutes.(3)

(1)

(2)

(3)

6. Manual cleaning of the motor:

• Delicately screw, without forcing, the cleaning key into the evamatic®.

• Fully immerse the evamatic®'s connectors in at least 5 L of water (increase the volume of water used if the connectors are not completely immersed) at a temperature between 45°C and 55°C (113-131°F).
Dilute the cleaning solution following the instructions provided by themanufacturer. Pump 15 times using the cleaning key.

• Repeat this operation in clean water (at least 5 L of water at a temperature between 45°C and 55°C (113-131°F) in order to rinse the motor.

• Delicately unscrew the cleaning key.

• Carefully and thoroughly rinse the evamatic® with distilled water for at least 3 minutes.

PHASE	STAGE	TIME (MINUTES)	TEMPERATURE	TYPE OF DETERGENT AND CONCENTRATION
DECONTAMINATION	Immersion	15:00	30-40°C (86-104°F)	Miltex® EZ-Zyme® *
	Rinsing	02:00	30-40°C (86-104°F)	N/A
CLEANING	Immersion	15:00	45-55°C (113-131°F)	Miltex® EZ-Zyme® *
	External cleaning	02:00	45-55°C (113-131°F)	Miltex® EZ-Zyme® *
	Internal cleaning	02:00	45-55°C (113-131°F)	Miltex® EZ-Zyme®*
	Central axis rinsing	02:00	45-55°C (113-131°F)	N/A
	Motor cleaning	15 times	45-55°C (113-131°F)	Miltex® EZ-Zyme® *
	Motor rinsing	15 times	45-55°C (113-131°F)	N/A
RINSING	-	03:00	-	N/A

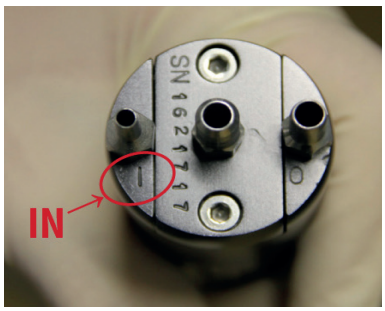
* Miltex® EZ-Zyme®: references 3-750 and 3-755 – 0.6% of cleaning solution. (6 mL per litre)
OR Aniosyme Synergy 5 - 0.5% of cleaning solution. (5 ml for 1 litre)

7. Drying:

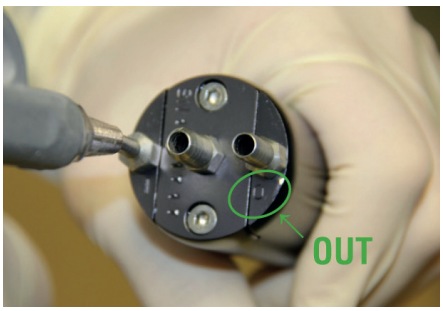
• Dry the interior of the evamatic® using a compressed air blower (1). Position the end of the blower at the entrance of the **I (IN)** (2) connector and dry until the air coming out of the **O (OUT)** (3) connector is completely dry. Dry for 1 to 3 minutes.

• Carefully and thoroughly dry the exterior of the evamatic® using a clean, lint-free cloth.

(1)



(2)



(3)

8. Maintenance and inspection:

- Use a 10x to 15x magnifying glass to inspect the evamatic® to check that there is no dirt remaining on the evamatic®. Repeat the cleaning procedure if dirt is still visible.
- Perform a visual inspection to check for any signs of damage and/or wear.

9. Oiling the motor:

- **Completely remove the cannula holder (extend downwards)**.
- Inject between 0.3 ml and 0.5 ml of oil (Codache 15 of Siprotec), approximately 20 drops, into the **I (IN)** connector.
- Use the compressed air blower in the **I (IN)** connector for, at most, 1 to 2 seconds to evenly distribute the oil in the engine.
- For the first ten uses of the evamatic®, repeat the motor oiling phase a second time.

10. Packaging:

After cleaning and inspection, the handpiece must be packed individually in a double sterilisation packaging of medical quality (such as the Convertors® Bio-Shield® sterilisation pouches from Cardinal Health® - supplier reference No. 4040). The packaging must be large enough to contain the handpiece without stretching the packaging. The packaging must be suitable for moist heat sterilisation.

11. Sterilisation:

Sterilise using moist heat: complete cycle according to the recommendations below:

TYPE OF CYCLE	ADJUSTMENT TEMPERATURE	EXPOSURE TIME	MINIMAL DRYING TIME	MINIMAL COOLING TIME
United Kingdom: Pre-vacuum/4 pulses	134°C	3 minutes	30 minutes	30 minutes
USA: Pre-vacuum/4 pulses	132°C	4 minutes	30 minutes	30 minutes
European Union: Pre-vacuum/4 pulses	134°C	18 minutes	30 minutes	30 minutes

(For regions other than the United States, the United Kingdom and the European Union, the same sterilization cycles can be applied, subject to local regulations and directives. If in doubt, please contact your local regulatory or health authority).

12. Information on the cleaning validation:

The validation was performed using the following equipment and chemicals:

Internal cleaning brush	GF-40 by Bontempi
External cleaning brush	Cleaning brush ref. 09478 STERILMED®
Packaging	Cardinal Health® Convertors® Bio-Shield® - supplier reference no. 4040
Sterilizer	Model: SMA 59/125 SP; Manufacturer: BBC; Capacity: 432 L

11. 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 evamatic® must be reported immediately to the competent authorities and to Euromi S.A. at the e-mail address: **materiovigilance@euromi.com**.

12. 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 cleaned (following the procedure defined in these instructions). If no proof of cleaning is provided, cleaning fees will be invoiced and the repair of the instrument will be delayed. 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.

13. 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 I Website : www.euromi.com

Tel : +32 (0) 87 29 22 22

14. 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 evasp® 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.


Read the instructions for use carefully

Identification of the responsible notified body


Name and address of the manufacturer

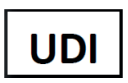

Date of manufacture

Commercial reference

Serial number


Warning

Medical device



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 evamatic® is intended to be used for:

Non-medical intended purposes:

- **Lipoinfilration:** Infiltration of tumescent solutions to facilitate the removal of tissue and/or fluid during aesthetic procedures
- **Liposuction:** The removal of tissue and/or fluid from the body during aesthetic procedures

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.

This technique can be used on both men and women from the age of 18 years, for any type of skin/fat (Caucasian, Asian, African, etc.) and also for patients already treated (2nd liposuction).
It must 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 Evamatic® 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.

NOTES

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Euromi

Zoning Industriel des Plenesses
11 rue des Nouvelles Technologies - 4821 Andrimont (BELGIUM)
Tel.: +32(0) 87 29 22 22
info@euromi.com - www.euromi.com

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