INSTRUCTIONS FOR USE

EVA SP ® 2

Euromi

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1. Identification of the medical device MD

1.1 General information

These instructions describe the procedures for safely using the evasp® 2.

This device is to be used only by qualified healthcare professionals. 

The evasp® 2 is an item of equipment with a class I electrical safety rating, designed for continuous function. It is classed as IP X0 equipment.

	evasp® 2 - 110V	evasp® 2 - 220V
Rated voltage	100 – 115V ~ 50/60Hz 5A	200 – 240V ~ 50/60Hz 2.5A
Fuses for the pump	T 6.3A H 250V	T 6.3A H 250V
Fuses for power supply	T 6.3A H 250V	T 3.15A H 250V
Pollution level	2	2
Over voltage category	II	II
Altitude	2000 m	2000 m

The evasp® 2 is a Class IIb medical device, in compliance with Directive 93/42/EEC concerning medical equipment.

The evasp® 2 has been CE certified since 2009. CE 2797

1.2 Technical performances

The technical performances of the evasp® 2 device are:
- Pressure: 0 to 6 bar
- Depressure: 0 to -0,9 bar.

Recommendations for use are specified in paragraph **6. Use of the medical device** - *6.5. Use*.

1.3 Composition

The device contains:

DESCRIPTION	REF. NUMBER
evasp® 2	1114SP216 (220V) 1114SP216110V (110V)
- 2 3L canisters	1752-DYNDCLO3000
- 2 pedals	5914E12467-005
- 1 power cord	5911BD2E12467-001
- 1 compressed air supply	5914ATL

The device does not include medicinal or biological substances.

1.4 Description

The evasp® range is a complete range of device to assist the practitioner during an intervention. (Regulation of the supply of compressed air, aspiration, infiltration ...).

The range of medical devices evasp® is a range of assistance to the realization of the Nutational Infrasonic Liposculpture®. Each evasp® is available in 110V or 220V.

The products are multi-patient and multi-use.

evasp® 2 system regulates the compressed air supplied to the evamatic® to achieve a Nutational Infrasonic Liposculpture® with aspiration.

2. Indications / Intended uses / Benefits

2.1 Indications

- **Medical indications** for use in treatment of conditions such as lymphedema and lipomatosis.
- **Non-medical indications** in aesthetic and plastic surgery, including lipoplasty for the purpose of aesthetic body contouring.

2.2 Intended uses

The evasp® 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.
- **Liposuction:** The removal of tissue and/or fluid from the body for the treatment of lipomatosis, lymphoedema.

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 and liposuction 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):

Patient satisfaction of at least 90% with the overall outcome.

3. Contra-indications

Liposuction is 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 anesthesia

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

4.2 Possible complications due to the surgical procedure

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

The following complications may be observed:

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

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

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

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

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

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

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

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

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

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

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

• **Extended or additional intervention / 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. The soreness is muscle pain.

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

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

• 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.

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

• Disposable components are single use (air tubing, fat tubing, intravenous line, syringes, N.L.F.® kits etc.). They must not be reused.

• The device is suitable to be used in a professional healthcare environment; Handle the evasp® 2 in aseptic conditions.

• It is strictly prohibited to modify the evasp® 2 in anyway.

• The evasp® 2 device must only be connected to an earthed socket to prevent the risk of electrical shock.

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

• The user must not use a power cable not supplied by Euromi.

• The ventilation grids must never be obstructed.

• 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.

• Risk of explosion: do not use in the presence of flammable products or oxygen.

• Do not use the device in areas where there is a risk of explosion. The ambient air should be free from dust or explosive vapours, gas or an explosive combination of gas and air. The device is not explosion-proof.

• All of the system components must be inspected for damage, excessive use, corrosion or malfunction prior to use.

• All of the eva® system leaflets must be examined prior to use for warnings and instructions for use.

• The evasp® 2 must not be used if it is damaged.

• Before each use with evamatic® or handle, this one must be cleaned and sterilised following the method described in the instructions of evamatic®.

• 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®.

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

• Liposuction is a real surgical operation which can only be performed by a competent and qualified user (refer to the legislation of the country in which the procedure is performed).

• 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.

• The re-sale of a Euromi device is strictly prohibited for reasons of traceability.

• Check the correct operation of various functions of the medical device before any intervention.

• Annual maintenance is required to use the evasp® 2 safely.

• Subject to the respect of annual maintenance operations, the evasp® 2 has a lifespan of 5 years following purchase. Any use exceeding this lifespan falls under the user's responsibility.

• The use of inappropriate pressure outside the recommendations indicated in the instructions for use may lead to increased risk of complications identified for the patient.

• The guarantee certificate attached to the evasp® 2 must be returned to Euromi S.A

Warnings linked to electromagnetic risks

• Based on the electromagnetic compliance test results it can be concluded that foreseeable electromagnetic disturbance will not result in an acceptable risk/danger to the user or to the patient.

• The user of the evasp® 2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the evasp® 2 as recommended below, depending on the maximum output power of the communications equipment.

Rated maximum output power of the transmitter (W)	Separation distance depending on transmitter frequency (M)		
	150 kHz to 80 MHz $d = 1,2P\sqrt{}$	80 MHz to 800 MHz $d = 1,2P\sqrt{}$	800 MHz to 2,5 GHz $d = 2,3P\sqrt{}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters with a maximum output power not listed above, the recommended separation distance ***d*** in meters (M) can be estimated using the equation applicable to the transmitter frequency, where ***P*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

The evasp® 2 device shouldn't be touched by the patient and must be placed at minimum 1.5 meters from him/her. This distance between the patient and the device is mandatory. Only a non-sterile person who is not in contact with the patient can control the evasp® 2 during an operation.

• Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

• The use of other cables and accessories other than the one supplied by Euromi may negatively affect EMC performance.

• The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR11 class A).

• The evasp® 2 has been evaluated for:
  • Immunity test levels according to IEC 60601-1-2 for a professional healthcare environment.
  • Emissions according CISPR 11, group 1, class A limits.

Euromi S.A. shall not be held responsible for any use of the device outside its intended use set out in these instructions for use.

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 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 cannula by moving it under the skin. It's the **lipoinfiltration procedure**.

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.

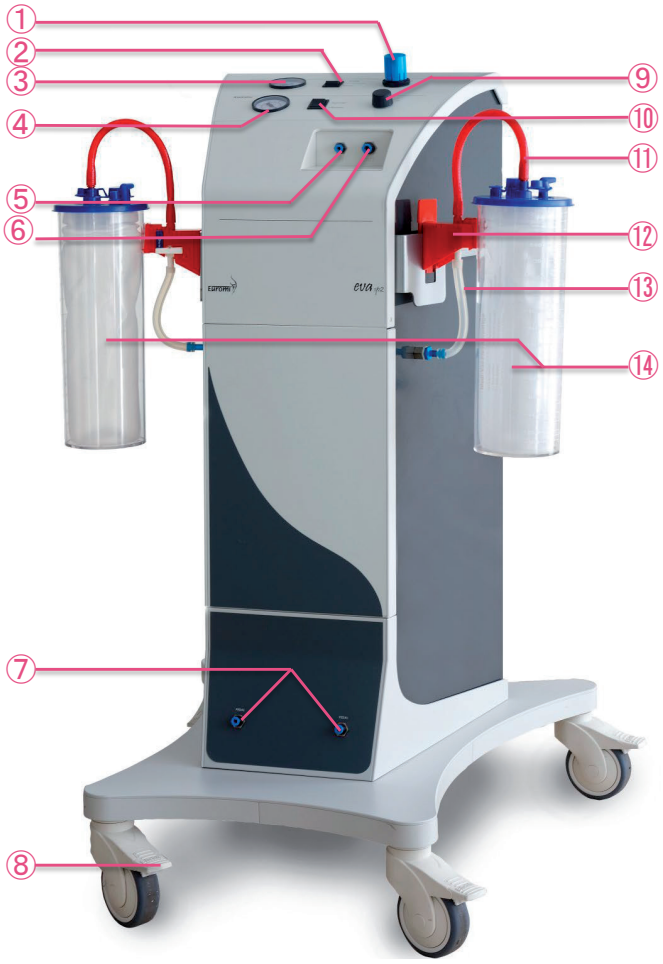
If all the instructions for use mentioned above are not respected by the surgeon, he is liable to cause complications affecting the health of the patient.

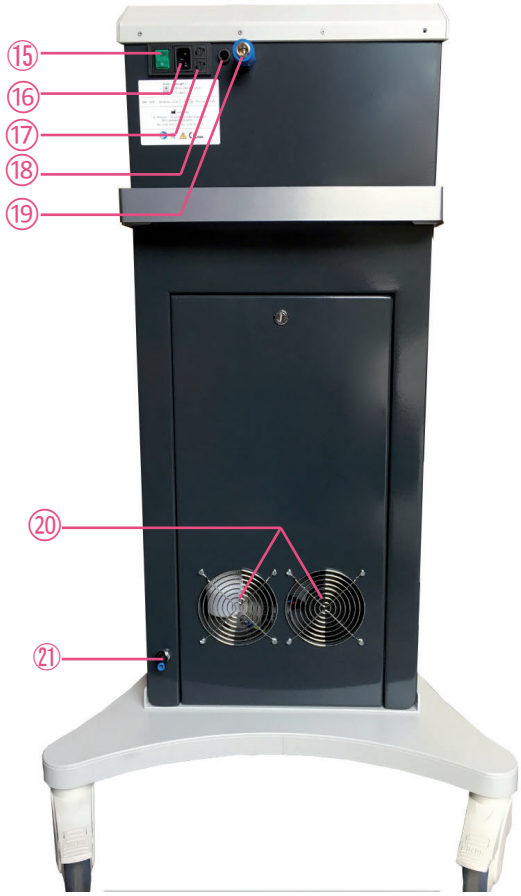
2) After, he can easily aspirate the fat thanks to the swelling of the fat cells with an aspiration cannula connected to an aspiration machine. It's the **liposuction procedure**.

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

6.3 Description

Users can have training by the manufacturer, if necessary, contact the distributor or EUROMI.





① **Air pressure regulator:**
- **+** : Turn clockwise to increase pressure
- **-** : Turn anti-clockwise to reduce it.

② **Operating mode:**
- Pedal
- Continuous

③ **Graduated manometer for air pressure**

④ **Graduated manometer for air depression**

⑤ **Air inlet connection (IN)**

⑥ **Air outlet connection (OUT)**

⑦ **Pedals connections**

⑧ **Wheel locking**

⑨ **Air depression regulator:**
- **+** : Turn clockwise to increase pressure
- **-** : Turn anti-clockwise to reduce it.

⑩ **Use mode:**
- Aspiration
- Infiltration

⑪ **Red tube for depression**

⑫ **Canister mounting bracket**

⑬ **Silicone tube for depression**

⑭ **Canister for MEDI-VAC bags**

⑮ **ON / OFF switch**

⑯ **Connection of the electricity supply**

⑰ **Access to fuses of main power**

⑱ **Access to fuses of suction pump**

⑲ **Connection of the air tubing**

⑳ **Ventilation grids**

㉑ **Oil drainage valve**

6.4 Installation

Moving the disposal:

- Unlock the evasp® by raising the **brake** ⑧ to move the device.
- Lock the evasp® wheels by pressing the **brake** ⑧ during the assembly and the surgery.

Pedals connexion:

- Connect **the pedals to the "pedals" connectors.** ⑦

Canisters installation:

- Attach the **canister** ⑭ **thanks to the mounting bracket** ⑫ on the side rail.
- Connect the **silicone tubes** ⑬ to the valve connectors under the **mounting brackets.** ⑫
- Place the **MEDI-VAC bag inside the canister.** ⑭
- Clips the cover by supporting the canister from the bottom (to not damage the mounting bracket).
- Connect the **red tubes for depression** ⑪ **to the « VACUUM » connector** of the MEDI-VAC bag cover.
- Connect the **green tip of the fat tubing to the « PATIENT » connector** of the canister.
- Connect the **white tip of the fat tubing to the evamatic® central connector.**

Installation of the infiltration cannula:

- Install the infiltration cannula on the evamatic®.
- Connect the tubing to the Luer connector of the infiltration cannula.

Connection of the power supply (air and electric):

- Connect the **air supply tubing to the evasp®** ⑲ and compressed air system.
- Connect the **small diameter air tubing to the evasp® air inlet connection** ⑤ **(IN)** and to the **I connection of the evamatic®** as directed in the hand piece instructions for use.
- Connect the **air tubing with large diameter to the evasp® air outlet connection (OUT)** ⑥ and to the **O connection of the evamatic®** as directed in the hand piece instructions for use.
- Before connecting the power cord from the wall socket, ensure that the **switch** ⑮ **is in the OFF position** (◯).
- Insert the **power cord into the power supply** ⑯. Switch on via an appropriate socket.

6.5 Use

To power up the device, place the **switch ⑮ in the ON position** (**I**).
The power light is now illuminated.

Infiltration:

1. Choose the use mode ⑩ : infiltration. The suction pump is therefore desactivated.

2. Press the pedal to start the infiltration.

Aspiration:

1. Choose the use mode ⑩ : aspiration.

2. Replace the infiltration cannula by the aspiration cannula.

3. Choose the operating mode: « **PEDAL** » or « **CONTINUOUS** »②.

- **In «PEDAL» mode**, press the pedal to start up the device and release to stop the device.
- **In «CONTINOUS» mode**, press the pedal once to power up the device, then release the pedal. The device will continue to function. Press the pedal once again to stop the device.

4. Set the pressure in bar depending on the area to be operated and the medical procedure to be carried out thanks to the **pressure regulator** ① :

- Recommended air pressure for aspiration: between 3 and 5 bar.

5. Set the depression thanks to the **depression regulator** ⑨ depending the medical procedure to be carried out:

- Recommanded air depression for suction: -0,9 bar maximum.

6. Put the used canister in ON position.

7. Check that the non-used canister is in OFF position to avoid aspiration losses.

8. Press the pedal to start the suction.

6.6 Stopping the device

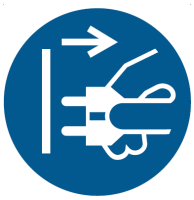
1. Place the **switch ⑮ in the OFF position** (◯). The light will go out.

2. Remove the air supply tubing from the evasp® device ⑲ and the compressed air system by pressing the blue ring.

3. Disconnect the pedals ⑦ and the tubings by pressing the blue ring.

4. Discard the single-use components.

7. Maintenance



The evasp® must be disconnected prior to maintenance/servicing.

The evasp® 2 casing must never be opened.

Maintenance and repair operations must always be carried out by the Euromi S.A. technical department or by a technician approved by Euromi. Please contact your supplier for more 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.

Preventive maintenance:

Once a month, open tap (21) to remove the oil that has collected in the filter.

The evasp® 2 must be returned to the Euromi S.A. company or to a technician approved by Euromi for routine testing and review at least once a year.
A manual hand piece (supplied with the evamatic®) is available in the event of unscheduled outage of the evasp® or the evamatic®.

- **The evasp® does not light up:**
  - Place the switch (15) in the OFF position (◯).
  - Check that the power cord is not damaged.
  - Check that the power cord is inserted correctly into the device and the power socket.
  - Check the fuses are not damaged (17) and (18).
    If a fuse is damaged, change it (cf. fuse changing).
  - Place the switch (15) in the ON position (I).
  - If the evasp® still does not function, contact the Euromi Customer Service Department.

- **The pedal does not work:**
  - Check that the pedal cord is not damaged.
  - Check that the cord is inserted correctly into the device.
  - If the evasp® still does not function, contact the Euromi Customer Services Department.

- **Absence of aspiration :**
  - Check that the MEDI-VAC bags (14) are well secured on the canisters.
  - Check that the silicone tubing for depression (13) are not damaged, teared or clamped.

- **To change a fuse:**
  - Never change a fuse during a procedure.
  - Place the switch (15) in the OFF position (◯) and disconnect from the power supply (16).

• Unscrew the lid of the fuse box ⑰ and ⑱ using a screwdriver.
• Remove the blown fuse and replace it only with a fuse supplied by Euromi with the same voltage, amp and type .

8. Disposal

Dispose of each type of waste through the appropriate channel:

• **Non-Infectious Clinical Waste:** such waste includes packaging, unused and noncontaminated medical devices.

• **Infectious and Medical Waste:** such waste includes tubing, contaminated cannulas, contaminated devices. This waste is to be disposed of according to the appropriate channel to prevent any contamination.

The evasp® must not be disposed of with public or communal waste. 

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

9. Transport and storage of the medical device

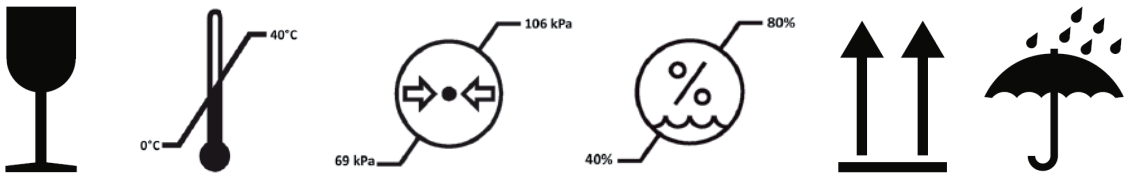
The evasp® should be transported in its original packaging.

The evasp® must be disconnected from all connections for storage.

The evasp® must be stored in a closed, dry, designated area, sheltered from dust and pests. Significant temperature variations should be avoided during storage to prevent condensation from forming on the evasp®. Do not store any chemical product with the evasp® device to prevent any risk of chemical contamination.

If stored for longer than 4 years, the evasp® device must be reviewed by the Euromi S.A. technical department prior to use.

Storage conditions:



10. Cleaning and sterilisation

The evasp® system must never be sterilised or immersed.

The evasp® system must be disconnected before cleaning.

The external surfaces of the device must always be cleaned carefully with a disinfectant after use.

Do not use abrasive or solvent-containing products.

Do not allow the liquid to flow into the equipment apertures.

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 evasp® 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 disinfected (following the procedure defined in these instructions). If no proof of cleaning and disinfection 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 date of installation, provided that Euromi S.A. receives the warranty certificate, duly completed and signed by the end client or on 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

14. Regulatory references

The main harmonized standards used by Euromi 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 is available on request.

Additionally, because the evasp® range 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.

Identification of the responsible notified body

Name and address of the manufacturer

Date of manufacture

Serial number

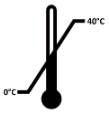
Commercial reference

Medical device

Alternating current

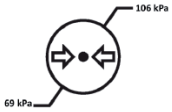
ON (power)

OFF (power)



Temperature limit

Humidity limit



Atmospheric pressure limit

Warning

Read the instructions for use carefully

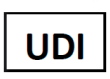
Disconnect the sector power supply

Fragile, handle with care

This way up

Keep dry

Must be collected separately



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 evasp® 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.
- **Liposuction:** The removal of tissue and/or fluid from the body for the treatment of lipomatosis, lymphoedema..

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

The following complications may be observed:

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

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

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

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

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

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

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

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

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

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

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

• **Extended or additional intervention / 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. The soreness is muscle pain.

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

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

Euromi

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