INSTRUCTIONS FOR USE

Reusable CANNULAS

Euromi

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1. Identification of the medical device

1.1 General information

These instructions apply to Euromi reusable liposuction system cannulas manufactured by Euromi S.A. They describe the procedures required to use, clean and sterilise the cannulas safely.
These devices are only to be used by appropriately qualified health care professionals.

Liposuction system cannulas are class IIa passive medical devices sold in a non-sterile and reusable format. These cannulas have been CE certified since 27/03/2009.

1.2 Composition

Medical grade stainless steels contain a low level of nickel and conform to ASTM Standard Specification for wrought Stainless Steels for Surgical Instruments.

A stainless-steel alloy containing cobalt is used as a raw material used in the manufacture of one or more components of this device. Cobalt is a substance(s) defined as CMR 1B in a concentration above 0.1% weight by weight: CAS No. 7440-48-4; EC No. 231-158-0.

The medical grade stainless steel are compatible with the commonly used tumescent solutions.

The device does not incorporate:
• any medicinal substances or biological materials
• any measurement functions.

1.3 Description

The reusable cannula is a non-sterile, reusable medical device used for liposuction, lipoinfiltration and lipofilling.

2. Medical purpose / Indications / Benefits

2.1 Indications

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

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

2.2 Intended uses

The Euromi reusable cannulas are intended to be used for:

<u>Medical intended purposes:</u>

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

• **Lipofilling:** Introduction of autologous adipose tissues during breast reconstruction procedures.

Non-medical intended purposes:

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

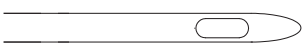
Fat removal is possible on all the parts of the body with adipose tissue, such as:

SITE NUMBER	SITE NAME	SITE NUMBER	SITE NAME
1	Cheeks	10	Abdomen
2	Chin	11	Waists
3	Neck	12	Buttocks
4	Buffalo hump	13	Pubis
5	Back	14	Hips
6	Arms	15	Thighs
7	Serratus anterior	16	Knees
8	Breasts	17	Calves
9	Chest	18	Ankles

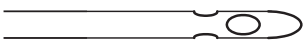
2.3 Characteristics and indications of aspiration / harvesting cannulas

• **1B:** indicated for all areas of the body; also suitable for superficial liposuction.

• **3G:** indicated for all areas of the body; also suitable for superficial liposuction.



• **Houyoux:** indicated for superficial liposuction and the treatment of cellulitis.

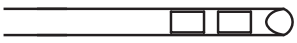


• **Illouz:** indicated for all areas of the body.

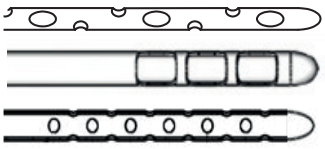
• **Mercedes:** indicated for the liposuction of deep fat; contraindicated for superficial liposuction; presents large orifices, therefore, it should be used with care.

• **Toledo:** indicated for the liposuction of the knees and chin; also suitable for removing fat in all areas of the body.

• **Viterbo / Brorson / 24H :** indicated for the liposuction of deep fat; contraindicated for superficial liposuction; they should be used with care.



Note :*Aspiration / Harvesting cannulas are also available in bayonet model except for Houyoux, Brorson and 24H models. Aspiration / Harvesting cannulas are available with* evamatic® *base for use with* evamatic® *5 or with a LUER base for a manual liposuction.*



2.4 Characteristics and indications of infiltration / injection cannulas

• **evamatic® 5 :** indicated for infiltration / injection in all areas of the body using an *eva*matic 5 or its previous version; allows the practice of the tumescent liposuction technique.

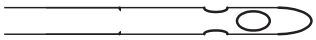
• **Luer:** indicated for manual infiltration / injection; allows the practice of tumescent liposuction technique.

2.5 Characteristics and indications of lipofilling cannulas

• **Aspiration / Harvesting:** indicated for removing fat during the course of lipofilling.

• **Infiltration / Injection:** indicated for the injection of fat during lipofilling

2.6 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. Contraindications

Liposuction and lipofilling are contraindicated in the following cases:

- Active cancer or tumours
- Family history of breast cancer
- Pre-existing pathology, wound or radiotherapy-related skin damage in the area of the procedure
- Generalized infection or ongoing erysipelas in the area of the procedure
- Severely irradiated patients
- Patients who had previously undergone surgery to the gluteal region, and post bariatric patient
- Smokers/smoking
- Use of antiplatelets or anticoagulants, previous thromboembolism, history of cardiovascular incidents or surgery, previous evidence of genetic predisposition to thromboembolism (such as Factor V Leiden disease, and thrombophilia), or bleeding (such as haemophilia and von Willebrand factor disease)
- Exclusion criteria included American Society of Anesthesia score 3 or 4 (high risk for anaesthesia), and collagen vascular diseases / General medical comorbidities contraindicating a general anaesthesia
- Patient with chronic health problems (diabetes / diabetes mellitus, heart disease, lung disease, circulatory system conditions, uncontrolled hypertension, obesity with a body mass index over 40)
- Patients with neurologic, vascular, or connective tissue disorders of the upper extremities
- Poor psychological and/or physiological condition
- Pregnancy
- Patient with very little fat to remove

- Recent surgery (less than 6 weeks)
- Patient under 18 years of age
- Patient not having the ability to understand the consequences, implications and risks related to the treatment
- High body temperature (pyrexia).

4. Possible complications

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

4.1 Possible complications due to anaesthesia

During the consultation, the anaesthesiologist will personally inform the patient of the anaesthetic risks. Patients must be informed that anaesthesia sometimes induces unpredictable reactions in the body. 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 residual risk may be observed:

- **Breakage of the cannula**

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).
- **Cobalt impacts:** A stainless-steel alloy containing cobalt is used as a raw material used in the manufacture of one or more components of this device. Cobalt is a substance(s) defined as CMR 1B (carcinogenic, mutagenic, toxic to reproduction and/or have endocrine-disrupting properties) in a concentration above 0.1% weight by weight: CAS No. 7440-48-4; EC No. 231-158-0

• **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.

• **Nickel allergy:** Hypersensitivity to nickel.

• **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

edness: 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. Cleaning and sterilisation

The Euromi reusable cannulas are supplied in a non-sterile condition and must be cleaned and sterilised before they are used.

The health facility must ensure that the combination of cleaning and sterilization used produces devices that are safe for surgery.

Automatic cleaning is not recommended for Euromi reusable cannula.

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.

• Cover the devices with a wet cloth.

• Other devices should be covered and transported with the cannula but cleaned and sterilised according to the instructions stated in their respective instructions for use.

• 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 that the organic materials dry up. The cleaning of the cannula cannot be guaranteed if the time between the use and the treatment is longer than 30 minutes. Discard the device if the allotted time is exceeded.

• Place soiled devices in a sealed bag or in a containment device for the transport to the decontamination area.

• Take the necessary precautions to avoid damaging the device.

2. Preparation of the cleaning solution:

• Wear personal protection equipment if necessary 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 since the active ingredient is corrosive for stainless steel.

• Cleaning 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:

• Fully immerse the device in a minimum of 5 L of cleaning solution that has been prepared in advance (increase the volume of water if the device is not totally immersed), respecting 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. Manual cleaning:

• Fill a container or sink large enough to fully immerse the device with a minimum of 5 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.

• 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 during the contact time recommended by the manufacturer. If no contact time is specified, immerse the device for 15 minutes.

• After the immersion time, externally clean the device in the cleaning solution. To do this, brush the external surfaces and the threads with a soft bristle brush (such as brush reference 09478 from

STERILMED®) for at least 2 minutes or until there are no more visible stains in the outer area of the cannula.

• Clean the cannula holes using a soft nylon bristle brush until all visible debris has been removed.

• Rinse each hole of the cannula for 10 seconds with a washing sprayer (such as the washing sprayer/ medical Selecta spray) and using running water at a temperature between 45°C and 55°C (113-131°F).

• *For aspiration / harvesting cannulas only:* Brush the inside of the cannula using a soft nylon bristle brush, of appropriate size* for each diameter and length of the cannula tube in the cleaning solution for at least 2 minutes or until no more signs of dirt are visible. Rotate the cleaning brush 3 times at 360°C, when it is at the end of the cannula.

see the table of diameters of the internal cleaning brush - part* **10. Information on the cleaning validation.

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

• Brush the holes on the cannula again.

• Dilute the cleaning solution in an ultrasonic bath that is large enough to immerse the device completely. Immerse the cannula and active the ultrasound for 15 minutes at 40-45 kHz.

• Remove the cannula from the ultrasonic bath and rinse carefully under running tap water for at least 2 minutes. Use a syringe to rinse the inside of the cannula with 60 ml of clean water.

• Prepare a second ultrasonic bath with a new dilution of cleaning solution. Immerse the cannula and active the ultrasound for 15 minutes at 40-45 kHz.

• Remove the cannula from the ultrasonic bath and rinse carefully under running tap water for at least 2 minutes. Use a syringe to rinse the inside of the cannula with 60 ml of clean water.

• Prepare an ultrasonic bath with clean water. Immerse the cannula in the ultrasonic bath for 15 minutes at 40-45 kHz.

• Remove the cannula from the ultrasonic bath and use the syringe to rinse the inside of the cannula with 60 ml of clean water at least 3 times.

• Rinse the cannula thoroughly using hot running water from the tap for at least 3 minutes.

PHASE	STEP	TIME (MINUTES)	TEMPERATURE	TYPE OF DETERGENT AND CONCENTRATION
DECONTA-MINATION	Immersion	15:00	30-40°C (86-104°F)	Miltex® EZ-Zyme® *
	Rinsing	02:00	30-40°C (86-104°F)	N/A
MANUAL 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® *
		00.10	45-55°C (113-131°F)	N/A
	Internal Cleaning *(aspiration cannula only)*	02:00	45-55°C (113-131°F)	Miltex® EZ-Zyme® *
	Ultrasonic bath	15.00	45-55°C (113-131°F)	Miltex® EZ-Zyme® *
		02:00	45-55°C (113-131°F)	N/A
		15.00	45-55°C (113-131°F)	Miltex® EZ-Zyme® *
		02:00	45-55°C (113-131°F)	N/A
		15.00	45-55°C (113-131°F)	N/A
RINSING		03.00	45-55°C (113-131°F)	N/A

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

5. Drying

• Dry the inside of the cannula using a compressed air blower fitted with a sterile filter.
• Carefully dry the inside of the cannula using a clean lint-free cloth.

6. Inspection:

• Use a magnifying glass (10x to 15x) to inspect the cannula and each hole on the cannula to check for any dirt remaining on the device.
• Repeat the cleaning procedure if any dirt is still visible.
• Perform a visual inspection to check for any signs of damage and/or wear. Discard the cannula, if there are any signs of wear, cracking or corrosion or if the cannula is bent, broken or deformed.

7. Packaging:

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

8. Sterilisation:

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

TYPE OF CYCLE	ADJUSTMENT TEMPERATURE	EXPOSURE TIME	DRYING TIME (MINIMUM)	COOLING TIME (MINIMUM)
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).

9. Storage and transport:

The cannulas must be transported in their original packaging. After cleaning and sterilisation, the cannulas must be transported in their double packaging, dry, and protected from dust and harm.
• The reusable cannulas must be kept in a clean, dark, and cool location under controlled cleanliness conditions (the walls, ground, ceilings and storage area must be smooth and easy to clean and disinfect), away from dust and harm.
• To prevent condensation from forming on the cannulas, significant fluctuations in temperature should be avoided during the storage.
• To avoid any risk of chemical contamination, storing chemical products with the cannulas is prohibited.
• The authorised storage time will depend on the sterile barrier system used and the storage conditions. The length of storage must be established by the competent authority at the hospital. In all cases, the length of storage at the client may not exceed 2 years or 200 uses.

10. Information on the cleaning validation:

The validation was performed using the following equipment:

Water sprayer	Washing sprayer/medical Selecta spray
External cleaning brush	Cleaning brush, reference no. 09478 STERILMED®

Internal cleaning brush	Cleaning brush, reference no. 24.098 STERILMED®
Packaging	Cardinal Health® Convertors® Bio-Shield® - supplier reference no. 4040
Sterilizer	Model: SMA 59/125 SP; Manufacturer: BBC; Capacity: 432 L

The Euromi reusable cannulas have been subject to cleaning studies that show that extractants do not leach harmful materials, or particulates into infiltration solutions from the reusable cannulas.

Internal cleaning brush recommended by cannula :

Diameter	Internal cleaning brush recommended
2	BR.18.087 STERILMED®
2.5	BR.18.105 STERILMED®
3	BR.18.125 STERILMED®
3.5	BR.18.125 STERILMED®
4	BR.18.197 STERILMED®
4.5	BR.18.197 STERILMED®
5	BR.16.236 STERILMED®

Comments:

- *The length of the cannula does not influence the recommended internal cleaning brush.*
- *The internal and external cleaning brushes must be cleaned according to the recommendations of the brush manufacturer.*

7. Use of the medical device

7.1 General

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 postoperation.

Euromi reusable cannulas 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, the cannula can be connected to an evamatic®, to a syringe or a manual handle. The **Euromi reusable cannula must not be cleaned and sterilised more than 200 times**.

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

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

• The cannula is most often damaged in the areas of greatest pressure (such as the holes, notches, etc.). If you have any doubts about the integrity of the cannula, use a magnifying glass (10x to 15x) to inspect the cannula, the tip and each hole on the cannula.

• Make sure that the size, model, diameter and length are appropriate for the procedure required.
• The cannula should be handled carefully and with caution.

• Before installing the cannula, the cannula monitoring form must be completed.

• Do not use the cannulas if they are damaged.

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

• A bent cannula cannot be straightened without breaking so must be discarded.

• Do not exert excess pressure on the cannula.

• Handle the cannula **under conditions of asepsis**.

• Do not use this type of cannula on a patient with HIV; use a single-use cannula.

• 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.

• The Euromi reusable cannulas must only be connected to a device from the Euromi medical device range (the evamatic® or the manual handle provided by Euromi).

• The user shall be responsible for the use of any accessories other than those supplied by Euromi S.A. These accessories do not comply with the requirements of the Euromi reusable cannulas.

• eva® system and evamatic® instructions for use must be examined prior to use for warnings and instructions for use.

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

• Disposables associated with cannulas are for single use only (Air tubing, fat tubing, perfusion line, syringes, N.L.F.® Kit…)

• 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 users must be trained in safe and effective use.

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

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

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

• **Cannulas must be decontaminated before they are discarded.**

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

• The "Monitoring the use of the cannula" form must be completed before each use and kept until the end of the life of the device. It will be requested whenever a cannula is returned.

The life of a cannula is 2 years following the receipt of the cannula **or 200 uses.**

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 vacuum is -0.9 bar maximum.

For tumescent liposuction, Euromi S.A. cannulas have been validated with 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 lidocaïne 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.

7.2 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* (see part 7.1) 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**.

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**.

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.

7.3 Installation of the cannula

The cannula can be connected to a:

• Pneumatic handpiece (evamatic® ref. 1101EKL5)(1) combined with a aspiration / harvesting machine (evasp® range).

• A handle (or manual handpiece)(2).

(1)

(2)

• Connection to evamatic®

1. Inspect the handpiece, the evasp® control unit and the canulas, to identify any damage, corrosion or any sign of excessive wear and tear.

2. Remove the mobile end (nose) of the evamatic®.

3. Install the cannula (1) manually screw the cannula on to the evamatic® without forcing it (it should screw on very easily). Then use the wrench to check it is screwed on tightly.

4. For infiltration / injection cannulas (2), connect the perfusion line to the luer end.

5. Connect the tubing according to the user instructions for evamatic®

(1)

(2)

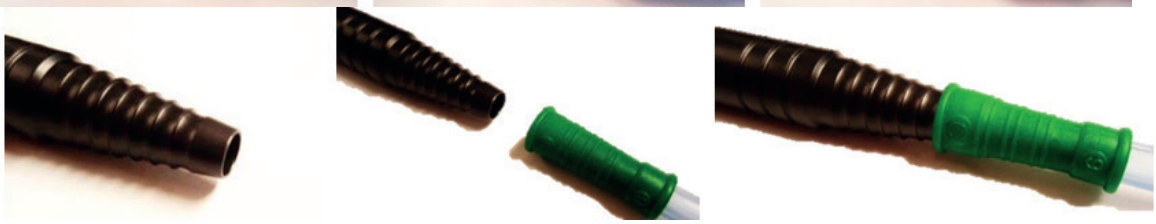
• Connection to a handle

1. Manually screw the cannula on to the handle.(1)
Then use the wrench to check that it is screwed on tightly.

2. Then, insert as far as possible the aspiration / harvesting piping (fat tubing) to the handle connector.(2)

(1)

(2)



7.4 Dismantling of the cannula

Unscrew the cannula from its bracket. A wrench can be used to facilitate the disassembly.

8. Disposal

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

• **Non Infectious Clinical Waste:** such waste includes packaging, medical devices not used and not contaminated.

• **Infectious and Medical Waste:** they include tubing, contaminated cannulas, contaminated devices. They are to be disposed of according to the appropriate channel to prevent any contamination.

Disposal must be disposed of in accordance with the national legislation in force.

9. Medical device vigilance cases

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 a cannula must be reported immediately to the competent authorities and to Euromi S.A. at the email address: **materiovigilance@euromi.com**.

10. Handling returns

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

11. 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. Pay attention on to the lifespan of cannulas - 2 years following the receipt of the cannula or 200 uses.

If our product is defective, despite the meticulous manufacturing process, please contact Customer Services - info@euromi.com.

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 / sales 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

12. 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 Euromi reusable cannulas 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.

MONITORING THE USE OF THE CANNULA

Stick the traceability label here

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Remember, **the life cycle of a cannula is 200 procedures OR 2 years from the date of receipt.**

Beyond this time, EUROMI S.A. shall not be held liable for any use of the cannula.

Consequently, cannulas must be replaced after this time, even if the required number of procedures has not been reached.

If you have any queries about the condition of the cannula, contact our technical department before you use the cannula.

Visually inspect each cannula before use.

Discard the cannula if there are any signs of wear, cracking, corrosion, or if the cannula is bent, broken or deformed.

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

This form will be requested whenever a cannula is returned.

Medical device


Read the user instructions carefully

Batch number

Non-sterile

Identification of notified body responsible


Date of manufacture


Name and address of manufacturer


Presence of CRM substance (Cobalt)


Warning

Commercial reference

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 Euromi reusable cannulas are intended to be used for:

Medical intended purposes:

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

Non-medical intended purposes:

• **Lipoinfilration:** Infiltration of tumescent solutions to facilitate the removal of tissue and/or fluid during aesthetic procedures.
• **Liposuction:** The removal of tissue and/or fluid from the body during aesthetic 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 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 a cannula 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 patient 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 residual risk may be observed:

• **Breakage of the cannula**

The following complications may be observed:

• **Breakage of the cannula**

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).

• **Cobalt impacts:** A stainless-steel alloy containing cobalt is used as a raw material used in the

manufacture of one or more components of this device. Cobalt is a substance(s) defined as CMR 1B (carcinogenic, mutagenic, toxic to reproduction and/or have endocrine-disrupting properties) in a concentration above 0.1% weight by weight: CAS No. 7440-48-4; EC No. 231-158-0

• **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.

• **Nickel allergy:** hypersensitivity to nickel.

• **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.

Euromi

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