INSTRUCTIONS FOR USE

Air & Fat tubings

Euromi

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1. Medical device presentation

1.1 General

These instructions for use describe the procedures for using the Air and Fat tubings safely. The devices are only to be used by appropriately qualified health care professionals.

The Air tubing is a class Is non-invasive medical device. Fat tubing is a class IIa non-invasive medical device.
The tubings are sold sterile after dry heat sterilization. They are for single use and single patient. They must not be re-used or re-sterilized under any circumstances.

Air and Fat tubings are packaged in a single-use double package to ensure a double microbiological barrier and guarantee its sterility until use.

1.2 Composition

The Air tubing is composed of : tubing PVC.

The Fat tubing is composed of : tubing PVC and PVC components.

The devices do not incoporate :

- Medicinal or biological substances
- Natural rubber (latex)

2. Medical purpose / Indications / Benefits

This tubing is intended to be used exclusively as an accessory with EUROMI devices and is designed to support the transfer of air or adipose tissue during the intended procedure. It has no standalone medical purpose, and shall be used in accordance with the instructions for use of the corresponding EUROMI device.

3. Contraindications

No specific contraindications are associated with this tubing when used as intended; the contraindications of the EUROMI device and the related procedure remain applicable, and for complete information, please refer to the instructions for use of the corresponding EUROMI device.

4. Possible complications

No specific complications are associated with this tubing when used as intended; complications, if any, are related to the EUROMI device and the associated procedure. Please refer to the instructions for use of the corresponding EUROMI device for further information.

5. Use of the medical device

5.1 Warning

• Tubings should be transported and stored in their original double packaging, in a dark, dry place, protected from dust and pests.

• Keep in original packaging.

• Check the integrity of the double packaging. NEVER use a device with damaged packaging. Sterile product as long as packaging has not been opened, damaged or punctured.

• Tubing must not be used if damaged, dropped or subjected to impact.

• Do not use this product after the expiration date indicated on the packaging.

• Handle tubing aseptically / Wear gloves when handling tubing.

• Handle tubing with care.

• Connect the tubing to Euromi devices only.

• Euromi S.A. is not responsible for the use of any other air source than medical or compressed air.

• Liposuction is a genuine surgical procedure which can only be performed by a competent, qualified operator.

• Regularly check the tubing and connections for leaks.

• Do not exert excessive traction on the tubing before, during or after use. Excessive traction may cause liquid in the tubing to leak out.

• Do not re-sterilize. Re-sterilization may cause significant degradation of mechanical properties.

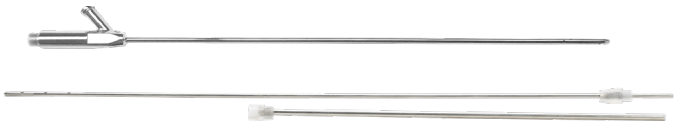
• Do not reuse. Re-use of the device may increase the risk of infection or other device malfunctions.

• This product is a device which may be contaminated after use. Handle and dispose of it together with other contaminated devices in accordance with established medical protocols and other applicable regulations.

Euromi S.A. is not responsible for any use of the device other than the one foreseen in this instructions for use

5.2 Devices used in combination with Air and Fat tubings

Description	Photo	Class
Evamatic® The evamatic® is a device (pneumatic) used to collect or reinject fat cell thanks to the technique N.I.L.®		IIb

Evasp® range The evasp® range is a complete range of devices to assist the practitioner during an intervention (Regulation of the supply of compressed air, aspiration, infiltration...).	 Evasp® 1 Evasp® 2 Evasp® 6 Evasp® 7	IIb
Reusable cannula **Sterile single-use cannula and crossing-tube**		IIa

5.3 Installation and use of the Air and Fat tubings

Installation

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

• **Install** the Evasp® according to the instructions given in the corresponding instructions for use.

*** FAT TUBING**

WITH EVAMATIC® :

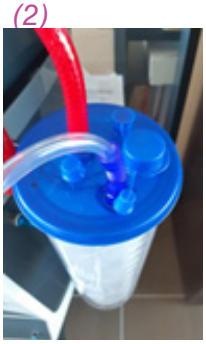
• Connect **the white funnel** of the fat tubing **to the central axis of the evamatic.** *(1)*
The recommended air pressure is as following:

- For aspiration / harvesting: 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.

• Fully insert **the blue funnel** of the fat tubing i**nto the PATIENT connector** of the Evasp® System fat canister. *(2)*

(1)

(2)



WITH MANUAL HANDLE:

• Connect **the white funnel** of the fat tubing directly to the handle.

WITH FAT/CANNULA ADAPTER

• Screw the **fat adaptor** on the Evamatic® or on manual handle.

• Connect **the white funnel** on the tip of the adapter.

• Screw **the cannula** on the adapter

*** AIR TUBING**

• Disconnect the two air tubings on each side.

• Connect **small-diameter air tubing to the (IN) plug of the Eva Sp® and to the I connector of the Evamatic®.**

• Connect the **larger diameter air connector to the (OUT) plug of the Eva Sp® and to the O connector of the Evamatic®.**

Disassembly

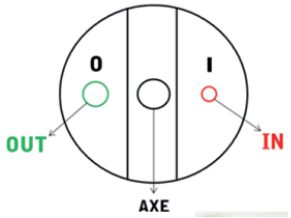
• Set the Evasp® switch to OFF. The light on the switch is now off.

• Remove the air supply hose from Evasp® and the compressed-air source socket by pressing on the blue ring.

• Disconnect the Air tubing from the IN port and OUT port.

• Disconnect the Fat tubing from the central port.

• Disconnect the pedal and tubing by pressing on the blue ring.



6. Disposal

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

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

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

The Air and fat tubings must not be disposed of with public or communal waste.
The device must be disposed of in accordance with current national legislation.

7. Transport and storage of the medical device

The Air and Fat tubings must be transported and stored in their original double packaging, away from light, in a dry place, protected from dust and pests.

To prevent condensation from developing on the Air and Fat tubings, large temperature fluctuations should be avoided during storage.
The Air and fat tubings must be stored at a temperature between 0°C and 40°C.

To avoid any risk of chemical contamination, the storage of chemicals with the Air and fat tubings is prohibited.

The shelf life of the product is 5 years. It is imperative to check the expiration date of the device on

the traceability label before use.

Storage conditions:

8. Resterilization and reuse

The Air and Fat tubings are supplied sterile and are for single use only. Any reuse of an Air or Fat tubing is strictly forbidden.

Any reuse of an Air or fat tubing may result in serious clinical complications, including death. Similarly, any resterilization of an Air or Fat tubing is formally forbidden, as it causes a significant deterioration in its mechanical properties.

9. Materiovigilance case

Any incident or risk of a serious incident which has led or could lead to the death or serious deterioration of the state of health of a patient, a user or a third party involving a Air or Fat tubing must be reported without delay to the competent authorities and to Euromi S.A. at the email address **materiovigilance@euromi.com**.

10. Handling returns

Products that are the subject of a complaint or that have caused an incident or risk of a serious incident must be reported and returned to the local Euromi S.A. material vigilance representative. Before returning the product to the manufacturer, it must first be decontaminated and disinfected (according to the procedures in force at the health care facility). The product should not be returned to Euromi S.A. if the patient is infected with HIV, hepatitis or if he/she is a known or suspected carrier of another infectious agent.

11. Guarantees and limits of guarantees

Euromi S.A. guarantees the Air and Fat tubings for a maximum of two years from the invoice date, or up to the product's expiration date, whichever comes first. Euromi S.A. guarantees that all products are supplied without any defects or malfunction.

If our product is defective, despite the meticulous manufacturing process, please contact the technical department.

The warranty applies if the defective product is presented during the guarantee period and if it is a defect coming directly from the manufacturer Euromi.

For more information, please contact the technical department at Euromi S.A. or consult our general sales conditions on our website.

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Medical device

Read the instructions for use carefully

Name and address of the manufacturer

Batch number

Commercial reference

Indication of notified body responsible

Warning

Single use product, do not use a second time

Do not sterilize a second time

Expiration. Do not use after the date indicated

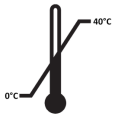
Date of manufacture

Product sterilized with dry heat, in double sterile packaging

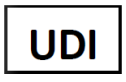
Keep away from light

Do not use if packaging is damaged

Keep in a dry place



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



UDI code

Fragile, handle with care

Vertical orientation

NOTES

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