

Warning: this IFU supplied by Juvaplus SA along with the Lipopen and its consumables is to be read in conjunction with the good assembling and handling booklet (quick start guide) relative to the usage and assembling of the Lipopen and its consumables.

Description

The Lipopen is a cordless and motorized injection system, non-sterile device intended to assist medical practitioners in injecting substances such as autologous fat, delivered in continuous flow of 3 different speeds or in boluses of 3 different sizes. Lipopen is compatible exclusively with its consumables, described hereafter.

The syringe holder (Lipolink) is a single-use sterilized consumable to be used exclusively in conjunction with Lipopen and not compatible with another device. It is compatible exclusively with Q-Ject Single Use Syringe 2-3mL Luer Lock.

The provided Q-Ject Single Use Syringe 2-3mL Luer Lock is to be used exclusively in conjunction with Lipopen and its syringe holder.

Lipopen is powered by a Lithium battery 6V/170 mAh. The Lipopen must be used with a certified battery IEC60086-4 only.

Precautions for use

Read the following instructions carefully and follow the proper safety measures.

- Only a qualified medical practitioner should use Lipopen.
- The use of Lipopen and the results thereof are the exclusive responsibility of the medical practitioner.
- Only the medical practitioner can evaluate the indications and contra-indications relative to the technique to employ, the product to be administered and the appropriate needle or cannula to be used.
- In all cases, the medical practitioner shall proceed only after having fully familiarized him/herself with both the product and its education material, including its instruction for use.
- Only the provided Q-Ject Single Use Syringe 2-3mL Luer Lock are recommended by the manufacturer. Do not re-use or re-sterilize the equipment. Discard immediately after use into a sharps waste container. Do not use if the package is opened or damaged.
- The syringe holder (Lipolink) is single-use only. Do not re-use or re-sterilize the equipment. Discard immediately after use into a sharps waste container. Do not use if the package is opened or damaged.

Adverse reactions and contra-indications

It is the medical practitioner’s full responsibility to read and follow the IFU in order to avoid any adverse reactions or complaints.

Possible side-effects and contra-indications can result from the use of products in conjunction with Lipopen (e.g. injectables, needles, cannula, etc.) It is the medical practitioner’s full responsibility to check and follow the instructions for use of any product used with Lipopen.

General recommendations

- Keep Lipopen and its consumables out of reach of children.
- The equipment cannot be used where there is an inflammable mixture of oxygen and nitrogen.
- Do not use Lipopen near equipment with emits electro-magnetic fields.
- Store Lipopen and its consumables away from heat, damp and sun exposure.
- Keep Lipopen and its consumables away from water and chemical products.
- Always check whether the device functions properly before use.

- If Lipopen is damaged, return to the manufacturer Juvaplus SA.
- Damage to Lipopen caused third-party consumables or batteries voids the warranty.
- The device must be turned off while changing the battery. Do not touch the user interface while inserting the battery.
- Do not sterilize any of the parts: device, syringe holder, syringe, battery.
- Wearing single-use gloves to use the equipment is highly recommended.
- No alteration of the equipment is allowed.
- Dispose of the consumables according to your local environmental regulations.
- Do not dispose of Lipopen. Return it to the manufacturer Juvaplus SA.

Cleaning

After each use, Lipopen must be cleaned with an adequate cleaning agent before reusing it. Do not immerse the device or its components in water.

We recommend using an appropriate cleaning product in accordance with your local regulation.

Handling conditions

It is recommended to store and transport Lipopen in its original packaging.

Operating conditions:	0-2000m
Temperature:	20°C to 25°C
Humidity:	60% RH at 30°C non-condensing

Transport and storage conditions	
Temperature:	-20°C to 40°C
Humidity:	60% RH at 30°C non-condensing

Assembly and use

Refer to the Quick Start Guide for assembly instructions.

- Attach the syringe to the Lipolink and connect them to the device.
- Press the On/Off button. The green light indicates that the device is switched on. When the light turns orange, change the battery. When the lights turns red, the device can power off at any time.
- Select the mode (M1 or M2) and delivery type (flow or bolus) and set-up the delivery speed or bolus size.
- The injection is performed by pressing either the lever of the Lipolink.
- After use, select the rewind mode and activate it by pressing the lever of the Lipolink. The screw will retract back to its initial position.
- Detach the assembled needle/cannula, syringe and Lipolink and dispose of them accordingly.
- Switch off the device using the On/Off button. Alternatively, the device will turn off automatically after 4 minutes of inactivity.

Warranty

The warranty for Lipopen is 24 months from date of purchase from manufacturer.

Controls and indicators



Activation
On/Off power button and battery charge level
Flow mode: slow, medium, fast
Bolus mode: slow, medium, fast
M1: Viscous mode / M2: Fluid mode / Rewind

Legends



Manufacturer



Reuse is not allowed



Manufacturing site



Temperature limitation



Lot Number



Non sterile



Serial Number



Read usage instructions



Catalogue Number



Keep dry



Caution, consult documents



Do not expose to sunlight



Sales

MDMS SA
Av. Miremont 12
CH-1206 Geneva

Manufacture



Juvaplus SA
Maladière 71C
CH-2002 Neuchâtel