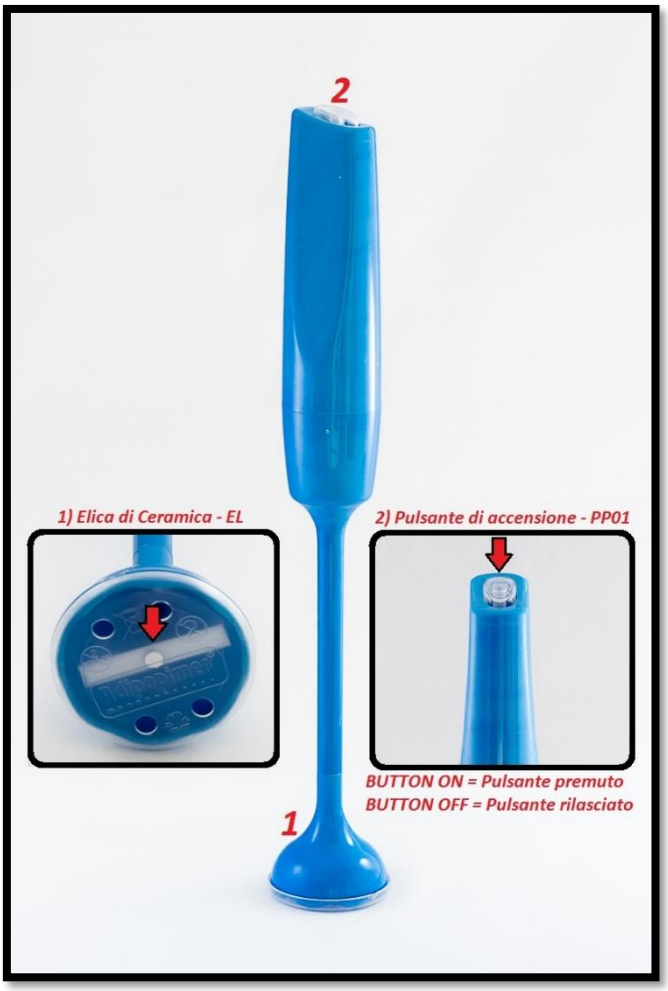
Instructions for use



1) Ceramic Blade - EL;
2) ON/OFF Button - PP01: BUTTON ON = Button pressed; BUTTON OFF = Button released.

Description

Adipopimer® is a disposable, sterile, battery-powered, patented medical device equipped with a rotating blade.

Indications and applications

Adipopimer® fragments lipoaspirated adipose tissue, transforming lobular fat into a suspension of single cells and small clumps of cells. **Adipopimer®** must only be used in a surgical environment, and the surgeon's experience and the surgical technique adopted must be borne in mind.
The device has no applied parts. During its normal functioning, it never comes into contact with the patient. Normal use of the device requires only the presence of the operator (surgeon or highly trained medical personnel).

Contraindications
None known.

Warnings / Precautions / Interactions

- **Adipopimer®** is to be used exclusively by ***surgical personnel*** or ***highly trained medical personnel.***
- Read the instructions carefully before using the device.
- The device is to be used only and exclusively for the purpose for which it was designed.
- Keep the device out of reach of children or incapable persons.
- Keep the device away from sources of heat.
- If the device falls into water, do not use it; consult a technician.
- Never open the device.
- Use only original Korpo accessories.
- Use the device in an air-conditioned environment.
- If the device does not operate when switched on, do not attempt to replace the batteries; contact the authorized distributor.
- If the device presents any visible anomaly when it is removed from its package, do not use it; contact the authorized distributor.
- No modification of the device, whether total or partial, is permitted.
- Use a 3 mm or 4 mm liposuction cannula to draw off the adipose tissue.
- Wash the adipose lobules thoroughly.
- Pour the lipoaspirate into a sterile container with a capacity of 150 mL or more.
- Only remove the cover from the bell-shaped head housing the ceramic blade immediately prior to use.
- Do not touch the ceramic blade with the hands.
- Do not run the motor without a load; operate the device only when the bell-shaped head is completely immersed in the lipoaspirate; this is done by keeping the ON/OFF button pressed.
- Move the head of the device up and down, avoiding contact with the bottom of the sterile container; the time required does not normally exceed 30 seconds. Fragmentation can be repeated in order to produce a cell suspension of smaller elements.
- The cell suspension can be injected superficially, in depth or intradermally with a syringe or cannula.
- The device is not impervious to penetration by liquids or solid dust particles (IPX0).

Note: operation of the device does not interfere with the functioning of other electrical equipment.
Note: the device can be used in proximity to other equipment.

Performance

To achieve a correct fragmentation, once you have removed the washing liquid, it is necessary to add to the lipoaspirate, 1/3 of lactated Ringer's or physiological solution's volume. It is also necessary to check that there are no long fibrous strands in the material to be fragmented. It is advisable to fragment amount of material less than 100 cc at a time.

Fragmentation transforms the lobular fat into a cell suspension. When smeared onto a histology slide, the suspension displays the presence of single cells or small clumps of cells. This reduction in size facilitates rooting of the graft.

When centrifuged at 400 rpm for 4 minutes, the suspension presents a thin layer of supernatant oil, which indicates that the adipocytes separated by the aspiration vortex created by the high-speed rotation of the ceramic blade have been only minimally damaged.

Centrifugation enables the stromal cells to be isolated and extracted from the unused material; these can be mixed into the suspension to be injected.

The operator must hold the device firmly in the hand and activate it by pressing the button at the top end of the device.

Warning: when the device is running, the operator must take great care to avoid being injured by the rotating blade.

Warning: the operator must use appropriate personal protection devices (protective glasses, mask, overall, disposable gloves) when using this device, as biological material may come into contact with the operator during the procedure.

Classification of the device

Device powered by internal batteries, without connection to the main electricity supply.

Device with an ordinary degree of protection against penetration by liquids and dust particles (IPX0).

Device sterilized with ethylene oxide.

Device suitable for continuous use.

Technical features of the device

Device powered by four internal AAA LR03 1.5V Alkaline batteries.

Device driven by an electric motor with the following technical characteristics:

MODEL		VOLTAGE		NO LOAD		AT MAXIMUM EFFICIENCY					STALL		
		OPERATING RANGE	NOMINAL	SPEED	CURRENT	SPEED	CURRENT	TORQUE		OUTPUT	TORQUE		CURRENT
		V		r/min	A	r/min	A	mN·m	gcm	W	mN·m	gcm	A
FF-260PA	3057	1.5 – 3.5	2.4	7800	0.15	6790	1.01	2.39	24.3	1.69	18.4	188	6.75

Sterility

Adipopimer® is sterilized by means of ethylene oxide (EO); do not re-sterilize it. Do not use the device if the package has been opened or damaged. If the product has been opened and left unused, it should be eliminated.

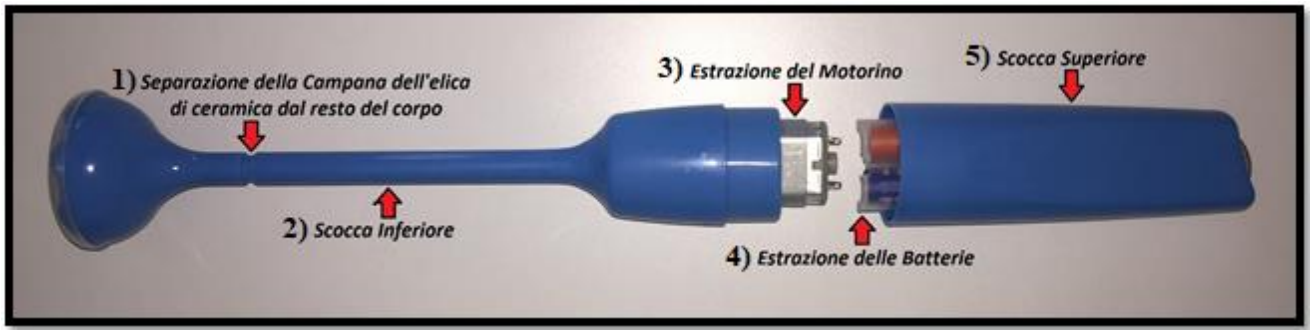
Conservation transport and conditions of use
Conserve and transport the device with care; keep away from humidity and sources of heat. Do not use the device after the expiry date.
The device contains alkaline batteries, which, if not used for a long time, may leak: ***do not use the product after the expiry date.***

Storage/Transport:
-20°C ÷ + 70°C
10 ÷ 100% relative humidity, no condensation
860 ÷ 1060 hPa

Normal use:
+15°C to +35°C,
45% to 75% relative humidity, no condensation
at 860 hPa – 1060 hPa

Disposal of the device
Replace the cover on the bell-shaped head housing the ceramic blade.
Separate the upper and lower sections of the case by applying slight flexion at the joint between the two (Fig. 1 - Disposal of the device).
Detach the bell-shaped head from the rest of the body by applying slight torsion at the joint (Fig. 1 - Disposal of the device).

Fig. 1 - Disposal of the device



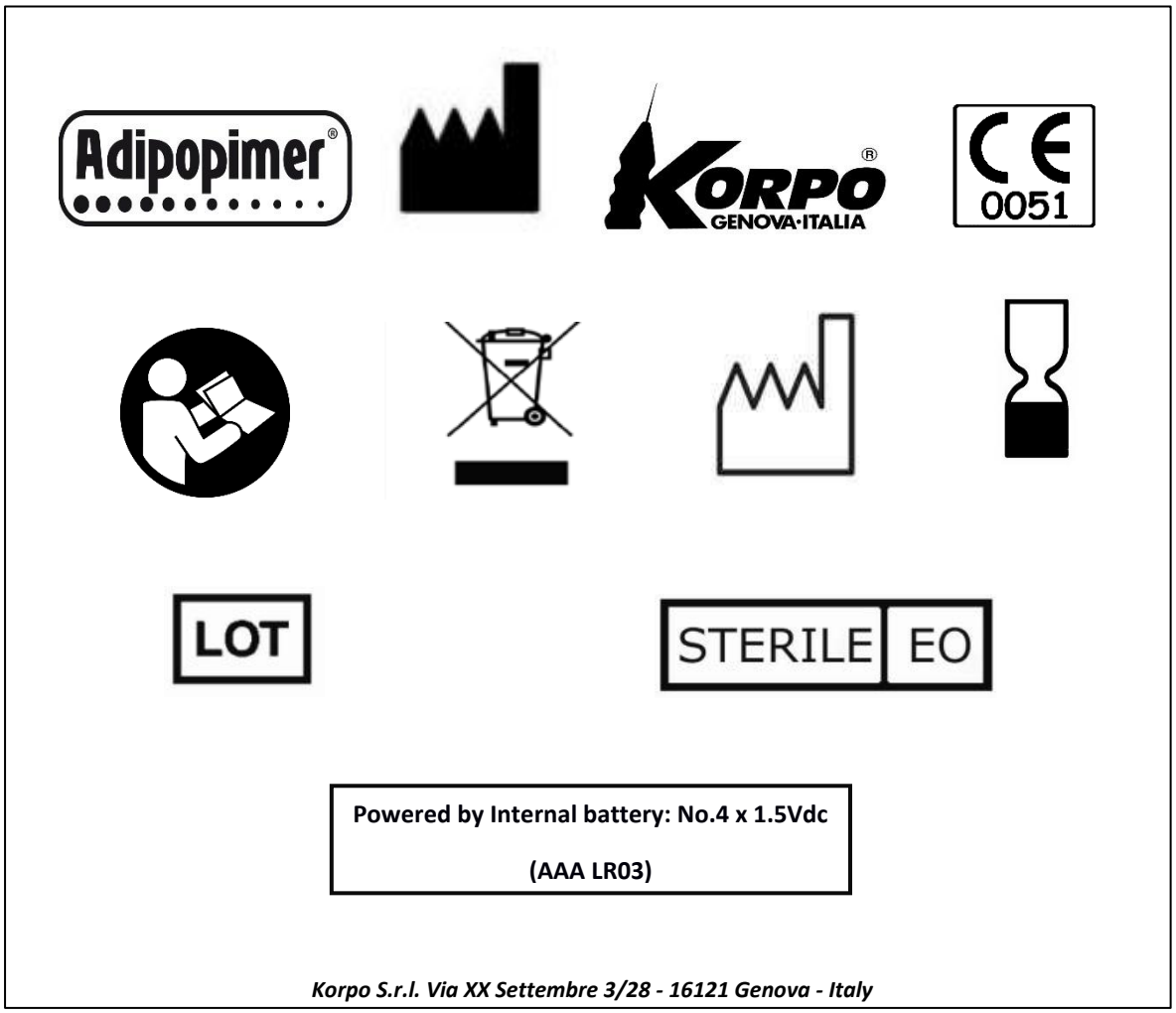
1) Separate the bell-shaped head from the rest of the body;
2) Lower section;
3) Remove motor;
4) Remove batteries;
5) Upper section.

The batteries, motor, plastic components and bell-shaped head housing the blade must be disposed of in the appropriate waste-disposal containers.

After use, the device is biologically contaminated. Take care to dispose of it properly, using only containers for the collection of biologically contaminated and dangerous materials.

Produced by Korpo S.r.l., Via XX settembre 3/28 - 16121 - Genoa, Italy - Tel. +39 (0)10 5535006; Fax +39 (0)10 566968; email: info@korpo.com - www.korpo.com - **patented**.

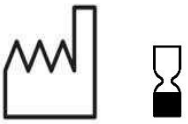
Label



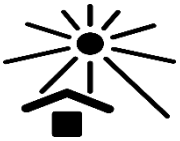
Symbols used on the label

Disposable

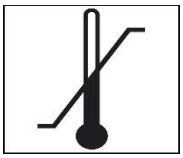
Do not re-sterilize



To be used by the year and month indicated

STERILE EO	If the package has not been opened or damaged, the product is sterile. Method of sterilization: ethylene oxide.
CE 0051	CE mark and identity number of organism notified. The product complies with the essential requirements of CEE Directive 93/42 on Medical Devices
Powered by Internal battery: No.4 x 1.5Vdc **(AAA LR03)**	Type and number of batteries used to power the DM
	Refer to instruction manual
LOT	Lot number
RoHS	RoHS
	Read the illustrative leaflet carefully
	Keep dry
	Do not expose to the sun
	Electrical and electronic equipment waste (RAEE) - Separate collection and subsequent disposal in accordance with current regulations

Recyclable waste



Temperature limits