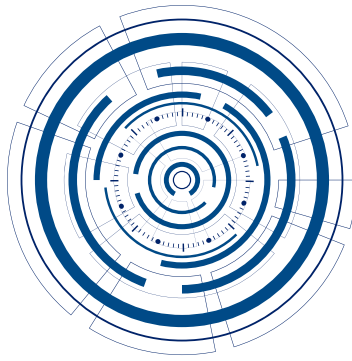




CHEMOEXFOLIATION ENERPEEL® EL



INFORMED CONSENT FORM

MEDICAL DEVICE FOR THE SKIN EXFOLIATION AND REMODELLING OF THE PERIOCCULAR AND PERIORAL AREAS

1. INTRODUCTION

The ENERPEEL® EL Device meets the requirements of Directive 93/42/EEC, 47/2007/EC and subsequent amendments/integrations regarding Medical Devices.

2. DEFINITIONS

ENERPEEL® EL is a Device made up by a single-phase gel (pH ~ 0.90) with a specially formulated acid blend base (lactic acid and trichloroacetic acid) indicated for the cutaneous exfoliation and remodelling (chemical peeling) of the periocular (including the eyelids) and perioral (not including the vermillion) areas.

The ENERPEEL® EL Device is designed to perform multi-layer applications (up to 4 layers are recommended) in a single treatment on each cutaneous area.

ENERPEEL® EL is a Device that can perform chemical-exfoliation (chemical "peeling") which can be defined as superficial (which involves the horny layer and the vital portion of the epidermis down to the basal layer) in relation to the exposure time before the neutralization process and the subjective response of each individual patient.

However, it cannot be ruled out that it may become a medium-depth peel (involving the papillary portion of the dermis) depending on the number of layers applied, the contact time, the number of treatment sessions previously performed, the time interval between one treatment session and another, the patient's genetic-ethnic characteristics, phototype and skin type.

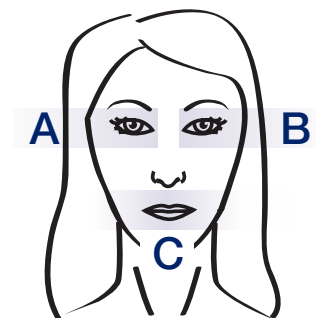
IMPORTANT WARNINGS

- In case of "frosting" formation, depending on the number of layers applied, the contact time, the number of treatment sessions previously performed, the time interval between one session and another, the genetic-ethnic characteristics, the phototype and skin type, proceed immediately with the neutralization using the appropriate NEU Neutralizer wipes.
- The delivery Device (TebiPen™) comes with disposable applicator tips, intended for a single patient and for a single session. The package contains 20 disposable applicator tips to be used for up to the same number of sessions
- The Device can only be used within the expiry date shown on the packaging.

Cutaneous area

The periocular and perioral application areas have been arbitrarily divided into the following cutaneous portions.

CUTANEOUS UNIT	DESCRIPTION
A	Patient's right periocular area
B	Patient's left periocular area
C	Perioral area



3. PURPOSE OF THE TREATMENT USING THE ENERPEEL® EL MEDICAL DEVICE

ENERPEEL® EL is indicated for performing a chemoexfoliation able to eliminate damaged keratinocytes and induce the formation of new epidermal cells, therefore preventing the development of a pathologies related with photo exposure (actinic damage, actinic keratosis etc.).

WARNING: ENERPEEL® EL MUST ONLY BE APPLIED TO UNBROKEN SKIN.

4. USAGE PROCEDURES

ENERPEEL® EL is a medical Device indicated for cutaneous exfoliation and remodelling (chemical peeling) of the periorcular (including the eyelids) and perioral (not including the vermillion) areas.

Chemical exfoliation, that is, the removal followed by the regeneration of epidermal cells, exerts a specific action of prevention, control, therapy or attenuation of some skin pathologies.

Cutaneous damage of actinic nature

- actinic keratosis*
- solar elastosis*
- solar lentigos*
- dermatoheliosis*
- alterations of pigmentation*

Hyperpigmented lesions

- melasma*
- post-inflammatory hyperpigmentation*

Other indications

- superficial scars*
- radiation keratosis*
- acne scars*
- plantar warts*
- loss of skin tone*
- wrinkles*
- photo and chrono-ageing*

5. EXCLUSION CRITERIA - WHEN NOT TO PERFORM CHEMICAL "PEELING"

- Incidence and/or history of viral infections caused by Herpes simplex in the area to be treated.
- Recent (in the last 6 months) surgery (blepharoplasty, eyelid lifting, etc.).
- Immuno-depressive diseases and treatments in progress.
- Previous radiation therapy of the portion of the cutis to be treated that could compromise the physiological regeneration of the cutis.
- Family history with the development of keloids and/or hypertrophic scars.
- Family history with the development of post-inflammatory hyperpigmentation.
- Pregnancy.
- Breastfeeding.
- Allergy and/or known hypersensitivity or any other known and/or probable incompatibility to one or more of the components.
- Other medical considerations.

IMPORTANT WARNINGS

- Avoid performing the treatment in very sunny seasons. Solar radiation may trigger hyperpigmentation.*
- Smoking can influence the result of the treatment, it increases the risk of scars and accelerate the formation of lines.*
- Phototypes IV, V and VI on the Fitzpatrick scale are at a higher risk of developing hyperpigmentation in the treated areas. Phototypes I, II, III are more susceptible to developing erythema and scars.*
- Herpes infections are more likely to develop, especially in the perioral area.*
- Injectable, fillers and botox based treatments should be performed only after the complete course of treatments with the Device.*

6. TREATMENT PROCEDURE USING THE ENERPEEL® EL MEDICAL DEVICE AND WARNINGS

The treatment performed with ENERPEEL® EL consists of three main stages:

- Delipidation
- Application of the chemoexfoliation solution
- Neutralization

IMPORTANT WARNINGS

- Depending on the patient's skin type, photo-type, the genetic-ethnic characteristics, the number of previously performed sessions, the contact time of the gel and the individual's response,*

during the application phases of the Device, "frosting" may occur: in order to modulate the desired depth of treatment, the area must be neutralized immediately after the appearance of the first whitish spots. The pre-treatment of the skin with the preparations based on alpha-hydroxy-acids (AHA), beta-hydroxy-acids (BHA) and/or substances with keratolytic activity could determine an increased irritative response of the skin to the Medical Device ENERPEEL® EL.

- The chemical "peeling" process thins the surface layer of the skin. For this reason, the natural barrier functions of the skin will be altered and the skin response to future treatments could be amplified. The doctor must be particularly careful when performing successive chemical "peeling" procedures.*
- Advise the patient to keep his/her eyes always closed during the entire treatment.*
- Apply the gel being sure to maintain a distance of 1-2 mm from the edge of the upper and lower eyelashes and from the edge of the vermillion. Always close the applicator with the cap after each use.*
- Throughout every application phase involving the spreading of the gel, it is very important to distribute the gel evenly; this can be performed using the applicator with which possible accumulations of gel are spread in a uniform way onto the entire cutaneous unit.*
- Each session should consist of up to 4 layers of gel. However, it is up to the doctor to decide whether or not to apply all 4 layers of gel, depending on the patient's different cutaneous reactions.*
- During the application the intervals of time between one layer and another and the contact time of the gel with the cutis after the last application, before the neutralization, can be increased at doctor's discretion, keeping in mind their own personal experience in performing the chemical "peeling" process using the ENERPEEL® EL Device, or decreasing the time based on each individual patient's cutaneous reactivity. Whenever the patient feels excessive pricking sensations it is recommended to reduce application times of the exfoliant gel and/or the number of applied layers.*
- The neutralization procedure is a very important step in controlling the intensity of the chemical "peeling" and must be performed effectively by applying the NEU Neutralizer wipe repeatedly, exerting a perceptible amount of pressure on the treated cutaneous area for a few seconds.*
- Block the cartridge turning it clockwise, remove the single use applicator and close the TebiPen™ with the cap after every single use. The cartridge containing the exfoliant gel must not be removed until complete depletion.*

7. DURATION OF A SINGLE TREATMENT

The layers and application times of the ENERPEEL® EL Device on the selected skin unit/s, before the neutralizing procedure, depend on the phototype, the degree of photo-ageing and/or chrono-ageing, the number of treatment sessions previously performed, the time intervals between one session and another, the patient's genetic-ethnic characteristics, skin type and on the subjective reactivity of the patient which must be carefully monitored and evaluated by the physician during the treatment procedure.

8. ESTIMATED NUMBER OF SESSIONS NECESSARY TO REACH THE PURPOSE OF THE TREATMENT

The session with ENERPEEL® EL is made up of four procedures (treatments), to be performed at 7-14 day intervals. We recommend a yearly cycle of two sessions.

The procedure with ENERPEEL® EL is normally carried out by applying four layers on each of the selected cutaneous areas.

Each Cartridge of ENERPEEL® EL contains enough gel for 83 applications of 0.15 ml each. The content of each cartridge is enough for 7 multilayer procedures – 4 layers (treatments).

9. POSSIBLE SIDE EFFECTS

Manifestations that may appear during, immediately after or in the post-treatment phase depend on various variables, such as the depth of the chemical "peeling", the patient's phototype, genetic-ethnic characteristics, skin type (thick, thin, keratotic, etc.), the subjective response of each individual subject, and include mainly:

- oedema
- erythema
- flaking
- pigment variations
- other irritating reactions.

ENERPEEL® EL induces a sensation of prickling/burning that tends to reach a peak of intensity after the first 2-3 minutes and then remains constant during the following minutes until disappearing after neutralization.

During treatment, the patient must:

1. keep eyes and lips closed;
2. not wear contact lenses;
3. have clean, cleansed and make-up-free skin.

1. Avoid exposure to the sun and UVA and UVB lamps. The patient must always use an adequate protection against sun and artificial light (solar protection factor 50+, according to the COLIPA method).
2. For preventive purposes, apply products capable of diminishing the biosynthesis process of melanin.
3. For maintenance purposes, apply products capable of increasing the skin elasticity and moisture level.
4. Delicately cleanse the treated area, avoiding any kind of rubbing.
5. Avoid using pharmaceuticals and/or cosmetics without first consulting the Physician.

The Patient was given the opportunity to ask questions and these questions were answered exhaustively.

Date / /

Surname _____
(in block letters)

Patient's signature _____

Date / /

Surname _____
(in block letters)

Patient's signature _____

The Patient was given the opportunity to ask questions and these questions were answered exhaustively.

Date / /
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Surname _____
(in block letters)

Doctor's signature _____



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