CHEMOEXFOLIATION

ENERPEEL®

CE 0373

INFORMED CONSENT FORM

CHEMICAL EXFOLIATION TREATMENT WITH ENERPEEL® MEDICAL DEVICES

1. FOREWORD

ENERPEEL® Medical Devices meet the requirements of European Directive 93/42/EEC, 47/2007/EC and subsequent amendments/ integrations regarding medical devices.

2. DEFINITIONS

According to the various therapeutic requirements, ENERPEEL® Medical Devices are formulated with different acids, and in some cases, the same acids are used at different concentrations.

3. PURPOSE OF TREATMENT WITH THE ENERPEEL® MEDICAL DEVICES

Chemical exfoliation (chemical peeling) is a medical procedure that exerts controlled cutaneous damage through the use of organic acids.
This procedure is carried out to improve specific skin conditions through the removal of dead skin cells of the horny layer, regeneration of new epidermis and dermal remodelling.
Exfoliation may be classified as very superficial, superficial, medium or deep, according to the nature of the exfoliating agent used and its application time on the treated area before neutralisation.

**** IMPORTANT WARNINGS***

a. *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 or with the removal of the exfoliating solution using the appropriate NEU Neutralizer or RW Remover Wipes.*

b. *The ampule has to be combined with single-use applicators, intended for a single patient and for a single session. The package contains 8/32 single-use applicators necessary to perform as many sessions.*

c. *For the indications given, ENERPEEL® Medical Devices, according to the acid used, application time, layers of chemical exfoliant applied, patient characteristics and pathology treated may exert a chemical exfoliation that ranges from superficial to medium-deep.*

d. *ENERPEEL® Medical Devices may only be used before the expiry date shown on the packaging.*

4. INDICATIONS OF USE

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. ENERPEEL® Medical Devices are intended to be applied onto the skin with the purpose of prevention, control, therapy or attenuation of various skin problems, such as for example hypertrophic scars, hyper-pigmented lesions, skin elastosis, inflammatory acne, comedonic acne, acne scars and the sequela of actinic damage such as keratotic lesions that may have a pre-cancerous potential.

4.1.1. Cutaneous damage of an actinic nature

a) *actinic keratosis*
b) *solar elastosis*
c) *solar lentigos*
d) *dermatoheliosis*
e) *alterations of pigmentation*

4.1.2. Hyperpigmented lesions

a) *melasma*
b) *post-inflammatory hyperpigmentation*

4.1.3. Acne and other dermatological indications

a) *superficial scars*
b) *radiation keratosis*
c) *acne vulgaris*
d) *acne scars*
e) *plantar warts*
f) *sebaceous hyperplasia*
g) *papular - pustular rosacea*

4.1.4. Skin blemishes

a) *photo and chrono-aging*
b) *wrinkles*
c) *loss of uniformity of skin complexion*
d) *loss of skin tone*

5. EXCLUSION CRITERIA – WHEN CHEMICAL EXFOLIATING TREATMENT SHOULD NOT BE CARRIED OUT

a) presence of herpes simplex in the area to be treated
b) recent (the last 6 months) surgery (blepharoplasty, eyelid lifting, etc.)
c) immuno-depressive diseases and treatments in progress
d) previous radiotherapy of the portion of the skin to be exfoliated that might compromise the physiological regeneration of the skin
e) a family history of developing keloids and/ or hypertrophic scars
f) a family history of development of post inflammatory hyperpigmentation
g) pregnancy
h) breastfeeding
i) allergy and/or known hypersensitivity or any other known and/or probable incompatibility to one or more of the components
j) other medical considerations

6. PROCEDURE OF THE TREATMENT WITH ENERPEEL® MEDICAL DEVICES AND WARNINGS

The chemoexfoliation procedure common to all ENERPEEL® Medical Devices consists of three principal moments:

1. DELIPIDATION
2. APPLICATION OF THE CHEMOEXFOLIATING SOLUTION
3. NEUTRALIZATION

Note: *in the case of a treatment performed with the devices* ***ENERPEEL® SA****,* ***ENERPEEL® SA-15*** *or* ***ENERPEEL® JR****, the neutralising procedure with* ***ENERPEEL® NEU Neutralizer****, is replaced by a procedure of removing the crystals that are formed on the skin surface with* ***RW Remover Wipes****.*

**** IMPORTANT WARNINGS***

1. *During application of the ENERPEEL® Medical Devices a slight burning sensation may be noticed, that normally ceases on application of the neutralising solution,* ***NEU Neutralizer****.*
2. *The chemoexfoliation process causes a thinning of the surface layer of the skin. Therefore the natural barrier functions of the skin are altered.*
3. *Avoid carrying out chemoexfoliation in the very sunny season. Solar radiation may trigger hyperpigmentation.*
4. *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.*
5. *Pre treatment of the skin with preparatory products containing alpha hydroxy acids (AHA), beta hydroxy acids (BHA) and/or containing ingredients that have a keratolytic action may result in an increased irritative response of the skin to ENERPEEL® Medical Devices.*
6. *The possibility of developing herpes infection on the labial area is more pronounced with respect to other cutaneous areas.*
7. *Smoking may influence the outcome of the treatment, increase the risk of scarring and accelerate the recurrence of wrinkles.*
8. *Current pharmacological treatments may interfere with the chemical peeling treatments.*
9. *Fillers and treatments containing botulinium toxin should be carried out at the end of a cycle of chemical peeling sessions with the ENERPEEL® Medical Devices.*

7. DURATION OF A SINGLE TREATMENT

The time of application of the ENERPEEL® Medical Device solution on an individual cutaneous unit before the neutralisation process is evaluated by the doctor according to the phototype (Fitzpatrick classification), the degree of photoageing (Glogau classification) and the individual genetic racial characteristics.
When the doctor believes it is necessary, the ENERPEEL® Medical Devices may be applied in multilayers.

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

To obtain the required result from treatment with ENERPEEL® Medical Devices, a cycle of treatments may be needed, spread out over a period of time.
The number of individual treatments, the time interval between one treatment and the next and the total duration of the treatment cycle are envisaged and evaluated by the Doctor who will inform the Patient.

9. POSSIBLE APPEARANCES

Appearances that, in general, may appear in the post-treatment stage, depend on the type of exfoliation and on the patient's individual characteristics and include:

- oedema
- swelling
- erythema
- desquamation
- post-inflammatory hyper pigmentation, usually temporary, that may become permanent
- epidermolysis and subsequent abrasions
- scars
- bacterial infections

10. WARNINGS AND PROCEDURES DURING AND AFTER THE TREATMENT

During treatment, the patient must:

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

The following points must be scrupulously adhered to in the post-exfoliation phase.

1. Avoid exposure to the sun and to UVA and UVB lamps and always use adequate protection against solar and artificial radiation (protection factor 50+ according to the COLIPA method).
2. For the purpose of prevention, apply products able to modulate the process of melanogenesis.
3. Apply, as a maintenance form of treatment, products that can enhance skin elasticity and moisture levels.
4. Use very delicate cleansers on the treated area, avoiding any form of rubbing.
5. Avoid using pharmaceuticals and/or cosmetics without first consulting the doctor.

Additional notes:

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The patient declares that he/she has read the **INFORMED CONSENT FORM** and has been informed of the purpose, the procedures and the characteristics of the exfoliation treatment with ENERPEEL® Medical Devices, of the beneficial effects, of all the possible side effects and of the post-treatment procedures to be followed.
The Patient was given the opportunity to ask questions and these questions were answered exhaustively.
The Patient declares that he has thoroughly considered the information provided in the **INFORMED CONSENT FORM** and is knowledgeable of the chemical exfoliation procedure that will be carried out.

Date __ __ / __ __ / __ __ __ __
dd *mm* *yyyy*

Name _____ Surname _____
(in block letters) *(in block letters)*

Patient's signature _____

The Patient authorizes the Doctor to carry out the exfoliation treatment with the ENERPEEL® Medical Device described before.

ENERPEEL® Medical Device utilised: _____

Date __ __ / __ __ / __ __ __ __
dd *mm* *yyyy*

Name _____ Surname _____
(in block letters) *(in block letters)*

Patient's signature _____

AREA RESERVED FOR DOCTOR

I confirm that the Patient has read the **INFORMED CONSENT FORM** and has been informed of the aim, procedures and treatment characteristics of chemical exfoliation carried out using the specified ENERPEEL® Medical Device, and has been informed of the favourable effects, any complications and the post-treatment procedures to follow.
The Patient was given the opportunity to ask questions and these questions were answered exhaustively.
The Patient has agreed to voluntarily undergo the exfoliation treatment.

Date __ __ / __ __ / __ __ __ __
dd *mm* *yyyy*

Name _____ Surname _____
(in block letters) *(in block letters)*

Doctor's signature _____