CHEMOEXFOLIATION

ENERPEEL® EL

CE

PATIENT RECORD CARD

1. PATIENT INFORMATION

Name and Surname _____

Address _____

Telephone / Mobile phone _____

Age _____ years Sex F M

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

a) Incidence and/or history of viral infections caused by Herpes simplex in the area to be treated.
b) Recent (in the last 6 months) surgery (blepharoplasty, eyelid lifting, etc.).
c) Immuno-depressive diseases and treatments in progress.
d) Previous radiation therapy of the portion of the cutis to be treated that could compromise the physiological regeneration of the cutis.
e) Family history with the development of keloids and/or hypertrophic scars.
f) Family history with the 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.

3. USAGE PROCEDURES

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

ENERPEEL® EL is indicated for the chemo exfoliation of damaged keratinocytes and to 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. PHOTOTYPE CLASSIFICATION ACCORDING TO THE FITZPATRICK SCALE

A photo-type identifies the kind of skin response to solar radiation on the basis of several characteristics such as the colour of the hair, eyes, skin, the presence of freckles and lentigo and on the individual's reaction to solar radiation.
There are 6 photo-types, distinguished by the following characteristics:

PHOTOTYPE	DESCRIPTION
Phototype I	Subjects with very pale skin, often with freckles, blond or red hair, blue or grey eyes. They generally develop obvious erythema on any unprotected exposure to the sun. Tanning is very slight or nonexistent. There is extreme reaction to the sun's rays, with high risk of permanent damage.
Phototype II	Subjects with pale skin, dark blond or light brown hair. They tend to get sunburnt easily. They develop a light (golden) tan.
Phototype III	Subjects with fairly dark skin, brown hair. They only get sunburnt after prolonged exposure. They develop a deep, even tan.
Phototype IV	Subjects with olive complexion, dark eyes and black hair. They rarely get sunburnt. They quickly develop a very deep, chocolate-coloured tan.
Phototype V	Subjects with very dark complexion, dark eyes and black hair. They very rarely get sunburnt.
Phototype VI	Subjects with black complexion, dark eyes and black hair.

** **Important warnings:** 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.*

PATIENT'S PHOTOTYPE

I ☐ II ☐ III ☐ IV ☐ V ☐ VI ☐

5. PHOTO-AGEING CLASSIFICATION ACCORDING TO THE GLOGAU SCALE

Photo-aging conditions can be described according to the scale developed by Glogau, as follows:

DEGREE	AGE	DESCRIPTION
Slight	from 28 to 35 years	Characterized by small wrinkles, without keratosis
Moderate	from 35 to 50 years	Characterized by small wrinkles, sallow complexion with presence of actinic keratosis
Advanced	from 50 to 65 years	Characterized by deep wrinkles, presence of teleangiectasis, pigmented lesions and actinic keratosis
Severe	from 60 to 75 years	Characterized by dynamic and gravitational wrinkles, photo-ageing and actinic keratosis

DEGREE OF PATIENT'S PHOTO-AGEING

Slight ☐ Moderate ☐ Advanced ☐ Severe ☐

6. GENETIC-ETHNIC CLASSIFICATION AND RELATED RESPONSE TO CHEMICAL "PEELING"

The ethnic differences in the skin response to chemical-exfoliation (chemical "peeling") can be divided into 6 categories, where the skin colour is related to the somatic features. These categories are based on the geographic location and are described in table here below:

RACIAL CATEGORIES	ORIGINAL GEOGRAPHIC HABITAT	CHARACTERISTICS OF SKIN AND FEATURES	COMPLICATIONS SIDE EFFECTS	CANDIDATE RATING
(A) **Nordics** (Swedish, Irish, etc)	Northern Europe	Light to very light color. Skin and features are very fine.	Erythema +++ Teleangiectasia Scarring	Very good
(B) **Europeans** (French, Italian, English, Germans, etc)	Mid-Europe Southern Europe	Average color and coarseness of skin and features.	Low incidence	Excellent
(C) **Mediterraneans** (Spanish, Greek, etc)	Northern Africa and Western Asia	Darker and coarser than the Europeans.	Hyper-pigmentation + to ++ Erythema +	Very good
(D) **Indo-Pakistan** (Pakistanis, Thais, etc)	Upper-Middle Africa and Lower Western Asia	Coarser and darker than the Mediterraneans with thick oily skin and hair.	Hyper-pigmentation +++ Hypo-pigmentation +	Passable for peels
(E) **Africans** (Black Americans, Sudanese, etc)	Middle and Lower Africa	Black to deep black color. Features and skin are coarse to very coarse.	Hypo-pigmentation +++ Hyper-pigmentation ++	Passable for peels
(F) **Asians** (Japanese, Koreans, etc)	Eastern Asia	A separate classification color varies from light to medium dark. Skin and features are coarse to very coarse.	Hyper-pigmentation +++ Erythema +++ turning to hyper-pigmentation	Good

Warning: *the correlation between the Fitzpatrick scale and the genetic-ethnic classification can be useful in predicting the skin's response to chemical peeling, both for evaluating its effectiveness and for determining possible side effects.*

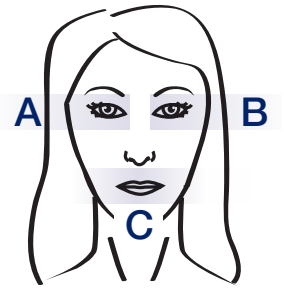
PATIENT'S ETHNIC CATEGORY

(A) ☐ (B) ☐ (C) ☐ (D) ☐ (E) ☐ (F) ☐

7. DEFINITION OF THE CUTANEOUS AREA

The periocular and perioral application zones have been arbitrarily divided into the following cutaneous areas:

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



CUTANEOUS UNIT / UNITS TO BE TREATED

A ☐ B ☐ C ☐

8. ESTIMATED NUMBER OF TREATMENT SESSIONS

Number of individual sessions _____

Time interval between one session and the next _____

Envisaged duration for the complete treatment course _____

9. MEDICAL DEVICE LAYERS AND APPLICATION TIMES

TREATED SKIN AREA	APPLICATION TIMES AND BATCH NUMBER OF PRODUCT USED BEFORE NEUTRALISATION											
	1st Course											
A	1st Session			2nd Session			3rd Session			4th Session		
	__ __ / __ __ / __ __ __ __ (dd / mm / yyyy)			__ __ / __ __ / __ __ __ __ (dd / mm / yyyy)			__ __ / __ __ / __ __ __ __ (dd / mm / yyyy)			__ __ / __ __ / __ __ __ __ (dd / mm / yyyy)		
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	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___
	☐ 3rd Layer	☐ ~1-2 min.	☐ Other:___	☐ 3rd Layer	☐ ~1-2 min.	☐ Other:___	☐ 3rd Layer	☐ ~1-2 min.	☐ Other:___	☐ 3rd Layer	☐ ~1-2 min.	☐ Other:___
	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___
B	1st Session			2nd Session			3rd Session			4th Session		
	__ __ / __ __ / __ __ __ __ (dd / mm / yyyy)			__ __ / __ __ / __ __ __ __ (dd / mm / yyyy)			__ __ / __ __ / __ __ __ __ (dd / mm / yyyy)			__ __ / __ __ / __ __ __ __ (dd / mm / yyyy)		
	Batch: _____			Batch: _____			Batch: _____			Batch: _____		
	☐ 1st Layer	☐ ~1-2 min.	☐ Other:___	☐ 1st Layer	☐ ~1-2 min.	☐ Other:___	☐ 1st Layer	☐ ~1-2 min.	☐ Other:___	☐ 1st Layer	☐ ~1-2 min.	☐ Other:___
	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___
	☐ 3rd Layer	☐ ~1-2 min.	☐ Other:___	☐ 3rd Layer	☐ ~1-2 min.	☐ Other:___	☐ 3rd Layer	☐ ~1-2 min.	☐ Other:___	☐ 3rd Layer	☐ ~1-2 min.	☐ Other:___
	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___
C	1st Session			2nd Session			3rd Session			4th Session		
	__ __ / __ __ / __ __ __ __ (dd / mm / yyyy)			__ __ / __ __ / __ __ __ __ (dd / mm / yyyy)			__ __ / __ __ / __ __ __ __ (dd / mm / yyyy)			__ __ / __ __ / __ __ __ __ (dd / mm / yyyy)		
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	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___
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	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___

TREATED SKIN AREA	APPLICATION TIMES AND BATCH NUMBER OF PRODUCT USED BEFORE NEUTRALISATION											
	2nd Course											
A	1st Session __ __ / __ __ / __ __ __ __ dd / mm / yyyy			2nd Session __ __ / __ __ / __ __ __ __ dd / mm / yyyy			3rd Session __ __ / __ __ / __ __ __ __ dd / mm / yyyy			4th Session __ __ / __ __ / __ __ __ __ dd / mm / yyyy		
	Batch: _____			Batch: _____			Batch: _____			Batch: _____		
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	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___
	☐ 3rd Layer	☐ ~1-2 min.	☐ Other:___	☐ 3rd Layer	☐ ~1-2 min.	☐ Other:___	☐ 3rd Layer	☐ ~1-2 min.	☐ Other:___	☐ 3rd Layer	☐ ~1-2 min.	☐ Other:___
	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___
B	1st Session __ __ / __ __ / __ __ __ __ dd / mm / yyyy			2nd Session __ __ / __ __ / __ __ __ __ dd / mm / yyyy			3rd Session __ __ / __ __ / __ __ __ __ dd / mm / yyyy			4th Session __ __ / __ __ / __ __ __ __ dd / mm / yyyy		
	Batch: _____			Batch: _____			Batch: _____			Batch: _____		
	☐ 1st Layer	☐ ~1-2 min.	☐ Other:___	☐ 1st Layer	☐ ~1-2 min.	☐ Other:___	☐ 1st Layer	☐ ~1-2 min.	☐ Other:___	☐ 1st Layer	☐ ~1-2 min.	☐ Other:___
	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___
	☐ 3rd Layer	☐ ~1-2 min.	☐ Other:___	☐ 3rd Layer	☐ ~1-2 min.	☐ Other:___	☐ 3rd Layer	☐ ~1-2 min.	☐ Other:___	☐ 3rd Layer	☐ ~1-2 min.	☐ Other:___
	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___
C	1st Session __ __ / __ __ / __ __ __ __ dd / mm / yyyy			2nd Session __ __ / __ __ / __ __ __ __ dd / mm / yyyy			3rd Session __ __ / __ __ / __ __ __ __ dd / mm / yyyy			4th Session __ __ / __ __ / __ __ __ __ dd / mm / yyyy		
	Batch: _____			Batch: _____			Batch: _____			Batch: _____		
	☐ 1st Layer	☐ ~1-2 min.	☐ Other:___	☐ 1st Layer	☐ ~1-2 min.	☐ Other:___	☐ 1st Layer	☐ ~1-2 min.	☐ Other:___	☐ 1st Layer	☐ ~1-2 min.	☐ Other:___
	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___	☐ 2nd Layer	☐ ~1-2 min.	☐ Other:___
	☐ 3rd Layer	☐ ~1-2 min.	☐ Other:___	☐ 3rd Layer	☐ ~1-2 min.	☐ Other:___	☐ 3rd Layer	☐ ~1-2 min.	☐ Other:___	☐ 3rd Layer	☐ ~1-2 min.	☐ Other:___
	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___	☐ 4th Layer	☐ ~3-5 min.	☐ Other:___

Notes regarding eventual other treatments performed contemporaneously to the chemo exfoliation

10. ANY MEDICAL NOTES

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

Stamp & signature

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