



CHEMOEXFOLIATION
ENERPEEL®



PATIENT RECORD CARD

1. PATIENT'S PERSONAL DETAILS

Name and surname _____

Address _____

Telephone/Mobile _____

Age _____ years Sex2 ☐ F ☐ M

2. EXCLUSION CRITERIA – WHEN THE EXFOLIATING TREATMENT SHOULD NOT BE CARRIED OUT

- presence of herpes simplex in the area to be treated.
- recent (the last 6 months) surgery (blepharoplasty, eyelid lifting, etc.).
- immuno-depressive diseases and treatments in progress.
- previous radiotherapy of the portion of the skin to be exfoliated that might compromise the physiological regeneration of the skin.
- a family history of developing keloids and/ or hypertrophic scars.
- a family history of 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.

3. 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 should 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.

3.1.1. cutaneous damage of an actinic nature

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

3.1.2. hyperpigmented lesions

- melasma
- post-inflammatory hyperpigmentation

3.1.3. acne and other indications

- superficial scars
- plantar warts
- radiation keratosis
- sebaceous hyperplasia
- acne vulgaris
- papular-pustular rosacea
- acne scars

4. PHOTOTYPE EVALUATION ACCORDING TO THE FITZPATRICK SCALE

Fitzpatrick classification of phototypes

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.

PHOTOTYPE OF THE PATIENT

I ☐ II ☐ III ☐ IV ☐ V ☐ VI ☐

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5. EVALUATION OF PHOTOAGEING ACCORDING TO THE GLOGAU CLASSIFICATION

Classification according to the Glogau scale

SCALE	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.

PHOTOAGEING

Slight ☐ Moderate ☐ Advanced ☐ Severe ☐

6. GENETIC-RACIAL CLASSIFICATION AND THE RELATIVE REACTIONS TO CHEMICAL EXFOLIATION

The different racial skin reactions to chemical exfoliation (chemical peeling) may be subdivided into 6 categories. For each category the skin colour is correlated to the somatic characteristics. These categories are based on the geographic distribution described in the table 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

WARNINGS:* correlation between the Fitzpatrick scale and the genetic-racial classification may be useful for predicting the cutaneous response to chemical peeling.

ENETIC RACIAL CHARACTERISTICS OF THE PATIENT

(A) ☐ (B) ☐ (C) ☐ (D) ☐ (E) ☐ (F) ☐

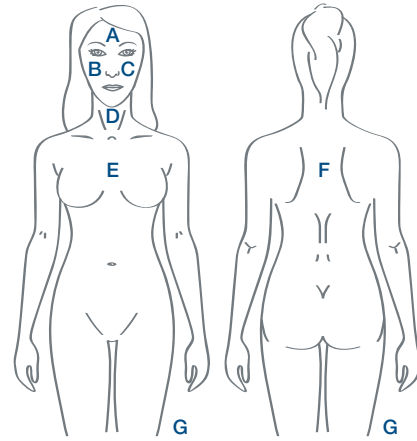


PATIENT RECORD CARD

7. DEFINITION OF THE SKIN UNIT OR UNITS TO BE TREATED

Cutaneous unit means the portion of skin that is to undergo exfoliation. The cutaneous units have been classified arbitrarily as follows:

CUTANEOUS UNIT	DESCRIPTION
A	Forehead
B	RIGHT cheek-zygomatic zone (including the periorcular area, the nasogenial sulcus and the nasolabial zone)
C	LEFT cheek-zygomatic zone (including the periorcular area, the nasogenial sulcus and the nasolabial zone)
D	Neck
E	Décolletage
F	Back
G	Other parts of the body



CUTANEOUS UNIT / UNITS TO BE TREATED

A ☐ B ☐ C ☐ D ☐ E ☐ F ☐ G ☐

8. CYCLE OF TREATMENTS INDICATEVELY ENVISAGED

Number of individual treatments _____ Date of execution of 1st treatment _____ / _____ / _____

Time interval between one treatment and the next _____ Date of execution of 2nd treatment (if any) _____ / _____ / _____

Envisaged duration for the complete treatment cycle _____ Date of execution of 3rd treatment (if planned) _____ / _____ / _____

_____ Date of execution of 4th treatment (if planned) _____ / _____ / _____

9. MEDICAL DEVICE USED AND TIME OF APPLICATION

Sequence of application of the Medical Device on the various cutaneous units to be treated (if more than one).

TREATED SKIN AREA	APPLICATION TIMES AND LOT OF PRODUCT USED BEFORE NEUTRALISATION AND/OR REMOVAL OF PRECIPITATES TREATMENTS							
	1 st treatment		2 nd treatment		3 rd treatment		4 th treatment	
A	min.	n. of layers	min.	n. of layers	min.	n. of layers	min.	n. of layers
	product	batch	product	batch	product	batch	product	batch
B	min.	n. of layers	min.	n. of layers	min.	n. of layers	min.	n. of layers
	product	batch	product	batch	product	batch	product	batch
C	min.	n. of layers	min.	n. of layers	min.	n. of layers	min.	n. of layers
	product	batch	product	batch	product	batch	product	batch
D	min.	n. of layers	min.	n. of layers	min.	n. of layers	min.	n. of layers
	product	batch	product	batch	product	batch	product	batch
E	min.	n. of layers	min.	n. of layers	min.	n. of layers	min.	n. of layers
	product	batch	product	batch	product	batch	product	batch
F	min.	n. of layers	min.	n. of layers	min.	n. of layers	min.	n. of layers
	product	batch	product	batch	product	batch	product	batch
G	min.	n. of layers	min.	n. of layers	min.	n. of layers	min.	n. of layers
	product	batch	product	batch	product	batch	product	batch

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