PLEXR® Plus

Plexr® Plus
Made in Italy

THE BREAKTHROUGH OF PLASMA IN AESTHETIC MEDICINE

by GMV

THE PLASMA EXERESIS WITH **PLEXR**

Plasma Exeresis technology has been conceived and developed by GMV, a company with over 10-year experience in plasma technology and holding the Plexr trademark, the first plasma device in medical aesthetics all over the world, internationally patented.
The intended use of Plexr involves many medical disciplines as dermatology, aesthetic medicine, oculoplastic surgery, dentistry, gynaecology.
The methodology/technique of use is constantly assisted by scientific research and clinical studies, in Italy and Worldwide, collaborating with top KOLs and prestigious Universities.

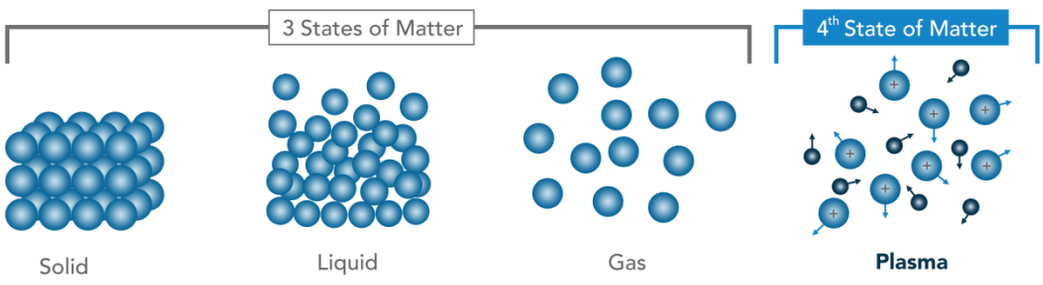
NEW
PLEXR PLUS

Plasma

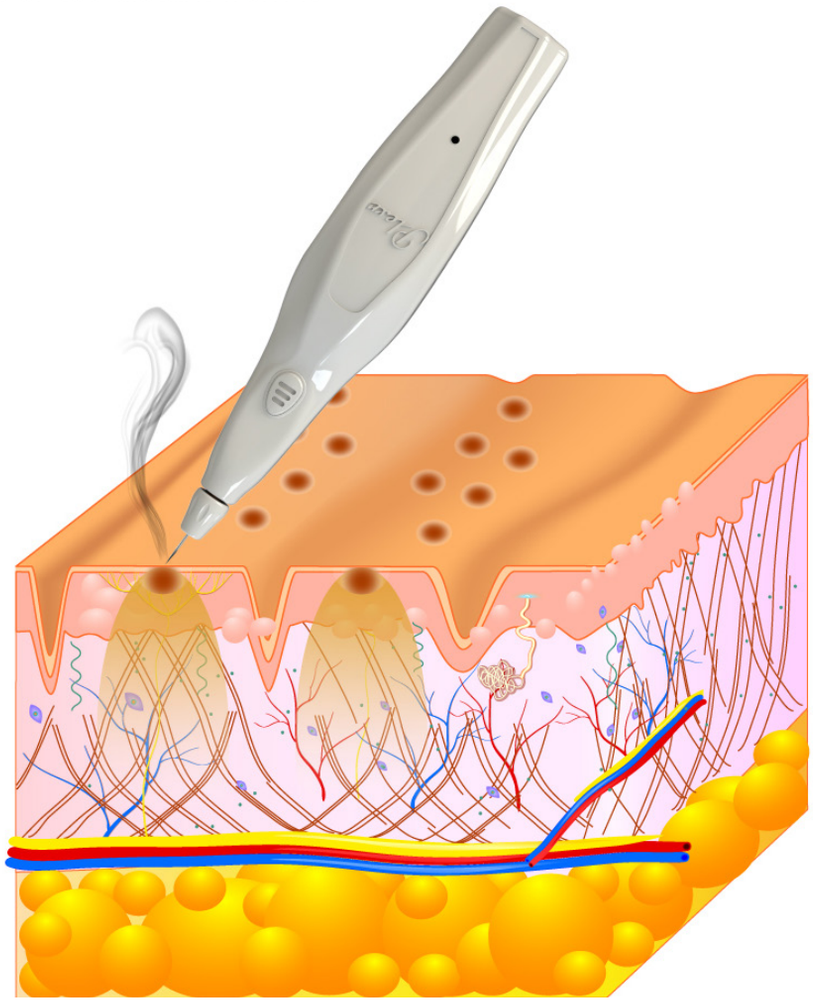
A term derived from the Greek for 'entity' or 'form', is the fourth state of matter and it is constituted by negatively charged electrons and positively charged ions with an overall neutral net charge. It can be created when a difference in voltage matches the dielectric breakdown of the gas included into the field.

Atoms are the elements of molecules; when the interaction among molecules is high, they result in a solid, able to maintain shape a volume until an extremely high strength can break such interaction. **When the interaction is weak among molecules, this can result respectively in a liquid, maintaining volume but losing shape, or in a gas, which maintains no shape or volume, but occupies all the available space.**

When an external energy can split the molecules of the gas in positive and negative parts, we reached the fourth state of the matter: plasma.
When activated, Plexr ionizes the air between the tip of the device and the human body by generating an appropriate potential difference.



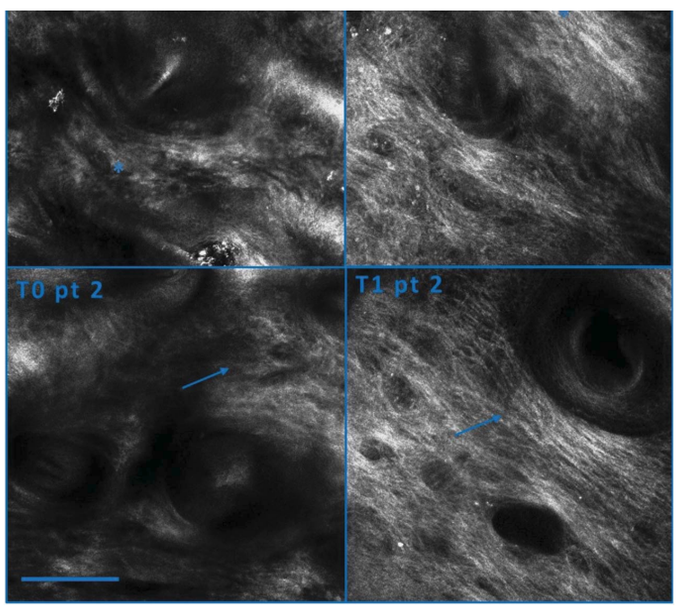
The electric breakdown of the air is around 3000 V per mm, depending from some factors such as humidity and bodies the physical phenomenon is generated by.
Using the Plexr / Plexr Plus signal parameters, around half millimetre is the needed distance for the ionization of the air atoms.
No plasma is generated when the probe is in direct contact with the tissue or too distant from it.



The plasma generation is similar to a micro lightning bolt that acts directly only on the epidermis. Before sublimating, the corneocytes transmit a selective estimated quantity of energy that reaches the right deepness of dermis, without irradiation (laser/light) or electric shock (radioscalpel/current).
No any form of energy is delivered directly from the device to the deeper tissue, no eddy currents are generated.

The action of Plexr on tissues allows:

1- immediate contraction of the collagen fibers
2- collagen reorganization
3- formation of new collagen (type III)
4- renewal the epidermal tissue.
This mechanism has been proved through several scientific studies (see literature section).



Rossi et al. 2017, Dermatologic surgery. Clinical and Confocal Microscopy Study of Plasma Exeresis for Nonsurgical Blepharoplasty of the Upper Eyelid: A Pilot Study. Dermal matrix architecture by reflectance confocal microscopy (RCM) of Patients 1 and 2: at baseline (T0), signs of skin aging characterized by a collagen with variable degrees of degeneration: in Patient 1 (T0 pt1) it was classified as huddled (asterisk) and in Patient 2 (T0 pt2) as coarse (arrow). At T1, a strong collagen remodeling process was detected in both patients: bright and long fibers with a parallel alignment are detected in Patient 1 (T1 pt1) and in Patient 2 (T1 pt2). Scale bar = 50 mm.

TABLE 1. Patient Demographic and Upper Eyelid Characteristics for All Female Patients Included in the Study, With Clinical and RCM Improvement

Patient No.	*Age, yrs*	*Skin Phototype*	*Eyelid Dermatochalasis, T0*	*Predominant Collagen Pattern, T0*	*Eyelid Dermatochalasis, T1*	*Predominant Collagen Pattern, T1*	*Time to Scab Healing, d*	*Time to Erythema Healing, d*	*Edema, d*	*Hyperpig-mentation*
1	69	II	8	Huddled	6	Long straight fibers	5	28	2	No
2	55	II	7	Coarse	4	Long straight fibers	7	40	2	No
3	52	I	6	Huddled	3	Long straight fibers	6	30	3	No
4	58	III	7	Huddled	5	Long straight fibers	4	35	2	No
5	72	II	8	Huddled	7	Long straight fibers	3	28	3	No
6	56	III	6	Huddled	3	Long straight fibers	6	36	2	No
7	40	I	7	Coarse	4	Long straight fibers	7	36	3	No
8	65	II	8	Coarse	5	Long straight fibers	3	30	2	No
9	48	II	6	Huddled	3	Long straight fibers	5	28	2	No
10	59	II	6	Coarse	3	Long straight fibers	6	30	2	No

RCM, Reflectance Confocal Microscopy.

Rossi et al. 2017, Dermatologic surgery. Clinical and Confocal Microscopy Study of Plasma Exeresis for Nonsurgical Blepharoplasty of the Upper Eyelid: A Pilot Study.

Technology and Applications

Plexr / Plexr Plus is conceived with three different handpieces: the output of each handpiece is in fact optimized so that an ad-hoc signal can be performed in function of the specific treatment. The choice of the handpiece is strictly dependent by the treatment the Dr. is going to perform.

White handpiece Blepharoplasty, lentigo solaris, moderate active acne, small wrinkles, umbilical lifting, small benign skin neoformations, coadjuvant for small keloids, moderate cutaneous renewal and skin rejuvenation, vaginal rejuvenation and vulvoplasty.

Green handpiece Active acne, medium benign skin neoformations, seborrheic keratosis, elastosis, dyschromia, small ruby angiomas, face lifting, xantelasmas, small fibromas, small scars.

Red handpiece Voluminous benign skin neoformations, big fibromas coadjuvant for keloids, big ruby angiomas, deep scars, acne scars, resurfacing, warts, seborrheic warts, hyperkeratosis, gingival whitening and so on.

However, there are factors that can furtherly influence the handpiece choice:

- **Experience** of the doctor: as initial approach it is suggested to use the white handpiece, in order to better achieve and understand functionality of the device. With constant attendance to training courses and acquisitions of experience you will gather the necessary skills to treat different types of skin pathologies.
- **Entity** of the skin pathology.
- **Skin type** of the patient.

GMV strongly recommends to use only official Plexr Tips.

These kinds of needles, made with medical-grade stainless steel, are conceived to work combined with Plexr's handpieces: they have been studied and designed to generate the correct quantity of Plasma. The Plexr Tips are single use to optimize the result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Why Plexr is different from other Plasma devices

Plexr is the unique device able to recreate the precise and stable phenomenon of Plasma intended for medical use, allowing the Doctor to work safely and successfully.
Plexr is designed to reproduce correctly the necessary physical dimensions observed in several scientific studies (see literature).
Producing a general and incorrect signal to generate plasma is definitely not sufficient and/or dangerous.
To do that, specific parameters and specific electronic design are mandatory. This property avoids deep thermic damage, electric shock and allows to reach the desired result with minimal downtime.
The focused micro-plasma beam due to the ionization of the gases contained in the air, sublimates the stratum corneum of the epidermal tissue where the spot is performed, but the ionic flow doesn't spread out to deeper tissue. The basal lamina is preserved and there is no dermal or electrical damage (see literature). A device designed with different parameters and composed by different electrical components causes different or even unpredictable/dangerous effects:
- **Lower working frequency**: too high penetration, thermic damage, high skin-tip distance (less accuracy).

- **Higher working frequency** (electrosurgical unit): reduced skin-tip distance, current flow, high superficial energy (skin cut).

- **Higher working voltage**: too high penetration, thermic damage, high skin-tip distance (less accuracy).

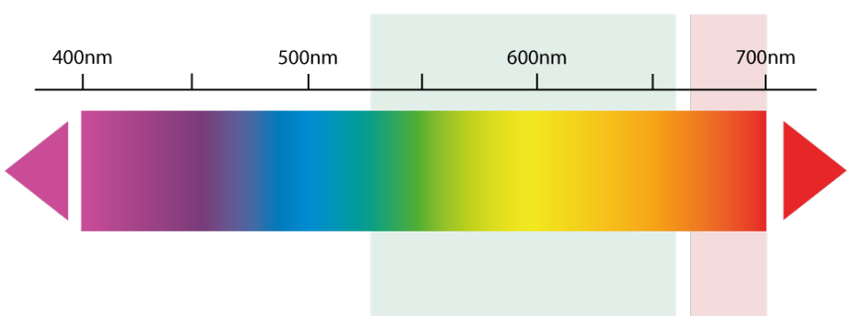
- **Lower working voltage**: no effect.

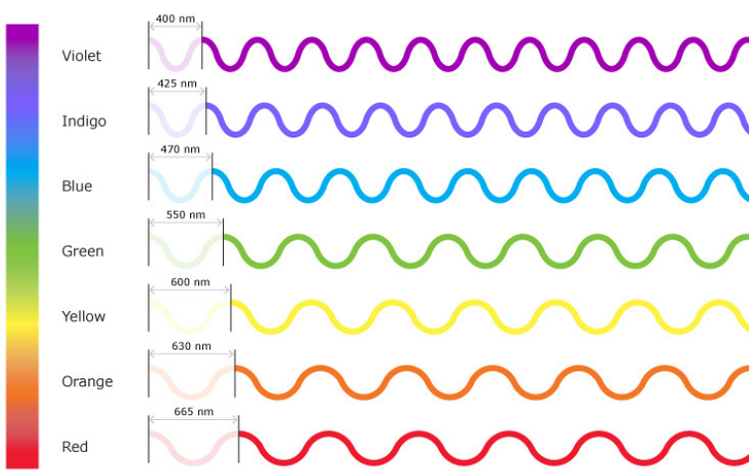
Therefore, possible consequences in using different devices are:
• more pain for the patient
• no same results
• scarring
• expertise of the operator: the space between good result and side effect (scars) is minimal. Trying to get better results means to risk scarring. Plexr does not produce scarring at all.
• Not estimable or long-lasting prominent side effects: redness (erythema), oedema and Post Inflammatory Hyperpigmentation (PIH).
• The stable plasma generated by Plexr opens to other protocol.

Why Plexr is different from LASERs

The target tissue of the coherent, monochromatic and unidirectional radiation turns out a new heat source, increasing temperature in the surrounding tissue.
Furthermore, LASER:

- Is skin colour and pathology depending
- Produces a not uniform effect
- Is more expensive
- Causes a longer downtime
- Implies more difficult treatment
- Is less versatile -cumbersome, no wireless, no portable

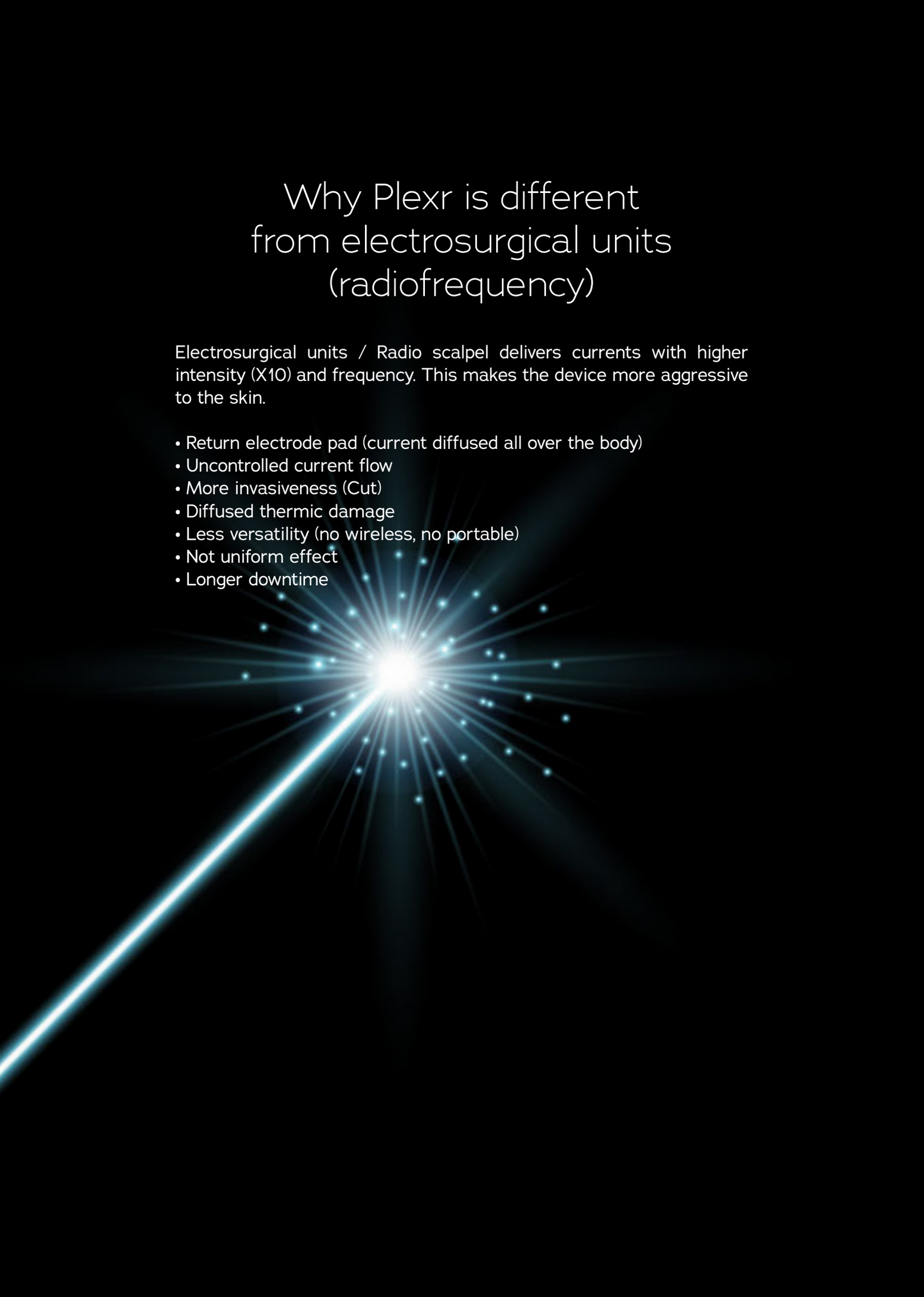




Why Plexr is different from electrosurgical units (radiofrequency)

Electrosurgical units / Radio scalpel delivers currents with higher intensity (X10) and frequency. This makes the device more aggressive to the skin.

- Return electrode pad (current diffused all over the body)
- Uncontrolled current flow
- More invasiveness (Cut)
- Diffused thermic damage
- Less versatility (no wireless, no portable)
- Not uniform effect
- Longer downtime



Literature

Scientific research proves the effectiveness and safety of Plexr. Doctors and researchers from all over the world have made studies using Plexr, and they published their results on different journals. Most of these journals also have the Impact Factor index, which is one of the most widely used research assessment indexes recognized at international level.

List of most important and recent publications:

- Sotirios TG, Nantia S. Non–Invasive Blepharoplasty with Plasma Exeresis (Plexr) Pre/Post Treatments. J Aesthet Reconstr Surg. 2018
- Rossi E, Paganelli A, Mandel VD, Pellacani G. Plasma Exeresis Treatment for Epidermoid Cysts: A Minimal Scarring Technique. Dermatol Surg. 2018
- Nalewczynska A. The use of device generating plasma for the treatment of vulvar and vagina atrophy symptoms (VVA). Plactic and Reconstructive Gynecology, 2018
- Rossi E, Paganelli A, Mandel VD, Pellacani G. Favre-Racouchot syndrome: report of a case treated by plasma exeresis. J Eur Acad Dermatol Venereol. 2018
- Rossi E, Farnetani F, Trakatelli M, Ciardo S, Pellacani G. Clinical and Confocal Microscopy Study of Plasma Exeresis for Nonsurgical Blepharoplasty of the Upper Eyelid: A Pilot Study. Dermatol Surg. 2018
- Rossi E, Mandel VD, Paganelli A, Farnetani F, Pellacani G. Plasma exeresis for active acne vulgaris: Clinical and in vivo microscopic documentation of treatment efficacy by means of reflectance confocal microscopy. Skin Res Technol. 2018
- TG Sotiris, G Nikolaos, G Irini New Treatment with Plasma Exeresis for Non-Surgical Blepharoplasty. EC Ophthalmology, 2017
- TG Sotiris, Combination of Autologous Treatments for Non–Invasive Blepharoplasty and Non–Surgical Full Face Lift. Journal of Clinical & Experimental Dermatology Research, 2017
- TG Sotiris, G Nikolaos, G Irini The Gas Ionization by Plasma Technology for Noninvasive Techniques in Oculoplastic. JOJ Ophthalmology, 2017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The revolution
will not be monospaced
FAVORIT
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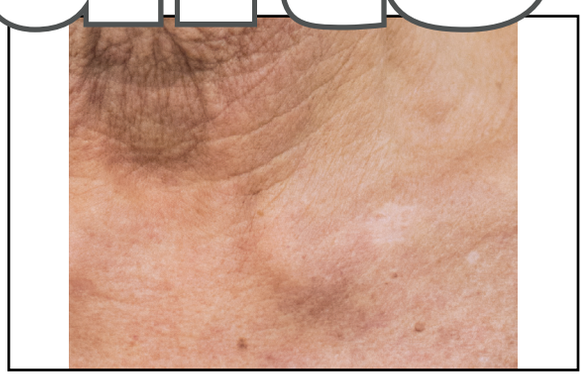
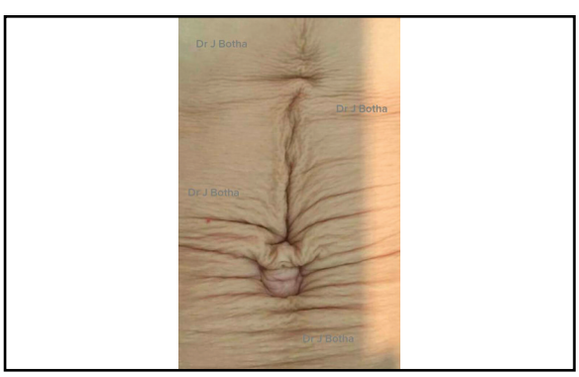
GMV

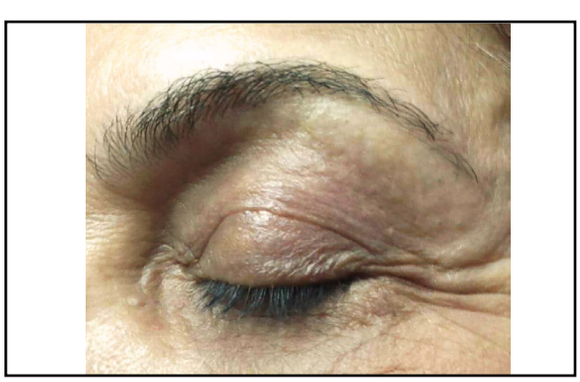
Results

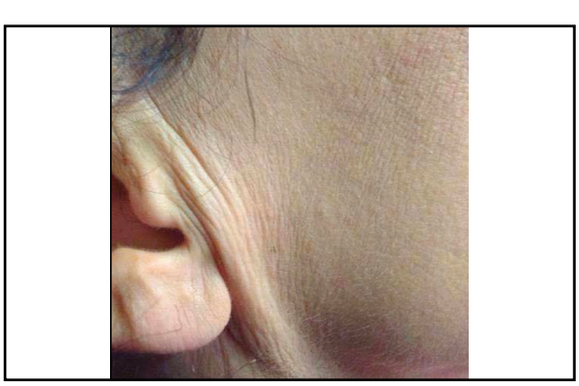
BEFORE

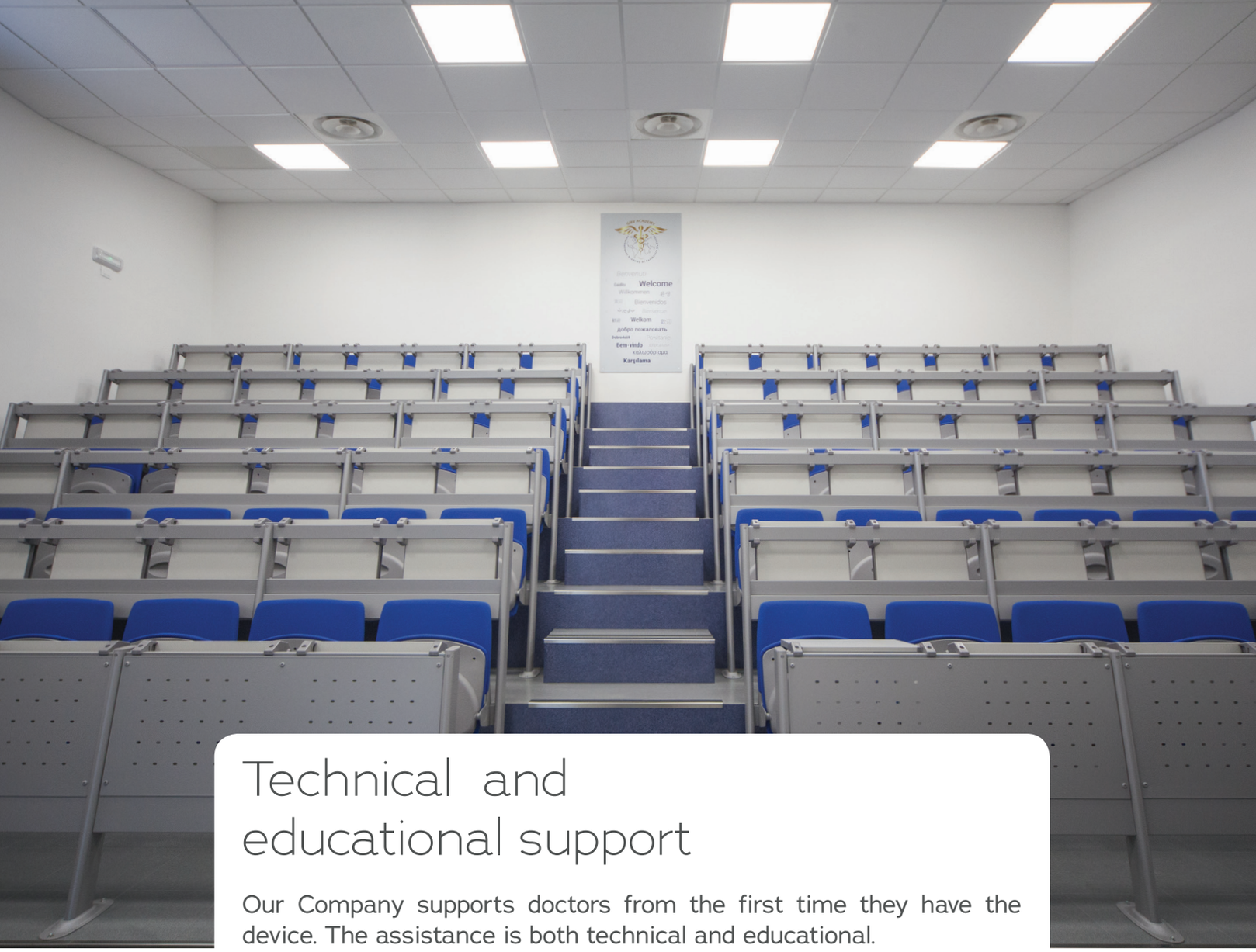
AFTER











Technical and educational support

Our Company supports doctors from the first time they have the device. The assistance is both technical and educational.
GMV is committed to supporting healthcare providers and clinicians with its support network and resources ensuring a high-level of customer satisfaction from design, delivery, installation to enduring product performance.

We periodically organize training courses: the aim is to guide each doctor through a training process which exalts to the max a practical approach, which allows to begin immediately with the techniques acquired providing latest technologies in the field of aesthetic medicine and beyond.

Before and After treatment protocols - General indication

Premise: the indication contained in this section explains the general precautions that are to be applied ALWAYS before and after treatments. We invite you to read single protocols to learn how to correctly execute each procedure.

Before

1. Removal of the makeup and skin cleansing.
2. Disinfect the area with a non-alcoholic disinfectant.
3. Apply the anesthetic cream 40 minutes before the treatment.
4. While treating, delicately remove the excessive cream, but do not remove it completely.
5.While treating, cleanse the treated area with a clean cotton pad.

Aftercare for the patient

- Wash in the morning and nights the treated area with Marseille soap.
- Use the "**Plexr Care Kit**" as per protocol:

1) Application of the skin cover on the treated area with high SPF to protect from the UVA and UVB rays until the healing process is over. Such process consists of onset of small scabs due the micro ablation and edema due to the formation of new skin.

2) Zinc Oxide cream antiseptic and anti-edema, to prevent and treat the formation of edema and redness, that in any case are essential and indicates skin turnover process.

3) K factor Cream which is a natural hydroquinone activator, is useful to prevent and treat the eventuality of hyperpigmentation on the treated area.

Treatment of the temporarily side effects

Scabs, edema and redness are part of the normal healing process and skin turnover. Normally this process lasts 7-20 days.
The only side effects -reported below with the related remedy- rarely appear and are subjective from patient to patient. They are mostly due to an improper application of the protocol by the doctor and/or to a missing/wrong post treatment allegiance by the patient. That's why the good communication doctor-patient is the goal.
Possible side effects:

- Excessive edema - Resolving spontaneously within one week. To accelerate the healing process can be used use Arnica Montana (2 pillows before sleeping) or antihistamine bilastine (as in the information sheet of the product).
- Persistent redness - Resolving spontaneously within three months without any interventional treatment. Patients with sensitive skin accounted for almost half of the patients presenting with prolonged erythema. To accelerate the process, apply an anti-dystrophic cream.
- Post Inflammatory Hyperpigmentation (PIH) - Even though it might occur such effect must not worry the doctor or the patient, if it should occur the patient must be informed that it is a temporarily effect and if not treated it can last up to maximum 6 months. There are lots of depigmenting agent in order to accelerate its complete disappearance, like creams with hydroquinone.

Always to remember that the first cause of such effect is given from the UV rays, thus such treatment is not to be recommended during the summer season and the skin cover is absolutely mandatory, especially in countries where there is major sun exposure or certain types of skin, Fitzpatrick higher than III
Higher proportional incidence of PIH among higher phototypes was observed but the transient nature of PIH was also demonstrated throughout Fitzpatrick spectrum (I-VI).

Therefore, to avoid or accelerate the healing process:

- Rigid adherence to protocols: Use of photo protective and lenitive measures (Plexr Care) since less PIH in patients who adhered to photo protective measures was observed.
- Do not scrub the crusts.
- Post treatment strategies: cream based on the Kingman's formula/ depigmenting /chemical peel shorten period of transient PIH.

Quality Certificates

Plexr, like all GMV medical devices, has been approved by the European Community and from notified bodies and government entities around the world.
List of most important international certificates:

ISO 9001
IQNET: International certification network
ISO 13485
EC CERTIFICATE: Full Quality Assurance System Approval Certificate


IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
CERTIFICATE
CISQ/IMQ has issued an IQNet recognized certificate that the organization:
GMV SRL
VIA ROBERTO PARIBENI 37 - 00173 ROMA (RM)
has implemented and maintains a
Quality Management System
for the following scope:
Design, production, placing on the market and service of active medical devices for aesthetic, sport and rehabilitation medicine
which fulfills the requirements of the following standard:
ISO 9001:2015
Issued on: 2018 - 07 - 20
Expires on: 2020 - 06 - 11
This attestation is direct linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document
Registration Number: IT - 96528
Alex Stoichitoiu
President of IQNet
Ing. Claudio Proventi
President of CISQ


CISQ
CISQ is a member of IQNet
CERTIFICATO N. 9120.GMV3
CERTIFICATE N.
GMV SRL
VIA ROBERTO PARIBENI 37 - 00173 ROMA (RM)
UNITA' OPERATIVE / OPERATIVE UNITS
VIA ROBERTO PARIBENI 37 - 00173 ROMA (RM)
E' CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD
ISO 9001:2015
PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES
Progettazione, produzione, immissione in commercio ed assistenza di dispositivi medici attivi per medicina estetica, sportiva e riabilitativa
Design, production, placing on the market and service of active medical devices for aesthetic, sport and rehabilitation medicine
IAF: 19
IMQ
CISQ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VIA ROBERTO PARIBENI 37 - 00173 ROMA (RM)
E' CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD
ISO 13485:2016
PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES
Progettazione, produzione, immissione in commercio ed assistenza di dispositivi medici attivi per microelettrochirurgia, elettroterapia, terapia ad ultrasuoni, carbossiterapia e terapia di fotobiomodulazione dinamica
Design, production, placing on the market and service of active medical devices for microelectrosurgery, electrotherapy, ultrasound therapy, carboxytherapy and dynamic photobiomodulation therapy.
IMQ
CISQ


IMQ
EC CERTIFICATE
Certificate No 1498/MDD
Full Quality Assurance System Approval Certificate
On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:
GMV SRL
00173 ROMA (RM) - VIA ROBERTO PARIBENI 37 (ITA) - Italy
manages in the factory of:
00173 ROMA (RM) - VIA ROBERTO PARIBENI 37 (ITA) - Italy
a quality assurance system ensuring the conformity of the following products:
Dermatological and plastic microsurgery equipment
Type ref. Vibrance: Plexr, O.F.F. Needle Shaping, PLEXR PLUS.
Trade mark: GMV
Carbon dioxide therapy equipment
Type ref. CARBOMAX
Trade mark: GMV
Electroporation transdermal equipment
Type ref. VEIKOS LEO.
Trade mark: GMV
Cavitation ultrasound therapy equipment
Type ref. SONIK.
Trade mark: GMV
Radiofrequency therapy equipment
Type ref. RF PLUS MED; RF POWER MED; THUZZLE.
Trade mark: GMV
with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.
Date: 2014-07-11
Updated: 2018-12-04
Substitution Date: 2017-09-18
Expiry Date: 2019-07-10
IMQ
This Approval Certificate is subjected to the provisions laid down in the "IMQ regulation for the certification of medical devices - CE Marking - Directive 93/42/EEC"
This is a translation of the Italian text, which prevails in case of doubts
IMQ S.p.A. | I-20138 Milano | Via Quintiliano 43 | www.imq.it

Extra UE Approvals:

Australian TGA
Columbian INVIMA
Iranian IFDA
Korean KFDA
Turkish MOH
Cofepris
Peruvian DIGEMIT

Ukrainian MOH
Uzbekistan MOH
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Israeli AMAR
Egyptian EDA
Brazilian ANVISA

Sağlık Bakanlığı
Türkiye İlaç ve Tıbbi Cihaz Kurumu

EDA
Egyptian Drug Authority

ANVISA

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

DIGEMID
DIRECCIÓN GENERAL DE MEDICAMENTOS INSUMOS Y DROGAS

KFDA
Korea Food & Drug Administration
식품의약품안전청

INVIMA
Instituto Nacional de Vigilancia de Medicamentos y Alimentos

State of Israel
Ministry of Health
משרד הבריאות, ישראל

IFDA
سازمان غذا و دارو

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration
TGA Health Safety Regulation

Awards

Aesthetics awards

(2015)

My face my body awards

(2016)

Pearls of Aesthetic Dermatology

(2016)

Azerbaijan Aesthetic & Anti-Age Medicine Congress

(2017)

Safety in Beauty – Diamond Awards

(2017)

The upgrade many people were looking for

-Microprocessor checking online the output signal -assuring the output is respecting the scientific literature parameters-
- Patented design by GMV
- Touch screen display
- Video tutorials
- Extractable lithium polymers battery pack (12h recharge)
- Software updates for new functions –fractional mode-
- High quality packaging
- The handpieces ion lithium battery (5h high performance)
- Portable charging-base for car lighter and power plug
- Quality of the components

About us

GMV is based in Rome, where the most advanced technologies are developed, following the rules of Made in Italy and in compliance with European standards in terms of safety, quality and reliability. The ISO 9001 and EN ISO 13485 quality management certifications confirm the professionalism of our company.

Our devices, certified according to the Directive 93/42 / EEC for medical devices, are made entirely within our company, from the generation of ideas and prototypes to production and sales.

GMV first introduced plasma technology in 2006 leading to a development in plasma medicine for aesthetic medicine. The Plexr plasma medical device was the first device to be used for minimally-invasive interventions. With over 9 years of scientific research, Plexr plasma medical device has been proven to be safe for clinical use.

Designed and manufactured in Italy, the Plexr technology is the most completely studied medical plasma device in the world today.

Numbers

More than 10.000 Plexr sold in 50 countries

More than 100.000 treatments with Plexr all over the world

94% satisfaction of people treated with Plexr

-55% on average overall time reduction for a treatment compared to classical treatments

-45% on average cost reduction for a treatment compared to classical treatments

Choose the safety for your body. Choose the best efficacy treatments. Choose Plexr: The Original One

WWW.GRUPPOGMV.COM

ISO 9001:2015
ISO 13485:2016

Rev. 0