

Genuine Dermaroller™ Therapy™ Procedure

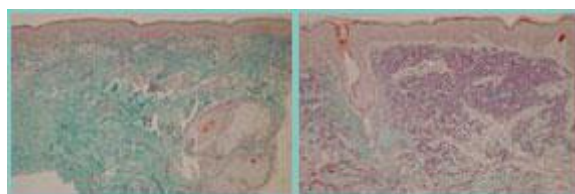
Your practitioner will use a Genuine Dermaroller™ medical device to produce thousands of micro-medical needle-columns in the skin. Each column will penetrate into the dermis of the skin and will be approximately 0.1mm in width. The column will close rapidly enabling the skin to recover quickly - often in the same day. Your practitioner will use a topical anaesthetic to numb the skin making the procedure comfortable; it will normally take up to 30 minutes for the topical anaesthetic to work and 20 - 30 minutes for the Genuine Dermaroller™ Therapy procedure.

After a Genuine Dermaroller™ Therapy™ procedure your body will start to naturally regenerate and repair the skin, working below the surface in the dermis. This takes time as new collagen is formed, new skin cells are generated and blood supply is enhanced. It can take up to 6 weeks before visible signs of regeneration and repair are seen and the process will continue over the following months, providing you with a natural and long lasting enhancement.

Your practitioner will normally recommend that your Genuine Dermaroller™ Therapy™ consists of a series of three Genuine Dermaroller™ procedures with approximately 6 weeks between them.

In the treatment of acne scars and other types of scarring it may be necessary for your practitioner to extend your Genuine Dermaroller™ Therapy™, carrying out up to five procedures.

Skin Biopsy images showing new collagen



Before

After

Before and after Genuine Dermaroller™ Therapy™. The area stained purple in the skin biopsy taken after a Genuine Dermaroller™ procedure is newly formed collagen.

Genuine Dermaroller™ Therapy™ Treatment Results



Acne scarring

Improvement of acne scarring after two Genuine Dermaroller™ procedures



Ageing & sun damaged skin/lines & wrinkles

Improvement of lines & wrinkles on ageing & sun damaged skin 3 months after one Genuine Dermaroller™ procedure



Stretch Marks

Improvement of stretch marks after two Genuine Dermaroller™ procedures



Efficacy and safety in pigmented skin

Improvement of acne scars after four Genuine Dermaroller™ procedures

Post-procedure skin care

Immediately after your Genuine Dermaroller™ Therapy™ you will look as though you have moderate sunburn and your skin may feel warm and tighter than usual. This will start to subside after 1 to 2 hours and will normally recover within the same day with only slight redness the following day.



Skin immediately after Genuine Dermaroller™ Therapy procedure



Your practitioner may well apply **Chiroxy Cream** after the procedure to help soothe and calm the skin, continue to use until the redness has cleared.

Use tepid water to cleanse the face for the following 48 hours and dry gently, always make sure your hands are clean when touching the treated area. It is recommended that make up is not applied for 12 hours after the procedure although your practitioner may be able to supply you with specialist mineral make-up that they feel would be suitable for use during this period.

If you will be in daylight immediately after the procedure apply a broad spectrum UVA/UVB sunscreen with a SPF50.



AesthetiCare® recommend **Heliocare Cream or Gel**, continue to apply this on a daily basis for at least two weeks even during the winter or on cloudy days.

In the days following your Genuine Dermaroller™ Therapy™ as the skin starts to regenerate and repair it may well feel drier than normal.



Genuine Dermaroller™ home meso-rejuvenation treatment

Genuine Dermaroller™ Therapy™

Frequently Asked Questions

Why should I use a trained practitioner and an authorised Genuine Dermaroller™ Clinic?

The Dermaroller™ medical devices are designed to be used by trained medical practitioners and their clinics in a procedure that will create approx 300 micro medical needle channels per cm² in to the dermis of the skin. Below the outer stratum corneum layer of the epidermis the needle is penetrating in to living tissue. In the dermis, the target area of Genuine Dermaroller™ Therapy™, there is a complex of epithelial cells, blood supply, nerve cells, extracellular matrix, collagen, elastin and cells such as fibroblasts that produce and repair this essential part of our bodies. By providing a controlled physical stimulation of the dermis your practitioner is able to initiate a natural skin regeneration and repair process that can lead to smoother, brighter, healthier, younger looking skin and that can help improve and smooth atrophic scarring caused by diseases such as acne and chicken pox, and injury. To achieve the desired results it is often necessary to carry out 3 procedures approx 6 weeks apart, this will always be done under consultation and agreement with your medical aesthetic clinic. To see and read some of the results that can be achieved check out the [treatment results page](#) and the [What the Practitioners and Patients say page](#) on this website.

But don't get fooled in to thinking that skin-needling is a procedure you should do yourself at home, no matter what some of the non-medical device needle roller re-sellers and websites say. For an effective treatment your practitioner will be looking to achieve pin-point bleeding, uniform redness and slight swelling across the treatment area. The Genuine Dermaroller™ Therapy™ will however be comfortable, a topical anaesthetic will be applied (this should only be used under medical supervision), this "numbing" effect along with the quality of the device and the technique of the trained practitioner will make the procedure a pleasant experience. Once the Genuine Dermaroller™ Therapy™ procedure has finished and the skin has been cleansed and soothed the treated area will look just like the sunburn we mentioned earlier and will feel warm and tight. Because Genuine Dermaroller™ practitioners have been through thorough training effective treatment can be provided around the delicate mouth area, around the sensitive eye contour and even on the eye-lids, **but this should only be done under the care of a trained medical professional within an approved Genuine Dermaroller™ medical aesthetic practice.**

The tremendous benefits of Genuine Dermaroller™ Therapy are not only the fantastic clinical results but the excellent safety profile and lack of down-time associated with the procedure. Because the Genuine Dermaroller™ medical device is of such high quality, with precision surgical needles that are incredibly sharp and fine and a medically engineered design (including needle-length), minimal pressure is required to achieve the creation of the multiple skin-needle columns and virtually no unnecessary peripheral damage is caused to the skin. Therefore your practitioner can achieve optimum stimulation of the dermis, whilst keeping the outer layer of the skin the epidermis intact. This reduces the risk of exposure to UV and minimises the "social down time". Normally after a procedure the skin looks like moderate sun-burn that will normally significantly reduce within 12 to 24 hours.

If you think you are a potential candidate for Genuine Dermaroller™ Therapy™ make sure you consult and discuss your needs with a trained and approved Genuine Dermaroller™ Therapy™ practitioner and clinic, initial information can be found on this website on the [find a clinic page](#). Only medical practitioners and clinics that have had their practitioners go through the thorough Genuine Dermaroller™ medical device training can use the Genuine Dermaroller™ if you are in doubt please contact us by [email](#) or **Freephone 0800 0195 322** and we can advise.

If you do not see the Dermaroller® logo on the outer packaging of the device then it is not a Genuine Dermaroller™ medical device, trained and approved Genuine Dermaroller™ medical professionals and clinics only use Genuine Dermaroller™ medical devices, we do not supply to any body else. Also please remember Genuine Dermaroller™ medical devices are sterile single-use, so your safety will never be compromised by a device that has been stored and re-used.

Is the Dermaroller™ a CE marked medical device and are any of the alternative skin needle-rollers CE marked?

To supply a medical device in the UK and the rest of the European Union the manufacturer must comply with the European Medical Device Directive MDD 93/42 EEU. To supply a sterile medical device the manufacturer and the manufacturing process must be inspected, audited and certified by a notified body and be able to provide a Certificate of Conformity issued by the notified body and the packaging must carry a CE mark accompanied by the notified body unique number which can be easily checked and verified.

Dermaroller™ Class IIa sterile single use medical devices are the only sterile skin-needle rollers in the world that comply with the European Medical Device Directive. They have a Certificate of Conformity issued by MedCert, Germany, are accordingly CE marked and their manufacturing process is certified according to ISO13485, the medical device manufacturing standard. Regulatory compliance of the devices and the manufacturing process are your assurance of quality. Only the Genuine Dermaroller™ meets this standard - do not accept substitutes.

Some skin needle rollers claim to be FDA approved and/ or registered, some even have the FDA logo on the pack and websites, does this mean they have a similar seal of quality and external validation and approval that the Genuine Dermaroller™ CE marking and European medical device certificates provide?

Compliance with the regulatory standards conveys assurance of quality and safety profile. It must be for this reason that a number of the needle-rollers, their distributors and re-sellers claim "FDA approval" or "FDA registration" and have the FDA logo printed on the packaging, literature or websites. Unfortunately none of the rollers can claim to have FDA clearance and can not state that they are "FDA approved", "FDA registered" or use the FDA logo. As you may be aware some of them do and this is mis-branding. Skin-needle rollers that currently make themselves available in the USA have found a way of doing so by self-classifying as a Class 1 Device described as a 'manual surgical instrument for general use' and as such should make no therapeutic claims.

Accordingly, under FDA 21 CFR878.4800, devices that fall in to this category are exempt from the FDA 510(k) pre-market notification requirements and it is only necessary to register the establishment and the device with the FDA on their website prior to sale. This is purely an administrative process **and it does not permit use of the FDA logo or convey assurance of quality or approval.**

To quote the FDA 21 CFR807.39;

"Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

Furthermore you will find the following statement on the FDA website;

"Misuse of FDA's logo may violate federal law; FDA's logo should not be used to misrepresent the agency nor to suggest that FDA endorses any private organization, product, or service".

Dermaroller SARL currently makes the Genuine Dermaroller™ available on a limited scale in the USA by this mechanism also. It is a grey area but they do play by the rules and neither they, nor we, make false claims about this status.