Dear Reader,

We invested great effort in producing this manual. All findings were thoroughly investigated and are based on the research of different scientific disciplines.

As science never rests, and as each of you may find new knowledge, we would appreciate it very much if you would share your findings with us. Each small discovery may be of importance and may be only a little stone for the entire mosaic in order to understand the full mechanism of action of Collagen Induction Therapy.

We are just at the beginning of understanding how and why Dermarolling has a therapeutic effect, and we hope our knowledge will continue to increase in future. Whenever new findings become available we shall send you the latest version of this manual.

My personal thanks go to all my friends, scientists, plastic surgeons, distributors and many other experts in the field of modern aesthetic treatment. They all contributed a lot that the DERMAROLLER-CONCEPT became an international success.

As an ISO-13485 certified German manufacturer for CE-marked medical devices, we guarantee you the best standards in quality and service. The fact that hundreds of thousands of Dermaroller users around the world are content is our driving force to develop new, innovative concepts for the future.

Sincerely yours,

Horst Liebl
President
Dermaroller Sarl.
About DERMAROLLER®

The Dermaroller Company was founded by Horst Liebl. The company and its activities in developing medical devices and medical implants date back to 1983. The development started parallel to the foundation of a clinic for plastic and reconstructive surgery in Stuttgart/Germany.

In 1997 the founder settled in France and started research and engineering of the Dermaroller in 1999. The initial purpose of the Dermaroller was to develop an instrument for fast, easy, side effect-free and painless infiltration of active substances through the stratum corneum. In 2000 the University of Marburg/Germany confirmed the efficacy of the Dermaroller in 2 clinical studies. The same year the device was patented in Germany and trademarked in Euro and USA.

Experimenting with various needles sizes finally confirmed that microneedles induce massively new collagen- and elastin fibres (neo-collagenesis) as well as new capillaries (neo-angiogenesis) in human skin. Clinical trials and blinded studies performed by the plastic surgeon M. Schwarz substantiated this phenomenon.

In 2004 Dermaroller instrument was registered as a medical device and initial sales started in Far East. The reason for this marketing concept was that Asian cultures appreciated needling devices since thousands of years. In less than 9 months the Dermaroller became popular all over Asia and sales moved to Europe and USA where the Dermaroller was FDA listed as a surgical hand held instrument.

In 2007 our first production centre in France became too small and a new fabrication site was established in Wolfenbuettel/Germany. The private owned capital company was re-structured and named in “Dermaroller S.a.r.l.” Deutschland and certified according to ISO 13485 as a manufacturer for medical devices. All Derm Rollers are medical devices and CE-marked by the Notifying Body “Medcert GmbH” in Hamburg/Germany with its registration number 0485. The company is managed by Horst Liebl and his son Michael Tomerius, Vive-President and director of sales.

The marketing success of the Dermaroller was based on two columns: intensive travelling with lecturing and workshops in over 40 countries worldwide, as well as the participation on internationals congresses for dermatology. The success of the Dermaroller exceeded all our estimations and resulted in sales figures of more than 150,000 pieces in less than 3 years.

The second column of success was and is based on intensive research with universities, clinics, hospitals and individual clinicians throughout the world. The main purpose was to proof the medical efficacy to treat atrophic scars, mainly acne scars, and many other skin disorders, as well as the enhancement of various drugs through the stratum corneum including DNA vaccination. Thanks to the support of many scientists as well to the intensive engagement of many of our business affiliates we could widen the therapeutic spectrum of the Dermaroller. Today the Dermaroller and the latest development, the DermaStamp®, are respected and acknowledged medical devices that entered the scientific literature under the synonym Dermaroller®, Collagen-Induction-Therapy (CIT), DermaStamp® and microneedling. Numerous articles and findings can be downloaded from our remote server.

Friesenheim/France, October 2008
Horst Liebl
Dear colleagues,

As a plastic surgeon I have learned and practiced many methods for aesthetic reconstruction. But seldom was I so impressed and convinced on first sight by such a simple looking, and especially NON-invasive method like the COLLAGEN-INDUCTION-THERAPY (CIT).

In a blinded study and in collaboration with other colleagues I could produce scientific evidence that the fine needles of the Dermaroller induce body-own collagen- and elastinfibers.

In contrast to all invasive techniques, such as Laser, Dermabrasion, Acid-Peelings, etc., when practicing the CIT the protective epidermis stays intact. This aspect I want to underline, because this innovative method for skin rejuvenation practically has no visible side effects. For the first time we managed to improve wrinkles, scars, acne-scars, cellulite and pigment changes successfully.

I am very much convinced that the DERMAROLLER-CONCEPT has opened a new page in the history of aesthetic treatments.

Sincerely yours,

Martin Schwarz M.D.
Member of the Association of German Plastic Surgeons
MECHANISM of ACTION IN MICRONEEDLING

IMPROVEMENT OF SKIN STRUCTURE BY NEO-COLLAGENESIS AND NEO-ANGIOGENESIS WITH THE DERMAROLLER®

Although the mechanism of action with the Dermaroller is not totally explored, nevertheless the results for the improvement of skin structure and scars, especially acne scars, in over 100,000 cases speak a clear language. The procedure with the Dermaroller became standard expressions in scientific literature with the terms COLLAGEN-INDUCTION- THERAPY (short: CIT) and MICRONEEDLING. Our present state of knowledge is the following: A drum shaped roller stud with 192 fine micro-needles from 0.5 to 1.5 mm in length and 0.1 mm in diameter penetrate to dermis repeatedly for about 20 times. The skin cells react to these micro injuries and stimulation with the release of various growth factors.

These in return stimulate the proliferation of undifferentiated cells and this reproduction results in NEO-COLLAGENESIS and NEO-ANGIOGENESIS. New tissue structures are generated in forms of elastin- and collagen fibers as well as new capillaries. They integrate into the existing upper dermal layer without any fibrotic traces. New fibroblasts and capillaries will migrate through the punctured scar tissue. Both processes result in a “fill” the former atrophic scar and new capillaries result in a significant better blood supply that in return results in an improved re-pigmentation.

So far we regarded the mechanism of action of the Dermaroller for skin improvement, especially for atrophic scars, from a more isolated aspect of the Neo-Collagenesis, and therefore the aspect of the Neo-Angiogenesis for scar re-pigmentation was considered too narrowly. There is enough evidence that both disfigurements can be successfully treated. In comparison to skin texture improvement the rectification of scars is easier to judge by the physician, patient and subtle objective observers. According to the reports and scientific findings and clinical cases we received from experts worldwide the rate of success for the treatment of atrophic scars is 70 to 80% after 2 to 4 procedures.

As explained further down, it is my point of view that the cell biological activities in the skin during and after Dermarolling are far more complex as assumed till today. The wound healing mechanisms after an injury are well re-
searched and do not require any further explanations. Although numerous needles with a diameter of 0.1 mm penetrate the dermis and sub-dermis repeatedly the same tissue spot (about 15 to 20 times) down to a depth of maximum 1.5 mm, no wounds in the classical sense at set, and traces of fibrotic tissue could not be detected in histological examination. (A tiny, but solid needle should not be mixed up with a hollow injection needle. Injection needles have always an inclined cut, and will therefore act as a cutting device, that usually results in a scar).

The tiny micro-bleedings after Dermarolling originate from punctured capillaries that are “emptied” and noted as tiny petechiae in the skin’s surface. But the needles do not cause bleeding in the classical sense. If the micro-bleeding sets free sufficient various growth factors to induce cell-proliferation is doubtful and requires more research. But if we replace the term injury after a needle prick with the term sensation we get a totally different picture of cell-biological sequence in the skin. But before we have a closer look at the reactions of various skin cells by signals, we would like to shed some light on the skin improvements after Dermarolling:

Facts after one or several Dermaroller sessions:
   a) Significant improvement of wrinkles and skin texture
   b) The skin looks fresher and more juvenile
   c) Scars and acne scars are drastically reduced
   d) Pigment spots become more even or disappear in total

After a Dermaroller therapy we always observe the same reactions: NEO-COLLAGENESIS and NEO-ANGIOGENESIS.
Up to what extent other cell formations are stimulated for regeneration is subject to further research. But at this point we definitely can make the statement that the Dermaroller definitely contributes to skin rejuvenation. Neo-Angiogenesis connotes a better blood flow. The supply with more oxygen and nutrition is increased, and the evacuation of metabolism debris is accelerated.

At this point we also would like to emphasize the fact that from our point of view no ablative procedure will stimulate Neo-Angiogenesis, and that includes also fractional lasers. We believe it is the opposite since the “hot” laser beam “fuses” the capillaries and other tissue, and stimuli for sprouting of new vessels will be suppressed. The laser beam transforms protein into necrosis (>50°C) that finally transforms into fibrotic tissue. These subdermally set fibrotic points become confluent after several treatments and result rather in an upholstering effect below wrinkles. But it is more than unlikely that a fractional laser beam stimulates neo-angiogenesis. And additionally to this fact, the laser beam suppresses bleeding by fusing capillaries, and this in return will stops the release of growth factors from blood platelets. And in addition the laser beam will destroy stems cells as well as other non-differentiated cells and obstructs their potential for proliferation.

Till 2005 we knew little about the mechanism of action of the Dermaroller in respect of neo-collagenesis. But the findings of Martin Schwarz changed the entire picture, and we were encouraged to invest more time and financial sources to analyze this phenomenon. The article of Min Zhao et al. in NATURE magazine 2006 was the ignition point to invest more time in the study of cell biology were we found many answers.

To any injury or sensation of the epithelium the organism reacts with electrical signals, and these in return initiate a cascade of regeneration mechanisms. Usually there is a resting potential of -80 mV between the cells and the surrounding electrolyte, the extra cellular liquid. The internal cell is charged negative, the surrounding interstitium and the skin surface is charged positive. Not only after an injury, but obviously already after a stimulation the skin cell membrane becomes semi-permeable to release various chemical elements such as potassium, sodium and anionic proteins, as well as growth factors into the interstitium. This process changes the electrolyte, the conductivity increases and the electrical resistance decreases dramatically. At the same time the electrical charge inside the cell drops to 0 mV or above to +30 mV. This potential difference is essential for the regenerative process. Research at Owen Biosciences and MatTek® laboratories show, that the needles of the Dermaroller have their own electrical potential that obviously increases the electrical potential between the intra- and extra cellular situation. These tests were performed on laboratory skin that does not have blood vessels. But still an increase of collagen fibers and released growth factors could be substantiated.

Based on these facts we have revised our articles and graphics about the mechanism of action during and after Dermarolling.
This change of the electrical potential was measured on a nerve cell and takes about 1 millisecond. Skin cells might have a slightly higher reaction time.

The left graphic shows the distribution of chemical elements in cells and the extra-cellular space before an injury or stimulation. In this stage the membrane is (almost) not permeable.

In case of epithelial stimulation nerve cells send signals within milliseconds to the surrounding skin cells. The membrane of the skin cells becomes permeable and releases the chemical properties in delayed steps into the interstitium. The electrolyte changes its conductivity (diagrammed in a deeper blue).

Within milliseconds this process is reversed. The membrane changes its permeability to the opposite and the previous released chemicals return into the cells. As long as the nerve signal persist, this release and return from and back to the cells continues. This continued process is called ion-pump.

We assume that cell-released growth factors, and possibly those from punctured capillaries, stimulate stem cells and other non-differentiated cells to proliferate. Newly produced fibroblasts migrate towards the point of injury for repair purposes.
But a „repair“ as in normal injuries does not take place. Since the needles are sterile and no gaping wound exists, the fibroblasts are possibly “fooled” by the needles. The needles penetrate the skin only for fractions of seconds, and the pricking channels are closed within minutes by skin’s elasticity. (As shown in in-vitro pictures of the University of Jena after Dermarolling).

The resting potential is restored and fibroblasts transform into collagen fibers. Point 5 indicated the neo-angiogenesis of capillaries (see more distinct graphics further down).

In relation to its seize the cell-membrane potential is enormous. In average the membrane has a thickness of 70 to 100 nm. If the membrane would be up-scaled to 1 m the electrical potential difference would be 10 million Volt. (Jaffe et al.)

Histological findings of a blinded study. Performed by Schwarz und Laaff, Freiburg/Germany, 2006. In the right biopsy an increase of exactly 1000% of new collagen- and elastin fibers (stained purple) could be found.

There are a lot of discussions “how long” a needle for collagen induction should be. The slide with the projected needle clearly indicates that new collagen formation only forms in the upper dermis and down to an average depth of 0.5 to 0.6 mm.

There is no logic reason to use longer needles when the average skin thickness is only 1.5 mm.

As postulated by Augst et al. the new collagen formation integrates into the elastic collagen grid below the corium but never forms a fibrotic cluster, as it is the case after wound repair by fibrosis.
Most Dermaroller treatments were performed on acne scars. The sharp needles perforate the stringent and hard scar tissue. This supports the migrating of new capillaries and collagen fibers into the previous scar bed to form new tissue.

Neo-Angiogenesis can only be logically explained when non-differentiated endothelial cells proliferate and new capillary sprouts migrate into the needled fibrotic tissue.

The previous hypo-pigmented scar tissue and its surrounding resume a normal blood circulation and the ivory-like scar disappears.
It sure would be a misjudgment to assume that only fibroblasts and endothelial cells would be stimulated by Dermarolling. This would be in contrary to the phenomenon that skin-needling obviously also simulates other cells to proliferate or to decrease over production (sebum, melanin, etc.). It was observed in many cases that pigment concentrations associated with acne scars were evenly distributed after the treatment. The only conclusion we have at this stage is that electrical signals stimulated by the needling process have a direct influence on all skin cells.

**SIGNAL PATH FOR PROLIFERATION**

ONLY stem cells in the **vicinity of a distance of 1 to 2 mm** around the point and path of injury receive signals to proliferate.

Therefore we can conclude: **NOT PRESSURE** stimulates the amount of new stem cells and undifferentiated cells but the **NUMBER** of passes of the Dermaroller-Needles through the skin.

**CONCLUSION**
The body reacts to all ablative procedures with its repair mechanism – fibrosis. To Dermarolling the body reacts with cell regeneration.

No doubt, during the development of the Dermaroller the coincidence acted like Godfather. As little was known about needling it was along and frustrating way for the achievement of our today's knowledge. 1999 we started with the development of a device for transdermal delivery with tiny and short needles (0.2 mm). Today the Dermaroller is widely used (>95%) for skin therapies such as scars, pigmentation problems, etc. But in respect of the entire mechanism of action we still are in need of explanation, but the facts speak a clear language. The therapeutic value of the Dermaroller is already beyond any doubt, but we are still looking for some missing stones to form the final mosaic. In 2007 and 2008 many physicians approached us and asked for support for further investigations and studies. It was our pleasure to comply with their demands. Therefore we would like to take the opportunity to thank all these scientists. Their commitment is our motivation.
COLLAGEN INDUCTION THERAPY (CIT)

Although the CIT is not classified as an invasive medical procedure, medical rules should be followed under all circumstances. Hygiene and sterility are the top rules!

General aspects:

- Make sure your client has a healthy skin and does not suffer from any skin disease.
- Exclude the possibility of keloids.
- Don’t forget the consent form is signed.
- Make “GOOD” photos. Not so much the number of pixels of your digital still camera are of importance. The quality of the lens and light are the secret. If possible buy one with a macro lens. Use always the same distance and light source for the before and after pictures.

THE CIT PROCEDURE

IMPORTANT CHANGES for numbing creams!

By the end of 2008 we changed from the widely used EMLA (Astra-Seneca) numbing Cream to LMX4 from Ferndale/UK. Here are the reasons:

- EMLA is limited in quantity (5 grams) and contains a vaso-constrictor that tightens the capillaries and prevents desired petechiae during the procedure. (Possible shock reaction).
- LMX4 is NOT limited in quantity and works within 30 minutes.
- 20 grams should be sufficient for a face.

- Clean the area to be treated.
- Apply numbing cream on the entire face.

ALTERNATIVE:
- Apply 5grams LMX4 in a thin layer and enhance the cream with the Dermaroller model C8. Roll each skin part 4 to 5 times.
- Now continue to distribute the last 15 grams LMX4 of the entire area.

With this alternative numbing is faster and deeper and should be preferred when 1.5 mm needles (MF8, MS4) are used.

- Remove numbing cream
- Disinfect the face with Betadine or alternative
• Start dermarolling.

• Roll each part 4 to 5 times in 4 directions: vertically, horizontally and in both diagonals. This will result in about 250 pricks per square centimeter.

• The best indication for a well performed procedure is the formation of an even pattern of petechiae in skins surface.
• Take your time. Roll slowly and systematically.
• Do not twist and turn the Dermaroller while rolling.
• Do not roll aggressively

Never use high pressure. This will result in needle damage and punctured vessels and hematomas.

• Remove blood traces with a sterile swab and sterile saline solution.
IMPORTANT NOTE:
So far over 200,000 CITs have been performed worldwide. No complications have been reported, including no post-
op infections! In general no wound dressing is required. If the patient lives in a dry environment (this applies also for
air conditioned rooms) a thin layer of white Vaseline can be applied to protect the skin against moisture loss. Antibiotics are not necessary!

Do NOT enhance any drugs, vitamins or other (magic) formulations into the skin during a CIT.

Hold the Dermaroller like Chinese chops sticks. You have much more feeling in your fingertips to manipulate your pressure.

Don’t hold it this way!

In this case the weight of your hand and forearm rest on the Dermaroller and pressure cannot be controlled.

SEQUENCE OF CIT – TREATMENTS
It must be understood that our skin is a living organ and it cannot be switched on and off like a light. Wrinkles or
scars cannot be considered as a disease. At the most they are disfiguring. Aged or damaged skin cells cannot be
repaired over night even not with a CIT. The new body own collagen and elastin fibers need time to transform from
type III into the more elastic type I. Collagen and elastin fibers need time for maturation!

Therefore tell your patients to be patient. Even though the skin may look better after the treatment, do not forget
slight swelling may prevail for some days. Results can only be judged objectively after 6 to 8 weeks. In the
meantime, before a 2nd or a 3rd treatment is considered, the patient can improve the result by using the home care
Dermaroller (model C8) along with the recommended skin care products.

As skin continues to age, we recommend a refresher-CIT every year.

SOCIAL DOWNTIME
There is virtually no social down time.

SUN PROTECTION
We recommend that the patients protect their skin after a CIT with a sun screen for 8 days. MOST sun blocks have
only a limited time effect and must be renewed every 2 hours. We highly recommend the use of sun block on darker
skins!
IMPORTANT NOTE
Also be informed that NEON light radiates an ultra violet (UV) spectrum! If you meet patients with melasma or chloasma, inform them that this skin disorder can be triggered not only from sun exposure but also from exposure to neon light.

FINAL REMARK

The CIT is a modern and effective form of treatment as laid out in the previous chapters. We know we are just at the beginning with this unique form of therapy. It is our aim to support science in finding new therapies in order to help those (e.g. burn scars, skin cancer, etc.) who suffer and cannot be treated at this very moment.

We therefore kindly request all our partners engaged in Dermaroller therapies to support us and to follow our guidelines. If you discover a better way or a new procedure alternative, report it to us and we shall spread the news.
**SCARS**

Scars are wound closures by unformatted collagen fibers. According to individual characteristics and the type of injury, scars can be more or less pronounced (hypertrophic scars). In any case they are disfiguring for the affected person, especially when exposed (face, hands, décolleté, etc.). Most scars are atrophic and hypo pigmented. Hypertrophic scars should not be confused with keloids. A keloid is a benign skin tumor and should **NOT** be treated with the Dermaroller!

In medical literature we find numerous therapies for scar treatments, but we should regards them more as proposals as school of medicine is (better was) very clear in respect of scar treatments: “Very difficult!”

Compared with conventional scar treatments (incision, creams, laser, silicon patches, etc.) the results of Dermaroller scars treatments are very promising. The target of the treatment is to perforate the stringent scar tissue in order to loosen it and to break the fibrotic tissue bundles to give new capillaries a chance for re-vascularization.

**ACNE SCARS**

These forms of scars develop during and after active acne. They are exceedingly disfiguring, especially for young people after puberty. As the acne scar treatment with the Dermaroller is extremely successful, especially compared with conventional procedures, we would like to focus on this new therapy.

According to the experience of many physicians that treated acne scars, they reported that remaining active acne in the range of 10 to 20% is not a contraindication for a Collagen-Induction-Therapy (CIT) on scars. Usually the active acne disappears after the CIT. The reasons for this phenomenon are not known.

Usually acne scars are atrophic or depressed. This means that the scar surface is below skin level and therefore the skin often looks like a cratered landscape. According to Jacob et al acne scars are classified in 3 types:

**ICE PICK & BOXCAR**

These types of scars only differ in seize. From a small ice pick channel, usually not wider than 2 mm, to about 4 mm on the boxcar type. They reach from the skin’s surface into the deep dermis, sometime into the sub-dermal tissue. These scar types with their vertical scar edges have an excellent response to the Dermaroller needling if a simple rule is observed: Stretching the scar edges in all 4 directions during needling. In this case the “scar walls” are declined and the vertically pricking needles perforate them.

**ROLLING SCARS**

This is the most common and most disfiguring form of acne scars. In most cases the lower part of this scar type is connected to the deeper fascia by collagen fibers. Some improvement may be achieved by subcision.
This means in simple words, the surgeon will cut these fibers with a special scalpel. Although these scars will have less tension after subcision, it should be pointed out that a scalpel also causes a scar, although it may be smaller.

According to the tens of thousands of acne scar treatments performed within recent years with the DERMAROLLER, acne scars respond vary well to needling. Depending on the affected skin area and quality of the scars several treatments (2 to 4) may be necessary in order to achieve a maximum possible result. The results vary from 50 to 70% improvement.

In general we can state, that all types of acne scars are improved after Dermaroller needling.

This young 28 years old male is a typical case of rolling acne scars. He underwent subcision first (before he knew about the Dermaroller) and then was treated with the Dermaroller.

The fine, but sharp needles perforate the vertical and horizontal scar edges and induce new collagen formation. This new formation fills the scar (crater) with new tissue from bottom to top. At the same time the needles break down the old and hardened collagen scar strands and allow new capillaries to migrate for an improved blood supply of the former scar tissue. This re-vascularization changes the pigmentation of the tissue around the (former) scar. All these are natural physiological processes. Therefore a subcision is not necessary as the needles will also break down the collagen fibers that connect the scar to the fascia. In any case we recommend to perform a CIT first before a subcision is considered.
For a better understanding of what happens during and after scar needling, have a look at the following drawings:

After scar perforation, venous & arterial capillaries, as well as new fibroblasts, migrate through and into the former scar tissue.

Make about 15 to 20 passes over the scar(s) until you note tiny micro blood jots (petechiae) at the scar edges (usually they are much less in the scar tissue itself). These jots originate from punctures capillaries, but not from punctures blood vessels. An even pattern of these jots is the best indication for a thorough Dermarolling – see right picture.

NOTE: The more pronounced the acne scar formation, the less it will bleed during the first treatment. But you will also note that the previously treated scar will show some more bleeding in during the consecutive treatments. This is a clear indication that new capillaries have migrated into the perforated “old” scar bed.

Note: Younger scars respond much faster and “better” to a Dermaroller procedure than old ones. “Old” may be defined by one year and more.

SEQUENCES of SCAR and ACNE SCAR TREATMENTS

The Dermaroller is a medical device with all its advantages, but also with its limitations. Miracles cannot be expected. The more the skin was destroyed (by scars) the less improvement can be seen. From our experience and that of many physicians around the world that use the Dermaroller we can state: If there is no clear improvement after the 4th treatment: DO NOT continue needling! For some reasons “this” skin has no natural respond (about 2%).
Rule of thumb in scar improvement:
After 1st treatment: 40%
After 2nd treatment: 50% of 1st treatment improvement
After 3rd treatment: 50% of 2nd treatment improvement
Total in average: 70%
Any percentage above these figures should be considered as a bonus.

Please keep in mind that the body needs time to transform the new collagen of type III into type I that has more elasticity (this process can take up to 1 year). The new collagen fibers have to mature, and this is the simple reason behind the recommendation to wait at least 6 - 8 weeks before the next procedure for further improvement is performed. Too short intervals (e.g. 1 week) can result in an advert effect and an overshoot of the healthy tissue around scars.

6 weeks after the 1st treatment. It can be well noted that the previous hyper pigmentation, often associated with acne scars, has diminished.
IMPORTANT NOTE:
For the safety of your patients, and for perfect results, as well as according to the European Directive for Medical Devices and the US FDA the medical Dermaroller is classified as a SINGLE USE, DISPOSABLE INSTRUMENT. One may be tempted to re-use the Dermaroller on the same patient, please keep in mind the following:

- Scar tissue is extremely hard and the fine and sharp needle tips are subject to wear (just like any scalpel)
- Plastic components cannot be autoclaved.
- Alcohol is a disinfectant but not a sterilizer!
- Do not attempt to use so-called ‘instrument cleaning solutions’. Most of them are so aggressive that the needle tips can rust or are destroyed.
- Dull needles will result in higher penetration forces and lead to less or even no results.
- Stored and often contaminated used Dermarollers can be mixed up.

A fine surgical needle compared with a 27 G injection needle.

NEVER puncture the skin with an injection-needle! The tip of such a needle will always act like a cutting device. An injection needle will cause fibrosis, but no cell regeneration. (That can be easily seen on addicts “that are hooked to the needle”).

BURN SCARS
The treatment of burn scars is a very sensitive and critical issue. So far there is no effective therapy known to reduce the pain these patients will suffer for life. However, we are most grateful to Dr. Wichai Hongjaru from Bangkok, Thailand who was the first dermatologist that tried a Dermarolling on a burned patient in 2005. It was not his main target to improve the appearance of burn scars but to reduce the enormous tension of these contracted fibrotic tissues.

Before and after needling. See improved mobility of fingers on the right picture
The main target to treat burn scars is to perforate the stringent collagen bundles to reduce the tension and to improve the mobility of the skin. In the case above Dr. Wichai treated a make-up artist after the scars were completely healed. The right hand picture clearly shows that the mobility of the hand, especially the thumb, has considerably improved. The patient is back to work. According to the therapist more treatments will follow for further improvement.

A major breakthrough in burn scar treatment was achieved in 2009 by a systematic clinical study of the Medizinische Hochschule Hannover (Medical High School) under the directorship of Prof. Vogt. Not only for these plastic surgeons, also for us, the inventor and manufacturer of the Dermaroller, a “dream” was fulfilled.

We are most grateful and now we know that all the work in the past 10 years were rewarded in the best possible way.
INFORMATION ABOUT DERMASTAMP®
Instruction for use

In case of bigger scar areas, such as acne scars and narrow scars such as stretch marks, we have achieved good to very good results with the models MF8 (2 cm wide) and MS4 (1 cm wide) respectively. But we had a technical gap for access in difficult located and smaller single scar, that we filled in with our latest development the DermaStamp®.

The advantages of this little, but most useful instrument are obvious:

- Scar treatment with difficult access (e.g. near the eyes, behind ears, etc.)
- Rapid treatment cycle
- Low costs with permanent results
- No social down time
- No negative side effects
- No post-op pain

The DermaStamp® is a SINGLE USE, DISPOSABLE CE-marked medical device and serves the treatment of atrophic scars (e.g. chicken pox). In general scar improvement of 70% can be achieved, everything above that should be regarded as a bonus. The 6 stainless steel needles of medical grade have an average length of 2 mm and a diameter at maximum penetration point of 0.12 mm. Needle arrangement and finishing cut guaranty penetration forces of less than 50 grams. The DermaStamp® should only be handled by licensed, professional skin care specialists.

CASE 1:
The scar on the pictures below was treated for 1 minute. The patient refused an anaesthetisation. Each part of the scar, as well as the scar edges, were punctured about 15 to 20 times until petechiae showed up on the scar edges. After the procedure the treated area was cleaned with sterile saline solution. Further wound dressing was not necessary. One month later the patient came back for follow-up pictures. The clinic staff judged the improvement with 70%. (A second treatment may bring another 10 to 15%).

Before treatment     After treatment     1 month later

The last picture clearly indicates that the former depressive scar was filled with a new collagen formation and the micro-needling induced new capillaries that migrated into the previous scar. The increased blood supply harmonised the old scar tissue with the surrounding pigmentation. (Pictures by Ivan Safonov and Horst Liebl)

CASE 2 and 3:
This young woman was tortured with burning cigarettes on her forehead and her arms as well. The after pictures were taken after one month.
If an anaesthetisation is desired the physician has 2 possibilities:

- Local injection (acts immediately)
- Numbing cream* (acts in about 25 minutes)

* For topical anaesthesia we recommend **MLX4** from Ferndale, UK. This cream was tested thoroughly in micro-needling in combination with the Dermaroller and DermaStamp. It acts faster (about 30 minutes) and has no vaso-constrictor (see our MEMO about numbing cream in combination with the Dermaroller C8). If the LMX4 is not (yet) available in your country, kindly contact: Ferndale-UK, Tel: +44 (0)1937 541122, Email: info@aestheticare.co.uk

**INSTRUCTIONS FOR USE**

The DermaStamp consists of a needle holder and a protection cap. The DermaStamp is fitted with 6 stainless steel needles of surgical quality. Needle length: 2.0 mm. Needle diameter at maximum penetration point: 0.12 mm. The DermaStamp is a gamma-sterilised instrument for SINGLE USE.

**INDICATIONS:**

- Isolated scars and smaller scar formations
- Distinct deeper mimic wrinkles
- Isolated pigment conglomeration
- Transdermal delivery of hydrophilic and lipophilic formulations
PROCEDURE: Only to be performed by licensed skin care professionals

- Photos, if possible in macro
- Disinfect scar and surrounding skin (avoid alcohol)
- Anaesthetisation of scars and peripheral skin by injection, topic anaesthetizing cream
- Support your hand (see picture below). Avoid inclined pricking and rotating of the needles whilst they are inside the skin! It could cause unnecessary skin lesions.
- Hold the DermaStamp vertically above the skin
- Prick the scar and the scar edges to the healthy skin several times. The needles are extremely sharp, so only soft to medium pressure is required. **15 to 20 pricks are sufficient.**
- In order to achieve an even pricking pattern, slightly displace the DermaStamp or rotate it lightly before the next prick.

- During and after the procedure an even pattern of petechiae should show on the skin’s surface.
- Clean the treated area with sterile saline solution. No further wound dressing is required.
- Place the protection cap and dispose the instrument according to local regulations

TREATMENT INVERVALS:
In order to achieve the best possible results, 2 to 3 treatments at the most must be considered. As neo-collagenesis and neo-angiogenesis needs time to mature, the treatment intervals should be at least 4, better 6 weeks and more apart.

CONTRA INDICATIONS:
- Active, flourishing acne
- Warts
- Infected skin
- Herpes
- History of keloids

SIDE EFFECTS:
Negative side effects were never reported.

Last change: 02/2009

Dermaroller Sarl
Horst Liebl
TREATMENT OF WRINKLES

Readers are often confused by the different terms such as Anti-Aging, Skin-resurfacing, Skin-rejuvenation, etc. All these are fashion words and in the end they do not come to the point. Whatever therapy-form or cream is chosen for improvement, the skin continues to age. The target of all these therapies is, to camouflage this aging process as effectively and as long as possible. We live in times of tough individual competition, and the most beautiful will win.

Besides many different factors such as inherited disposition, environmental influences (excessive sunbathing, smoking and eating habits, etc.) contribute to the skin aging relentlessly. Facial expression and gravity are other influences that cause wrinkles to become more visible. Against pronounced and deep wrinkles around the mouth and forehead even the best Dermaroller will have only limited improvement.

The best visible results are achieved with the Dermaroller on wrinkles around the eyes (craw’s feet) and on the upper lip - areas where visible skin aging begins. The earlier and more often these kinds of wrinkles are treated with the Dermaroller the better and the more lasting are the results.

CIT around the eyes.

Upper lip 6 weeks after a CIT.
(The skin was dermarolled during a lifting procedure, as this facial part cannot be surgically lifted)
PIGMENTATION PROBLEMS
It often can be observed that acne scars are combined with pigmentation problems, especially on darker and Asian skin. For some reasons, that still need to be investigated, the melanin concentrations react to the Dermaroller needling in such a way that the pigments are more evenly distributed, and the dark spots disappear – permanently!
Unlike ablative skin techniques (such as dermabrasion, laser and deep chemical peels) it has never been reported that the skin reacts negatively to needling with hypo- or hyper pigmentation.

Darker skin is very difficult to treat with ablative laser, acid peeling or dermabrasion. The skin reacts to these relatively invasive treatments with significant and often permanent pigment changes. In such cases, as shown in the above pictures, the DERMAROLLER is a perfect alternative. Acne scars are often associated with pigmentation spots. When such a skin is dermarolled not only the scars are significantly softened, but also the pigmentation spots disappear or become less visible.
We have no perfect answer for this phenomenon, but it seems to us, that the electrical fields induced by the needles also re-organize and even out melanin distribution in the skin.

BIG PORES
Big and enlarged pores react to the Dermarolling with a reduction of the pore seize. Also the production of the sebaceous glands is reduced to a normal level. Although this is a fact, we still do not know the mechanisms of action for this phenomenon after needling. We recommend model CIT8/1.0 mm
Lax skin responds very well to Dermarolling. Recommended model: MF8, 1.5 mm

SEQUENCE OF TREATMENTS:
The sequence and intervals of CIT treatments mainly depend on the client’s skin condition. According to our experience and the feedback we have received from thousands of physicians around the world, we would like to recommend the following:

1. For facial skin rejuvenation and treatment of wrinkles around the eyes and upper lips we recommend the model CIT8/1.0 mm
2. Depending on skin condition and depth of wrinkles several treatments are required. In order to achieve an optimal result, in general 3 procedures are required.
3. As collagen and elastin fibers need time to mature, the results of the previous treatment can be judged best after 6 to 8 weeks at the earliest.
4. As skin continues to age, it is advisable to go for an annual CIT refresher.
5. In order to maintain the results from the initial CIT procedures, we recommend the use of the home care Dermaroller model C8 in combination with an appropriate lipo-peptide. 3 times Dermarolling with the C8 per week is sufficient. The peptide can be used daily.
6. Also very short needles (model C8) open the stratum corneum for some minutes. Therefore we highly recommend application of a good moisturizer cream after Dermarolling.

What you should NOT do:

Remember, the needles as such and alone do induce natural collagen. Therefore:

- Do NOT Enhance so called “miracle serums or special cocktails” while performing the CIT.
- NEVER use a copy!
TRANSDERMAL DELIVERY

Although this uppermost epithelial layer, the Stratum Corneum (SC), is extremely thin, about 10 to 20 μm, it protects the body against environmental influences, bacteria, etc. Even the best and tiniest liposomes, with a diameter of 200 μm or less, have difficulties to penetrate this layer. As chemical enhancers are critical to some extent it was our aim to find a simple and painless mechanical device to enhance active substances into the skin. We achieved this goal with the invention of the DERMAROLLER that was patented in 2000.

At those days we postulated that transdermal delivery will play a major role and its popularity will increase in the future. Skin problems in all their varieties, e.g. skin cancer, can be treated more easily when the drug is directly delivered to the effected skin part, only fractions of a millimeter below the skin’s surface. Using such transdermal delivery systems as the DERMAROLLER® or Dermastamp®, the use of systemic drugs, delivered orally or i.v., can be avoided. This will reduce systemic side effects to an absolute minimum and possibly down to zero. Today we have evidence, based on several scientific papers that skin problems such as actinic keratoses, basalioma, warts, etc. can be effectively treated with the Dermaroller/Dermastamp in combination with ALA and Photo Dynamic Therapy.

The most suitable Dermaroller model for painless and superficial transdermal delivery is a model with a needle length of 0.15 to 0.2 mm and a diameter of only 0.07 mm at maximum penetration point. This needle length is perfect to penetrate the epidermis with an average thickness of 0.1 to 0.15 mm. As the skin nerve receptors are located about 0.2 mm below the SCs, the Dermarolling is free of pain. At the most, Dermarolling with such short needles may be felt as a slight tickling.

The stratum corneum reacts so fast and flexibly that the fine penetration channels created by the needles are closed within 10 minutes.

In order to understand this phenomena from a more practical point of view, here is a little example that mainly concerns men: after shaving with a blade razor, normally an after shave lotion is applied. Usually these lotions are based on alcohol with some perfume. If such a lotion is applied to the skin directly after shaving, you can feel a “burning sensation”. This is normal because the razor blade has removed the entire stratum corneum and the alcohol can penetrate into deeper skin layers. If you repeat this little experiment about 10 minutes after shaving no burning sensation will be felt – a new stratum corneum has formed, and the lower skin is perfectly protected again.

Findings of the University of Marburg clearly show, that even the best liposomes with their active substances can penetrate the epidermal barrier, the stratum corneum, only with about 0.3% (99.7% are wasted). But if these substances are enhanced with the Dermaroller, about 200 times and more substance will penetrate the skin, depending on the number of roller movements.
ROUND or FLAT enhancing devices?

The cosmetic and pharmaceutical industry has made many efforts to develop simple devices for transdermal delivery.

Usually the needles are etched from silicon wafers. Round arrangement of silicon needles is very difficult. They are widely used in combination with patches for controlled drug release (e.g. hormones, etc.)

The needles of the Dermaroller have a round arrangement. With 20 mm in diameter, only 8 needles penetrate the skin at a time, and the maximum force required to Dermaroller the skin is only 100 gram.

A flat silicon chip with 12 mm side length and studded with 8 by 8 (64) needles with a tip separation of 1.5 mm requires a penetration force of 25 N (2.5 kg). So it is obvious that a round needle arrangement has many advantages, not to mention the fast Dermarolling movement.
Epidermis increases in thickness

In recent research results it was confirmed that even the short needles of the Home Care Dermaroller C8 with a needle length of only 0.15 to 0.2 mm (0.0078 inch) have a positive effect on the epidermis without any skin care products. Many believe that the epidermis consists of dead skin cells, but this is not the case. It is the contrary! Especially in the lowest layer, the basal membrane, we can observe very vital processes. In order to highlight and to see what happens in the epidermis with an average thickness of 0.1 mm (0.0034 inch), please refer to the up-scaled schemes.
What influence have fine needles of the Dermaroller on the epidermis?

The renewal cycle of the epidermal cells is between 20 and 30 days. In aged skin this process is prolonged. From research in the laboratories of MatTek™ and Owen Biosciences™ (USA) with the Dermaroller® we know that even short needles influence the cell communication by electrical signals, especially in the basal membrane. Growth Factors Signals stimulate and accelerate the cell proliferation of keratinozyts, basal cells, etc.

This cell stimulation caused by Dermarolling the skin, reduces the proliferation cycle and increases the re-production of undifferentiated and differentiated cells. This again results in an increase of the keratin layer of 30% and more. The keratin layer is pushed upward and finally forms the stratum corneum. This last layer of skin scales with an average thickness of one hundreds of a millimeter (0.0004 inch) finally forms the first protection layer of our skin towards environmental influences.

Aged skin often has a matt, grayish appearance. This is caused by the slowed cell proliferation and the keratin loses its transparency and looks like a matt coating. This transparency is the substantial optical difference between young and old skin.

**These matt scales are removed by the fine needles of the Dermaroller.**

The Home Care Dermaroller combines several advantages in one: Increase of the epidermal cells and improvement of transparency.

In order to achieve this effect, the Dermaroller may be used only 2 to 3 times per week. Verifiably suitable skin care products can support this effect.

Following observations were reported by individual users of the Home-Care-Dermaroller. They used it for 2 to 3 months on a regular basis of 2 to 3 applications per week:

1. Reduction and normalization of big pores in connection with a reduction of sebum production.
   (We assume that the fine needles carry away excessive keratin and keep the sebum ducts open).

2. A significant cutback of transient acne associated with the monthly cycle.
   (We assume that the fine needles carry away excessive keratin and keep the sebum ducts open).

3. A softer and more transparent skin.

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**Over 30% increase of epidermal thickness by Home Care Dermaroller C8**

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## DERMAROLLER MODELS & DERMASTAMP

**Indications – Contra-indications**

**Pain management – Practical hints**

<table>
<thead>
<tr>
<th>Model</th>
<th>Indication</th>
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<tbody>
<tr>
<td>C8</td>
<td>192 needles in 8 rows, needle length 0.20 mm, needle-Ø 0.07 mm</td>
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<tr>
<td></td>
<td><strong>INDICATION:</strong></td>
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<tr>
<td></td>
<td>Transdermal delivery of products</td>
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<tr>
<td></td>
<td>Improvement of skin texture</td>
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<td></td>
<td>Thickening of epidermis</td>
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<tr>
<td>CIT8/0.5</td>
<td>192 needles in 8 rows, needle length 0.5 mm, needle-Ø 0.8 mm</td>
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<tr>
<td></td>
<td><strong>INDICATION:</strong></td>
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<tr>
<td></td>
<td>Melasma, hypo- and hyper pigmentation</td>
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<td></td>
<td>Deeper transdermal delivery of products</td>
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<tr>
<td>CIT8/1.0</td>
<td>192 needles in 8 rows, needle length 1.0 mm, needle-Ø 0.9 mm</td>
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<tr>
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<td><strong>INDICATION:</strong></td>
</tr>
<tr>
<td></td>
<td>Melasma, hypo- and hyper pigmentation</td>
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<td></td>
<td>Skin resurfacing</td>
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<td></td>
<td>Sun damaged skin</td>
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<tr>
<td></td>
<td>Wrinkles (light to medium)</td>
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<tr>
<td></td>
<td>Large pores, excessive sebum production</td>
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<tr>
<td>MS4</td>
<td>96 needles in 4 rows, needle length 1.5 mm, needle-Ø 0.10 mm</td>
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<tr>
<td></td>
<td><strong>INDICATION:</strong></td>
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<tr>
<td></td>
<td>Scars (small)</td>
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<td></td>
<td>Stretch marks</td>
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<td></td>
<td>Acne Scars (smaller areas)</td>
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<tr>
<td></td>
<td>Burn scars</td>
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<tr>
<td></td>
<td>Deeper wrinkles</td>
</tr>
</tbody>
</table>
**MF8**  
192 needles in 8 rows, needle length 1.5 mm, needle-Ø 0.10 mm

**INDICATION:**  
Scars (wider areas)  
Acne Scars (wider areas)  
Burn scars

---

**M925**  
172 needles in 9 rows, needle length 2.5 mm, needle-Ø 0.13 mm

**INDICATION:**  
Burn scars

---

**Beauty Mouse**  
3 C8 roller heads, 480 needles, needle length 0.20 mm, Ø 0.07

**INDICATION:**  
Treatment of Cellulite  
Enhancement of active substances  
Improvement of skin texture  
Thickening of epidermis

---

**TREATMENT INTERVALS:**  
Recommended average number of treatments: 2 to 3  
Treatment intervals: 6-8 weeks for 2\textsuperscript{nd} and 10 weeks for 3\textsuperscript{rd} treatment, (the longer you wait, the more can collagen mature from phase III to I)  
Possible average success rate: 50 – 70%  
**Any higher success rate after a CIT should be considered as a bonus.**

**Home Care Dermaroller**  
In between and after the last treatment (CIT) we recommend that the patient use the Home Care Dermaroller model C8 (needle length: 0.15 mm) in combination without or with an appropriate skin care product. As tolerated the C8 should be used 2 to 3 times per week before bedtime.
PAIN MANAGEMENT
Micro needling with needles longer than 0.3 mm is painful, and there is no reason for patients to experience pain during the procedure. There is a simple rule: The longer the needles and the higher the pressure on the device, the more pain will be experienced.

Physicians have to opt between 4 different ways of anesthesia:

a) Full anesthesia (usually only for burn scars)
   b) Nerve block
   c) Sub dermal injection
   d) Topical anesthetics - numbing cream. We recommend LMX4. It works faster and more efficient than EMLA and has no vaso- constrictor. LMX4 does not require an occlusive wrapping foil.

After the treatment and/or in between of treated areas, skin can be cooled by applying cold swabs soaked in saline solution.

Contraindications:
Patients with, or a history of, keloids. Patients with, or a history of Herpes simplex and labialis. Areas of infected skin. Areas of skin that have warts, skin cancers, solar keratoses. Patients receiving anti-coagulant therapy, chemotherapy, radiotherapy, high doses of corticosteroids, oral retinoids. Patients with uncontrolled Diabetes mellitus. Lidocain has negative side effects on pregnant or breastfeeding patients.

Negative side effects:
Side effects are not anticipated or reported but good skin hygiene before and after the procedure is advised to further minimise the risk of infection, and prolonged sun or other UV exposure is not recommended after the procedure to further minimise the unlikely risk of pigmentation.
The stainless steel of the Dermaroller needles contains about 8% nickel. During the short procedure it is most unlikely that a patient could develop an allergic reaction - it was never reported.

USEFUL AND PRACTICAL HINTS
The patient experiences the procedure, especially with longer needles (MF8, MS4), like a coarse brush is driven over the skin. Each person has a different pain level that is psychologically influenced by the circumstances. But in any case the pain level is physiologically lowered by high pressure on the needling device and tissue. Therefore we recommend considering the following points:

• **NEVER APPLY TOO MUCH PRESSURE!** The needles are so sharp that they will penetrate the skin effortless with their whole length. If you apply too much pressure the needle tips can touch the bones and become bent, or they penetrate lower muscles and vessels that will result in avoidable hematoma. High pressure causes more pain!
• Roll evenly with a constant and moderate speed.
• **DO NOT TWIST OR TURN** the Dermaroller while the needles are inside the tissue! A routed professional will change rolling direction **DURING** the roller movement by 2 to 3° in order to achieve an even pricking pattern on the entire area. A static twist and turn will result in bent needles and this will result in additional tissue lesions.
• **NEVER APPLY LATERAL FORCES!** Also this will result in bent needles and tissue lesions, such as scratches.
• Please remember, skin needling not only triggers fibroblasts to proliferate, but obviously also “encourages” more or less all other cells in the skin to regenerate – what ever the mechanism of action may be.
• Therefore, each skin part must be needled intensively several times, best 4 to 5 or more times in each direction. The best indication for a sufficient “Dermarolling” is the appearance of petechiae. But it also should be known that scar- and aged skin or that of smokers often will not show any petechiae or only a few during the 1st treatment. This picture often changes during the 2nd or 3rd CIT with a significant higher amount of petechiae (some may call it micro bleeding). Higher amount of petechiae can be especially noted on acne scars during the follow-up procedures. A clear indication that a new capillary vessel formation already have formed and penetrated the previous scar formation (after the first or previous treatment).

• Also keep in mind to stretch narrow acne scars (ice pick and box car) in all four direction during needling. Stretching ensures that the vertical scar edges are inclined and penetrated by the needles.

• Especially by using the MF8 and MS4 for scar and acne scar treatments, the physician can “feel” the cracking of the old fibrotic tissue, while the patient virtually can “hear” the cracking.

• After a skin zone was completely needled, remove the blood traces with sterile saline solution before you move to the next skin area.

• Encourage the patient to “work and cooperate” with you, by asking him/her, to “blow up” the cheek or to retract the lips for better access and a stretched skin.

• Some patients may experience a “burning sensation” after the procedure. This will last for 20 to 30 minutes and depends on the concentration and duration of the anesthetic cream. After this burning feeling is gone, the patient will feel comfortable with no post-op pain.

• So far we have had no reports of sun sensitivity after a CIT. But to exclude any risk, we recommend to use a sun screen (SPF30) in sunny areas for at least 8 days. In cooperation with Owen Biosciences, USA, we have developed a sunscreen that has to be applied only once in the morning and that lasts the entire day without re-application. It also contains anhydrous ingredients that support the healing process and it also contains a camouflage component that makes the CIT traces less visible.
COMBINING CIT DERMAROLLER WITH OTHER TREATMENTS

Once more we would like to emphasize that the COLLAGEN-INDUCTION-THERAPY (CIT) with the Professional and Medical DERMAROLLER™ is a unique and separate procedure in its own right. To perform a CIT successfully, Professional and Medical Dermrollers with needles of 0.5 mm and longer are required. The mechanism of action is based on the electrical potential difference between the intra and extra cellular space that triggers cell regeneration. This short-term demarcation current stimulates cell proliferation and the distribution of cell TGF.

As the mechanism of action of other skin resurfacing techniques is quite different, in most cases a combination with the Dermaroller is not recommended!

CIT DERMAROLLER and PEELING
To combine these two procedures would be a grave mistake. All peeling acids – phenol or fruit acids – target the epidermal layer and have it chemically (totally or partly) removed. Peeling is a topical form of treatment. Therefore, if a peeling is performed before or after a CIT either the acid could be transported into the skin by the needles or acid parts can flow to the lower dermis by passing through the pricking. When acid comes in contact with living tissue in can result in extreme skin irritation or possibly dermal damage.

CIT DERMAROLLER and COSMETICS
We do not recommend to combine a CIT with cosmetics! Apart from special therapeutic ointments or other special skin care products given under professional supervision, so-called “cosmetics” are designed for topical application. More or less all cosmetics contain preservatives, perfumes, color and other additives that could harm the dermis when transported into deeper skin layers. Regardless if cosmetic manufacturer claims of “how fantastic their action is”, the percentage of active ingredients is – by law - so minor that they do not and CANNOT have any therapeutic effect. Cosmetic substances may be harmless when applied on the skin but they could cause harm and severe skin irritation if transported into the deeper dermis with a Dermaroller!

CIT DERMAROLLER and IONTOPHORESIS or ULTRA SOUND
As a medical treatment, iontophoresis is used to enhance lidocaine and other painkillers into joints. But there are no findings available that iontophoresis can enhance skin care products through the stratum corneum in large volumes. Most cosmetics cannot be ionized and therefore they are not suitable for DC current enhancement. For example, the ability of topically applied vitamin A (even embedded in liposomes) to penetrate the stratum corneum was tested by the University of Marburg. Only 0.3% penetrated the top layer of the skin (the stratum corneum). It also is a fact that iontophoresis’ direct current changes the molecule structure of drugs and makes them ineffective.

The same applies for Ultra Sound.

CIT DERMAROLLER and THERMAL ABLATIVE TECHNIQUES
Thermal ablative techniques are usually known as “laser resurfacing”. Unfortunately the lay person does not know that the extremely intense laser beam essentially evaporates the epidermis creating a painful second or third degree burn. The body reacts to this injury with its repair mechanism: the production of fibrotic tissue. (Note: The needles of the Dermaroller triggers cell regeneration – something totally different). The real (and unfortunately hidden) disadvantage of laser resurfacing is that the skin becomes thinner and stays thinner, although the resurfacing effect may last for some time.

To combine laser resurfacing with a Dermaroller CIT is not recommended!

DERMAROLLER and FRACTIONAL LASER
While the ablative laser works horizontally on the skins surface, fractional lasers work different. A much smaller light beam creates vertical necrotic burn wounds into the dermis with a depth that ranges from 300 to 700 μm (0.3 – 0.7 mm). Fractional means, that only fractions of the skin can be lasered lasered (20%). This laser method needs so-called bridges of intact tissue between the laser holes.
The body reacts to these thermal injuries by “repairing” them with fibrosis. In order to avoid the fibrosis becoming confluent, single thermal wounds need a certain separation. This explains why several sessions (minimum 5 and more) are needed in order to get a visible skin rejuvenation result. Many patients report that often 2 or 3 times the number of treatments are required as previously promised. The hot laser beam is an extreme thermal burden for the nerve cells and that is the reason why treatments with fractional lasers are so painful. Even numbing cream has little effect in reducing that pain. Another real disadvantage is that the client has to buy a laser head. It only lasts 3 to 4 treatments and adds additional costs. (Read our MEMO on Fractional Lasers).

The medical term fibrosis means scar. Therefore, the combination of Dermaroller CIT before or after a fractional laser treatment is not recommended.

CIT DERMAROLLER and DERMABRASION
The aim of Dermabrasion is the ablation of the epidermis or parts if it. Complete removal is usually done with a fast rotating skin mill. The partial removal of the protecting epidermis is performed with aluminum oxide crystals. As it is technically extremely difficult to remove only fractions of a millimeter evenly, there is always a danger that too much epithelial tissue is removed and that the underlying dermis is damaged. Besides having a long healing period the skin becomes irreversibly thinner.

The purpose of the CIT with the Dermaroller is to build up new collagen fibers. Therefore, the combination of Dermaroller CIT before or after a dermabrasion is not recommended.

IMPORTANT NOTE TO AVOID MISUNDERSTANDINGS
Medicine uses many different laser models with high therapeutic efficacy. Depending on the desired therapeutic effect they vary in wavelength, number of pulses and power.

We leave it up to the therapists if they want to combine a (soft-) laser treatment with a Dermaroller procedure. But from our point of view it does not make sense! After a combined treatment, the therapist will never know what was the cause for a successful treatment outcome, the Dermaroller or the light beam – visible or invisible. Although it may cost a little more time and effort, we feel that single treatments are better. At least one gains clear knowledge.
A proposal for your own consent form

QUESTIONNAIRE & CONSENT FOR COLLAGEN INDUCTION THERAPY

Name, Forename: ____________________________________________________________________________

Address: ___________________________________________________________________________________

Phone: ____________________________________    E-Mail: ________________________________________

Collagen Induction Therapy (CIT) Consent

I am requesting collagen induction treatment of the skin for fine wrinkles, acne scaring or skin changes associated with actinic damage or aging, and voluntarily by consent authorize this procedure. The preferred areas to be treated are:
___________________________________________________________________________________________

I understand that collagen induction therapy utilizes the Dermaroller device that creates micro-needle punctures to the skin surface. As a consequence, the repair process releases numerous growth and healing factors that stimulate new collagen to be deposited under the skin surface. The repair process will actually extend over a twelve to sixteen week period after treatment. I also understand that I may require a series of CIT treatments to achieve the maximum cosmetic result. The procedure and complications have been explained to me and I have had the opportunity to have my questions answered.

I have been advised that the object of the procedure I have requested is improvement in appearance, not perfection. It is possible for imperfections to persist, and that the result might not live up to my expectations or goals. I fully understand that the practice of medicine and surgery is not an exact science and that any reputable physician cannot guarantee results. I acknowledge that no written or implied verbal guarantee, warranty, or assurance has been made to me regarding the outcome of the procedure that I herein requested and authorized. I also understand the limitations of this procedure.

I understand the complications of CIT therapy to be as follows: Please initial each line.

Erythema: The skin may remain red for three to four days after CIT treatment. As the skin heals the erythema will resolve. Six hours after treatment makeup can be used to camouflage the erythema. _______

I understand that CIT can be combined with the application of serums, nutritional factors, and vitamins to stimulate optimal collagen production. _______

I understand bruising may occur as a result of treatment.

Hyper-pigmentation: A small number of patients may experience a hyper-pigmentation of the skin surface (especially if the skin is not protected from the sun's rays). This will resolve in several weeks and may be treated with a pigment gel cream. _______

I understand in order to avoid possible postoperative hyper-pigmentation that I net to refrain from any intensive sun light exposure and/or solarium for a period of 2 weeks. I shall use a sun block with a protection factor of 20 or higher. _______

I understand that I may require additional treatments in order to achieve maximum results and that some imperfections are not amenable to CIT treatment. _______
I understand that patients with a history of herpes simplex (cold sores) may experience a flare up of the disease. If I have had herpes sores, I will inform the physician so that he can pre-treat me appropriately.

I understand that infection is a rare possibility.

I hereby give permission for photographs of the intended treatment site for diagnostic purposes and to enhance the medical record. I agree that these photographs will remain the physician’s property. I further authorize to use these photographs for teaching purposes to illustrate scientific papers, books or for use in general lectures. It is specifically understood that in any such publication or use, I shall not be identifiable.

I agree to follow the instructions given to me by the clinic to the best of my ability before, during, and after the procedure. I understand that patient responsibility and proper performance of the postoperative care and regular return office visits are critical to the success of the treatment. I have thoroughly read and understand the postoperative instructions and reviewed them with the physician’s staff. I acknowledge that I have read and filled out the patient registration and medical history form fully and correctly to the best of my knowledge, and that the information that I have supplied is correct.

Date,

_________________________________                      ____________________________________
Patient’s signature           Signature