Your physician has recommended a medical microneedling treatment of your skin. Therefore the device Revive / Revive MN of amiea med aesthetics – a medical devices class IIa – will be used.

The devices Revive / Revive MN of amiea med aesthetics offer a new way for minimal invasive percutaneous collagen induction therapy in the field of aesthetic medicine. The application leads to a lot of very small punctual incisions into the skin, which starts a healing cascade which can also be observed during injuries. The cells release growth factors directly after the treatment, stimulating the production of collagen, elastic fibres and hyaluronic acid. This leads to an improvement of the appearance of the skin.

The field of medical microneedling includes wrinkles, scars (acne scars, surgical scars, burn scars,...) and stretch marks.

The following pages contain all important information regarding the microneedling treatment, questions about your physical health and a consent form for the treatment.
QUESTIONNAIRE

Are you suffering from skin disease or other disease?  
[ ] Yes  [ ] No

If yes, please specify:

Are you under dermatological treatment?  
[ ] Yes  [ ] No

If yes, please specify the reason:

Are you suffering from skin cancer or actinic keratosis in the areas that should be treated?  
[ ] Yes  [ ] No

Are you suffering from active acne?  
[ ] Yes  [ ] No

Are you suffering from warts or herpes simples?  
[ ] Yes  [ ] No

Are you developing hyper pigmentation after infections of the skin?  
[ ] Yes  [ ] No

Are you going through a radiation- or chemotherapy treatment at the moment?  
[ ] Yes  [ ] No

Are you suffering from uncontrolled diabetes mellitus (wound healing disorder)?  
[ ] Yes  [ ] No

Are you under drug medication?  
[ ] Yes  [ ] No

If yes, please specify:

Are you ingesting hormonal drugs?  
[ ] Yes  [ ] No

Are you ingesting cortisone?  
[ ] Yes  [ ] No

Are you ingesting anticoagulant drugs (Aspirin, Marcumar)?  
[ ] Yes  [ ] No

Have you had a laser treatment, microdermabrasion or facial treatments with fruit acid?  
[ ] Yes  [ ] No

If yes, please specify the date

Have you had a filler treatment?  
[ ] Yes  [ ] No

If yes, please specify substance and date:

Are you using Vitamin A Acid or are you ingesting isotretinoin?  
[ ] Yes  [ ] No

Are you suffering from allergies?  
[ ] Yes  [ ] No

Are you tending to Keloid formation or are there family members who tend to?  
[ ] Yes  [ ] No

Are you protecting your skin regularly from the sun?  
[ ] Yes  [ ] No

Are you pregnant?  
[ ] Yes  [ ] No

Smoking can cause intense contractions of the vessels which can leads to a decreased building of petechiae. Therefore it would be good to avoid smoking at least three hours before the treatment.

CLARIFICATION AND INFORMED CONSENT

After a detailed clarification though the physician I wish to have a microneedling treatment (and if necessary also further treatment) of the following area:

[ ]

I understand that the fine needles induce the production of new body’s own collagen. Therefore the needles penetrate the epidermis (top layer of the skin) and cause micro injuries. Due to the wound healing process a lot of different healing factors are released in the skin. This leads to formation of collage- and elastin fibres under the skin surface. This process will take place during 12-16 Weeks after the treatment. For an optimal result more than one treatment can be necessary.

[ ] Yes

I understand that the treatment can have the following side effects:

**Redness and swelling:** During the first days after the treatment redness and swelling can occur. This is because the needle penetration does force micro lesions which will disappear during the healing process. The wounds will be closed very quickly and about three hours after the treatment an appropriate makeup can be used. **Keloid:** If you have the tendency to form keloid scars, the micro lesions which are caused during the microneedling can also lead to keloids. **Hyperpigmentation:** It is very rare but possible that hyperpigmentation occurs in the treated skin area, e.g. after excessive sun exposure. A sun protection factor of 30+ can prevent this. **Herpes simplex:** If you already suffered from herpes simples, the microneedling treatment can force it once more. A premedication can prevent this.

Furthermore Hematomata (bruises), Inflammation, Itching and moderate pain can occur after the treatment.

[ ] Yes

I understand that it is important to keep out of the sun after the treatment to avoid hyperpigmentation (also no solarium). If I stay outdoors during sunny weather it is recommended to use sun protection with at least SPF 30.

[ ] Yes

I understand that inflammation of the skin after the treatment happens very seldom but is possible.

[ ] Yes

Herewith I confirm that pictures of the treated area can be taken to document the results. These pictures are owned by the physician and he or amiea med can use them for the purpose of presentations, studies or for advertisement.

[ ] Yes