Aqualyx Consent Form

FORMULATION

AQUALYX is an injectable, hydrous, micro-gelatinous solution, which is biocompatible and biodegradable. It causes the dissolution of fat cells, after which the body then expels the released fatty acids naturally. AQUALYX is a complex containing detergent from the desoxycholate family that has been physically modified in order to reduce the biological half-life and the sugar-based slow release system results in minimal side effects. The ingredients are a polymer from 3,6-Anhydro-L-Galactose and D-Galactose, buffer systems, sodium salt of (3a, 5a, 12a) - 3,12-dihydroxy-5-cholan-24-acid, water for injection purposes, and sodium chloride. During AQUALYX treatment, AQUALYX is injected directly into the subcutaneous fat tissue using very thin, sharp cannulas. Within the following weeks the treated fat cells are gradually dissolved. The metabolism in the treated area is increased. AQUALYX is intended for patients with localised adipose tissue not responding to diet or increased physical exercise. AQUALYX is not intended for weight loss, it is used to improve and alter the contour of the body. Results cannot be compared to liposuction, as that is an operative method of fat reduction where large amounts of fat are permanently removed from the body. The results of AQUALYX are permanent; however the procedure takes time to reach its full effect. Patients that have undergone follow-up examinations seven years after treatment still show a relevant diminution of fat tissue in the treated areas. AQUALYX is a medical device that is generally not reimbursable by government or private health care insurers. The patient must bear all expenses.

THERAPY

AQUALYX can be used as a means of mederate reduction of fat tissue as well as a treatment against benign adipoma for patients that do not want to undergo surgery. AQUALYX is injected directly into the fat tissue. Administration of anaesthesia is usually not required. To date, not one single incident of overdose or toxication has been recorded.Intervals between treatments should amount to three to four weeks. The amount of treatments can vary between two and eight sittings according to the characteristics of the treated area. In support of the therapy, a localised ultrasound treatment can be administered directly after injection. However, ultrasound treatment is not the decisive factor in the process of the desired fat reduction. As with all aesthetic medicinal therapies, there is no guarentee for a fully successful treatment. A minimum of two treatments will be required. About 1% of treated patients have experienced nil to minimal effects after AQUALYX.

I have been informed about the following points concerning my intended AQUALYX

I am of legal age *

◯ Yes ◯ No

I am pregnant or breastfeeding *

◯ Yes ◯ No

I am a diabetic with vascular diseases (microangiopathy) *

◯ Yes ◯ No

I suffer from the following diseases:

Autoimmune disease (e.g. Scleroderma) *

◯ Yes ◯ No

Hypersensitivity against ingredients *

◯ Yes ◯ No

Severe hepatic disease *

◯ Yes ◯ No

Severe kidney disease *

◯ Yes ◯ No

Acute infections and chron. infection risk *

◯ Yes ◯ No

Allergies *

◯ Yes ◯ No

Severe adipositas (adipastitas per magna BMI > 30) *

◯ Yes ◯ No

Blood coagulation disease *

Disturbed menstruation *

◯ Yes ◯ No

Furthermore I have been informed about the following adverse effects: General Risks: Injection therapy may result in permanent damage of nervous tissue and nerves, as well as inflammatory reactions and infections that may result in irreversible scarring. Expected adverse effects: Swelling and hyperthermia of injected area, haematoma, pressure sensitivity, moderate pain and itching within the treated area. Possible adverse effects: Redness of the skin that may become permanent, permanent punctual rigidity or lumps within the tissue, denting of the treated area due to irregular reduction of fat cells, dizziness immediately after the procedure for around 2 hours (please be sure to hydrate by drinking a sufficient amount of water), increased sweating, nausea, diarrhoea (uncommon), intracyclic menstrual bleeding (women), allergic reactions (very uncommon) such as nettle rash, bronchial asthma, symptoms of shock, hyperpigmentation if the treated areas are exposed to sun immediately afterwards (may last up to several months). To date there has been no recordedcases of permanent redness or hyperpigmentation. I have been informed about alternative therapies such as dietary measures, increased physical activity or operative correction (Liposuction). I am not considering any of these options.

CLINICAL CONTROL

A clinical control will be carried out after completing all arranged treatments and after passing the appointed time intervals.

I have read this informed consent and certify that I understand its content in full. I have been informed that i must not apply any kind of cosmetics onto the treated area within the first 12 hours following the treatment, and that immediate exposure to heat sources during the following days are to be avoided. I am aware of the fact that after therapy, treatments using laser, cryolipolysis or radio-frequency therapy must not be administered. Furthermore, I should abstain from particularly demanding physical activity for seven days. I have been given a copy of this consent form. My consent and authorisation for this procedure is strictly voluntary. By signing this consent form, I grant authority to my physician to perform AQUALYX and to administer an additional ultrasound treatment as may be deemed necessary or advisable in the diagnosis and treatment of my condition. The nature and purpose of this procedure, with possible alternative methods of treatment as well as complications, have been fully explain to my satisfaction. No guarantee has been given by anyone as to the results that may be obtained by this treatment. I understand that no refund can be given for any treatment or product. I have had enoigh time to consider the information from my physician and feel that I am sufficiently advised to consent to this procedure. I hereby give my consent to this procedure and have been asked to sign this form after my discussion with the healthcare professional.

Area to be treated:

Patient Name: *: _____

Patient signature *

Date *: _____ dd / mm / yyyy **Doctor Name:** _____

Doctor's signature

Date: _____ dd / mm / yyyy