

FAT DISSOLVING CONSENT FORM

BACKGROUND

AQUALYX was developed by the renowned aesthetic surgeon Prof. Pasquale Motolese in 2002 and has been used for many years in different countries of the European Community and abroad. The manufacturer Marllor states sales of two million vials in two years. No major side effects occurred and the treatment was well-tolerated and successful.

FORMULATION

AQUALYX is an injectable, hydrous, micro-gelantuous solution, which is biocompatible and biodegradable. It causes the dissolution of fat cells, after which the body then expels the released fatty acids naturally. AQUALYXTM 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 an polymer from 3, 6-Anhydro-L-Galactose and D-Galactose, buffer systems, sodium salt of (3?, 5?, 12?) - 3, 12-dihydroxy-5-cholan-24-acid, water for injection purposes and sodium chloride.

During intralipotherapy AQUALYXTM is injected directly into the subcutaneous fat tissue using very thin, sharp cannulas/needles. Within the following weeks the treated fat cells are gradually dissolved. The metabolism in the treated area is increased. Intralipotherapy is intended for patients with localised adipose tissue not responding to diet or increased physical exercise. Intralipotherapy is not intended for weight loss, it is used to improve and alter the contour of the body. Results can not be compared to a liposuction, as that is an operative method of fat reduction where large amounts of fat are permanently removed from the body. The results of intralipotherapy are permanent, however the procedure takes time to reach its full effect. Patients that have undergone follow-up examinations seven years after therapy still show a relevant diminution of fat tissue in the treated areas. Intralipotherapy is an aesthetic-medicinal treatment that is generally not reimbursable by government or private health care insurers. The patient must bear all expenses.

THERAPY

Intralipotherapy can be used as a means of moderate 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 phenomenon 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 guarantee 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 intralipotherapy.

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

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 rigidification or lumps within the tissue, denting of the treated area due to irregular reduction of fat cells, vegetative disorder, as well as temporary debility of the circulatory system (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, asthma bronchiale, symptoms of shock, hyperpigmentation (may last up to several months).

I have been informed about alternative therapies such as dietary measures, increased physical exercise or operative correction (e.g. 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 contents in full. I have been informed that I must not apply any kind of cosmetics onto the treated area within the first twelve hours following the treatment with AQUALYX and that immediate exposure to heat sources during the following days are to be avoided (e.g. sunlight, UV-radiation, sauna). I am aware of the fact that after therapy with AQUALYX treatments using laser, kyrolipolysis or radio-frequency-therapy must not be administered. Furthermore, I should abstain from particularly demanding physical exercise for seven days.

I have been given access to a copy of this consent form via the practitioners website www.mmtaesthetics.co.uk. My consent and authorisation for this procedure is strictly voluntary. By signing this informed consent form, I grant authority to the practitioner to perform intralipotherapy using 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 explained to my satisfaction. No guarantee has been given by anyone as to the results that may be obtained by this treatment.

I have had enough time to consider the information from the practitioner 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 practitioner.

I have read this informed consent and certify I understand its contents in full. All of my questions have been answered to my satisfaction and I consent to the terms of this agreement. I agree to adhere to all safety precautions and instructions after the treatment. I have been instructed in and understand post treatment instructions and have been given a written copy of them. I understand that medicine is not an exact science and acknowledge that no guarantee has been given or implied by anyone as to the results that may be obtained by this treatment. I also understand this procedure is "elective" and not covered by insurance and that payment is my responsibility. Any expenses which may be incurred for medical care I elect to receive outside of this clinic, such as, but not limited to dissatisfaction of my treatment outcome will be my sole financial responsibility. Payment in full for all treatments is required at the time of service and is non-refundable. I understand and agree that all services rendered to me are charged directly to me and that I am personally responsible for payment. I further agree in the event of non-payment, to bear the cost of collection, and/or Court cost and reasonable legal fees, should this be required. PHOTOGRAPHS: I authorise the taking of clinical photographs and their use for scientific and educational publications and presentations. I understand my identity will be protected. I understand photos are mandatory for insurance purposes.

Pre and Post treatment care

I confirm I have read and understood the pre treatment care recommendations provided and I am happy to proceed with the treatment. I confirm I have read and understood the post treatment care provided and will follow these instructions.

By accepting, I acknowledge that I have read the foregoing informed consent and agree to the treatment with its associated risks. I hereby give consent to perform this and all subsequent treatments with the above understood. I hereby release the doctor, the person injecting the Botulinum A Toxin and the facility from liability associated with this procedure.



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