Genesis
PLASTIC SURGERY

Informed Consent
BOTOX / XEOMIN (*Botulinum Toxin A*) Injection

INSTRUCTIONS
This is an informed-consent document which has been prepared to help your plastic surgeon inform you concerning BOTOX / XEOMIN (*Botulinum Toxin A*) injection, its risks and alternative treatments.

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent for this procedure as proposed by your plastic surgeon.

INTRODUCTION
Botulinum Toxin A is processed from a bacteria product and purified to produce a sterile product suitable for specific therapeutic uses. Once the diluted toxin is injected, it produces a temporary paralysis of muscle by preventing transmission of nerve impulses to muscle. The duration of muscle paralysis generally lasts for approximately four months. Continuing treatments are necessary in order to maintain the effect of *Botulinum Toxin A* over time.

The FDA approved *Botulinum Toxin A* for the cosmetic treatment of forehead wrinkles caused by specific muscle groups. Other areas of the face and body such as crows feet wrinkles and neck bands may be treated in an "off-label" fashion.

Botulinum Toxin A injections are customized for every patient, depending on his or her particular needs. These can be performed in areas involving the eyelid region, forehead and neck. *Botulinum Toxin A* cannot stop the process of aging and it cannot treat all types of wrinkles. It can, however, temporarily diminish the look of wrinkles caused by contraction of the facial muscle groups. *Botulinum Toxin A* injections may be performed as a singular procedure or as an adjunct to a surgical procedure.

ALTERNATIVE TREATMENTS
Alternative forms of management include not treating the skin wrinkles by any means. Improvement of skin wrinkles may be accomplished by other treatments or alternative types of surgery such as a blepharoplasty, face or brow lift when indicated. Minor skin wrinkling may be improved through chemical skin-peels, lasers, injection of filling material or other skin treatments. All of these alternative procedures have their own risks and complications.

RISKS OF *Botulinum Toxin A* INJECTIONS
Although the majority of patients do not experience the following complications, every procedure involves a certain amount of risk, and it is important that you understand these. An individual's choice to undergo this procedure is based on the comparison of the risk to the potential benefit.

Bleeding and Bruising: It is possible, though unusual, to have a bleeding episode from a *Botulinum Toxin A* injection. Bruising in soft tissue may occur. Do not take any aspirin or anti-inflammatory medications for 10-14 days before *Botulinum Toxin A* injections, as this may contribute to a greater risk of bleeding and bruising.

Headache: *Botulinum Toxin A* injections may cause a temporary headache.

Migration of *Botulinum Toxin A*: *Botulinum Toxin A* may migrate from its original injection site to other areas and produce temporary paralysis of other muscle groups or other unintended effects. Muscles that raise the eyelid may be inadvertently affected by *Botulinum Toxin A*, should this material migrate downward from other injection areas and cause a drooping eyelid. This is treated with eye drops.

Facial Asymmetry: The human face and eyelid region is normally asymmetrical with respect to structural anatomy and function. There can be a variation from one side to the other in terms of the response to *Botulinum Toxin A* Injection.

Pain: Discomfort associated with *Botulinum Toxin A* injections is usually of a short duration.

Unsatisfactory or non-response to *Botulinum Toxin A*: There is the possibility of a poor or inadequate response from *Botulinum Toxin A* injection(s). Additional *Botulinum Toxin A* injections may be necessary. Surgical procedures or treatments may be needed to improve skin wrinkles including those caused by muscle activity.

Allergic reactions: As with all biologic products, allergic and systemic life-threatening anaphylactic reactions may occur.

Antibodies to *Botulinum Toxin A*: Presence of antibodies, to *Botulinum Toxin A* in a patient's serum, may reduce the effectiveness of this material in subsequent injections.

Long-term effects: Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss or gain, sun exposure, or other circumstances not related to *Botulinum Toxin A* injections. Future surgery or other treatments may be necessary. *Botulinum Toxin A* injection does not arrest the aging process or produce permanent tightening of the eyelid region. Continuing treatments are necessary in order to maintain the effect of *Botulinum Toxin A* over time.

Pregnancy and nursing mothers: Animal reproduction studies have not been performed to determine if *Botulinum Toxin A* is safe for pregnant or nursing mothers. It is not recommended that pregnant women or nursing mothers receive *Botulinum Toxin A* treatments.

Drug Interactions: The effect of *Botulinum Toxin A* may be potentiated by aminoglycoside antibiotics or other drugs known to interfere with neuromuscular transmission.

Neuromuscular disorders: Patients with peripheral motor neuropathic disorders (amyotrophic lateral sclerosis, myasthenia gravis, motor neuropathies) may be at greater risk of clinically significant side effects from *Botulinum Toxin A*

Migraine headache and other medical disorders: *Botulinum Toxin A* has been used to treat forehead muscle groups that are involved with the migraine headache condition. Patients are advised that results of off-label *Botulinum Toxin A* treatment for migraine headaches and other medical disorders may be variable and improvement may not occur following *Botulinum Toxin A* treatments.

ADDITIONAL TREATMENT NECESSARY

Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances. However, informed-consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Informed-consent documents are not intended to define or serve as the standard of medical care.

It is important that you read the above information carefully and have all of your questions answered before signing the consent on the next page.

CONSENT FOR TREATMENT

1. I HEREBY AUTHORIZE Dr. Frederick Thompson and such assistants as have to be selected to perform the following procedure or treatment: ***Botulinum Toxin A*** **injection**

2. I have received the following information sheet: Informed Consent for BOTOX / XEOMIN (*Botulinum Toxin A)* Injections

3. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.

4. I consent to the photographing of procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.

5. **It has been explained to me in a way that I understand:**
   a. The above treatment or procedure to be undertaken.
   b. There may be alternative procedures or methods of treatment.
   c. There are risks to the procedure or treatment proposed.

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS. I AM SATISFIED WITH THE EXPLANATION.

Signature: _____ Date: _____
Patient or Person Authorized to Sign for Patient

Witness: _____ Date: _____

1. _____ Date: _____
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