Kairos Beauty

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NEUROTOXIN INFORMED CONSENT

This informed consent document has been prepared to help your injector inform you about neurotoxin injections and their risks. It is important that you read this information carefully and thoroughly. Please initial each page, indicating that you have read the page, and sign the consent for this procedure as proposed by your injector.

GENERAL INFORMATION

Clostridium botulinum bacteria produce a class of chemical compounds known as "toxins." The Neurotoxins are processed and purified to yield a sterile product suitable for specific therapeutic uses. Once the diluted toxin is injected, it produces a temporary paralysis of muscle by preventing the transmission of nerve impulses to the muscle. The duration of muscle paralysis generally lasts three to four months. Continuing treatments are necessary to maintain neurotoxins' effect over time.

Neurotoxins have been approved to treat certain conditions involving crossed eyes (Strabismus), eyelid spasm (Blepharospasm), Cervical Dystonia (spastic muscle disorder with the neck), and motor disorders of the facial nerve (VII cranial nerve). As of April 2002, it has been FDA approved 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. Neurotoxins have also been used "off-label" to treat migraine headaches, colorectal disorders, excessive perspiration disorders of the armpit and hands, and musculoskeletal pain disorders.

Neurotoxin 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. Neurotoxins cannot stop the process of aging. It can, however, temporarily diminish the look of wrinkles caused by muscle groups. Neurotoxin injections may be performed as a single procedure or adjunct to a surgical procedure.

Initial: _____

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. Other forms of eyelid surgery may be needed should you have intrinsic disorders affecting the function of the eyelid, such as drooping eyelids from muscle problems (eyelid ptosis) or looseness between the eyelid and eyeball (ectropion). Minor skin wrinkling may be improved through chemical skin peels, lasers, injection of filling material, or other skin treatments. Risks and potential complications are associated with alternative medical or surgical treatment forms.

RISKS OF NEUROTOXINS

Every procedure involves a certain amount of risk, and you must understand these risks and the possible complications. In addition, every procedure has limitations. An individual's choice to undergo this procedure depends on comparing the risk to the potential benefit. Although most patients do not experience these complications, you should discuss each with your injector to ensure you understand the risks, possible complications, limitations, and consequences of neurotoxin injections.

Risks include but are not limited to: Incomplete Block, Bleeding and Bruising, Damage to Deeper Structures, Corneal Exposure Problems, Dry Eye Problems, Migration of Neurotoxins, Drooping Eyelid (Ptosis), Double Vision, Eyelid Ectropion, Other Eye Disorders, Blindness, Asymmetry, Pain, Allergic Reaction, Antibodies to Neurotoxins, Infection, Skin Disorders, Neuromuscular Disorders, Migraine Headache Disorders, Unsatisfactory Result, Long Term Effects, Pregnancy and/ or nursing complications, Drug Interaction, and any other Unknown Risks.

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.

Initial:_____

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your injector may provide you with additional or different information based on all of the facts pertaining to your particular case and the current state of medical knowledge.

Informed consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

OFF-LABEL FDA USE

There are many devices, medications and injectable fillers and botulinum toxins that are approved for specific use by the FDA, but this proposed use is "Off-Label", that is not specifically approved by the FDA. It is important that you understand this proposed use is not experimental and your physician believes it to be safe and effective. Examples of commonly accepted "Off-Label" use of drugs or devices include the use of aspirin for the prevention of heart disease, retinoids for skin care, and injection of botulinum toxin for wrinkles around the eyes. Botox® is approved for Glabellar frown lines, Blepharospasm, and would be Off-Label for all other uses.

____ I acknowledge that I have been informed about the Off-Label FDA status of Botox®, and I understand it is not experimental and accept its use.

ADDITIONAL TREATMENT NECESSARY

There are many variable conditions in addition to risk and potential complications that may influence the long- term result of BOTOX injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with BOTOX injections. 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.

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.

Initial: _____

INFORMED CONSENT FOR NEUROTOXIN INJECTIONS

Patient Name: _____ Date: _____

- I hereby authorize _____ and such assistants as may be selected to perform the following procedure or treatment: BOTOX, JEAUVEAU OR XEOMIN INJECTION
- I recognize that during the course of the procedure, unforeseen conditions may necessitate different procedures than those above.
- I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
- I consent to be photographed or televised before, during, and after the procedure to be performed, including appropriate portions of my body, for medical, scientific or educational purposes.
- For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.

IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:

- THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
- THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
- THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED
- I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVELISTED ITEMS. I AM SATISFIED WITH THE EXPLANATION.

Patient Signature: _____ Date: _____

Injector Signature: _____ Date: _____

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