SIX ZONES
botox & fillers

REBECCA A. PAPPALARDO, MD

CONSENT FORM: BOTULIN TOXIN TYPE A: BOTOX AND DYSPORT

BOTOX Cosmetic is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adults less than 65 years of age.

BOTOX Cosmetic for injection is a sterile vacuum-dried purified botulinum toxin type A, produced from fermentation of Hall Strain Clostridium botulinum type A grown in a medium containing casein hydrolysate, glucose, and yeast extract intended for intramuscular use. BOTOX Cosmetic blocks neuromuscular transmission by binding to acceptor sites on motor nerve terminals, entering the nerve terminals, inhibiting the release of acetylcholine. This inhibition occurs as the neurotoxin cleaves SNAP-25, a protein integral to the successful docking and release of acetylcholine from vesicles situated within nerve endings. When injected intramuscularly at therapeutic doses, BOTOX Cosmetic produces partial chemical denervation of the muscle resulting in a localized reduction in muscle activity.

Administration of BOTOX Cosmetic and/or DYSPORT is not recommended during pregnancy. There are no adequate and well-controlled studies of BOTOX Cosmetic in pregnant women. It is not known whether this drug is excreted in human breast milk. Because many drugs are excreted in human milk, caution should be exercised when BOTOX Cosmetic is administered to a nursing woman.

DYSPORT is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients less than 65 years of age.

The effects of DYSPORT and all botulinum toxin products may spread from one area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults particularly in those patients who have underlying conditions that would predispose them to these symptoms.

DYSPORT is contraindicated in patients with known hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation. This product may contain trace amounts of cow's milk protein. Patient's known to have an allergy to cow's milk protein should not be treated with DYSPORT.

DYSPORT in contraindicated for use in patients with infection at proposed injection sites.

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CONSENT FORM: BOTULIN TOXIN TYPE A: BOTOX AND DYSPORT (CONTINUED)

I authorize and direct Dr. Rebecca Pappalardo permission to perform the following procedure of BOTOX/DYSPORT injections on_____(patient name) for the treatment of the following areas:

_____Glabella Initials: _____

_____Forehead Initials: _____

_____Crows feet Initials: _____

_____ Other Initials: _____

Please initial the following:

_____ The details of the procedure have been explained to me in terms I understand.

_____ Alternative methods and their benefits and disadvantages have been explained to me.

_____ I understand that the FDA has only approved the cosmetic use of BOTOX Cosmetic and DYSPORT for frown lines between the brows. Any other cosmetic use is considered off label.

_____ I understand and accept the most likely risks and complications of BOTOX Cosmetic and DYSPORT injections.

Some are listed below:

- Paralysis of nearby muscles that could interfere with opening of eye(s)
- Local numbness
- Headache, nausea, or flu- like symptoms
- Swallowing, speech, or respiratory disorders
- Disorientation and double vision
- Temporary asymmetrical appearance
- Abnormal or lack of facial expression
- Inability to smile when injected in the lower face
- Facial pain
- Product ineffectiveness

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CONSENT FORM: BOTULIN TOXIN TYPE A: BOTOX AND DYSPORT (CONTINUED)

_____ I understand and accept that the long-term effects of repeated use of BOTOX Cosmetic and DYSPORT injections are unknown. Possible risks and complications that have been identified, but are not limited to:

- Muscle atrophy, nerve irritability, production of antibodies

_____ I understand and accept the less common complications, including the remote risk of death or serious disability that exists with this procedure.

_____ I am aware that smoking during pre/post operative periods could increase chances of complications.

_____ I have informed Dr. Pappalardo of all known allergies, including latex and cow's milk protein.

_____ I have informed Dr. Pappalardo of all medications I am currently taking including prescriptions, OTCremedies, herbal therapies, and all others.

_____ I have been advised whether I should take any or all of the medications on the days surrounding the procedure.

_____ I am aware and accept that no guarantees regarding the result of this procedure have been made or implied.

_____ I have been informed of what to expect post treatment, including but not limited to procedures I can do if I wish to maintain the appearance that this procedure provides.

_____ I am not currently pregnant or nursing, and I understand that should I become pregnant while using BOTOX/DYSPORT there are risks, including fetal malfunction.

_____ If pre/post treatment photos and/or video are taken of treatment for record purposes; I understand that these photos will be the property of Dr. Pappalardo.

_____ Dr. Pappalardo has answered all my questions regarding this procedure.

_____ I have been advised to seek immediate medical attention if swallowing, speech, or respiratory disorders should arise following injections.

_____ I certify that I have read and understand this agreement and that all spaces were initialed PRIOR to my signature.

Patient Signature: _____ Date: _____

I certify that I have explained the nature, purpose, risks, benefits, complications, and alternatives of proposed procedure to patient. I have answered fully and believe patient fully understands what I have explained.

Physician Signature: _____ Date: _____