

# CONSENT FOR TREATMENT

#### Neuromodulator Injection Procedure

#### PURPOSE AND BACKGROUND

As a patient of Nourished MedSpa and Wellness Center, I have requested injection of a neuromodulator, which is used to treat wrinkles involving the eyelid region, forehead and brow. The procedure may require multiple sequential treatments.

## PROCEDURE

The most widely known neuromodulator is Botox<sup>®</sup>. An equally effective product is Xeomin<sup>®</sup>. The mechanism of action for both is by causing temporary ( $\sim$ 3-4 month) relaxation of muscles to reduce the appearance of fine lines and dynamic wrinkles. Common injection sites include the forehead, between the eyebrows, corners of the eyes and the sides of the chin. Neuromodulators can also be used to reduce sweating in the armpits, reshaping the jaw, wrinkles around the mouth and chin.

#### **RISKS AND COMPLICATIONS**

- 1. It is possible to have bleeding after a neuromodulator injection. Bruising in soft tissues is common, especially around the eyes. It would be highly unusual, but excessive bleeding may require emergency treatment or surgery. I understand that I should not take any aspirin or anti-inflammatory medications for seven days before an injection. I understand that I need to ask my cardiologist or primary care physician before stopping any medications prescribed to me.
- 2. An infection of the wound is always possible. Should an infection occur, additional treatment including antibiotics may be necessary. Any blistering or bleeding must be dressed with an antibiotic ointment and covered. Any infection could last seven to ten days and could lead to scarring or skin discoloration. Skin rash and swelling may occur.
- 3. Deeper structures such as nerves, blood vessels and the eyeball may be damaged during the course of injection. Injury to deeper structures may be temporary or permanent.
- 4. Neuromodulators may migrate from their original injection site to other areas and produce temporary paralysis of other muscle groups or other unintended effects. Depending upon the area treated, muscles near the injection site may be affected. Muscles that raise the eyelid may be affected by neuromodulators (ptosis). Abnormal looseness of the lower evelid can occur. Eyebrow drooping can occur. Muscles of the lips may be affected causing drooping or asymmetry.
- 5. Common side effects of neuromodulators are: headache(s), dry eye(s), hypersensitivity including anaphylaxis. Very uncommon but serious side effect would be systemic botulism.
- 6. The long-term effect of neuromodulator on tissue is unknown. There is the possibility that additional risk factors may be discovered. The presence of antibodies to neuromodulators may reduce the effectiveness of this material in subsequent injections. The health significance of antibodies to neuromodulators is unknown.
- 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 neuromodulator injections. Neuromodulator injections do no arrest the aging process or produce permanent tightening of the eyelid region.
- 8. It is very possible that this procedure may fail to achieve your desired results. Strict adherence to the pre-op and postop instructions is essential. You may need to repeat your treatments to achieve the desired results.
- 9. I understand that a physician is not required to use the medication as the labeling suggests. This is called off label prescribing and is specifically provided for by the FDA. I believe the probability of such side effects is outweighed by the benefit of the neuromodulator for the given dose and indication. I have decided that I am willing to accept the risks of side effects, even if they might be serious, for the possible help the medication may give.

#### **BENEFITS**

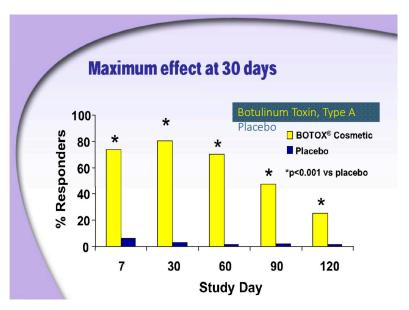
Neuromodulator injections have been shown to be safe and effective in treating cosmetic wrinkles. Xeomin® has been FDA approved for wrinkles of the eyebrows. Botox® has been FDA approved for wrinkles of the forehead, eyebrows and next to the eyes, "crow's feet." I understand that any other use would be considered "off-label."

#### **ALTERNATIVES**

This is strictly a voluntary cosmetic procedure. No treatment is necessary or required. Other alternative treatments which vary in sensitivity, effect and duration include: dermaplaning, microdermabrasion, ablative laser resurfacing, and more.

## RESULTS

I am advised that though good results are expected, the possibility and nature of complications cannot be accurately anticipated and there can be no guarantee as expressed or implied either to the success or other result of treatment. I am aware that full correction is important and that follow-up touch ups/treatments will be needed to maintain the full effects. I am aware that the duration of treatment is dependent on many factors including but not limited to: age, sex, tissue condition, my general health and lifestyle conditions, and sun exposure. Clinical results will vary per patient. The correction, depending on these factors and product used may last 3-4 months and, in some cases, longer. It could be anywhere from 30 days to 3-4 months. I understand that in one study from the manufacturer, upwards of 20% of patients did not improve their eyebrow lines. This means that 2 out of 10 patients will have no improvement in their wrinkles.



# **QUESTIONS**

This procedure has been explained to me by the staff of Nourished MedSpa and Wellness Center. I have had an opportunity to ask any questions and research the procedure to my satisfaction.

## **CONSENT**

I understand that my consent and authorization for this procedure is strictly voluntary. I have already read and signed the Clinic's general consent and understand that it is still in effect. By signing this informed consent form, I hereby grant authority to Nourished MedSpa and Wellness Center and Dr. Jason Carter, MD (or other delegated medical providers for Nourished MedSpa and Wellness Center) to perform neuromodulator injections and/or administer any related treatment as may be deemed necessary or advisable in the diagnosis and treatment of my condition. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.

The nature and purpose of this procedure and the complications and side effects have been fully explained to me. Alternative treatments and their risks and benefits have been explained to me and I understand that I have the right to refuse treatment. 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 no refunds will be given for treatments received. No guarantee has been given or implied by anyone as to the results that may be obtained from this treatment.

I have read this informed consent and certify that 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 have had enough time to consider the information given me by my physician/practitioner and feel that I am sufficiently advised to consent to this procedure. I accept the risks and complications of the procedure. I certify that if I have any changes occur in my medical history I will notify Nourished MedSpa and Wellness Center immediately.

I hereby voluntarily consent to this procedure and release Nourished MedSpa and Wellness Center, medical staff, and all associated professionals from liability associated with the procedure. I certify that I am a competent adult of at least 18 years of age and am not under the influence of alcohol or drugs. This consent form is freely and voluntarily executed and shall be binding upon my spouse, relatives, legal representatives, heirs, administrators, successors and assigns.

Patient Name (please print)	Patient Signature	Date
Performed by (please print name and title)	Practitioner Signature	Da



# PRE-TREATMENT INSTRUCTIONS

## **Neuromodulator Injection Procedure**

- To avoid bruising, it is best not to use anything that thins the blood such as Aspirin, Advil, Motrin, Vitamin E or alcoholic drinks for 72 hours before treatment.
- Sunburned skin is difficult to treat so avoid exposure to the sun.
- Avoid waxing, bleaching, tweezing, or the use of hair removal cream on the area to be treated.
- Avoid the use of Alpha Hydroxy Acids higher than 10% and Retinoids (such as Retin A) for 72 hours before treatment.
- Some muscle movement will remain. The objective of treatment is to improve the appearance of the lines, not completely paralyze the muscle. In this way, you benefit from continued subtle facial expression.
- Please call the office at 903-357-5108 for any questions



## **POST-TREATMENT INSTRUCTIONS**

# Neuromodulator Injection Procedure

- You may have bruises in the treated areas. This is normal and temporary.
- It may take up to two weeks for you to experience the full effect of the treatment. Remain patient. It takes time for the muscles to lose strength and the lines to fade. Please wait until this time has passed before assessing if you are pleased with the result.
- Exercising the treated areas for 1-2 hours after treatment (e.g. practice frowning, raising your eyebrows, or squinting) is thought to help work the solution into the muscles. However, it will NOT decrease your results if you forget to do this.
- For 4 hours after treatment, do NOT rub or massage the treated areas, practice Yoga or any type of strenuous exercise, or use a sauna. Doing so may cause the medication to move into unwanted areas. It may cause dysfunction with other muscle groups. This will also minimize the risk of temporary bruising. Feel free to shower and go about most other regular daily activities, just don't rub the area(s) treated.
- Do NOT lie down for 4 hours after treatment. This is to avoid the risk of pressure on the treated areas (from your pillow) or having the area rubbed accidentally.
- Be assured that any tiny bumps or marks will go away within a few hours. If you need to apply make-up within 4 hours after your <u>treatment</u>, only use a GENTLE touch to avoid rubbing the treated area.
- This is a temporary procedure and, at first, you may find that your treatment results last approximately 3 or 4 months. If you maintain a regular treatment schedule (every 3-4 months initially), the results of each treatment result may last longer.
- Initially, Nourished MedSpa and Wellness Center sees patients for additional treatments between 3-months (12 weeks) and 4 months (16 weeks) because we feel we are able to create the best clinical results for you during this period. If you allow the medicine to wear off completely, it is difficult for the doctor to see how your muscles have reacted and therefore optimal individualized results may be more difficult to achieve.
- Very rare symptoms that would require immediate emergency care are: double or blurred vision and/or drooping eyelids; difficulty in speaking clearly and/or swallowing; Hoarseness or change/loss of voice; Difficulty breathing; Loss of strength and muscle weakness all over the body ; Loss of bladder control.

Please contact our office at 903-357-5108 with any questions or concerns. If you have an emergency or urgent pressing clinical issue, call Dr. Carter at 903-818-3467. Texting is the best way to reach Dr. Carter.

Please make an appointment for follow-up and reassessment in 2 weeks.

Patient Name (please print)

Patient Signature

Date