

# Botulina Toxin injections

## Botox® and Dysport® Injections

*Informed Consent*



## INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you about Botulina Toxin injections, its risks, as well as alternative treatment(s).

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 surgery as proposed by your plastic surgeon and agreed upon by you.

## GENERAL INFORMATION

Clostridia botulina bacteria produce a class of chemical compounds known as "toxins". The Botulina Type A Toxin (BOTULINA TOXIN INJECTIONS) is processed and purified to produce a sterile product suitable for specific therapeutic uses. Once the diluted toxin is injected, it produces a temporary paralysis (chemodenervation) of muscle by preventing transmission of nerve impulses to muscle. The duration of muscle paralysis generally lasts for approximately three to four months.

BOTULINA TOXIN INJECTIONS has 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. BOTULINA TOXIN INJECTIONS has also been used to treat migraine headaches, colorectal disorders, excessive perspiration disorders of the armpit and hands, and musculoskeletal pain disorders.

BOTULINA TOXIN INJECTIONS 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. BOTULINA TOXIN INJECTIONS cannot stop the process of aging. It can however, temporarily diminish the look of wrinkles caused by muscle groups. BOTULINA TOXIN INJECTIONS 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. 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 forms of medical or surgical treatment.

## INHERENT RISKS OF BOTULINA TOXIN INJECTIONS (BOTULINA TYPE A TOXIN) INJECTIONS

Every procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure has limitations. An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience these complications, you should discuss each of them with your plastic surgeon to make sure you understand risks, potential complications, limitations, and consequences of BOTULINA TOXIN INJECTIONS injections. Additional information concerning BOTULINA TOXIN INJECTIONS may be obtained from the package-insert sheets supplied by Allergan.

## SPECIFIC RISKS OF BOTULINA TOXIN INJECTIONS (BOTULINA TYPE A TOXIN) INJECTIONS

### Incomplete Block:

It is possible to not experience a complete block of desired muscles. Additional injections to reach the desired level of block can be performed until the goal is achieved.

### 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 BOTULINA TOXIN INJECTIONS injection.

### Drooping Eyelid (Ptosis):

Muscles that raise the eyelid may be affected by BOTULINA TOXIN INJECTIONS, should this material migrate downward from other injection areas.

### Pain:

Discomfort associated with BOTULINA TOXIN INJECTIONS injections is usually of short duration.

### Migration of BOTULINA TOXIN INJECTIONS:

BOTULINA TOXIN INJECTIONS may migrate from its original injection site to other areas and produce temporary paralysis of other muscle groups or other unintended effects. BOTULINA TOXIN INJECTIONS has been reported to cause swallowing problems in patients treated for spastic muscle disorders of the cervical region (cervical dystonia).

### Bleeding and Bruising:

It is possible, though unusual, to have a bleeding episode from a BOTULINA TOXIN INJECTIONS injection. Bruising in soft tissues may occur. Serious bleeding around the eyeball during deeper BOTULINA TOXIN INJECTIONS injections for crossed eyes (strabismus) has occurred. Should you develop post-injection bleeding, it may require emergency treatment or surgery. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, ginkgo biloba, and other "herbs / homeopathic remedies" may contribute to a greater risk of a bleeding problem. Do not take these for ten days before or after BOTULINA TOXIN INJECTIONS injections.

### Damage to Deeper Structures:

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.

### Corneal Exposure Problems:

Some patients experience difficulties closing their eyelids after BOTULINA TOXIN INJECTIONS injections and problems may occur in the cornea due to dryness. Should this rare complication occur, additional treatments, protective eye drops, contact lenses, or surgery may be necessary.

### Unknown Risks:

The long-term effect of BOTULINA TOXIN INJECTIONS on tissue is unknown. The risk and consequences of accidental intravascular injection of BOTULINA TOXIN INJECTIONS is unknown and not predictable. There is the possibility that additional risk factors may be discovered.

Dry Eye Problems:

Individuals who normally have dry eyes may be advised to use special caution in considering BOTULINA TOXIN INJECTIONS injections around the eyelid region.

Double-Vision:

Double-vision may be produced if the BOTULINA TOXIN INJECTIONS material migrates into the region of muscles that control movements of the eyeball.

Eyelid Ectropion:

Abnormal looseness of the lower eyelid can occur following BOTULINA TOXIN INJECTIONS injection.

Other Eye Disorders:

Functional and irritative disorders of eye structures may rarely occur following BOTULINA TOXIN INJECTIONS injections.

Blindness:

Blindness is extremely rare after BOTULINA TOXIN INJECTIONS injections. However, it can be caused by internal bleeding around the eyeball or needle stick injury. In a period of 10 years of BOTULINA TOXIN INJECTIONS administration, complications of blurred vision, retinal vein occlusion, and glaucoma have been reported in three patients. The occurrence of eye problems appears to be very rare.

Allergic Reactions:

As with all biologic products, allergic and systemic anaphylactic reactions may occur. Allergic reactions may require additional treatment.

Antibodies to BOTULINA TOXIN INJECTIONS:

Presence of antibodies to BOTULINA TOXIN INJECTIONS may reduce the effectiveness of this material in subsequent injections. The health significance of antibodies to BOTULINA TOXIN INJECTIONS is unknown.

Infection:

Infection is extremely rare after BOTULINA TOXIN INJECTIONS injection. Should an infection occur, additional treatment including antibiotics may be necessary.

Skin Disorders:

Skin rash, itching, and swelling may rarely occur following BOTULINA TOXIN INJECTIONS injection.

Neuromuscular Disorders:

Patients with peripheral motor neuropathic disorders (amyotrophic lateral sclerosis, myasthenia gravis, and motor neuropathies) may be at greater risk of clinically significant side effects from BOTULINA TOXIN INJECTIONS.

Migraine Headache Disorders:

BOTULINA TOXIN INJECTIONS has been used to treat forehead muscle groups that are involved with the migraine headache condition. Patients are advised that results of BOTULINA TOXIN INJECTIONS

treatment for migraine headaches may be variable and improvement in this disorder may not occur following BOTULINA TOXIN INJECTIONS treatments.

Unsatisfactory Result:

There is the possibility of a poor or inadequate response from BOTULINA TOXIN INJECTIONS injection. Additional BOTULINA TOXIN INJECTIONS injections may be necessary. Surgical procedures or treatments may be needed to improve skin wrinkles including those caused by muscle activity.

Long-Term Effects:

Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss, weight gain, sun exposure, pregnancy, menopause, or other circumstances not related to BOTULINA TOXIN INJECTIONS injections. BOTULINA TOXIN INJECTIONS injection does not arrest the aging process or produce permanent tightening of the eyelid region. Future surgery or other treatments may be necessary.

Pregnancy and Nursing Mothers:

Animal reproduction studies have not been performed to determine if BOTULINA TOXIN INJECTIONS could produce fetal harm. It is not known if BOTULINA TOXIN INJECTIONS can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive BOTULINA TOXIN INJECTIONS treatments.

Drug Interactions:

The effect of BOTULINA TOXIN INJECTIONS may be potentiated by aminoglycoside antibiotics or other drugs known to interfere with neuromuscular transmission.

GENERAL RISKS

Healing Issues:

Certain medical conditions, dietary supplements and medications may delay and interfere with healing. Patients with massive weight loss may have a healing delay that could result in the incisions coming apart, infection, and tissue changes resulting in the need for additional medical care, surgery, and prolonged hospitalizations. Patients with diabetes or those taking medications such as steroids on an extended basis may have prolonged healing issues. Smoking will cause a delay in the healing process, often resulting in the need for additional surgery. There are general risks associated with healing such as swelling, bleeding, possibility of additional surgery, prolonged recovery, color changes, shape changes, infection, not meeting patient goals and expectations, and added expense to the patient. There may also be a longer recovery due to the length of surgery and anesthesia. Patients with significant skin laxity (patients seeking facelifts, breast lifts, abdominoplasty, and body lifts) will continue to have the same lax skin after surgery. The quality or elasticity of skin will not change and recurrence of skin looseness will occur at some time in the future, quicker for some than others. There are nerve endings that may become involved with healing scars from surgery such as suction-assisted lipectomy, abdominoplasty, facelifts, body lifts, and extremity surgery. While there may not be a major nerve injury, the small nerve endings during the healing period may become too active producing a painful or oversensitive area due to the small sensory nerve involved with scar tissue. Often, massage and early non-surgical intervention resolves this. It is important to discuss post-surgical pain with your surgeon.

Bleeding:

It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood or you may require a blood transfusion, though such occurrences are rare. Increased activity too soon after surgery can lead to increased chance of bleeding and additional surgery. It is important to follow postoperative instructions and limit exercise and strenuous activity for the instructed time. Do not take any aspirin or anti-inflammatory medications for at least ten days before or after surgery, as this may increase the risk of bleeding. Non-prescription "herbs" and dietary supplements can increase the risk of surgical bleeding. Hematoma can occur at any time, usually in the first three weeks following injury to the operative area. If blood transfusions are necessary to treat blood loss, there is the risk of blood-related infections such as hepatitis and HIV (AIDS). Heparin medications that are used to prevent blood clots in veins can produce bleeding and decreased blood platelets.

### Infection:

Infection is unusual after surgery. Should an infection occur, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary. It is important to tell your surgeon of any other infections, such as ingrown toenail, insect bite, or urinary tract infection. Remote infections, infection in other part of the body, may lead to an infection in the operated area.

### Scarring:

All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, abnormal scars may occur within the skin and deeper tissues. Scars may be unattractive and of different color than the surrounding skin tone. Scar appearance may also vary within the same scar. Scars may be asymmetrical (appear different on the right and left side of the body). There is the possibility of visible marks in the skin from sutures. In some cases scars may require surgical revision or treatment.

### Firmness:

Excessive firmness can occur after surgery due to internal scarring. The occurrence of this is not predictable. Additional treatment including surgery may be necessary.

### Change in Skin Sensation:

It is common to experience diminished (or loss of) skin sensation in areas that have had surgery. Diminished (or complete loss of) skin sensation may not totally resolve.

### Skin Contour Irregularities:

Contour and shape irregularities may occur. Visible and palpable wrinkling of skin may occur. Residual skin irregularities at the ends of the incisions or "dog ears" are always a possibility when there is excessive redundant skin. This may improve with time, or it can be surgically corrected.

### Skin Discoloration / Swelling:

Some bruising and swelling will normally occur. The skin in or near the surgical site can appear either lighter or darker than surrounding skin. Although uncommon, swelling and skin discoloration may persist for long periods of time and, in rare situations, may be permanent.

### Skin Sensitivity:

Itching, tenderness, or exaggerated responses to hot or cold temperatures may occur after surgery. Usually this resolves during healing, but in rare situations it may be chronic.

Delayed Healing:

Wound disruption or delayed wound healing is possible. Some areas of the skin may not heal normally and may take a long time to heal. Areas of skin may die. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Individuals who have decreased blood supply to tissue from past surgery or radiation therapy may be at increased risk for wound healing and poor surgical outcome. Smokers have a greater risk of skin loss and wound healing complications.

Damage to Deeper Structures:

There is the potential for injury to deeper structures including nerves, blood vessels, muscles, and lungs (pneumothorax) during any surgical procedure. The potential for this to occur varies according to the type of procedure being performed. Injury to deeper structures may be temporary or permanent.

Surgical Anesthesia:

Both local and general anesthesia involves risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation.

Shock:

In rare circumstances, your surgical procedure can cause severe trauma, particularly when multiple or extensive procedures are performed. Although serious complications are infrequent, infections or excessive fluid loss can lead to severe illness and even death. If surgical shock occurs, hospitalization and additional treatment would be necessary.

Pain:

You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after surgery. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue or due to tissue stretching.

Cardiac and Pulmonary Complications:

Pulmonary complications may occur secondarily to blood clots (pulmonary emboli), fat deposits (fat emboli) or partial collapse of the lungs after general anesthesia. Pulmonary emboli can be life-threatening or fatal in some circumstances. Inactivity and other conditions may increase the incidence of blood clots traveling to the lungs causing a major blood clot that may result in death. It is important to discuss with your physician any past history of swelling in your legs or blood clots that may contribute to this condition. Cardiac complications are a risk with any surgery and anesthesia, even in patients without symptoms. If you experience shortness of breath, chest pains, or unusual heart beats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatment.

Venous Thrombosis and Sequelae:

Thrombosed veins, which resemble cords, occasionally develop in the area of the breast or around IV sites, and usually resolve without medical or surgical treatment. It is important to discuss with your surgeon any birth control pills you are taking. Certain high estrogen pills may increase your risk of thrombosed veins.

Allergic Reactions:

In rare cases, local allergies to tape, suture material and glues, blood products, topical preparations or injected agents have been reported. Serious systemic reactions including shock (anaphylaxis) may occur

in response to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

Drug Reactions:

Unexpected drug allergies, lack of proper response to medication, or illness caused by the prescribed drug are possibilities. It is important for you to inform your physician of any problems you have had with any medication or allergies to medication, prescribed or over the counter, as well as medications you now regularly take.

Asymmetry:

Symmetrical body appearance may not result after surgery. Factors such as skin tone, fatty deposits, skeletal prominence, and muscle tone may contribute to normal asymmetry in body features. Most patients have differences between the right and left side of their bodies before any surgery is performed. Additional surgery may be necessary to attempt to diminish asymmetry.

Persistent Swelling (Lymphedema):

Persistent swelling can occur following surgery.

Unsatisfactory Result:

Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. The body is not asymmetric and almost everyone has some degree of unevenness which may not be recognized in advance. One side of the face may be slightly larger, one side of the face droopier. The breast and trunk area exhibits the same possibilities. Many of such issues cannot be fully corrected with surgery. The more realistic your expectations as to results, the better your results will be in your eye. Some patients never achieve their desired goals or results, at no fault of the surgeon or surgery. You may be disappointed with the results of surgery. Asymmetry, unanticipated shape and size, loss of function, wound disruption, poor healing, and loss of sensation may occur after surgery. Size may be incorrect. Unsatisfactory surgical scar location or appearance may occur. It may be necessary to perform additional surgery to improve your results.

ADDITIONAL ADVISORIES

Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray):

Patients who are currently smoking or use tobacco or nicotine products (patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin dying and delayed healing and additional scarring. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smoking may have a significant negative effect on anesthesia and recovery from anesthesia, with coughing and possibly increased bleeding. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of this type of complication. Please indicate your current status regarding these items below:

I am a non-smoker and do not use nicotine products. I understand the potential risk of second-hand smoke exposure causing surgical complications.

I am a smoker or use tobacco / nicotine products. I understand the risk of surgical complications due to smoking or use of nicotine products.



\_\_\_ I have smoked and stopped approximately \_\_\_\_\_ ago. I understand I may still have the effects and therefore risks from smoking in my system, if not enough time has lapsed.

It is important to refrain from smoking at least 6 weeks before surgery and until your physician states it is safe to return, if desired. I acknowledge that I will inform my physician if I continue to smoke within this time frame, and understand that for my safety, the surgery, if possible, may be delayed.

Smoking may have such a negative effect on your surgery that a urine test just before surgery may be done which will prove the presence of Nicotine. If positive, your surgery may be cancelled and your surgery, scheduling fee, and other prepaid amounts may be forfeited. Honestly disclose smoking to your surgeon.

Sleep Apnea / CPAP:

Individuals who have breathing disorders such as "Obstructive Sleep Apnea" and who may rely upon CPAP devices (constant positive airway pressure) or utilize nighttime oxygen are advised that they are at a substantive risk for respiratory arrest and death when they take narcotic pain medications following surgery. This is an important consideration when evaluating the safety of surgical procedures in terms of very serious complications, including death, that relate to pre-existing medical conditions. Surgery may be considered only with monitoring afterwards in a hospital setting in order to reduce risk of potential respiratory complications and to safely manage pain following surgery.

Please consider the following symptoms of sleep apnea:

- \_\_\_ I am frequently tired upon waking and throughout the day
- \_\_\_ I have trouble staying asleep at night
- \_\_\_ I have been told that I snore or stop breathing during sleep
- \_\_\_ I wake up throughout the night or constantly turn from side to side
- \_\_\_ I have been told that my legs or arms jerk while I'm sleeping
- \_\_\_ I make abrupt snorting noises during sleep
- \_\_\_ I feel tired or fall asleep during the day

It is important for you to inform and discuss any of the above symptoms that you have experienced with your surgeon.

Off-Label FDA Issues:

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.

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

Medications and Herbal Dietary Supplements:

There are potential adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with bleeding. These include non-steroidal anti-inflammatories such as Motrin, Advil, and Aleve. It is very important not to stop

drugs that interfere with platelets, such as Plavix, which is used after a stent. It is important if you have had a stent and are taking Plavix that you inform the plastic surgeon. Stopping Plavix may result in a heart attack, stroke and even death. Be sure to check with your physician about any drug interactions that may exist with medications which you are already taking. If you have an adverse reaction, stop the drugs immediately and call your plastic surgeon for further instructions. If the reaction is severe, go immediately to the nearest emergency room. When taking the prescribed pain medications after surgery, realize that they can affect your thought process and coordination. Do not drive, do not operate complex equipment, do not make any important decisions and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

Sun Exposure – Direct or Tanning Salon:

The effects of the sun are damaging to the skin. Exposing the treated areas to sun may result in increased scarring, color changes, and poor healing. Patients who tan, either outdoors or in a salon, should inform their surgeon and either delay treatment, or avoid tanning until the surgeon says it is safe to resume. The damaging effect of sun exposure occurs even with the use sun block or clothing coverage.

Travel Plans:

Any surgery holds the risk of complications that may delay healing and your return to normal life. Please let the surgeon know of any travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that appropriate timing of surgery can occur. There are no guarantees that you will be able to resume all activities in the desired time frame.

Long-Term Results:

Subsequent alterations in the appearance of your body may occur as the result of aging, sun exposure, weight loss, weight gain, pregnancy, menopause or other circumstances not related to your surgery.

Body-Piercing Procedures:

Individuals who currently wear body-piercing jewelry in the surgical region are advised that an infection could develop from this activity.

Female Patient Information:

It is important to inform your plastic surgeon if you use birth control pills, estrogen replacement, or if you suspect you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

Intimate Relations After Surgery:

Surgery involves coagulating of blood vessels and increased activity of any kind may open these vessels leading to a bleed, or hematoma. Activity that increases your pulse or heart rate may cause additional bruising, swelling, and the need for return to surgery to control bleeding. It is wise to refrain from intimate physical activities until your physician states it is safe.

Mental Health Disorders and Elective Surgery:

It is important that all patients seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional surgery and often are stressful. Please openly discuss with your surgeon, prior to surgery, any history that you may have of significant emotional depression or mental health disorders. Although many individuals may benefit psychologically from the results of elective surgery, effects on mental health cannot be accurately predicted.

DVT/PE Risks and Advisory:

There is a risk of blood clots, Deep Vein Thrombosis (DVT) and Pulmonary Embolus (PE) with every surgical procedure. It varies with the risk factors below. The higher the risk factors, the greater the risk and the more involved you must be in both understanding these risks and, when permitted by your physician, walking and moving your legs. There may also be leg stockings, squeezing active leg devices, and possibly medicines to help lower your risk.

There are many conditions that may increase or affect risks of clotting. Inform your doctor about any past or present history of any of the following:

- Past History of Blood Clots
- Family History of Blood Clots
- Birth Control Pills
- Swollen Legs
- History of Cancer
- Large Dose Vitamins
- Varicose Veins
- Past Illnesses of the Heart, Liver, Lung, or Gastrointestinal Tract.

I understand the risks relating to DVT/PE and how important it is to comply with therapy as discussed with my surgeon. The methods of preventative therapy include:

- Early ambulation when allowed
- Compression devices (SCD/ICD)
- ASA protocol when allowed (Aspirin)
- Heparin protocol when allowed
- Enoxaparin protocol when allowed

The risks of DVT/PE may be almost as great as the prophylactic therapy when involving Aspirin, Heparin, and Enoxaparin. Be aware that if your surgery is elective, those patients with very high risks should consider not proceeding with such elective surgery.

ADDITIONAL SURGERY NECESSARY (Re-Operations)

There are many variable conditions that may influence the long-term result of surgery. It is unknown how your tissue may respond or how wound healing will occur after surgery. Secondary surgery may be necessary to perform additional tightening or repositioning of body structures. Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are particularly associated with this surgery. Other complications and risks can occur but are even more uncommon. 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. In some situations, it may not be possible to achieve optimal results with a single surgical procedure. You and your surgeon will discuss the options available should additional surgery be advised. There may be additional costs and expenses for such additional procedures, including surgical fees, facility and anesthesia fees, pathology and lab testing.

### PATIENT COMPLIANCE

Follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the surgical incisions are not subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activity needs to be restricted. Protective dressings and drains should not be removed unless instructed by your plastic surgeon. Successful post-operative function depends on both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation and the need for return to surgery. It is wise to refrain from intimate physical activities after surgery until your physician states it is safe. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

### REVISION POLICY

Surgical revision surgery is a common part of elective surgery. Your procedure will not stop you from aging, sagging, scarring, or experiencing ongoing skin changes that are more genetically controlled. If revision surgery is either desired or advisable within one year after the initial surgery, there may be a physician's fee. Additionally, there may be fees associated with the hospital, facility, anesthesia, pathology, lab, and any supplies such as implants, etc. Revision policy and courtesy discounts only apply to patients who comply with post-op orders and visits.

### HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic surgical operations or any resulting complications. Please carefully review your health insurance subscriber-information pamphlet. Most insurance plans exclude coverage for secondary or revisionary surgery due to complications of cosmetic surgery. It is unethical and fraudulent to bill insurance for cosmetic procedures. We cannot participate in such activities.

### FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes fees charged by your surgeon, the cost of surgical supplies, anesthesia, laboratory tests, and possible outpatient hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with revision surgery will also be your responsibility. In signing the consent for this surgery/procedure, you acknowledge that you have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.

\_\_\_ I understand that with cosmetic surgery, I am responsible for the surgical fees quoted to me, as well as additional fees for anesthesia, facility (OR), and possibly laboratory, X-ray, and pathology fees. Surgicenters, Outpatient Centers and Hospitals often have rules that certain tissue /implants removed during surgery must be sent for evaluation that may result in additional fees. Please check with your surgeon for approximate additional costs you will be responsible for.

\_\_\_ I understand that there will be a non-refundable fee for booking and scheduling this surgery of \$\_\_\_\_\_, which is a part of the overall surgical fee.



will notify you if there has been a violation from these other sources, and we will protect your privacy to the best of our ability.

PATIENT CONSENT FOR USE OF CREDIT CARDS, DEBIT CARD, AND FINANCING -  
DISCLOSURE OF PROTECTED HEALTH INFORMATION

It may become necessary to release your protected health information to financial parties, credit card entities, banks, and financing companies, when requested, to facilitate your payment.

Services that are performed and are paid with a credit card, debit card, or financing third party are not eligible for payment challenges after services are provided. By signing this form, I am irrevocably consenting to allow Dr. \_\_\_\_\_ to use and disclose my protected health information to any credit card entity, bank, or financing company when they request such information to process an account and assist with payment.

\_\_\_ I will not challenge such credit, debit, or financing card payments once the services are provided. The practice encourages complete post-op care and follow-up interaction to address any issues that might arise, which are further addressed in the Revision Policy.

\_\_\_ I agree that this non credit card challenge agreement is irrevocable.

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), including no surgery. 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. Your plastic surgeon may provide you with additional or different information which is based on all the facts in 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.

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 SURGERY / PROCEDURE or TREATMENT**

1. I hereby authorize Dr. \_\_\_\_\_ and such assistants as may be selected to perform the following procedure or treatment:

I have received the following information sheet:

2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.

3. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.

4. I understand what my surgeon can and cannot do, and understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks to the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.

5. I consent to be photographed or televised before, during, and after the operation(s) or 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.

6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.

7. I consent to the disposal of any tissue, medical devices or body parts that may be removed.

8. I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.

9. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.

10. I understand that the surgeons' fees are separate from the anesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.

11. I realize that not having the operation is an option.

12. 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



**Informed Consent – Botulina Toxins - Botulina Toxin injections® Injection**

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-12).  
I AM SATISFIED WITH THE EXPLANATION.

\_\_\_\_\_  
Patient or Person Authorized to Sign for Patient

Date \_\_\_\_\_ Witness \_\_\_\_\_