Cosmetic Clinical and Medical Botox Policy and Procedure

Purpose
To ensure safe and effective treatment of patients undergoing Botox® administration at a Sunalta Medical Clinic medspa franchise or corporate store, the following policies and procedures have been developed.

Policy
A Physician, Nurse Practitioner (NP), or Registered Nurse (RN) with current active licensure shall be able to assess, consult and treat clients with Botox® following the guidelines set herein. The medical director, the Physician or the NP, must perform a good faith examination prior to the use of Botox®.

(i) Setting
The Physician, Nurse Practitioner (NP), or Registered Nurse (RN) can perform the administration of Botox® in various settings and locations, such as but not limited to:

• Within the designated Sunalta Medical Clinic location. All safety policies and procedures, as set out in the Sunalta Medical Clinic Policy and Procedure manual, must be strictly adhered to.

All Botox® administration procedures shall be performed in a clean, safe environment, equipped with proper sharps disposal system, and universal precautions in place.

(ii) Supervision
The Registered Nurse (RN) shall function under the general supervision of the Medical Director who is immediately available for consultation in person or via telecommunication and is physically available as medically necessary. The Sunalta Medical Clinic will seek out and provide medical directors for the best medical care and medical supervision.

Side effects may appear either at the time of treatment or shortly thereafter. Adverse reaction(s) shall be documented in the client’s Sunalta Medical Clinic treatment record and the chart. All adverse reactions such as lid ptosis, diplopia, lower eyelid retraction, and weakening of the lacrimal pump shall be reported immediately to the Medical Director. Adverse reaction(s) shall be documented in the client’s chart.

The Physician, Nurse Practitioner (NP), or Registered Nurse (RN) will not knowingly treat any clients with:

1. Allergies to eggs, egg products, albumin,
2. Any clients with significant autoimmune or neurological diseases, or
3. Pregnant clients.
The Registered Nurse [RN] will only treat patients with Botox® after completing the Sunalta Medical Clinic comprehensive clinical training program and reviewed the sections in the clinical services manual dealing with the face and will not treat any portion of the face below mid-cheek areas.

### Botox® Procedure

The Registered Nurse [RN] will:

1. Complete the Sunalta Medical Clinic assessment and a medical history questionnaire with all new clients.

2. Clients with a history of allergies to human albumin, clients with significant neurological and autoimmune diseases, or pregnant clients will be denied treatment.

3. Upon passing medical screening, clients will be fully informed of risks, benefits, and potential adverse reactions, including the off label cosmetic use of Botox® for areas that extend beyond the frown lines of the forehead and a Sunalta Medical Clinic informed consent will be signed.

4. Botox® shall be stored in a freezer [–5 degrees C or lower] until ready for use. Once reconstituted, it must be refrigerated [2–8 degrees C], not refrozen. Reconstituted Botox® should be clear, colorless and free of particulate matter.

5. Botox® shall only be reconstituted just prior to use and should be used within the first 4 hours according to the manufacturer. However, the Sunalta Medical Clinic feels that the Botox® can be refrigerated up to 30 days without any loss of efficacy. Gently rotate the vial and record the date and time of reconstitution on the Sunalta Medical Clinic Botox® and injectable fillers.

6. Vacuum will be released, using a ½-gauge, 2.5 inch length-needle prior to reconstitution. If no vacuum is present the Botox® vial will be sent back to the manufacturer and a new vial shall be used following the same procedure.

7. Botox® should be reconstituted using 2.0 ml of preserved or non-preserved saline¹ [0.9%] as a diluent, resulting in a 2.5 – 3.3 units per 0.1 cc. A 3–5 cc syringe containing non-preserved saline is attached to the ½-gauge needle [at a 45° angle] and SLOWLY injected into the vial. Allow the saline to flow down the sides of the vial, thus minimizing air bubble formation and not damaging the delicate Botox®.

8. Botox® is gently drawn up into a 1 ml tuberculin syringe using a ½-gauge needle. The injection is to be administered with a 31-gauge [½ inch] needle.

9. Clients are injected while in a seated position.

10. Clients are asked to demonstrate dynamically the function of the muscle groups to be injected.

11. Prior to administration the Registered Nurse [RN], or Physician or Nurse Practitioner (NP) will map out points of injection according to landmarks and location of muscle belly. The only areas of
administration will be the corrugator, procerus, frontalis, and orbicularis oculi muscles in the forehead and periorbital region in the upper face. Mid-facial application. [Corrugator and procerus muscles for frown lines, frontalis muscle for horizontal forehead lines, and orbicularis oculi muscle for crow’s feet.] Midfacial Botox* may be added for lifting of the corners of the mouth (Depressor angularis oris,) Vertical lip lines (orbicularis oris), elevation of the tip of the nose (depressor septi Nasi muscle) smoothening of dimpled chin skin (mentalis) and softening of neck Cords (platysma).

**Note:** increased toxin dose may be necessary in older and male clients.

12. In an effort to reduce the complications of ptosis the following steps should be adhered to:
   a. Administer at least 1 cm above the central eyebrow and 1.5 cm–2 cm from the lateral canthus.
   b. Ensure the injected volume/dose is accurate and kept to a minimum.
   c. Avoid injection near the levator superioris, particularly in patients with larger brows.
   d. Medial corrugator injections should be placed 1 cm above the bony supraorbital ridge.

If mild lid ptosis should occur the nurse will instruct the client that this will resolve within a few weeks and in the use of [over the counter] Vasocon to assist in alleviating the ptosis. Ptosis or any other complications shall be immediately reported to the Medical Director and documented in the Sunalta Medical Clinic client record.

1. Allergan recommends using 2.5 ml of non-preserved saline resulting in 4.0 units per 0.1 cc. However the accepted industry practice is as stated.

2. The RN shall be familiar with all general adverse reactions that can be associated with the administration of Botox® Cosmetic [Botulinum Toxin Type A]. Refer to Allergan Inc., publication, page 3, “Adverse Reactions – General” enclosed with each vial of product.

13. Syringe is inserted perpendicular to the skin and completed at a depth just beneath the dermis, 2.5 units to 5 units of Botox* is injected into each site.

14. After each injection the skin may be massaged moderately and pressure held with a gauze.

15. When procedure is completed the client will be educated to perform the dynamic facial expressions for the next hour, not to rub or manipulate the injection sites, not to lie down for a period of 4 hours, and to report any problems or complications to the clinic immediately.

16. Typically, the initial doses of reconstituted Botox* induce chemical denervation of the injected muscles 3 to 5 days after procedure, increasing in intensity during the first week.

(iv) **Record Keeping**

The Physician, Nurse Practitioner (NP), or Registered Nurse (RN) shall be responsible for maintaining client Sunalta Medical Clinic Botox® treatment records, including but not limited to client assessment, signed informed consent of risks, benefits, and potential adverse effects, number of treatments, treatment sites, number of injections, solution/concentration used, and the client response to treatment.
Requirements for Clinical Personnel

(v) Training / Education

The Registered Nurse [RN], or Physician Assistant must complete the Sunalta Medical Clinic certification and clinical training program as offered by the Vancouver Laser & Skin Care Centre. The Sunalta Medical Clinic Medical Director, either a Medical Doctor, or Nurse Practitioner, must also have completed the training. Advanced Practice Nurses experienced in this procedure, or a teaching institution specializing in this procedure, may perform this training and certification. Competencies to successfully demonstrate shall include:

• Mechanism of Action of Botox®
• Basic Theory of Treatment for Cosmetic Purposes
• Facial Anatomy
• Storage, preparation, and dilution of Botulinum Toxin A
• Safety, efficacy, and complication issues
• Assessment and identification of areas to be treated
• Safe application of injection techniques [minimum 8 hours hands on training]
• Complications and their management

v) Competencies & Documentation

The Physician, Nurse Practitioner (NP), or Registered Nurse (RN) shall:

• Document [on the appropriate form] the initial evaluation and final determination recording satisfactory completion of training and competence.
• Evaluate the competence of the Registered Nurse [RN] or licensed medical personnel on an annual basis and/or as needed if indicated by client dissatisfaction or efficacy issues.
• The evaluation shall be maintained in the personnel file of the Registered Nurse, Physician Assistant or licensed medical personnel at the appropriate administrative office [employing facility].
Development and Approval of Standardized Procedure

The Sunalta Medical Clinic Clinical Policies and Procedures for the Administration of Botox® have been developed jointly by the Medical Director, Administrator, Advanced Practice Nurse and/or Registered Nurse. This procedure shall be reviewed on an annual basis and documentation pertinent to that review shall be kept on file in the designated administrative office.

Signatures of authorized personnel approving the standardized procedure:

____________________________________________________________________
Nurse Date

____________________________________________________________________
Medical Director Date

____________________________________________________________________
Administrator Date
**Personnel Authorized to Perform Procedure**

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Botox® Post Treatment Instructions

- Avoid lying down for several hours following treatment.
- Facial exercise in the area of treatment is recommended [frown/smile 1 hour].
- Avoid manipulation of the area for the first four hours after procedure.

**Note:** These measures should minimize the possibility of ptosis.

- Treatment effect may take 3–8 days to appear.
- **The benefits may last 3–6 months, the average is 4 months.**
- A touch-up may be necessary in 1–2 weeks.
- Contact the practitioner as soon as possible after the eighth [8th] day if you have not achieved the desired effect.
**BOTOX COSMIC™**

*(Botulinum Toxin Type A For Injection)*

**NEUROMUSCULAR PARALYTIC AGENT**

**DESCRIPTION:** BOTOX COSMIC™ *(Botulinum Toxin Type A For Injection)* is a sterile, vacuum-dried form of purified botulinum neurotoxin type A complex, produced from a culture of the Hal strain of Clostridium botulinum grown in a medium containing N-acetyl amine, glucose and yeast extract. It is purified from the culture solution by a series of acid precipitations to a crystalline complex consisting of the neurotoxin, a non-toxic protein and four major proteolytic proteins. The crystalline complex (average molecular weight of 900,000 Kd) is re-dissolved in saline solution containing albumin (human) and is sterile filtered (0.2 microns) prior to vacuum-drying. BOTOX COSMIC™ is to be reconstituted with unpreserved sterile saline solution for injection or sterile water for injection.

Each vial of BOTOX COSMIC™ contains 100 units (U) of Clostridium botulinum type A, 0.5 milligrams of albumin (human), and 0.9 milligrams of sodium chloride in a sterile, vacuum-dried form without a preservative. One unit (U) corresponds to the calculated median lethal dose in mice (LD₅₀) in mice using reconstituted BOTOX COSMIC™ and injected intraperitoneally.

One unit (U) of BOTOX COSMIC™ corresponds to the calculated median intraperitoneal lethal dose (LD₅₀) in mice. The method utilized for performing the assay is specific to Clostridium botulinum type A. BOTOX COSMIC™ is to be used in the diluent provided, as recommended. Due to specific details of this assay such as the vehicle, dilution scheme and laboratory protocols for the various mouse LD₅₀ assays, Units of biological activity of BOTOX COSMIC™ cannot be compared to nor converted into Units of any other botulinum toxin or any toxin assessed with any other specific assay method. Therefore, differences in sensitivity of the assay to different botulinum neurotoxin serotypes precludes extrapolation of animal dose activity relationships to human dose estimates. The specific activity of BOTOX COSMIC™ is approximately 2000 units/mg of neurotoxin protein complex.

**CLINICAL PHARMACOLOGY:** BOTOX COSMIC™ *(Botulinum Toxin Type A For Injection)* blocks neurovascular conduction by binding to receptor sites on motor nerve terminals, entering the nerve terminals, and inhibiting the release of acetylcholine. When injected intramuscularly at therapeutic doses, BOTOX COSMIC™ produces partial chemical denervation of the muscle resulting in localized muscle paralysis. When chemically denervated, the muscle may atrophy, axonal sprouting may occur, and extrajunctional acetylcholine receptors may develop. There is evidence that reinervation of the muscle may occur, thus reversing muscle weakness produced by localized injection of BOTOX COSMIC™.

In clinical studies involving patients with moderate-to-severe glabellar lines at maximum frown, BOTOX COSMIC™ injections significantly reduced the severity of the glabellar lines for up to 120 days, as measured by investigator rating of glabellar line severity at maximum frown and at rest and by subjective global assessment of change in appearance of glabellar lines. Thirty days after injection, 84% of BOTOX COSMIC™-treated patients were considered by investigators as treatment responders (none or mild severity at maximum frown), and 90% of patients felt they had moderate or better improvement, compared to 6% of placebo-treated patients.

**INDICATIONS AND CLINICAL USE:** BOTOX COSMIC™ *(Botulinum Toxin Type A For Injection)* is indicated for the treatment of glabellar lines associated with corrugator and/or procerus muscle activity.

**CONTRAINDICATIONS:** BOTOX COSMIC™ *(Botulinum Toxin Type A For Injection)* is contraindicated in patients with myasthenia gravis or Eaton Lambert Syndrome. BOTOX COSMIC™ *(Botulinum Toxin Type A For Injection)* is contraindicated in the presence of infection at the proposed injection sites. BOTOX COSMIC™ *(Botulinum Toxin Type A For Injection)* is contraindicated in individuals with known hypersensitivity to any ingredient in the formulation.

**WARNINGS:** The recommended dosages and frequencies of administration for BOTOX COSMIC™ *(Botulinum Toxin Type A For Injection)* should not be exceeded.

The effect of botulinum toxin may be potentiated by aminoglycoside antibiotics or spectinomycin, or other drugs that interfere with neuromuscular transmission (e.g., tubocurarine-type muscle relaxants). Caution should be exercised when BOTOX COSMIC™ *(Botulinum Toxin Type A For Injection)* is used in the presence of botulinum toxin type A or type B serum and tissue. Caution should be exercised when BOTOX COSMIC™ *(Botulinum Toxin Type A For Injection)* is being used in patients with any history of peripheral nerve disorders, or disorders that produce peripheral neuromuscular dysfunction.

**PRECAUTIONS:** General: The safe and effective use of BOTOX COSMIC™ *(Botulinum Toxin Type A For Injection)* depends upon proper storage of the product, selection of the correct dose, and proper reconstitution and administration techniques. In order to reduce the complications of botulinum neurotoxin, avoid injection near the levator palpebrae superioris, particularly in patients with larger brow-depressor complexes. Minimal corrugator injections should be placed at least 1 cm above the brow supero-orbital ridge. As with all biologic products, an anaphylactic reaction may occur. Necessary precautions should be taken and epinephrine should be available.

Over the course of the double-blind and open-label studies, 120 subjects who had received three consecutive injections of 20 U of BOTOX COSMIC™ at four month intervals had serum antibody titer increases, which peaked at each injection and four months after the third injection. Four of these subjects had a positive antibody result at one time-point during the study. None of these subjects had a positive antibody result from the blood sample taken four months after the third consecutive injection. The results of these tests are highly dependent on the sensitivity and specificity of the assay, and may be influenced by several factors including sample handling, concomitant medications, and underlying disease. Treatment with BOTOX COSMIC™ does not generally result in the formation of antibodies that may reduce the effectiveness of subsequent treatments with BOTOX COSMIC™ for other purposes.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies in animals have not been performed to evaluate the carcinogenic potential of BOTOX COSMIC™. BOTOX COSMIC™ was not mutagenic in in vitro and in vivo mutagenicity studies. A fertility and reproductive toxicity study following intramuscular injection of BOTOX COSMIC™ in rats indicated the ‘no observed effect level’ (NOEL) on reproduction was at dosages of 4 U/kg in male rats and at dosages of 6 U/kg in female rats.

**Pregnancy:** Teratogenic Effects: The teratogenic effects of BOTOX COSMIC™ were evaluated in mice, rats and rabbits. No teratogenic effects were observed when pregnant mice were injected intramuscularly with doses of 4 U/kg (approximately 2/3 of the maximum recommended human dose) and 8 U/kg on days 5 and 13 of gestation; however, dosages of 16 U/kg induced a slightly lower fetal body weight. No teratogenic effects were observed in rats when injected intramuscularly with doses of 16 U/kg on days 6 and 13 of gestation, and 2 U/kg/day on days 6 through 15 of gestation. In rabbits, daily injections at dosages of 0.5 U/kg/day (days 6 through 18 of gestation) and 4 and 6 U/kg (days 6 and 13 of gestation) caused death and abortions among surviving animals. At lower doses (0.125 U/kg/day and at 2 U/kg/day), external malformations were observed in one fetus per dose. The rabbit appears to be a more sensitive species to BOTOX COSMIC™.

Reproductive and Developmental Effects: The reproductive and developmental effects of BOTOX COSMIC™ were evaluated in rats at dose levels of 4, 6 and 16 U/kg. Muscle atrophy at the injection site, reduced body weight gain and reduced absolute food consumption were observed following intramuscular injection of BOTOX COSMIC™ at dosages of 4 U/kg and higher on days 5 and 13 of presumed gestation, and day 7 of lactation. No effects on maternal reproductive performance were observed at the highest dose tested, 16 U/kg (approximately three times the maximum recommended human dose). No adverse effects on development of the pups was observed at 4 U/kg; however, higher dosages were associated with reduced pup body weight and/or pup viability at birth.

There are no adequate and well-controlled studies of BOTOX COSMIC™ administration in pregnant women. Because animal reproduction studies are not always predictive of human response, BOTOX COSMIC™ administration is not recommended during pregnancy. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential risks, including abortion or fetal malformations, which have been observed in rabbits.

**Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when BOTOX COSMIC™ is administered to a nursing woman.

**Pediatric Use:** Use of BOTOX COSMIC™ is not recommended in children.

Information to be Provided to the Patient: Patients or caregivers should be advised to seek immediate medical consultation if swallowing, speech, or respiratory disorders arise.

If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential risks, including abortion or fetal malformations, which have been observed in rabbits.

**ADVERSE REACTIONS:** General: In general, adverse events occur within the first week following injection of BOTOX COSMIC™ *(Botulinum Toxin Type A For Injection)*, and are transient. As is expected for any intramuscular injection procedure, localized pain, tenderness and/or bruising may be associated with the injection. Local weakness represents the expected pharmacological action of botulinum toxin.
Safety was evaluated in two multicenter, double-blind, placebo-controlled, parallel group studies of identical design (N=535; 405 in the BOTOKUS®-treated group and 130 in the placebo-treated group). The most frequently reported treatment-related adverse events were headache (9.4% in the BOTOKUS®-treated group and 15.4% in the placebo-treated group) and blepharoptosis (3.2% in the BOTOKUS®-treated group and 0% in the placebo-treated group). Blepharoptosis is consistent with the pharmacologic action of BOTOKUS®, and may be technique related.

Adverse events that were reported as treatment-related and were reported in 1-3% of BOTOKUS®-treated patients are listed in decreasing order of incidence: injection site pain/burning/stinging (2.5%), face pain (2.2%), erythema (1.7%), local muscle weakness (1.7%), injection site edema (1.5%), ecchymosis (1.0%), skin tightness (1.0%), parasthesia (1.0%) and nasoconjunctival symptoms (<1%). Most adverse events reported were of mild-to-moderate severity and all were transient.

In a multicenter, open-label, repeat injection study, 318 patients who had previously undergone one of the two double-blind studies and who had glabellar line severity of at least mild severity at maximum frown received 2 additional treatments of BOTOKUS®. In this study, adverse events were comparable in type, incidence, severity, and causality to those reported in the two placebo-controlled, double-blind studies.

The following events have been reported rarely (<0.1%) since BOTOKUS® has been marketed: rash (including erythema multiforme, urticaria, and purpuric-eruption), purpura, allergic reaction, and facial paralysis.

In the treatment of other indications with botulinum toxin type A, there have been rare spontaneous reports of deaths, sometimes associated with dysphagia, pneumonia, and/or other significant debility. There have also been rare reports of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors, including cardiovascular disease.

OVERDOSAGE: In the event of overdose or injection error, additional information may be obtained by contacting Allergan, Inc. at (800) 433-8871.

No cases of systemic toxicity have been reported following accidental injection or oral ingestion of BOTOKUS® (Botulinum Toxin Type A For Injection). Should accidental injection or oral ingestion occur, the patient should be monitored for approximately one week for signs or symptoms of systemic weakness or muscle paralysis.

Patients with botulism may present with symptoms of ptosis, diplopia, swallowing and speech disorders, cranial nerve findings, generalized weakness, or paralysis of the respiratory muscles. Overdose of BOTOKUS® is a relative term and depends upon dose, site of injection, and underlying tissue properties. Localized weakness is usually tolerated and resolves spontaneously without intervention. However, dysphagia may result in loss of airway protection and aspiration pneumonia.

DOSAGE AND ADMINISTRATION: For Intramuscular Use Only

The use of one vial for more than one patient is not recommended because the product and diluent do not contain a preservative. Do not freeze reconstituted BOTOKUS® (Botulinum Toxin Type A For Injection). Once opened and reconstituted, use within four hours and discard remaining solution.

BOTOKUS® is reconstituted with 0.9% sterile non-preserved saline (100 units in 2.5 mL or injected as 4 units/mL). 0.1 mL (4 U) should be administered using a 30 gauge needle in each of 5 sites, 2 in each corrugator muscle and 1 in the procerus muscle for a total dose of 20 U.

In order to reduce the complication of ptosis, injection near the levator palpebrae superioris should be avoided, particularly in patients with large brow-depressor complex. Medial corrugator injections should be placed at least 1 cm above the brow supraorbital ridge.

An injection of BOTOKUS® is prepared by drawing into a sterile 1.0 mL tuberculin syringe an amount of the properly diluted toxin (see Dilution Table) slightly greater than the intended dose. Air bubbles in the syringe barrel are expelled and the syringe may be attached to the electromyographic injection needle, preferably a 1.5 inch, 27 gauge needle. Injection volume in excess of the intended dose is expelled through the needle into an appropriate waste container to assure patency of the needle and to confirm that there is no syringe-needle leakage. A new sterile needle and syringe should be used to enter the vial on each occasion for dilution or removal of BOTOKUS®.

Lack of Response: There are several potential explanations for a lack or diminished response to an individual treatment with BOTOKUS®. These may include inadequate dose selection, selection of inappropriate muscles for injection, muscles inaccessible to injection, underlying structural abnormalities such as muscle contractures or bone disorders, change in pattern of muscle involvement, patient perception of benefit compared with initial results, inappropriate storage or reconstitution, as well as neutralizing antibodies to botulinum toxin. A neutralizing antibody is defined as an antibody that inactivates the biological activity of the toxin. However, there were patients who continued to respond to therapy and demonstrated presence of neutralizing antibodies; the proportion of patients which lose their response to botulinum toxin therapy and have demonstrable levels of neutralizing antibodies is small.

The critical factors for neutralizing antibody production are the frequency and dose of injection. To reduce the potential for neutralizing antibody formation, it is recommended that injection intervals of BOTOKUS® should be no more frequent than two months. More frequent injections should not be required, as BOTOKUS® treatment reduces the severity of the glabellar lines for up to 120 days.

A suggested course of action when patients do not respond to BOTOKUS® injections is: 1) wait the usual treatment interval; 2) consider reasons for lack of response listed above; 3) more than one treatment course should be considered before classification of a patient as a non-responder; 4) test patient serum for neutralizing antibody presence.

RECONSTITUTED SOLUTIONS: To reconstitute vacuum-dried BOTOKUS®, use sterile normal saline without a preservative. 0.9% Sodium Chloride Injection is the recommended diluent. Draw up the proper amount of diluent in the appropriate size syringe. Since BOTOKUS® is denatured by bubbling or similar violent agitation, inject the diluent into the vial gently. Discard the vial if a vacuum does not pull the diluent into the vial. Record the date and time of reconstitution on the space on the label. BOTOKUS® should be administered within four hours after reconstitution.

During this time period, reconstituted BOTOKUS® should be stored in a refrigerator (2° to 8° C). Reconstituted BOTOKUS® should be clear, colorless and free of particulate matter. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration and whenever the solution and the container permit.

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<th>Dilution Table</th>
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<td>2.5 mL</td>
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SPECIAL INSTRUCTIONS: All vials, including expired vials, or equipment used with the drug should be disposed of carefully as is done with all medical waste.

STORAGE: Store the vacuum-dried product either in a refrigerator at 2° to 8° C, or in a freezer at or below –5° C. Administer BOTOKUS® within four hours after the vial is reconstituted. During this four hours, reconstituted BOTOKUS® should be stored in a refrigerator (2° to 8° C). Reconstituted BOTOKUS® should be clear, colorless and free of particulate matter.

HOW SUPPLIED: Each vial contains 100 U of vacuum-dried Clostridium botulinum toxin type A.

Product Monograph available on request.

April 2003

ALLERGAN Inc.
Markham, Ontario, Canada, L3R 9S1

71711EC10M
Discussion Points for Educating clients about Botox® (Not an Educational Pamphlet)

What is Botox Cosmetic™?
Botox Cosmetic™ is a treatment for wrinkles such as crow’s feet, frown lines and the furrow in your brow.

You know what would help you out – is a proper consultation here in our office – why don’t we book one for you?

All of your questions will be fully answered!

Is it safe?
Yes! Botox® has been available for 20 years and has been used to treat many diseases (including cerebral palsy) and has been proven to be very safe through extensive testing and research.

Botox Cosmetic™ is an approved drug used to treat patients for cosmetic wrinkles.

Why don’t we book a consultation for you so that all of your questions can be answered?

Will it give me food poisoning/Is it botulism?
No – Botox Cosmetic™ is NOT botulism and it will not cause food poisoning. To clarify for you, Botulism is the name of an illness.

The product is a natural, purified protein. It is an approved prescription drug that is used in tiny doses.

It comes from a naturally occurring bacteria and it is purified in a lab – similar to how Penicillin comes from mould!

Why don’t we book a personal consultation for you so that all of your questions can be answered?

Isn’t Botox Cosmetic™ a toxin/poison?
No, it is not a poison! No, it is not toxic to you!

Botox Cosmetic™ is a natural, purified protein. It is an approved drug that is used in tiny doses.

It comes from a naturally occurring bacteria – similar to how Penicillin comes from mould!

Why don’t we book a consultation for you so that all your questions can be answered?

How do I know it won’t be toxic for me?
Typically, for a cosmetic treatment, you may receive under 100 units.

Botox Cosmetic™ would only be toxic to you if you received over 3,500 units all at one time. You really are getting very tiny doses.

Why don’t we book a consultation for you so that all your questions can be answered?

How does it work?
Botox Cosmetic™ works by relaxing the muscles underneath the skin to create a smooth and refreshed appearance.

Why don’t we book a consultation for you where you can ask all of your questions? (When asked in office, bring to front desk to book a consultation.)
**How long does the procedure take?**
Generally, after the consultation, the procedure only takes up to 15 minutes.
Since there is no downtime – you can do it on your lunchtime!
Why don’t we book a consultation for you?

**How quickly does it work?**
It can take up to 2 weeks for it to take full effect.
Why don’t we book a consultation for you?

**My treatment didn’t work!**
Botox Cosmetic™ takes up to 14 days to take full effect. When was your treatment done?
If LESS than 2 weeks ago, say to patient:
You will need to wait until the full 2 weeks has passed and then please call us if you have any concerns.
If MORE than 2 weeks ago, say to patient:
Okay, then let’s book an appointment with the Doctor so that you can be re-assessed and to see if you require a little more product. Are you available on ?

**How long does Botox Cosmetic™ last?**
No – Botox Cosmetic™ is not permanent. It lasts between 3–4 months on average but everyone is different.
Why don’t we book a consultation for you?

**How is it done?**
It is injected with a very tiny needle (it only feels like a little pinch).
Why don’t we book a consultation for you?

**Does it hurt?**
Most patients say the injections feel similar to a little pinch, although everyone is different.
I usually hear that patients say, “Is that all?” Why
don’t we book a consultation for you?

**How much does it cost?**
The cost of treatment varies by each patient and a personal consultation can give you a specific amount.
The cost can range from $300 and up. There are a few things you should consider in addition to price:

- Medical Licence of physician
- Years of experience of physician
- We have treated hundreds of patients here who keep returning
The doctor is wonderful!

Why don’t we book a consultation for you so that you can get a specific amount?

If patient persists on cost per unit:

Our clinic charges $_________/unit but the details of what it may cost for you needs to be discussed with the doctor.

*What about the cost/experience of the injector (Why should I come to you?)*

Dr. XXXXXXX has been specializing in Botox Administration since 19XX. He/She is Certified in Canada and is a member of the XXXXXXX Society of Physicians.

Why don’t we book a consultation for you so that you can meet him and get more information?

*What is a unit?*

A unit of Botox Cosmetic™ is simply a very tiny measurement of drug.

The number of units you require (to achieve the look you want) needs to be discussed with the doctor during the consultation.

Why don’t we book a consultation for you so that you can discuss this in more detail with him?

*I don’t want to look like a mask without expression – will that happen?*

No. We ensure you get the look you want – as natural as you want.

Everyone wants a different look and we strive to make you happy!

Why don’t we book a consultation for you so that all your questions can be answered?

*What are the side effects?*

Side effects are rare and are not permanent.

There can be some minor bruising (which is easily covered up with makeup) or a slight headache.

Why don’t we book a consultation for you where all the details can be discussed?

*I have heard that you can get a drooping eyelid – is this true?*

Side effects are rare and are not permanent and this can include a drooping eyelid.

The incidence of these side effects are less than 1%.

Why don’t we book a consultation for you where you can ask all of your questions?

*Where does it go in my body?*

Botox Cosmetic™ stays local to the muscle where it is injected.

Why don’t we book a consultation for you where you can get more detailed information from the doctor?

If the patient wants more information, you can answer with:
“After the injection Botox Cosmetic™ is simply metabolized and broken down into natural by-products.”

**I have (any medical condition). Can I get Botox Cosmetic™?**

That is a great question! However, I am not a physician and therefore, that can only be answered during a private consultation with Dr. XXXXX.

Why don’t we book an appointment for you so that all your questions can be answered?

**What to do when a patient wants to keep asking you detailed questions about a procedure on the phone:**

Since you are asking a lot of great questions, I recommend that you write down all your questions on a piece of paper. We should book a personal consultation for you... you can bring your list and ensure that nothing is overlooked!

It has been a pleasure speaking with you and answering some of your questions. However, I must excuse myself. Our patient coordinators are better able to answer your questions.

We have an opening on ________________.

**How to explain the consultation process and try to minimize no shows.**

I’d like to tell you about your consultation so that you know what to expect:

We book a dedicated appointment with you and one of our highly qualified staff. This can be done with one of our highly trained patient coordinators or with the doctor.

You have the entire time to ask questions, discuss your individual concerns and expectations.

If you feel comfortable, we have also included special time for you to have the treatment done during the appointment, although you are not obligated.

We will call to confirm your appointment, BUT since we have set aside dedicated time to meet with you, it is very important that you let us know if you cannot make your appointment.

**Some industry data**

2002 global survey on “Public Perceptions and Attitudes Towards Facial Appearance”

- 80% of Canadians consider physical attractiveness somewhat to very important in today’s society
- 67% of Canadians want their face to look young for their age.
- 35% of Canadians agree that there are things about their face that they would like to change.
- 78% of women under 45 consider using various treatments and procedures to improve their appearance.
- 63% of Canadians would go to their doctors (dermatologists, plastic surgeons or family/general physicians) as their main source of information about facial treatments or procedures

**The Botox Cosmetic™ Boom**

- Botox Cosmetic™ is the most common and fastest growing cosmetic procedure performed in North America
- More than 100,000 Botox injections on 50,000 patients in 2003 in Canada
• 325% increase in number of practices offering non-surgical procedures
• 1 in 2 Canadians have heard about Botox Cosmetic™
• 75% of the core target have heard about Botox Cosmetic™

Consumer Perceptions of Treatment Options
• Surgery
• Injectables
• Superficial
  – removing unwanted blemishes/hair
  – peels/facials
• Lotions & Potions

Larger mental step for many consumers from superficial to injectables.

Top 10 Tips to Retain More Patients
1. Provide consistently great service.
2. Under promise and over deliver.
3. ALWAYS book a 2 week follow-up.
4. ALWAYS take before & after photos.
5. ALWAYS be proactive about booking the next treatment date!!!!!
6. Personalize your interaction with the patient.
7. Cross sell all your services – don’t be afraid to make suggestions.
8. Maintain a wait list (be proactive).
9. Calculate your retention rates.
10. Set goals to improve retention.
Consultation Process

Botox®

1. Client must complete a Medical/Surgical History, review and sign Payment Policy, review and initial pages of Botox® Consent Form. A good candidate for Botox® would be individuals with expression lines or facial wrinkles that persist despite other treatments.

2. Review history with client in consultation. Consent is reviewed as well until client has no further questions.

3. Explain indications for Botox® such as glabellar lines, horizontal brow lines, crow’s feet, lower lid roll, bunny lines on the side of the nose, lips, chin, mandible, and neck bands. A good candidate, as stated above has had a thorough discussion of product description, risks, benefits, post care and longevity (which can be up to 6 months). This is also a good time to discuss all other services that Sunalta Medical Clinic offers. Information pages are available on all procedures.

4. Be sure client is aware of post treatment instructions, and that they have a post care page to take home with them. It includes the clinic phone number on the bottom of the page if they have any concerns.

5. Discuss all issues regarding injection technique so the client is aware of our Num It cream; our cryo cooler is also available.

6. All pages of consent must be initialed, the last page to be filled out by injectable nurse as to specific area of injection. Have client sign the bottom of this page and the nurse will witness with her signature.

7. Photos are taken with the Polaroid camera, usually kept in treatment room one. Photos are labeled and kept in the patient’s chart in envelopes that will stick in the front of the chart. These are kept at the front desk.

Medical/Surgical History

Patient Name: ___________________________ I.D. # __________________

In this time of rapidly expanding medical knowledge and the increasing specialization associated therewith, there exists a very real risk of the specialist physician not being aware of the general health and medical background of the patient. On occasion such information may critically affect what procedures we may safely undertake on you and under what circumstances. We therefore ask that you give us the following medical information.

Age: ______ Height: ______ Weight: ______ Occupation: __________________________

Please list all medications which you are currently taking or have used in the past 6 months (be sure to include any of the following: birth control pills, aspirin or ibuprofen containing drugs, Phen-Fen, Redux, diabetic medications, steroids, glaucoma drops, asthma medications, Digoxin, Lanoxin, nitroglycerin, Isordil, Inderal, other heart medications, Lasix, other diuretics, high blood pressure medications, Coumadin, Persantine, tranquillizers, sleeping pills, anti-depressants, pain pills or injections, epilepsy medications). Use back of page if necessary.

<table>
<thead>
<tr>
<th>Medication(s):</th>
<th>Amount</th>
<th>Frequency</th>
</tr>
</thead>
</table>

Please list all Naturopathic or Health Food Supplements:

List all drug and/or latex allergies:

Have you ever used (circle): LSD/speed/cocaine/marijuana?

If yes, when did you last use ________________________________

Are you a smoker? YES/NO Ex-Smoker YES/NO Non-Smoker YES/NO

How much are (were) you smoking? _______ How long? _______ Quit how long ago? _______

How much alcohol do you drink? ___________________________ Caffeine? ______________

Please circle all of the following medical conditions you now have or have had in the past:

bleeding tendency / diabetes / blood transfusions / glaucoma / dry eyes / lung disease / TB / asthma or wheezing / emphysema / bronchitis / irregular heart beat / chest pain / heart disease / high blood pressure / heart attack / stroke / epilepsy / heart burn / intestinal ulcers or bleeding / rheumatoid arthritis / sclerodema / lupus / depression / mental illness / drug or alcohol addiction / hepatitis B / hepatitis C / HIV / any other serious illness or injury / None of the above
Is there any possibility that you may be pregnant at this time? **YES/NO**

Do you have a history of herpes simplex (cold sores)? ________________________________

When was the last outbreak? _____________________________________________________

Do you have a history of developing keloids? _______________________________________

Have you ever been on accutane? ___________________________ When? ___________________

List all surgeries that you have had (include plastic surgery): Date:

Have you or anyone in your family ever had unusual reactions to anesthesia (muscle weakness, jaundice, breathing problems or unexpected fever(s))? **YES/NO**

Do you have (circle): loose or chipped teeth/caps/dentures/contact lenses/None Have you ever seen a cardiologist? **YES/NO**

Physician Name: ________________________________

Date of last EKG: _______________________________________________________________

**I acknowledge that I have disclosed my complete medical history and the above is a complete and accurate representation of my medical and psychological status.**

Patient Signature: ___________________________ Date: ___________________________

**Authorization for Examination and Treatment**

**Name:** ___________________________ **Birthdate (mm/dd/yy):** __________

**Address:** ___________________________ **City:** ___________________________

**Province:** ___________ **Postal Code:** ___________ **Home Phone:** ___________

**Work Phone:** ___________________________ **Referred by:** ___________________________

**Health Card No. (& version code):** _____________________________________________

**Emergency Contact Name & Number:** ___________________________________________
I, ________________________________ , represent to the physicians and staff that I am at least 18 (eighteen) years of age or, if not, am accompanied by a legal guardian. I hereby consent to and authorize a history examination by my doctor and such assistant or staff as may be assigned by him/her.

If appropriate, I authorize the release of any medical information for the purpose of processing insurance claims on my behalf. I authorize payments of medical benefits directly to the doctor for services provided to me. A copy of this authorization shall be considered as valid as the original. I understand that photography is a necessary part of planning and evaluating cosmetic procedures. I authorize the taking of photographs at the direction of my physician or physician delegate and under such conditions as may be approved by him/her. These photographs will be used solely for documentation purposes and will be kept confidential unless otherwise disclosed.

I understand that there is a consultation fee for the initial visit which is due at the time of my appointment unless other arrangements have been made in advance.

SIGNATURE: ________________________________ DATE: ______________

RELATIONSHIP: (circle one) PATIENT SPOUSE PARENT GUARDIAN
Payment Policy for Aesthetic Consults and/or Procedures

A VISA or MasterCard number, or debit or cash are required to reserve your appointment time.

Charges will not be applied to your credit card until you arrive for your treatment.

48 business hours are required for cancellation of your appointment to avoid being charged for your treatment.

If you cancel your appointment in less than 48 business hours, or fail to appear for your treatment, a charge of $100.00 will be applied to your credit card.

Although we will do our best to accommodate you, if you are late for your appointment, you may be required to rebook for another day. If this is necessary, the $100.00 fee will be waived.

Client signature ____________________________ Date ____________________
**Botox® Injections**

**Informed-Consent Booklet**

**Instructions**

This is an informed-consent document that has been prepared by Sunalta Medical Clinic to help inform you concerning Botox® injections, the risks, and alternative treatment. During your consultation, you will review the potential benefits of Botox® injections, the alternatives and all the points in this booklet. You will be able to ask any questions and be provided with answers to these questions to the best of our ability. It is important that you read this information again carefully and completely. Only when you have no questions or concerns do you initial each page, indicating that you have read and fully understood all the items it discusses. When you arrive at the end of this booklet, sign the consent for the procedure as proposed by Dr. Mulholland or your nurse injector. If you have any remaining questions, do not initial or sign the consent until they have been answered to your satisfaction.

**Introduction**

Botox® injections are a non-surgical procedure designed to paralyze the portions of overactive facial muscles that cause deep furrows, creases and fine wrinkles in the face. Botox® is a sterile, vacuum-dried form of purified botulinum neurotoxin type A complex, produced from a culture of the A strain of bacteria called Clostridium Botulinum. Although the Clostridium bacteria causes botulism, the Botox® extract does not. The Botox® extract is the purified, sterilized product from the bacteria and is a potent localized muscle, paralytic agent. Botox® contains a small amount of pasteurized human albumin. No cases of viral diseases have ever been identified for albumin. Botox® has been used safely for many years in the treatment of muscle disorders of the eyes and voicebox. Its most recent application has been in the treatment of cosmetic wrinkles, creases and lines in the face. Botox® is a simple injection performed in the office by one of the Medical Directors or a Sunalta Medical Clinic nurse injector. The improvement in the wrinkles begins 5–7 days after the injection and lasts for 3–6 months. It may be repeated indefinitely.

**Alternative Treatment**

Alternative forms of treatment or management consist of not treating the wrinkles or creases and continuing to use camouflage makeup. Topical wrinkle creams or Retin-A may add some minor improvement. Microdermabrasion and Pulsed Light therapy, called WrinkleLite® and/or FotoFacial® can provide noticeable improvement in fine wrinkles without any recovery or down time (ask our staff about these treatments) and are often performed in conjunction with Botox®. Injectable treatments such as collagen, Hyaluronic Acids, and/or Microfat may help fill out the wrinkle. Implantable substances such as Softform (Gortex) or AlloDerm may help fill out a defect. Topical laser treatment (CO₂ or Erbium) may improve or eliminate certain wrinkles. Cosmetic plastic surgery procedures such as Endoscopic Browlift, Eyelid Tucks or Face-Neck Lifts may also improve the creases or wrinkles. These alternative treatments are not performed at Sunalta Medical Clinic however they can be discussed and recommendations for referrals to our colleagues can be made.
**Potential Benefits of Botox**

Prolonged softening of the fine lines, wrinkles, creases and furrows of the forehead, eyes and neck, creating a more serene-looking face with fewer active muscles and creases.

**Risks of Botox Injections**

**Pain/Discomfort:** There is a minor degree of discomfort from the small-gauge needle that is inserted under the skin. There is a slight burning discomfort as the Botox is injected into the muscle. Most patients find the process less painful than an immunization. The Botox treatment only takes a few minutes to complete and is performed in the office.

**Bruising/Swelling:** Most patients have some swelling in the injection area for a couple of hours. It is rare to develop bruising after, but if this were to occur, it should disappear in 7–10 days and can be camouflaged with makeup immediately following treatment.

**Infection:** Like any injection technique, an infection may rarely occur (less than 0.5% risk) and can usually be treated with an oral antibiotic. Severe infections, although exceedingly rare, may require a drainage procedure or surgery.

**Treatment Failure:** Occasionally, the Botox may fail to completely paralyze the facial muscle or soften the wrinkle and a repeat treatment within 2 weeks may be necessary. In the rare event that the initial Botox injection failed to exhibit a clinical effect, there will be no charge for the subsequent single retreatment session.

**Long-term Effects:** The duration of improvement with the Botox varies between patients, but generally, 3–6 months of decreased muscle activity and wrinkle improvement may be achieved. Repeat treatments can be performed but prolonged use over many years may result in a permanent weakness of muscle function.

**Pregnancy:** Botox should not be used while pregnant as there is a risk of premature delivery. If there is any chance that you may be pregnant, you should first exclude the possibility with a pregnancy blood test, or not have the Botox.

**Lactation:** There is no known risk of Botox during lactation but, if you are concerned, we recommend postponing your Botox until you have completed breastfeeding.

**Asymmetry:** When two sides of the face are being treated for the same problem, there may be some asymmetries that result between the Botox performed on one side and the same treatment on the other side.

**Functional Problems:** Although extremely rare, if the Botox treatment is too effective or there is subcutaneous migration of the substance, functional or esthetically displeasing effects may occur such as Brow Ptosis (drooping of the brow), Eyelid Ptosis (subtle drooping of an eyelid), Diplopia (double vision), Lagophthalmous (weakness of eye closure) or a smile droop. Fortunately, these side-effects are extremely rare and temporary (as the Botox effect wears off in a few months). Depending upon the area treated, smile and lip asymmetry, failure of adequate lip closure, articulating abnormalities, swallowing and coughing may be affected.
General Body Symptoms: These occur very rarely (less than 0.1%) but can include skin rash, itchiness, general malaise, headaches, drowsiness, fever or flu-like symptoms that last for several hours or several days. These symptoms are temporary and may be remedied with a plain Tylenol or ibuprofen as directed on the bottles’ instructions.

Additional Surgery Necessary
Should any of the aforementioned or other complications occur, additional procedures or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited and those you have just reviewed are those risks particularly associated with Botox® injections. 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.

Health Insurance
Most health insurance companies including OHIP, exclude coverage for cosmetic surgical operations such as Botox® injections. Please carefully review your health insurance subscriber-information pamphlet. Generally, complications arising from such surgery are covered by health insurance.

Financial Responsibilities
The cost of surgery involves several charges for the services provided. The total includes fees charged by Dr. Mulholland, the cost of surgical supplies, anaesthesia, nursing costs and outpatient facility charges. 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. Additional costs may occur should complications develop from the surgery. Secondary surgery or facility day-surgery charges involved with revisionary surgery would also be your responsibility.

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 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.

What Dr. Mulholland has discussed with you and included again in this booklet are the material risks, both common and uncommon, that he feels a reasonable person would want to know, understand and consider in trying to decide if Botox® injections are something they would like to proceed with. However, informed consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Dr. Mulholland may provide you with additional or different information which is based on all the facts in your particular case and the 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 contained on this and all preceding pages carefully and have all of your questions answered before signing the consent on the next page. Questions and concerns can be addressed by contacting the Sunalta Medical Clinic office at 1-403-333-5620.

**Consent for Surgery/Procedure or Treatment**

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

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. As part of the requirements of Accreditation of Ambulatory Surgical Facilities, your chart may be subject to a peer review for quality control.

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

6. I consent to the photographing or televising of the operation(s) or procedure(s) to be performed, including appropriate portions of my body for medical, scientific or educational purposes. These photographs may be used for medical meetings, advertising, or any promotional or public relations purposes.

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

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

9. I understand that the signature of the witness (if a non-physician) on this document indicates only that the signing of my name has been observed and not that the witness has necessarily provided information regarding the procedure.
10. IT HAS BEEN EXPLAINED TO ME BY MY MEDICAL DIRECTOR 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
   d. ANY QUESTIONS I MAY HAVE ASKED HAVE BEEN ANSWERED TO MY SATISFACTION

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1–10). I AM SATISFIED WITH THE EXPLANATION.

__________________________________________
Patient or Person Authorized to Sign for Patient        Please Print Name Here

__________________________________________
Date        Witness
Botox® Injections

Who is a Candidate?

- Patients with expression lines/facial wrinkles that persist despite autologen/collagen or laser treatments.

Intended Results

- The muscle is paralyzed over a period of several days and the expression line softens dramatically, becoming less noticeable.
- Results last 3–4 months, when a repeat injection can be performed.

Procedure Description

- Botox® is an injectable drug that paralyzes small areas of muscle for 3–4 months.
- It is injected around deep expression lines of the forehead and bridge of nose that are caused by overactive muscles of expression.
- The muscle is paralyzed over a period of several days and the expression line softens dramatically, becoming less noticeable.
- This procedure takes about 15 minutes to perform.

Recuperation and Healing

- Most patients return to work the next day with very minor bruising that will disappear quickly and can be camouflaged with make-up.

Other Options

- Additional procedures that may enhance the result are Laser Resurfacing, Brow lift, or Blepharoplasty.

Insurance Guidelines

- Botox® injection is considered cosmetic and therefore is not covered by insurance. The patient is responsible for payment.

Surgical Fee Range

- From $300.00 to $1,200.00