The SpaMedica® Lift Management of Rhytidogenic Hyperdynamic Facial Musculature and the Treatment of Cervical Facial Depressors

During the SpaMedica® non-surgical facelift, dynamic corrective balancing of the muscles that depress the facial soft-tissue, muscles that elevate the facial features and soft-tissue landmarks and paralysis of Hyperdynamic Rhytidogenic Mimetic muscles is critical to achieving a rejuvenated appearance. Botox® therapy alone will never achieve the cumulative, aesthetic rejuvenation that the SpaMedica® lift achieves. Botox® is an important component of the SpaMedica® but, only one element, one support on the foundation. Without Botox®, the other components of the SpaMedica® lift will still provide soft-tissue elevation and rejuvenation, however, the power of the Botox®, injectable fillers and the various technological therapies delivered by the M.E.D.U.C.E™ deliver the optimal results. The various technological therapies and injectables of the SpaMedica® lift, MyoFacials®, SonoFacials®, SonoPeels®, Botox®, Injectable fillers and FotoFacial® can all be delivered by themselves. The SpaMedica® facial mimetic muscle classification, stratifies and organizes muscles based upon their influence upon the aging process:

**SpaMedica® Facial Muscle Classification**

(i) Prime Facial Elevators
(ii) Prime Facial Depressors
(iii) Prime Hyperdynamic Rhytidogenic Mimetic Facial Muscles

Each of these muscle groups undergoes dynamic, complementary and synergistic therapy during the SpaMedica® lift to achieve maximal youthful facial restoration.

The prime facial elevators are the Frontalis, Zygomaticus Major and Minor, Levator Labii Superioris, Digastric Sling and lateral Platysmal musculature. The prime elevators are responsible for elevating the facial skin and soft-tissue features in those individuals where the skin is still relatively closely coapted to the underlying facial muscles via the cutaneous fascial ligaments. The

*Fig. 28: The prime muscles of the facial elevators which provide a superior influence and support for the soft tissue of the face. (Prime facial elevators.) These are the Frontalis (A.), the Zygomaticus major and minor (B.), the Levator Labii Superioris (C.), the Digastric sling (D.) and the Lateral Platysmal fibers (E.). The horizontal lower lid fibers of Orbicularis Oculi (E) provide lower sling support of the aging lower lid, which is prone to laxity and senile ectropion or scleral show (in youth, this muscle can also be hypertrophied and overactive, causing a lower lid roll or bulge on animation).*
prime elevators are vigorously treated with the SpaMedica® Isotonic Myofacial Hypertrophy and Myofacial Engorgement training to augment facial muscle mass, size and provide cutaneous elevation (see SpaMedica® Isotonic Myofacial Hypertrophy) (Fig. 28).

Where the prime facial muscle elevators are responsible for the youthful superior, vertical vector to the face, the Prime Muscle Depressors provide strong inferior vectors to the facial soft-tissue and features and they counterbalance and often overcome the Prime Muscle Elevators. The prime muscle Depressors of the face that contribute to cervico-facial ptosis include the lateral, vertical fibers of Orbicularis Occuli (depessors of the lateral brow) laterally, Corregators, Procerus and Depressor Supracillicary medially (prime depressors of the medial brow, and the Depressor Anguli Oris and medial Platysma inferiorly. The secondary facial muscle depressors include the Depressor Septi Nasii and the Depressor Orbicularis Oris (Fig. 29). If we could somehow turn off, or partially disable the most powerful and clinically evident of these depressors then the prime elevators would act in an uncoupled, unopposed fashion to elevate the soft-tissue of the face to a more youthful position. Further, if we can synchronously strengthen and hypertrophy these elevators with MyoFacials®, then the vertical rejuvenative action would be synergistic and optimized.

Acting as the Facial Muscle Depressors are the Hyperdynamic Rhytidogenic Mimetic Facial Muscles. These are the facial muscles that can be overactive, or over-animated, and act to fissure and crimp the facial skin, in an accordion fashion, helping to create the deep dermal rhytides that can contribute to the appearance of an aged face. The prime Hyperdynamic Rhytidogenic facial muscles are the Corregator Supracilii and the corresponding frown lines, Frontalis and its corresponding horizontal forehead lines, the Orbicularis Oculi and its resulting crow’s feet and lower lid rhytides, the Levator Alae Nasi and their resulting bunny lines, the Orbicularis Oris and the corresponding upper lip lines and the Platysma and its resulting horizontal neck lines (Fig. 30).
Successful SpaMedica® lift management of the Facial Muscle Elevators involves making these muscles larger, more active and more efficacious through a hypertrophy and dilation processes called **Myofacial Isotonic training and engorgement**. While the MyoFacial therapy lifts the muscles of facial rejuvenation for best results, the physician should counteract the downward vector of the Depressor Facial muscles with paralysis and relaxation. Similarly, for the Hyperdynamic Rhytidogenic Mimetic Facial muscles, the SpaMedica® lift should down modulate, or deactivate these muscles, without compromising function, to minimize the most obvious wrinkles and aging lines on the face. The SpaMedica® non-surgical facelift then is dependent upon the successful, focal paralysis of certain, undesirable facial muscles and Isotonic Hypertrophic elevation effects of the others. This selective, rejuvenative muscle paralysis occurs through the intelligent and artistic use of Botox®. This chapter will focus on the SpaMedica® approach to Botox®, its pharmacology and physiology.

**Botox®: Definition**

Botox® (BTX) is a trademarked paralytic muscle neurotoxin manufactured by Allergan. Botox® stands for Botulinum Toxin. The allergan product is Botulinum Toxin A, which has the most clinical experience worldwide for both cosmetic and non-cosmetic use. In Europe, Botulinum Toxin A is called Dysport and has a different dose response curve than its North American counterpart. The other serotype forms of Botulinum toxin, such as Monobloc (Botox® B), Botulinum Toxin C, E and F may also provide focal aesthetic muscle paralysis, but with different dose-response curves and durations and with far less clinical aesthetic experience than Botox®.

**Botox®: Chemical Structure**

The bacteria Clostridium botulinum produces seven serologically distinct toxins that are named by letters, A, B, C, D, E, F, and G. Each of these subtypes of botulinum toxin are antigenically unique, but structurally very similar. All seven types of Botulinum toxin have molecular weights of approximately 150,000 daltons. All subtypes of Botox® are two molecule structures with two chains, a heavy chain (100,000 Daltons) and a lighter chain (approximately 50,000 Daltons) (Fig. 31a–b).
**SpaMedica®**

**Botox®: Mechanism of Action**

BTX is a neurotoxin that acts at the neuromuscular junction (Fig. 32). During normal striated muscle contractions, the motor neuron action potential arrives at the presynaptic junction and results in exocytosis and release of acetylcholine, which, in turn, traverses the synaptic gap and stimulates a sarcoplasmic action potential and muscle contraction. Botox® acts to block the release of acetylcholine at the presynaptic junction. Without acetylcholine, there is no contraction of the targeted muscle and flaccid paralysis of this muscle ensues. Logically, if the blocked muscle exhibits flaccid paralysis, then the Facial Depressor, the ptotic vector and the hyperdynamic rhytidogenic mimetic muscles and the wrinkle effects will be greatly improve the aging elements of the face.

There are three basic steps to the action of BTX at the neuromuscular junction. These steps are binding, internalization and the inhibition of neurotransmitter release. BTX is a double chained molecule, with a heavy and light chain. The heavy chain is responsible for the binding of the BTX to membrane of the terminal motor neuron and end plate (Fig. 31a). Binding is followed by a heavy chain, receptor mediated endocytosis which imports the BTX into a presynaptic vesicle (Fig. 31b). Once inside the secretory vesicles, the light chain migrates across the membrane wall. The light chain is a protease which acts upon an essential protein and enzyme that is responsible for the docking and ultimate exocytosis and release of the acetylcholine. The action of the light chain blocks release of the acetylcholine (Fig. 32a–c).

**Botox®: Duration of Action**

Without acetylcholine there is flaccid paralysis of the distal, targeted muscle. Over time there is demonstrable, denervation atrophy of the muscle. Early on, there are newly formed sprouts of neuromuscular junctions that will effect early reinnervation of the paralyzed muscle which show up at approximately 28 days (Fig. 33a). However, this early reinnervation is not clinically apparent or demonstrable. Over time, generally about three months, clinically evident reinnervation occurs through return of vesicle activity at the original terminals and the collateral.
sprouts disappear (Fig. 33b). By 90 days, function of the original junctions has returned, clinically evident muscle contraction returns and the sprouts completely disappear (Fig. 34).

The different botulinum toxins have varying durations of action. Type F and Type E toxins have a shorter duration of action, whereas Type C and B may have similar length of duration as BTX A.

**Botox®: Unit Potency and LD$_{50}$**

The potency of BTX A is determined through a standardized in vivo mouse assay. One unit of BTX A is defined as the amount of toxin required to kill 50% (LD$_{50}$) of a cohort of 18–20g female Swiss-Webster mice. This unit is referred to as a mouse unit, a mouse LD 50 unit, or just a “unit”. The LD$_{50}$, or the lethal dose in humans is not known. It has been estimated that the lethal dose of BTX in humans would be 3500 times that needed to cause paralysis and death of a Swiss-Webster mouse. Therefore, the estimated lethal dose would be 2500 to 3500 units. To date, I am unaware of any fatalities attributed to the administration of BTX in humans. Unlike the facial aesthetic and the SpaMedica® uses of BTX, where relatively small amounts of BTX are used, the treatment of dystonia’s and spasticities can result in very large amounts of BTX being used at a single treatment. The usual maximal, single session, single site recommended dose of BTX is < 400 U per treatment every 3 months. Small amounts of BTX may circulate in the blood briefly after administration.
Botox® is manufactured and distributed in North America and is controlled and regulated by the FDA in the US and by Health Protection Branch in Canada. In England, BTX A is called Dysport and uses slightly different manufacturing techniques, dilutions and LD50 assays. The potency for these two types of BTX A is different and generally, it is reported that 1 unit of Botox® is equivalent to 3 to 4 units of Dysport.

**Botox®: Maximum Dosage suggestions.**

To date, I am unaware of systemic complications from cosmetic dosages of Botox®. Generally, the maximum cosmetic dosage is 1–2 Units/Kg of body weight. For the average 70 Kg patient, cosmetic dosage should not exceed 150 Units per visit and should be administered no frequently than every 3 months. (Remember, one can inject up to 400 Units and still be safe and the LD50 is likely over 3000 units.)

By contrast, the dosage usage for the treatment of spastisicity and hypertonic neurological disorders is 15–18 units/Kg body weight, or 1050–1260 Units per visit.

As mentioned, it is believed that the LD50, median lethal dose of Botox® is estimated to be 40 Units per Kg, or 2800 Units for the average 70 Kg patients. Thus, it would appear that, for cosmetic purposes, Botox® has a very healthy margin of safety.

The SpaMedica® lift is a very safe procedure. With proper certification, the various clinical therapies that are delivered by the M.E.D.U.C.E™, specifically the Isotonic MyoFacial®, the SonoPeel®- CaviFacial™ and SonoFacial® are very safe, have few complications and, thus, attractive procedures to delegate to health care professionals under employment by the proprietor physician. The SpaMedica® Botox®, although also very safe, has more risk attributed to it the any of the SpaMedica® M.E.D.U.C.E™ therapies. During the management of the SpaMedica® patient, one must disclose risks, alternatives and potential benefits. The risks associated with the M.E.D.U.C.E™ derived therapies are relatively minor and unlikely. Although safe, the risks for Botox® must be understood and disclosed by the SpaMedica® lift physician.

The BTX A risks and adverse drug effects can be classified as local and distant.

a. **Distant**

**Distant Muscle weakness**

Small amounts of BTX may circulate in the bloodstream briefly after administration. There have been isolated reports of systemic effects after small-dose cosmetic injections (less than 100 units) and larger dose dystonic applications. These systemic effects can rarely manifest as increase jitter in limb muscles on single-fiber EMG measurements. Other theoretical and presumable rare “remote effect” adverse reactions to BTX include distant muscle weaknesses and undesirable cardiovascular reflexes.
Auto-Antibiotics
Some individuals manifest resistance after one of more Botox® injections. It has been demonstrated that a minority of individuals can form antibodies to Botox®. In these individuals, BTX injections will have a diminishing, or little to no clinical effectiveness. Between 3–10% of cervical dystonia patients show BTX antibodies in mouse assays. Rather than perform immunoassays, perform a FTAT test (frontalis antibody test). 15U of BTX is injected into a unilateral corrugator and, if after two weeks, there is no unilateral corrugator paresis, then the patient has BTX antibodies.

Myalgia and Arthralgia
A rare number of BTX patients will exhibit temporary muscle and joint aches and pain, starting within 1–2 hours of the injection and which last for less than 24 hours. These symptoms can be treated with successfully with acetaminophen or NSAIDS.

Headaches
Similar to the myalgia and arthralgias, some patients develop a tension headache or migraine after upper facial BTX. This is particularly interesting and paradoxical given that, injected into the correct anatomic location, BTX can provide symptomatic migraine relief.

Rash—systemic
There have been rare reports of systemic rash symptoms following BTX, which a self limited and treated symptomatically with topical steroids and antihistamines.

Pregnancy and Lactation
No aesthetic procedure should be offered during pregnancy. Although there is no known tetratogenic effects or adverse outcomes of Botox® upon an embryo or fetus, there is one reported case of premature delivery in a women receiving Botox® and, as such, it is not recommended that Botox® be delivered to pregnant or lactating women. I would advise you ensure females who believe they may be at risk of pregnancy, get a confirmatory serum pregnancy test which is negative, prior to having any injectable therapy, including Botox®.

Auto-immune Diseases
Although there is no association between Botox® and the exacerbation of auto-immune diseases, such as Lupus, Rheumatoid Arthritis, Multiple Sclerosis, Scleroderma, or Diabetes, such an association may exist and the patient should be informed of the unknown risk. Certainly, disorders which compromise muscle weakness, such as ALS, Myasthenia Gravis, or MS, should not receive Botox® without signed consent and full disclosure.
b. Local

Ecchymosis and Swelling
Depending upon traumatic needle induced microvenous or microarterial trauma, there may be occasional bruising and ecchymosis. Care and attention, with small bore needles can prevent most vein or arterial trauma. If there is accidental vessel damage, then pressure, with adjunctive Arnica and/or Bromelin can help resolve the ecchymosis quickly.

Redness and Erythema at the injection site
Usually temporary and self-limited.

Infection and abscess at the injection site
This should be exceedingly rare. Use sterile technique, needles, alcohol wipes and keep unused BTX sterile.

Rash—local
The treatment of a localized rash is topical steroid. The rash is usually self limited. Rashies are thought to be idiosyncratic IgE mediated phenomenon and are uncommon. Ptosis can occur in these rare circumstances, even when an injection distant from the brow or periocular region has been administered.

Ineffective
If there is no clinical paralysis of the injected facial muscle 3–5 days after BTX injection, then one must consider one of three possibilities. First, the BTX has lost efficacy, which can happen if you store your unused BTX, or if it has been left out at room temperature for a prolonged period of time. The second cause of a lack of a clinical BTX effect may be that the injector may have missed the target muscle. A second injection can be performed with EMG guidance (see technique). Finally, the patient may have developed autoantibodies and once can screen for this with the FTAT test or an immunoassay.

Short Lasting Effects
Most BTX injections have clinical efficacy and muscle weakness for about 90 days. The return of muscle strength, once there is evident contractions, is gradual and returns over 30 days. Usually, full clinical return of function is apparent a 4 months (120 days).

In order to minimize the risk of tachyphylaxis (diminishing effectiveness and longevity with repeated use), I encourage patients to come for BTX injections 2–3 times per year and discourage intercurrent, frequent injections, which has been associated with BTX antibody formation.
Adjacent Muscle Weakness

BTX has a reported ability to diffuse, in the subcutaneous suprafascial and subfascial planes for 1 cm to 1.5 cm and, as such, must be used with great caution around the periorbital and cervical region.

- **Ptosis**
  When injecting in the Brow region, most notably the lateral fibers of the corrugators, there is a risk of diffusion inferiorly onto the levator palpebrae superioris causing a minor to moderate lid ptosis, which can last for several weeks (Fig. 35). Treatment is, initially preventive, by using concentrated dilutions, injecting well away from the orbital rim, avoiding rubbing the region after injection and not lying down. In the rare event of a BTX mediated ptosis, relieve can be obtained with sympathemimetic drops, until levator function returns. The drops are sympathemimetic stimulators of Mullers muscle.

- **Diplopia**
  Injection of the orbicularis occuli for the treatment of crow’s feet must be performed 0.5 cm to 1.0 cm lateral to the orbital rim to avoid intraorbital diffusion and paresis of an extra-ocular muscle (most commonly the lateral rectus) and diplopia. If this occurs, there are some opthalmological prisms and glasses that can be used until the extraocular muscle function returns.

- **Dysphagia**
  Treatment of platysmal bands must be done with care to avoid inadvertent deep injection of the constrictors and other extrinsic muscles of the neck, which can lead to dysphagia.

- **Oral Sphincter Incompetence**
  Overly zealous injection of the perioral, orbicularis oris for the treatment of perioral rhytides or uncoupling of the lateral lip depressor can lead to loss of the perioral sphincter function and can lead to oral incompetence, drooling and articulation disorders.

- **Pre-existing Muscle Weakness Syndromes**
  Conditions with pre-existing muscle weakness, such as ALS, Myasthenia, MS, Eaton Lambert Syndrome, Senile lower lid laxity and stroke, may contraindicate the use of Botox®. This requires physician judgment. For example, cervical aesthetic Botox® in an ALS patient with dysphagia may be an absolute contraindication. Lower lid Botox® for rhytides or orbicularis hypertrophy may be contraindicated in patients with deficient lower lid tone, as indicated by the lower lid snap back and lower lid retraction tests.
**Botox®: Preparation, Dosing and Concentration**

Botox® is available in a standard vial that contains 100 Units of the toxin. The commercially available Botox® is purported to be chemically unstable. The toxin is frozen and lyophilized and is shipped from the manufacturer on dry ice, stored in the freezer at -5 degrees Celsius. Unopened Botox® should be stored in a freezer at -5 degrees Celsius and the shelf life for the product is measured in years.

When you are ready to use the Botox®, it is reconstituted with 0.9% non-preservative sterile saline (The bottle must say no preservatives, or the preservatives will deactivate the toxin. Some BTX users use saline with preservatives and claim that it is less painful). The technique of dilution that I recommend is drawing up the dilution quantity of sterile preservative free saline, actually removing the metallic top off of the Botox® bottle (but saving the rubber cork for later use) and slowly injecting with the 18 gauge needle used to draw up the saline directly into the Botox® (Fig. 36b). (Injecting through the rubber top in the vacuum sealed Botox® bottle, with or without a small bore needle may be too high velocity and too traumatic for the freeze dried and lyophilized Botox®). There is some belief that aggressive reconstitution technique may deactivate some of the toxin. Allow the saline to reconstitute and solubilize the lyophilized toxin. Avoid aggressive shaking of the reconstituted Botox®, avoid bubbles that can result from severe agitation that might denature the toxin.

There is some variation and controversy as to the amount of saline one should dissolve the Botox® in. Generally, the three most common techniques are outlined below.

a. **Dilute Technique** = 4 cc Saline to 100 Unit vial of Botox®
   therefore, 1 cc of Saline = 25 units of Botox®
   therefore, .20 cc of Saline = 5 units of Botox® or .1 cc = 2.5 units

b. **Semi-Dilute Technique** = 2 cc of Saline to a 100 Unit vial of Botox®
   therefore, 1 cc of Saline = 50 units of Botox®
   therefore .1 cc of saline = 5 units of Botox®

c. **Concentrated Technique** = 1 cc of Saline to a 100 Units of Botox®
   therefore, .05 cc of Saline = 5 units of Botox®
My personal approach has moved towards utilizing the more concentrated technique. The reason for these more concentrated techniques is the belief that the dispersion distance is directly related to the amount of diluent. The more saline is used to dissolve that Botox®, the higher the risk that there will be subcutaneous diffusion to surrounding structures, which if there are important clinically significant muscles, such as the levator palpebrae superioris, extraocular muscles or zygomaticus major and minor, may result in some undesirable functional impairment, such as lid or lip ptosis. Of course, conversely, the more concentrated the technique, each drop of Botox® that inadvertently falls out of the syringe onto the patient’s skin during an injection may cost up to $20.

My SpaMedica® Botox® Preparation Technique:

1. Conservative Estimation of the Botox® to be used that day.

2. Group SpaMedica® Botox® patients together on an afternoon or morning to facilitate economical use of Botox®.

3. Use a larger pair of dressing scissors to remove the metal sleeve clasping the rubber top. Be careful not to cut or injure yourself during this maneuver and point the scissors away from yourself (Fig. 36a).

4. Inject 1–2 cc (depending upon your concentration preference) of sterile, preservative free 0.9% saline directly into the open Botox® vial, after removing the rubber top. Inject, or rather drip the saline gently into the bottle, using an 18 g needle to avoid high stream forces (Fig. 36b).

5. Gently stir or decant the reconstituted Botox®, trying to avoid bubbles.

6. With the bottle of the Botox® open, use the 0.3 Diabetic syringe to draw up 30 units of Botox® (Fig. 36c–d).

7. The advantage of this syringe is that many anatomic sites require, on average 30 units of Botox®, or 15 units on each side, which are the exact multiples contained in this syringe. With a 2 cc dilution technique each syringe contains 15 units of Botox®.

8. Additionally, each line of demarcation represents one unit of Botox® (in the 1 cc dilution technique) or two units of Botox® (in the 2 cc dilution technique) for easy monitoring as the Botox® is being injected.

9. Store all the pre-drawn 30 unit (1 cc dilution technique) or 15 unit (2 cc dilution technique) Botox® syringes and store them all in the refrigerator (not freezer).
Fig. 36: SpaMedica® Botox® Preparation Technique

Fig. 36a–b: The Botox® bottle is removed from the box. The metal sleeve is removed from the Botox® bottle.

Fig. 36c–d: 2cc of preserved saline is dripped gently into the open Botox® vial to reconstitute. Care is taken to avoid any contamination by replacing the rubber stopper immediately.
Fig. 36: SpaMedica® Botox® Preparation Technique (continued)

Fig. 36d

Fig. 36e

Fig. 36f

Fig. 36e–f: Use of a small, 30 gauge, 0.3cc diabetic syringe to draw up all the reconstituted Botox® (with the 2 cc dilution technique, each of these syringes contains 15 units of Botox® and each 2 incremental lines contains 1 unit).
My Personal SpaMedica® Botox® Injection Technique

There is some considerable variation amongst clinicians in the actual Botox® injection technique. There is variation and personal preference on how to dilute the lyophilized toxin, injection technique, syringe selection, number of muscles injected, unit doses used for each muscle, actual muscles injected, amount of Botox® used for each muscle, combinations of muscles injected and use of EMG guided injections. What I will share with you is my own personal technique of SpaMedica® lift Botox®. My goal is the use of Botox® to uncouple facial elevators by the selective paralysis of depressors, facilitating facial shaping and contouring with the SpaMedica® lift MyoFacials®.

My SpaMedica® Botox® technique actually represents an aggregation of various techniques from around the United States, Europe and Canada learned from numerous luminary Botox® injectors and, of course, my own personal observations using Botox® in conjunction with the M.E.D.U.C.E™. I believe that my SpaMedica® lift Botox® technique is simple, successful and reproducible and has been deployed in thousands of successful and happy patients.

1. **Approach:** It is important that you have a sound, practical and economical approach to presenting Botox® to your SpaMedica® patients. Of course, the initial meeting will involve of a discussion of the patient’s various concerns, goals and expectations and you will assess client candidacy. Following a disclosure of the risks and benefits of the SpaMedica® and Botox®, you will also have to discuss with the client the cost. It is important that every physician have an approach to SpaMedica® economics and Botox® pricing. The initial SpaMedica® lift Botox® approach is very simple, the first treatment with Botox®, occurs at the beginning of the 4th week. At this time in the SpaMedica® lift program, the Botox® is injected as the patient begins Resistive, Isotonic MyoFacials®. The Botox® paralyzes depressor activity and uncouples and amplifies the hypertrophic effects of the elevators.

The initial SpaMedica® non-surgical facelift includes the initial SpaMedica® Botox® regions as part of the SpaMedica® lift price. The SpaMedica® lift is designed to be moderately profitable with the initial purchase of the SpaMedica® program, but, because of excellent patient outcomes, and the desire of the patient to maintain their “lift” effects, the SpaMedica® lift patient is required to come back to your clinic on a booster schedule. Once completed the SpaMedica® lift, these booster visits will be to accomplish at least three things.

2. Office booster MyoFacial®, SonoPeel® and SonoFacials® (every 4–6 weeks).

3. Purchase another 3 month supply of skin care products.

4. Receive a booster SpaMedica® Botox® treatments (every 12 weeks).

5. Receive a booster SpaMedica® injectable filler treatment (every 12 weeks).

6. Undergo a FotoFacial® or FotoFacial RF® treatment (every 12 weeks).
For the physician, every SpaMedica® patient who is very happy with their results (over 80% satisfaction), the physician can expect an in perpetuity revenue stream of in office treatments, injectable fillers and SpaMedica® Botox® through the SpaMedica® Booster program. Thus, only moderately profitable “up-front”, done well, the SpaMedica® is optimally and often enormously profitable in the long-term or the “back-end”. The profitability of the SpaMedica® program is covered in the SpaMedica® lift economics chapter. Once the SpaMedica® patient has completed their lift and return for their maintenance therapies, the physician needs to understand how to charge their SpaMedica® patients.

There are two basic approaches to charging for booster SpaMedica® Botox®.

After the “bundled” initial 10 week SpaMedica® lift, one must then charge for the booster programs, including SpaMedica® Botox®.

a. The first is to charge by the site, usually $200–400 per site (the average physician price is $300). The average amount of Botox® used per site is 30 units. Most physicians charge by the site and most offer complimentary treatment, if the first does not completely paralyze the area involved.

b. The second Botox® payment scheme is to charge the patient by the unit. This is the program that I most prefer as every individual’s localized muscle mass and response to the Botox® differs. Some patients do not have a complete paralysis of their corrugators, despite 30 units of Botox®. For these individuals, who have had a noticeable improvement, if they want to improve their local facial hyperdynamic muscle paralysis further, then they would come back for a few more units two weeks after the initial injection and they would understand that they would pay for these extra few units. Most physicians charge between $8–$20 dollars per unit, with the most common being between $8–10 per unit. The average amount of Botox® used per site is 30 units. For the SpaMedica® non-surgical facelift patient, once they have completed their program, their maintenance therapy is offered at 25%–50% off the price you would charge your regular patients (the Botox® becomes $8–10 per unit).

2. **Skin Preparation:** The skin overlying the muscles to be injected with Botox® is cleansed with an alcohol wipe. Most patients require nothing in the way of analgesia, while others will insist of some topical analgesia, which can take the form of Ela-max or EMLA, to help take the initial transcutaneous sting out of the needle injection. I also incorporate a topical skin “chiller”, called the Cryo 5 (Zimmer, Insine California) (see Fig. 57), which cools the skin with air providing profound anesthesia for laser or needle treatments. It is important to warn patients on whom you elect to use topical anesthesia that there will still be some pain associated with the injection as there is pain as the Botox® diffuses in the subcutaneous and intramuscular space.
3. **Positioning:** I treat most patients sitting upright on the treatment bed, rather than lying down. I engage the patient with conversation while I am preparing the injection. With my patient still in sitting position, I distract the patient further, by rubbing another area of the patient's face with a finger, or I cool the skin with the Cryo 5 to approximately 7–8°, at which point needles no longer hurt. I then inject while the patient is being distracted by the other area of facial therapy. Of course, for those patients who do get dizzy, or light headed, have them lie on their back on the treatment bed. Whether standing or lying, I generally treat both sides of a patient's face from one side of the bed.

4. **Injection:** I ask the patient to activate the muscle in question. While the patient is dynamically contracting the muscle, you can see the cutaneous extent of the muscle's dermal attachments. I then begin to move along the skin overlying the muscle, injecting 2.5–5 units every 2–3 cm. Depending upon the desired clinical effects, the injections can be into the subcutaneous space just above the investing muscle fascia, or, through the muscle or periosteum. The subcutaneous Botox® will spread through the subcutaneous spaces to the target muscle. This technique is much less painful than deeper techniques that rely upon direct injection into the muscle, or through the periosteum. The superficial technique when used in the “frown” area will also paralyzed the frontalis (which is moving up to the dermis at the level of the brows and drop the medial brow. The deep technique will not paralyzed the frontalis nor drop the brow. It is significant to note the 1–2 cm of subcutaneous spread is common for Botox®. The amounts of SpaMedica® lift Botox® that are deposited into the muscle and the locations are shown in the next chapter. Some Botox® injectors advocate an intradermal injection (with subsequent diffusion to the muscle) as there is less risk of hematoma. I have found the clinical efficacy of the intradermal technique to be less reliable than the intramuscular or subcutaneous technique and I rarely employ it.

5. **Post Injections Instructions:** The patient is warned of the subcutaneous spread of the Botox® and instructed not to rub the injected area and not to lie down, cough or strain for 4 hours. The patient is also asked to activate the muscle injected (for example frown) 10–15 times every 15 minutes for the first 3–4 hours. The theory of immediate post-injection muscle contraction is that the muscle activity will somehow “suck up” the Botox® into the muscle from the surrounding soft-tissue. The patient is again reminded about the rare symptoms that can occur after injection and given a post-injection instruction sheet. The patient is usually asked to come back in two weeks to assess the efficacy of outcome and undergo any additional injections or refinements.

SpaMedica® Botox® therapy requires that the SpaMedica® physician have an artistic sense of which hyperactive rhytidogenic facial musculature and overactive strong depressors would benefit from selective paralysis by providing an elevated, rejuvenated, smoother appearance to the face. The next chapter deals specifically with locations and dosages of Botox® therapy, or on the “art” of the SpaMedica® Botox® technique.
The SpaMedica® Botox® Consent

Instructions
This is an informed-consent document that has been prepared by your physician to help inform you concerning Botox® injections, the risks, and alternative treatment. During your consultation, your physician will have reviewed the potential benefits of Botox® injections, the alternatives and all the points in this booklet. He will have allowed you to ask any questions and provided you with answers to these questions to the best of his 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 surgery as proposed by your physician. If you have any remaining questions, do not initial or sign the consents without calling the office and speaking with your physician or injector delegate.

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® 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 your physician, one of the clinic dermatologists or a nurse injector. The improvement in the wrinkles beings 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 the 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.

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 less 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).
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 bottle’s 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 your physician, 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 your physician 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. Your physician 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 office and speaking with your physician.

Consent for Surgery/Procedure or Treatment
I have received the following information booklet:

Informed consent for

1. I hereby authorize Dr. __________________ 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 involves 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.

Patient Initials __________

SpaMedica® Franchisee Clinical Training Manual
V – 1.20

INITIALS
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 or 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 authorize the release of my Social Insurance Number to appropriate agencies for legal reporting and medical-device registration, if applicable.

10. I understand that the signature of the witness (if a non-physician) on this document indicates that the signing of my name has been observed and not that the witness has necessarily provided information regarding the procedure.

11. IT HAS BEEN EXPLAINED TO ME BY MY PHYSICIAN 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 (1–11). I AM SATISFIED WITH THE EXPLANATION.

________________________________________
Patient or Person Authorized to Sign for Patient

________________________________________
Please Print Name Here

Date _______________ Witness __________________________

Patient Initials __________

SpaMedica® Franchisee Clinical Training Manual
V – 1.21
Acknowledgment of Complete Comprehension

I ________________________, franchise trainee, on this date of ____________ have carefully read and have a thorough understanding of every page of this chapter. I have initialed each page that signifies I have no further questions whatsoever regarding the information in this chapter, and that all my questions have been answered by the SpaMedica® franchisor trainer to my complete and total satisfaction.

Franchisee Signature __________________________________________________________

Name ___________________________________________ Date ________________

Franchisor Trainer Signature __________________________________________________

Name ___________________________________________ Date ________________