



## Isolaz for Acne Informed Consent Booklet

### **INTRODUCTION**

The Isolaz System uses photopneumatic technology (i.e., pneumatic/vacuum energy and broadband light) to treat the following: mild to moderate acne, pustular acne, comedonal acne, mild to moderate inflammatory acne, acne vulgaris. The Isolaz System utilizes a treatment tip that applies a gentle vacuum pressure to draw the area to be treated into the hand piece of the System. This "pulling up" motion brings the treatment targets (acne) closer to the surface of the skin. Broadband light energy is then applied to the targets. The light energy is then converted to heat energy and absorbed by the targets, there destroying the targets.

Acne is an individual medical skin condition and not all individuals obtain the same results. While treatments are effective in most cases, no guarantee can be made that a specific client will benefit from the procedure. Additionally, the nature of laser/light based procedures may require multiple treatments in order to achieve the desired results, or to determine that treatments may not be completely effective in treating the client's particular condition. Compliance with your physician's prescribed acne medications will help you achieve faster results along with the Isolaz treatments.

### **ABSOLUTE CONTRAINDICATIONS**

**It is imperative that you notify DR. STEWART, DR. GIOE, or their staff if you meet any of these contraindications prior to the procedure:**

Pregnancy (not a contraindication if only the vacuum component of the device is being utilized), recent sun exposure, tanning bed use, or use of self-tanning products prior to treatment, planned sun exposure including tanning lamps/beds post treatment, patients who have taken Accutane within the past year.

**RELATIVE CONTRAINDICATIONS TO THE PROCEDURE:** use of medications that increase photosensitivity, diabetes, history of keloid scarring, use of anticoagulants, history of bleeding disorders. **Please notify your Doctor or Treatment Professional if you have been on Isotretinoin (Accutane) in the previous 6 months.**

**POTENTIAL SIDE EFFECTS AND RISKS:** I am aware of the following possible experiences with laser/light based treatments: pain, redness, swelling, bruising, burns, blistering, bleeding, infection, scarring, local nerve damage, unwanted hair removal (which may be permanent), appearance of telangiectasia (tiny blood vessels), hyperpigmentation (treated area becomes darker), hypopigmentation (treated area becomes lighter).

- Discomfort may be experienced during the procedure. If the sensation of a moderate to severe pin prick or heat is felt, or any discomfort is felt during the procedure, please notify DR. STEWART, DR. GIOE, or the office staff.
- Laser/light treatments may not completely remove or prevent acne.
- During the healing process, there is a possibility of the treated area becoming either darker (hyperpigmented) or lighter (hypopigmented) in color than the surrounding skin. This is usually temporary, but on rare occasion, it may be permanent.
- Transient epidermal (skin) injury manifested with symptoms including mild sunburn-type pain, erythema (redness), edema (swelling), itching, and/or blistering may be experienced. Skin infection is a possibility any time a skin procedure is performed.
- Transient textural changes such as weeping, crusting, scabbing, or flaking of the treated areas may be experienced. These changes may require one to three weeks to heal. Bruising of the treated area may also occur.
- Scarring is a rare occurrence, but is a possibility when the skin's surface is disrupted. To minimize the chances of scarring, it is important to follow all post-treatment instructions carefully. Persons with a history of keloid scar formation may be more prone to scarring after any skin trauma, including laser/light treatments; therefore, caution is advised.
- Those who carry the herpes simplex virus and receive treatments near the affected area may have a "flare-up" of their condition following the procedure. Please notify your provider before your treatment if you have a history of fever blisters.
- Strictly adhering to the post-treatment care instructions can minimize these side effects and risks.
- The laser/light based technology used in the Isolaz System creates a potential risk of eye damage. To minimize this risk, you will be provided with the appropriate protective eyewear for use during your treatment.

### **Pre- and Post- Procedural Instructions**

The pre-and post-care instructions have been created to help you prepare for your treatment. Following these instructions will maximize your aesthetic outcome. The booklet will also provide you with a few of the post-procedural warning signs that may herald a complication. Please read these instructions carefully. If you do not understand any of the components or items in the pre- and post-care instructions, please do not hesitate to call the clinic and speak with one of our staff.

**1-3 MONTHS PRIOR TO TREATMENT:** Treatment areas should not be exposed to the sun prior to or following treatment. For optimal results, refrain completely from sun tanning, using tanning beds, or self-tanning products for 1-3 months prior to therapy. Skin must be protected from UV exposure. Always apply a broad-spectrum (UVA/UVB) sunscreen, SPF 30 or greater even on a cloudy day. If you have recently tanned skin, appointments should be postponed for 4 weeks, until your skin returns to its normal color.



**3-4 weeks PRIOR TO TREATMENT:** If you have received any fillers in the treatment area you must wait at least 3-4 weeks before doing the procedure.

**2 WEEKS PRIOR TO TREATMENT:** You must wait at least 2 weeks after Botox injections in the treatment area.

**1 WEEK PRIOR TO TREATMENT:** Client is advised to discontinue the use of exfoliating products. Avoid skin irritants (i.e. hydroquinone, benzoyl peroxide, glycolic acid, retinoic acid, alpha-hydroxy acid products and astringents).

**THE DAY OF TREATMENT:**

1. The treatment area must be clean (no make-up, perfumes, powders, deodorants, or moisturizers).
2. Excess hair in treatment area needs to be shaved prior to procedure.
3. Jewelry, including body piercing jewelry, in treatment area must be removed before the procedure. If the skin in the treatment area is broken, inflamed or has an active infection, your appointment will have to be rescheduled.

**POST-PROCEDURE INSTRUCTIONS DAY 1-7:** The healing time for any given treatment varies between different clients. The following represents the general recovery phases you might expect. Individual clients may experience variations from this course. **NOTIFY THE OFFICE IF ANY OF THE FOLLOWING OCCUR:** blistering, skin burns, redness or swelling lasting more than 48 hrs.

1. **DO NOT SCRATCH OR RUB THE TREATED AREA.**
2. **FOLLOWING TREATMENT:** the treated site should be washed gently twice a day with a mild facial cleanser and water.
3. **AVOID EXFOLIATING PRODUCTS AND SKIN IRRITANTS** (i.e. hydroquinone, benzoyl peroxide, glycolic acid, retinoic acid, alpha-hydroxy acid products and astringents) **FOR AT LEAST 2-3 DAYS FOLLOWING TREATMENTS.**
4. **SWELLING /DISCOMFORT/REDNESS:** There will be redness and very minimal warmth emanating from the area for the first 24 hours (feels like a mild sunburn). If swelling occurs, apply ice. Wrap the ice in a soft cloth. Discomfort or stinging may be alleviated with Tylenol or Advil. An over-the-counter hydrocortisone cream may help minimize redness and swelling. You should notify us if you experience pain that is severe or excessive, as this is unusual. Please note you may be more sensitive or uncomfortable if you are premenstrual, tired, or taking antibiotics.
5. **MAKE-UP:** After 24 hours, most clients are ready for make-up to hide the pinkness of the skin. When applying make-up, it must be applied and removed delicately. Excessive rubbing can open the skin on the treated area and increases the chance of scarring.

**SUN AVOIDANCE:** Treatment areas should not be exposed to the sun. Sun avoidance should become a permanent component of your long-term skin care program. Always use an SPF 30 or greater beginning 24-48 hours later if the skin has fully healed. Sun exposure, tanning beds and artificial sunless tanning lotions are not allowed in the treated areas during the course of the treatment. Sun protection is vital to your skin care and treatment results. Apply a broad-spectrum (UVA/UVB) sunscreen of SPF 30 or higher, even on cloudy days, at least 2-4 weeks before and after treatment. For optimal results, refrain completely from sun tanning, use of tanning beds, or self-tanning products for 1-3 months prior to therapy.

**WARNING SIGNS:** The following are some of the symptoms that should alert you to the possibility of an impending or existing complication and you should contact the clinic.

**Infection:** Infection may be present if you notice:

- (i) Increased (rather than decreasing) facial swelling after the first 24-36 hours.
- (ii) Redness spreading beyond the area of resurfacing that is warm and tender to touch.

**Disclaimer** Informed Consent Booklets are used to communicate information about the proposed treatment of a condition along with disclosure of risk. 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 skin care professional has discussed with you and has been included in this booklet are the material risks both common and uncommon that they feel a reasonable person would want to know, understand and consider in trying to decide if the proposed treatment of a condition is something they would like to proceed with. However, Informed Consent Booklets should not be considered all-inclusive in defining other methods of care and risk encountered. Your skin care professional may provide you with additional or different information that 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 by your skin care professional before signing the consent on the last page.