Chapter 13:
Informed Consent

At this point, the various methods of rejuvenation, chemical, mechanical, photon and RF based, as well as laser or surgery should be outlined briefly for the patient. If, upon the basis of the history and physical, the client appears to be a good candidate for a series of FotoFacial RF Pro® treatments, then a discussion of the actual procedure, technique, number of visits, length of time, recovery, potential benefits, risks and costs should be discussed freely with the client. The patient should be afforded an opportunity to ask any questions they may still have, and these questions and your exact responses to them, should be written down. In addition, it is a wise and careful habit to record on paper the benefits and risks that were discussed, as well as the questions that were raised by the patient and your response.

You can find an actual FotoFacial RF Pro® “Informed Consent” document (on page 64) that you can use as a template for your own consent document. This FotoFacial RF Pro® consent is also contained on the CD inside your FotoFacial RF Pro® marketing kit.

If the patient would like to proceed with treatment, they are then given the opportunity to read and review the consent booklet, which is a written recapitulation of the verbal discussion. The client must initial each page in the document, confirming they understand each item on that page, that all questions were answered to their satisfaction and that they have no further unanswered questions. The final consent page is then signed and witnessed. The same consent form is used for each subsequent visit and the patient is asked to initial and date each page with each subsequent visit. On occasion, patients would like to go home and consider the treatment program before proceeding and they are given the consent booklet to take home, review and consider. In some offices, mailing out the consent booklet to interested contacts facilitates the process, although, as you will see in the marketing chapters, this may serve to needlessly frighten away potential clients.

As you can see from the informed consent booklet included, all the serious complications of any Intense Pulsed Light, radio
frequency energy and laser treatments are listed and discussed. However, the FotoFacial RF Pro® settings and parameters have been purposely established to minimize the risk of “downtime” or excessive epidermal, dermal or chromophoric target reactions and, as such, have a very low incidence of complication and this should be related to the patient.

The following complication incidences, based on thousands of FotoFacial RF Pro® treatments, can be used in risk discussions. More detail will be repeated in the ensuing informed consent document.

**Scarring** – less than 1%

**Hyperpigmentation** – less than 5% in types 5 and 6 and less than 1% in types 1-3

**Hypopigmentation** – less than 1%

**Blistering, Crusting** – less than 10%

**Swelling and Edema** – about 10% of rosacea patients and less than 1% of non-rosacea patients swell

**Infection** – less than 1%

**Herpetic Eruption** – less than 1%

**Blindness** – theoretical with periorbital Nd:YAG, not yet reported with FotoFacial RF Pro®

**Lack of Results and Incomplete Resolution** – can be 10-50% depending upon the indication

**Excessive Discomfort** – less than 5% with topical anesthesia, and synercool, and 20% with cooling gel alone

**Repeated or Prolonged treatment** – for ideal results, intermittent re-treatment to maintain result is required in 80-100% of patients
**Patient Dissatisfaction** – in properly selected patients, the incidence of treatment satisfaction is greater than 85% 

**“Arch” Injury** – this is a complication of the RF energy and occurs when there is incomplete contact of one of the bipolar RF electrodes with the skin. The partial contact allows transmission of the electrical energy across the epidermal surface. Arch injuries usually lead to a small crust that heals over in 8-10 days (similar to a curling iron injury.) The incidence of arch burns should be 1-3%, but not higher (they are very rare with skill, experience and proper technique.)
FotoFacial RF Pro® - Informed Consent Document

The following is an actual example of the FotoFacial RF Pro® informed consent document utilized at my clinic, and it is also available in a Word document on the CD in your FotoFacial RF Pro® Marketing Kit.

FOTOFACIAL RF PRO®, ALA FOTOFACIAL® AND ALA BLUE LIGHT

INFORMED CONSENT BOOKLET

INSTRUCTIONS

This Informed Consent Booklet has been prepared by SpaMedica® to help inform you about the potential benefits, associated risks and alternatives of FotoFacial Pro® Treatments (FotoFacial RF Pro®, ALA FotoFacial® and ALA Blue Light). During your consultation and medical assessment, your SpaMedica® Treatment Professional will have reviewed with you the potential benefits, associated risks and alternatives of FotoFacial RF Pro® Treatments that are outlined in this booklet and they will have provided you with answers to any and all questions you may have had about the procedure. It is important that you read the information contained in this booklet again carefully and completely. Only when all of your questions and concerns about FotoFacial RF Pro® Treatments have been addressed should you then initial each page, indicating that you have read and fully understood all the items this booklet discusses. When you reach the end of the booklet, please sign the consent for the procedure as proposed by your SpaMedica® Treatment Professional. If you have any remaining questions or concerns about the potential benefits, associated risks or alternatives of FotoFacial RF Pro® Treatments, do not initial any pages or sign the consent without speaking to your SpaMedica® Treatment Professional.

INTRODUCTION

FotoFacial RF Pro® Treatments are new, proven, high-tech skin care procedures. Under Dr. Mulholland, SpaMedica® co-developed the FotoFacial RF Pro® procedure and refined the technology. Published studies indicate that FotoFacial RF Pro® Treatments can significantly improve the appearance of fine lines, wrinkles, pore size, textural irregularities and vascular and pigmentation blemishes in over 80% of cases, with clients reporting a noticeable improvement in the cosmetic appearance of their skin during and at the completion of their program.
A FotoFacial Pro® Treatment consists of directing Intense Pulsed Light (IPL), Infra-red (IR) and Radio Frequency (RF) energy at the skin. The energy passes through the outer surface of the skin, called the epidermis and penetrates into the under carpet of the skin known as the dermis. Once in the dermis, the IPL and RF energy stimulates a cell called fibroblast to produce your own new collagen. Over several treatments, this new collagen smooths and softens the appearance of your wrinkles, pore size and textural irregularities. Using special filters to control the wavelength of pulsed light, sun-damaged skin with pigmentation abnormalities, vascular blemishes, such as spider veins and rosacea can be lightened and improved. A Crystal Peel (Microdermabrasion) and/or SonoPeel® is usually performed in conjunction with a FotoFacial RF Pro® treatment, as removing the dead cell layers results in more efficient optical light, IR and RF penetration of the skin.

Some FotoFacial RF Pro® clients will benefit from tightening, firming and shaping of the brow, cheek, jowl and neck areas. For these clients, the "ST" applicator may be recommended. The "ST" applicator blends IR and RF to optimize non-surgical skin tightening and shaping. This applicator may be done solo or in combination with standard FotoFacial RF Pro® Treatments that target colour, texture and toning.

Amino Levulinic Acid (ALA) is a topical chemical that photosensitizes your skin. The ALA is then photo activated by blue light (ALA BlueLight) and/or FotoFacial IPL-RF energy (ALA FotoFacial®), a process called Photodynamic Therapy. ALA treatments may be added to a FotoFacial RF Pro® treatment program, as treatments number 2 and 4, to optimize the inflammatory response and the ultimate aesthetic outcome, and are also an important part of the SpaMedica® Acne Program. ALA treatments do improve the desired skin response BUT also lead to 48 hours of sun sensitivity; exposure to sunlight, UV radiation and fluorescent light MUST be avoided for 48 hours after an ALA treatment. SpaMedica® highly recommends that each client, where appropriate, incorporate the ALA into their treatment program.

FotoFacial RF Pro® Treatments are simple office procedures performed by a physician and/or laser nurse and require no needles, medications or surgery. When delivering the laser energy to the skin, it is important to cool that skin to avoid injury. A skin chiller, which blows cool air onto the skin is one method of protecting the skin during FotoFacial RF Pro® treatments. This skin chiller, used in combination with topical anesthetic cream, makes the FotoFacial RF Pro® treatments very comfortable and there is normally no pain or discomfort associated with the procedure.

Following FotoFacial RF Pro® Treatments, there may be a minor degree of redness and puffiness to the skin, with some tingling discomfort that usually disappears within 1 hour to 2 days. You may apply makeup immediately and return to your regular daily activities with no "downtime". A comprehensive SpaMedica® Skin care program will be recommended for you to use in conjunction with your FotoFacial RF Pro® treatments. It is highly recommended you discuss a maintenance program and begin a home skin care program to prevent potential complications, optimize and maintain the cosmetic improvements you obtain with your FotoFacial RF Pro® treatments.
Before beginning a FotoFacial RF Pro® Treatment program, you must first attend an Assessment and Information consultation with a SpaMedica® Treatment Professional, during which your skin type, facial cosmetic concerns, expectations and goals will be assessed and discussed. The SpaMedica® Treatment Professional will work with you to select the best treatment or combination of treatments for your skin type, facial cosmetic concerns, expectations and aesthetic goals. The estimated duration and cost of each session or series of sessions will also be provided and you may, if you are a candidate, schedule your treatments and test spots at the time of this initial consultation.

**POTENTIAL BENEFITS OF FOTOFACIAL RF PRO® TREATMENTS**

The most obvious potential benefits are an improvement in the appearance of wrinkles, pore size, textural irregularities, acne scarring, vascular and pigmentation blemishes of aging or sun-damaged skin.

**RISKS ASSOCIATED WITH FOTOFACIAL RF PRO® TREATMENTS**

SpaMedica® is one of Canada’s most sophisticated, full service cosmetic surgery and laser skin care centers. We have treated thousands of skin care, laser hair removal, laser leg vein and cosmetic surgery clients, and our large experience has proven our treatments to be very safe. However, every cosmetic procedure involves a very small degree of risk and, although exceedingly uncommon, it is important that you understand and accept the rare risks involved with FotoFacial RF Pro® Treatments. An individual’s informed decision to undergo any cosmetic procedure is based upon a comparison of the risks against the potential benefits, alternatives and costs.

Although the vast majority of FotoFacial RF Pro® Treatment clients never experience any of these complications, you should discuss each of them with a SpaMedica® Treatment Professional to ensure you fully understand the alternatives, risks, potential complications and average outcomes of FotoFacial RF Pro® treatments.

**Discomfort:** The FotoFacial RF Pro® Treatments are very well tolerated office treatments. Client comfort is optimized with the use of a topical anesthetic cream and a skin chiller. With these treatments you may experience a minor and tolerable degree of burning and/or tingling discomfort with each treatment.

**Skin Wound:** It is exceedingly rare for FotoFacial RF Pro® Treatments to cause a blister or skin wound. This is more of a risk in darker or tanned skin types. If a blister or skin wound develops it may take 5-10 days to heal, and, in extremely rare instances, may leave a noticeable whitening or darkening of the skin or, even more rarely, a scar. Blisters or skin wounds are much more common if you do not follow the recommended avoidance of sunlight, self tanners, UV light and fluorescent light exposure.
Scarring: Occurs less than 0.1%. If you have developed a wound and a scar, the scar may end up being flat and white (hypotrophic), large and red (hyper-trophic) or extend beyond the margins of the injury (keloid). Subsequent treat-ment or surgery may be required to improve the appearance of the scar. The scar may be permanent. Not following pre and post treatment instructions may increase the likelihood of a skin wound or scar.

Pigment Change: With the IPL, IR and RF energies used in FotoFacial RF Pro® Treatments, there is a small risk of <1% of temporary hyperpigmentation (increased pigment or brown discoloration) or hypopigmentation (whitening of the skin). Usually these pigment effects are temporary and resolve over several weeks or months. Permanent hyperpigmentation or hypopigmentation is very rare and may occur in less than 1% of cases. The majority of FotoFacial RF Pro® clients will receive skin care products. The medical skin care prod-ucts are important to obtain optimal results.

Tanning: It is essential that you NOT tan your skin or use tanning creams prior to FotoFacial RF Pro® treatments as the pigment in your skin will absorb some of the IPL and RF energy and this will increase your risk of pigment change or skin wound. You should not have FotoFacial RF Pro® Treatments if you have tanned skin until the tan has faded appreciably (at least 6 weeks) and avoiding tanning for 2 weeks afterwards. If you are using artificial tanning creams, allow these to fade (for 2-3 weeks) prior to beginning treatment.

Bruising: It is exceedingly uncommon to have any skin bruising following treatment. If bruising occurs, it can be camouflaged immediately and will usually resolve in 8-10 days. As the bruising fades, there may be a rust-brown discoloration of the skin (hyper pigmentation) that may take special creams to fade away.

Infection: Because FotoFacial RF Pro® treatments involve no actual cutting, surgery or skin penetration, infection is exceedingly rare.

Excessive Redness and Swelling: Rarely, a minor degree of redness and/or puffiness of the skin may follow treatment and usually lasts 1-2 hours and is easily camouflaged with make-up. This may persist, in rare instances, for 1-2 days. A mild steroid cream (0.5% hydrocortisone available at the clinic) or ice application, will usually settle this.

ALA Blue Light and ALA FotoFacial RF Pro® Treatments will leave your skin photosensitized for 48 hours after each treatment and you must avoid light. Failure to do so will result in significant redness and swelling that may be quite disfiguring and may increase the rare risk of complication, such as blisters, scarring and pigmentation changes.

Fragile Skin: The skin overlying the treatment area may become quite frag-ile. Although uncommon, the fragile skin can become reddened and the outer layer may peel off, much like a blister. This usually settles in 8-10 days. Fragile skin or blisters may be more common after ALA if post ALA instructions are not followed. If you are subject to cold sores, please notify your SpaMedica®
treatment professional, as cold sore eruptions can be common with FotoFacial RF Pro® and ALA treatments, you may need to go on an anti-viral medication during your treatment.

**Accutane:** An acne medication that must be stopped 3 months prior to treatments.

**Additional Treatment:** Your final result and maximum cosmetic facial enhancement will likely take 4 Sonopeel® treatments and 6 FotoFacial RF Pro® Treatments. Over time, with gravity, sun exposure, hormonal influences and normal aging, your wrinkles, large pores, textural abnormalities, vascular and pigment blemishes will reappear. You may elect to treat again. In most instances, it is recommended that you have a maintenance Crystal Peel and/or Sonopeel® every 4-6 weeks and a FotoFacial RF Pro® session every 3 months (once a season) after completion of the initial course.

**Lack of Satisfaction:** No facial wrinkles, blemishes and skin types respond the same to FotoFacial RF Pro® Treatments. Your response may be subject to variation, but on average, almost 100% of clients who have undergone treatment report a noticeable improvement of between 40-70% in the appearance, quality and youthful vitality of their skin. However, there is a risk that you may not see an appreciable improvement in the quality and appearance of your skin.

**Pregnancy:** Although no known adverse reactions upon a fetus are known to result we do not recommend proceeding with treatment if you are known to be pregnant.

There are many variable conditions in addition to risks and potential complications listed above that may influence the long-term result from FotoFacial RF Pro® Treatments. Even though risks and complications can occur infrequently, the risks cited in this booklet are particular for FotoFacial RF Pro® Treatments. Other complications and risks can occur but are even less common. Should complications occur, additional surgery or treatment may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is not a guarantee or warranty expressed or implied as to the results that may be obtained. Infrequently, it is necessary to perform additional treatment to improve your results.

**ALTERNATIVES TO FOTOFACIAL RF PRO® TREATMENTS**

The easiest and safest alternative is to leave your cosmetic skin concerns alone and camouflage them with make-up. Laser resurfacing, chemical peels, injectable collagen, hyaluronic acid and micro fat. Thermage and cosmetic surgery are all alternative therapies. However, each of these alternative treatments will require some recovery time whereas with FotoFacial RF Pro® Treatments you should have little to no recovery time and can usually return to work immediately.
HEALTH INSURANCE

Facial wrinkles, pores, textural irregularity, vascular and pigment blemishes are cosmetic concerns and pose no medical or health care threat. Most health insurance companies, including OHIP, exclude coverage for these treatments.

Complications that may occur from such treatments are usually considered a health care concern and may be covered. Please carefully review your health insurance subscriber-information pamphlet, if you have a private insurance carrier.

FINANCIAL RESPONSIBILITIES

Depending on whether the cost of treatment is covered by an insurance plan, you will be responsible for necessary payments. Additional costs may occur should complications develop from treatment. There are no refunds once a treatment has been performed.

DISCLAIMER

Informed Consent booklets are used to communicate information about the proposed treatment of a condition along with disclosure of risk and alternative treatment(s). The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most clients in most circumstances.

What your SpaMedica® Treatment Professional has discussed with you and has been included in this booklet are the material risks both common and uncommon that SpaMedica® feels 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 SpaMedica Treatment 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 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 a SpaMedica® Treatment Professional before signing the consent on the next page.
INFORMED CONSENT FOR PROCEDURE AND/OR TREATMENT

I have received the following information/informed consent booklet for:
FOTOFACIAL RF PRO® TREATMENTS

1. I hereby authorize a SpaMedica® Treatment Professional and/or such assistants as may be selected to perform the following procedure and/or treatment: FotoFacial RF Pro® Treatments

2. I recognize that during the course of the procedure/treatment unforeseen Conditions may necessitate different procedures than those above. I therefore authorize the SpaMedica® physician and/or 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 treatment professional at the time the procedure is begun.

3. I consent to the administration of such anesthesia 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 the Canadian Association for Accreditation of Ambulatory Surgical Facilities, my 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 of appropriate portions of my body, for medical, scientific or educational purposes, provided they do not reveal my identity.

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

8. 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.
9. IT HAS BEEN EXPLAINED TO ME BY A SPAMEDICA® PHYSICIAN AND/OR ASSISTANTS OR DESIGNEES IN A WAY THAT I UNDERSTAND:

i. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
ii. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
iii. THERE ARE RISKS TO THE PROCEDURE/TREATMENT PROPOSED
iv. ANY QUESTIONS I MAY HAVE ASKED HAVE BEEN ANSWERED TO MY SATISFACTION

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-9). I AM SATISFIED WITH THE EXPLANATION.

__________________________________________________________
Client or Person Authorized to Sign for Client Please Print Name Here

__________________________________________________________
DATE WITNESS

With this approach to informed consent, there should rarely be any miscommunication that results in unhappy patients or, worse, litigious patients.