



Colorado *Facial*
Plastic Surgery
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Creating Beautiful Faces

Aesthetics by Design
Creating Beautiful Skin

InMode RFAL Consent

INSTRUCTIONS

This Informed Surgical Consent has been prepared to help inform you about the potential benefits, associated risks and alternatives of RFAL FaceTite, NeckTite or BodyTite, Radiofrequency-Assisted Lipolysis surgery. During your consultation and medical assessment, the doctor, surgical representative and pre-operative professional will have reviewed with you the potential benefits, associated risks and alternatives of liposuction that are outlined in this consent. They will have also 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 consent again, carefully and completely. Only when all of your questions and concerns about the procedures have been addressed should you then initial each page, indicating that you have read and fully understood all the items this informed consent discusses. Please sign the consent for the procedure as proposed by Dr. Imola and/or Dr. Kowalczyk. If you have any remaining questions or concerns about the potential benefits, associated risks or alternatives RFAL, do not initial any pages or sign the consent without speaking with Dr. Imola and/or Dr. Kowalczyk.

INTRODUCTION

The InMode RF system utilizes Radio-Frequency Assisted Lipolysis (RFAL), providing surgery-like results with an insertion port similar to that of a 16-18 gauge needle. Skin tightening are achieved without the scalpel or scars using novel **BodyTite** & **FaceTite** procedures. Results are achieved by simultaneously contracting the internal fibrous septae and external skin's surface. This includes a contained thermal field for maximum safety.

RFAL is a surgical technique to remove unwanted deposits of fat from specific areas of the body, including the face and neck, upper arms, trunk, abdomen, buttocks, hips, thighs, knees, calves, and ankles. This is not a substitute for weight reduction, but a method for removing localized deposits of fatty tissue that do not respond to diet or exercise. The doctor may recommend that your liposuction be performed as a primary procedure for body contouring or be combined with other surgical techniques such as facelift, abdominoplasty, or thigh lift procedures to tighten loose skin and supporting structures.

The best candidates for liposuction are individuals of relatively normal weight who have excess fat in particular body areas. Liposuction surgery is performed by inserting a hollow metal surgical instrument known as a cannula through small skin incisions and passing it gently and slowly back and forth through the area of fatty deposit. The cannula is attached to a vacuum source, which provides very low-pressure suction needed to remove the fatty tissue.

RISKS ASSOCIATED WITH RFAL AND LIPOSUCTION SURGERY

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 liposuction. 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 patients never experience any of these complications, you should discuss each of them with your physician and clinic professional to ensure you fully understand the alternatives, risks, potential complications and average outcomes of the various techniques of liposuction.

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Patient Selection: Individuals with medical problems, obesity, or unrealistic expectations may not be candidates for RFAL or liposuction. Patients who should not be treated:

- Patients who are pregnant or breastfeeding
- Pacemaker or internal defibrillator - must be kept 1 cm away from cochlear implants
- Permanent implant in the treated area such as metal plates and screws, silicone implants or an injected chemical substance
- Patients who have taken Accutane® (Isotretinoin) within the past 6 months
- History of bleeding disorders or use of anti-coagulants within the last 10 days
- Impaired immune system due to immunosuppressive diseases (such as HIV or AIDS) or use of medications that weaken the immune system
- Severe medical conditions including cardiac disorders, epilepsy, uncontrolled hypertension, and liver or kidney disease
- Patients with diseases stimulated by heat, including recurrent Herpes Simplex (i.e. cold sores) in the treatment area, may be treated following a prophylactic regimen
- Any active skin condition in the treatment area including open wounds, eczema, psoriasis, inflammatory rosacea, sunburn, excessively/freshly tanned skin, or very dry and fragile skin
- Skin disorders such as keloid scarring, hypertrophic scarring abnormal wound healing or any condition that might impair skin healing
- Poorly controlled endocrine disorders, such as diabetes or thyroid disease
- Any surgical, invasive, or ablative procedure within the past 3 months or before complete healing

Consent for Surgery/Procedure or Treatment

I hereby authorize Dr. Mario Imola and Dr. David Kowalczyk and such assistants as may be selected to perform the following procedure or treatment.

- FaceTite
- BodyTite
- AccuTite
 - Face/Neck
 - Abdomen
 - Arms
 - Flanks
 - Knees

I have received and read the following information documents:

- 1) RFAL Perioperative Patient Instructions
- 2) RFAL Consent

Patient Signature _____

Bleeding: It is possible, though unusual, to have a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood or require a blood transfusion. Do not take any aspirin or anti-inflammatory medications or the specified naturopathic medications for 21 days before surgery and 10 days after, as they may increase the risk of bleeding.

Infection: An infection is quite unusual after this type of surgery. Should an infection occur, treatment including antibiotics or additional surgery may be necessary. Smokers have a greater risk of skin loss and wound healing complications.

Initial _____

Skin Scarring: Although good wound healing after a surgical procedure is expected, abnormal scars may occur within the skin and deeper tissues. In rare cases, abnormal scars may result. Scars may be large, unattractive and of a different color than surrounding skin. Additional treatments, including surgery, may be necessary.

Nerve Injury: Marginal mandibular nerve palsy – inability to depress lower lip
Hyperactivity – temporary change in smile or any facial expression

Change in Skin Sensation: A temporary decrease in skin sensation over the operative area may occur. This usually resolves over a period of time. Diminished (or complete loss of skin sensation) infrequently occurs and may not totally resolve. Rarely, the skin of the areas treated may be hypersensitive temporarily or permanently.

Skin Discoloration/Swelling: Skin discoloration (bruising) and swelling normally occurs and lasts for 1-3 weeks following liposuction. In rare situations, swelling and skin discoloration may persist for long periods of time. Permanent skin discoloration is rare.

Skin Contour Irregularities: Contour irregularities and depressions in the skin may occur after liposuction. Visible and palpable wrinkling of skin can occur. RFAL is a procedure to reduce the risk and occurrence of irregularities. Additional treatments, including surgery, may be necessary to treat contour irregularities, wrinkling, or loose skin following liposuction. Most areas of modest cellulite show some improvement.

Asymmetries: It will not be possible to achieve a completely symmetrical appearance following liposuction surgery. Factors such as skin tone, bony prominences, muscle tone, and residual fat may contribute to normal asymmetries in body features.

Seroma: Trapped fluid accumulations infrequently occur in areas where liposuction has been performed. Additional treatments or surgery to drain accumulations of fluid may be necessary. There is a risk that a seroma may become infected. Wearing your compression garment as directed will help decrease this risk.

Dissatisfaction with your Results: You may be disappointed with the results of your surgery. Infrequently, it is necessary to perform additional surgery to improve your results.

Before and After Photos: The doctor may have reviewed and discussed computer images. It is important to remind you once again that these images are used as an educational tool designed to allow you to visualize the general range of body shape improvements that may be achieved with your proposed surgery. The computer images are not meant to be guarantees of actual or exact outcomes. It is very rare for a patient not to achieve the general range of body contour improvements that have been demonstrated in the computer-simulated surgery.

Scars: The procedure required ports for insertion of canola's, probes and electrodes and to extract the fat. The ports or opening usually heal well and leave inconspicuous scars, but on occasion may leave unattractive, visible scars that may be permanent.

Burns: Ultrasonic, Laser and Radiofrequency devices have been reported to produce burns and tissue damage, either at the location where the cannula, laser, probe or electrode is inserted into the skin or in other areas if the cannula or electrode touches the edges or undersurface of the skin for prolonged periods of time. If burns occur, additional treatment and surgery may be necessary. The burn may leave an unattractive, permanent scar.

Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray): Patients who are currently smoking, use tobacco products, or nicotine products (patch, gum or nasal spray) are at a greater risk for significant surgical complications of skin dying, delayed healing and additional scarring. Individuals' exposed

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to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smokers may have a significant negative effect on anesthesia and recovery from anesthesia, with coughing and possible increased bleeding. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of this type of complication. Please indicate your current status regarding these items below:

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

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

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

It is important to refrain from smoking at least 3 weeks before surgery and until your physician states it is safe to return, if desired. I acknowledge that I will inform my physician if I continue to smoke within this time frame, and understand that for my safety, the surgery, if possible, may be delayed.

Patient Signature _____

DRIVING AFTER REAL SURGERY

Surgery, sedation and post-operative discomfort often limit full mobility of the body and/or face and may compromise the ability to safely drive a car. Post-operative patients are not to drive or take public transportation home on the day of surgery. Patients that do not have someone to accompany them are advised to arrange for a person to drive them home. Patients are advised not to take a taxi home unaccompanied.

FINANCIAL RESPONSIBILITIES

The total includes fees charged by your surgeon, the cost of surgical supplies, anesthesia, nursing staff, and possible outpatient facility charges, depending on where the surgery is performed. 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

1. I recognize that during the course of the operation, 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.

2. 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.

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

4. I acknowledge that any image manipulation reviewed with Dr. Imola and/or Dr. Kowalczyk and his staff is for surgical planning purposes and does not imply a guaranteed result.

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

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

7. The following has been explained to me in a way that I understand:

- a. The treatment or procedures to be undertaken.
- b. There may be alternate procedures or methods of treatment.
- c. There are risks associated with the proposed procedure.

I consent to the procedures and items listed above and I am satisfied with all explanations.

Patient Date _____

Witness Date _____

Mario Imola M.D., DDS, FRCSC Date _____
David M. Kowalczyk, MD MBA

Initial _____