



INFORMED CONSENT- CO₂ LASER TREATMENT PROCEDURES OF SKIN

INSTRUCTIONS

This is an informed consent document which has been prepared to help inform you about carbon dioxide (CO₂) laser treatment procedures of skin, risks, and alternative treatments.

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent for surgery as proposed by your plastic surgeon.

INTRODUCTION

Lasers have been used by plastic surgeons as a surgical instrument for many years. Laser energy can be used to cut, vaporize, or selectively remove skin and deeper tissues. There are many different methods for the surgical use of lasers.

Conditions such as wrinkles, sun damaged skin, scars and some types of skin lesions/disorders may be treated with the CO₂ laser. Certain surgical procedures may use the CO₂ laser as a cutting instrument. In some situations, laser treatments may be performed at the time of other surgical procedures.

Skin treatment programs may be used both before and after CO₂ laser skin treatments in order to enhance the results.

ALTERNATIVE TREATMENT

Alternative forms of treatment include not undergoing the proposed CO₂ laser skin treatment procedure. Other forms of skin treatment (chemical peel) or surgical procedures (dermabrasion or excisional surgery) may be substituted. In certain situations, the CO₂ laser may offer a specific therapeutic advantage over other forms of treatment. Alternatively, CO₂ laser treatment procedures in some situations may not represent a better alternative to other forms of surgery or skin treatment when indicated. Risks and potential complications are associated with alternative forms of treatment that involve skin treatment(s) or surgical procedures.

RISKS OF CO₂ LASER TREATMENT PROCEDURES OF SKIN -

There are both risks and complications associated with all laser treatment procedures of the skin. Risks involve both items that specifically relate to the use of laser energy as a form of surgical therapy and to the specific procedure performed. An individual's choice to undergo a procedure is based on the comparison of risk to potential benefit. Although the majority of patients do not experience these complications, you should discuss each of them with your plastic surgeon to make sure you understand the risks, potential complications, and consequences of laser skin treatment.

Infection- Although infection following laser skin treatment is unusual, bacterial, fungal, and viral infections can occur. **Herpes simplex virus** infections around the mouth, can occur following a laser treatment. This applies to both individuals with a past history of Herpes simplex virus infections and individuals with no known history of Herpes simplex virus infections in the mouth area. Specific medications must be prescribed and taken both prior to and following the laser treatment procedure in order to suppress an infection from this virus. Should any type of skin infection occur, additional treatment including antibiotics may be necessary.

Scarring- Although normal healing after the procedure is expected, abnormal scars may occur both in the skin and deeper tissues. In rare cases, keloid scars may result. Scars may be unattractive and of different color than the surrounding skin. Additional treatments may be needed to treat scarring.

Burns- Laser energy can produce burns. Adjacent structures including the eyes may be injured or permanently damaged by the laser beam. Burns are rare, yet represent the effect of heat produced within the tissues by laser energy. Additional treatment may be necessary to treat laser burns.

Color change- Laser treatments may potentially change the natural color of your skin. Skin redness usually lasts 1-3 months and occasionally 6 months following CO₂ laser skin treatment. There is the possibility of irregular color variations within the skin including areas that are both lighter and darker. A line of demarcation between normal skin and skin treated with lasers can occur.

Accutane (isotretinoin)- Accutane is a prescription medication used to treat certain skin diseases. This drug may impair the ability of skin to heal following treatments or surgery for a variable amount of time even after the patient has ceased taking it. Individuals who have taken this drug are advised to allow their skin adequate time to recover from Accutane before undergoing CO₂ laser skin treatment procedures.

Fire-Inflammable agents, surgical drapes and tubing, hair, and clothing may be ignited by laser energy. Laser energy used in the presence of supplemental oxygen increases the potential hazard of fire. Some anesthetic gases may support combustion.

Laser smoke (plume)- Laser smoke is noxious to those who come in contact with it. This smoke may represent a possible bio-hazard.

Bleeding- Bleeding is rare following CO₂ laser skin treatment procedures. Should bleeding occur, additional treatment may be necessary.

Skin tissue pathology-Laser energy directed at skin lesions may potentially vaporize the lesion. Laboratory examination of the tissue specimen may not be possible.

Visible skin patterns- Laser treatment procedures may produce visible patterns within the skin. The occurrence of this is not predictable.

Patient failure to follow through-Patient follow through following a laser skin treatment procedure is important. Post operative instructions concerning appropriate restriction of activity, use of dressings, and use of sun protection need to be followed in order to avoid potential complications, increased pain, and unsatisfactory result. Your physician may recommend that you utilize a long-term skin care program to enhance healing following a CO₂ laser skin treatment.

Distortion of anatomic features-Laser skin treatments can produce distortion of the appearance of the eyelids, mouth, and other visible anatomic landmarks. The occurrence of this is not predictable. Should this occur, additional treatment including surgery may be necessary.

Damaged skin- Skin that has been previously treated with chemical peels or dermabrasion, or damaged by burns, electrolysis (hair removal treatments), or radiation therapy may heal abnormally or slowly following treatment by lasers or other surgical techniques. The occurrence of this is not predictable. Additional treatment may be necessary.

Unsatisfactory result- There is the possibility of an unsatisfactory result from these procedures. CO₂ laser treatment procedures may result in unacceptable visible deformities, skin slough, loss of function, and permanent color changes in the skin. You may be disappointed with the final result from CO₂ laser treatments.

Skin cancer/skin disorders- CO₂ laser skin treatment procedures may not offer protection against developing skin cancer or skin disorders in the future.

Pain- Very infrequently, chronic pain may occur after CO₂ laser skin treatment procedures.

Allergic reactions- In rare cases, local allergies to tape, preservatives used in cosmetics or topical preparations have been reported. Systemic reactions which are more serious may result from drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

Lack of permanent results- CO₂ laser or other treatments may not completely improve or prevent future skin disorders, lesions, or wrinkles. No technique can reverse the signs of skin aging. Additional surgical procedures may be necessary to further tighten loose skin.

Delayed healing-It may take longer than anticipated for healing to occur after laser treatments. Skin healing may result in thin, easily injured skin. This is different from the normal redness in skin after a laser treatment.

Unknown risks- There is the possibility that additional risk factors of CO₂ laser skin treatments may be discovered. The results of performing skin tightening surgery and CO₂ laser treatments is unknown in terms of the combination effect of the two procedures and potential complications, depending on the area treated.

Surgical anesthesia- Both local and general anesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia and sedation.

ADDITIONAL TREATMENT OR SURGERY NECESSARY

There are many variable conditions which influence the long term result of CO₂ laser skin treatments. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with these procedures. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. 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.

FINANCIAL RESPONSIBILITIES

The cost of CO₂ laser skin treatment involves several charges for the services provided. This includes fees charged by your doctor, the cost of pre and post-operative skin care medications, surgical supplies, laser equipment and personnel, laboratory tests, and possible outpatient hospital charges, depending on where the procedure is performed. It is unlikely that cosmetic surgery costs would be covered by an insurance plan. Even if there is some insurance coverage, 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 hospital day-surgery charges involved with revisionary surgery or treatments 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 forms of 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.

However, informed consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Your plastic surgeon 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 carefully and have all of your questions answered before signing the consent on the next page.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

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

I have received the following information sheet:

INFORMED CONSENT FOR CO₂ LASER TREATMENT OF THE SKIN

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. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
5. 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, provided my identity is not revealed by the pictures.
6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
7. I consent to the disposal of any tissue, medical devices or body parts which may be removed.
8. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
9. IT HAS BEEN EXPLAINED TO ME 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

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