



Richmond Surgical Arts, Inc.

Where the Art and Science of Plastic Surgery Meet

MC1 Informed Consent

INSTRUCTIONS

This is an informed-consent document that has been prepared to help educate you on the MC1™ procedure, its risks, and alternative treatment. This document may use words you do not understand. Please ask your physician or a staff member to explain any words or concepts that you do not clearly understand.

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read and understand the page. If you understand all of the information in this document and want to have the treatment described in it, please follow the instructions at the end of the document and sign it where indicated.

INTRODUCTION

The MC1 System delivers a non-invasive treatment that uses therapeutic massage and the combined action of two low-frequency ultrasound heads cross-sectioned onto the area being treated. This advanced ultrasound handpiece is placed over the skin so that the deep penetrating action of the ultrasound is concentrated onto the affected tissue only, offering a treatment that is both effective and safe.

The action of the low-frequency ultrasound must always be followed with a lymphatic drainage massage, which helps eliminate excess liquids produced by the treatment. The MC1 System is the first system with an integrated lymph drainage handpiece, offering a complete and safe treatment. Lymphatic drainage is performed through use of a special elastomeric membrane, which applies movement to the tissue. This membrane operates in an undulating motion which gently lifts, folds and compresses the tissue following a sequence of movements specific to each area being treated. This manipulation of the cutaneous and subcutaneous tissues improves lymphatic, arterial and venous circulation. With the same handpiece, the lymph nodes are opened prior to drainage, thus allowing the elimination of toxins in the interstitial spaces caused by the action of the ultrasound.

The MC1 System therapeutic massage function is indicated for temporary relief of minor muscle aches and pains; relief of muscle spasms; temporary improvement of local blood circulation; and temporary reduction in the appearance of cellulite. The MC1 System ultrasonic diathermy function is indicated for relief of pain, treatment of muscle spasms, and treatment of joint contractures. The MC1 System is not indicated for the treatment of malignancies.

ALTERNATIVE TREATMENT

Alternative forms of management of the condition or conditions being treated may include diet and exercise regimens which may be of benefit in the overall appearance of cellulite, and both over-the-counter and prescription drugs, as well as mild heat therapy and certain types of physical therapy or massage, which may provide temporary relief of minor muscle aches and pains, muscle spasms, and joint contractures, and temporarily improve local blood circulation. Certain of these conditions may be relieved or improved through surgery, which carries with it risks and potential complications. An alternative you should consider is to have no treatment at all.

Patient Initials _____

PATIENT SLECTION CRITERIA

The MC1™ System should not be used on you if you have any of the following conditions. If you are not sure whether or not you have any of the conditions or fall into any of the categories below, be sure to ask you physician to clarify the answer for you before signing this Consent.

Thrombo phlebitis

Diabetes

Phlebitis

Epilepsy

Cardiac problems

Tuberculosis

Auxiliary electric organs
(such as pacemakers), metal
or myoelectric prosthesis

Endocrine syndromes

Hematologic (blood) problems,
(anemia, leucosis, etc.)

Thyroid hyperfunction

Any type of hemorrhagic
(bleeding) status

Cutaneous (skin) infections

Dermatologic (skin) infections, mycosis

Hypertension or abnormally high blood pressure

Psychiatric or psychosomatic illness

Varicose veins

Grave forms of hepatic or kidney insufficiency

An implanted deep brain stimulation system

High cholesterol

The MC1 System should not be used:

Over or near bone growth centers until bone growth is complete

Over the thoracic area if the patient is using a cardiac pacemaker

In an area of the body where a malignancy is known to be present

Over a healing fracture

Over eyes or ears

Over the pregnant uterus

Over ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase in metabolic demand and tissue necrosis might result.

Over an area of the spinal cord following a laminectomy, i.e., when major covering tissues have been removed

Over numb areas

Patient Initials _____

Skin Contour Irregularities: Since the MC1™ System is designed to temporarily reduce the appearance of cellulite, skin contour irregularities and depressions in the skin are unlikely but possible.

Ultrasonic Technology: Risks associated with the use of ultrasound in treatment include, in addition to the risks listed above, the following specific risks:

Burns: Ultrasonic energy may produce burns to the skin and deep tissue damage at the site if application results in a high temperature for prolonged periods of time. If burns occur, additional treatment may be necessary.

Unknown Risks: The long term effect on tissue and organs of exposure to short-duration, high intensity ultrasonic energy is unknown. The possibility exists that additional risk factors resulting from the use of ultrasound in treatments with MC1 System could be discovered.

Other: While we have attempted to assist you in building realistic expectations for your MC1 treatment, you may be disappointed with your results. However infrequent, it may be necessary in your case to perform additional treatments to improve results or you may not achieve satisfactory results even after additional treatments.

FINANCIAL RESPONSIBILITIES

The cost of treatment with the MC1 System includes charges for the services provided and fees charged by your physician. You are responsible for these costs. You may incur additional costs should complications develop from the treatment.

THE NATURE OF INFORMED CONSENT

Informed consent documents are used to communicate information about the proposed treatment of a disease or condition along with disclosure of risks and alternative forms of treatment. The informed consent process provides 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 possible methods of care (alternative treatments) or all possible risks that may be present. Your physician 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, and you must also consider that information in making your decision whether or not to sign this Consent and to have treatment with the MC1 System.

Informed-consent documents are not intended to and do not 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.

Patient Initials _____

YOUR INFORMED CONSENT

I received and read the information sheet: MC1™ Informed Consent

Treatment with the MC1 System has been explained to me in a way that I understand. I have had the opportunity to ask questions, and my questions have been answered to my satisfaction. Alternative methods of treatment and risks of treatment have been discussed with me. My physician and his or her staff have discussed with me the results that I reasonably may expect from treatment with the MC1 System. Although a good result is expected, I acknowledge that no guarantee has been given by anyone as to the results that I may obtain.

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

I hereby authorize Dr. _____ and such assistants as she or he may select to perform treatment on me with the MC1 System.

Please rewrite in your own handwriting: "I understand that the practice of medicine is not an exact science and although good results are expected, there can be no guarantee as to my results from treatment with the MC1 System."

Patient Signature _____ Date: _____, 20__

Witness Signature _____ Date: _____, 20__

I, _____, certify that I or a member of my staff has discussed all of the above with the patient and have answered all questions regarding treatment with the MC1 System, I believe the patient fully understands what I have explained and answered.

Physician Signature _____ Date: _____, 20__

Patient Initials _____

Patient name (please print): _____ DOB: _____

Requested By: _____

I, _____, hereby consent that photographers, videotape, and/or computer imaging may be taken of me or parts of my body under the following conditions.

Pre- and post-treatment photographs will be taken of my treatment for record purposes. The photographs shall be taken by my physician or a photographer approved by my physician. I understand that these photographs will be the property of the attending physician and Sound Surgical Technologies LLC.

Such photographs and/or videotape shall be used only for medical records, research, education, or science purposes by my physician and/or Sound Surgical Technologies LLC. Photographs and information relating to my case may be published and replubished, either separately or in connection with each other in professional journals, medical books, and doctor or patient presentation materials, or used for any other purpose that may be deemed proper in the interest of medical education, knowledge, or research, provided that in any such publication or use my name and identify is kept confidential and protected. Such photographs may be retouched, at the discretion of my physician and/or Sound Surgical Technologies LLC, in any way deemed desirable by either or both of them.

I have had the opportunity to discuss this consent with my surgeon and agree that all of my questions have been answered. This authorization is granted in furtherance of medical education and other good and valuable consideration and as a voluntary contribution. I hereby waive all rights I might have to such photographs, videotape, and computer images and do hereby release, discharge, and save harmless my physician and Sound Surgical Technologies LLC and their respective managers, employees and agents from all claims and liabilities whatsoever in law and in equity arising from the use of such photographs, videotape and computer images described as above.

I have read and fully understand this Photo/Video/Computer imaging Consent and agree to all of its terms.

Patient Signature _____ Date: _____, 20____

Witness Signature _____ Date: _____, 20____

Patient Initials _____