CONSENT FOR CELLFINA® CELLULITE REDUCTION TREATMENT

INSTRUCTIONS - This is an informed consent document that has been prepared to help inform you concerning using Cellfina® Cellulite Reduction Treatment. Cellfina® treatment has its risks and alternative treatments.

CELLFINA® - The Cellfina® System is a device used to treat cellulite and involves injection of a local anesthetic (numbing solution) prior to the insertion of a small motorized micro-blade through the skin and into the fat below the surface of the skin. The blade is used to cut the tissue that is pulling the skin down in the dimpled areas. The doctor will identify and mark intended treatment areas on your buttocks and thighs.

The Cellfina vacuum is placed over the area to be treated and holds the area in the correct position during treatment. Local anesthetic solution will be injected into the selected treatment sites using a multi-hole needle and syringe. Although this causes a sharp discomfort at first, it should quickly subside. This is repeated several times until all the areas to be treated have been injected with the anesthetic solution. Once the anesthetic solution has been given time to take effect, the micro-blade portion of the Cellfina device, which is connected to a small motor, will be inserted through the skin, and into your buttck or thigh area.

The motor will then be activated and the doctor will release the tissue under the cellulite dimples. The vacuum will be moved to the other treatment locations and the steps repeated until all the areas have been treated. The total time of your procedure will depend upon the number of treatment areas but typically takes one to three hours. Cellfina is only approved for the treatment of the thighs and buttocks at this time. Any other cosmetic use is considered “off label.”

ALTERNATIVE TREATMENTS - There are alternative forms to Cellfina® that are non-surgical and surgical. The non-surgical alternatives consist of topical anti-cellulite products, weight loss, various aesthetic treatments, and homeopathic treatments. The surgical alternatives are liposuction, thigh and buttock lift surgery. Risks and potential complications are associated with alternative forms of treatment.

DOWNTIME - Immediately after the procedure, the treatment area will be dressed with sterile gauze and tape. You will be given compression garments to wear to limit post treatment bleeding, swelling, and bruising. Your doctor may limit your activities for a few days following the Cellfina® procedure and will advise you when you can return to normal activities. As with any procedure, every patient is different. Some patients return to normal activities quickly and others take much longer. Gentle walking is helpful for your recovery but avoid anything strenuous until you have completely recovered. Ask your provider if you are unsure when you can return to normal activities. Your permanent results may take some time to be visible. The healing process after treatment results in fluid accumulation within the released areas. This is a desired consequence of the treatment which leads to new tissue formation necessary to lift and smooth the dimples. The transition from fluid to more solid tissue may result in a feeling of firmness or hardness under the skin which should diminish with time.

RISKS - There are risks of having Cellfina® treatment. Every cosmetic procedure involves a certain amount of risk, and it is important that you understand the risks involved. An individual’s choice to undergo a cosmetic procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience complications, you should discuss each risk with your provider or affiliated medical personnel.
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Some, but not all of the risks of Cellfina® include:

- blanching (generalized whiteness)
- fluid accumulation (i.e., swelling, edema)
- hematoma (localized collection of blood)
- hemosiderosis (long lasting bruising)
- hyperpigmentation (darkening of the skin)
- hypopigmentation (lightening of the skin)
- induration (firmness or hardness under the skin)
- inflammation
- generalized redness
- mild bleeding (from needle and blade punctures)
- skin sensitivity change
- redness
- erythema
- rash
- red spots (from needle and blade punctures)
- skin surface profile change or irregularity
- soreness
- pain
- marks from device or marking pen
- abscess (localized collection of puss)
- development and/or removal of fluid
- anetoderma (area of skin looseness or laxity)
- bleeding
- extravasation (migration) of fluid
- fibrosis (development of excess fibrous tissue)
- infection
- nausea and vomiting
- numbness and tingling
- scarring
- keloid (raised, pinkish scar like formation)
- seroma (persistent pocket of clear fluid)
- skin necrosis (death of skin cells)
- toxicity, allergy, or other reaction from the device or injected anesthetic
- suction marks “hickies” that take weeks to heal

BLEEDING - It is possible to experience a bleeding episode during after Cellfina®. Should post-procedure bleeding occur, it may require emergency treatment to drain accumulated blood (hematoma). Ask your provider before taking any aspirin or anti-inflammatory medications for ten days before your procedure, as this may contribute to a greater risk of bleeding.

INFECTION - Infection is unusual after Cellfina®. Should an infection occur, additional treatment including antibiotics or an additional procedure may be necessary.

BRUISING - Bruising is common after Cellfina®. You should count on having bruising after Cellfina® for at least a week, so time your treatments with your schedule accordingly. The bruising is similar to a “Hickey” in terms of appearance and longevity. Although wound healing after a Cellfina® is expected, you will want to keep ice on the treated area until it subsides. You may be asked to take a medication to reduce or prevent bruising such as Arnica Montana. Wearing post-surgical garments will help reduce swelling. Contact your provider if bruising lasts longer than two weeks or anytime if you are concerned.

DAMAGE TO DEEPER STRUCTURES - Deeper structures such as nerves, blood vessels and muscles may be damaged during treatment with Cellfina®. The potential for this to occur varies according to where the treatment is being performed. Injury to deeper structures may be temporary or permanent.

UNSATISFACTORY RESULT – There is the possibility of an unsatisfactory result from Cellfina®. You may be disappointed with the results of Cellfina®. Normally the effects of Cellfina® take several weeks to become apparent but may take several months in rare instances. Cellfina® treatment should be considered permanent and may not be reversible. Keep in mind that lifestyle, your weight, and the normal aging process can diminish the effects of any aesthetic treatment over time.

ALLERGIC REACTIONS - In rare cases, local allergies to injectables, lidocaine, or topical preparations have been reported. Systemic reactions, which are more serious, may result. Allergic reactions may require additional treatment. Although these reactions are rare with Cellfina®, tell your provider if you have an allergy to lidocaine or other allergies.

(Continued on Next Page)
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MEDICATION REACTION - Tell your provider if you are on, or were recently on, any medications as they may interfere with the ability of the aesthetic injectables to function. Even use of Aspirin should be brought to your provider’s attention. Tell your provider if you are on blood thinners.

PREGNANCY - Women should not have Cellfina® if they are pregnant or may become pregnant, or are breast feeding.

ADDITIONAL TREATMENTS MAY BE NECESSARY - In some situations, it may not be possible to achieve optimal results with a single Cellfina® treatment. Multiple sessions may be necessary. Should complications occur, additional treatments or other methods may be necessary.

DISCLAIMER – Informed consent documents are used to communicate information about the proposed Cellfina® treatment along with disclosure of risks and alternative forms of treatments. The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

This informed consent should not be considered all-inclusive in defining other methods of care and risks encountered. Your provider or affiliated medical personnel 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. 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.

Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with Cellfina® treatment. Other complications and risks can occur but are even more uncommon. The practice of medicine and cellulite reduction is not an exact science. Although good results are expected, there cannot be any guarantee or warranty expressed or implied on the results that may be obtained.

(Continued on Next Page)
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PLEASE READ THE STATEMENTS BELOW AND SIGN IF YOU AGREE.

I hereby authorize Dr. Steven Gitt or delegated staff and such assistants as may be selected to perform the following procedure or treatment:

Cellfina® Cellulite Reduction Treatment of the thighs and or buttocks.

I recognize that during the course of the Cellfina® treatment, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician or affiliated medical personnel 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.

I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthetics involve risk and the possibility of complications, injury, and sometimes death.

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

For purposes of advancing medical education, I consent to the admittance of observers to my aesthetic injectables.

I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.

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.

I certify that I have read all pages of this document and give my consent for my Cellfina® procedure.

__________________________________  ________________________
Patient Signature / Date          Witness Signature / Date

__________________________________  ________________________
Print Patient Name               Print Witness Name

I certify that I have explained the nature, purpose, benefits, risks, complications, and alternatives to the proposed procedure to the patient. I have answered all questions fully, and I believe that the patient fully understands what I have explained.

____________________________________
Physician Signature / Date