Informed Consent- Cellfina Treatment

Instructions:

In considering a Cellfina® treatment with the Cellfina® System, please read the following Information carefully and discuss any questions you may have with your physician.

General Information:

The Cellfina™ System is cleared by the FDA and is intended for long-term improvement in the appearance of cellulite in the buttocks and thigh areas of adult females, as supported by clinical data demonstrating no significant reduction in treatment benefits up to 2 years of observation. Safety and effectiveness in other anatomical areas have not been established. The Cellfina™ System has been studied in women between the ages of 25 and 55, and who had a BMI (Body Mass Index) between 18 and 35 showing moderate to severe cellulite.

Cellfina™ 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.

Prior to receiving a Cellfina treatment, a review of your medical history, assessment of your medical condition(s) and completion of a physical examination will be done to ensure a safe and effective outcome. In addition, as a precautionary measure against infection, your doctor may prescribe an oral antibiotic for you to be taken before treatment and continued for several days after the treatment.

What to expect:

On the day of your Cellfina treatment, the doctor will identify and mark intended treatment areas on your buttocks and thighs, and photographs may be taken of the areas. Cellfina utilizes a vacuum hand piece, which is placed over the area to be treated, to hold the area (skin and fat) in the correct position during treatment. Local anesthetic solution will be injected into the selected treatment site(s) using a multi-hole needle and syringe. 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 (approximately 10 minutes to numb the area), a vacuum hand piece using light suction will be attached to your skin. Then, a micro-blade operated by a small motor will be inserted through the skin and into the fatty tissue in your buttock or thigh area. The motor will then be activated and the doctor will release the tissue under the dimple(s). The vacuum hand piece will be moved to additional treatment locations and the steps repeated until all the areas have been treated. The total time of your treatment will depend upon the number of treatment areas and may take approximately 30 to 60 minutes. Immediately after the Cellfina treatment, the treatment area will be dressed with sterile gauze and bandage/tape. You may be given compression garments to wear to limit post treatment bleeding, swelling, and/or bruising. Your doctor may limit your activities for a few days following the Cellfina treatment and will advise you when you can return to normal activities.

Side effects:

There are several side effects that can occur in and around the areas treated. Such side effects can include, but are not limited to, the following:

- Allergic reaction: Can be a reaction to the anesthetic medicine used to numb the areas prior to treatment.
- Blanching: Generalized whiteness.
- Bruising: Bleeding into the tissue, which can be a result of needle used during anesthetic (numbing) medicine administration or from the Cellfina micro blade used during treatment.

Use of blood thinning (anticoagulant) medications, such as Warfarin, Coumadin or nonsteroidal anti-inflammatory drugs (such as aspirin or ibuprofen medications in the form of

Motrin, Advil, and Aleve), in the first few weeks following treatment may increase the risk of bruising. Avoid these medications for 2 weeks before and after procedure to help decrease bruising and bleeding.

- Fluid accumulation: i.e. swelling.
- Hematoma: Localized collection of blood.
- Hemosiderosis: Appearance of bruising that lasts longer than normal due to iron deposits under the skin.
- Hyperpigmentation: Darkening of the skin.
- Hypopigmentation: Lightening of the skin.
- Induration: Firmness or hardness under the skin.
- Inflammation, generalized redness, rash or red spots: May result from needle/blade punctures.
- Mild bleeding: From needle/blade punctures.
- Numbness, tingling, or sensitivity change
- Skin surface profile change or irregularity of the skin
- Soreness and/or pain
- Vacuum acquisition marks: Can result from use of the device's vacuum pressure against the skin during treatment time.

Risks:

As with any medical procedure, there are also possible risks associated with the treatment. Potential risks associated with the use of the Cellfina device may include:

- Abscess: Localized collection of pus in the tissue.
- Seroma: Development of fluid which may or may not need to be removed.
- Extravasation: Migration of fluid.
- Anetoderma: Area of skin looseness or laxity.
- Fibrosis: Development of excess fibrous tissue in the treated areas.
- Infection: Any treatment piercing through the skin (natural protective barrier for the body) has potential for infection.
- Nausea/vomiting: Can be associated with infection.
- Numbness/tingling
- Scar tissue formation: Can be in the form of a small scar, either from the anesthetic needle puncture(s) or micro blade puncture(s) made during treatment. Keloid scar formation, or raised and pinkish scar-like formation can result and has been more commonly associated with specific ethnicities.
- Skin necrosis: Skin cell death, as a result of local blood supply loss to a treated area.
- Skin discoloration: Can be a result of bruising or as a result of the light suction applied to your skin during treatment, resulting in a "hickey".

You may be asked to return to see your physician after the Cellfina treatment to evaluate your overall condition and that of the treated areas. Photographs of the treatment areas may be taken. These follow-up visits may take approximately 30 minutes, including the time spent with your physician and photography time. If you have any problems, please contact your doctor for instructions or advice.

Post-treatment Care and Management of Complications

In the pivotal clinical study, subjects were advised of the following by their treating healthcare provider (HCP):

- Antibiotic therapy should be continued as prescribed – if prescribed by the HCP.

- Pain may occur during the first days of the postoperative period and can be controlled with common analgesics such as acetaminophen.
- Compressive garments should be worn as often as possible the first 2 weeks after treatment.
- Light physical activity is allowed in the first 30 days, but extreme physical activity should be avoided during this time.
- Hematomas, bruising, and some hemosiderosis (skin discoloration from bruising) are expected. None of these was visible at 3 months in the pivotal clinical study.
- A seroma (pocket of fluid in the tissue) can occur and may need to be drained by your HCP during a follow-up visit(s).
- Palpable areas of firmness (or softness) are expected. Patients are usually reassured when they are told that these areas are reported to be desirable for correcting the depressions that previously existed. If the areas are slow to improve, patients can be asked to perform firm massage with their fingertips for a few minutes a day, until resolved.

DISCLAIMER:

The above list is not meant to be inclusive of all possible risks associated with Cellfina™, as there are both known and unknown side effects. Also, complications may arise with this treatment or any medication(s) used in conjunction with this treatment. I understand medical attention may be required to resolve any complications that arise associated with my treatment. The overall results from the Cellfina treatment may take some time to be visible, due to the healing process. After treatment, the healing process results in fluid accumulation within the released areas and is a desired consequence of the treatment. This 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.

By signing below, I acknowledge and agree that:

- I have been given an opportunity to read, and have read, the foregoing informed consent form.
- I have discussed any questions I have regarding the Cellfina™ treatment with my HCP.
- My HCP has answered all of my questions to my satisfaction.
- I hereby consent to the treatment described above, including all of its associated risks.
- I understand I have the right not to consent to this treatment, and my consent is voluntary.
- I hereby release Dr. McCormack and staff performing the Cellfina™ treatment, and the facility from liability associated with this procedure.