INSTRUCTIONS FOR USE

INDICATIONS FOR USE

The Cellfina System 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 3 years of observation.

CAUTION: Federal law restricts this device to use by or on the order of a physician.

CONTRAINDICATIONS

The System should not be used on patients who have (or who are):

- Coagulant disorders
- Diabetic
- Excessive obesity
- Had recent surgery (6 weeks)
- On anticoagulant medications
- Phlebitis and vasculitis
- Pregnant
- Skin infections/ open lesions
- Uncontrolled hypertension
- Tumors
- Vascular fragility
- Varicose veins (in the area of treatment)

WARNINGS

- Failure to carefully follow all applicable instructions may result in injury to the patient, physician, or attendants and may have an adverse effect on procedural outcomes.
- The safety and effectiveness of the Cellfina System has been evaluated in the buttocks and thighs of adult females between the ages of 25 and 55, with a body mass index (BMI) between 18 and 35, and with moderate to severe cellulite. Safety and effectiveness in other anatomical areas or in patients outside of these criteria has not been established.
- The safety and effectiveness of more than one treatment with the Cellfina System has not been established.
- The sterile products provided as part of the Cellfina System are for single use only. Do not re-use or re-sterilize. Re-sterilization of the device or components may result in a risk of device malfunction and/or contamination due to residual fluids/tissue in the device.
- Do not operate the Cellfina System Motor Module and Power Supply where aerosol (spray) products, flammable anesthetics, or oxygen administering equipment is used.
- The Cellfina System Motor Module and Power Supply are intended for indoor, dry area use only. Do not allow to be exposed to liquids. Never immerse any of the components in any liquid, or place the product where it can fall or be pulled into liquid.
- Make sure the Cellfina System Motor Module and Power Supply and your hands are completely dry before plugging in the AC Power Cable.
- Avoid using around alcohol or other flammable solutions. If alcohol is used to clean any component, assure that the product is dry and the area ventilated of fumes before plugging in.
- To avoid electrical shock, never clean the Cellfina System Motor Module and Power Supply with the power supply plugged in or the Motor Module powered on.
- The Anesthesia Delivery Needle and Micro-Blade Assembly contain sharp areas – handle with extreme caution and dispose of in appropriate sharps containers per standard practice.
- Do not sterilize any of the Cellfina System Motor Module and Power Supply.

- Prior to use, inspect packaging for damage or breach of sterile packaging seals. Do not use product if there is any evidence of damage or breach.
- There are no user serviceable or replaceable parts inside the Cellfina System Motor Module or Power Supply. Do not open housings under any circumstances.

ADDITIONAL WARNINGS

Additional boxed warnings are provided within the **Directions for Use Section** of the IFU for specific procedural steps.

PRECAUTIONS

- The Cellfina System should only be used by physicians who have read and understood the User Manual.
- To protect sterility after opening, the blade and needle should remain covered prior to use.

RISKS

Potential adverse events are those typically associated with anesthesia infiltration, liposuction, Subcision® and other methods of body sculpting including:

- Abscess
- Anetoderma
- Anxiety (nervousness, apprehension)
- Blanching (generalized whiteness)
- Blurred or double vision
- Bleeding
- Dizziness, drowsiness, confusion
- Ecchymosis/bruising
- Fluid accumulation (swelling, edema)
- Fluid extravasation
- Hematoma
- Hemosiderosis
- Hyperpigmentation
- Hypopigmentation
- Induration, fibrosis
- Infection
- Inflammation / generalized redness
- Nausea/vomiting
- Numbness, tingling, or sensitivity change
- Petechiae or purpura (vacuum acquisition marks)
- Red Spots (from needle punctures)
- Redness, erythema, or rash
- Scarring or keloid formation
- Sensations of heat or cold
- Seroma
- Skin necrosis
- Skin surface convexity, depression or other irregularity
- Soreness or discomfort - pain
- Tinnitus
- Toxic, allergic, or other reaction from the injected anesthetic

COMPLAINTS AND ADVERSE EVENTS

No serious adverse events were observed during the clinical study evaluation of the Cellfina™ System.

Ulthera follows MDR (Medical Device Reporting) rules for handling complaints and adverse events. Should an adverse event be suspected or reported, contact Ulthera, Inc. at 1.877.ULTHERA.

NOTE:

This document is for web purposes only. It has been condensed from its original version. For additional information, contact 1.877.ULTHERA.

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