

Reaction - Safety and Performance Information

In Europe, the Reaction device is indicated for temporary reduction of cellulite and body contouring via temporary circumference reduction.

In the United States is indicated for the relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation, temporary reduction in the appearance of cellulite.

CONTRAINDICATIONS

- Pregnancy.
- Any skin disease in the treatment area (such as herpes, eczema, rash).
- Treatment over tattoo or permanent makeup.
- History of hip replacement, hip or femur surgery, or other metallic device in the treatment area.
- Cardiac pacemaker, defibrillator, or another implanted electronic device.
- Blood coagulopathy or excessive bleeding or bruising.
- History of deep vein thrombosis.
- Use of Accutane within the past 6 months.
- Use of blood thinning medications (anticoagulants).
- Active or recent malignancy (cancer).
- Uncontrolled thyroid disease.
- Impaired immune system (such as HIV).
- Any prior aesthetic or medical surgery affecting the area to be treated, 3 months prior to treatment.
- Any history of disease which may be stimulated by heat, such as Herpes in the treatment area.
- Any endocrine disorder, such as diabetes.
- Use of drugs that influence the immune system
- Extra dry or sensitive skin
- Sunburns in the treatment area

- Suffering from Keloid scars or impaired wound healing

Additional Contraindications for ST treatment:

- Do not treat patients who have undergone synthetic filler procedures (i.e. silicon) in the designated treatment area.
- Patients who have not undergone any cosmetic procedures may begin the treatment course.

However, in other cases, the following guidelines must be applied:

- Patients who receive Botulinum toxin injections should avoid any treatment for 2-4 days thereafter.
- Patients who have undergone chemical peels or natural fillers should avoid treatment for at least two weeks before beginning the ST treatment.
- Patients should wait at least 3-6 months after deep chemical peels and laser fillings.
- Patients who undergone needle epilation treatments must wait at least 6 weeks before commencing the treatment course.

NOTE: A qualified practitioner is solely responsible for assessing each patient's suitability for Reaction treatment and for providing comprehensive information about potential risks, pre- and post-treatment care, and any other relevant information.

WARNINGS AND CAUTIONS

WARNING: Any intense radiofrequency (RF) device can cause injury if used improperly.

WARNING: No modification of this equipment is allowed.

WARNING: It is important that the operators of this system familiarize themselves with all safety requirements and operating procedures prior to operating the system.

WARNING: Any intense RF device may cause injury if used improperly.

WARNING: In case of improper coupling, the trigger should be released immediately, and the applicator should be re-oriented on the skin. In rare cases superficial burns may occur from the heat generated by the RF electrodes.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: Improper treatment may cause local burns.

WARNING: Untrained operators should not operate the system before reading the safety section!

WARNING: Proper grounding is essential for safe operation.

WARNING: You may treat patients only after passing appropriate training and adhere to all local and state regulations regarding the use of this system.

WARNING: Be careful not to spill any liquids on the system.

WARNING: While gently cleaning the applicator, avoid moisture and dirt from getting into the applicator's filters.

WARNING: It is extremely important to completely clean the entire surface of the electrodes to avoid coupling materials accumulation.

WARNING: Before using the device, please check local regulations. If any local legislation is violated, use cannot be authorized.

WARNING: In the United States, federal law restricts prescription medical devices to sale by or on the order of a physician, or properly licensed practitioner. Sincalir makes no representations regarding federal, state, or local laws or regulations that might apply to the use and operation of this device.

CAUTION: To avoid clogging the applicator's internal filters, the applicator tip must be removed and cleaned immediately after every treatment.

CAUTION: Do not use any anesthesia or numbing cream before RF procedure to ensure proper patient feedback during the treatment.

CAUTION: Re-connect the applicator to the handpiece only when completely clean and dry.

CAUTION: Do not use any harsh chemicals to clean the applicator tips.

CAUTION: Do not sterilize the applicator tips.

SIDE EFFECTS

All side effects are considered mild, of a short duration, self-resolving which did not require medical attention. This includes discomfort and local pain, erythema, edema, changes in skin texture, urticaria, bruising, allergic contact dermatitis to the contact oil or gel, itching and sensitivity to touch, hyper- and hypopigmentation.