

EnerJet Safety and Performance Information

INDICATIONS

In Europe, the EnerJet device is indicated for delivery of hyaluronic acid, corticosteroids and lidocaine for the treatment of acne scars and keloids.

In the United States, the EnerJet device is indicated for the administration of various medicines and vaccines to the body by means of a high-velocity jet of fluid that penetrates the skin.

In Canada, the EnerJet device is indicated for the uniformed administration of hyaluronic acid and steroids into the dermis by means of a high velocity jet of fluid that penetrates the skin.

CONTRAINDICATIONS

- Uncontrolled diabetes
- Pregnancy and lactation
- History of collagen vascular disease
- Keloid diathesis (genetic predisposition to keloid development)
- Laser skin-resurfacing within the preceding 3 months prior to EnerJet treatment
- Chronic use of anti-coagulants (aspirin, dipyridamole, clopidogrel, Plavix, warfarin-Coumadin, etc.) and nonsteroidal anti-inflammatory drugs
- Presence of chronic or autoimmune skin disorders (eczema, scleroderma, psoriasis) in the areas intended for treatment.
- Presence of inflammatory and/or infectious cutaneous diseases in the areas intended for treatment.

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

WARNINGS AND CAUTIONS

WARNING: This system should be used only by a licensed healthcare practitioner who was properly trained by Sinclair or by a Certified Authorized Representative of the Company.

WARNING: Use this system only for its intended use as described in this manual.

WARNING: The treatment kit (i.e., delivery kit and sterile empty syringe) is supplied sterile and is intended for a single patient treatment only. To avoid cross contamination and/or delivery kit failure do not use the treatment kit beyond its recommended number of shots (if overused it could be subject to breakage).

WARNING: To avoid cross contamination, after each treatment replace the treatment kit and follow the cleaning instructions according to the User Manual.

WARNING: Never aim the applicator directly at the eyes.

WARNING: The applicator emits a certain level of noise when operated. If applying a significant amount of shots close to the patient's ear, it is recommended to take precautions such as the use of earplugs.

WARNING: Do not use the system in the presence of flammable mixtures.

WARNING: Do not perform treatment over open bruises or visible blood vessels.

CAUTION: Use the treatment material only according to its manufacturer's instructions.

CAUTION: Patients with a tendency to develop hypertrophic scarring or keloids should be treated with caution.

CAUTION: Use the treatment kit only as instructed.

CAUTION: E It is recommended to perform a sensitivity test prior to the first treatment.

SIDE EFFECTS

All side effects are considered mild, of a short duration, self-resolving which did not require medical attention. This includes continuous erythema, bruising, edema, nodulation of injection sites and post inflammatory hyperpigmentation (PIH).