

EnerJet Safety and Performance Information

INDICATIONS

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.

CONTRAINDICATIONS

1. Individuals with fragile skin or dermatological disorder at injection sites.
2. Individuals with history of keloid formation.
3. Individuals using anti-coagulant medications.
4. Individuals with clotting disorders.
5. Pregnancy and lactation.
6. Individuals with chronic skin diseases.
7. Areas exhibiting inflammatory and/or infectious cutaneous diseases (such as herpes).
8. Individuals suffering from autoimmune disorders.
9. Individuals suffering from clotting disorders.
10. Diabetes patients are generally more prone to infection; therefore, post-treatment management should be implemented to avoid risk.
11. Use of anticoagulants should be taken under the physician's consideration.

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

WARNINGS:

To reduce the risk of fire, electric shock or injury:

- a. The device is only intended for provisional use.
- b. 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.
- c. Use this system only for its intended use as described in this manual.
- d. Never operate this system if the power or applicator cord or plug is damaged, is not working properly, or has been subjected to liquid spillage. In such cases, contact your nearest representative.
- e. Under no circumstances should one attempt to open any part of the system. Only a qualified technician should service the system. The device contains line voltage, high pressure and internal components that move while the system is active.

- f. Always switch off the system when not in use. If not switched off, the system's internal component could remain under pressure.
- g. Unplug the system before cleaning the console and trolley.
- h. 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).
- i. The treatment kit is supplied in a sterile state. Do not use a kit:
 - If the product is damaged or the sterile barrier appears compromised. Discard any open, unused product.
 - After the expiration date or if the label is missing.
- j. To avoid cross contamination, after each treatment replace the treatment kit and follow the cleaning instructions according to section 6 of the User Manual.
- k. Never aim the applicator directly into the eyes or to the orbit of the eye, as this may cause eye injury. Never aim the device directly at any other sensitive organ of the body.
- l. 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.
- m. Do not use the system in the presence of flammable mixtures.
- n. The system should only be used with a properly grounded 3-prong electrical cord suitable for the country of use.
- o. Do not perform treatment to open bruises or visible blood vessels.

CAUTIONS:

- a. The user must read and understand all the instructions before operating the system. All warnings and cautions must be strictly followed.
- b. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
- c. Do not apply the system on open bruises.
- d. Use proper technique. Do not inject directly into a vein. Doing so may produce an adverse reaction such as hematoma or be ineffective.
- e. Take care when handling the applicator. Avoid dropping or banging it. Always return it to its cradle when not in use.
- f. Use the treatment material and kit only according to its manufacturer's instructions.
- g. Patients with tendency to develop hypertrophic scarring or keloids should be treated with caution.

- h. Dispose all parts of the delivery kit:
 - i. At the end of treatment or between patients
 - ii. If 30 minutes have elapsed since the last shot (to avoid obstruction of the nozzle by dried solution which may lead to nozzle failure).
- i. It is recommended to perform a sensitivity test prior to the first treatment.
- j. Make sure the medication is labeled for jet injection.

SIDE EFFECTS

All side effects are considered mild, of a short duration, self-resolving which did not require medical attention. This includes:

- During treatment
 - Bleeding from entry points
 - Pain in injection point
- After treatment
 - Hematoma.
 - Erythema
 - Small papules for up to fourteen days (may be longer depending on skin type and sensitivity)
 - Visible entry points for up to one month
 - Hyper pigmentation in certain types of skin