



## General Information - 0.5mL Needle-free Injection System

The PharmaJet Needle-free Injection System delivers liquid medications and vaccines **intramuscularly** or **subcutaneously** by creating a very narrow, high velocity fluid stream (essentially a “fluid needle”) which penetrates the skin and delivers the medicine or vaccine into the body. Energy to propel the vaccine is supplied by a hand-held spring powered injector. When released, the spring energy is transferred to the syringe plunger, expelling the vaccine through a very small orifice in the face of the syringe contacting the patient.

### **Indications for use**

The PharmaJet Needle-free Injection System is intended to deliver various medications and vaccines either intramuscularly or subcutaneously by means of a narrow, high velocity fluid jet, which penetrates the skin and delivers the medicine or vaccine to the body. Healthcare providers who routinely administer injections may use the PharmaJet Needle-free Injection System. It may be used for adults and children. It can also be used by patients authorized by their physicians to self-inject, or have other individuals administer injections of prescribed medication.

### **Less expensive by design**

Our patented syringe is **made from polypropylene** - the same material used in standard syringes, which is much less expensive than polycarbonate, the syringe material used by most other needle-free producers. Large-scale production of our needle-free syringes allows jet-injection technology to be cost competitive with auto-disable needle products and **affordable** even for developing country mass vaccination programs.

### **Designed to keep going and going**

Requiring no external power source, the smart design of our **extremely robust injector** (only 4 moving parts during an injection) ensures a minimum of 20,000 injections can be achieved with each unit. This translates to one injection every five minutes, seven hours a day every working day of the year.

### **Ease of use**

Four simple steps: Reset injector, fill syringe, insert syringe into injector and administer injection. This simplicity enables less experienced staff, or even patients to become rapidly proficient, enabling wider global acceptance and utility.

### **No Needle!**

The PharmaJet syringe contains no needle; and its auto-disable feature makes it impractical to re-use. This **eliminates two of the greatest concerns in health care**: Needle stick injury to health care givers, and cross contamination caused by re-use of needles. No needle, **no sharps elimination** issues.

### **Certificates and Market Clearances**

- US Food & Drug Administration - **FDA 510k** Market Clearance
- PharmaJet, Inc. has established and maintains a Quality Management System that complies with the requirements of **ISO 13485:2003**
- **ISO 21649:2006** Needle Free Worldwide Standard compliant
- Our single use, sterile products are tested with guidance from:  
**ISO 10993, ISO 11737, ISO 11607 and ISO 11137**

## Product Specification - .5mL Needle-free Injection System

- **Depth of penetration:** Intramuscular (IM) or subcutaneous (SC), depending on injection technique.
- **Dose:** 0.5mL with Automatic Dose Adjustment assuring a dose accuracy  $\pm 5\%$  (ISO 21649:2006).
- **Major components:** 0.5mL Needle-free Syringe; Filling Adapter; Light (purple) and Heavy (blue) Injector; Reset Station.
- **Syringe:** Needle-free, single use, auto-disabling, disposable, delivers a fixed fluid volume of 0.5mL.  
  
The #9 Needle-free Syringe has a *blue* plunger and is used with the Purple and Blue injectors to deliver 0.5mL injections IM or SC.  
  
Syringe has a diameter of 0.63cm, is 2.2cm long and weighs 4.1g.
- **Filling Adapter:** Single use, disposable, transparent adapter that facilitates transfer of medicine or vaccine from any size of primary vial packaging (single or multi-dose) into the needle-free syringe.
- **Injector:** The Injectors are reusable, compact and spring-actuated, consisting of an outer body with an inner housing, trigger, and spring. Each Injector has dimensions of 14.9cm L by 4.57cm H by 4.57cm W and a weight of 6.4oz.  
  
The Purple "Light" Injector is for patients with lighter tissue densities, such as infants and geriatrics, and the Blue "Heavy" Injector is for all other patients. Light and Heavy refer to the spring power, thus the energy imparted to the fluid during delivery.
- **Reset Station:** The Reset Station is used to energize the injector spring. It has the dimensions of 23.11cm by 8.12cm by 5.58cm and a weight of 31.7oz.
- **Operational/Storage Temp:** 41°F to 104°F (5°C to 40°C) / -40°F to 158°F (-40°C to 70°C).
- **Safety mechanism** Automatic; virtually eliminates accidental discharge.
- **Sterilization method:** Disposable products are sterilized using electron beam sterilization. Sterility is guaranteed unless packaging is opened or damaged.  
  
The Injector can be immersed in chemical sterilizing liquids, rinsed and air-dried.
- **Warranty** The Injector and Reset Station carry a warranty against defects in materials and workmanship for one year from the date of purchase.