

LectraJet® HS High Speed Jet Injection System for Mass Immunization Campaigns

CLIENT: Centers for Disease Control and Prevention (CDC) Atlanta, Georgia

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PROBLEM:

The US Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) have identified the need for an easy-to-use, reliable, rapidly deployable needle-free (NF) injection system that provides protection against pre-injection vaccine contamination and that eliminates the risk of cross-infection for the billions of vaccinations administered annually throughout the world. This safe and effective way to rapidly vaccinate large numbers of people is needed, not only for mass immunization campaigns in developing countries, but also to prepare for the possibility of bioterror attacks and disease pandemics world-wide. The reason for this need is that injections often come with the risk of cross-infection and other types of infection due to:

- Reuse of disposable needles and syringes
- Reuse of sterilizable needles and syringes without proper sterilization
- Improper disposal of contaminated sharps
- Accidental needlesticks
- Advance filling of multiple syringes (typically done to circumvent slow syringe filling process)

Unsafe injection and disposal practices put the patient, the healthcare worker and the community at risk.

SOLUTION:

The LectraJet® Disposable Syringe Jet Injector (DSJI) system is a high-speed needle-free jet injection system for both routine and mass immunization programs. The fact that the device is needle-free eliminates needle reuse, needlestick injuries, sharps disposal, and reduces the pain and fear associated with needle injections. The system is low cost, reliable, hand-held, and lightweight to reduce the likelihood of user fatigue. Both manual and battery power options are available, with the battery option providing several thousand injections per battery charge.

LectraJet® HS High Speed Jet Injection System for Mass Immunization

- 1) A High-Speed, Needle-Free Injector which is capable of inoculating up to 600 patients per hour.
- 2) A Syringe Magazine for managing the syringes during an injection procedure.
- 3) A Hand Pump and a Filling Station which allow the magazine syringes to be filled without any contact by the user.
- 4) The LectraJet® Syringe.

The DCI LectraJet® High-Speed, Needle-Free Injector is a battery-powered, intuitive, easy to use, durable, compact, lightweight (one pound with battery attached), reliable and water-resistant device. It is fired by pulling a safety and injection trigger simultaneously. Once the injection is delivered, the injection trigger is again pulled, and the device automatically rearms while ejecting the used syringe. It uses individual, sterile, single-dose, disposable plastic syringes that are considered single-use only.



It has an Automatic Grasping Jaw feature at the front end. The “Jaw” technique allows the user to grasp and withdraw a sterile syringe from the magazine, insert it into the injector, give the shot, and then properly dispose of it without ever touching it or requiring any twisting motion to secure it in place or to release it. This is accomplished without the risk of transferring blood borne pathogens between patients, the health care worker or the injector while providing the ultimate safety by eliminating needle disposal problems, needle stick injury, the possibility of cross-infection by reuse, and needle phobia.

DCI technology uses a common Needle-Free syringe and Drive System. The combination of an outstanding scientific design for the syringe and its exit nozzle along with preselected and highly tested pressure profiles was shown to produce a Highly Coherent, High-Velocity Jet Stream that is capable of ID, SQ or IM delivery. All three of these delivery routes have been proven in laboratory where studies were conducted with human subjects, harvested tissue from plastic surgery procedures and dissection of the injection site. In addition, injection site imaging on live subjects (US & Brazil) were done with Ultrasound, MRI and CAT scan to confirm the quality, depth and distribution patterns for these injection experiments.

The Syringe Magazine.

No other technology has the Syringe Magazine for managing the syringes during an injection procedure. While the magazine was primarily developed for vaccinating large numbers of people as quickly, safely and efficiently as possible, it also has utility in clinical situations where routine injections are given over the course of a day or more. It is a 30-syringe disposable magazine that is sterilized and wrapped. It is filled through the orifice end of the syringes and can be pre-filled in the field. The entire magazine can be refrigerated for vaccine safety. At the moment, 30 syringes per magazine is the norm in order to be compatible with a standard 15ml bottle of vaccine.



The Filling Station and Hand Pump.



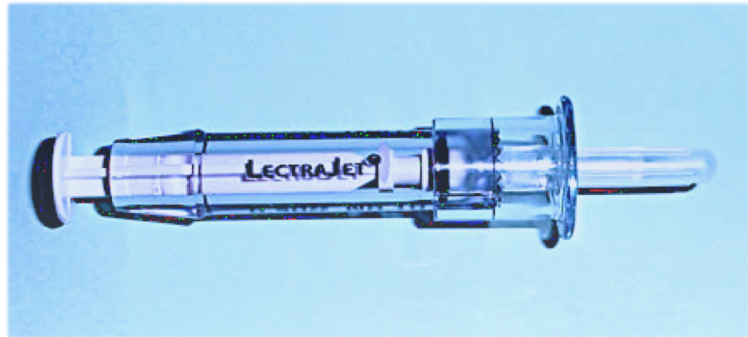
The primary High-Speed injection protocol will fill the syringes by forcing injectate into the orifice or exit nozzle. This procedure allows the magazine to be adapted with posts of the correct length for the intended dose. When the magazine is assembled, the syringes are placed over these posts thus allowing this procedure to limit the distance the piston is able to move back during the filling process. By doing this, an accurate value for the correct dose is assured. The magazine into which the syringes are inserted can be Color or Bar-Coded for antigen sparing ID (0.1 ml) as opposed to the international standard at 0.5 ml. They will also be identified by orifice size.

Two methods for filling of the syringes have been developed.

1. A manual Hand Pump which can be used to directly fill into the syringe orifice from a Multi-Shot vaccine bottle.
2. A Filling station where a lever is used to force the injectate into the orifice. The magazine is systematically moved from syringe to syringe until the filling is completed. This approach allows the magazine syringes to be filled without any touching by the user. The magazine is then removed and used for the injection procedure.

The LectraJet® Syringe.

Considerable time and resources were directed to a syringe with enough physical strength to withstand the high NF Pressure without any risk of deformation or bursting. The process began with the design of a single cavity mold. Several iterations were needed from the time of initial design until the optimum results were seen. The final results were conducted by PMP (Precision Medical Products). These syringes have a mating surfaces at the rear end to allow for the injector grasping jaws to automatically and securely engage when the two are brought together. Outstanding orifice geometry by highly skilled people at San Diego State University led to an excellent, coherent jet stream for the greatest ability to penetrate cleanly. This syringe has now been repeatedly tested at over 100 high pressure cycles without any sign of damage, although, when put into field use, the syringe is adapted with an auto-destruct feature to discourage any attempt at reuse.



The orifice is covered by the septum spike thus maintaining the sterile orifice surface even when it is being handled. The cover is part of the filling process and is not removed until after the syringe is inserted into the automatic grasping jaws. The cover is removed without touching the orifice and is therefore still sterile when the shot is given. It is ejected without touching it as well.

Manual Filling LectraJet® Needle-Free Syringe.



LectraJet® NF Syringes are filled directly from the vaccine vial, or alternatively, directly from a reconstitution syringe. The filling process is extremely rapid (NF syringes are filled twice as fast as a vaccinator can deliver injections). This high-speed filling process removes the incentive to fill in advance. In addition, all fluid path components are disposable and single-use so that no reuse issues exist, such as improper sterilization.