LectraJet® HS (high speed)

Needle-Free Injection System for Routine Immunization and Mass Immunization Campaigns

Funding provided by Centers for Disease Control and Prevention (SBIR Contract # 200-2000-10049)

D'Antonio Consultants International, Inc. (DCI)

www.dantonioconsultants.com

DCI, Inc. Jet Injection Projects

- **1988:** Grant with Johns Hopkins
  - develop battery-powered injector
- **1996-1998:** USDA Small Business Innovation Research (SBIR) Grants, Phase I & II
  - veterinary injectors
- **1997:** CDC Phase I SBIR Contract
  - multi-channel injector
- **1998:** Two CDC Phase I SBIR Contracts
  - high- and low-workload injectors
- **2000-Present:** CDC Phase II SBIR Contract
  - high-workload for measles mass campaigns

Status of Research and Development

- ✓ Proof-of-principles demonstrated
- ✓ Working prototypes built
- ✓ Bench/laboratory performance testing done
- ✓ Animal testing for depth and dispersion done
- ✓ Design review for manufacture and risk analysis

<u>Remaining stages</u>

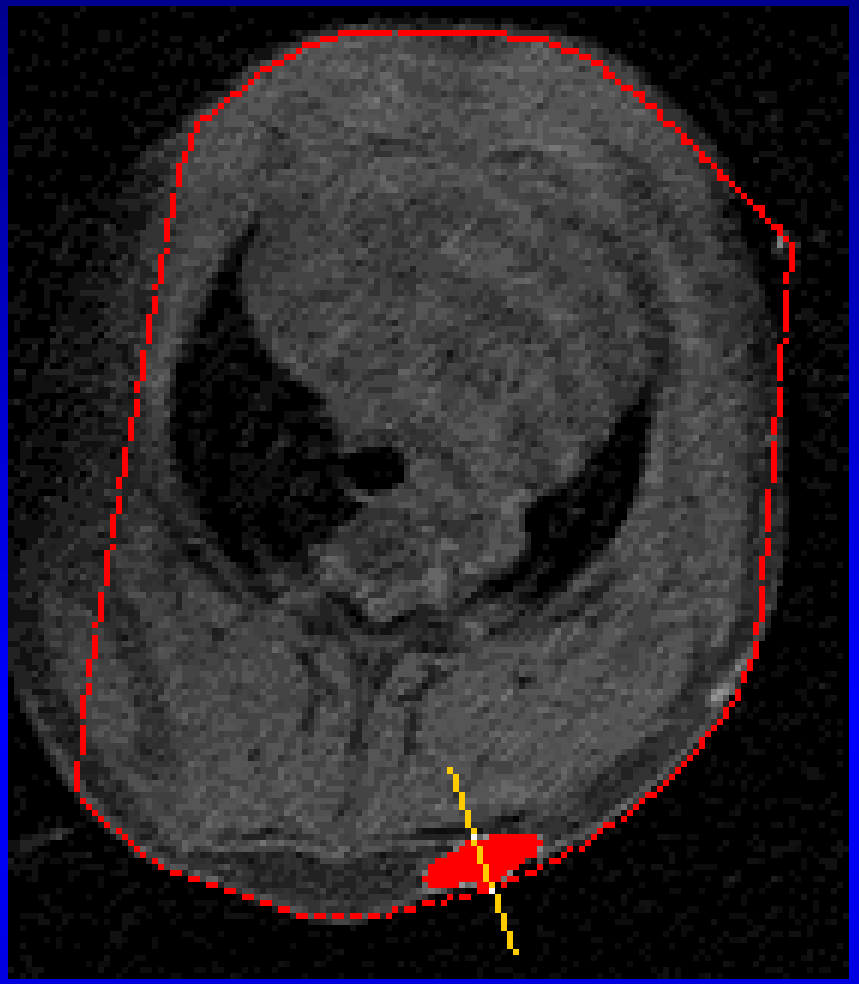
- 510(k) clearance
- Human adult depth and dispersion MRI studies
- Human adult Anthrax trials
- Pediatric **MMR** or **MEA** safety and efficacy trials
- Developing country field feedback
- Developing country mass campaign feasibility trials

LectraJet® HS

Subcutaneous (SC) Injection

(10 kg piglet)

Post-mortem cross-section photo of india ink injectate in fat.



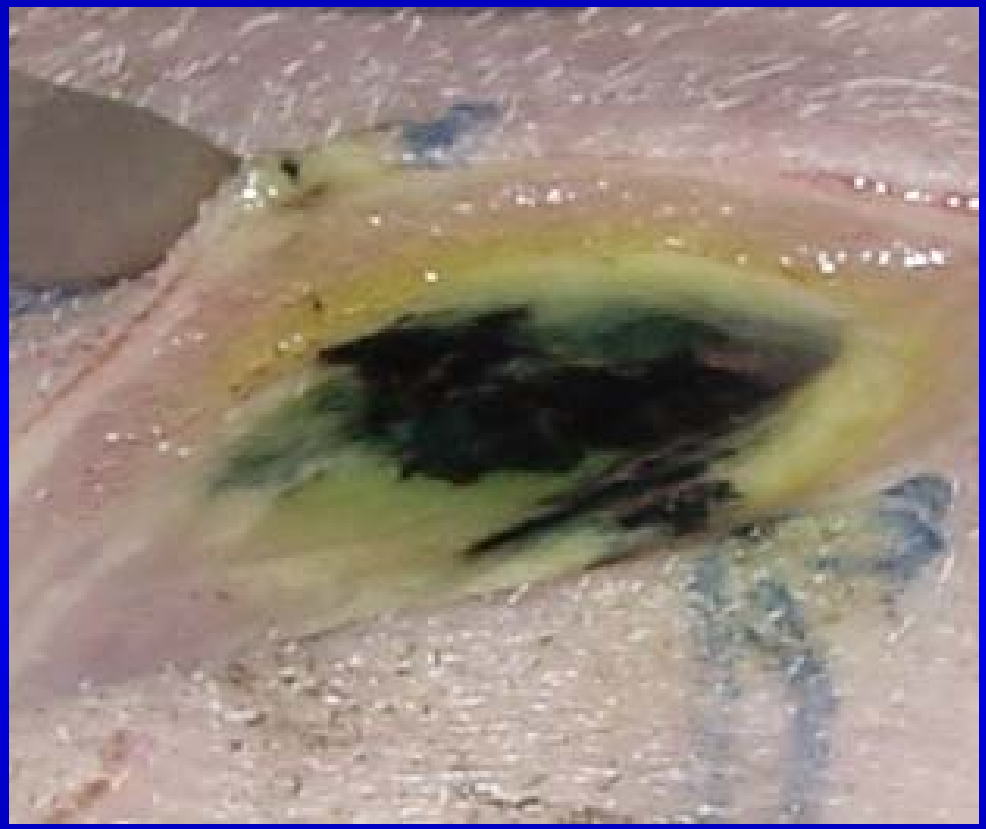
In vivo Magnevist® injectate enhanced in red on MRI. Yellow line is computed central axis of injection.

Courtesy: N.M. Szeverenyi, SUNY Upstate Medical University, Syracuse

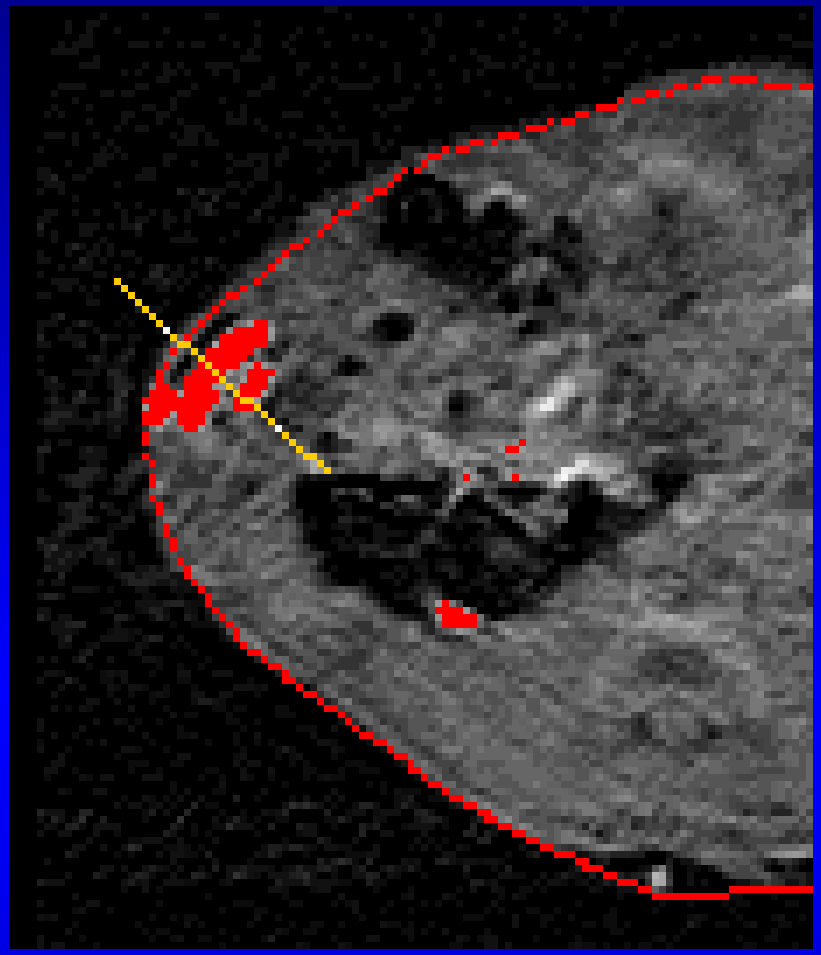
LectraJet® HS

Intramuscular (IM) Injection

(10 kg piglet)



Post-mortem cross-section photo of india ink injectate in muscle.



In vivo Magnevist® injectate enhanced in red on MRI. Yellow line is computed central axis of injection.

Courtesy: N.M. Szeverenyi, SUNY Upstate Medical University, Syracuse

Desired Characteristics: Design Specifications of CDC

- ***Safety***
  - Disposable, single-use, auto-disabling cartridges
  - Clean end-user filling of cartridges
  - Cartridges capable of vaccine manufacturer pre-filling
  - Hands-free loading and ejecting of cartridges
  - All sterile components provided; no field sterilization
  - Prevent firing if filled cartridge not properly seated
  - No sharps waste

Desired Characteristics: Design Specifications of CDC

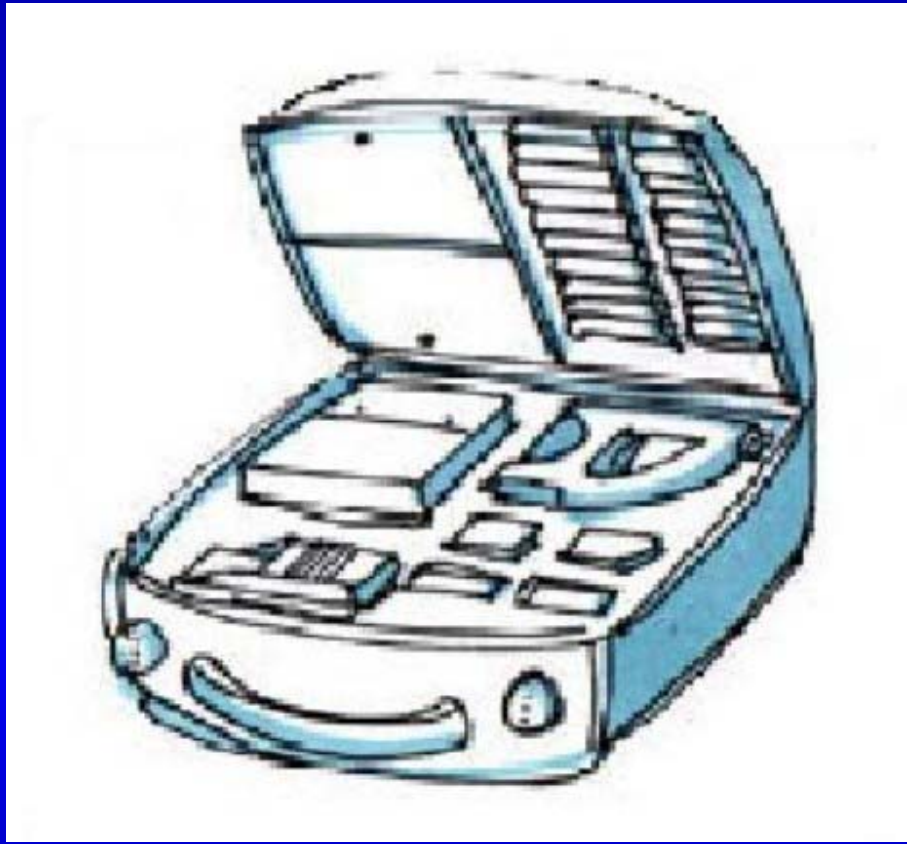
- ***Speed*** ***(for Mass Campaigns)***
  - ≥600 injections / hour
    (>10 / minute = < 6 seconds each)
- ***Low cost***
  - Competitive with autodisable syringes

LectraJet® HS System Components

- Case
- Cartridges
- Handpieces & power sources
- Magazine
- Filling System

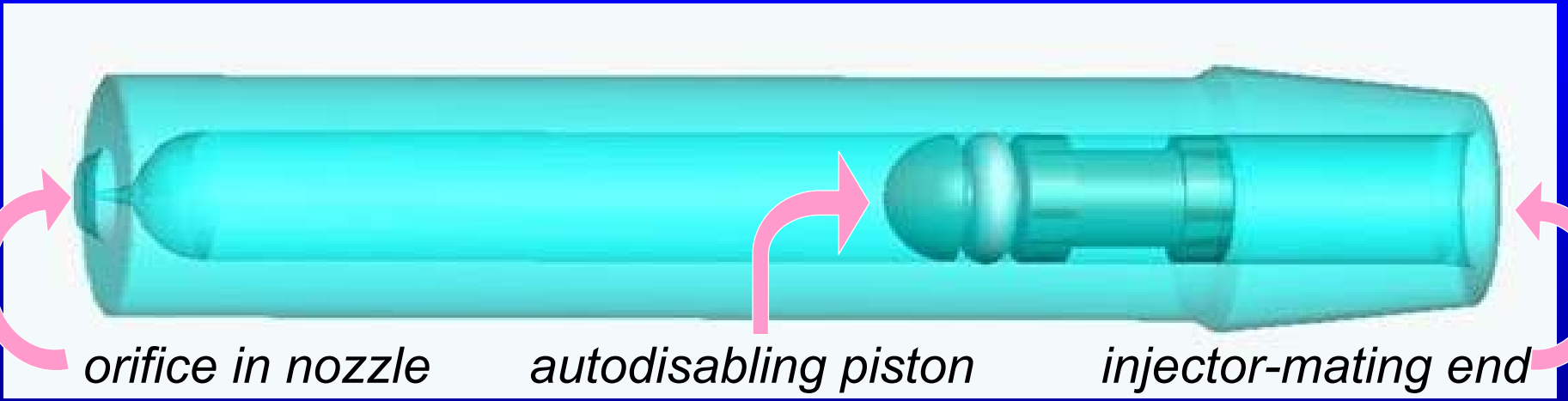
LectraJet® HS Case

- For shipping and travel
- Includes legs to use case as work platform



LectraJet® Cartridges

- Polycarbonate with molded orifice
- Autodisabling piston ➡ Single use
- Packaged sterile for end-user filling
- Filled on-site via orifice
- Capable of manufacturer prefilling
- Low cost at high volumes



LectraJet® Handpieces and Power Sources

- Two versions: Manual and Motorized
- Steel spring creates force to deliver shot
- “Fingers-free” grasping of filled cartridge
- “Fingers-free” release of used cartridge
- Rapid delivery of injections
- Very little maintenance required
  - No o-rings or seals to change
  - No sterilization required

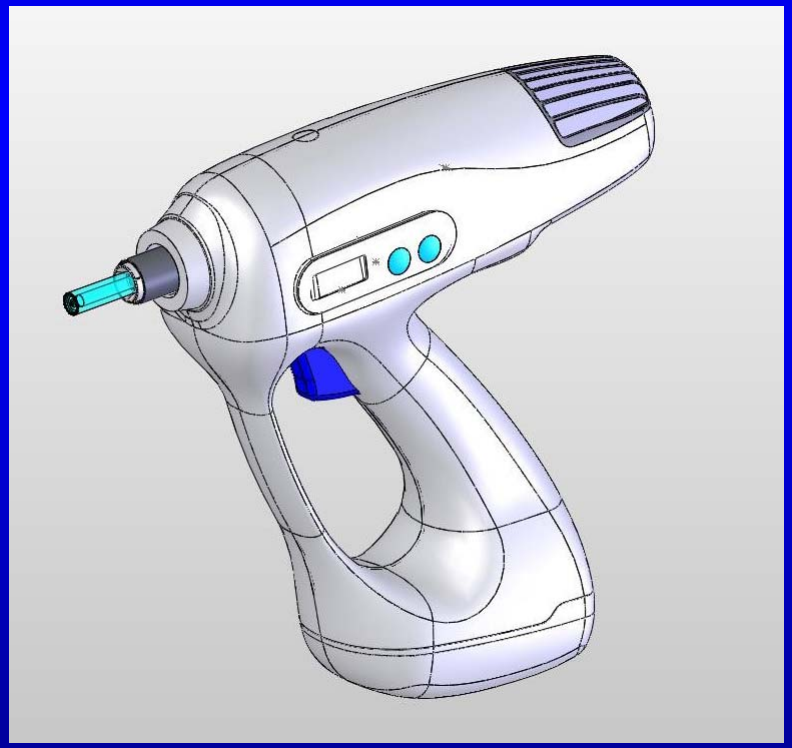
Handpiece – Manual Model

- Spring compressed manually
- Suitable for either …
  - High-speed mass campaigns without electricity (600/hr)
  - Routine clinic use

Manual LectraJet in Action

Handpiece – Motorized Model

- Spring compressed by internal motor
- Rechargeable, replaceable battery pack in handle
- Several thousand injections per charge
- Battery-charging – AC mains,vehicle battery, solar, etc.
- Backup manual spring compression possible

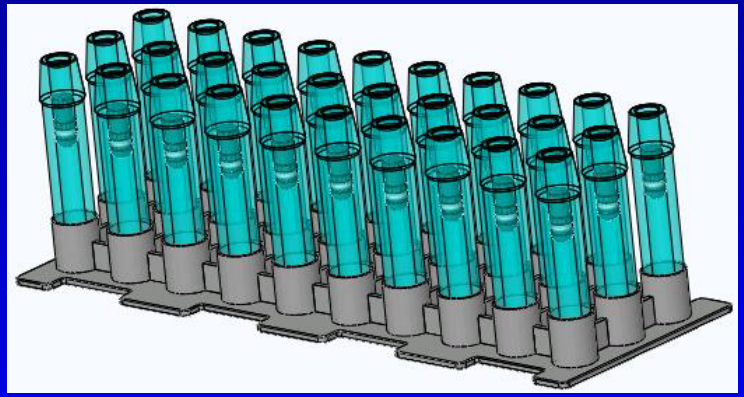


Magazine

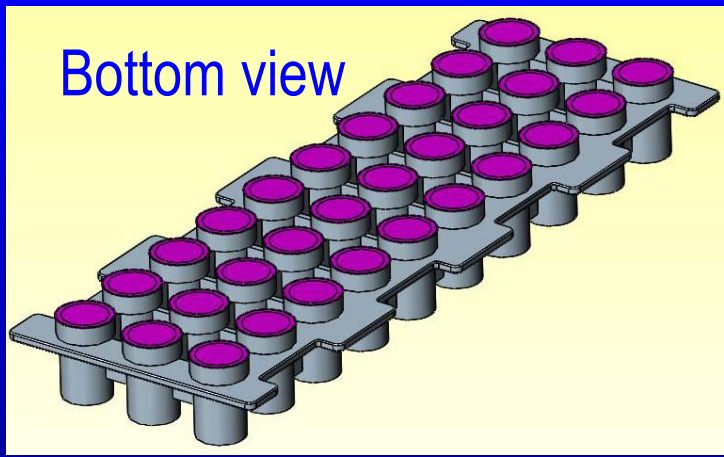
- Manages cartridges for efficiency and speed
- Minimizes cartridge handling
- Maintains cartridge cleanliness

Magazine

- Orifice end of cartridge…
  - Friction fits into magazine
  - Recessed and protected by covering to maintain cleanliness before and after filling



- Mounts on carrying case, vaccinator's arm, or any firm surface
- Low cost plastic
- Cost for 30 cartridges in magazine (sterilized and wrapped) is similar to cost of autodisable syringes, in quantity

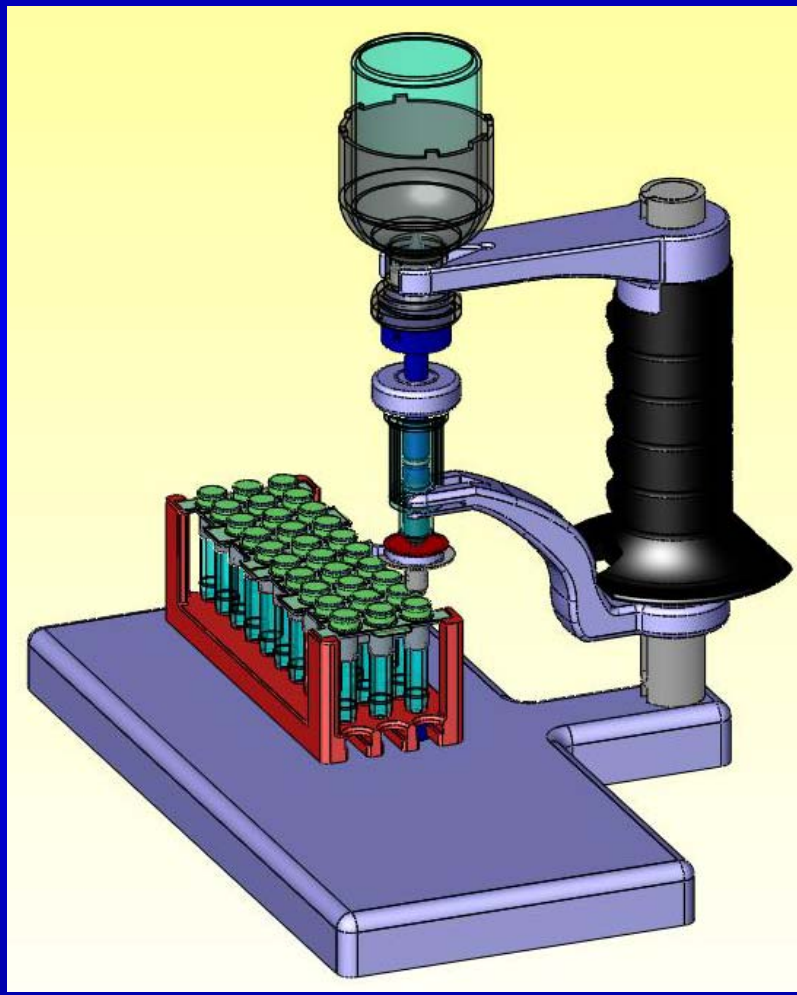


Filling System

- Fill on-site from vaccine vial through cartridge orifice
- Can also fill from autodisable reconstitution syringe
- Use with liquid or reconstituted lyophilized vaccines
- Minimize vaccine handling
- Disposable fluid path ➡ no field sterilization requirements

Filling System

- Pump fluid from vial into cartridge
- No finger contact with sterile pathways between vial changes
- No wasted doses in fluid path
- Fully disposable fluid path
- Manually index to next cartridge



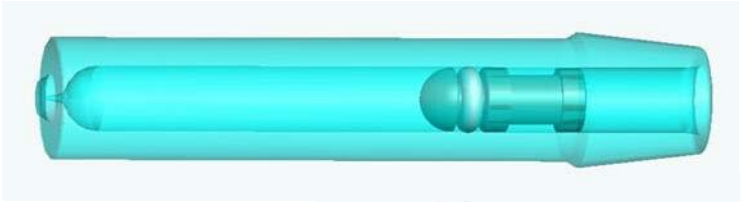
Review of *LectraJet* ® Attributes

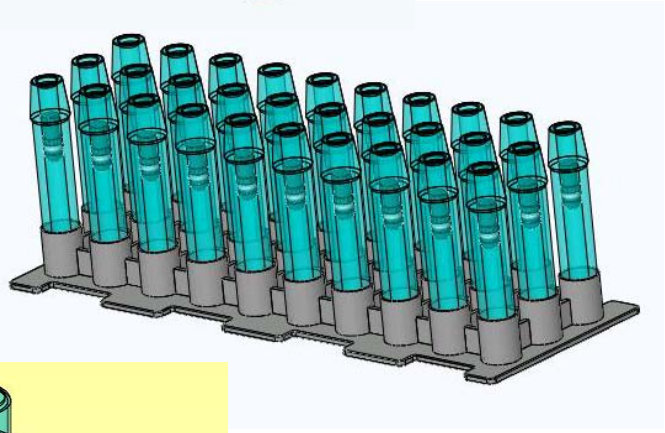
- No cross-infection risk
- SQ or IM delivery of vaccines
- High or low speed operation
- Long-term reliability for high workload use
- Minimal training and maintenance
- No field sterilization
- Cost competitive with autodisable syringes

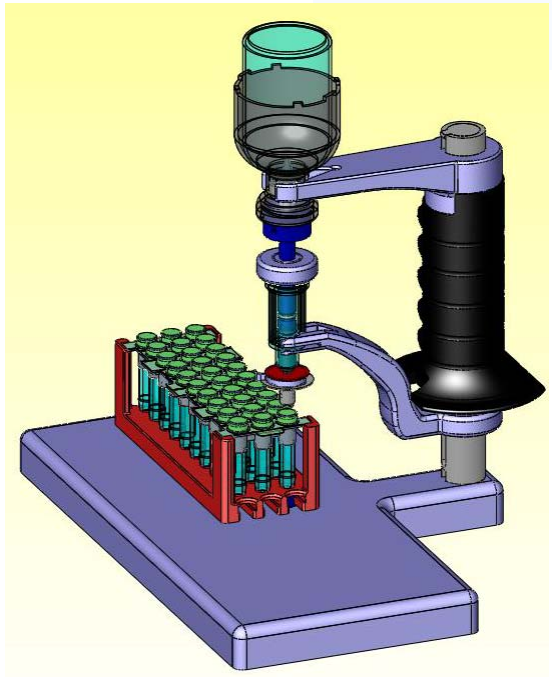
LectraJet ®
Regulatory Timeline

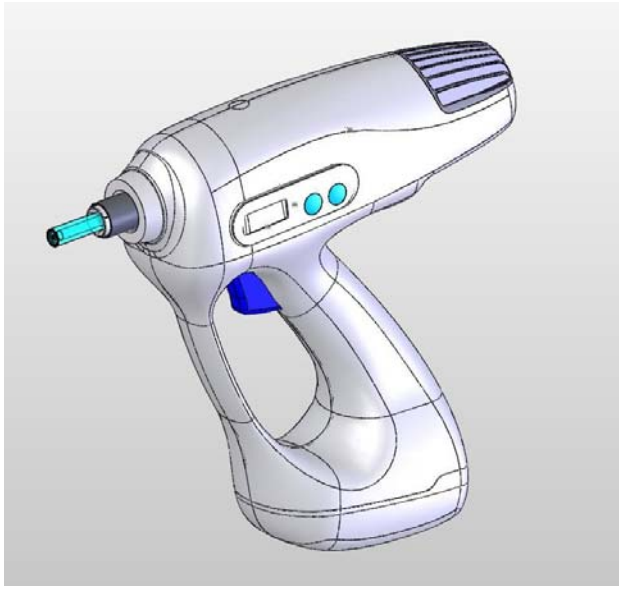
- 510(k) submission expected January, 2004
- Review and clearance expected March, 2004
- Human trials begin March 2004

LectraJet® HS (high-speed) Needle-free Injection System









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