Solving the Problems of Mass Vaccination with Needle-free Technology.

Mike Mathews

VP, Operations

Who is Felton?

High Workload
Jet Injection
Drug Delivery System

- Safe
- Fast
- Cost Effective
- Efficacious

Human

- Mass Vaccinations
- Bio-terrorism
- Epidemics

Animal

- Swine
- Beef Cattle
- Dairy Cattle

Russian Injectors

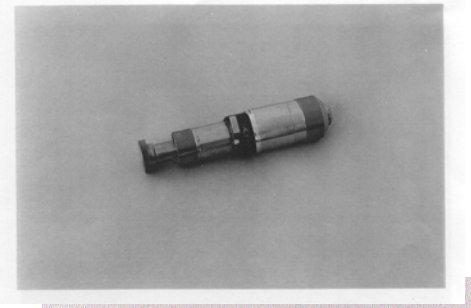
Rights Purchased for 17 Injectors

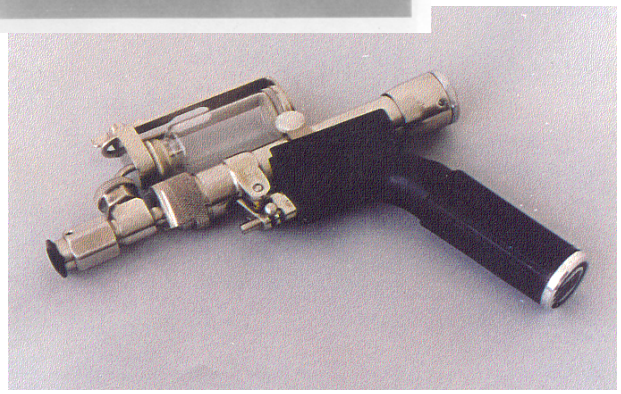
Felton used the technology base and expertise from Russia to focus on two injectors:

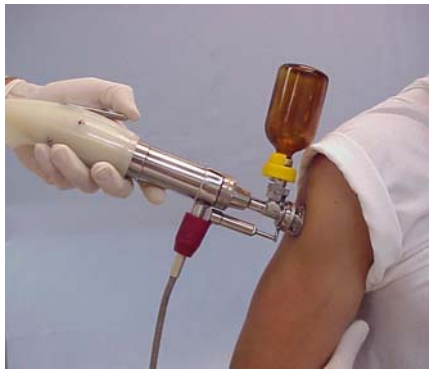
+Animal (Swine and Cattle)

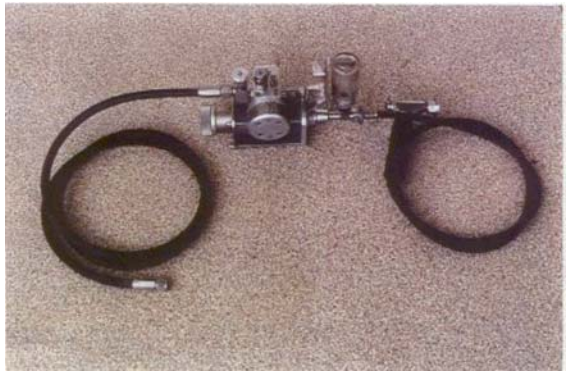
+Human (mass campaign)

Over the past 2 years we have modified these designs to be more ergonomic and to improve manufacturability.









Felton Injectors

Swine Devices

(> 20 million injections given in 2003)

High Cutoff

Low Cutoff

Handpiece

+ weight is less than 8 oz

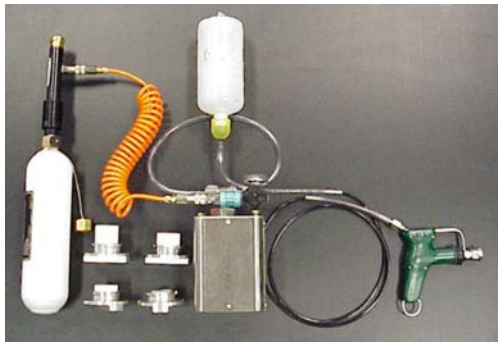
+ 2 Safeties

+ Reverse Trigger

+ 2 Versions

- High Pressure for Hogs

- Low Pressure for Baby Pigs



Pulse 250

+ Settable dose

- 0.5ml to 2.5ml

+ Variable power

+ CO2 or air driven

+ Cycle time < 1.2 second

Felton Injectors

Cattle Devices

Dairy Backpack

+ 2 vaccines delivered
+ Nitrogen based

Cattle Handpiece

+ Modified Nozzle design
+ Stronger Spring for better skin contact

Feedlot Hanger

+ Air or CO2
+ Can be linked together on a single air line.

Felton Injectors

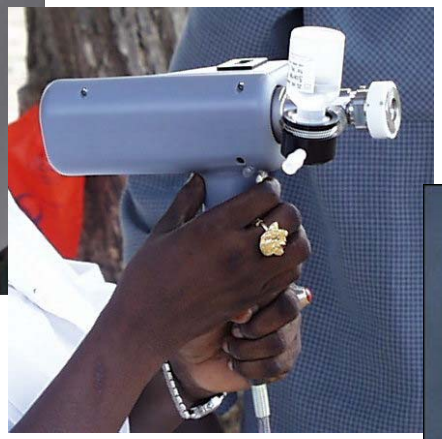
Human Devices

Bi-3M

This device had the first Protector cap and was used to give over 100 million injections in the Former Soviet Union. The FDA 510k clearance Is on the Bi-3M.

Bi-100

This prototype was developed as a fixed dose system aimed at the WHO measles campaign. It is lighter And has automatic cap removal.



Pistol Grip

This device was Used in the trial in Senegal.

Prototype Device

This device was completed in April 2003. It is smaller, lighter, power adjustable, and will accept a wide Range of vials.

The New Human Injector

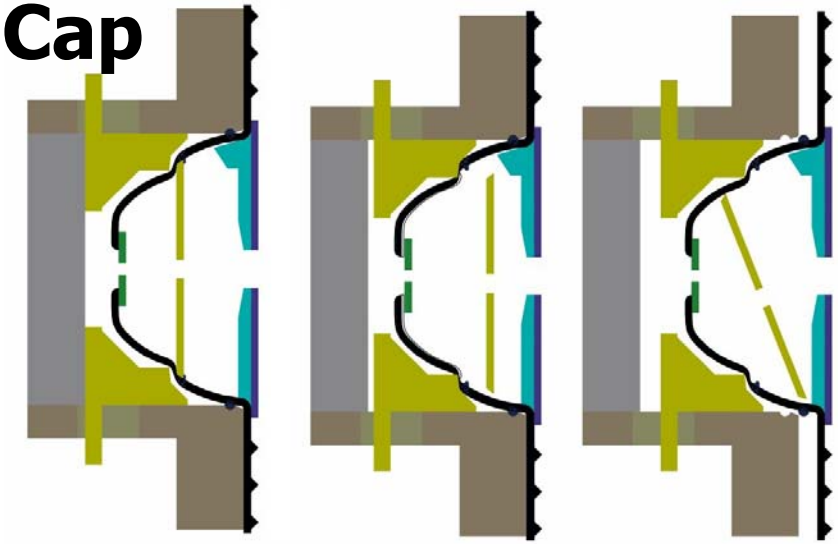
- Redesigned based on inputs from PATH and other collaborators.
  - Much lighter
  - User friendly (non-threatening) format
  - Easy to clean and sterilize
- Will be ready for trials in 2004.

Human Mass Campaign Injector

- Dose size is fixed at 0.5ml
- Target tissue is SQ in the deltoid or thigh region
- Adjustable force
- Self powered
- Protector cap is auto-disabled after use
- Next iteration will include an interlock to prevent injection without a cap in place

Technology Key

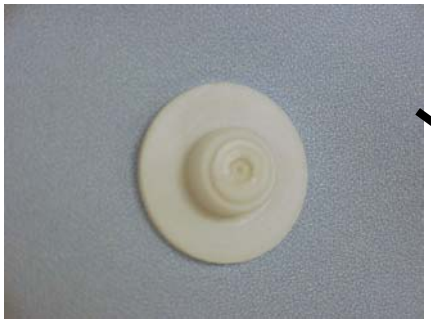
Protector Cap



- Single use protector is placed between the nozzle face and the skin
- Injection cannot take place without a protector cap in place.
- Injection takes place through a film
- The protector contains any “splash-back” from the injection.
- There are 4 “challenges” to any fluid reaching the nozzle, including the film.
- Cap is auto-disabled after use.
- Protector is inexpensive when compared to needle and syringe.
- Cap disposal is low energy and environmentally safe.
- The injector will be interlocked to prevent an injection without a cap in place.

Felton Injectors

Protector Caps



Mark 4

This cap was the latest iteration of The original Russian cap design. It was made of rubber and has a stainless steel insert. These caps Were reusable.

Mark 5

This cap was used for safety testing on the 510k application. It provides 4 challenges to any contaminant, including a poly-ethylene film.

Mark 6

This cap will auto-disable on ejection. It can be manufactured inexpensively and is made completely of poly-ethylene for safe inexpensive disposal.

Needle-free Mass Campaign Advantages

- Eliminate needle stick injuries for health workers.
- Eliminate the re-use of needles.
- Easier injection compared to needle & syringe.
- Reduce direct costs associated with mass campaigns.
  - Logistical costs
  - Injection costs
  - Disposal costs
- Reduce pain and stress for patients.

Getting to the Market

- A safety trial is required.
  - Prove in the field what has been verified in the lab.

    Pathogens are not transferred between patients using the protector cap device.
  - Reverse the ban that currently exists against multi-dose injectors.
  - Trial issues include assay, protocol and sample size.
  - Felton, PATH and WHO are working toward a human trial scheduled for the summer of 2004.

PATH Partnership

- PATH is focused on bringing needle-free technologies to the developing world.
  - Working with WHO to create a protocol and assay to prove the safety of the device.
  - Management of the safety trial
    - Preliminary trial to prove feasibility
    - Full trial to prove injector safety
  - Design input and product testing
    - Provide user feedback for the injection system.
    - Help with design decisions and test design implementation

U.S. Army SBIR Status

- Phase I complete with excellent results.
  - Grant to study needle-free application of an enzyme to protect against poisonous gas.
- Phase I Option is complete.
  - Grant to develop a human needle-free specification for Army use.
- Phase II is started.
  - Grant to continue the animal trials and to develop a prototype IM injector for Army use.
  - Start date is December 15, 2003 and is expected to last 18 months.

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THANK YOU