

Plenary Session 1: Lessons Learned

Jet injectors

Next-Generation Vaccine Delivery Technology Meeting
Geneva, Switzerland

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Photos (clockwise from top left): PharmaJet; Medical International Technologies; PharmaJet; Bioject

Jet injection: History and background

- Decades of extensive [clinical experience and program use](#) with jet injector devices.
- Multi-use nozzle jet injectors (MUNJIs) demonstrated to generate cross contamination.
- Safer disposable-syringe jet injectors (DSJIs) developed.
- [WHO prequalification](#) requirements established.
[DSJI device prequalified.](#)
- DSJI technology becomes available for use in clinical trials and programs.
- [FDA recommendation](#) established for relabeling of vaccines for “jet injection” use.



Photo: CDC

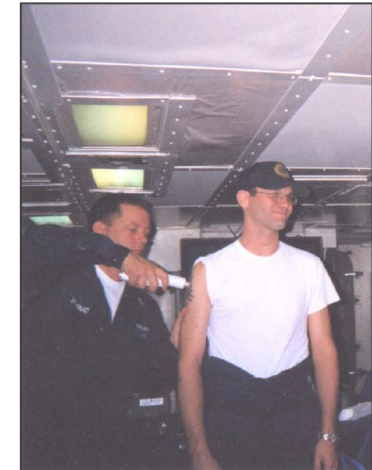


Photo: Bioject



Photo: PharmaJet



Photo: PharmaJet

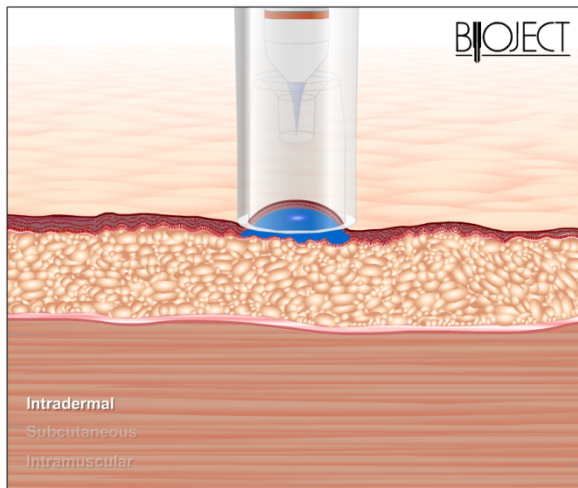
Jet injection: Mechanism of action

Jet injectors deliver vaccines and medicines without using needles; instead, jet injectors generate a pressurized liquid stream that pushes through the skin, penetrating it to deliver injections into the tissue.

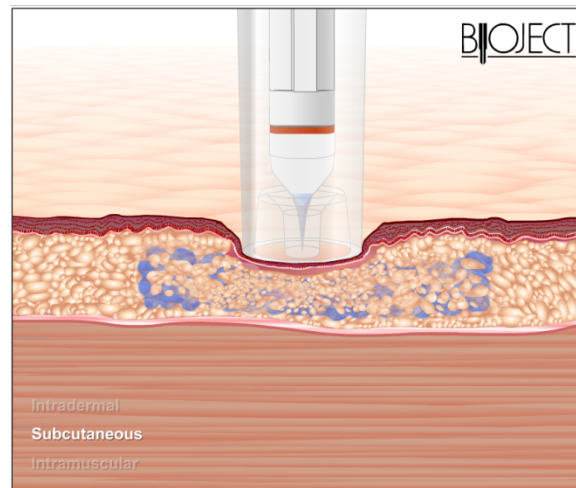


Photo: PharmaJet

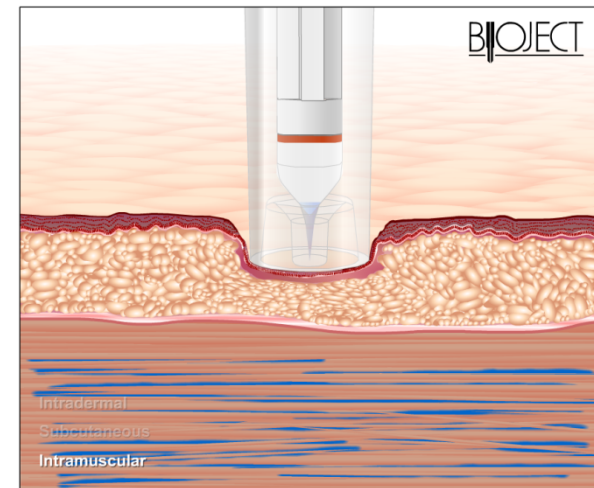
PharmaJet DSJI injection in action.



ID injection with a DSJI.



SC injection with a DSJI.

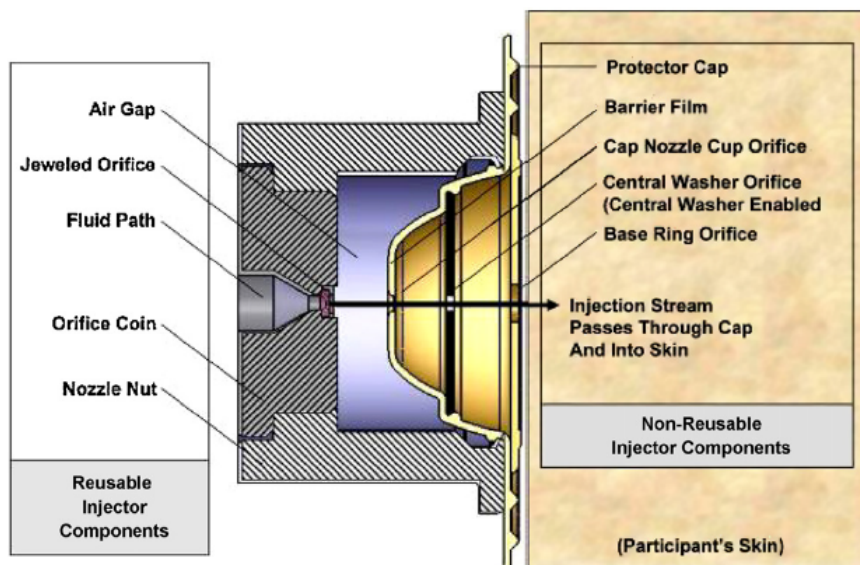


IM injection with a DSJI.

All photos: Bioject

Jet injectors—lessons learned: MUNJIs

- MUNJI/hybrid MUNJI devices:
 - Challenge to demonstrate safety—risk/benefit.
 - Shift in size of multi-dose vials.



Vaccine (2008) 26, 1344–1352

available at www.sciencedirect.com

ScienceDirect
journal homepage: www.elsevier.com/locate/vaccine

Preventing contamination between injections with multiple-use nozzle needle-free injectors: A safety trial

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KEYWORDS
 Multiple-use nozzle jet injectors (MUNJIs);
 Needle-free injections;
 Cross-contamination;
 Hepatitis B virus (HBV)

Summary Multiple-use nozzle jet injectors (MUNJIs), a type of needle-free injector, use a high-pressure stream to penetrate skin and deliver medication. Concerns for their potential to transmit blood borne pathogens led to developments. The HSI-500[®], referred to here as a pre-disposable cap as a shield between the nozzle and the skin, was developed to reduce the risk of contamination. This study aimed to determine if contamination in post-injection ("next person") HBV carrier adults. Tolerability and pain were PCNFI failed to prevent contamination in the torso were very well tolerated, with most fo (7.8%), 55.2% of participants experienced no injection.
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Introduction
 By 1999, rough of non-immun considered as cause million

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Nozzle Side (film)

Injection Site (skin) Side

All images: Pulse NeedleFree Systems

Jet injectors—lessons learned: DSJIs

Value proposition

- Technology uptake—experience with auto-disable syringes.
- Price comparison—economies of scale.

1994 AD syringe price: 11.8 cents



http://www.unicef.org/supply/files/Overview_of_UNICEFs_procurement_of_Immunization_devices_2012_and_past_years.pdf

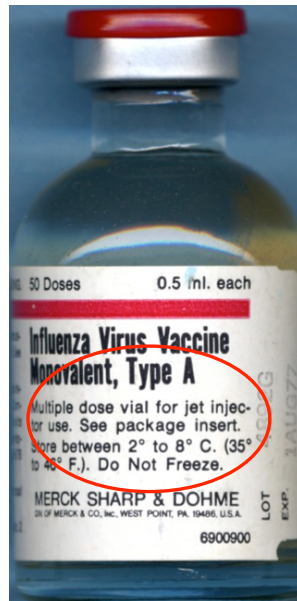
[http://www.who.int/bulletin/archives/77\(12\)1001.pdf](http://www.who.int/bulletin/archives/77(12)1001.pdf)

Jet injectors—lessons learned: DSJIs

Regulatory pathway shift

- General indication versus vaccine relabeling.
- Technology class category—“jet injection”
- SRA versus NRA

 PERFORMANCE QUALITY SAFETY	
E008: Auto-disable syringe for fixed dose immunization	
PQS code: E008050	
Description: single-use auto-disable needle-free jet injector	
Manufacturer's reference: Pharmajet Stratell	
Company: United States	
Address: PharmaJet, Inc. 400 Corporate Circle, Suite N Golden, Colorado 80401 USA	
Telephone: +1 (303) 326-6278 Email: melissa.kay@pharmajet.com Web address: http://www.pharmajet.com/	
Specifications	
Graduations: 0.5ml	Quality standard: ISO 9001, ISO 13485
Syringe material(s): —	Markings: FDA 510(k) CE 559625
Fixed needle size: —	Pieces per carton: 1
AD mechanism: Plunger break	Volume per carton (mL): 0.037 mL
AD location: Start of injection	Weight per carton (kg): 3.23 kg
Number of components: 2 pieces	Minimum order: 1 unit
Other needle options: No	Incoterms: EXW
Primary packaging: Paper blister pack	Prices per unit: Upon request to RF
Year base price: 2012	
<small>Single-use auto-disable needle-free jet injector. Note: All injections (single-use auto-disable needle-free syringe injectors) are medical devices. Class II as regulated by National Regulatory Authorities. A jet injector prequalified by the WHO PQS programme to deliver medications and vaccines is to be used according to label to deliver ONLY those medications and vaccines that have been approved by the relevant Authorities.</small>	
<small>Current PQS status: pre-qualified: 21 Jun 2013 Valid until: Apr 2014</small>	
<small>Note: If Current PQS status is "Suspended" or "Withdrawn", this product is NOT to be purchased.</small>	
<small>NEW Product AD AT 31.01.2013</small>	



YELLOW FEVER VACCINE

YF-VAX®

Caution: Federal (USA) law prohibits dispensing without prescription.

For special instructions on use of Yellow Fever for **JET INJECTOR USE** — see other side of insert.

DESCRIPTION

YF-VAX®, Yellow Fever Vaccine, for subcutaneous use, is prepared by culturing the 17D strain of yellow fever virus-free (ALV-free) chicken embryos. The vaccine, containing sorbitol and gelatin as a stabilizer, is lyophilized under nitrogen. No preservative is added. The vaccine must be reconstituted immediately before use (Sodium Chloride Injection USP – contains no preservative). YF-VAX® is formulated to contain not less than 1 Unit (PFU) per 0.5 mL dose. The vaccine appears slightly opalescent and light orange in color after reconstitution. YF-VAX® complies with official potency tests and other requirements of the US Food and Drug Administration (FDA).

Labeling note:

Jet injectors (single-use, autodisable, needle-free syringe injectors) as medical devices (Class II) are regulated by National Regulatory Authorities. A jet injector prequalified by the WHO PQS programme to deliver medications and vaccines is to be used according to label to deliver ONLY those medications and vaccines that have been approved by the relevant Authorities.

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FDA U.S. Food and Drug Administration
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FDA Updated Communication on Use of Jet Injectors with Inactivated Influenza Vaccines

Date Issued: October 26, 2011

Audience: Health care professionals who administer inactivated influenza vaccines

Purpose: The Food and Drug Administration (FDA) is recommending that health care professionals use a sterile needle and syringe to administer inactivated influenza vaccines.

Summary of the Issue

FDA has recently received questions regarding the use of jet injector devices to administer inactivated influenza vaccines. Inactivated influenza vaccines that are approved by the FDA have information in their labeling stating how the vaccines should be administered, such as, by intramuscular (IM) or intradermal (ID) administration. The FDA is clarifying its October 21, 2011, communication to inform the public that inactivated influenza vaccines labeled for IM injection are intended for administration using a sterile needle and