Plenary Session 1: Lessons Learned

Jet injectors

Next-Generation Vaccine Delivery Technology Meeting

Geneva, Switzerland

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A catalyst for global health

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

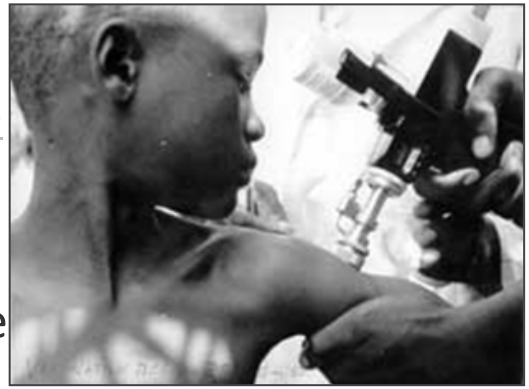

Photo: CDC

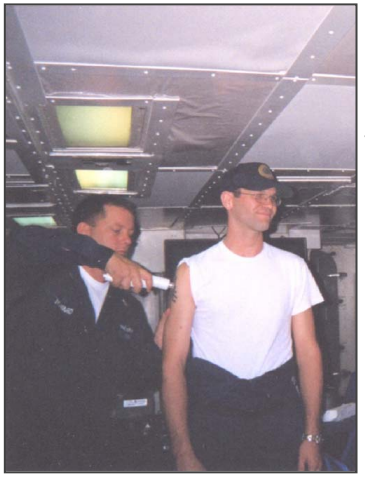

Photo: Bioject

Photo: PharmaJet

Photo: PharmaJet

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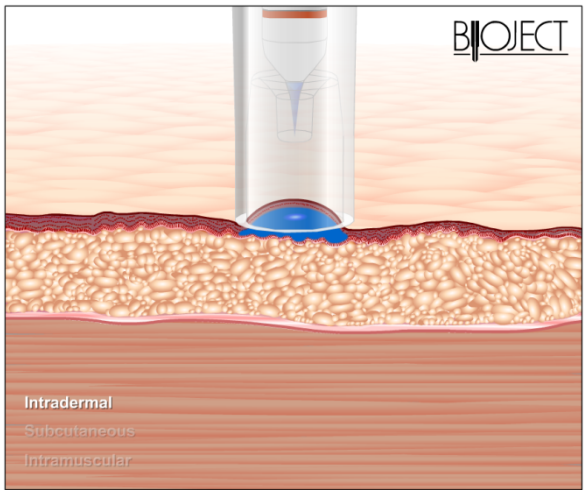
Jet injection: Mechanism of action

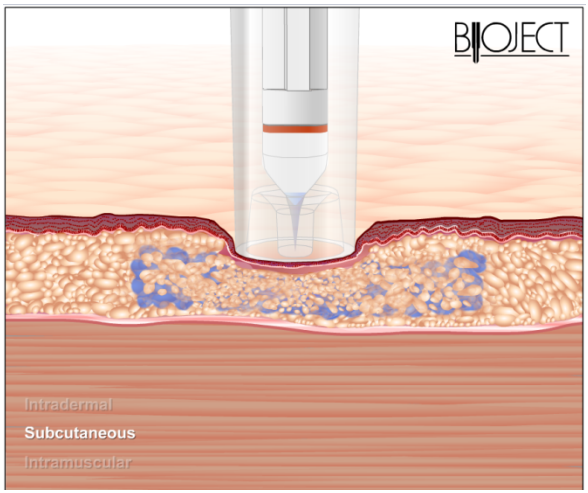
Jet injectors deliver vaccines and medicines without using needles; instead, jet injectors generate a pressurized liquid stream that pushes through the skin, penetrating it to deliver injections into the tissue.

Photo: PharmaJet

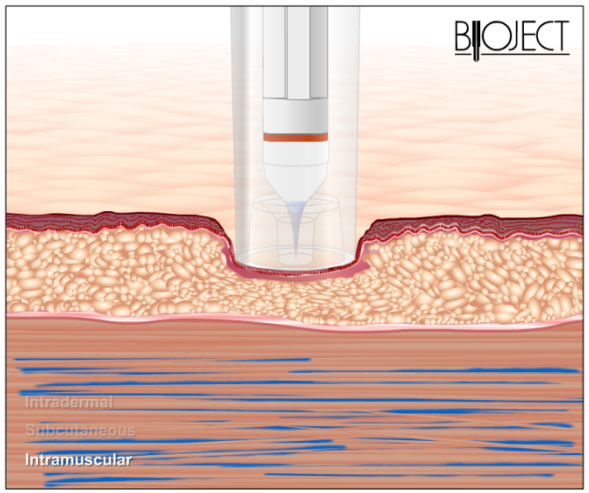
PharmaJet DSJI injection in action.



ID injection with a DSJI.



SC injection with a DSJI.



IM injection with a DSJI.

All photos: Biojject

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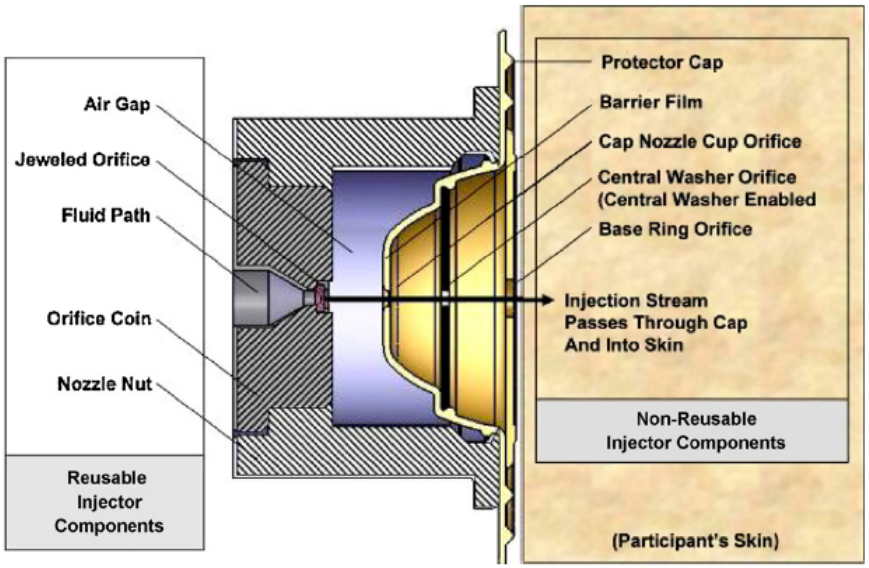
Jet injectors—lessons learned: MUNJIs

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



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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 injection; 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 medicament. Concerns for their potential to transmit blood borne pathogens led to develop
tions. The HSI-500®, referred to here as a pro
a disposable cap as a shield between the neu
risk of contamination. This study aimed to de
contamination in post-injection ("next perso
HBV-carrier adults. Tolerability and pain were
PCNFI failed to prevent contamination in the
tions were very well tolerated, with most fo
(7.8%). 55.2% of participants experienced no p
injection.
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By 1999, roug
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cause million

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All images: Pulse NeedleFree Systems

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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

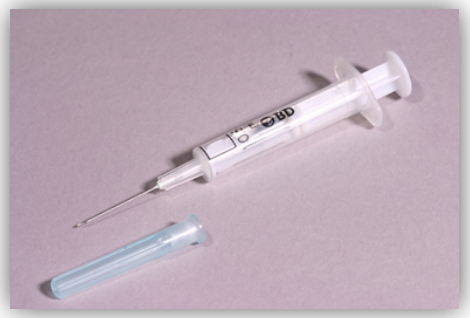

Photo: Becton Dickinson (BD)

Photo: PharmaJet

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

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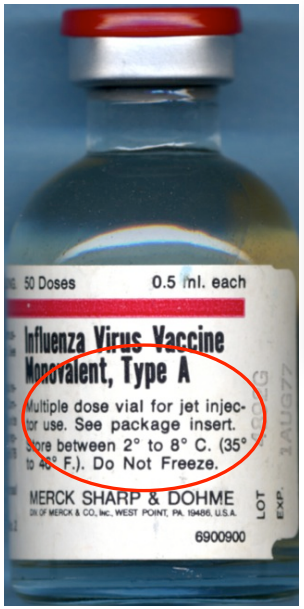
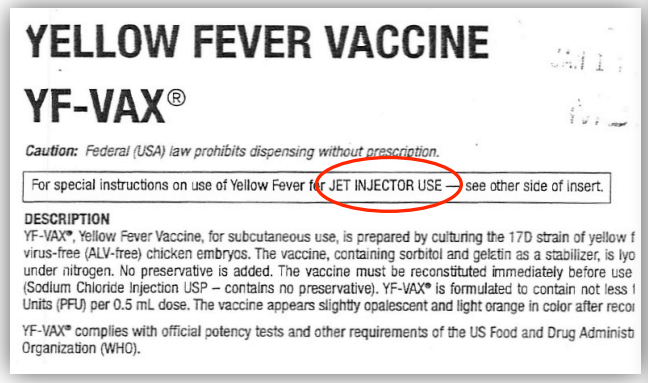
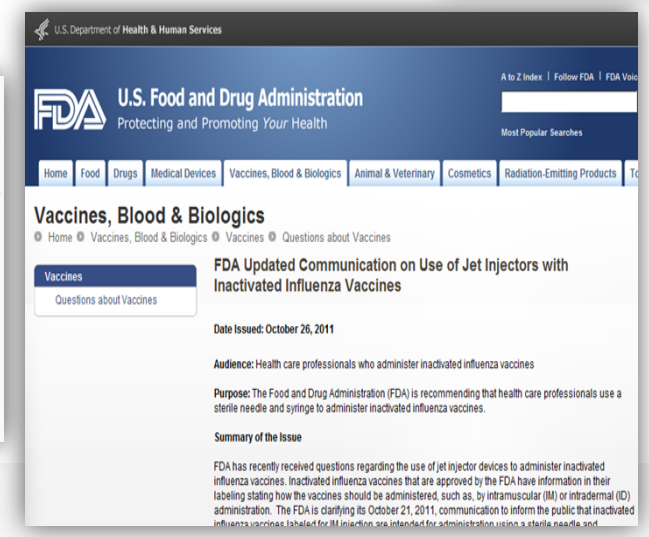
Jet injectors—lessons learned: DSJIs

Regulatory pathway shift

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







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.