

Plenary Session 2: Landscape

Intradermal devices

Next-Generation Vaccine Delivery Technology Meeting
Geneva, Switzerland

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Photos (clockwise from top left): West Pharmaceuticals; Star Syringe; NanoPass Technologies; Sanofi Pasteur

Intradermal devices: Description

Technology description:

- Intradermal (ID) delivery—a modified approach to traditional Mantoux needle and syringe (N&S) injection.
- Examples include:
 - BD Soluvia™.
 - NanoPass.
 - Debiotech Nanoject
 - West ID adapter.
 - Star Syringe ID syringe.
 - Disposable syringe jet injectors.



Photo: West Pharmaceutical Services

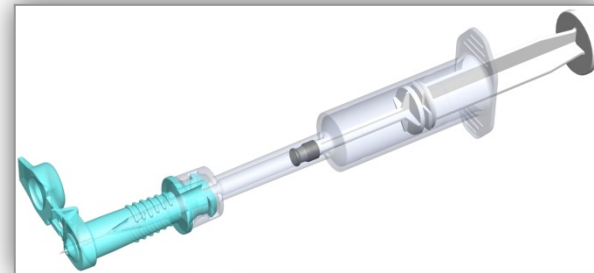


Photo: Star Syringe



Photo: NanoPass

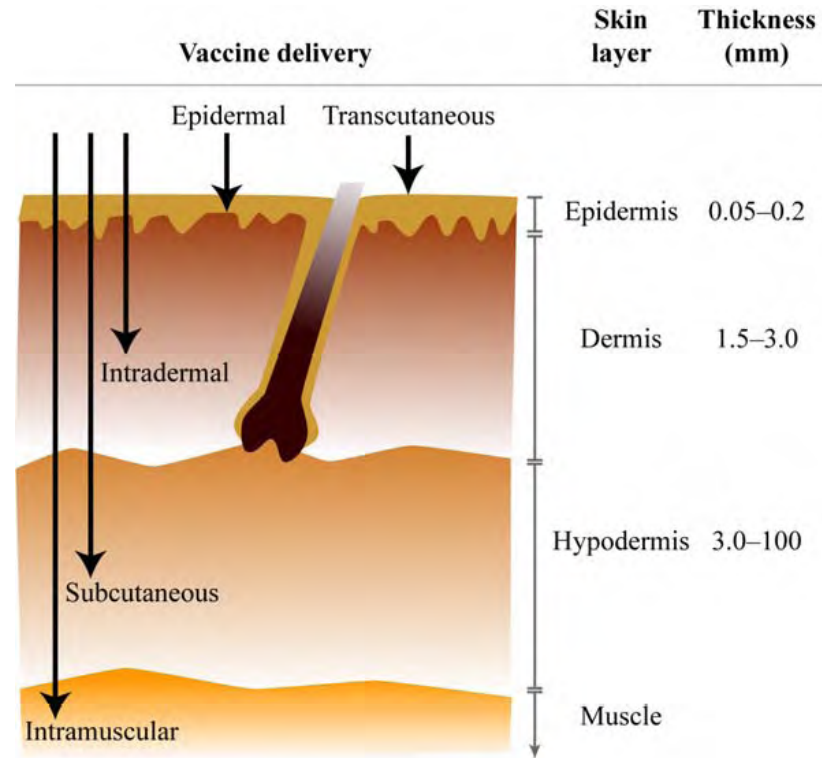


Photo: Becton Dickinson (BD)

ID devices: Mechanism of action

Overview:

- Dermis is rich in antigen-presenting cells (APCs).
- Licensed vaccines delivered via ID: BCG, influenza (ID Fluzone), rabies, and smallpox.
- Mantoux technique—tuberculin test.
- Training specific to health care workers—can be a challenging technique.



Images: PATH

ID devices: BD Soluvia™

Description:

- 1.5 mm mini-needle in pre-filled syringe with needle-shield feature.

Status:

- Licensed to Sanofi Pasteur—currently used for influenza vaccine for adults (Intanza®/IDflu®/Fluzone® Intradermal). Global introduction: US/Canada, EU, etc..



All photos: Sanofi Pasteur

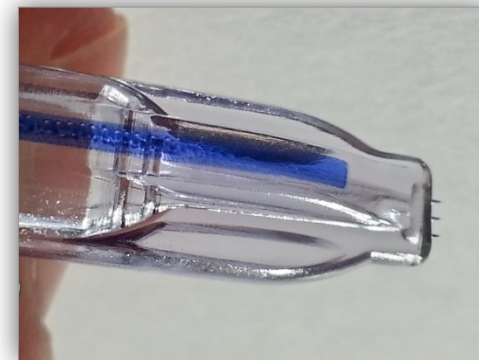
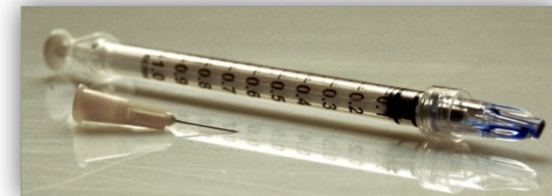
ID devices: NanoPass MicronJet (MJ600)

Description:

- Hub with hollow microneedles which attaches to a luer syringe.

Status:

- Regulatory clearance (FDA/CE Mark) — market available.
- Used in clinical trials with influenza vaccine and IPV.



All photos: PATH

ID devices: Debiotech Nanoject

Description:

- Hub with hollow microneedles which attaches to a syringe or infusion pump.

Status:

- In development.



All photos: Debiotech

ID devices: West ID adapter

Description:

- Injection aid/adapter for a conventional needle and syringe. Syringe is filled prior to attaching adapter for delivery.

Status:

- Regulatory clearance (FDA/CE Mark)—market available.
- Clinical data (performance).
- Auto-disable version in development.

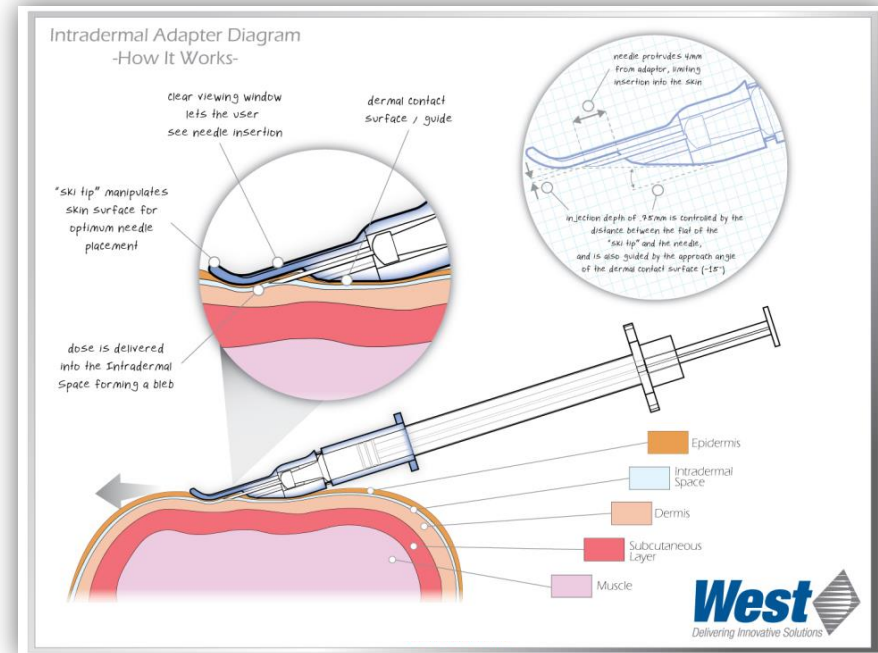


Photo: PATH



All images except where noted: West Pharmaceutical Services

ID devices: Star Syringe

Description:

- Integrated plastic needle allows for filling from vial. Device has 1.5 mm mini-needle with cap. Includes plunger autodisable feature.

Status:

- In development—prototypes soon to be ready for research use.



All graphics: Star Syringe

ID devices: Disposable-Syringe Jet Injectors (DSJIs)

Description:

- Needle-free syringe uses pressure to deliver vaccine intradermally. Powered by a reusable handpiece (manual or gas-powered.)

Status:

- Used in clinical trials for ID delivery of vaccines including IPV, dengue, BCG, influenza, and hepatitis A.



Photos: PharmaJet, Bioject, and MIT

ID devices: Benefits and challenges

Benefits:

- Increased ease of ID delivery.
- Allows for reduced dose ID (↓ cost).
- Compatible with existing vaccine vial/ampoule presentation (Star Syringe/West/NanoPass/DSJIs)—no reformulation.



Photo: PATH

Challenges:

- BD Soluvia—prefilled format (↑ cost).
- Perception of difficulty of needle and syringe ID delivery (need for alternative devices).
- Represents additional cost over needle and syringe.

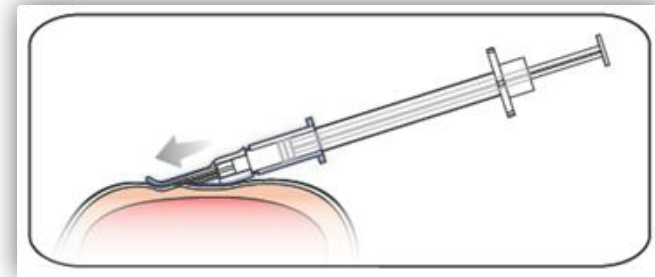


Photo: Star Syringe

ID devices: Opportunities and way forward

Challenges for global public health:

- Vaccine availability and cost (examples: rabies, IPV).
- Mass campaign ID N&S.



Graphic: West Pharmaceuticals

Technology availability:

- Immediate and near-term.
- Application to additional vaccines, as well as program procurement and use.
- Include in future clinical research.



Photo: PATH