# Plenary Session 2: Landscape

## Integrated Reconstitution Devices

**Next-Generation Vaccine Delivery Technology Meeting**

Geneva, Switzerland

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February 18th, 2014

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# Integrated reconstitution devices: Description

## Technology description:

- Integrated reconstitution (IR) devices – a prefilled device designed to store, mix and deliver two or more components of a vaccine, most commonly a dry powder and diluent.

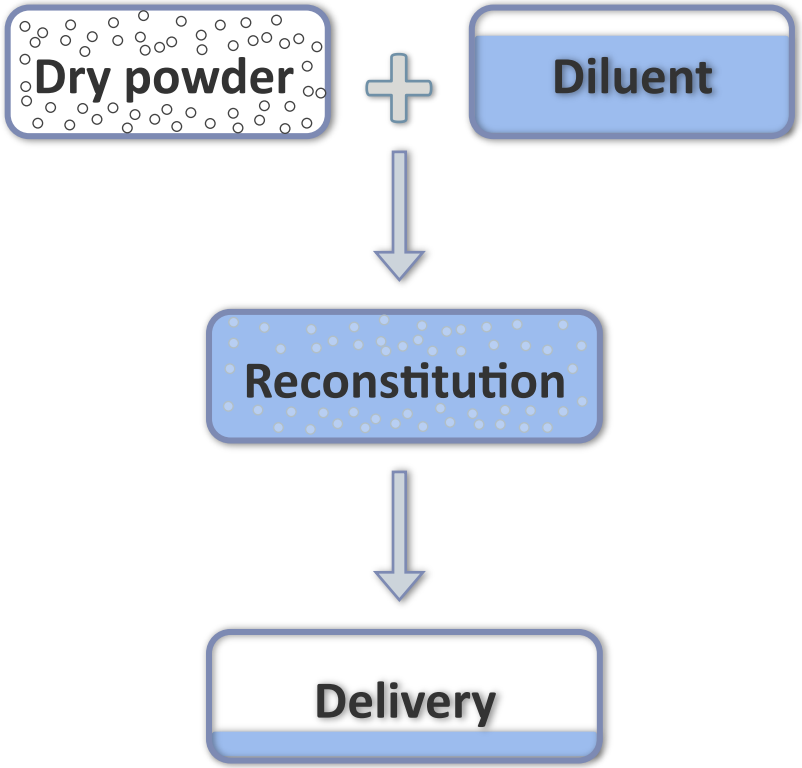
## Examples include:

- Vial
  - Eulysis
- Prefilled Syringe
  - VaccJect
  - LyoGo
  - LyoTip
- Point of delivery
  - AktiVax ARCH

# IR devices: Mechanism of action

## Overview:

- Dried vaccines requiring reconstitution place additional burden on the user in order to achieve safe delivery.
- Integrated reconstitution devices reduce the burden on the user by combining the reconstitution and often the delivery steps into a single device



# IR devices: Eulysis Single Vial System

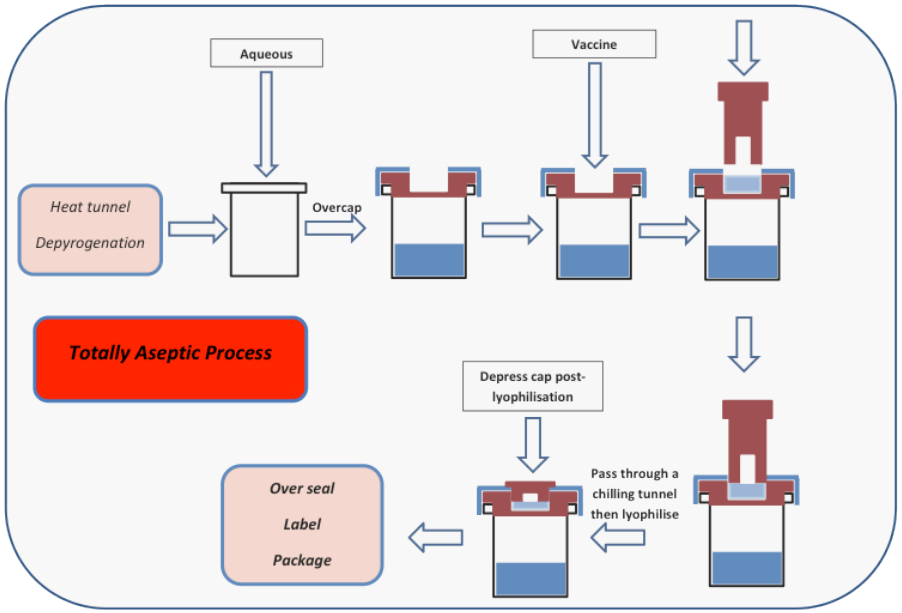
## Description:

- Glass vial system
- Cake stored in cap, diluent stored in vial
- Activated by pressing cap
- Delivery by separate needle and syringe

## Status:

- E. coli vaccine tested in SVS
- Accelerated stability studies
- Available for research

All graphics: Eulysis



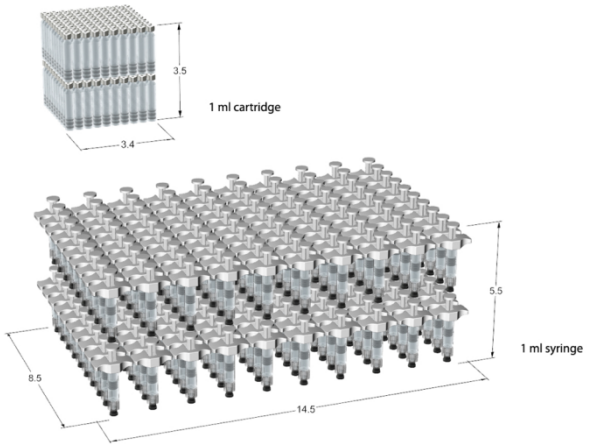
# IR devices: Duoject VaccJect

## Description:

- ISO standard 1 ml glass cartridge contains powder & diluent
- Delivery using single use, retractable needle delivery device


## Status:

- ISO facilities in France and Canada
- Seeking 510(k) approval

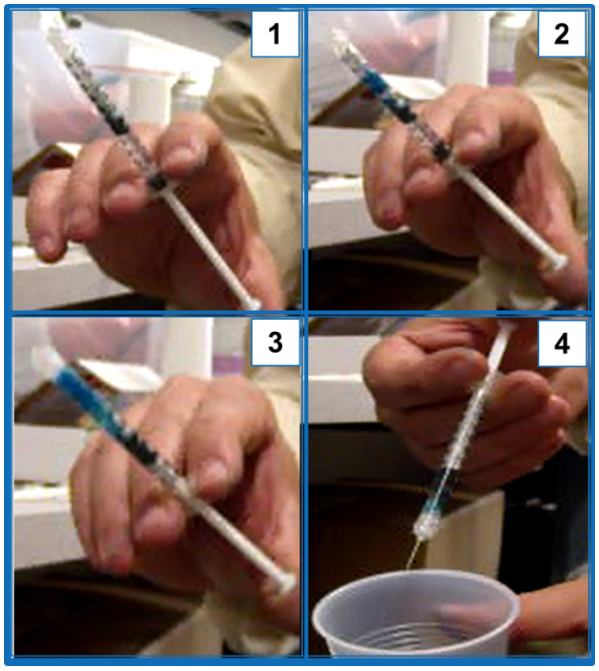



All photos:Duoject

# IR devices: LyoGo

## Description:

- Glass cartridge contains powder & diluent
- Valve inside intermediate stopper activates with pressure
- Screw on plunger and needle




## Status:

- Available for research

All graphics: Lyogo



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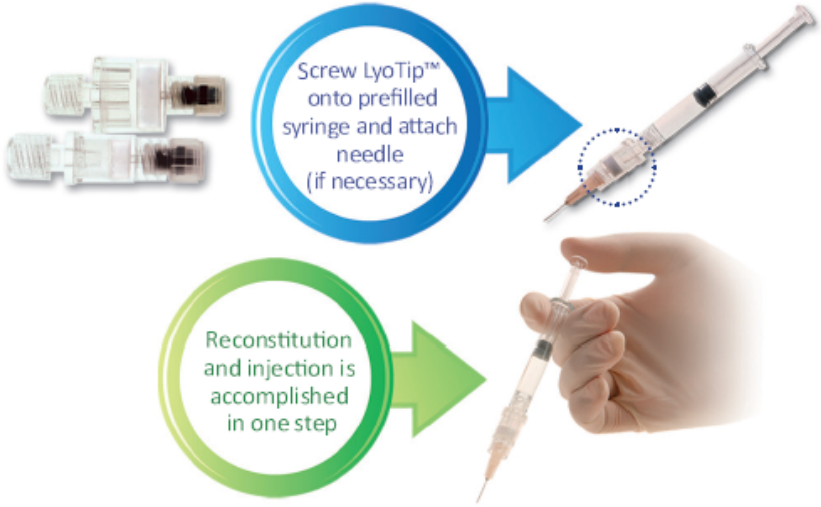
# IR devices: LyoTip

## Description:

- Lyophilized vaccine contained within screw cap
- Attached to luer-lock prefilled syringe
- Reconstitution and delivery step combined

## Status:

- Commercially available




All graphics: LyoTip

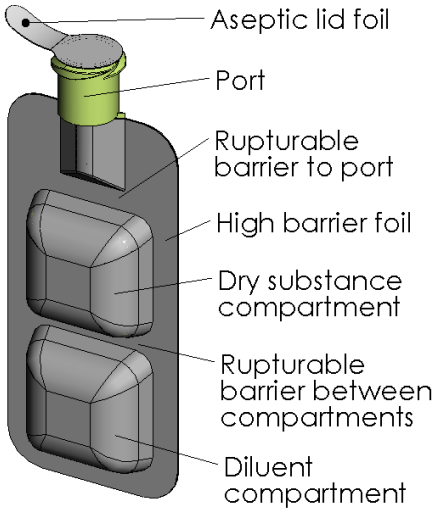
# IR devices: AktiVax ARCH

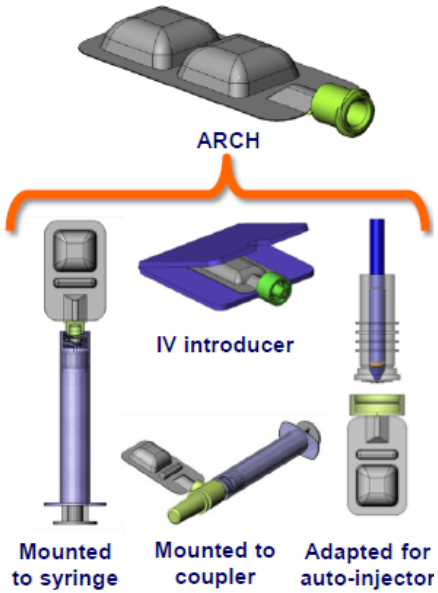
## Description:

- ARCH (Aseptic Reconstitution Package Hybrid)
- Frangible seal between compartments
- Deliver using variety of methods

## Status:

- In development
- SBIR funding




All photos: AktiVax

# IR devices: Benefits and challenges

## Benefits:

- Reduced burden (and errors) associated reconstitution and delivery
- Can be used with existing or new vaccines
- Compatible for all routes of administration

## Challenges:

- Complexity and cost
- Maintaining integrity of dry powder
- May require non-standard filling lines
- Cold chain volume

# IR devices: Opportunities and way forward

**Challenges for global public health:**

- Value proposition
- Vaccine application (cost/benefit trade-off)

**Technology availability:**

- Most technologies are available for clinical research
- Application to additional vaccines