

Compact Pre-filled Autodisable Device (cPADs – Uniject)

DCVMN WORKSHOP on New Packaging Technologies, 11 May 2022

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PACKAGING DEPARTMENT PT BIOFARMA (PERSERO)



WHO WE ARE

Supported by competence, experience and learning processes for more than 130 years, we are here as part of the struggle, in saving and improving the quality of human life, playing an important role in building the nation's health, so that its existence is maintained from time to time. With the philosophy of "**Dedicated to Improve Quality of Life**" we are ready to dedicate our hard work to global health security, so that through Biotech for a Better Future provides solutions for global prosperity.



Largest in southeast asia



The only vaccine and antisera producer in indonesia



Bio farma vaccine has been used in more than 130 countries in the world



The center of excellence for vaccine and biotechnology research for oic countries

GMP, GLP, GCP, ISO9001, ISO14001, OHSAS 18001, GCG, ERM, CSR Based ISO 26000

Implement integrated system

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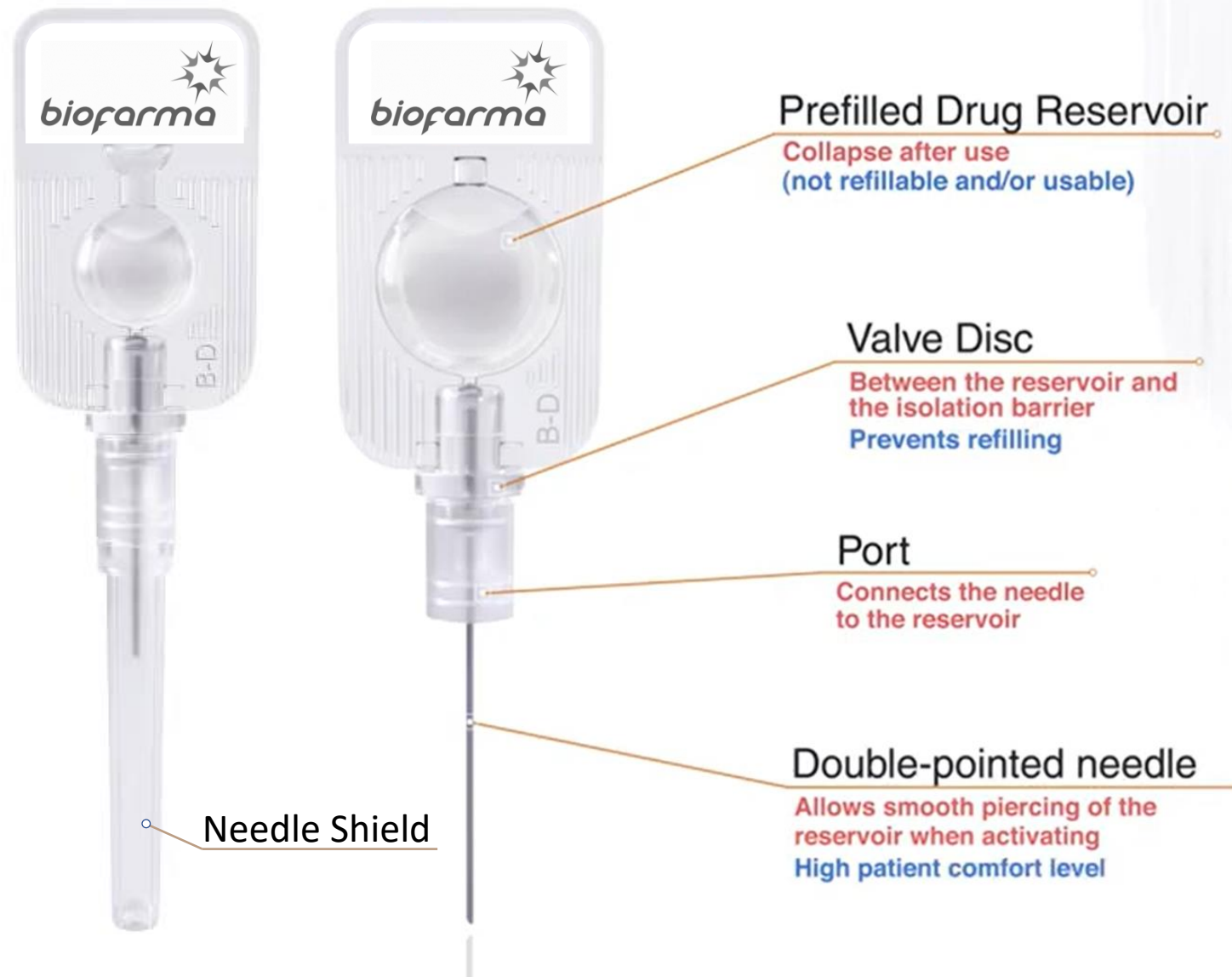
Hepatitis B Vaccine Recombinant



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AUTO-DISABLE PREFILLABLE INJECTION SYSTEM

Features and components

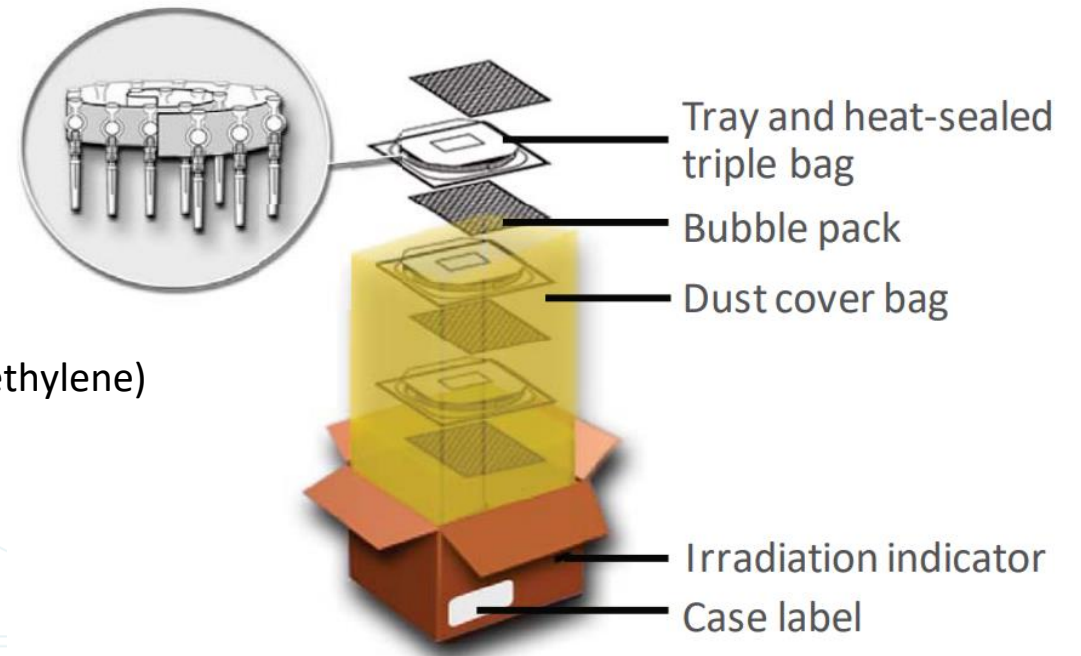


SPECIFICATION



Uniject 1 mL 23GA Long Needle (1") Uniject 0.5 mL 25GA Short Needle (5/8")

- Capacity : 0.5 mL
- Material
 - Reservoir : LLPDE (Linier Low Density Polyethylene)
 - Port : Low Density Polyethylene
 - Needle : 304 Stainless Steel
 - Hub : Polystyrene
 - Needle Shield : Polypropylene



BD Uniject™ System is delivered Sterile (Gamma Radiation), Clean, and Ready to Fill (SCF™)

FILLING PROCESS



Filling machine for uniject

Speed 120 unit/ minutes

FILL

SEAL

Receive sterile, non-pyrogenic reel of the BD Uniject™ System in cartons

Remove carton and outer dust bag;
Transfer to immediate class room

Remove outer heat-sealed bag;
Transfer bagged reels to sterile area

Remove inner bags;
Load reel on filling machine

Fill and heat-seal the BD Uniject™ System

Accumulate in reel form

Transfer reel out of sterile area

Store reel or continue
to packaging operation

PACKAGING PROCESS



Labelling & Trimming machines
Speed 80-300 unit/ minutes

Apply front label

Print Lot Number and expiration date

Cut strip into individual units



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PACKAGING PROCESS

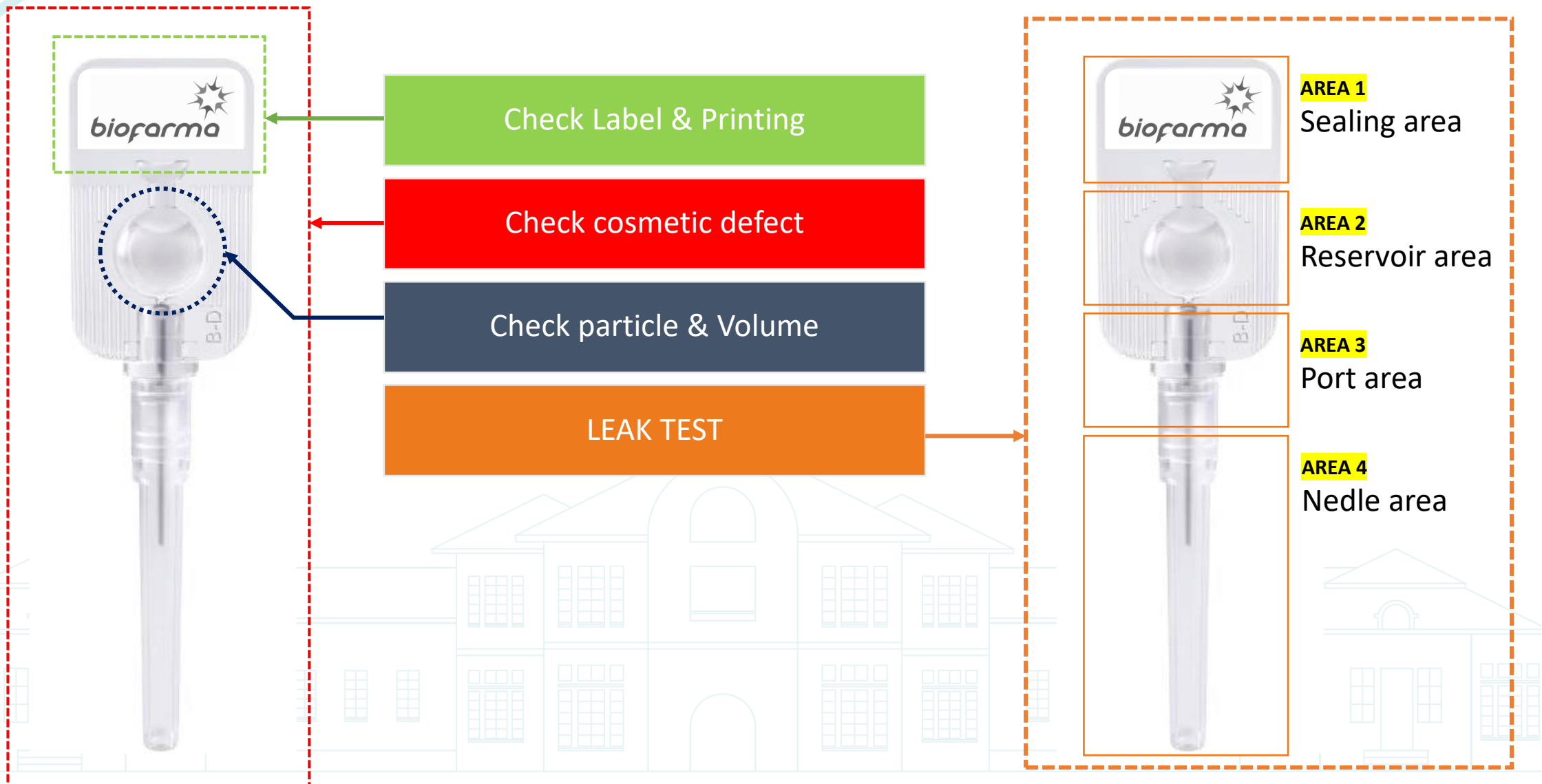
Visual Inspection & Leak Test



BUMN
KEMENTERIAN
BADAN USAHA
MILIK NEGARA
REPUBLIK
INDONESIA



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PACKAGING PROCESS

Pouching & Packaging

VVM label applicator

ADS inserting to foil

Foil Hot Sealing

Print Lot Number and expiration date

Cut foil into individual pouch

Heat Sealing Machine
Speed 80-300 unit/ minutes

Manual Packaging to Carton Box



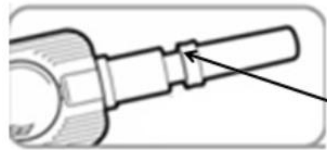
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ACTIVATE THE UNIJECT

Pouching & Packaging



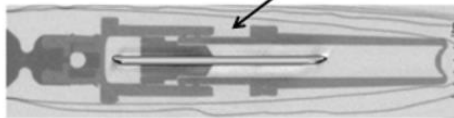
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Drawing



Photograph



Inside the Uniject (X-ray)

- The needle is pushed through a barrier that holds the DMPA.
- The DMPA goes into the needle.
- The injection will work.

Gap is closed



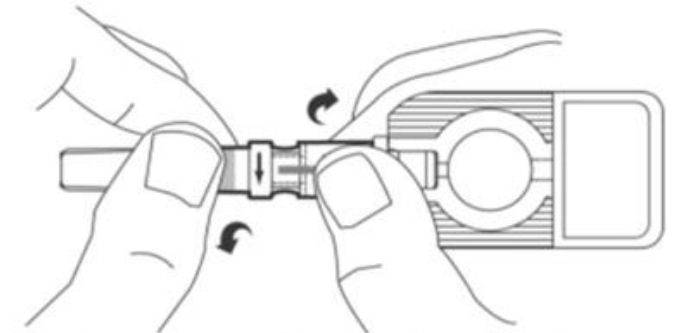
Inside the Uniject (X-ray)

STEP 1



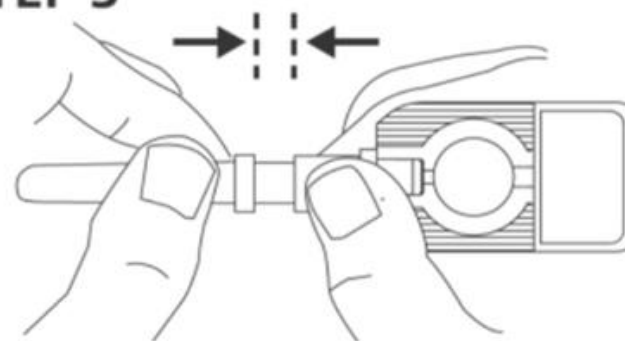
Hold Uniject™ by the port, shake to homogenize liquid suspension.

STEP 2

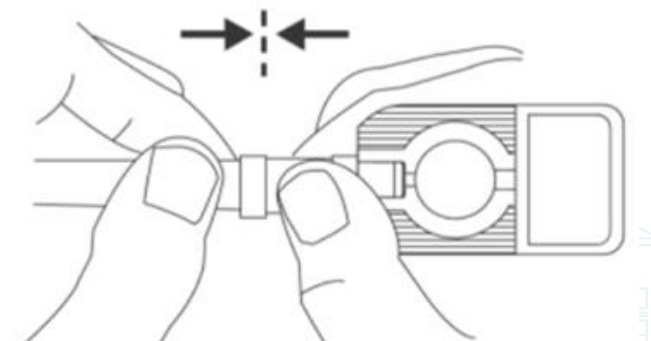


Twist tamper-evident seal to break it.

STEP 3



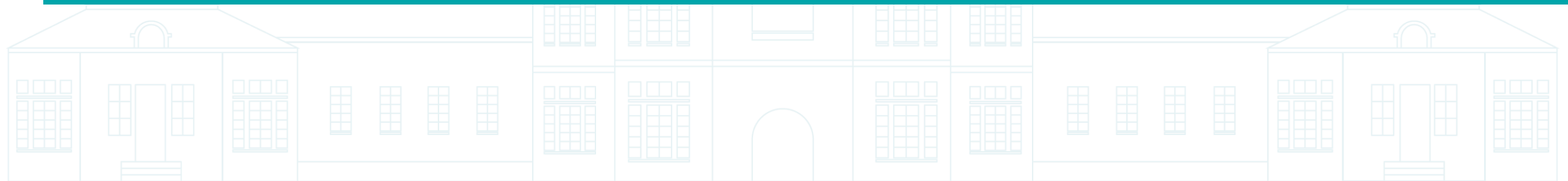
With a firm, rapid motion, push the needle shield into the port until the gap between the needle shield and port closes completely.



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- Easy to use
- High accuracy dose
- Low volume overflow
- Easy to destruct
- Eases drug delivery
- Contributes to injection safety



PRICE COMPARISON & ESTIMATION



$$\% \text{ Comparison} = \frac{\text{Blank uniject price}}{\text{COGS Hep B Vaccine}}$$

Conclusion= the comparison is **under 25 %**



THANK YOU



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