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# Instructions for Use

## — Disposable Pen Injector Assembly —

Specification & Model: NIVD series

Preparation		Time	
Review		Time	
Approval		Time	

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# Disposable Pen Injector Assembly

## 1. Preface

- Thank you for choosing the Disposable Pen Injector Assembly from Wuxi NEST Biotechnology Co., Ltd. Please read instructions for use carefully prior using the Disposable Pen Injector Assembly for the first time, or use it under professional guidance.
- This product is disposable.
- This product is compatible with a standard 3 mL cartridge that complies with ISO 11608-3:2022, i.e. only to be used with HUMALOG (U-100, insulin lispro) injection.
- This product is compatible with a pen needle that complies with ISO 11608-2:2022, Hantech Medical Device Co. ,Ltd(K222739) ” ,The product specifications are 32G\*4mm, 31G\*4mm, 31G\*5mm, and 31G\*6mm.The pen needle’s label information is as follow:



- This product is intended for adult patients with self-care ability and professional caregivers under prescriptions.
- If any part of your Disposable Pen Injector Assembly is fractured or broken, do not use it and contact the after-sales service center of Wuxi NEST Biotechnology Co., Ltd. or your health care professionals.

## 2. Product Introduction

### Product Model:

NIVD-01, NIVD-02, NIVD-03, NIVD-04, NIVD-05, NIVD-13



NIVD-01( Blue, 80 units)



NIVD-02 (Grass Green, 75 units)



NIVD-03 (Orange, 74 units)



NIVD-04 (NEST Green, 60 units)



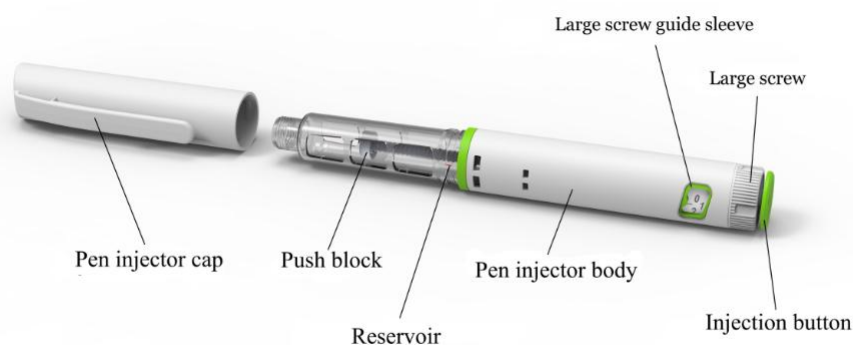
NIVD-05 (Yellow, 50 units)



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NIVD-13 (Purple, 37 units)

**Structural Diagram:**



**Product Structure:**

This product consists of the pen injector body, a push block, injection button, dose display window, dose adjustment knob, reservoir and a pen injector cap.

**Product performance:**

Main performance:

1. Visual feedback:

The scale line should be evenly distributed, and the scale line and corresponding value of the set dose should be clearly observed through the window. After injection, the scale line and corresponding value should be returned to zero.

2. Reliability of the injection dose knob:

The injection dose setting knob shall make a click sound once for each whole number of turns, and the scale shall not change when no external force is applied to the injection button.

3. Injection force:

The maximum injection force of the injection button is lower than 30N. During injection, the button can be pressed smoothly to the end at one time without sticking.

4. Dose accuracy:

The dose accuracy shall be within  $\pm 5\%$  of the set injection dose.

**Product Indications for Use:**

The Disposable Pen Injector Assembly is a disposable pen injector designed for single patient use by diabetics for the subcutaneous self-injection of a desired dose insulin. The disposable pen injector assembly uses 3mL cartridge of HUMALOG™ (U-100, insulin lispro for injecton) , and a single use detachable and disposable insulin pen needle (supplied separately).The pen injector allows the user to dial the desired dose up to 80 units in 1 unit increments. It is intended for general population.

### 3. Product Application

#### 3.1 Preparation

Wash hands and verify that the following items are ready before injection:

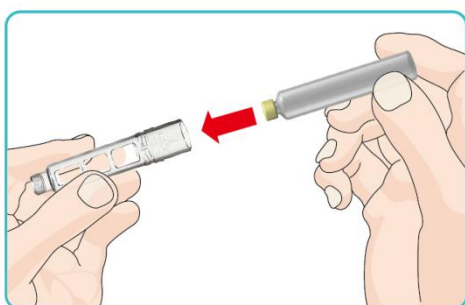
- Disposable Pen Injector Assembly
- 3mL cartridge
- New needle
- Alcohol cotton pad

#### 3.2 Check the product

Check the label on the product to confirm the correct medication and that the product is within its expiration date.

#### 3.3 Insert the cartridge

Insert the smaller end of the 3 mL cartridge into the reservoir



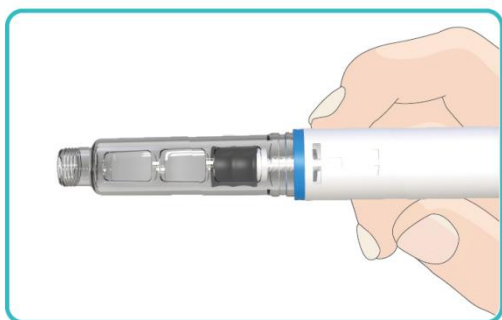
Note:

- Before loading, the cartridge shall be checked and ensure to be free from fracture and damage.

#### 3.4 Install the reservoir

Advance the Pen body and reservoir in a straight line to lock them together.

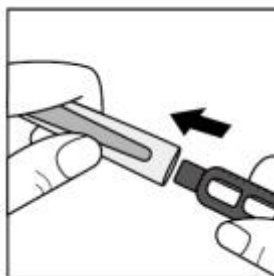
Wipe the rubber seal at the end of the cartridge with an alcohol cotton pad.



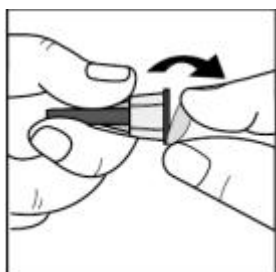
### 3.5 Install the needle

Only use needles suitable for this product. Use a new sterile needle for each injection.

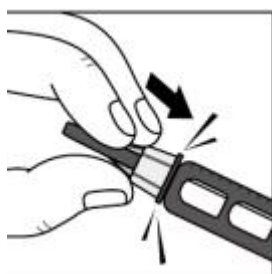
- Remove the pen cap and wipe the rubber surface of the 3mL cartridge with 75% surgical spirit.



- Remove the needle protective film.



- Push the needle straight into the pen body. Turn the needle until the needle is tight.

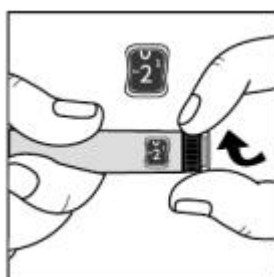


Note: Make sure the needle is securely positioned after tightening. If the needle is not

installed in a straight line, the push block will be damaged and the solution will leak out or the needle will be damaged.

### 3.6 Perform safety test

- Perform a safety test before each injection to ensure the proper functioning of the injection pen and needle, and to remove air bubbles.
- Rotate the dose adjustment knob to select a dose of 2 units.
- Remove the outer and inner needle caps.

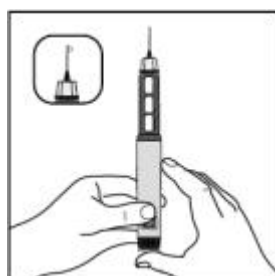


NIVD-01, NIVD-04



NIVD-02, NIVD-03, NIVD-05, NIVD-13

- Hold the pen with the needle pointing upward and flick the medication cartridge with your finger several times to move any air bubbles towards the needle. Then, press the injection button all the way down until the window displays the number "0".
- If the liquid overflows from the tip of the needle, the product can be used normally. If the liquid does not overflow, repeat the air removal process until liquid overflows.



### 3.7 Set the dose

- Rotate the dose adjustment knob to display the desired dose on the window. Each grid represents a change of 1 unit in dose. The minimum set dose is 1 unit, the maximum is list as follows. If the required dose exceeds the maximum, multiple injections should be performed.

Product Model	maximum
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NIVD-01	80 units
NIVD-02	75 units
NIVD-03	74 units
NIVD-04	60 units
NIVD-05	50 units
NIVD-13	37 units

- During the safety test, the window should display "0". The dose can then be selected.



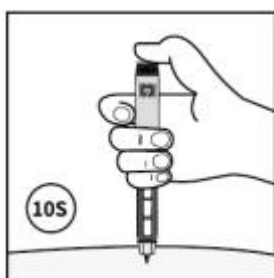
Note:

- To avoid leakage of medication, never press the release button while adjusting the dose. If your required dose exceeds the remaining amount in the medication cartridge, use a new pre-filled pen to inject the remaining dose.

### 3.8 Injection

Before injection, please read this step carefully or use the injection technique recommended by your doctor or healthcare professional.

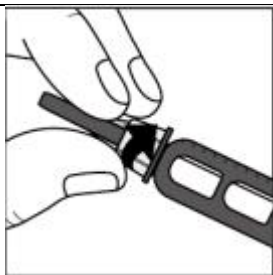
- Hold the pen and ensure that the window is visible during the injection. Insert the needle into the skin.



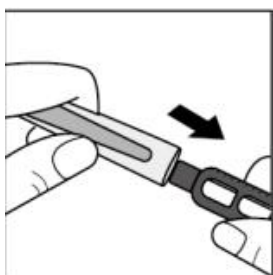
- Press the release button all the way down.
- Hold the release button for 10 seconds before removing the needle from the skin. This ensures that an adequate dose of medication is injected.

### 3.9 Disposal of the needle

- After each injection, remove the needle to prevent contamination, infection, air entering the medication cartridge, and medication leakage. Do not reuse the needle.



- Exercise caution when removing and disposing of used needles. Follow recommended safety methods to minimize the risk of needlestick injuries and disease transmission.
- Replace the pen cap on the pre-filled injection pen.



## 4. Precautions

### 4.1 Symbols used on labels



User should consult the important warning information in the IFU.



Consult the IFU.



Indicates the medical device is for provision and use only at a licensed physician's direction and under medical supervision.



Non-sterile.

### 4.2 Safety requirements

- When using with needles, do not insert the needle into fragile areas such as the eyes to avoid injury.
- Please use medications that comply with national laws and regulations in conjunction with this product.

- Keep this product out of reach of children.
- This product is only suitable for pen injector assembly needles.
- Sharing pen injector assemblies or needles with others is strictly prohibited to prevent cross-infection.



If the patient experiences adverse reactions during use, please seek medical treatment in time.

### 4.3 Usage requirements

- Please read the instructions for this product carefully before use.
- Please strictly follow the operating steps.
- Do not forcefully twist the dose distribution device, as this may prevent proper use.
- Use 75% surgical spirit and a medical cotton swab to disinfect the skin surface before use.
- Do not touch the matching needle directly with your hands to prevent contamination.
- Dispose of the medication cartridge properly according to relevant regulations after use.
- This product is intended for use by self-managed patients in accordance with medical advice.
- If the patient cannot use this product properly due to visual impairment or other reasons, please seek assistance from another person following the instructions.



1. Please use the standard medication cartridge and disposable liquid injection needle in conjunction with this product.

- 2. Please read the instructions for use of the accompanying medicine cartridge and needle carefully.

### 5. Maintenance and storage

- Store the unused pen injector assembly without HUMALOG at room temperature. Avoid moisture, dust, extreme cold or heat, and direct sunlight.
- Store the unused pen injector assembly with HUMALOG in the refrigerator at 2°C to 8°C. Do not freeze your insulin. Do not use if it has been frozen.
- Store the Pen you are currently using in the refrigerator at 2°C to 8°C or at room temperature[up to 86°F (30°C)]. Keep away from heat and light. Throw away thePen you are using after 28 days, even if it still has insulin left in it.

- Clean the pen cap, pen body, and pen case with a damp cloth. Do not wipe the pen body and dose window with alcohol.
- Do not use alcohol, hydrogen peroxide, bleach. Do not immerse the pen in liquid or cover it with liquid. Do not use oil or other lubricants to avoid damaging the pen injector assembly.
- Store the medication cartridge according to the instructions in the medication cartridge manual.

## 6. Troubleshooting and solutions

Number	Symptom	Solution	Cause
1	Unable to push the injection button screw rod	First, confirm if the cartridge chamber is fully installed. Next, check if the needle is blocked. If the problem persists after installation, please contact our designated agent.	Incomplete installation of the cartridge chamber. Needle blockage prevents injection.
2	Unable to rotate the dose adjustment knob	Confirm if there is any foreign object jamming the dose adjustment knob. If not, please contact our designated agent.	Foreign object obstructs the rotation of the dose adjustment plunger. Internal mechanical structure may be misaligned.

## 7. Quality assurance

- If users encounter quality issues caused by manufacturing during the warranty period while following the storage and usage conditions specified in this manual, they can contact our company or our designated agent for assistance.
- In case of product malfunction, please contact our company or our authorized agent promptly. Do not attempt to open the product components for repair without permission from our company. Our company will not be responsible for any repairs performed without authorization or by non-designated agents.

- During the product warranty period, if damage to the product occurs due to failure to comply with the instructions in this manual, the user will be responsible for material costs, logistics fees, travel expenses, etc.
- The content of this manual is subject to change without further notice in case of registration changes, etc.

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