

## Manufacturer

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## EU Authorized representative

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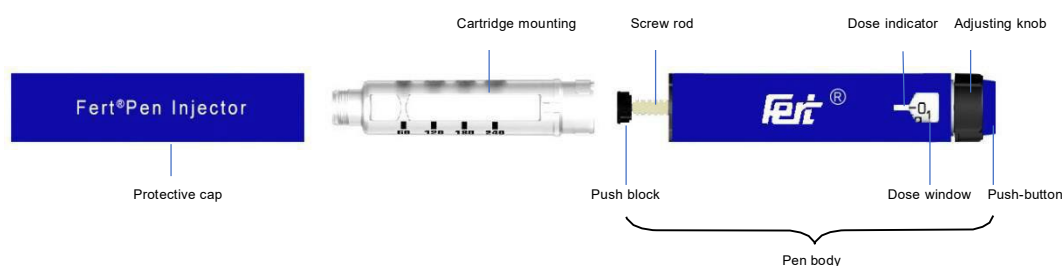
## 1. PRODUCT NAME

Product name: Pen Injector

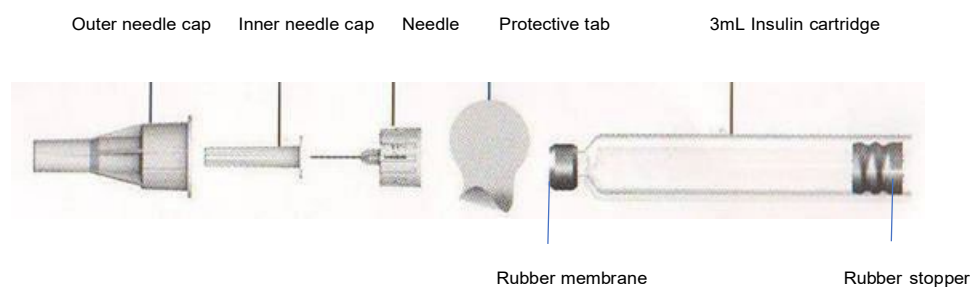
## 2. DEVICE DESCRIPTION

The Pen Injector is a reusable mechanical pen injector capable of injecting a dose of up to 60 units of insulin, in 1 unit increments, from a 3 mL insulin cartridge. Pen Injector is designed to be used with all standard pen needles according to ISO11608-2, and compatible with standard 3 ml cartridges according to ISO 11608-3. Pen Injector is available in green color and blue color. This allows you to have a different color Pen Injector for each type of insulin you use. Pen Injector is designed to simplify insulin therapy. The intended dose is mechanically set by rotating a Push-button. The insulin is injected by depressing the Push-button which via mechanical coupling causes the piston in the insulin cartridge to move forward thereby expelling the intended dose.

The structure of the Pen Injector:



The structure of the pen needle (supplied separately) and insulin cartridge (supplied separately):



### **3. INTENDED PURPOSE**

#### **3.1 MEDICAL INDICATIONS**

Designed for a desire dose of insulin self-injection by diabetics and injection by professional caregiver. The pen injector uses 3.0 mL cartridges of insulin and a single use, detachable and disposable pen needle (supplied separately).

#### **3.2 CONTRAINDICATIONS**

There are no contraindications directly related to the pen injector currently. The use of a pen injector is contraindicated if the opinion of a qualified physician is that such applications pose a risk to patients, for example due to the patient's general condition.

#### **3.3 INTENDED PATIENT POPULATIONS**

The Pen Injector is used for individuals with diabetes.

#### **3.4 INTENDED USERS**

The Fert® Pen Injector is intended to be used by diabetics for self-injection of a desire dose of insulin. In addition, the device can also be used by professional caregiver under the guidance of doctors in a hospital, home environment or healthcare facility.

### **4. CLINICAL BENEFITS TO BE EXPECTED**

The expected clinical benefit of the device is to maintain patient's blood sugar balance through insulin injections

### **5. RESIDUAL RISKS AND UNDESIRABLE SIDE-EFFECTS**

Residual risks and undesirable side-effects that may be related to the use of Fert® Pen Injector can include but may not be limited to the following:

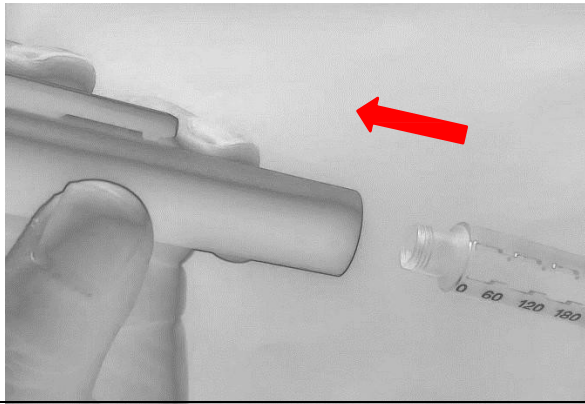
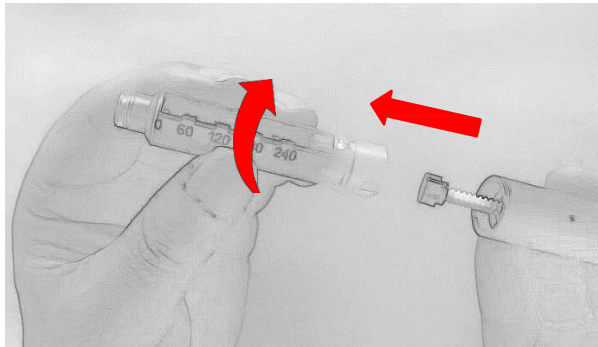
- Adverse reactions caused by wrong insulin dose
- Bleeding
- Infection
- Pain
- Stabbed
- Swelling

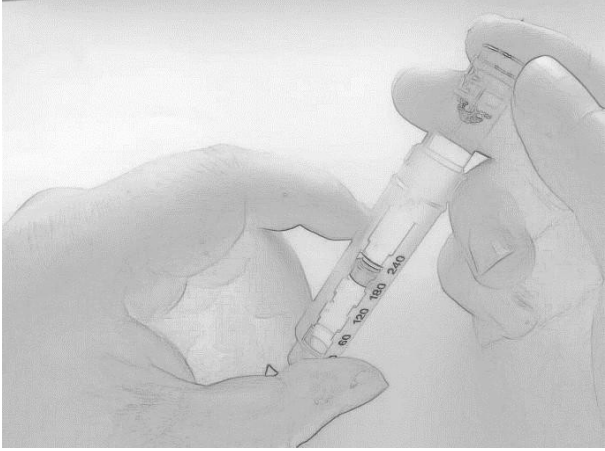
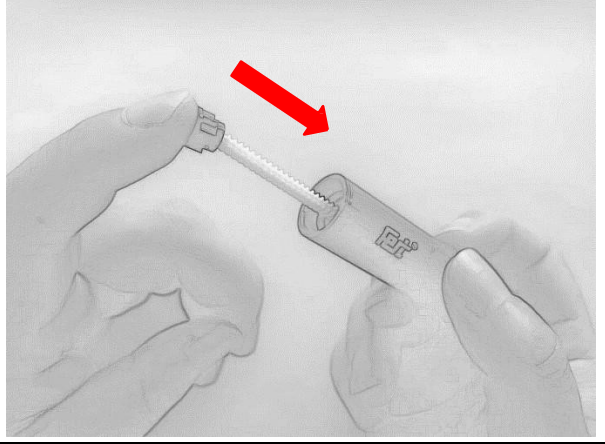
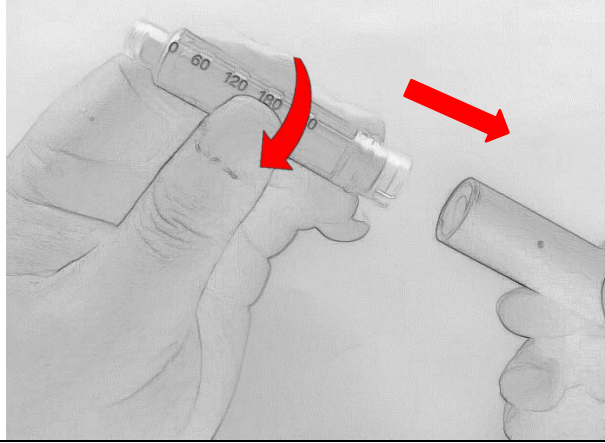
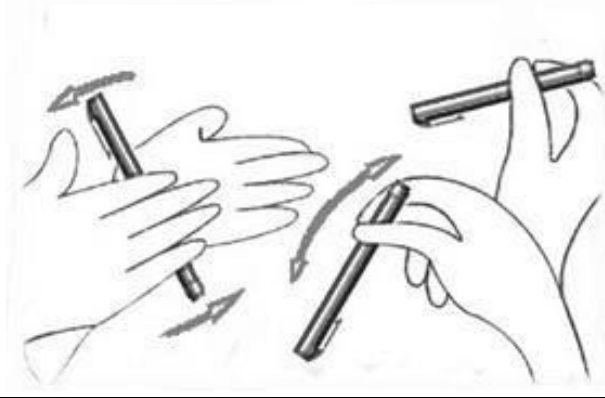
### **6.MODEL**

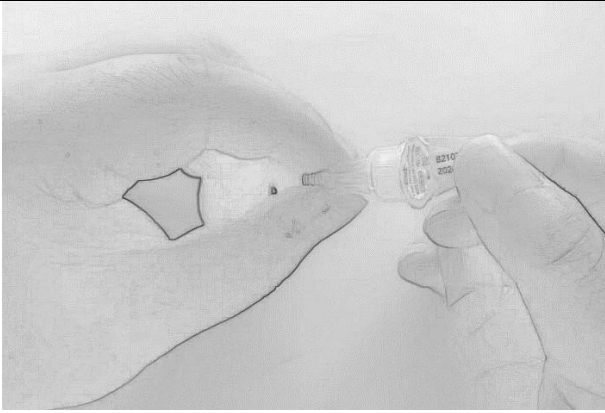
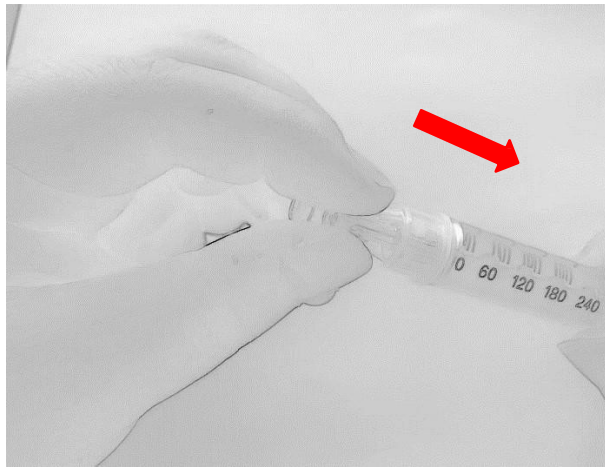
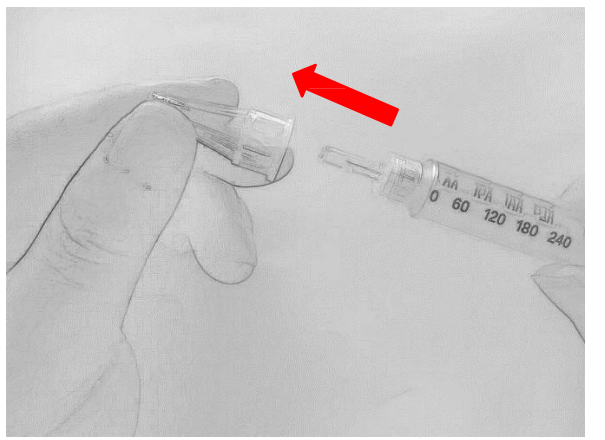
There are only 2 models of Pen Injector, divided according to the color of pen body: Blue Pen Injector and green Pen Injector. The only difference between these two models is color of pen body.

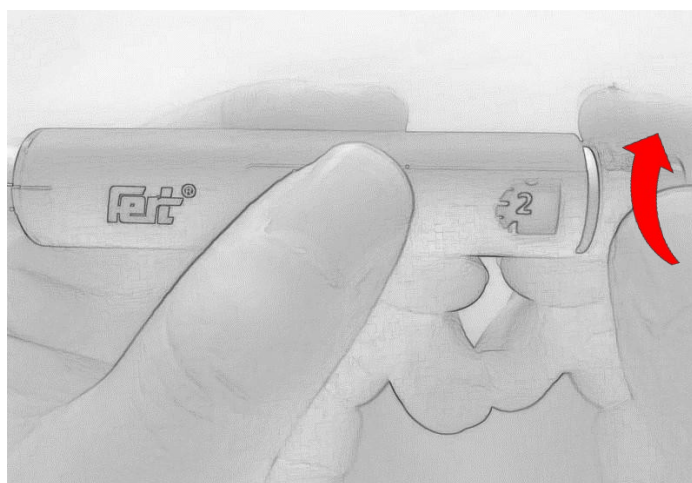
## 7. INSTRUCTION FOR USE

It is important to read, understand, and follow the instructions below before using the Fert® Pen Injector. Failure to follow instructions may result in getting too much or too little insulin.

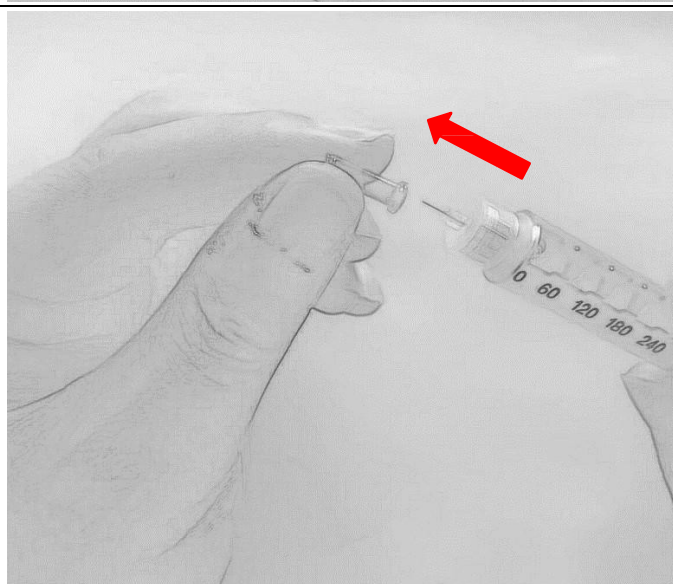
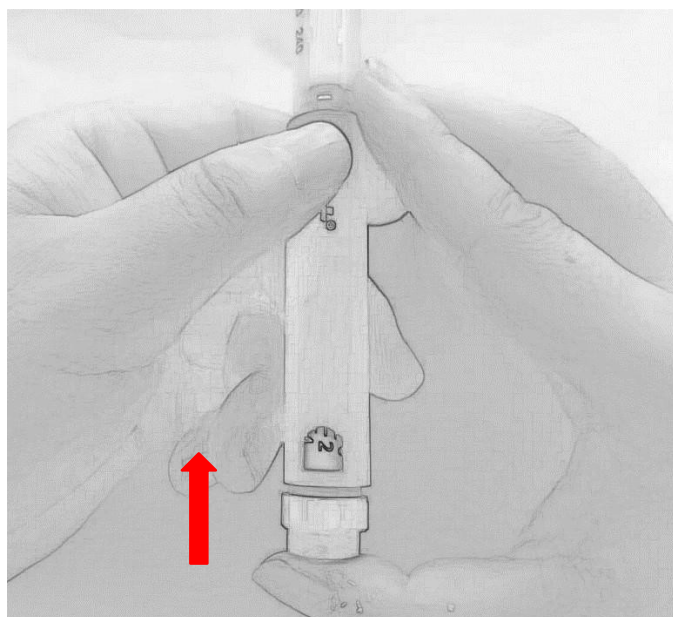
1) Supplies you will need for insulin injection	
<ul style="list-style-type: none"><li>- Fert® Pen Injector</li><li>- Standard 3 ml insulin cartridges according to ISO 11608-3</li><li>- Standard pen needles according to ISO 11608-2</li><li>- Alcohol wipe</li><li>- Clean cloth</li></ul>	
2) Loading the insulin cartridge	
Wash your hands	
	Remove the Protective cap.
	Unscrew the Cartridge mounting from the pen body. If you need to change old cartridge to a new one, please remove the old cartridge first.

	<p>Before proceeding, refer to the Instruction for Use of insulin cartridge on checking the appearance of your insulin.</p> <p>Use a 75% alcohol wipe to wipe the rubber membrane of the insulin cartridge before loading.</p> <p>Load the insulin cartridge into the Cartridge mounting with the cap in first.</p>
	<p>Check to ensure that the Screw rod is fully retracted. If the Screw rod is extended, please push the Screw rod gently until the Screw rod is fully retracted.</p>
	<p>Screw the Cartridge mounting and pen body firmly together.</p>
	<p>If using a cloudy insulin you will need to resuspend the insulin by rolling the insulin pen in the palm and turning it up and down as per the cartridge instructions</p>
<b>3) Attaching the pen needle</b>	

	<p>Remove protective tab on pen needle packaging. Please use a new needle for each injection.</p>
	<p>Attach the pen needle by firmly screwing it onto the threads at the end of the Cartridge mounting. Make sure that the pen needle is screwed on straight rather than at an angle.</p>
	<p>Remove the outer needle cap from the pen needle. Please do not dispose the outer needle cap, the outer needle cap is necessary for disposition used pen needle later.</p>
<p><b>4) Priming</b></p>	


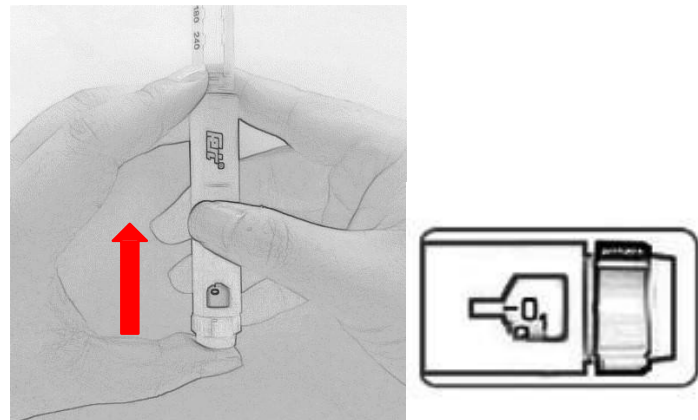
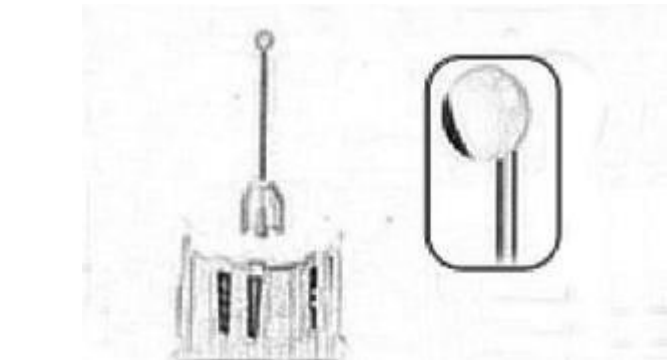


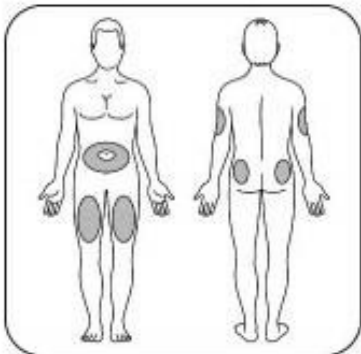

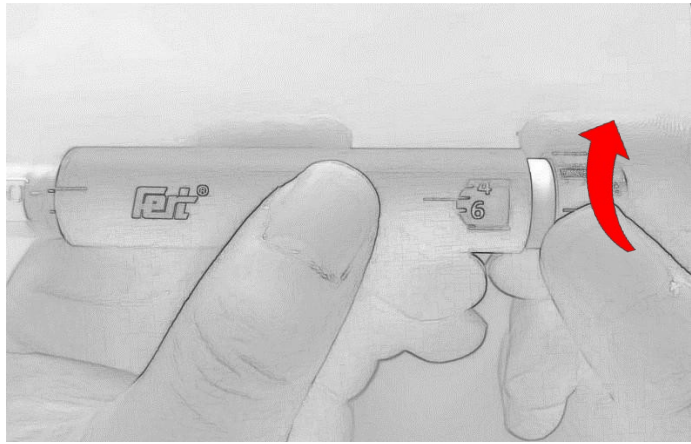
It is important to “Prime” the Fert® Pen Injector before use to remove any air that may be inside the needle and cartridge. Dial 1-2 units on the dose indicator.



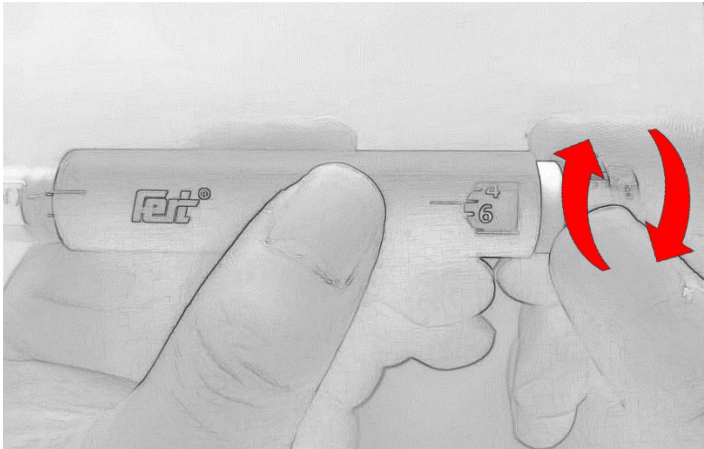
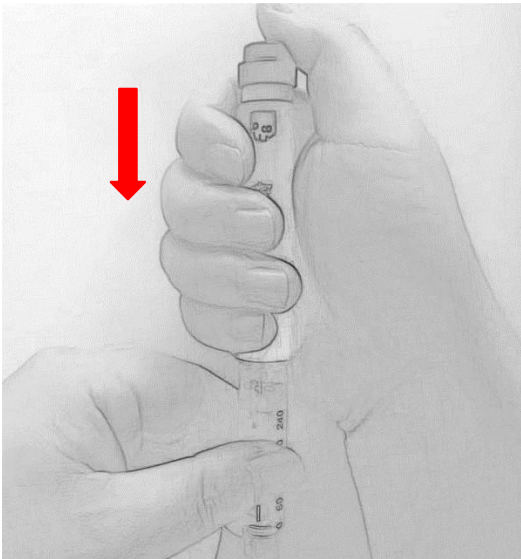
Remove the inner needle cap from the pen needle.

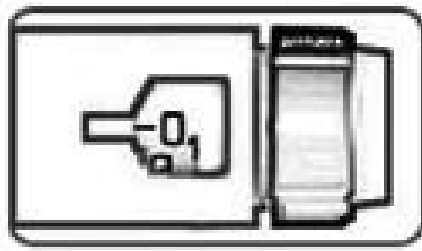


	<p>Hold the Fert® Pen Injector vertically with the needle pointing up. Tap the insulin cartridge gently with your finger so air bubbles can be collected near the top.</p>
	<p>Push and hold the Push-button towards the pen needle until the gap on the pen body points to the 0 line on the dose indicator.</p>
	<p>Repeat priming step 1 to step3 until a drop of insulin appears at the needle tip. The Fert® Pen Injector is now ready for use.</p> <p>Please be aware small air bubbles may remain in the cartridge after completion of the priming steps. If you have properly primed the pen, these small air bubbles will not affect your insulin dose.</p>
<p><b>5) Injecting the dose</b></p>	
<ul style="list-style-type: none"> <li>- Fert® Pen Injector should be used only after consultation with your healthcare professional.</li> <li>- Fert® Pen Injector is able to inject a dose of up to 60 units of insulin, in 1 unit increments.</li> </ul>	

<ul style="list-style-type: none"> <li>- If the injection dose larger than 60 units, please take another injection.</li> <li>- For each injection, please use a new needle and prime the pen.</li> </ul>	
 <p>1.</p>	<p>To avoid tissue damage, choose a site for each injection that is at least 1/2 inch (1.3 cm) from the previous injection site. The usual sites of injection are abdomen, thighs, and arms.</p>
<ul style="list-style-type: none"> <li>- Clean the skin with alcohol wipe where the injection is to be made.</li> </ul>	
	<p>If using a cloudy insulin you will need to resuspend the insulin before injection by rolling the insulin pen in the palm and turning it up and down as per the cartridge instructions.</p>
	<p>Make sure the dose indicator points to the 0 line on the dose indicator. Dial the adjusting knob to the number of units required. The Dose Indicator should line up with your dose.</p> <ul style="list-style-type: none"> <li>-The Pen dials 1 unit at a time.</li> <li>-The adjusting knob clicks as you turn it.</li> <li>-Do not dial your dose by counting the clicks. You may dial the wrong dose.</li> <li>-The even numbers (for example, 36) are printed with thick line.</li> <li>-The odd numbers (for example, 35) are indicated with thin line.</li> </ul>



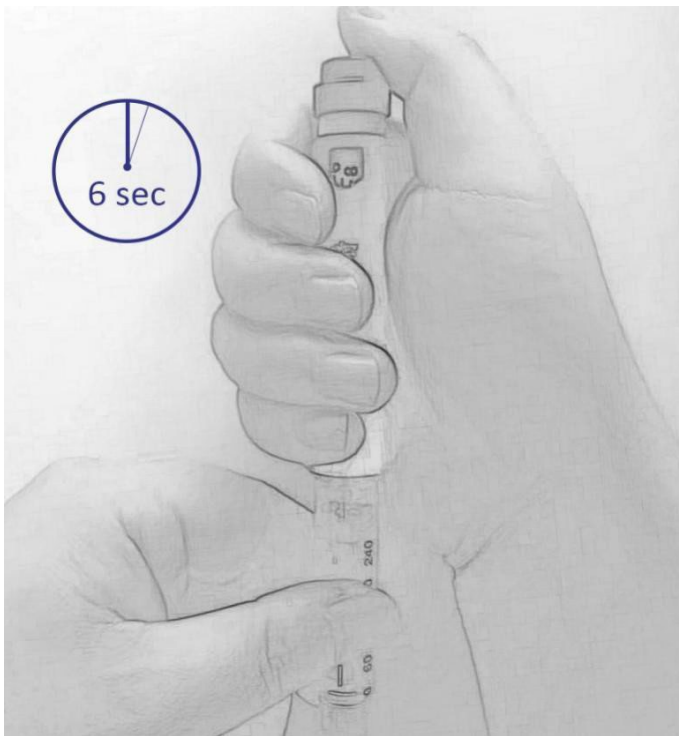
	<p>If the insulin cartridge becomes empty during injection, please follow the instruction below:</p> <ul style="list-style-type: none"><li>- If the insulin cartridge becomes empty, the pen will stop and the dose indicator will show the dose deficit.</li><li>- Remove the needle and the empty insulin cartridge. Insert a new insulin cartridge and prime the Fert® Pen Injector as described in step "Priming".</li><li>- Complete the dose by injecting the dose deficit.</li></ul>
	<p>If the dose needs to be corrected, dial the adjusting knob in the opposite direction until the correct number of units showed on the dose indicator. Make sure before injecting that dose indicator shows correct number of units.</p> <p>-It is normal to see a small amount of insulin left in the Pen that you can not inject.</p>
	<p>Insert the needle, push the Push-button towards the pen needle and hold down until you feel or hear a "click" sound.</p>

**6.**

ter injection, make sure the dose cator points to the 0 line.

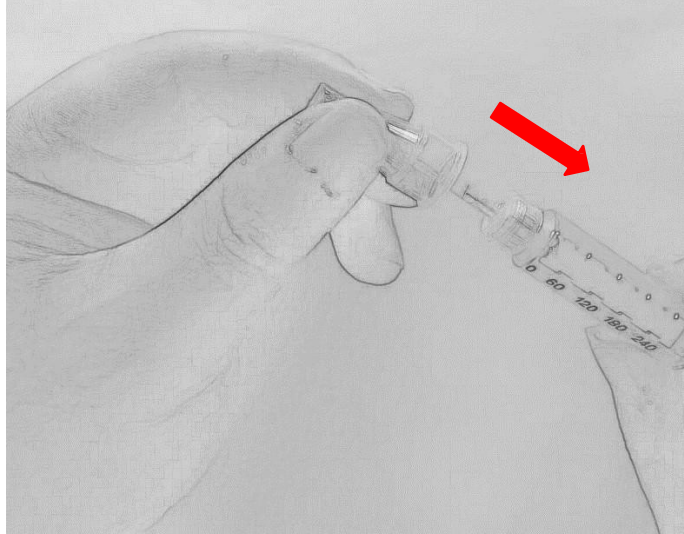
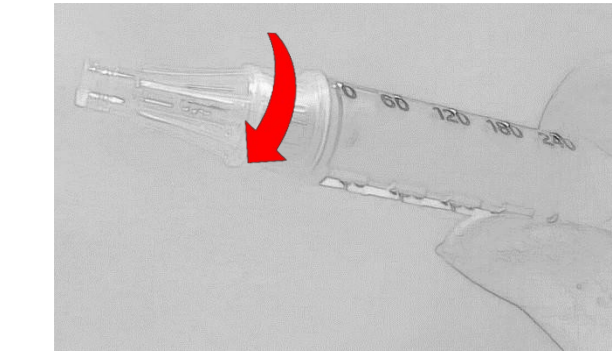
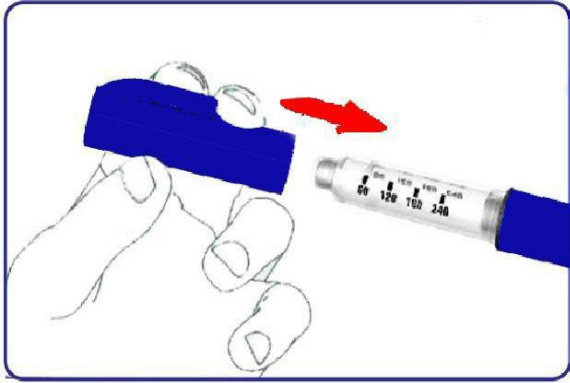
If you do not see “0” in the Dose Window, do not redial. Keep the needle in your skin and finish your injection.

If you think you did not receive the full dose for your injection, do not start over or repeat the injection. Monitor your blood glucose as instructed by your healthcare provider.



Do not pull the needle out immediately after injection. Hold the Fert® Pen Injector for at least 6 seconds, then pull the needle out and apply gentle pressure over the injection site for several seconds. Do not rub the area.

**6) Removing the needle**

	<p>Reattach the outer needle cap carefully.</p>
	<p>Remove the pen needle. Dispose the used needle in a puncture-resistant disposable container and properly throw it away as directed by your healthcare professional.</p>
 3.	<p>Replace the protective cap onto the Fert® Pen Injector after each use.</p>

## 7. Cleaning and storage

- Clean the outside of your pen by wiping it with a damp cloth after injection. Do not soak, wash, or lubricate the pen as this may damage it.
- The Pen Injector should always be stored or carried with the pen needle removed, and the Protective cap on. It should not be stored with a dialed dose.
- Cartridges can be carried in the Pen Injector or as spares according to the cartridge instructions.
- Handle your Pen Injector with care, do not drop it and avoid knocking it against hard surfaces.

**8. Storage**

- Store your Pen Injector in the environment temperature 0°C to 40°C and relative humidity no more than 50%RH.
- Please store your Pen Injector in a dry, dust-free, clean and away from direct sunlight environment.
- Keep your Pen Injector and Pen Needles out of reach of children.

**9. TROUBLE SHOOTING**

- 1) If you cannot remove the protective cap, gently twist the cap back and forth, and then pull the cap straight off.
- 2) If the Push-button is hard to push:
  - Pushing the Push-button more slowly will make it easier to inject.
  - Your Needle may be blocked. Put on a new needle and prime the Pen.
  - You may have dust, food, or liquid inside the Pen. Throw the Pen away and get a new Pen.
- 3) If you have any questions or problems with your Fert® Pen Injector, please call your healthcare provider for help.
- 4) If you dialed wrong insulin dose,
  - Screw the adjusting knob counter-clockwise until the correct number of units showed on the dose indicator.
- 5) If the insulin cartridge becomes empty during injection, please follow the instruction below:
  - If the insulin cartridge becomes empty, the pen will stop and the dose indicator will show the dose deficit.
  - Remove the needle and the empty insulin cartridge. Insert a new insulin cartridge and prime the Fert® Pen Injector as described in step “Priming”.
  - Complete the dose by injecting the dose deficit.
- 6) Please be aware small air bubbles may remain in the cartridge after completion of the priming steps. If you have properly primed the pen, these small air bubbles will not affect your insulin dose.
- 7) If you observed large air bubbles within insulin cartridge, please repeat “4) Priming” step to get rid of any large air bubbles
- 8) After pulling the needle out of your skin. A drop of insulin at the needle tip is normal. It will not affect your dose.

**10. CAUTIONS, WARNINGS AND INDICATIVE STATEMENTS**

1. Pen Injector should be used only after consultation with your healthcare professional.
2. You should read the instructions in this manual before using the Pen Injector.
3. Fert® Pen Injector should only be used in combination with compatible products that allow the pen to function safely and effectively.
4. This Pen Injector is not recommended for use by blind or visually impaired persons without the assistance of a person trained in the proper use of the product.
5. Keep your Pen Injector and needles out of the reach of children.

6. Always inspect your Pen Injector for any signs of damage before use. Do not use your Pen if any part looks broken or damaged.
7. Do not use your Pen Injector if dropped onto a hard surface as this may result in damage to the device. Always carry an extra Pen in case yours is lost or damaged.
8. Before each injection ensure that the Pen Injector contains the correct insulin type, as prescribed by your healthcare professional.
9. Every time you inject, please use a new needle.
10. Always ensure that Pen Injector has been primed in accordance with the instructions. Failure to follow the exact priming procedures could result in an inaccurate dose being delivered.
11. Do not share your Pen with other people, even if the needle has been changed. You may give other people a serious infection or get a serious infection from them.
12. Inject the dose as prescribed by your healthcare professional.
13. Place the used needle in a puncture-resistant disposable container and properly dispose of it as directed by your Health Care Professional.
14. Do not store or dispose of the Fert® Pen Injector with a needle attached. Storing the Fert® Pen Injector with the needle attached may allow insulin to leak from the Pen Injector and air bubbles to form in the cartridge.
15. Make sure you get your full dose.
16. Never use a Pen Injector after the expiration date stamped on the label.
17. Consult your healthcare professional should you encounter abnormal blood glucose levels.
18. Please dispose the Pen Injector following your local medical waste disposal procedure after 3 years of use.
19. If any serious incident occurs with the use of this device please report to Beijing Fert Technology Co. Ltd., and your local Competent Authority.


## 11. Replacement
















Pen Injector can be used for 3 years after first starting use and no more than 3300 times, production date is shown in the user package. Please note the date of your first use.

**First use day:** \_\_\_\_\_

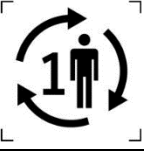
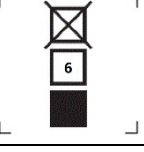

After 3 years of use, you can contact a health care professional to purchase a new Pen Injector with a prescription or at a pharmacy.

## 12. EXPLANATION OF SYMBOL

SYMBOL	Explanation of Symbol
	Catalogue number

	Medical Device
	Batch code
	Use-by date
	Temperature limit
	Humidity limitation
	Keep dry
	Fragile, handle with care
	Caution
	Consult instruction for use
	Country and date of manufacture
	Manufacturer
	Authorized representative in the European Community
	CE Mark And Identification Number of Notified Body
	Do not use if package is damaged and consult instructions for use
	Keep away from sunlight



	Single patient multiple use
	Maximum number of packages permitted to be stacked on the bottom package is 6.
	Unique device identifier

**13.TRANSPORTATION**

During transportation, keep the product clean and dry, keep them away from sunlight and rain.

Fert® Pen Injector is valid for 3 years.

**14.DATE OF APPROVAL AND REVISION OF THE INSTRUCTION OF USE**

Approved on June 26, 2024

Version number: A/3