

## Instructions for Use

### Lyumjev 100 units/mL Tempo Pen solution for injection in pre-filled pen insulin lispro



#### PLEASE READ THESE INSTRUCTIONS BEFORE USE

Read the instructions for use before you start using Lyumjev and each time you get another Lyumjev Tempo Pen. There may be new information. This information does not take the place of talking to your healthcare professional about your medical condition or your treatment.

Lyumjev 100 units/mL Tempo Pen (“Pen”) is a disposable pre-filled pen containing 3 mL (300 units, 100 units/mL) of insulin lispro solution for injection.

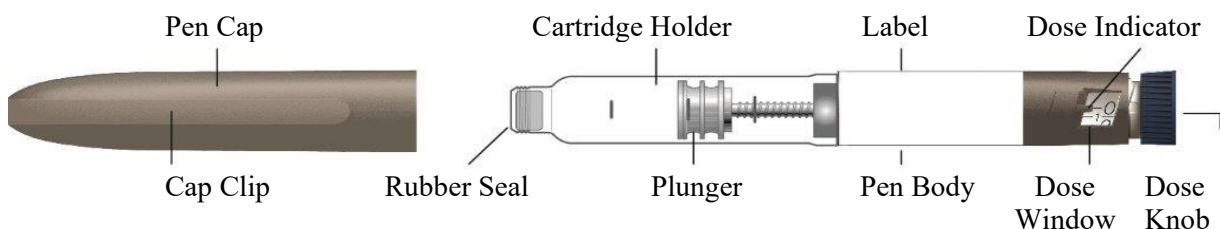
- Your healthcare professional will tell you how many units to give as your dose and how to inject your prescribed dose of insulin.
- You can give yourself more than 1 dose from the Pen.
- Each turn of the dose knob dials 1 unit of insulin. You can give from 1 to 60 units in a single injection.
- If your dose is more than 60 units, you will need to give yourself more than 1 injection. Always check the number in the dose window to make sure you dialed the correct dose.
- The plunger only moves a little with each injection, and you may not notice that it moves. The plunger will only reach the end of the cartridge when you have used all 300 units in the Pen.

The Tempo Pen is designed to work with the Tempo Smart Button. The Tempo Smart Button is an optional product that can be attached to the Tempo Pen dose knob and aids in transmitting Lyumjev dose information from the Tempo Pen to a compatible mobile application. The Tempo Pen injects insulin with or without the Tempo Smart Button attached. Your Tempo Smart Button must be attached to a Tempo Pen to record or transfer dose data. Push the Tempo Smart Button straight down on the dose knob until you hear a snap or feel the Tempo Smart Button snap into place. To transmit data to the mobile application, follow the instructions provided with the Tempo Smart Button and the instructions with the mobile application.

**Do not share your Lyumjev Tempo Pen with other people, even if the needle has been changed. Do not reuse or share needles with other people. You may give other people a serious infection or get a serious infection from them.**

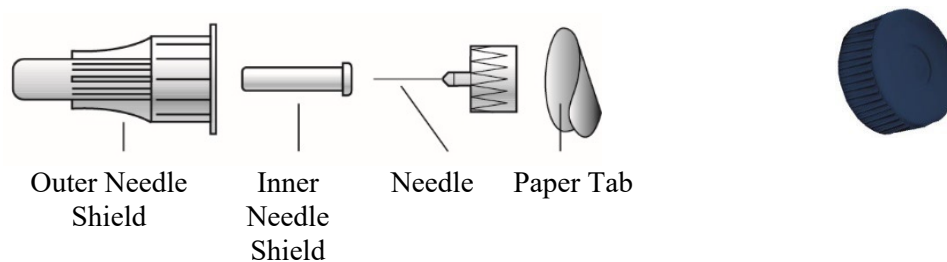
People who are blind or have vision problems should not use the Pen without help from a person trained to use the Pen.

#### Lyumjev Tempo Pen Parts



**Pen Needle Parts  
(Needles Not Included)**

**Dose Knob**



### How to recognize your Lyumjev Tempo Pen

- Pen colour: Taupe
- Dose Knob: Blue, with raised ridges around the entire side
- Label: Blue, green and white

### Supplies needed to give your injection

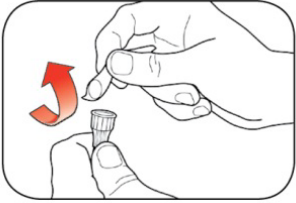
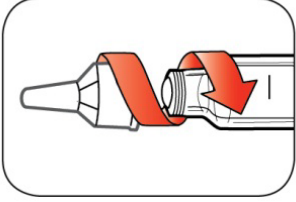
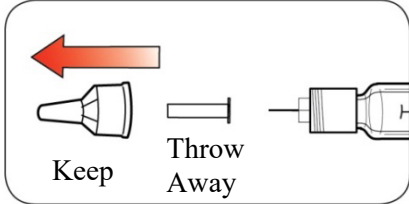
- Lyumjev Tempo Pen
- Tempo Pen compatible needle (BD [Becton, Dickinson and Company] Pen needles recommended)
- Swab or gauze

Needles, swab or gauze are not included.

### Preparing your Pen

- Wash your hands with soap and water.
- Check the Pen to make sure you are taking the right type of insulin. This is especially important if you use more than 1 type of insulin.
- **Do not** use your Pen past the expiry date printed on the label or for more than 28 days after you first start using the Pen.
- Always use a **new needle** for each injection to help prevent infections and blocked needles.

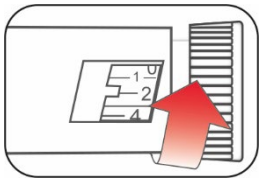

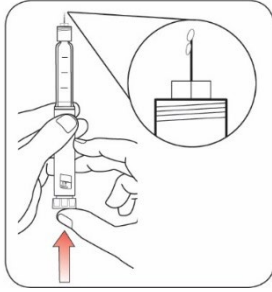
<p><b>Step 1:</b></p> <ul style="list-style-type: none"> <li>• Pull the Pen cap straight off. <ul style="list-style-type: none"> <li>– <b>Do not</b> remove the Pen label.</li> </ul> </li> <li>• Wipe the rubber seal with a swab.</li> </ul>	<p>The diagram shows a Lyumjev Tempo Pen with its cap removed. A red arrow points to the left, indicating the direction to pull the cap off.</p>
<p><b>Step 2:</b></p> <ul style="list-style-type: none"> <li>• Check the liquid in the Pen.</li> <li>• Lyumjev should look clear and colourless. <b>Do not</b> use if it is cloudy, coloured, or has particles or clumps in it.</li> </ul>	

<p><b>Step 3:</b></p> <ul style="list-style-type: none"> <li>• Select a new needle.</li> <li>• Pull off the paper tab from the outer needle shield.</li> </ul>	
<p><b>Step 4:</b></p> <ul style="list-style-type: none"> <li>• Push the capped needle straight onto the Pen and twist the needle on until it is tight.</li> </ul>	
<p><b>Step 5:</b></p> <ul style="list-style-type: none"> <li>• Pull off the outer needle shield. <b>Do not</b> throw it away.</li> <li>• Pull off the inner needle shield and throw it away.</li> </ul>	

### Priming your Pen

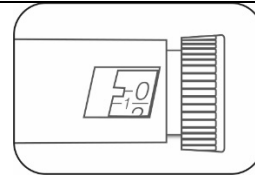
#### Prime before each injection.

- Priming your Pen means removing the air from the needle and cartridge that may collect during normal use and ensures that your Pen is working correctly.
- If you **do not** prime before each injection, you may get too much or too little insulin.

<p><b>Step 6:</b></p> <ul style="list-style-type: none"> <li>• To prime your Pen, turn the dose knob to select 2 units.</li> </ul>	
<p><b>Step 7:</b></p> <ul style="list-style-type: none"> <li>• Hold your Pen with the needle pointing up. Tap the cartridge holder gently to collect air bubbles at the top.</li> </ul>	
<p><b>Step 8:</b></p> <ul style="list-style-type: none"> <li>• Continue holding your Pen with the needle pointing up. Push the dose knob in until it stops and “0” is seen in the dose window. Hold the dose knob in and <b>count to 5 slowly</b>.</li> </ul> <p>You should see insulin at the tip of the needle.</p> <ul style="list-style-type: none"> <li>– If you <b>do not</b> see insulin, repeat priming steps 6 to 8, but not more than 4 times.</li> </ul>	

- If you **still do not** see insulin, change the needle and repeat priming steps 6 to 8.

Small air bubbles are normal and will not affect your dose.

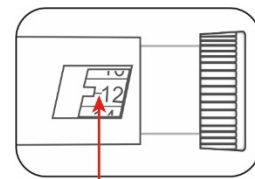
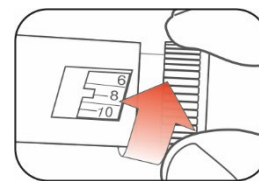


### Selecting your dose

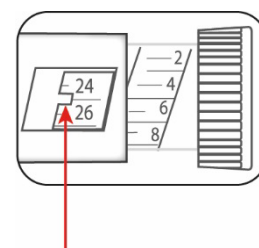
- You can give from 1 to 60 units in a single injection.
- If your dose is more than 60 units, you will need to give more than 1 injection.
  - If you need help with dividing up your dose the right way, ask your healthcare professional.
  - Use a new needle for each injection and repeat the priming steps.

### Step 9:

- Turn the dose knob to select the number of units you need to inject. The dose indicator should line up with your dose.
  - The Pen dials 1 unit at a time.
  - The dose knob clicks as you turn it.
  - **Do not** dial your dose by counting the clicks. You may dial the wrong dose. This may lead to getting too much insulin or not enough insulin.
  - The dose can be corrected by turning the dose knob in either direction until the correct dose lines up with the dose indicator.
  - The **even** numbers are printed on the dial. The example to the right shows 12 units.
  - The **odd** numbers, after the number 1, are shown as full lines between the numbers. The example to the right shows 25 units.
- **Always check the number in the dose window to make sure you have dialed the correct dose.**



Example: 12 units shown in the dose window



Example: 25 units shown in the dose window

- The Pen will not let you dial more than the number of units left in the Pen.
- If you need to inject more than the number of units left in the Pen, you may either:
  - inject the amount left in your Pen and then use a new Pen to give the rest of your dose,

**or**

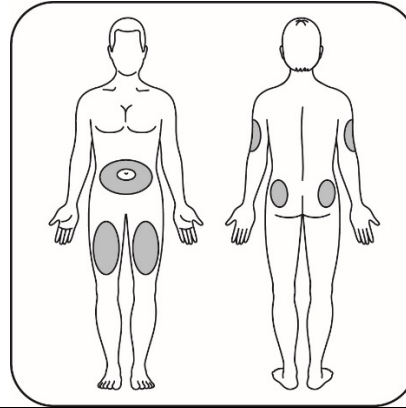
  - get a new Pen and inject the full dose.
- It is normal to see a small amount of insulin left in the Pen that you cannot inject.

## Giving your injection

- Inject your insulin as your healthcare professional has shown you.
- Change (rotate) your injection site for each injection.
- **Do not** try to change your dose while injecting.

### Step 10:

- Choose your injection site.  
  
Lyumjev is injected under the skin (subcutaneously) of your stomach area, buttocks, upper legs or upper arms.
- Wipe your skin with a swab, and let your skin dry before you inject your dose.

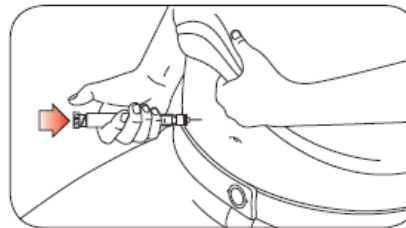


### Step 11:

- Insert the needle into your skin.
- Push the dose knob all the way in.
- Continue to hold the dose knob in and **slowly count to 5** before removing the needle.



**Do not** try to inject your insulin by turning the dose knob. You will **not** receive your insulin by turning the dose knob.

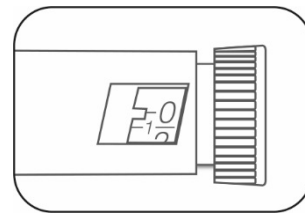


**Step 12:**

- Pull the needle out of your skin.
  - A drop of insulin at the needle tip is normal. It will not affect your dose.
- Check the number in the dose window.
  - If you see “0” in the dose window, you have received the full amount you dialed.
  - If you do not see “0” in the dose window, you did not receive your full dose. **Do not** redial. Insert the needle into your skin and finish your injection.
  - If you **still** do not think you received the full amount you dialed for your injection, **do not start over or repeat that injection**. Monitor your blood glucose as instructed by your healthcare professional.
  - If you normally need to give 2 injections for your full dose, be sure to give your second injection.

The plunger only moves a little with each injection, and you may not notice that it moves.

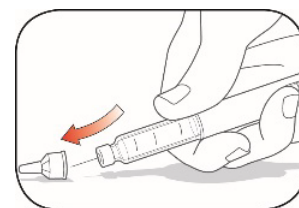
If you see blood after you take the needle out of your skin, press the injection site lightly with a piece of gauze or a swab. **Do not** rub the area.



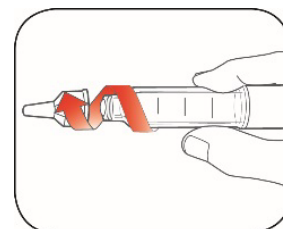
### After your injection

**Step 13:**

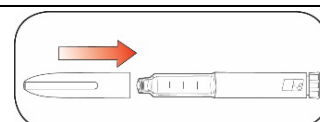
- Carefully replace the outer needle shield.

**Step 14:**

- Unscrew the capped needle and dispose of it as described below (see **Disposing of Pens and needles** section).
- **Do not** store the Pen with the needle attached to prevent leaking, blocking the needle, and air from entering the Pen.

**Step 15:**

- Replace the Pen cap by lining up the cap clip with the dose indicator and pushing straight on.



### Disposing of Pens and needles

- Put used needles in a sharps container or a hard plastic container with a secure lid. **Do not** throw needles directly into your household waste.
- **Do not** recycle the filled sharps container.
- Ask your healthcare professional about options to dispose of the Pen and the sharps container properly.
- The directions regarding needle handling are not intended to replace local, healthcare professional or institutional policies.

### Troubleshooting

- If you cannot remove the Pen cap, gently twist the cap back and forth, and then pull the cap straight off.
- If the dose knob is hard to push:
  - pushing the dose knob 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. You may need to get a prescription from your healthcare professional.

If you have any questions or problems with your Lyumjev 100 units/mL Tempo Pen, call your healthcare professional for help or contact your local Lilly affiliate.

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