

## **ClikSTAR - Important facts about your new insulin delivery device.**

### **Instruction for Use**

#### **ClikSTAR®**

Insulin delivery device

#### **Before you start:**

**Read these instructions and follow them completely each time you use ClikSTAR to ensure that you get the right dose. If you do not follow these instructions completely, you may get too much or too little insulin, which may affect your blood glucose levels.**

If you are not able to use ClikSTAR or follow all the instructions completely on your own, you must use ClikSTAR only if you have help from a person who is able to follow the instructions completely.

- ClikSTAR is a re-usable pen for the injection of insulin.
- You can set doses from 1 to 80 units in step of 1 unit.
- ClikSTAR can only be used with 3 mL (300 units) insulin cartridge (U-100) from sanofi-aventis Canada Inc.
- The insulin cartridge contains 300 units and can be used for multiple injections until it is empty or 28 days have passed after first use.
- The plunger will only move to the end of the cartridge when 300 units have been given.

ClikSTAR has been designed to be used for up to 4 years after first use.

Record the date your pen was first used here:   /   /   .

#### **Important information for use of ClikSTAR:**

- Always attach a new needle before each injection. Needles are available in different lengths and gauges. Artsana, Becton Dickinson and Company, Ypsomed and Owen-Mumford needles should be used with ClikSTAR pens. Contact your health professional for further information.
- ClikSTAR is only for your use. Do not share it.
- Always perform the safety test before each injection (see Step 3).
- Always check the label of your insulin before use.
- Do not use ClikSTAR if it is damaged or if you are not sure that it is working properly.
- Never use an insulin cartridge if it is damaged.
- The alignment marks must be lined up with each other.
- Always have a back-up method for delivering your insulin (e.g. U-100 insulin syringe).
- Do not insert a partially used cartridge.
- If you use Lantus® and Apidra®, you should use a different color pen for each insulin. ClikSTAR is available in different colors. For each color pen, the injection button has a different feel, e.g. raised or smooth area.

- You cannot turn the dosage selector past the number of units left in the cartridge. Do not force the dosage selector to turn. In this case,
  - inject what is remaining in this cartridge and complete your dose with a new cartridge,
  - or use a new cartridge for your full dose.

Contact your health professional to get a new ClikSTAR when your pen has been used for 4 years.

If you have any questions about ClikSTAR or about diabetes, ask your health professional, or call sanofi-aventis at 1-888-852-6887.

### **Information about storing and maintenance of ClikSTAR**

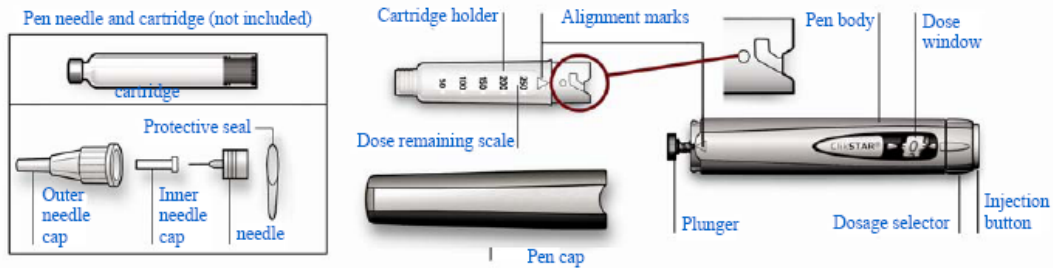
- If your new unopened insulin cartridge is in cool storage (for example refrigerator), take it out 1 to 2 hours before you inject. This is to allow insulin to warm up. Cold insulin is more painful to inject.
- Protect your ClikSTAR from dust, dirt, and direct sunlight.
- Keep ClikSTAR without insulin cartridge attached at room temperature below 30°C. See Patient Insert for 3 mL sanofi-aventis insulin cartridge for complete cartridge storage information when attached to ClikSTAR.
- Do not refrigerate ClikSTAR.
- After 4 years of using pen, dispose of the pen safely as instructed by your health professional.
- You can clean the outside of your ClikSTAR by wiping it with a damp cloth.
- Do not soak, wash or lubricate ClikSTAR as this may damage it.
- Handle your ClikSTAR with care. Avoid situations where your ClikSTAR might be damaged. If you are concerned that your ClikSTAR may be damaged use a new one.
- Keep ClikSTAR out of the reach and sight of children.

### **ClikSTAR: Getting started with your insulin delivery device**

**ENSURE THAT YOU READ THE FULL INSTRUCTIONS FOR USE**  
Read both sides before using your ClikSTAR

What you need for your injection:

- Your ClikSTAR re-usable insulin injection pen
- One sanofi-aventis 3 mL insulin cartridge (supplied separately)
- Pen needle (supplied separately)
- An alcohol swab (supplied separately)
- A puncture resistant container for disposing of used needles (supplied separately)
- Please read instruction steps 1 to 7.



### Use of ClikSTAR in special situations

- For use in a multi-patient environment, e.g. hospital or nursing home, special caution must be taken to ensure identification of the correct pen for each patient.
- If you are giving an injection to another person or if your injection is given by another person, special caution must be taken to avoid accidental needle injury and transmission of infection, especially when injecting and when removing the needle.
- When safety needles are used, please read the needle instructions.

### Step 1: Insert a new insulin cartridge

A. Pull or twist off the Pen Cap.



B. Unscrew the insulin cartridge holder from the pen body.

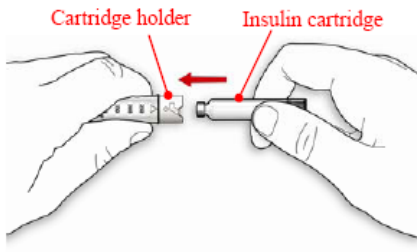


C. Check your insulin

- Make sure you have the correct insulin.
- Follow the instructions provided with your insulin cartridge to check expiry date and the conditions of your insulin

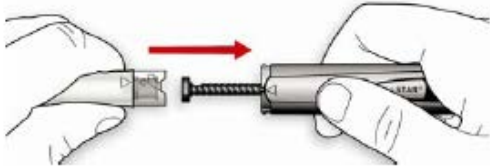


**D.** Place the cartridge in the cartridge holder

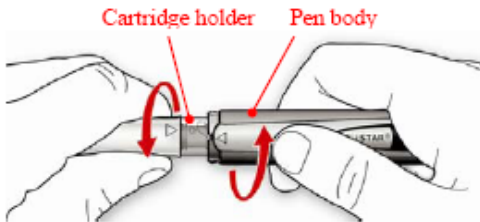


**E.** Push back the plunger if needed

If the plunger is sticking out it will be pushed back automatically as you attach the cartridge holder to the pen.



**F.** Twist the insulin cartridge holder back on to the pen body. Make sure it clicks into place.



**CHECK**

Make sure the alignment marks on the cartridge holder and the pen body are lined up.



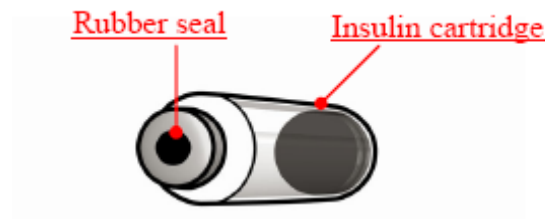
## Step 2: Attach the needle



### IMPORTANT

Always use a new sterile needle for each injection. This helps prevent contamination, inaccurate dosing, and needle blocks.

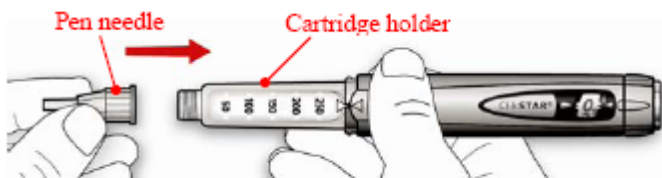
- A. Check the appearance of your insulin.
  - If you are using clear insulins (Lantus and Apidra), do not use this cartridge if the insulin is cloudy, colored or has particles.
- B. Wipe the rubber seal (on the end of the cartridge) with alcohol swab.



- C. Remove the protective seal from a new needle.



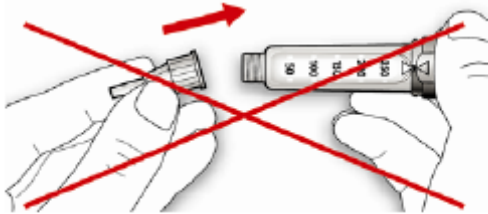
- D. Attach the pen needle to the cartridge holder. Keep it straight as you attach it.
  - Screw or push on needle, depending on the needle type you are using (see needle instruction).





### Check

Make sure that you attach the needle straight and firmly



### Step 3. Perform a safety test

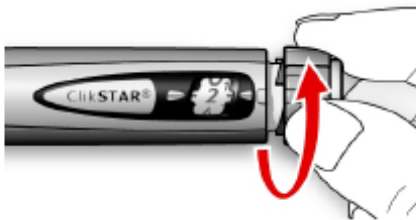


### IMPORTANT

**Always** perform the safety test before each injection to make sure that you get the correct insulin dose.

The safety test removes air bubbles and ensures that pen and needle are working properly.

- A. Select a dose of 2 units by turning the dosage selector.
- The dose window will read “2”.

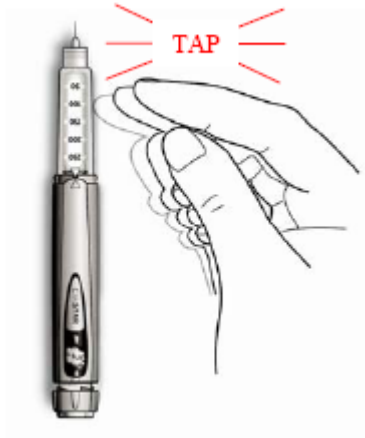


- B. Take off the outer needle cap. Take off the inner needle cap and discard it safely.



C. Hold the pen with the needle pointing upwards.

Tap the insulin cartridge holder so that any air bubbles rise up towards the needle.

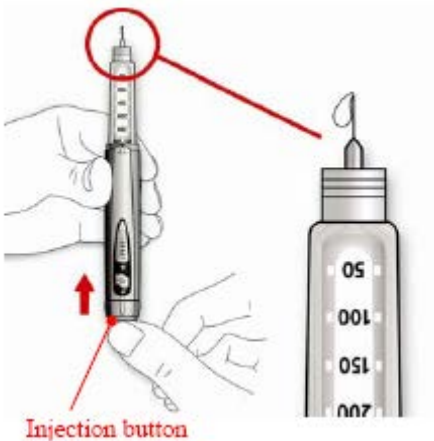


D. Press the injection button all the way in.



### CHECK

Check if insulin comes out of the needle tip.



### IMPORTANT

You may need to do this several times before you see insulin.

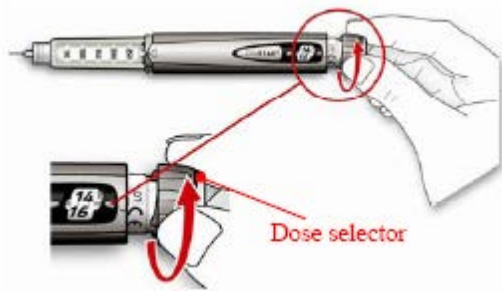
If you have still not seen insulin come out of the needle tip

- Change the needle.
- Check that the cartridge is properly inserted and not damaged.
- Repeat the safety test

If after this you still do not see insulin come out of the needle tip, do not use this ClikSTAR. Call sanofi-aventis at 1-888-852-6887.

#### Step 4: Select the dose

- A. Select your dose by turning the dosage selector
- If you turn past your dose, you can turn back down.



How to read the dose window.

The maximum dose you can select is 80 units.

Odd numbers are shown as a line between even numbers.



Example: Selected dose: 15 units

The dose window shows even numbers.



Example: Selected dose: 30 units



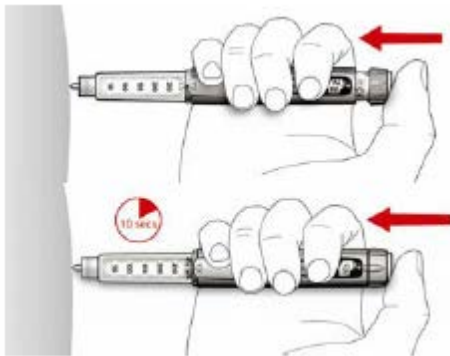
## Step 5: Give the injection

Give the injection exactly as shown by your health professional.

- A. Insert the needle into the skin.

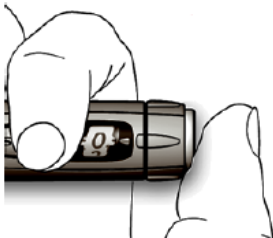


- B. Inject your dose by pressing the injection button slowly all the way in and wait for 10 seconds.



- C. Keep the injection button pressed all the way in. Slowly count to 10. Then remove the needle from the skin.

If you have injected your entire dose, you will see “0” in the dose window.



### **IMPORTANT**

To make sure that the full dose is injected, it is important that you press the injection button all the way in and keep pressing it for **10 seconds**.

## Step 6: Discard of the pen needle



Always remove and discard the used needle after each injection. This helps prevent contamination, inaccurate dosing, and needle blocks.



Take care to avoid touching the needle tip and, particularly, take care to prevent any other person risking infection by touching the needle tip.

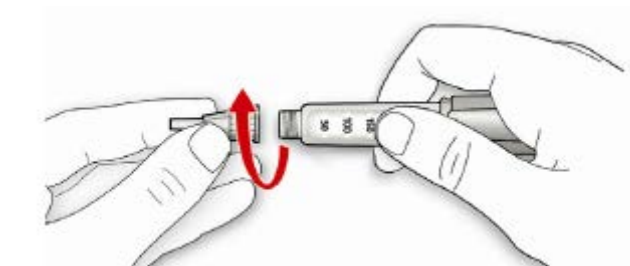


Remove needle and discard the needle exactly as shown by your health professional.

- A. For example “scoop” the outer needle cap back on the needle.

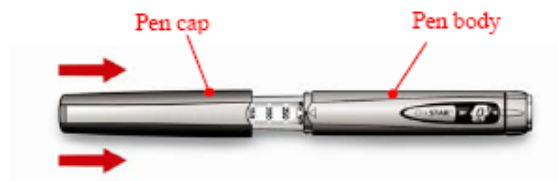


- B. Unscrew the used needle from KlikSTAR while holding the outer needle cap in one hand and the cartridge holder in the other hand.
- C. Discard the used needle into a puncture resistant container. Dispose of the needle safely. Follow recommended safety measures for removal and disposal of needles (e.g. contact your health professional) in order to reduce the risk of accidental needle injury and transmission of infectious diseases. Used needles should be placed in sharps containers (such as biohazard containers), hard plastic containers (such as detergent bottles), or metal containers (such as an empty coffee can). Such containers should be sealed and disposed of properly.



## Step 7: Store ClikSTAR

- A. Replace the pen cap onto ClikSTAR and store the pen until your next injection.



### IMPORTANT

**The insulin cartridge is re-usable. Your ClikSTAR should be stored with the insulin cartridge attached, ready for your next injection.**

You should not store ClikSTAR in the refrigerator. The insulin does not have to be kept in the refrigerator once it has been attached to ClikSTAR. See Patient Insert for 3 mL sanofi-aventis insulin cartridge for complete cartridge storage information.

If you have followed the instructions on this page you will know the basic steps of use for ClikSTAR.

Turn the page over for a full description of ClikSTAR storage, maintenance, what to do when insulin cartridge is almost empty and how to get help.

### **Manufacturer:**

sanofi-aventis Deutschland GmbH, D-65926 Frankfurt am Main, Germany

### **Importer/Distributor:**

sanofi-aventis Canada Inc. Laval (Quebec) Canada H7V 0A3

Call toll free 1-888-852-6887.

ClikSTAR is a registered trademark of the sanofi-aventis Group.

ClikSTAR meets the current dose accuracy and functional requirements of ISO 11608-1:2012 with sanofi-aventis 3 mL cartridges.

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