

Instruction for Use

JuniorSTAR®

Insulin delivery device

JuniorSTAR – Read this first – Important facts about your new insulin delivery device.

Before you start:

Read these instructions and follow them completely each time you use JuniorSTAR 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.

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

JuniorSTAR is a re-usable pen for the injection of insulin. Your healthcare professional has decided that JuniorSTAR is appropriate for you, based on your ability to handle JuniorSTAR. Talk with your healthcare professional about the proper injection technique before using JuniorSTAR.

Hold the pen as shown in this instruction leaflet. To ensure that you read the dose correctly, hold the pen horizontally, with the needle on the left and the dosage selector to the right as shown in the illustrations below.

You can set doses from 1 to 30 units in steps of 0.5 units. JuniorSTAR can only be used with Lantus, Apidra, and Admelog 3 ml (300 units) insulin cartridges (U-100) from sanofi-aventis. Each cartridge contains multiple doses.

JuniorSTAR is available in different colours. If you use different types of insulin, you should use a different colour pen for each insulin.

Important information for use of JuniorSTAR:

- Always attach a new needle before each use.
Only use needles that are compatible for use with JuniorSTAR.
- Always perform the safety test before each injection (see Step 4).
- Always check the label of your insulin before use.
- If you use different types of insulin you should use a different color for each insulin pen. JuniorSTAR is available in different colors.
- This pen is only for one person's use. Do not share it with anyone else.
- Never use JuniorSTAR if it is damaged or if you are not sure that it is working properly. Never use a cartridge if it is damaged.
- Always have a back-up method for delivering your insulin available (e.g. U-100 insulin syringe).

- Do not insert a partially used cartridge.
- 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.
- Never store JuniorSTAR in the refrigerator.

Use of JuniorSTAR 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.

Keep this leaflet for future reference.

If you have any questions about JuniorSTAR or about diabetes, ask your healthcare professional or call sanofi-aventis Canada Inc. at: 1-888-852-6887.

JuniorSTAR has been designed to be used for up to 2 years after first use.

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

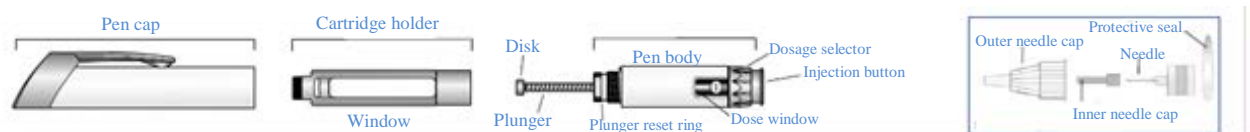
Contact your healthcare professional to get a new JuniorSTAR when your pen has been used for 2 years.

JuniorSTAR: Getting started with your insulin delivery device

ENSURE THAT YOU READ THE FULL INSTRUCTIONS FOR USE
Read both sides before using your JuniorSTAR.

What you need for your injection:

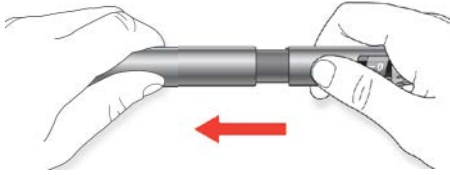
- Your JuniorSTAR re-usable insulin injection pen
- One sanofi-aventis 3 ml insulin cartridge (supplied separately)
- Pen needle (supplied separately)
- An alcohol swab (supplied separately)
- A puncture resistant container for disposing of used needles (supplied separately)
- Please read instruction steps 1 to 8.



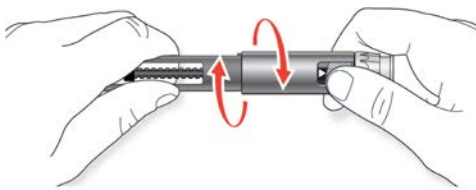
Schematic diagram of JuniorSTAR

Step 1. Insert a new Cartridge

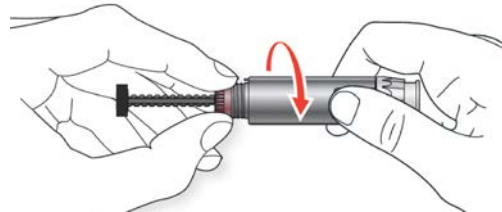
- A. Pull off the pen cap.



- B. Unscrew the cartridge holder from the pen body. If there is an empty insulin cartridge, remove it.



- C. Fully rewind the plunger to the starting position.
1. If the dose window does not show “0”, push the injection button completely down.
 2. Hold the plunger reset ring.
 3. Turn the **pen body** anti-clockwise until it cannot be turned further and the plunger is fully retracted.

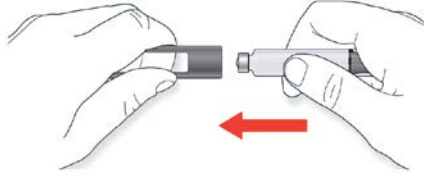


- Do not touch the disk at the tip of the plunger.
- Do not try to push the plunger back in. This could damage the plunger and cause malfunction of the pen.

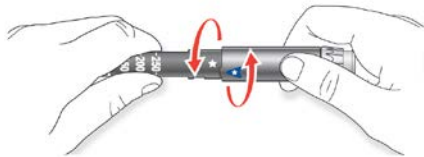
D. Check your insulin

- Check the label on your cartridge to make sure you have the correct insulin. Using the wrong insulin may result in unwanted changes in blood sugar that could be harmful to your health.
- Follow the instructions provided with your insulin cartridge to check expiry date and the conditions of your insulin

- E.** Insert the new cartridge into the cartridge holder. Do not insert a partially used cartridge. Make sure that the name on the insulin cartridge is visible in the cartridge holder window.



- F.** Screw the insulin cartridge holder firmly back on to the pen body.



CHECK: The alignment marks on the cartridge holder and the pen body must line up. If not, unscrew the cartridge holder and repeat the instructions from **C** onwards. Do not use force.



Step 2. Check your insulin

Check the name on the insulin cartridge each time before you inject. In case the name of the insulin is not visible in the cartridge holder window, turn the cartridge with your fingers until the name is visible.

- A.** Check the appearance of your insulin.
- If you are using clear insulin (Lantus[®], Apidra[®] or Admelog[®]), do not use this cartridge if the insulin is cloudy or colored or has particles.

Step 3. Attach the needle

IMPORTANT: Always use a **new** sterile needle for each injection. This helps prevent contamination and potential needle blocks.

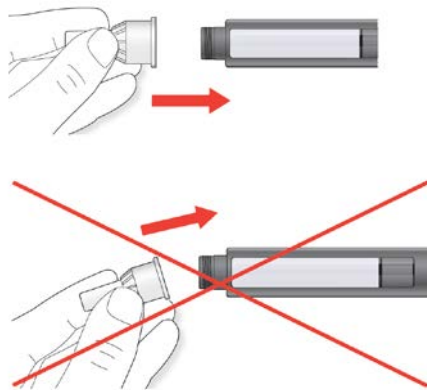
Before use, carefully read the “Instruction for Use” accompanying the needles. Please note: The needles shown are for illustrative purposes only.

A. Remove the protective seal from a new needle.



B. Line up the needle with the pen, and 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 firmly.

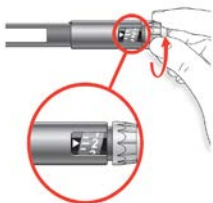
Step 4. Perform a safety test

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

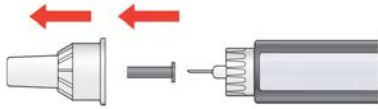
The safety test removes air bubbles and ensures that pen and needle are working properly.

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 and keep it to unscrew the needle from the pen after injection. Take off the inner needle cap and discard it.



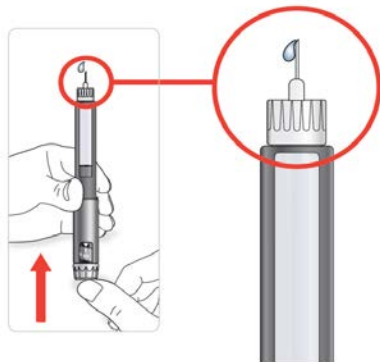
- C.** Hold the pen with the needle pointing upwards.

Tap the 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 have to perform the safety test several times before insulin is seen.

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 JuniorSTAR. Call sanofi-aventis Canada Inc. at 1-888-852-6887.

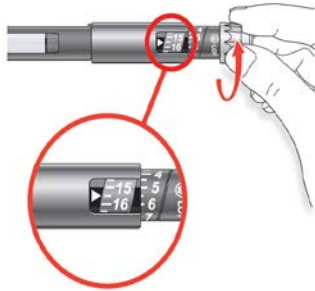
Step 5. Select the dose

You can set the dose in steps of 0.5 units from a minimum of 1 unit to a maximum of 30 units. The dose window shows every number. Half unit steps are shown with a line (for example, in the picture below, the selected dose of 15.5 units is shown as the line between 15 and 16 units). If you need a dose greater than 30 units, you should give it as two or more injections.

A. Check that the dose window shows “0” following the safety test.

B. Select your required dose (in the example below, the selected dose is 15.5 units).

- If you turn past your dose, you can turn back down.
- Lines or numbers closest to the center of the dose window show your selected dose



- Do not push the injection button while turning, as insulin will come out.
- 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 you can

- either inject what is remaining in this cartridge and complete your dose with a new cartridge
- or use a new cartridge for your full dose.

IMPORTANT: How to read the dose window.

The maximum dose you can select is 30 units.

Half units are shown as a line between numbers.



Selected dose: 15.5 units

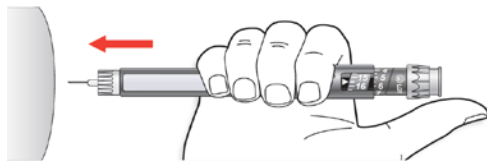
The dose window shows full numbers.



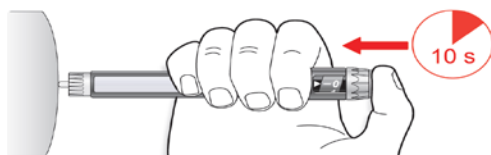
Selected dose: 30 units

Step 6. Give the injection

- A. Give the injection exactly as shown by your healthcare provider.
- B. Insert the needle into the skin.



- C. Deliver the dose by pressing the injection button slowly all the way in. The number in the dose window will return to “0” while you inject.



- D. Keep the injection button pressed all the way in. Slowly count to 10 before you withdraw 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 will be injected, it is important that you press the injection button all the way in and keep pressing it for **10 seconds**.

The pen plunger moves with each dose. The plunger will reach the end of the cartridge when the total of 300 units of insulin have been used.

Step 7. Remove and discard the needle

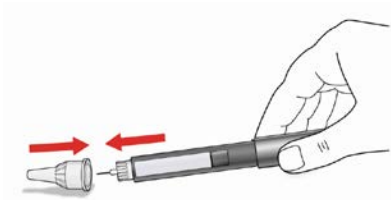
Always remove the needle after **each** injection and store JuniorSTAR without a needle attached. This helps prevent contamination, inaccurate dosing and needle blocks.

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

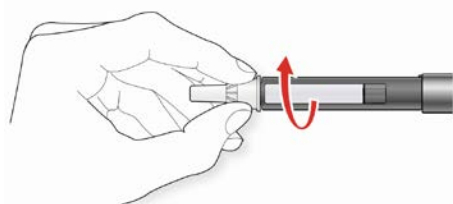
Remove needle and discard the needle exactly as shown by your healthcare provider.

A. Place outer needle cap on a flat surface. Guide the needle into the outer needle cap.

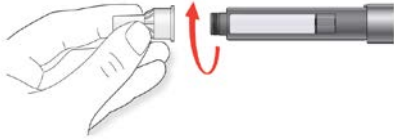
Put the outer needle cap back on.



B. Squeeze the outer needle cap to grip the needle and use it to unscrew the needle from JuniorSTAR while holding the pen at the cartridge holder.



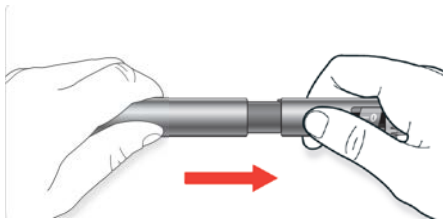
C. Discard the used needle into a puncture resistant container.



If your injection is given by another person, or if you are giving an injection to another person, special caution must be taken when removing and disposing the needle. Follow recommended safety measures for removal and disposal of needles (contact your healthcare professional) in order to reduce 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 8. Store JuniorSTAR

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



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

You should not store JuniorSTAR in the refrigerator. The insulin does not have to be kept in the refrigerator once it has been attached to JuniorSTAR. 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 JuniorSTAR.

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

MAINTENANCE

Protect your JuniorSTAR from dust and dirt.

You can clean the outside of your JuniorSTAR by wiping it with a damp cloth (water only).

Do not soak, wash or lubricate the pen as this may damage it.

Your JuniorSTAR is designed to work accurately and safely. It should be handled with care. Avoid situations where JuniorSTAR might be damaged.

If you are concerned that your JuniorSTAR may be damaged, use a new one.

If you are not sure whether or not your JuniorSTAR is damaged, contact your health care provider or call sanofi-aventis Canada Inc. at: 1-888-852-6887.

If damaged, it is no longer safe to use it. In an emergency, you can draw up the insulin from the cartridge using a U-100 insulin syringe.

Storage Instructions

Protect JuniorSTAR from, heat, direct sunlight or cold.

Always store your JuniorSTAR without the needle and with the pen cap on, at temperature 5°C to 30°C. Do not refrigerate JuniorSTAR. Please check the insulin leaflet for instructions on how to store JuniorSTAR with the sanofi-aventis 3mL insulin cartridge in the pen.

Keep JuniorSTAR out of the reach and sight of children.

Choking Hazard – Small parts. Caution in children under 3 years.

When you need a new cartridge, take it out of the refrigerator 1 to 2 hours before you inject to allow it to warm up to room temperature. Cold insulin is more painful to inject.

After 2 years of using the pen, dispose the pen safely according to local requirements.

Miscellaneous

In case the pen is defect contact sanofi-aventis Canada Inc. at: 1-888-852-6887.

Please state the reason for your reclamation.

Pens that are sent back to us will always be disposed of appropriately after examination.

No liability whatsoever will be assumed for the safety, accuracy of dosage and functional capability if insulin cartridges or needles that are not compatible for the JuniorSTAR are used, nor will any damages be compensated.

In case of loss or malfunction of JuniorSTAR have insulin, syringes and needle available as alternative.

Help

Question	Possible Reason	How to deal with the problems
No insulin is coming out (when the injection button is pressed in)	After changing the cartridge, the safety test might have to be repeated several times till insulin comes out	Repeat the safety test until insulin comes out of the needle.
	The Plunger is not in the correct position against the cartridge.	Repeat the safety test until insulin comes out of the needle.
	There are air bubbles in the cartridge.	Repeat the safety test until insulin comes out of the needle (small air bubbles will not affect the dose).
	The needle is blocked or damaged.	Replace the needle by a new one if it is blocked or damaged.
	The cartridge holder is not screwed in completely on to the pen body.	Screw in the cartridge holder on to the pen body until it reaches the stop position.

Question	Possible Reason	How to deal with the problems
<p>The injection button cannot be pressed in.</p>	<p>The needle is blocked or damaged.</p> <p>The needle has not been attached, or it has not been attached firmly enough.</p> <p>No dose has been set.</p> <p>You might be pressing the injection button at an angle.</p>	<p>Turn back the dosage selector to “0”. Replace with a new, full cartridge. Use a new needle. Repeat the safety test before each injection.</p> <p>Attach the needle properly.</p> <p>Set the desired dosage by turning the dosage selector.</p> <p>Press down the injection button straight down into the pen, so that the dosage selector can be turned freely.</p>
<p>The dose window is not showing “0” after the injection</p>	<p>If the dose window shows any other number other than “0” after the injection, the entire dose of insulin has not been injected.</p>	<p>Make sure that you press the injection button until the “0” position is reached. If this is not possible, you may not have injected your full dose. Do not try to make up the shortfall by giving a second injection (otherwise you may be at risk from low blood sugar). Please check your blood sugar and consult your healthcare professional.</p>
<p>The cartridge contains many bubbles.</p>	<p>The pen has been stored with a needle attached.</p> <p>The cartridge could be broken.</p>	<p>Always store the pen without a needle attached. Perform the safety test until the large air bubbles are removed from the cartridge.</p> <p>If large air bubbles remain in the cartridge, replace the cartridge with a new one.</p> <p>Replace the cartridge with a new one.</p>

Question	Possible Reason	How to deal with the problems
The dosage selector cannot be turned.	The insulin cartridge does not contain enough insulin for your full dose.	EITHER inject what is remaining and then complete your dose from a new cartridge; OR use a new cartridge for your full dose.
The plunger cannot be screwed back to its initial position (after changing the cartridge).	The mechanism could be blocked because you have tried to extract more units from the cartridge than are present.	Hold the plunger reset ring firmly in one hand. Hold the dosage selector with the other hand. Turn the dosage selector back in the anti-clockwise direction until it reaches "0".
The cartridge holder cannot be screwed on to the pen body. The rubber seal of the cartridge is bulging out.	<p>The plunger has not been screwed back completely to its initial position before the cartridge holder was attached.</p> <p>A dosage has been set and the injection button pressed without attaching the needle or when the needle is blocked or not properly attached.</p>	<p>Screw the plunger properly back into the pen body and then attach the cartridge holder to the pen body.</p> <p>If the rubber seal is bulging out, you may not be able to fix the needle properly. The rubber seal might even break. Please use a new insulin cartridge.</p>

Manufactured by:
Haselmeier GmbH
Vaihinger Straße 48
70567 Stuttgart
Germany

Manufactured for:
sanofi-aventis Canada Inc.
2905 Place Louis-R.-Renaud, Laval (Québec) Canada - H7V 0A3

JuniorSTAR is a registered trademark of the Sanofi group.

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



The right to make technical changes reserved.

Date of revision: October 23, 2014

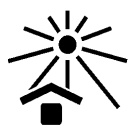
Symbols



Consult instructions for use



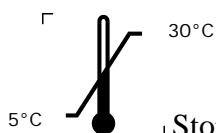
Batch Code



Keep away from sunlight



Manufacturer



Storage Temperature



Reference Number

Needles from Artsana, Becton Dickinson and Company, Ypsomed and Owen-Mumford are compatible with JuniorSTAR.

See the instruction for use that came with the needle for further important needle details.