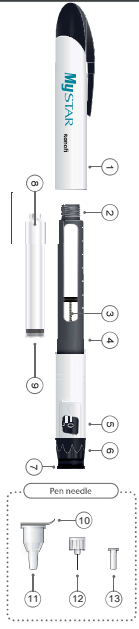


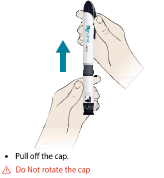
Schematic drawing



- Parts of MyStar® Pen :**
1. Cap
 2. Thread for the needle
 3. Threaded rod
 4. Cartridge sleeve
 5. Dosing window
 6. Dosing ring
 7. Injection button
- Other Supporting Accessories:**
8. Cartridge
 9. Rubber Plunger
 10. Protective foil
 11. External needle protection cap
 12. Needle
 13. Inner needle protection cap

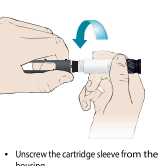
How to Insert new cartridge

Remove the cap



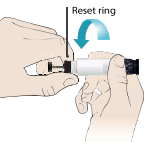
- Pull off the cap.
- ⚠ **Do Not rotate the cap**

Unscrew the cartridge sleeve



- Unscrew the cartridge sleeve from the housing.

Screw the threaded rod back



- If "0" does not appear in the dosing window, press the injection button fully.
- Turn the reset ring fully until the threaded rod reaches the starting position back. Do not press the injection button.

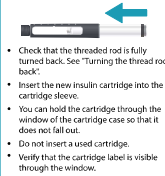
- At the stop of the reset ring, feel that the threaded rod is completely turned back.
- Do not try to push or pull the threaded rod. This can damage the pen.

Check the insulin cartridge

- # Description of your insulin cartridge to ensure that you use the right insulin.
- # The expiration date on the cartridge.
- # The integrity of the cartridge.

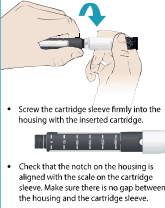
⚠ **Never use a damaged or expired insulin cartridge**

Insert new cartridge



- Check that the threaded rod is fully turned back. See "Turning the thread rod back".
- You can hold the cartridge through the window of the cartridge case so that it does not fall out.
- Do not insert a used cartridge.
- Verify that the cartridge label is visible through the window.

Screw the sleeve onto the housing



- Screw the cartridge sleeve firmly into the housing with the inserted cartridge.
- Check that the notch on the housing is aligned with the scale on the cartridge sleeve. Make sure there is no gap between the housing and the cartridge sleeve.

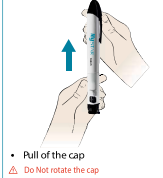
Insert the cap



- Put the cap back on the body.
- ⚠ **Do Not rotate the cap**

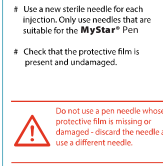
1. Attachment of needle

1a. Remove the cap



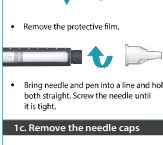
- Pull off the cap
- ⚠ **Do Not rotate the cap**

1b. Attach new needle



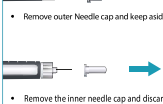
- Use a new sterile needle for each injection. Only use needles that are suitable for the MyStar® Pen
- Check that the protective film is present and undamaged.

1c. Remove the needle caps



- Remove the protective film.
- Bring needle and pen into a line and hold both straight. Screw the needle until it is tight.

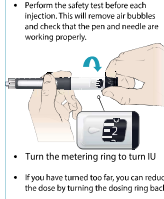
1c. Remove the needle caps



- Remove the outer Needle cap and keep aside.
- Remove the inner needle cap and discard it.

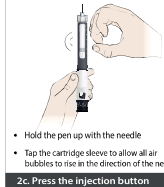
2. Test for safety

2a. Turn the metering ring



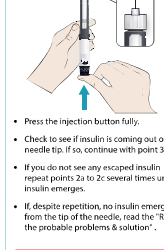
- Perform the safety test before each injection. This will remove air bubbles and check that the pen and needle are working properly.
- Turn the metering ring to turn IU
- If you have turned too far, you can reduce the dose by turning the dosing ring back.

2 B. Collect bubbles



- Hold the pen up with the needle.
- Tap the cartridge sleeve to allow all air bubbles to rise in the direction of the needle.

2c. Press the injection button

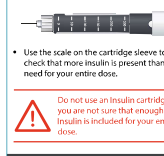


- Press the injection button fully.
- Check to see if insulin is coming out of the needle tip. If so, continue with point 3a.
- If you do not see any escaped insulin repeat points 2a to 2c several times until insulin emerges.
- If despite repetition, no insulin emerges from the tip of the needle, read the "Read the probable problems & solution".

⚠ **Never use the MyStar® Pen if the cartridge or the needle is damaged or not working safely.**

3. Injection dose

3a. Check the cartridge contents



- Use the scale on the cartridge sleeve to check that more insulin is present than you need for your entire dose.

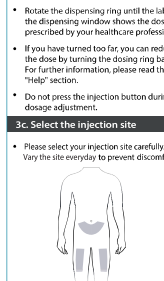
⚠ **Do not use an insulin cartridge if you are not sure that enough insulin is included for your entire dose.**

3b. Dose



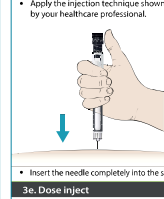
- In the dosing window you can see the dose set. You can set the dose in steps of 1. Odd numbers are displayed with a dash between the numbers.
- If you require a dose of more than 60 IU, you need to administer more than one injection.

3c. Select the injection site



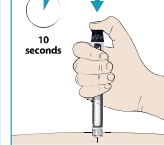
- Make sure that the safety test in the dosing window is "0".
- Rotate the dispensing ring until the label in the dosing window shows the dose prescribed by your healthcare professional.
- If you have turned too far you can reduce the dose by turning the dosing ring back. For further information, please read the "Help" section.
- Do not press the injection button during dosage adjustment.
- Please select your injection site carefully. Vary the site everyday to prevent discomfort.
- Choose the injection site on the abdomen or thighs and avoid the belly button.

3d. Insert the needle into the skin



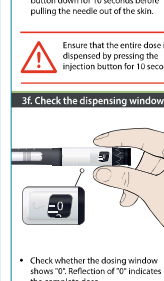
- Apply the injection technique shown by your healthcare professional.
- Insert the needle completely into the skin.

3e. Dose Inject



- Inject the dose by slowly depressing the injection button. Hold the injection button down for 10 seconds before pulling the needle out of the skin.

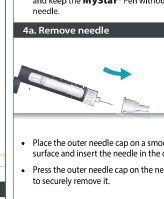
3f. Check the dosing window



- Ensure that the entire dose is dispensed by pressing the injection button for 10 seconds.
- Check whether the dosing window shows "0". Reflection of "0" indicates the complete dose.
- If the dosing window does not display "0", refer to the "Help" section on the back cover of this manual.

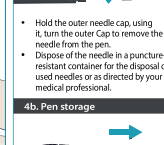
4. After injection

4a. Remove needle



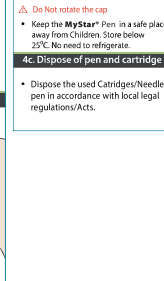
- Remove the needle after each injection and keep the MyStar® Pen without a needle.
- Place the outer needle cap on a smooth surface and insert the needle in the cap.
- Press the outer needle cap on the needle to securely remove it.

4b. Pen storage



- Hold the outer needle cap, using it, turn the outer Cap to remove the needle from the pen.
- Dispose of the needle in a puncture-resistant container for the disposal of used needles or as directed by your medical professional.

4c. Dispose of pen and cartridge



- Insert the cap.
- Do not rotate the cap
- Keep the MyStar® Pen in a safe place away from Children. Store below 25°C. No need to refrigerate.
- Dispose the used Cartridges/Needles/pen in accordance with local legal regulations/Acts.

Pen User Manual (Instructions for Use)



Pen manufactured by:
Haselmeier India Private Limited,
Sy No 27/4 A2, JR Tech Park, Yarandahalli,
Bommasandra Industrial Area 4th Phase,
Hemangara Poo, Bengaluru (Bangalore),
Rural, Karnataka (India) – 560 105.

Repacked by:
M. J. BIOPHARM PVT. LTD.
1/7, M.I.D.C. Industrial area, Talaja,
Dist. Raigad- 410 208, Maharashtra, India.
Mfg. Lic. No.: MG/MD/2024/000196

Marketed by:
Sanoofi India Limited.
Sanoofi House, CIS No. 11/74,
L&T Business park, Saki Vihar road,
Powai, Mumbai-400072,
Maharashtra, India.

MyStar is a Registered Trade Mark of Sanoofi

MyStar fulfills the regulations of the EU directives on Medical Products 93/42/EEC.

MyStar fulfills the requirements concerning dosing accuracy & function according to the ISO 11608-1:2012.

Pen injector for medical use. Part 1: Requirements & test methods.

Source: M.J. pen manufactured by M.J. Biopharm Pvt. Ltd.
Manufacturing Date: 02/2020 1024001811
Created: Apr 2024 11/19/24/11

Read instructions carefully before use :

MyStar Pen is a Reusable, Insulin Administration Pen Device. Your Healthcare specialist has recommended **MyStar** Pen in combination with a drug product, get advice from him/her regarding suitable dosage and injection method for your treatment.

Please read the instructions for use carefully and strictly follow when using the Pen to make sure that you will be getting the correct dose of Medicine. If you are unable to handle on your own, please get required help from a person who can read and understood the instructions for use.

If you are using different strengths of the drug product, then please make sure that you are using a differently marked pen for each strength. Always check, what dosage you are currently using before preparing injection.

Do not use –

- If the cartridge that contains less insulin than your complete dose
- Pen, insulin cartridge, or a needle if they are damaged or if you are not sure they are working properly.

- Always keep an alternative to inject your insulin, in case of your **MyStar** Pen lost or damaged. **Do not use your MyStar** Pen together with other people.

- Recommended to be used with **INSUTAGE® 30/70** and **INSUTAGE® R 100/10ml** 3 ml Cartridges manufactured by **M. J. BIOPHARM PVT. LTD.** and marketed by Sanoofi India Limited
- Use a sterile needle of 4mm/32G. Always attach a new needle before each use.

This needle is not part of this pack.

For injection you require:
MyStar Pen
INSUTAGE® Cartridges 3 ml as prescribed by your Health care Specialist.
New Pen needle and a puncture-proof container for disposal of used needle.

General information

Special use of the MyStar Pen in environments with multiple patients, e.g. in the hospital or nursing home, special care must be taken to ensure that each pen is used for the right patient.

If you are administering another person's injection or are given by another person, special caution is required, especially when removing and disposing of the needle. Follow safety recommendations to determine the risk of accidental injury and transmission of infectious diseases. Save the pen user manual until pen is in use.

The **MyStar** Pen recommended for 2 years after commissioning. Speak / Contact your healthcare professional to get a new pen after 2 years of use. Record the date of the First use

About your Insulin

Refer Leaflet provided with each Cartridges pack.

The dose

To ensure proper reading of the dose in the display hold the pen horizontally, with the needle pointing to the left and the dosing ring to the right, as shown in the figures.

The maximum dose you can adjust is 60 units. The **MyStar** Pen displays numbers as 11. Odd numbers are displayed with a dash between the numbers. The dispensing window shows numbers.

Dose adjusted: 22 IU.



Dose adjusted: 23 IU.



The rubber plunger moves with each injection along the window in the cartridge case.



Check if there is sufficient insulin in the cartridge for your next dose by comparing the position of the rubber plug with the scale of the cartridge plunger.

After delivering the 300 IU content the pen will get locked, and some residual content will remain in the Cartridge which cannot be delivered, hence after locking of Pen do not try to operate the pen and replace the use cartridge with new one to avoid damage to the Pen.

Maintenance and Care

Protect your **MyStar** Pen away from water, moisture and dust.

You can wipe the **MyStar** Pen with a cloth moistened with water. Please do not use alcohol, other solvents or detergents.

The pen must not be soaked, washed, glued or oiled, as all these can damage the device.

The **MyStar** Pen is designed for accurate and safe operation. Handle it with care. Avoid situations where it could be damaged.

If you are concerned that your **MyStar** Pen might be damaged, do not use it or repair it.

In case of an emergency, you can withdraw insulin from the insulin cartridge with a suitable 100 IU insulin syringe.

If you are not sure whether a malfunction is there, please contact your healthcare professional.

Storage instructions:
Keep the **MyStar** Pen out of reach of children. The pen contains small parts that can be swallowed so it should be kept away from reach of children.

Always store the **MyStar** Pen at room temperature (5 °C to 25 °C) without a needle and with an inserted cap. Do not place the **MyStar** Pen in the refrigerator.

Protect the **MyStar** Pen from direct sunlight or cold. Read the "About your Insulin section properly".

If you need a new insulin cartridge, remove it from the refrigerator 1 to 2 hours before injection to allow it to reach room temperature. Cold insulin is more painful to inject.

Other

In case of a defect:

Please give us the reason for complaint. Pens which are sent to us will in all cases be disposed off according to the legal regulations.

When using insulin cartridges, needles or accessories which are not suitable for the **MyStar** Pen, no liability is assumed for the safety, dosing accuracy and functionality as well as possible damage.



Probable problems & solution

What should I do if insulin does not leak when the injection button is pressed in?	Help for the problems
Possible Cause After the insulin cartridge change, the safety test may have to be repeated several times until insulin emerges.	Help for the problems Repeat the safety test until insulin emerges.
Possible Cause The threaded rod is not in the correct position to the rubber plug. Inside the insulin cartridge there are air bubbles.	Help for the problems Repeat the safety test until insulin emerges from the tip of the needle. Repeat the safety test until insulin emerges from the tip of the needle (small air bubbles do not affect dosage). Replace a clogged or damaged needle with a new one. Remove the inner needle cap.
Possible Cause The needle is clogged or damaged. The inner needle cap is attached.	Help for the problems Repeat the safety test until insulin emerges from the tip of the needle (small air bubbles do not affect dosage). Replace a clogged or damaged needle with a new one. Remove the inner needle cap.
Possible Cause The cartridge sleeve is not completely screwed to the housing.	Help for the problems Screw the cartridge sleeve as far as it will go against the housing.

What should I do if the injection button can not be pressed?	Help for the problems
Possible Cause The needle is clogged or damaged.	Help for the problems Turn the dosing ring back to '0'. Insert a new full insulin cartridge. Use a new needle. Perform the safety test before each injection.
Possible Cause This needle is not attached or loosely fixed.	Help for the problems Fasten the needle correctly.
Possible Cause You have not set a dose yet. You may not press the injection button straight.	Help for the problems Set the desired dose by rotating the dosing ring. Press the injection button straight so that the dosing ring can rotate freely.

What should I do if the dose window does not show '0' after injection?	Help for the problems
Possible Cause If the dosage window after injection shows a different number instead of '0', then it indicates that whole dose of insulin has not been injected.	Help for the problems Always press the injection button until the display is '0'. If this is not possible, you have not injected the whole dose. Do not attempt to compensate the defect by a second injection (otherwise there is a risk of hypoglycaemia). Please monitor your blood glucose level to take further decision. Contact your healthcare professional.

What should I do if the insulin cartridge contains many air bubbles?	Help for the problems
Possible Cause The MyStar Pen has been stored with an attached needle. The insulin cartridge may get damaged.	Help for the problems Always store the MyStar Pen without a needle. Run the safety test until the large air bubbles are removed from the cartridge. If there are still big air bubbles in the insulin cartridge, replace the cartridge with a new one.

What should I do if the dosing ring can not be rotated?	
Possible Cause The insulin cartridge does not contain enough insulin for your complete dose.	Help for the problems Use a new insulin cartridge for the entire dose and discard old one.
What should I do if the threaded rod can not be returned to the starting position?	
Possible Cause The mechanism may get stuck because you have attempted to remove more units from the insulin cartridge than are present.	Help for the problems Hold the reset ring with one hand. Using the other hand, turn the dosing ring counterclockwise to '0'. The blockade will get released.
What should I do if the cartridge sleeve is not screwed to the housing?	
Possible Cause The threaded rod was not fully turned back to the initial position before the cartridge sleeve was attached.	Help for the problems Turn the threaded rod back into the housing and then secure the cartridge sleeve to the housing.
What should I do if the rubber disc of the insulin cartridge bulges out?	
Possible Cause A dose is set and the injection button is depressed without a needle attached, or the needle is blocked or not properly fixed.	Help for the problems You may not be able to attach the needle properly. The rubber sheet may thereby break. Please use a new insulin cartridge.
What should I do if the reset ring can not be turned?	
Possible Cause The reset ring was turned too high. The mechanism may be corrupted.	Help for the problems Turn the dosing ring and press the injection button until the dosing window '0' is displayed. This releases the reset ring. Never use the MyStar Pen if it is damaged or if you are not sure it is working properly.