	<b>HI-TECH MEDICS PRIVATE LIMITED</b> <b>AL-04 SECTOR-13, GIDA, GORAKHPUR,</b> <b>UTTAR PRADESH -273209. INDIA.</b>	<b>Doc. No.:</b>	<b>HMPL/IFU/003</b>
	<b>QUALITY STANDARD</b>	<b>Rev. No.:</b>	<b>00</b>
	<b>INSULIN SYRINGE</b>	<b>Effective date:</b>	<b>10.01.2023</b>
	<b>INSULIN SYRINGE USER MANUAL (IFU)</b>	<b>Page 1 of 4</b>	

### Instruction for use

#### Product: Insulin

Hi-tech Insulin: Sterile hypodermic insulin with U-40 & U-100 variant.

#### Material Used:

- PP, TPE/TPR/PVC & Stainless Steel.

#### Intended User:

Trained Premedical Staff, MBBS, BHMS and Doctors.

#### Intended Population:

All age group (i.e. Child, Male & Female)

#### Intended Use:

Insulin syringes are used for **administering the prescribed insulin dose to diabetic patients**. The subcutaneous administration of insulin is meant to imitate the naturally occurring pancreatic secretions. The insulin injection is typically put on the abdomen, arms, thighs, and buttocks.

#### Indication:

Insulin syringes are used for administering the prescribed insulin dose to diabetic patients. The subcutaneous administration of insulin is meant to imitate the naturally occurring pancreatic secretions. The insulin injection is typically put on the abdomen, arms, thighs, and buttocks.

#### Contra-indication:


- Product should not be used on patient with known hypersensitivity to any of the material used.

#### Instruction for Use:

- To expose the plunger, pull off the bottom cap.
- To expose the needle, pull straight off the upper cap without damaging the needle point or bending the needle.
- To measure the correct dose, align the top edge of the plunger tip with advised dose to the marked scale on the syringe.
- To prevent misuse, destroy the syringe and its needle after use.

#### Caution:

- Never try to reinsert the partially or completely or withdrawn needle.

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**Warning:**

- Do not attempt to re-sterilize and reuse.
- Device is single use only.
- Device must not be reused. Reuse of the device may;
- Cause serious infection, cross contamination, transmission of bacteria, viruses and blood Related transfusion of serious diseases like HIV, Hepatitis.
- Alter the performance & function like sharpness of needle, smoothness of plunger movement and needle tube fluidity.
- Read instruction before use.
- Ensure before use that device /packing is not tempered or damage.
- The device should be use according to the instruction for use.
- Use the device immediately after opening the individual pack.
- Check expiry date prior to use.
- This device should be used .by a Doctor/Registered Practitioner or Paramedic.
- Avoid any air bubble in the syringes during infusion procedure.
- Gloves should be worn at all times during vein puncture to minimize exposure hazard.
- Causation must be taken when collecting blood samples from immobilized, haemophile or epileptic patients. For example: - Due to risk of surface contamination from residual blood that may be on the needle tip, it is recommended to dispose of the needle with the tip directed upwards.
- Discard after use. Do not re-cycle, change or re-sterile.
- Improper transport and mishandling may cause structural and /or functional damage to devices or packaging.

**Storage condition:**

- Store in a clean, dry place.
- Keep product away from light, moisture and heat.
- Store the product away from walls without direct contact with the floor.
- Temperature should be 10 to 40° C.
- Hi-tech medics private limited disclaims any responsibility for possible consequences resulting from improper use.

**Disposal Method:** After use, dispose the device and packaging in accordance with hospital, administrative and/or local government policy



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**10.01.2023**

**INSULIN SYRINGE USER MANUAL (IFU)**

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S. No	Descriptions	Symbol	S. No.	Descriptions	Symbol
1	Caution/ Warning (Read IFU before use)		15	Moisture limitation	
2	Product reference/Art. No.		16	Temperature limitation	
3	Do Not Reuse		17	Do not use if package is damaged	
4	Lot Number/Batch Number		18	Consult for IFU	
5	Date of Manufacturing		19	CE Marking	
6	Use By / Expiry Date		20	Keep away from sunlight	
7	Sterilized by Ethylene oxide		21	European Authorized Representative	
8	Manufactured by		22	Do not re-sterilize	
9	Keep dry		23	Non-Pyrogenic	
10	Fragile, Handle with Care		24	Latex Free	
11	Unique Device Identifier		26	Safe Disposal of syringe	
12	Medical device		27	Single sterile barrier system	

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<b>13</b>	Do Not use hook		<b>28</b>	Store and stack in upright condition	
<b>14</b>	Moisture limitation		<b>29</b>	MR Safe	

	Name	Designation	Signature	Date
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