



**HI-TECH MEDICS PRIVATE LIMITED  
AL-04 SECTOR-13, GIDA, GORAKHPUR,  
UTTAR PRADESH -273209. INDIA.**

**Doc. No.:**

**HMPL/IFU/006**

**QUALITY STANDARD**

**Rev. No.:**

**00**

**IFU (INSTRUCTION FOR USE)**

**Effective date:**

**10.01.2023**

**I.V SET**

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### **Instruction for use**

#### **Product: IV Set**

Hi-tech: Infusion set without air vent

#### **Material Used:**

- PP, ABS, Natural Rubber & PVC tube.
- Needle PP & SS needle.

#### **Intended Use:**

To provide fluid therapy and to administer medicines and blood products.

#### **Intended User:**

Trained Premedical Staff, MBBS, BHMS and Doctors.

#### **Intended Population:**

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

#### **Indication:**


- Infusion of fluid such as parenteral nutrition and administration of other drugs and medicines.
- Maintaining hydration and/or correct dehydration in patients who are unable to take sufficient volume of oral fluids

#### **Contra-indication:**

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

#### **Instruction for use:**

- Firmly close the Flow regulator.
- Remove Spike cover & insert its full length into the container.
- Squeeze and fill half of the drip chamber with solution.
- Remove the needle protector.
- Gently open the flow regulator to let the solution. Flow for displacing the entire air from tubing and needle.
- Perform vein-puncture and regulate the flow rate by opening the regulator gradually.

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**Caution:**

- Do not use if packing is opened/damaged.
- Do not use if protective camps are detached/missed.
- This product contains natural rubber (latex) which may cause allergic reaction.
- After use this product may be potential bio-hazard.
- Not to be used for blood or blood components.
- Keep away from direct contact of wall & surface.

**Warning:**

- The use of this product is restricted to a qualified doctor or a paramedic.
- Read instructions before use thoroughly and use product accordingly.
- Do not expose to heat or direct sunlight.
- Visually inspect and carefully check the product and packaging before use. Improper transportation and handling may cause structural and / or functional damage to device or packaging.
- The product should be used immediately after opening the packaging.
- The product must be kept in its original packaging until the moment of its use.
- The product is guaranteed to be sterile & non-pyrogenic if the package has not been opened or damaged prior to use.
- Verify that integrity of the packing and expiration date before use.
- Latex free product.
- It should be replaced every 72 to 96 hours.
- Discard after single use.

**Storage condition:**

- Store in a clean, dry place.
- Keep product away from light, moisture and heat.
- Do not knead or weight the product and/or packaging.
- 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.

**Note:** in case of any ambiguity in the translated language version's interpretation, the original English language text shall be the authoritative/Reference text.



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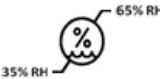

**10.01.2023**

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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	

**APPROVAL SIGNATURE:**

	Name	Designation	Signature	Date
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