



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

**Doc. No.:**

**HMPL/IFU/004**

**QUALITY STANDARD**

**Rev. No.:**

**00**

**IFU (INSTRUCTION FOR USE)**

**Effective date:**

**10.01.2023**

**HYPODERMIC NEEDLE**

**Page 1 of 4**

### **Instruction for use**

#### **Product: Hypodermic needle**

Hi-tech: Hypodermic needle for single use

#### **Material Used:**

- PP, Epoxy, & Stainless Steel.

#### **Intended Use:**

Hypodermic single use Needle is use with Syringe as a medical device on the patient who is required to be administered intravenous medicines frequently.

#### **Intended User:**

Trained Premedical Staff, MBBS, BHMS and Doctors.

#### **Intended Population:**

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

#### **Indication:**

Hypodermic Needle is designed to aspire / inject fluid under the skin (hypodermic) and/or other soft tissues. These needles consist of hollow, sharply pointed, stainless steel cannula with the distal end finished in a connector (Female Luer slip) that can be easily attached to a syringe or tube or catheter. This is a single-use device. Hypodermic needles have a small diameter (18 to 27 gauges) and length (13 to 25 mm).

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

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

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

- Peel apart to expose Hub.
- Push & twist the needle (from hub side) clock wise on the syringe tip to seat it firmly and ensure a tight fitting
- Be careful to pull the needle cap (protector) straight off without damaging the needle point
- To prevent misuse, destroy the needle after use
- Do not use with medicines reactive to plastic
- Do not use if previously opened od damaged



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

**Doc. No.:**

**HMPL/IFU/004**

**QUALITY STANDARD**

**Rev. No.:**

**00**

**IFU (INSTRUCTION FOR USE)**

**Effective date:**

**10.01.2023**

**HYPODERMIC NEEDLE**

**Page 2 of 4**

**Caution:**

- Never try to reinsert the partially or completely or withdrawn needle.

**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.
- Discard after single use.

**Storage condition:**

- Store in a clean, dry place.
- Keep product away from light, moisture and heat.
- Handle with care.
- Store the product away from walls without direct contact with the floor.
- Temperature should be 10 to 40° C.
- Do not put extra weight to avoid damage.
- 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.

| S. | Descriptions | Symbol | S. | Descriptions | Symbol |
|----|--------------|--------|----|--------------|--------|
|----|--------------|--------|----|--------------|--------|



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

**Doc. No.:**

**HMPL/IFU/004**

**QUALITY STANDARD**

**Rev. No.:**

**00**

**IFU (INSTRUCTION FOR USE)**


**Effective date:**





**10.01.2023**

**HYPODERMIC NEEDLE**

**Page 3 of 4**

| No |   |  | No. |                                    |  |
|----|---|--|-----|------------------------------------|--|
| 1  | Caution/ Warning<br>(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      |  |

|  |   |                        |                     |
|--|---|------------------------|---------------------|
|  | <b>HI-TECH MEDICS PRIVATE LIMITED</b><br><b>AL-04 SECTOR-13, GIDA, GORAKHPUR,</b><br><b>UTTAR PRADESH -273209. INDIA.</b> | <b>Doc. No.:</b>       | <b>HMPL/IFU/004</b> |
|  | <b>QUALITY STANDARD</b>   | <b>Rev. No.:</b>       | <b>00</b>           |
|  | <b>IFU (INSTRUCTION FOR USE)</b>  | <b>Effective date:</b> | <b>10.01.2023</b>   |
|  | <b>HYPODERMIC NEEDLE</b>  | <b>Page 4 of 4</b>     |                     |

|           |                     |   |           |                                      |   |
|-----------|---------------------|---|-----------|--------------------------------------|---|
| <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 |
|-------------|---------------------------------|-------------------|-----------|------|
| Prepared By | Mr. Rahul Kumar                 | Officer Q.A & Q.C |           |      |
| Checked By  | Mr. Shahzad Ansari              | Manager Q.A & Q.C |           |      |
| Approved By | Mr. Rakesh Kumar<br>Vishwakarma | Quality Head      |           |      |
| Issued By   | Mr. Rakesh Kumar<br>Vishwakarma | MR                |           |      |