

Instructions for Use

Product name: Disposable Insulin Pen Needle

Product model: Model CF,CFW,CFR

Specifications:

| Model | Sizes |
|-------|--------------------------------------------------------------------------------------------------------------------|
| CF | (29G, 30G,31G)×(3mm, 3.5mm, 4mm, 5mm, 6mm, 8mm, 10mm, 12mm) (32.5G, 33G, 34G)×(3mm, 3.5mm, 4mm, 5mm, 6mm, 8mm) |
| CFW | (29G, 30G, 31G, 32G)×(3mm, 3.5mm, 4mm, 5mm, 6mm, 8mm, 10mm, 12mm) (32.5G, 33G)×(3mm, 3.5mm, 4mm, 5mm, 6mm, 8mm) |
| CFR | (34G)×(3mm, 3.5mm, 4mm, 5mm, 6mm, 8mm) |

Device description: The Disposable Insulin Pen Needle is a sterile, single-use medical device intended to be used with a pen injector device for the subcutaneous injection of insulin. There are different product models: Model CF, CFW, CFR. Model CF, CFW, CFR are the standard type and is composed of needle hub, needle tube, needle shield, needle container and sealing film. The needle tube of Model CF, CFW are with thin wall. Model CFR are with regular wall. The needle tube tip is in three-bevel shape for Model CF, CFR. The needle tube tip is in five-bevel shape for Model CFW. For these models, there is a needle shield assembled over the patient end of the cannula to protect the needle point from damage and prevent accidental needle stick injuries.



Compatible insulin pen: HumaPen Luxura, HumaPen Luxura HD, HumaPen Ergo II, NovoPen Echo, ClikSTAR, YpsoPen, GensuPen 60-1, NovoPen4, NovoPen5, AllStar.

Intended purpose: Disposable Insulin Pen Needle is intended to be used with a pen injector device for the subcutaneous injection of insulin.

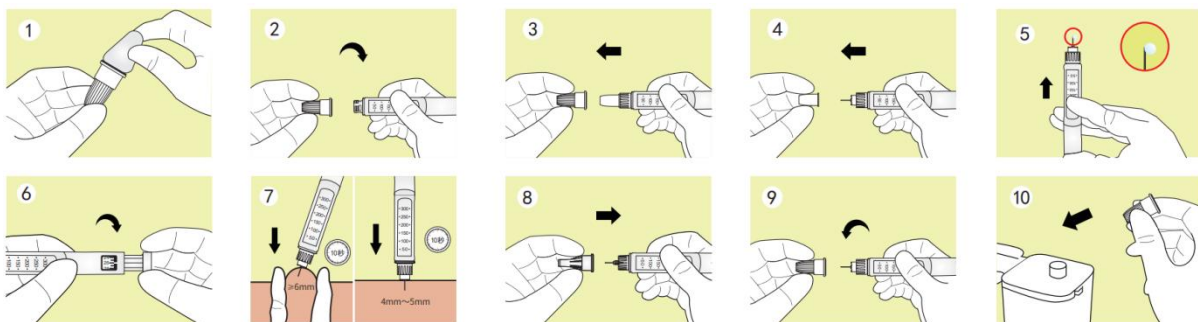
Intended users: healthcare professional and lay person

Intended patient population: Paediatric patients and adults with type1 or type 2 diabetes who require insulin injections.

Indications: Disposable insulin Pen Needle is intended to be used with a pen injector device for the subcutaneous injection of insulin. It is indicated for patients with type1 or type 2 diabetes who require insulin injections.

Contraindication: There are no noted contra-indications for the Disposable Insulin Pen Needle.



Instructions for use:



1. Peel off the sealing film (dialysis paper).
2. Align the end of the needle hub to the pen refill, then screw it on the insulin injection pen.
3. Remove the external protective cap and internal protective cap gently, do not bend the needle when removing the internal protective cap. Discard the internal protective cap.
4. Put the needle tip facing upwards, flick the pen to let the air bubbles float to the top, and then press the injection button until the liquid is discharged from the needle tip.
5. Select the insulin drug injection dose on the insulin pen according to the instructions for use of the insulin pen.
6. It is recommended to disinfect the injection site with alcohol pads. Consult with your healthcare professional ahead of time about the injection technique that is right for you.
7. Do not change direction while the needle is in the body, otherwise it will cause the needle to bend or break.
8. After completing the injection, hold needle in place more than 10 seconds before pull out the needle from the skin.
9. After use, put the external protective cap on the used insulin pen needle, unscrew the needle, and discard it in the sharps container.

Warnings:

















1. Pen needles are supplied sterile.
2. Pen needles are medical devices specifically for injection. The users should receive relevant training or instructions.
3. Pen needles are for single use. Do not reuse. Repeated use can increase injection pain and even cause the breaking of needles.
4. Consult your healthcare professional for assistance on the appropriate model and specification, technique and site for you.
5. Used needles should be disposed as medical waste. Do not discard them casually.
6. The needles are not allowed to use in the following cases: the packing is damp and moldy; the individual packaging is open or damaged; the product is expired; the product has been used; the needle tube is bent.
7. Use product with care to avoid needle stick injuries. If accidentally pricked, please seek medical help immediately.
8. This product is only for subcutaneous injection of insulin and must not be used for other medical purposes. In case of redness and swelling after injection, stop and consult a doctor.
9. The needle tube of this device contains the following substance(s) defined as CMR 1B in a concentration above 0.1% weight by weight:

|  # | Material Present | Residual Risk |
|------------------------------------------------------------------------------------------|--------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  1 | Cobalt: CAS No. 7440-48-4 EC No. 231-158-0 | Current scientific evidence supports that medical devices manufactured from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects. |

Shelf life: 5 years

Symbols:

| | | | | | |
|-------------------------------------------------------------------------------------|--------------|-------------------------------------------------------------------------------------|--------------------------|---------------------------------------------------------------------------------------|---------------|
|  | Manufacturer |  | Date of manufacture |  | Use-by date |
|  | Batch code |  | Do not use if package is |  | Do not re-use |

| | | | | | |
|-------------------------------------------------------------------------------------|--------------------------------|-----------------------------------------------------------------------------------|----------------------|-------------------------------------------------------------------------------------|----------------------------------------------------|
| | | | damaged | | |
|  | Sterilized using ethylene oxid |  | Do not resterilize |  | Consult instructions for use |
|  | Medical device |  | Caution |  | Single sterile barrier system |
|  | Keep away from sunlight |  | Keep dry |  | Fragile, handle with care |
|  | Unique device identifier |  | Made in China |  | Non-pyrogenic |
|  | Importer |  | Recyclable packaging |  | CE mark and Identification number of Notified Body |
|  | Contains hazardous substances | — | | | |

Incident reporting:

The user and/or patient shall report any serious incident that has occurred in relation to the device to Ningbo Medsun Medical Co., Ltd and the competent authority of the EU Member State in which the user and/or patient is established.

Manufacturer:

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