

Instructions for Use

Product name: Disposable Insulin Pen Needle

Product model: Model SK, SKW

Specifications:

Model	Sizes
SK	(30G, 31G, 32G, 32.5G)×(3mm, 3.5mm, 4mm, 5mm, 6mm, 8mm)
SKW	(30G, 31G, 32G, 32.5G)×(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 SK, SKW. Model SK, SKW are the safety type. Model SK, SKW is composed of needle container, needle tube, needle shield, inner shell, slider, spring, needle hub and sealing film. The needle tube of Model SK is in three-bevel shape. The needle tube of Model SKW is in five-bevel shape. The needle tube is thin wall. For these models, the needle tip is completely hidden inside the needle shield, which is only visible when the needle shield is pressed during injection (passive safety feature). After injection, the needle shield will automatically spring back, and the device cannot be used again. A red warning mark will be displayed after use to indicate that the pen needle has been used. This safety function is intended to guard against the accidental needlestick.



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.

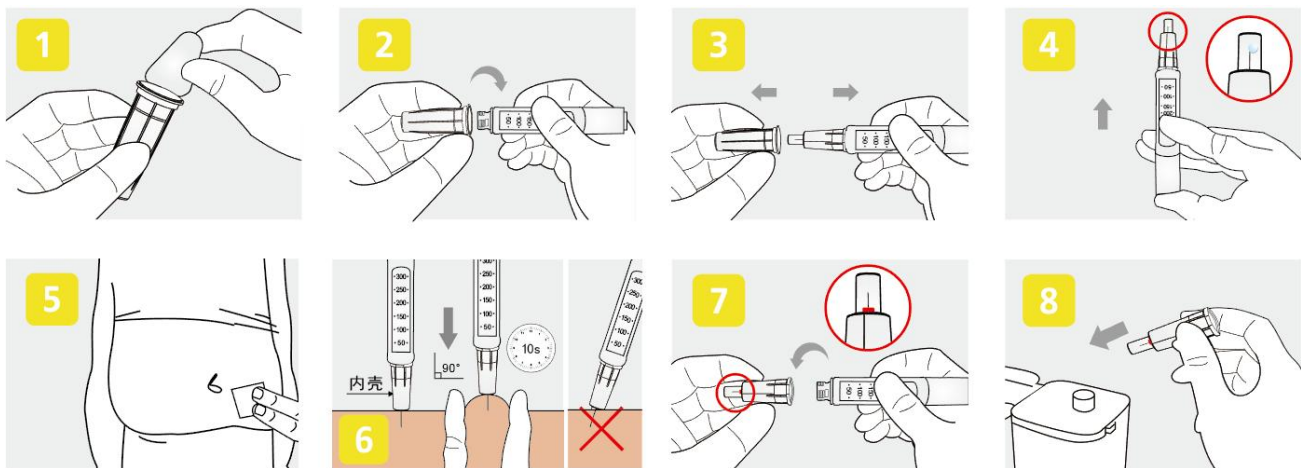
Indications: Disposable insulin Pen Needle is intended to be used with a pen injector device for the subcutaneous injection of insulin. It is indicated for patients with type1 or type 2 diabetes who require insulin injections.

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

Safety Mechanism Trigger Instructions:

1. Before use, red slider is hidden in the inner shell, needle tip is in needle shield and seen.
2. In use, needle shield is pressed down and the needle tip is exposed for injection.
3. After use, needle shield will rebound and red slider is exposed in the transparent needle shield. The red slider will be seen by user and indicate that safe-lock guard have be activated. The needle cannot be used again.

Instructions for use:





1. Confirm the integrity of the single package of the product before use, and peel off the sealing film from the shield of the pen needle;
2. Holding the shield, align the end of needle hub with the refill, and screw it clockwise on the injection pen;
3. Gently remove the shield horizontally;
4. Before each injection, adjust the dose of 2 units, put the needle tip upward, flick the injection pen to let

- the bubble float to the top, then press the injection button until the liquid is discharged from the needle tip. If there is no liquid comes up, please repeat the steps recommended in the instruction manual of injection pen. If the liquid still does not come up, replace the needle and repeat the above steps;
5. Select the insulin drug dose on the injection pen according to the instruction manual of the injection pen.
 6. It is recommended to clean the injection site with alcohol pads. When using, pierce the needle vertically (90°) into the skin until the transparent protective cap is fully retracted, and the end face of the inner protective cap is in contact with the skin for injection. Hold down the injection button for at least 10 seconds and pull out the needle. Do not change direction while the needle is still in the body, as this may cause the needle to bend. Injection is complete.
 7. After the needle tip is withdrawn from the skin, the protective jacket rebounds and the safety mechanism is automatically activated without additional action. After the safety mechanism is activated, the protective jacket hides the needle tip to prevent the needle tip from being exposed and stabbing; the needle cannot be used again. If you are concerned about the risk of intramuscular injection, you can pinch a certain area of skin to complete the injection.
 8. Hold the needle and turn it counterclockwise to remove the needle. Dispose the used pen needles 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 re-use. 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. Prohibited to use the product when the red warning sign has been floated or the needle tip is exposed to the protective jacket.
8. Use product with care to avoid needle stick injuries. If accidentally pricked, please seek medical help immediately.
9. 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.
10. 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.

Storage: It should be stored indoors at room temperature, well ventilated, dry, and free of corrosive gases (acidic gases), avoiding direct exposure to light.

Shelf life: 5 years

Symbols:

	Manufacturer		Date of manufacture		Use-by date
	Batch code		Do not use if package is damaged		Do not re-use
	Sterilized using ethylene oxid		Do not re-sterilize		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:

Ningbo Medsun Medical Co., Ltd.
No.298 Huangjipu Road, Jiangbei, 315031 Ningbo, P.R.China

European Representative:

Name: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Tel: 0049-40-2513175
Fax: 0049-40-255726
Email:shholding@hotmail.com