

Classification Name : Safety Pen Needle

Model Name : Written separately **Manufacturing date** : Written separately
Expiration date : 5 years from Mfg. date **Sterilization method** : EO gas sterilization
Lot Number : Written separately **Packaging unit** : Written separately

INTRODUCTION

1. The safety shield indicates that the safety pen needle has been used.
If the safety shield is not visible, the safety pen needle cannot be used
2. SureComfort Safety Pen Needle is a sterile single-use pen needle with a safety mechanism that automatically activates after the injection process.
3. It shall be used by health care professionals, caretakers and patients.

INTENDED USE

Sure Comfort Safety Pen Needle is intended for use with insulin pens for subcutaneous injection of insulin. The attached safety shield automatically locks in place and avoids cross infection caused by accidental puncture injuries from the patient's end of the cannula.

✳ **This product is single-use sterilized medical device. Do not reuse or re-sterilize.**

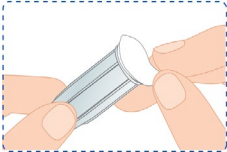
[Instructions for use]

A. Before use

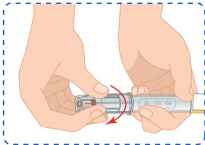
1. Before using the safety pen needle, consult its instructions for use
2. Before use, take care not to activate the safety mechanism accidentally, as the safety Pen needle cannot be used any more

B. How to operate

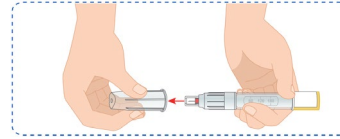
1. Clean the rubber seal on the pen with an alcohol swab.
2. Take the sterile paper off from the SureComfort.



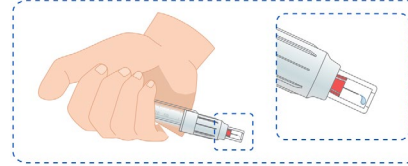
3. Holding the sterile cap, push and twist the pen needle straight onto the pen in a clockwise direction until it meets resistance with crunching sound



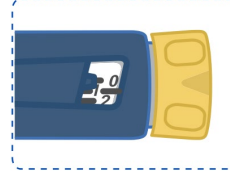
4. Remove the sterile cap from pen needle



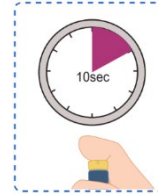
5. Check cannula to see if it's damaged (bent, broken, etc.).
Venting the pen: Set 1-2 insulin units and allow 1-2 drops to flow out of the pen needle



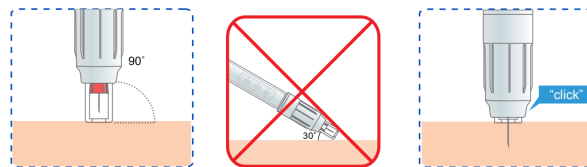
6. Dial the prescribed dosage on the pen



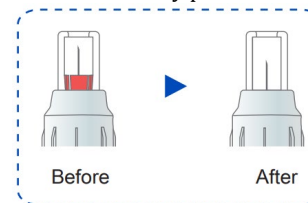
7. Pull the skin tight and insert the pen needle straight into the skin at an angle of 90° until the middle cap touches the skin and the "click" sound is audible.



8. Inject insulin according to instructions for use of the insulin pen. Leave the insulin pen in the skin for 10 seconds after injection.



9. Remove safety pen needle from skin. The safety mechanism is released automatically



10. After injection twist the insulin pen counterclockwise to remove the pen needle from the pen



[Cautions for use]

A. Warnings

- Do not use the safety pen needle if:
 - the sterile cap or sterile paper is damaged.
 - the sterile paper is detached.
 - the cannula is bent or damaged.
- Do not use the pen needle if the shelf life is exceeded.

B. Caution

- Always perform the injection at a 90° angle to the skin. Do not change the angle in order to prevent bending or breaking of the pen needle
- Only use compatible pens with Autokeeper Safety Pen Needle.
- Store the needles in a dry place at 1 °C up to 30 °C

Compatible Pens

The insulin pens listed in the IFU may have different external features but they have the same joints as the pens that are tested in the compatibility test. Therefore the results of the test cover the entire pen described in the IFU.

If your insulin pen is not listed in this IFU and you wish to check its compatibility. Please contact us.

▪ HumaPen Savvio	▪ Humatropen	▪ HumaPen Luxura
▪ Humalog Mix25tm	▪ Humulin Pen	▪ NovoPen 3
▪ NovoPen 4	▪ NovoPen 5	▪ Novo Echo
▪ NovoPen Junior	▪ Novo Let N	▪ NovoMix 30 FlexPen
▪ Induo	▪ Lantus Solosta Pen	▪ Allstar Pro
▪ Sanofi Optiset	▪ Core Tropin	▪ JuniorStar
▪ Owen Autopen	▪ BD Pen	▪ Wangbang
▪ Delfu		

Symbols	Description	Symbols	Description
	Manufacturer		Authorised representative in the European Community
	Consult instructions for use		Use-by date
	Do not use if package is damaged		Date of manufacture / Country of manufacture
	Temperature limitation		Caution
	Keep dry		Do not re-use
	Do not re-sterilize		Batch code
	Medical device		Sterilized using ethylene oxide
	Unique device identifier		CE Mark of Conformity with NB Identification Number (NB0197)

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