

IV512305 - IV512316 Dual Safety Insulin Pen Needle

i INSTRUCTION FOR USE

DESCRIPTION

m|devices Dual Safety Insulin Pen Needle is intended for subcutaneous injection of insulin in the treatment of diabetes and helps prevent needlestick injury during injection and disposal. The user is protected with the automatic safety shields activating at both ends after injection. This device is packaged in a sealed sterility barrier, and it can be used by physician, health care professional or patient itself.

This product can be used with the following brands of insulin pens: Sanofi Aventis, Lilly, Novo Nordisk, Owen Mumford and Berlin Chemie.

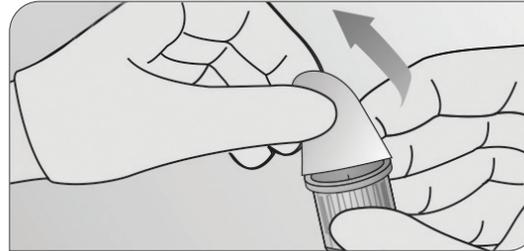
FOR USE BY AN ADEQUATELY TRAINED USER. THE BELOW IS ONLY A SUGGESTION AND THE USER SHOULD BE THOROUGHLY EDUCATED PRIOR TO ATTEMPTING TO SELF ADMINISTER INSULIN.

⚠ CAUTION

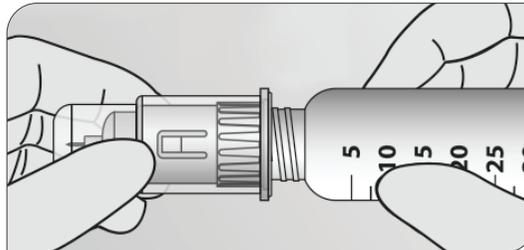
- Single use.
- DO NOT re-sterilise.
- DO NOT store at extreme temperatures and humidity, avoid direct sunlight. Handle with care.
- STERILE (EO), DO NOT use if the package or product has been damaged or contaminated.
- EU Notice: any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and /or patient is established.

STEPS

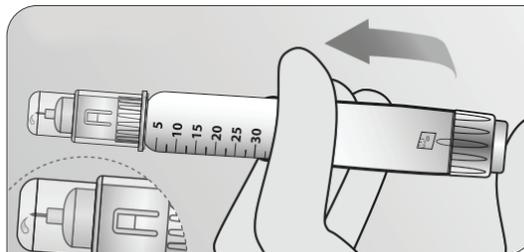
1. Select desired needle gauge and length as per health care professional recommendation.
2. Remove protective seal.



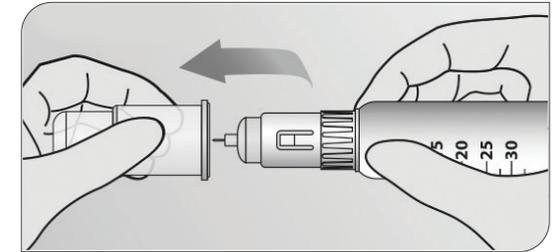
3. Whilst maintaining aseptic technique, align the needle end of the needle holder directly with the injection pen and keeping it straight, push and screw it onto the pen in a clockwise direction.



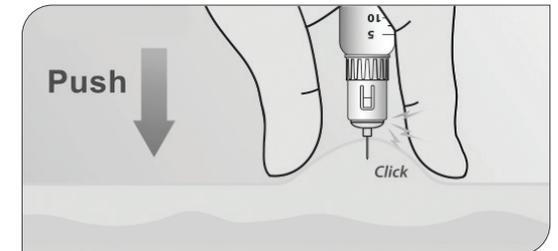
4. Before injection, prime needle by dialling 2 units on insulin pen, point the pen up and press the insulin pen button. A drop or stream of liquid should appear at the needle tip. IF NOT, repeat as recommended on the pen's instructions. If the pen still does not prime, change the needle, and repeat the priming steps.



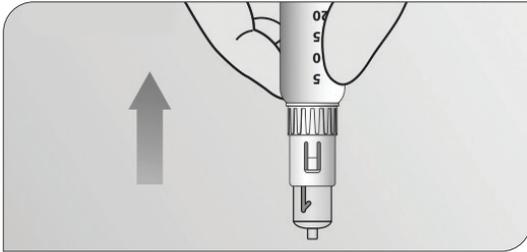
5. Dial required dosage and remove protective cap. **CAUTION** - needle is exposed, please handle with care.



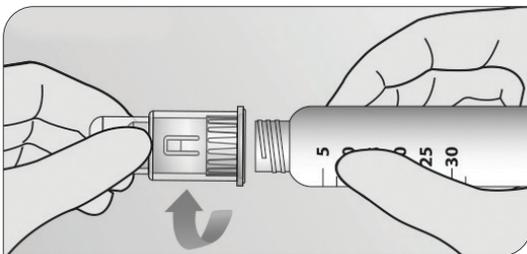
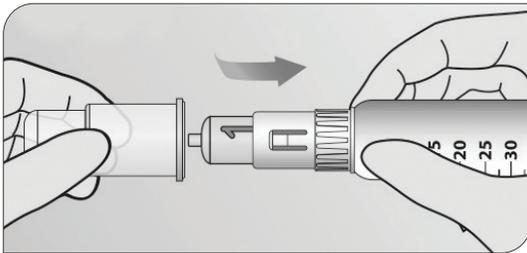
6. Insert the Insulin Pen Needle 90° or as per recommendations by health professional/facility protocol. Press the dose button and slowly administer the injection and leave the needle in the fatty tissue for 10 seconds. Do not change the direction of the pen needle while it remains in the body as this can result in bending or breaking of the needle.



7. Lift needle straight up from injection site and shield will activate.



8. Screw the needle off the pen in an anticlockwise direction and dispose in sharps container in accordance with facility protocol. .



PRECAUTIONS

- Alternate injection location regularly to reduce the risk of adipose hyperplasia. As a guide, the distance should be approximately 3cm between each injection site.
- Always follow instructions for use and facility protocol.
- Ensure skin is clean prior to injecting to reduce any risk of infection.
- Handle with care to avoid needlestick injuries.

m|devices[®]

27 Llewellyn Avenue
Villawood NSW 2163
Australia
T +61(0)2 8718 2800
F +61(0)2 8718 2801

V VENOUS ACCESS **Hypodermic Needles**

Promisedmed Hangzhou Meditech Co., Ltd.
No. 1388 Cangxing Street
Cangqian Community
Yuhang District, Hangzhou City
311121 Zhejiang, China

EC|REP **OBELIS S.A**
Bd. Général Wahis
53 1030 Brussels
Belgium

STERILE EO **MD** **CE 0197**