

IV493315 - IV505326 Insulin Pen Needle

INSTRUCTION FOR USE

DESCRIPTION

m|devices Insulin Pen Needles are intended for use with pen injector devices for the subcutaneous injection of Insulin. Our Insulin Pen Needles consist of seal, needle hub, needle tube, needle shield and needle container. Available in a range of gauges and lengths to meet all clinical requirements. Two needle bevels available; 3 and 5 bevel depending on the size selected.

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

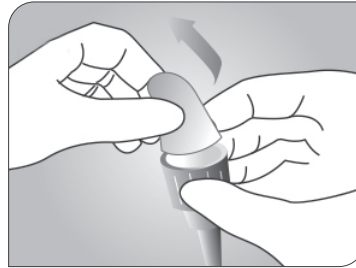
FOR USE BY AN ADEQUATELY TRAINED USER. THE BELOW IS ONLY A SUGGESTION AND THE USER SHOULD BE THOROUGHLY EDUCATED PRIOR TO ATTEMPTING TO SELF ADMINISTER INSULIN

CAUTION

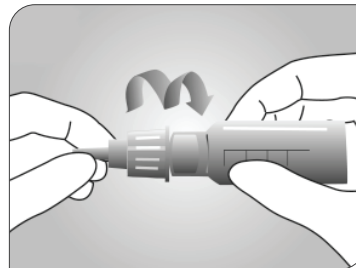
- Single use.
- DO NOT re-sterilise.
- DO NOT store at extreme temperatures and humidity, avoid direct sunlight. Handle with care.
- STERILE (EO), DO NOT use if the package or product has been damaged or contaminated.
- EU Notice: any serious incident that has occurred in relation to the device should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

STEPS

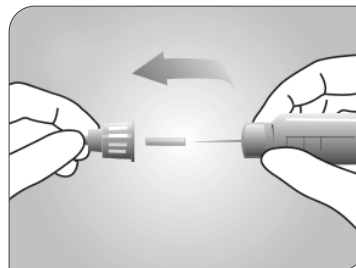
1. Select desired needle gauge and length as per health care professional recommendation.
2. Remove protective seal.



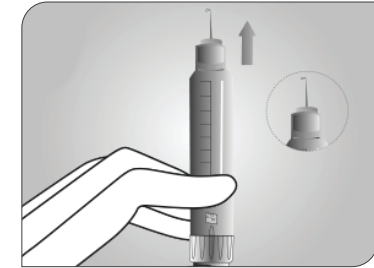
3. Whilst maintaining aseptic technique, align the needle end of the needle holder directly with the injection pen and keeping it straight, screw it onto the pen.



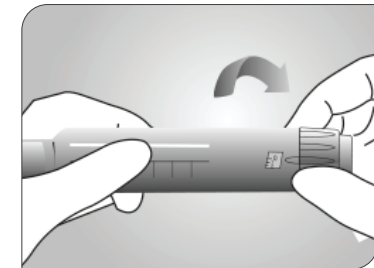
4. Remove the outer needle shield and the inner needle cap. When removing the inner needle cap, avoid bending the needle.



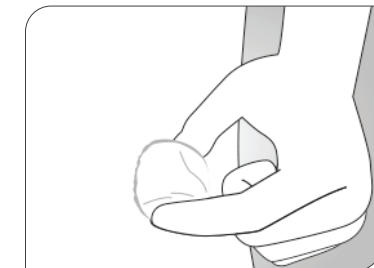
5. Before injection, prime needle by dialling 2 units on insulin pen, point the pen up and press the insulin pen button. A drop or stream of liquid should appear at the needle tip. IF NOT, repeat as recommended on the pen's instructions. If the pen still does not prime, change the needle, and repeat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



6. Dial required dosage on pen and 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. User may wish to pinch skin to support administration of insulin.



8. Unscrew the needle and dispose used pen needle safely in sharps container in accordance with local regulations.

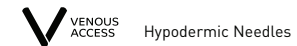


PRECAUTIONS


- Alternate injection location regularly to reduce the risk of adipose hyperplasia. As a guide, the distance should be approximately 3cm between each injection site.
- Follow the instructions for use and only use this product after consultation with your physician and/or healthcare professional.
- 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



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

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

