

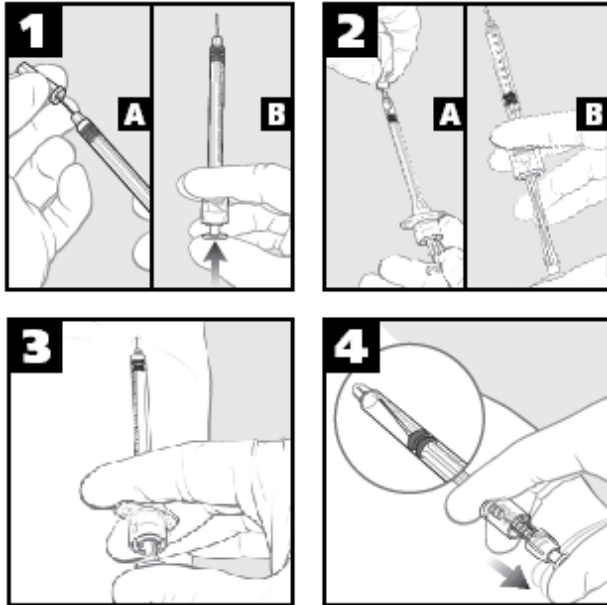
# IMPORTANT INFORMATION

**UNITRACT**  <sup>®</sup>™

Passive Sharps Protection

## Insulin Syringe with retracting needle

Insulin  
1.0mL  
U-100  
English



www.unitract.com

### Indications For Use:

The syringe, as supplied, is a device with a small barrel, plunger and fixed needle, calibrated in units of insulin (U-100), to be used to administer (infuse) insulin subcutaneously. It incorporates features that include reuse prevention and sharps injury prevention.

**Please read precautions, product information and Instruction for Use carefully before attempting to use this device.**

### Precautions:

- Sterile, non-pyrogenic and non-toxic. Do not use if unit pack is opened or damaged.
- Do not pull back on plunger until ready to draw up fluid. When pulling back the plunger, there might be a slight increase in force near the 20-unit mark.
- Patients who mix two types of insulin should not change the order of mixing.
- Engagement of the needle retraction process occurs prior to the full dose being expelled—for full dose administration ensure the plunger is depressed to the zero marker.
- Full automatic needle retraction should occur only when the plunger is fully depressed.
- The syringe is not suitable for blood aspiration following injection, and after the plunger has connected with the needle.
- Store syringe at 20°-25°C (68°-77°F). Excursions are permitted between 15° and 30°C (59° and 86°F).
- To prevent premature needle retraction do not:
  - depress the plunger beyond 10 units during pressurization of a drug container
  - pull back on the plunger below 10 units before the entire dose is administered

### Product Information:

- Contains no natural rubber latex
- Automatic needle retraction: This syringe has an automatic needle retraction feature that is activated before the needle is removed from the patient (body). Ensure the plunger is pulled back beyond the 20 unit mark as the injection cannot begin until this has been completed.
- Control of the speed of retraction: The user has the ability to control the speed of needle retraction through the amount of pressure applied to the plunger by the thumb/finger. This allows for needle retraction directly from the patient (body).
- Dose Accuracy:  $< 0.5\text{mL} \leq \pm 0.025\text{mL}$   
 $\geq 0.5\text{mL} \leq \pm 0.05\text{mL}$

### Instructions For Use:

Prepare and give injections using aseptic technique according to institutional policy or as directed by your healthcare professional. Dispose of the syringe in an approved sharps container.

### Ampoule and Cartridge:

- 1** Immediately before use, (a) carefully remove the syringe cap and (b) push down on the syringe plunger to expel excess air.
- 2** (a) Draw up the required dose. Where the required dose is less than 20 units, ensure to pull the plunger beyond the 20 unit mark and (b) expel any excess air or fluid.
- 3** Insert the needle into the injection site and then push down on the plunger, passing through any resistance from the needle engagement, until the full dose is expelled (or the plunger reaches the zero mark).
- 4** The automatic needle retraction feature is activated before the needle is removed from the patient (body). The operator may control the speed of needle retraction directly from the body, by the release of thumb or finger pressure on the plunger.

### Pressurizing a Vial

- 1** (a) Remove syringe cap and (b) draw up air [10 units more than the required dose]. Inject the air into the vial, but do not push the plunger beyond the 10 unit mark. Then follow steps 2, 3 and 4.



**UNILIFE**   
medical solutions

**MANUFACTURED BY:**  
Unilife Medical Solutions Limited  
633 Lowther Road  
Lewisberry, PA, USA

Patents applied for internationally – see www.unilife.com.  
European Patent Applications – 01925194.1; 04721775.7.  
US Patent – 6,083,199.  
US Patent Applications – 10/258,385; 10/549,710.  
Canadian Patent Applications – 2406567; 2518360.  
Australian Patents – 731159; 2001252019.  
Australian Patent Application – 2004222676.

 CAUTION!

 SEE INSTRUCTIONS FOR USE

 DO NOT USE IF PACK IS OPENED OR DAMAGED

20°C  
-25°C  
TEMPERATURE LIMITATIONS

**STERILE EO**

 SINGLE USE

**CE**  
0123

**EC REP**

Emergo Europe, Molenstraat 15  
2513 BH, The Hague, The Netherlands