

Device Description

The U-100 insulin syringe is a standard single-use plastic syringe intended for the injection of U-100 insulin into the subcutaneous tissue. It features an orange needle shield and a U-100 symbol. It is a single-use, sterile, nontoxic syringe. The syringe is sterilized by ethylene oxide gas. The fluid path of the syringe is sterile and non-pyrogenic. Medical grade polypropylene is used for the barrels of the syringes. TPR is used for the piston. The surface of the piston is being lubricated with Polydimethylsiloxane. PE is used for the plunger of the syringe.

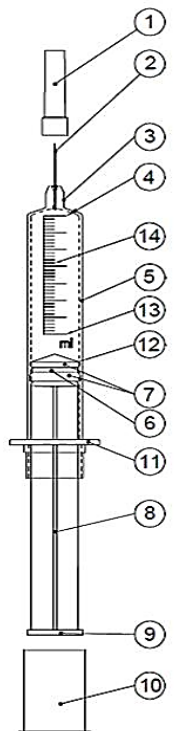
In the AVA Insulin syringe, the needle tube is fixed to the syringe barrel and the syringe is known as the unibody syringe. In this kind of syringe (unibody), the dead space of the syringe and consequently wasting Insulin is the least.

Insulin syringes are protective by two protective caps. Protective caps of this syringe are not only used to protect needle and plunger but also they are used to protect the sterility of specially designed Insulin syringe.

Material of construction

The following figure shows a syringe profile and its components.

- 1.needle cap
- 2.needle tube
- 3.nozzle
- 4.zero line
- 5.barrel
- 6.plunger stopper
- 7.seals
- 8.plunger
- 9.push-button
- 10.plunger cap
- 11.finger grips
- 12.fiducial line
- 13.nominal capacity
- 14.graduation lines



Instructions for Use: Sterile Insulin Syringe for single use

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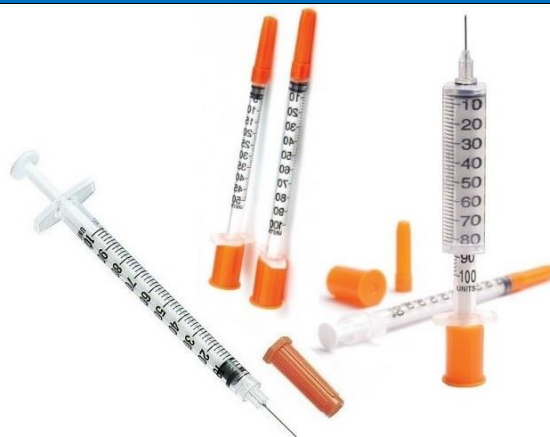
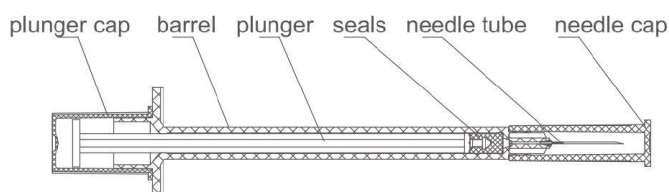
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Row	Parts name	Material	Function
1	Plunger stopper	TPE (PVC/NBR)	The function is leakproofness
2	Plunger	Polyethylene+ White Masterbatch	Its purpose is to fill or empty the barrel. The plunger is pulled back to fill the barrel and is pushed forward for injection.
3	Barrel	Polypropylene + Silicone oil	It is calibrated to make precise measurements of the quantity of the fluid that is to be given or removed.
4	Needle tube	Stainless Steel 304 + Silicone oil	Inserted into the body, often for the delivery or removal of fluid
5	Jointing medium	UV Glue	Union between hub and needle
6	Needle cap	Polyethylene + Orange Masterbatch	To maintain the sterility of the needle tube and to protect physically the needle tube
7	plunger cap	Polyethylene+ Orange Masterbatch	To enclose the projecting portion of the plunger and push-button at one end

Size Specifications



AVA Ref no.	Description	Packaging	
IN05321	0.5 ml Insulin syringe 100 I.U Fixed needle Type 7 (unit packaging) 31G (0.25mm x 8mm)	100/box	2000/case
IN1131	1 ml Insulin syringe 100 I.U Fixed needle Type 7 (unit packaging) 27G (0.4 mm x 13 mm)	100/box	2000/case
IN1221	1 ml Insulin syringe 100 I.U Fixed needle Type 7 (unit packaging) 30G (0.3 mm x 8 mm)	100/box	2000/case
IN1321	1 ml Insulin syringe 100 I.U Fixed needle Type 7 (unit packaging) 31G (0.25 mm x 8 mm)	100/box	2000/case
IN1311	1 ml Insulin syringe 100 I.U Fixed needle Type 7 (unit packaging) 31G (0.25 mm x 6 mm)	100/box	2000/case
IN05322	0.5 ml Insulin syringe 100 I.U Fixed needle Type 8 (fitted with protective end caps and packaged) 31G (0.25mm x 8mm)	40/box	2000/case
IN1132	1 ml Insulin syringe 100 I.U Fixed needle Type 8 (fitted with protective end caps and packaged) 27G (0.4 mm x 13 mm)	40/box	2000/case
IN1222	1 ml Insulin syringe 100 I.U Fixed needle Type 8 (fitted with protective end caps and packaged) 30G (0.3 mm x 8 mm)	40/box	2000/case
IN1322	1 ml Insulin syringe 100 I.U Fixed needle Type 8 (fitted with protective end caps and packaged) 31G (0.25 mm x 8 mm)	40/box	2000/case



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IN1312

1 ml Insulin syringe 100 I.U Fixed needle Type 8 (fitted with protective end caps and packaged) 31G (0.25 mm x 6 mm)

40/box

2000/case

Intended use

Unibody Insulin Syringe: Sterile, single-use insulin syringes (Type 7 and 8, based on ISO 8537:2016) made of plastic materials and intended solely for the subcutaneous injection of a desired dose of insulin, with which the syringes are filled by the end user. the syringe has a graduated barrel, a plunger rod, and a needle/hub assembly.

Intended Target Population

Unibody Insulin syringe: For diabetic patients and includes children and adults.

Indication

The insulin syringe is indicated for subcutaneous injection of U-100 insulin. The insulin syringes primarily intended for human use.

Contraindications

The insulin syringes are appropriately graduated and labelled for only one concentration of insulin. Serious problems can result if a syringe is used with a concentration of insulin that is different from the one for which it was designed. They are intended for use (i.e. insulin injection) immediately after filling and are not intended to contain insulin for extended periods of time.

Device must not be used other than as indicated in intended use.

Device should not be used for administration of blood and blood components. Device should not be used for high viscous fluid.

Description of the device intended for use with the device

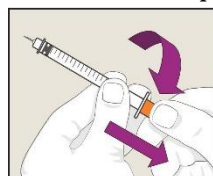
Insulin syringe is designed to be used with insulin vials. 0.5 ml insulin syringes are ideal for doses under 50 units and 1ml insulin syringes are ideal for doses over 50 units.



Instruction for Use

- To expose the plunger, twist the orange cap, then pull it off.
- To expose the needle, twist the orange needle shield then pull it straight off, being careful not to bend the needle or let the needle touch anything.
- Pull the insulin syringe plunger down; align the thin black line of the plunger (closest to the needle) with the desired number of units on the insulin syringe. You need air in the insulin syringe equal to the amount of insulin you will take.
- Hold the insulin syringe like a pencil. Push the needle straight through the center of the rubber top of the insulin bottle and push the plunger down completely.
- Leave the needle in the insulin bottle. Carefully turn the bottle and the insulin syringe upside down so the bottle is on top.
- Pull the plunger down slowly. Align the thin black line of the plunger (closest to the needle) with the desired number of units on the insulin syringe.
- If air bubbles appear in the insulin syringe, inject the insulin back into the vial. Then redraw the insulin following steps 6 and 7.

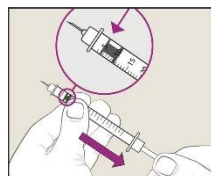
- Confirm the dose is correct, and then clean a small area of skin. Let it dry completely before injecting.
- Hold the insulin syringe like a pencil. Pinch up your skin and push the needle quickly through the skin at 90° (straight in) to the skin surface. Push the insulin in with the plunger. Pull the needle out of your skin. Release the skin pinch-up.
- Do not recap used needles. Use the needle once and dispose of it properly.



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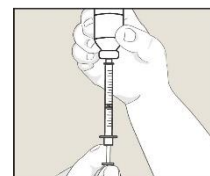
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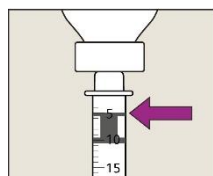
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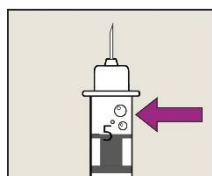
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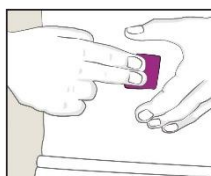
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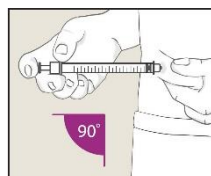
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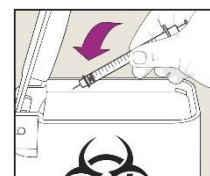
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Classification

A set of criteria is used in order to determine classification.

Row	Criteria			
1	Duration of use	Transient ☒	Short term ☐	Long term ☐
2	Invasiveness	Invasive device ☒	Non Invasive device ☐	
3	Source of energy	Active medical devices ☐	Non Active medical devices ☒	
4	Devices with a measuring function	measuring function ☒	Non measuring function ☐	
5	Systems and procedure packs	NA		
6	Reusable surgical instrument	Single used ☒	Reusable ☐	

Based on the above criteria according to Rule 6 insulin syringes are classified as class IIa of the EU Medical Device Regulation (MDR) 2017/745



Cautions

- Contents are sterile, non toxic, and non pyrogenic.
- Sterilization is valid until the caps are NOT removed. Do not use if caps are damaged or opened.
- Patients, who mix two types of insulin, do not change:
 - a) The order of mixing that the physician has prescribed.
 - b) The model and brand of the syringe or needle without consulting your physician or pharmacist.
- Failure to attend this warning can be resulted in dosage error.

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Storage Conditions

- Keep in dry and cool place
- Do not store in high temperatures and humidity.
- Hand with care
- Keep away from direct sunlight.

Description of the symbol used

Reference number and graphic	Title	barrel of syringe	Unit packaging (type 7)	Multiple unit packs (type 8)	user packaging (box)	storage packaging (carton)
	Do not re-use "for single use"	✓	✓	✓	✓	✓
	Trademark of the manufacturer	✓	✓	✓	✓	✓
			✓	✓	✓	✓
	Iran national standard		✓	✓	✓	✓
	Name and the address of the authorized representative in the European Union		✓	✓	✓	✓
	Batch code		✓	✓	✓	
	sterilized by ethylene oxide		✓		✓	✓
	Insulin syringe with sterile interior			✓	✓	✓
	Use-by date		✓	✓	✓	
	Date of manufacture		✓	✓	✓	
	Manufacturer		✓	✓	✓	✓
	Caution		✓	✓	✓	
	Fragile. Handle with care					✓
	Keep dry				✓	✓
	Keep away from sunlight				✓	✓
	Move vertically					✓



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