

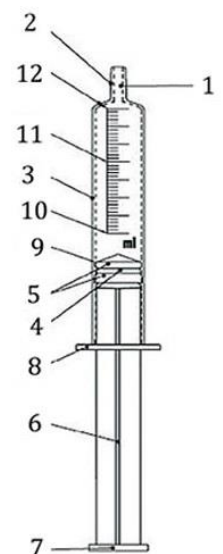
Device Description

The AVA sterile disposable syringe is a piston syringe consisting of graduated barrel, plunger rod and gasket. Individual components are made from medical grade materials. Additionally, there is a small amount of lubricant for moving the plunger rod smoothly along the inside surface of the barrel. The nozzle is a universal luer lock/luer slip connector. The syringe is single –use only, sterile, non-toxic, non-pyrogenic and sterilized by ethylene oxide gas.

Material of construction

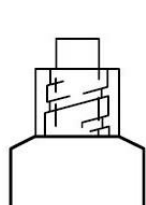
The following figure shows a syringe profile and its components.

1. nozzle lumen
2. nozzle
3. barrel
4. plunger stopper (3-piece only)
5. seals
6. plunger
7. push-button
8. barrel flanges (finger grips)
9. fiducial line
10. nominal capacity
11. graduation lines
12. zero line



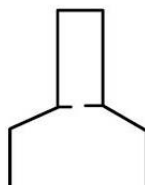
Row	Parts name	Material	Function
1	Plunger stopper	TPE (PVC/NBR) or TPR (SEPS)	The function is leakproofness
2	Plunger	Polyethylene+ Masterbatch	Its purpose is to fill or empty the barrel. The plunger is pulled back to fill the barrel and is pushed forward for injection.
3	Barrel	Polypropylene + Silicone oil	It is calibrated to make precise measurements of the quantity of the fluid that is to be given or removed.

Size Specifications



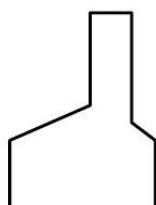
Luer-Lok tip sizes:

3 mL
5 mL
10 mL
20 mL



Slip tip sizes:

3 mL
5 mL



Eccentric tip sizes:

10 mL
20 mL



AVA Ref no.	Description	Packaging	
LS31110	3ml Luer Slip syringe central cone with needle, 23 G (0.6 mm ×32 mm)	-	2000/case
LS31111	3ml Luer Slip syringe central cone with needle, 23 G (0.6 mm ×32 mm), boxed	100/box	2000/case
LS31211	3ml Luer Slip pre assembled syringe central cone with detachable needle, 23 G (0.6 mm ×32 mm), boxed	100/box	1000/case
LS51110	5ml Luer Slip syringe central cone with needle, 22 G (0.7 mm×32 mm)	-	2000/case
LS51111	5ml Luer Slip syringe central cone with needle, 22 G (0.7 mm×32 mm), boxed	100/box	2000/case
LS51211	5ml Luer Slip pre assembled syringe central cone with detachable needle, 22 G (0.7 mm×32 mm), boxed	100/box	1000/case
LS102110	10ml Luer Slip syringe eccentric cone with needle, 21 G (0.8 mm×38 mm)	-	600/case
LS202110	20ml Luer Slip syringe eccentric cone with needle, 20 G (0.9 mm ×38 mm)	-	350/case
LL31110	3ml Luer Lock syringe central cone with needle, 23 G (0.6 mm ×32 mm)	-	2000/case
LL31111	3ml Luer Lock syringe central cone with needle, 23 G (0.6 mm ×32 mm), boxed	100/box	2000/case
LL31211	3ml Luer Lock pre assembled syringe central cone with detachable needle, 23 G (0.6 mm ×32 mm), boxed	100/box	1000/case
LL31221	3ml Luer Lock pre assembled syringe central cone with detachable needle 23 G (0.6 mm ×32 mm) & a draw up needle 18 G (1.2 mm×38 mm), boxed	100/box	1000/case
LL51110	5ml Luer Lock syringe central cone with needle, 22 G (0.7 mm×32 mm)	-	2000/case
LL51111	5ml Luer Lock syringe central cone with needle, 22 G (0.7 mm×32 mm), boxed	100/box	2000/case
LL51211	5ml Luer Lock pre assembled syringe central cone with detachable needle, 22 G (0.7 mm×32 mm), boxed	100/box	1000/case
LL51221	5ml Luer Lock pre assembled syringe central cone with detachable needle 22 G (0.7 mm×32 mm) & a draw up needle 18 G (1.2 mm×38 mm), boxed	100/box	1000/case
LL101110	10ml Luer Lock syringe central cone with needle, 21 G (0.8 mm×38 mm)	-	600/case
LL201110	20ml Luer Lock syringe central cone with needle, 20 G (0.9 mm ×38 mm)	-	350/case

Intended use

Sterile hypodermic syringes (Luerlock and Luerslip syringes): Sterile hypodermic syringes are intended for use with hypodermic needles. Sterile single-use hypodermic syringe made of plastics materials and intended for the aspiration and injection of fluids after filling by the end- users. Sterile syringes are intended for use immediately after filling as they are not suitable for containing fluids over extended periods of time. The syringe has a graduated barrel, a plunger, a hub and a needle

Intended Target Population

The device is designed for use by a qualified physician or clinician.

There is no particular intended patient population for the use of disposable syringes.

Indication

Administrations of injections or medicinal fluids intra muscular and intra venous. Sterile hypodermic single use Syringes and Needles, intended for the injection of intravenous and/or intra muscular fluids immediately after filling by the end-users.

Contraindications

The role of medical devices is for treatment and alleviation of disease. The devices are used for injecting the medicinal fluids as fixed dosage in the body.

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.

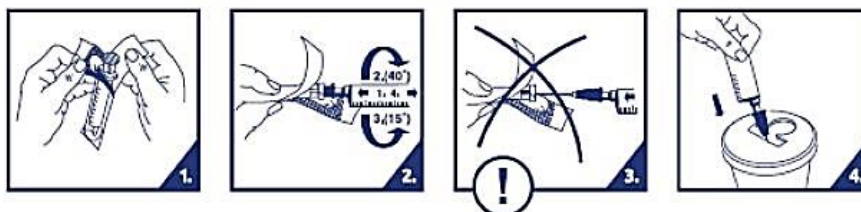
Description of the device intended for use with the device

The hypodermic syringe is designed for use with a needle, plastic cannula or IV port for parenteral (non-oral) administration of medication.



Instruction for Use

- Peel open the syringe package as shown on the package
- To expose the needle, pull the cover straight off. Be careful not to damage needle.
- Twist the needle onto the nozzle and lock into place.
- Throw away the syringe after use in an approved waste sharps container.



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☐

	Instructions for Use: Sterile Hypodermic Syringe for single use	Code: WI-TA-03 Rev: 3 Page: 4 of 5 Date: 09/2025
---	--	---

Based on the above criteria Hypodermic syringes without needles are classified as class I but hypodermic needles with needles are classified as class IIa (the classification of the highest- risk device is applied) of the EU Medical Device Regulation (MDR) 2017/745

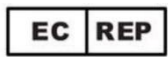
Cautions

- Single use
- Sterilized by EO
- Non Pyrogenic
- Non Toxic
- Do not use if package is opened or damaged
- Do not re-use
- Reuse of the product may cause infections, cross-contamination and sepsis.
- If any serious incident occurs, it should be reported to the manufacturer and the competent authority

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	user packaging (box)	storage packaging (carton)
	Trademark of the manufacturer	✓	✓	✓	✓
	Name and the address of the Manufacturer		✓	✓	✓
	Marking for meeting the requirements of all relevant European Medical Device Directives/European Legislation The number displayed on the bottom is the Notified Body Number		✓	✓	✓
	Do not re-use "for single use"	✓	✓	✓	✓
	Iran national standard		✓	✓	✓
	Name and the address of the authorized representative in the European Union		✓	✓	✓
	Batch code		✓	✓	✓
	sterilized by ethylene oxide		✓	✓	✓
	Use-by date		✓	✓	✓
	Date of manufacture		✓	✓	✓
	Caution		✓	✓	
	Fragile. Handle with care				✓

	Instructions for Use: Sterile Hypodermic Syringe for single use	Code: WI-TA-03 Rev: 3 Page: 5 of 5 Date: 09/2025
---	--	---

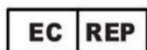
	Keep dry			✓	✓
	Keep away from sunlight			✓	✓
	Move vertically				✓

Manufacturing Site



Avapezeshk Co.
Factory: Ashtian industrial city, Ashtian, Iran
Tel: (+98) (86) 37236440, (+98) (86) 37236470
Fax: (+98) (86) 37236449
Email: info@avapezeshk.com
Website: www.avapezeshk.com

Authorized Representative



ORYX Healthcare (ORYX DIŞ TİCARET LİMİTED ŞİRKETİ)
Address: Serifali Mah. Baser Sok, No: 32/2, Umraniye, 34775 Istanbul, TURKIYE
Tel: +90 535 926 95 55
Fax: +906481344930
Email: info@oryxhealthcare.com
Website: www.oryxhealthcare.com