

Device Description

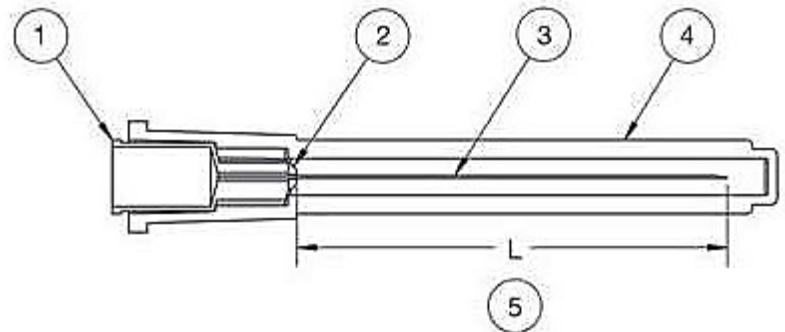
The AVA hypodermic needle is comprised of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a hypodermic syringe or an intravascular administration set.

The AVA hypodermic needle for single use intended to inject or withdraw fluids from primarily the human body. The AVA hypodermic needle is compatible for use with standard luer slip and luer lock syringes.

Material of construction

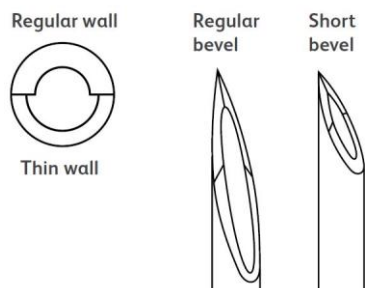
The following figure shows a needle profile and its components.

1. Hub
2. Jointing medium
3. Needle tube
4. Needle cap
5. length



Row	Parts name	Material	Function
1	Hub	Polypropylene + Colour Masterbatch	Part to fix a needle tube by adhering and connects the needle to the syringe
2	Jointing medium	Epoxy glue	Union between hub and needle
3	Needle tube	Stainless Steel 304+ Silicone oil	inserted into the body, often for the delivery or removal of fluid
4	Needle cap	Polypropylene	Intended to physically protect the needle tube prior to use.

Size Specifications



AVA Ref no.	Description	Colour code	Packaging	
N32122	32 G (0.23 mm ×12mm), Regular Wall	Deep Green	100/box	5000/case
N32062	32 G (0.23 mm ×6mm), Regular Wall	Deep Green	100/box	5000/case
N32042	32 G (0.23 mm ×4mm), Regular Wall	Deep Green	100/box	5000/case
N31122	31 G (0.25 mm×12mm), Regular Wall	White	100/box	5000/case
N31062	31 G (0.25 mm×6mm), Regular Wall	White	100/box	5000/case
N31042	31 G (0.25 mm×4mm), Regular Wall	White	100/box	5000/case
N30122	30 G (0.3 mm×12mm), Regular Wall	Yellow	100/box	5000/case
N30062	30 G (0.3 mm×6mm), Regular Wall	Yellow	100/box	5000/case
N30042	30 G (0.3 mm×4mm), Regular Wall	Yellow	100/box	5000/case
N29122	29 G (0.33 mm×12 mm), Regular Wall	Red	100/box	5000/case
N29062	29 G (0.33 mm×6 mm), Regular Wall	Red	100/box	5000/case
N29042	29 G (0.33 mm×4 mm), Regular Wall	Red	100/box	5000/case
N27251	27 G (0.4 mm ×25 mm), Thin Wall	Medium Grey	100/box	5000/case
N27192	27 G (0.4 mm ×19 mm), Regular Wall	Medium Grey	100/box	5000/case
N27122	27 G (0.4 mm ×12 mm), Regular Wall	Medium Grey	100/box	5000/case
N27121	27 G (0.4 mm ×12 mm), Thin Wall	Medium Grey	100/box	5000/case
N27062	27 G (0.4 mm ×6 mm), Regular Wall	Medium Grey	100/box	5000/case
N27042	27 G (0.4 mm ×4 mm), Regular Wall	Medium Grey	100/box	5000/case
N25321	25 G (0.5 mm ×32 mm), Thin Wall	Orange	100/box	5000/case
N25251	25 G (0.5 mm ×25 mm), Thin Wall	Orange	100/box	5000/case
N23381	23 G (0.6 mm ×38 mm), Thin Wall	Deep Blue	100/box	5000/case
N23321	23 G (0.6 mm ×32 mm), Thin Wall	Deep Blue	100/box	5000/case
N23251	23 G (0.6 mm ×25 mm), Thin Wall	Deep Blue	100/box	5000/case
N22381	22 G (0.7 mm×38 mm), Thin Wall	Black	100/box	5000/case
N22321	22 G (0.7 mm×32 mm), Thin Wall	Black	100/box	5000/case
N22251	22 G (0.7 mm×25 mm), Thin Wall	Black	100/box	5000/case
N21382	21 G (0.8 mm×38 mm), Regular Wall	Deep Green	100/box	5000/case
N21381	21 G (0.8 mm×38 mm), Thin Wall	Deep Green	100/box	5000/case
N21321	21 G (0.8 mm×32 mm), Thin Wall	Deep Green	100/box	5000/case
N21251	21 G (0.8 mm×25 mm), Thin Wall	Deep Green	100/box	5000/case
N21192	21 G (0.8 mm×19 mm), Regular Wall	Deep Green	100/box	5000/case
N21121	21 G (0.8 mm×12 mm), Thin Wall	Deep Green	100/box	5000/case
N21122	21 G (0.8 mm×12 mm), Regular Wall	Deep Green	100/box	5000/case

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AVA Ref no.	Description	Colour code	Packaging	
N21101	21 G (0.8 mm×10 mm), Thin Wall	Deep Green	100/box	5000/case
N21081	21 G (0.8 mm×8 mm), Thin Wall	Deep Green	100/box	5000/case
N20381	20 G (0.9 mm ×38 mm), Thin Wall	Yellow	100/box	5000/case
N20321	20 G (0.9 mm ×32 mm), Thin Wall	Yellow	100/box	5000/case
N20252	20 G (0.9 mm ×25 mm), Regular Wall	Yellow	100/box	5000/case
N20191	20 G (0.9 mm ×19 mm), Thin Wall	Yellow	100/box	5000/case
N20121	20 G (0.9 mm ×12 mm), Thin Wall	Yellow	100/box	5000/case
N20122	20 G (0.9 mm ×12 mm), Regular Wall	Yellow	100/box	5000/case
N20101	20 G (0.9 mm ×10 mm), Thin Wall	Yellow	100/box	5000/case
N20082	20 G (0.9 mm ×8 mm), Regular Wall	Yellow	100/box	5000/case
N20081	20 G (0.9 mm ×8 mm), Thin Wall	Yellow	100/box	5000/case
N19381	19 G (1.1mm ×38 mm), Thin Wall	Cream	100/box	5000/case
N19321	19 G (1.1mm ×32 mm), Thin Wall	Cream	100/box	5000/case
N19251	19 G (1.1mm ×25 mm), Thin Wall	Cream	100/box	5000/case
N18381	18 G (1.2 mm×38 mm), Thin Wall	Pink	100/box	5000/case
N18382	18 G (1.2 mm×38 mm), Regular Wall	Pink	100/box	5000/case
N18321	18 G (1.2 mm×32 mm), Thin Wall	Pink	100/box	5000/case
N18322	18 G (1.2 mm×32 mm), Regular Wall	Pink	100/box	5000/case
N18251	18 G (1.2 mm×25 mm), Thin Wall	Pink	100/box	5000/case
N18191	18 G (1.2 mm×19 mm), Thin Wall	Pink	100/box	5000/case
N18192	18 G (1.2 mm×19 mm), Regular Wall	Pink	100/box	5000/case
N18121	18 G (1.2 mm×12 mm), Thin Wall	Pink	100/box	5000/case
N18122	18 G (1.2 mm×12 mm), Regular Wall	Pink	100/box	5000/case
N16381	16 G (1.6 mm ×38 mm), Thin Wall	White	100/box	5000/case
N16382	16 G (1.6 mm ×38 mm), Regular Wall	White	100/box	5000/case
N16321	16 G (1.6 mm ×32 mm), Thin Wall	White	100/box	5000/case
N16322	16 G (1.6 mm ×32 mm), Regular Wall	White	100/box	5000/case
N16252	16 G (1.6 mm ×25 mm), Regular Wall	White	100/box	5000/case
N16191	16 G (1.6 mm ×19 mm), Thin Wall	White	100/box	5000/case
N16122	16 G (1.6 mm ×12 mm), Regular Wall	White	100/box	5000/case
N16121	16 G (1.6 mm ×12 mm), Thin Wall	White	100/box	5000/case

Intended use

Sterile hypodermic needles for single use intended to inject or withdraw fluids from primarily human body. Needles are intended for use with syringes having a 6% conical fitting.


Intended Target Population

The intended patient population is unrestricted and includes children and adults

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. The role of medical devices is for

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treatment and alleviation of disease. The devices are used for injecting the medicinal fluids as fixed dosage in the body. The shelf life of product is 5 years.

Contraindications

Hypodermic needles are not used on more than one patient. The product can be used in a one-time sterile condition with a single patient. Cleaning or re-sterilization cannot be performed. The device must not be used other than as indicated in the intended use. After usage, dispose of the product as medical waste.

Description of the device intended for use with the device

The needle is intended for use in the aspiration and injection of fluids from vials and ampoules for medical purposes. The needle is designed to mate with a male connector (nozzle) of a piston syringe or an intravascular administration set. The needle is compatible for use with standard Luer slip and Luer lock syringes. The used needles shall be disposed of following the policies and procedures of your facility, as well as national regulations for sharps disposal.

Instruction for Use

- Open the packaging by stripping it from the opening place indicated by the arrow sign.
- Visually inspect that the content of package is complete and the package is undamaged.
- The product packaging consists of a sterile needle.
- Without removing the protective cap of the needle, firmly secure the syringe and needle together, pushing the needle toward the syringe tip and turning it clockwise.
- Carefully remove the protective cap of the needle without damaging the needle.
- Inject the liquid to be injected into the intravenously, intramuscularly, or subcutaneously, according to the application procedure.
- Throw away the syringe after use in a waste sharps container.

Classification

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

Row	Criteria			
1	Duration of use	Transient <input checked="" type="checkbox"/>	Short term <input type="checkbox"/>	Long term <input type="checkbox"/>
2	Invasiveness	Invasive device <input checked="" type="checkbox"/>		Non Invasive device <input type="checkbox"/>
3	Source of energy	Active medical devices <input type="checkbox"/>		Non Active medical devices <input checked="" type="checkbox"/>
4	Devices with a measuring function	measuring function <input type="checkbox"/>		Non measuring function <input checked="" type="checkbox"/>
5	Systems and procedure packs	NA		
6	Reusable surgical instrument	Single used <input checked="" type="checkbox"/>		Reusable <input type="checkbox"/>

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



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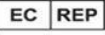










Cautions

- 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

Description of the symbol used

Reference number and graphic	Title	Unit packaging	user packaging (box)	storage packaging (carton)
	Trademark 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	✓	✓	✓
	Manufacturer	✓	✓	✓
	Caution		✓	
	Fragile. Handle with care			✓
	Keep dry		✓	✓
	Keep away from sunlight		✓	✓
	Move vertically			✓



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EC REP