

STERILE HYPODERMIC SYRINGE WITH NEEDLE FOR SINGLE USE Luer/Luer Lock



1

USAGE FEATURES*

Intended Use:

The Sterile Hypodermic Syringe for Single use is intended to be used for medical purpose to inject fluid into or withdraw fluid from body.

*: Product features may vary depending on the intended use and usage of the product.

1.1	Recommended usage period	Transient
1.2	Usage	<input checked="" type="checkbox"/> Invasive <input type="checkbox"/> Non invasive
1.3	Ergonomical features	Perfect sealing. Easy and regular sliding of the plunger. No air leakage through gasket and end piece.
1.4	Patient and user safety	The product is for single use only and required warnings about the reuse of the product is prepared as an insert IFU.

2 PRODUCT RANGE

2.1	Volume	2ml	2,5ml	3ml	5ml	10ml	20ml	50ml
2.2	Barrel Marking Specs	0.1ml	0.1ml	0.1ml	0.2ml	0.5ml	1ml	1ml
2.3	Dead Space Volume	< 0.07ml	<0.075ml	<0.075ml	<0.075ml	<0.10ml	<0.15ml	<0.20ml
2.4	Nozzle/Tip Type and Configuration	Luer, 2P Barrel, plunger	✓	✓	-	✓	✓	-
		Luer, 3P Plunger, Barrel, Piston(gasket)	✓	✓	✓	✓	✓	✓
		Luer Lock, 3P Plunger, Barrel, Piston(gasket)	✓	✓	✓	✓	✓	✓
2.5	Barrel Transparency	Transparent	✓	✓	✓	✓	✓	✓
		UV Resistant	✓	✓	✓	✓	✓	✓
		Opaque	-	-	-	-	-	✓
2.6	Length (mm)	64.05	64.05	70.20	74.40	84.80	98.00	182
2.7	Diameter (mm)	10.09	10.09	11.20	13.65	17.94	21.62	31.6
2.8	Nozzle Type	Luer, Luer lock, % 6 conical, 1.2mm						
2.9	Hypodermic Needle	Needle configurations are in the table below						
2.10	Operation Mode	The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient.						
2.11	Graduation Legibility	Legible						

Hypodermic needle product range table

2.12	Sizes	14G	15G	16G	18G	19G	20G	21G	22G	23G	25G	26G	27G	29G	30G	
	Needle lengths (*): with 15 microns filter	1"	1 1/4"	1"	1"	1 1/2"	1 1/2"	5/8"	1 1/4"	1"	1"	1/2"	1 1/2"	1/2"	1/2"	
				1"(*)	1"(*)			1 1/2"	1 1/4"	1 1/4"						
		1 1/2"	1 1/2"	1 1/4"	1 1/2"			1 1/2"	1 1/2"	1 1/4"			2"			1/3"
				1 1/2"												
2.13	Needle Cap Color					Transparent and colorless										
2.14	Needle Hub Color					Transparent and with above colors										
2.15	Needle Tip Configuraiton					Back bevel needle										
2.16	Configuration					Protective cap, needle, silicone oil, adhesives, needle hub										

2P: 2 Parça, 3P: 3 Parça

3 PRODUCT COMPONENTS

3.1	Barrel Material	PP – Polypropylene	
3.2	Plunger Material	PE – Polyethylene PP - Polypropylene	
3.3	Plunger Stopper (Gasket) Material	Isoprene rubber, Latex free	
3.4	Lubricant Composition	Silicone oil	
3.5	Protective Cap Material	PP - Polypropylene	
3.6	Adhesive Material	Epoxy Resin	
3.7	Needle and Needle Hub Material	Needle	SS304 Stainless Steel
		Needle Hub	PP – Polypropylene
3.8	Packing Material	Medical grade paper and transparent film for EO (individually blister packed)	

4 REGULATORY INFORMATION

4.1	Related Directive	93/42/EEC Medical Devices Directive, FDA 21 CFR part 820	
4.2	Risk Sınıfı ve Kuralı	IIa, Rule 6	
4.3	Ürün Standardı	ISO 6009 ISO 7864 ISO 7886-1 ISO 7886-2 ISO 80369-7 ISO 9626	
4.4	GMDN Kodu	35904 Syringe, hypodermic, metered-delivery.	

5 STERILIZATION AND SHELF LIFE

5.1	Sterilization Method	EO sterilized
5.2	Shelf Life	5 years

6 STORAGE / TRANSPORTATION CONDITIONS

20-80 %RH, 0-45°C
Protect from direct sunlight.
Should be protected from impacts during transportation.