



PRODUCT DATA SHEET

Sterile Hypodermic Syringe for Disposable Luer / Luer Lock with Needle

A.USAGE FEATURES*

Intended Use;

The Sterile Hypodermic Syringe for Disposable Luer/ Luer Lock with needle - No Needles and Infusion Set is intended to be used for medical purposes to inject withdraw fluid from body.

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

A.1	Recommended usage period	Transient
A.2	Usage	Invasive
A.3	Ergonomical features	Perfect sealing. Easy and regular sliding of the plunger. No air leakage through gasket and end piece. Sealed hose and clamp combination. Sealed air flap. Plastic bag and glass bottle compatible piercing tip.
A.4	Patient and user safety	The products is for single use only and required warnings about the reuse of the product is prepared as an insert IFU.

B.PRODUCT RANGE-HYPODERMIC SYRINGE

B.1	Volume	1 ml	1,4 ml	2 ml	2,5 ml	5 ml	10 ml	20 ml	50 ml
B.2	Barrel Marking Specs	0.01 ml	0.1 ml	0.1 ml	0.1 ml	0.2 ml	0.2 ml	1 ml	2 ml
B.3	Dead Space Volume	<0.07 ml	<0.07 ml	<0.07 ml	<0.07 ml	<0.075 ml	<0.10 ml	<0.15 ml	<0.20 ml
B.4	Nozzle/Tip Type and Configuration	Luer, 2P Barrel, Plunger	-	-	-	✓	-	✓	-
		Luer, 3P Barrel,Plunger ,Gasket	✓	✓	✓	✓	✓	✓	✓
		Luer Lock, 3P Barrel, Plunger,Gasket	-	✓	✓	✓	✓	-	-
B.5	Barrel Transparency	Transparent	✓	✓	✓	✓	✓	✓	✓
		UV Resistant	✓	✓	✓	✓	✓	✓	✓
		Opaque	-	-	-	-	-	-	-
B.6	Needle	Needle configurations are mentioned in the hypodermic needle product description table.							
B.7	Length (mm)	83.30	63.8	63.8	63.8	74.3	81.8	98.05	122.14
B.8	Diameter (mm)	6.70	10.4	10.4	10.4	13.9	17.5	23.00	31.10



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B.9	Nozzle Type	Luer, Luer Lock, %6 conical, 2.10 mm	
B.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.
B.11	Graduation Legibility		Legible

2P: 2 Parts, 3P: 3 Parts

Hypodermic Needle Product Description Table

B.12	Sizes	14G	15G	16G	18G	19G	20G	21G	22G	23G	25G	26G	27G	29G	30G
B.13	Needle Lengths	1"	1 ¼"	1"	1"	1 ½"	1 ½"	5/8"	1 ¼"	5/8"	1"	1/2"	1 ½"	1/2"	1/2"
		1 ½"	1 ½"	1 ¼"	1 ½"			1"	1 ½"	1"			2"		1/3"
B.14	Needle Cap color	Transparent and colorless													
B.15	Needle Hub Color	Transparent and with above colors													
B.16	Needle Tip Configuration	Back bevel needle													
B.17	Components	Protective cap, Needle, Adhesives, Needle hub													

C. REGULATORY INFORMATION

C.1	Related Directive	93/42/EEC Medical Device Directive	
C.2	Risk Class and Rule	Needle Syringe	IIa, Rule 6
		Needle Free Syringe	I-s, Rule 1 and I-m Rule 1
C.3	Product Standard	ISO 7864, ISO 7886-1, ISO 7886-2, ISO 9626	
C.4	GMDN Code	Needle Syringe	63095
		Needle Free Syringe	47017, 35904

D. STERILIZATION AND SHELF LIFE

D.1	Sterilization method	EO sterilized
D.2	Shelf life	5 years

E. STORAGE / TRANSPORTATION CONDITIONS

E.1	5-40°C
E.2	Protect from direct sunlight.
E.3	Should be protected from impacts during transportation.