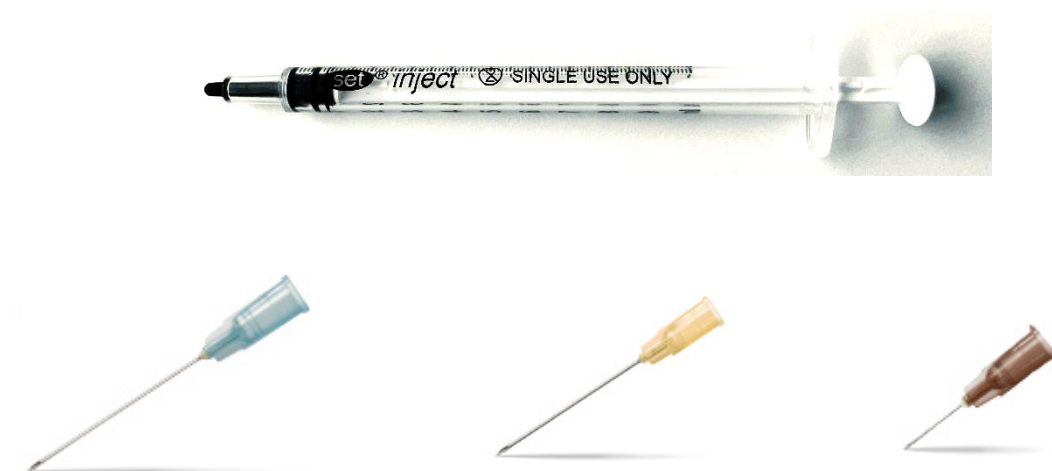


Sterile Hypodermic 1 ml Ultra Low Dead Space Syringe with Needle for Single Use



1

USAGE FEATURES*

Intended Use:

The Sterile Hypodermic 1 ml Syringe with Needle for Single Use is intended to be used for medical purposes to inject medicine into the 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		1ml				
2.2	Barrel Marking Specs		0.01 ml		0.05 ml		
2.3	Dead Space Volume	Mean	<0.035 ml				
		Std. Deviation	0.004 ml				
2.4	Nozzle/Tip Type and Syringe Configuration		Luer, 6% conical, 1.2mm				
			Barrel, Plunger, Plunger Stopper (Gasket)				
2.5	Barrel Transparency		✓		✓		
2.6	Length (mm)		89,1		89,1		
2.7	Diameter (mm)		6,85		6,85		
2.8	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.				
2.9	Graduation Legibility		Legible				
2.10	Hypodermic Needle Gauges		23G		25G		26G
2.11	Hypodermic Needle		1"	1 ½ "	1"	1 ½ "	½"
2.12	Needle Cap Color		Transparent and colorless				
2.13	Needle Hub Color		Transparent and with above color				
2.14	Needle Tip Configuration		Back bevel needle				
2.15	Components		Protective Cap, Needle, Needle Hub, Adhesive, Silicone Oil				

3 PRODUCT COMPONENTS

3.1	Barrel Material	PP – Polypropylene			
3.2	Plunger Material	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 Hub Material	Needle	Stainless Steel, SS304		
		Hub	PP-Polypropylene		

4 REGULATORY INFORMATION

4.1	Related Directive	93/42/EEC Medical Device Directive
4.2	Risk Class and Rule	Ila, Rule 6

4.3	Product Standard	ISO 6009 ISO 7864 ISO 7886-1 ISO 80369-7 ISO 8537 ISO 9626
4.4	GMDN Code	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.

7 HISTORY OF DOCUMENT REVISION

Rev. Date	Rev. No	Reason for Revision
05.06.2021	00	First published.