

Sterile Hypodermic Syringe for Single use, with/without needle; luer/luer lock



1 USAGE FEATURES*

Intended Use:

The Sterile Hypodermic Syringe for Single Use with/without needle is intended to be used for medical purposes 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	Double ring contact point on the gasket to provide perfect sealing Easy and regular sliding of the plunger No air leakage through gasket and end piece Integrated plunger stopper ring at the bottom of the barrel to prevent unintended pull out of the plunger rod
1.4	Patient and user safety	The product is a single use product and required warnings about the reuse of the product is prepared as an insert IFU.

2 PRODUCT RANGE

Volume	2ml		5 ml		10ml		20ml	
Barrel Marking Specs	0,1ml		0,2ml		0,5ml		1ml	
Tip type	Luer, 6% conical		Luer, 6% conical		Luer, 6% conical		Luer, 6% conical	
Configuration	Gasket, Plunger, Barrel		Gasket, Plunger, Barrel		Gasket, Plunger, Barrel		Gasket, Plunger, Barrel	
Barrel Transparency	Transparent		Transparent		Transparent		Transparent	
Needle Size	23G 1"	23G 1 ¼"	22G 1 ¼"	22G 1 ½"	21G 1 ½"	22G 1 ½"	20G 1 ½"	21G 1 ½"
Reference Code	21IN-0203232502	21IN-0203233201	21IN-0503223201	21IN-0503223801	21IN-1003213801	21IN-1003223801	21IN-2003203801	21IN-2003213801
Syringe Length (mm)	87,1	64,05	64,05	70,20	74,40	84,80	98,00	182
Syringe Diameter (mm)	6,85	10,09	10,09	11,20	13,65	17,94	21,62	31,6
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.							
Graduation Legibility	Legible							

3 PRODUCT COMPONENTS

3.1	Piston(Gasket) Material	Isoprene rubber, Latex free
3.2	Barrel Material	PP – Polypropylene
3.3	Plunger Material	PE – Polyethylene PP – Polypropylene
3.4	Lubricant Composition	Silicone oil for three part syringe Slip additive for two part syringe

4 REGULATORY INFOMATION

4.1	Related Directive	93/42/EEC Medical Device Directive
4.2	Risk Class and Rule	IIa, Rule 2
4.3	Product Standard	ISO 7864 ISO 7886-1, ISO 7886-2 ISO 8537 ISO 9626 ISO 80369-7
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, 5-35°C
Protect from direct sunlight.
Should be protected from impacts during transportation.

7 HISTORY OF DOCUMENT REVISION

Rev. Date	Rev. No	Reason for Revision
03.01.2020	00	First published.