

STERILE HYPODERMIC SYRINGE FOR SINGLE USE



1 USAGE FEATURES*

Intended Use:

Sterile single use hypodermic syringes without needles are devices used for the introduction and withdrawal of medicinal products and body fluids to and from the body. Syringes are used for intravenous, intramuscular, subcutaneous and intradermal injection. It is also used for the aspiration of the pharmaceutical/drugs from its container in order to administer them to the patient via systems (for ex. via intravenous (IV) port).

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

1.1	Recommended Usage Period	Short term
1.2	Usage	<input type="checkbox"/> Invasive <input checked="" 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.

1.5	Indications	Sterile single use hypodermic syringes without needles are devices used for the introduction and withdrawal of medicinal products and body fluids to and from the body. Syringes are used for intravenous, intramuscular, subcutaneous and intradermal injection, It is also used for the aspiration of the pharmaceutical/drugs from its container in order to administer them to the patient via systems (for ex. via intravenous (IV) port). The shelf life of product is 5 years.
1.6	Contraindications	Syringes without Hypodermic needles are not used in 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. It is not intended for use outside the specified intended use. After usage, dispose of the product as medical waste.
1.7	Intended patient population(s)	There is no limitation for the patient population.
1.8	Intended user(s)	Healthcare personnel
1.9	Warnings	<ul style="list-style-type: none"> Do not use the product if the package is damaged. Visually inspect that the content of package is complete and the package is undamaged. Do not use the product after the expiration date printed on the primary packaging. After injection or aspiration, dispose of the product as medical waste. The product is for single use only. It cannot be reused or re-sterilized. If the sterile packaging is not opened and used immediately, there is a risk of contamination. Product sterility cannot be maintained, do not use the product. Reuse of the product may cause infections and other illnesses.

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	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.						
2.10	Graduation Legibility	Legible						

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 Material	3P Syringe	Silicone oil
		2P Syringe	Slip additive
3.5	Packing Material	Medical grade paper and transparent film for EO (individually blister packed)	

4 REGULATORY INFORMATION

4.1	Related Directive	93/42/EEC Medical Device Directive, Medical Device Regulation – Regulation (EU) 2017/745	
4.2	Risk Class and Rule	Is, Im, Rule 2	
4.3	Product Standard	ISO 7886-1 ISO 80369-7	
4.4	GMDN Code	35904 Syringe, hypodermic, metered-delivery.	
4.5	EMDN Code	A020102010102 - Luer 2 part A020102010202 - Luer 3 part A020102020102 - Luer Lock 3 part	
4.6	Basic UDI-DI	8699207STLS2PONXZ - Luer 2 part 8699207STLS3PONY8 - Luer 3 part 8699207STLL3PONVT - Luer Lock 3 part	

5 STERILIZATION AND SHELF LIFE

5.1	Sterilization Method	EO sterilized
5.2	Self Life	5 years



PRODUCT DATA SHEET

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STORAGE / TRANSPORTATION CONDITIONS

20-80 %RH, 0-45°C

Protect from direct sunlight.

Should be protected from impacts during transportation.