

# Syringe for Bloodgas Set Bloodgas With Needle



## 1 USAGE FEATURES\*

### Intended Use:

Sterile single use syringes for Blood Gas Analysis are not intended for injection, but are used to withdraw blood to be used in gas analysis by using a hypodermic needle. It contains the anticoagulant lithium Heparin cellulose plate. The anticoagulant prevents the blood coagulation.

\*: 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. Reduced dead space volume between luer tip and tip cap.
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	Blood gas analysis provides information about patients' respiratory and metabolic status, with measurements of pH, carbon dioxide (pCO <sub>2</sub> ) and oxygen (pO <sub>2</sub> ), as well as electrolytes, lactate and hemoglobin. Blood Gas Analysis Syringes are used to collect blood to be used in gas analysis. The anticoagulant it contains prevents blood from clotting. The syringe was pre-treated with approximately 80 IU of dry electrolytebalanced heparin (porcine intestinal mucosa).
1.6	Contraindications	Bloodgas syringes with needle should not be used in more than one patient. The product can be used in a one-time sterile condition with a single patient.

		Cleaning or resterilization is not possible. It is not intended for use other than its stated intended use. Dispose of as medical waste after use.
1.7	Intended patient population(s)	There is no limitation for the patient population.
1.8	Intended user(s)	Healthcare personnel
1.9	Warnings	<p>Do not use the product if the package is damaged.</p> <p>Visually inspect that the content of package is complete and the package is undamaged.</p> <p>Do not use the product after the expiration date printed on the primary packaging.</p> <p>Before use, check that the hypodermic needle is not blocked and the flow is not obstructed.</p> <p>After injection or aspiration, dispose of the product as medical waste.</p> <p>The product is for single use only. It cannot be reused or re-sterilized.</p> <p>Do not touch the needle tip to prevent contamination/ needle sticks. Skin puncture with a contaminated needle may result in serious illness such as hepatitis, AIDS and known/unknown diseases.</p> <p>If the sterile packaging is not used immediately after opening, there is a risk of contamination. Product sterility cannot be maintained, do not use the product. Reuse of the product may cause infections, cross-contamination and sepsis.</p> <p>Work within the specified temperature and time between blood collection and analysis.</p> <p>If any serious incident occurs, it should be reported to the manufacturer and the competent authority.</p>

<b>2 PRODUCT RANGE</b>		
2.1	Volume	<b>2 ml</b>
2.2	Barrel Marking Specs	0.1 ml
2.3	Nozzle/Tip Type and Syringe Configuration	Luer, 6% conical, 3P
		Barrel, Plunger, Gasket, Cap, Lyophilized Li-Heparin
2.4	Diameter (mm)	10.4 mm
2.5	Length (mm)	79.5 mm
2.6	Operation Mode	The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in the blood. 80 IU Li-Heparin will keep the blood uncoagulated.
2.7	Graduation Legibility	Legible
2.8	Needle Gauge	22G
2.9	Needle Length	1 ¼ "

3		PRODUCT COMPONENTS	
3.1	Barrel Material	PP – Polypropylene	
3.2	Plunger Material	PE – Polyethylene	
3.3	Plunger Stopper (Gasket) Material	Isoprene rubber, Latex free.	
3.4	Cap Material	PP – Polypropylene	
3.5	Anticoagulant	Lyophilized Electrolyte-Balanced Lithium Heparin (Porcine origin)	
3.6	Lubricant Composition	Silicone Oil	
3.7	Adhesive Material	Epoxy Resin	
3.8	Needle and Hub Material	Needle	Stainless Steel, SS304
		Hub	PP – Polypropylene
3.9	Needle Cap Material	PP – Polypropylene	
3.10	Packing Material	Medical grade paper and transparent film for EO (individually blister pack)	

4		REGULATORY INFORMATION	
5.1	Related Directive	93/42/EEC Medical Device Directive, Medical Device Regulation – Regulation (EU) 2017/745	
5.1	Risk Class and Rule	Ethylene Oxide Sterilization IIa, Rule 6	
5.2	Product Standard	ISO 786-1 ISO 80369-7 ISO 7864 ISO 6009	
4.3	GMDN Code	58095 - Blood gas syringe/needle, lithium heparin	
4.4	EMDN Code	A02010501 - Luer 3 Part A02010501 - Luer Lock 3 Part	
4.5	Basic UDI-DI	869920721HP3PWR6 - Luer 3 Part 869920721HPLL3PSM - Luer Lock 3 Part	

## 6 STORAGE / TRANSPORTATION CONDITIONS

20-80 %RH, 2-32°C

Protect from direct sunlight.

Should be protected from impacts during transportation.