TECHNICAL INFORMATION SHEET

BD Preset™ Eclipse™ Arterial Blood Gas Collection Syringe

Product Catalogue Number: 364390

Product Description

Single use, sterile blood collection syringes with needle, specifically intended to be used for the collection, primary containment and preservation of blood specimens derived from the human body for the purposes of in-vitro diagnostic examintation. This device includes a user activated safety shield to reduce the risk of an accidental needle stick injury. There products are inteded for use by healthcare professionals.

Manufacturing Information

(Legal) Manufacturer:	Becton, Dickinson and Company Belliver Industrial Estate Belliver Way Roborough, Plymouth, PL6 7BP, UK
Standards & Certificate Numbers:	ISO 13485:2003 & EN ISO 13485:2012, MD 613320, ISO 14001:2004, EMS 37154, CE 00362
Country of origin:	UK
Certification body:	BSI UK (0086)
Notified Body:	BSI NL (2797)
EU Authorised Representative:	Becton Dickinson Ireland Ltd., Donore Road, Drogheda, Co. Louth, A92 YW26, Ireland

Sterilisation

Method:	Gamma Radiation
SAL:	10^{-6}
Standards applied:	EN ISO 11137

Product Standards & Guidelines

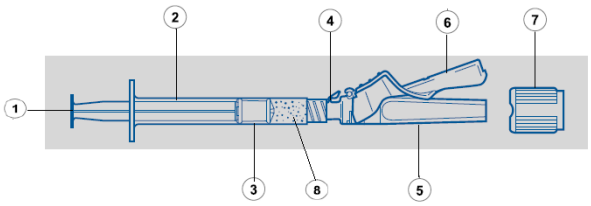
Standards:	EN ISO 11137

Compliance

Regulation:	European Medical Devices Directive 93/42/EEC
Classification:	Class IIa

Product Specification

Product Storage:	Do not expose to direct sunlight
Shelf-life:	2 years
Global medical device nomenclature (GMDN):	58095
Material Safety Data Sheet (MSDS):	VS8020500
External Dimensions (gauge x inch):	22G x 1
Recommended Fill Volume:	1.6 mL
External Dimensions (mm):	0.7 x 25
Latex (NRL):	No
Dry Natural Rubber (DNR):	No
Phthalates:	No
Material of animal origin:	Lithium Heparin: Porcine Origin



1. **Syringe Plunger Rod** Polypropylene (PP)
2. **Syringe Barrel** Polypropylene (PP)
3. **Syringe Stopper** Synthetic Isoprene / Carboxymethyl Cellulose (CMC)
4. **Hub** Polypropylene (PP)
5. **IV Shield** Polypropylene (PP)
6. **IV Safety Shield** Polypropylene (PP)
7. **BD Hemogard™ Tip cap** Polypropylene (PP)
8. **Additive** Spray Dried Calcium Balanced Lithium Heparin (≈50 IU/mL) at recommended fill volume
9. **IV Cannula (not shown)** Stainless Steel (304 Grade)

Packaging Specifications

1 unit pack weight (kg):	0.0324	1 unit packaging material:	Polyester film
1 unit pack volume (m^3):	0.000155	1 unit packaging weight (kg):	Not Available
1 unit pack dimensions LxHxW (mm):	239 x 53	100 unit pack weight (kg):	3.240
100 unit packaging material:	Cardboard	100 unit pack volume (m^3):	0.015547
100 unit packaging weight (kg):	Not Available	100 unit pack dimensions LxHxW (mm):	310 x 295 x 170

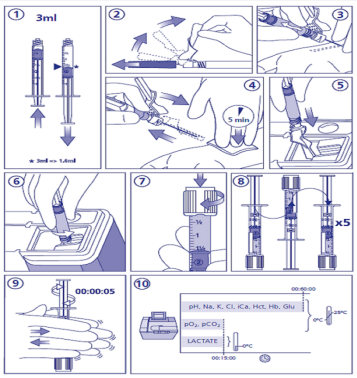
Product Catalogue Number: **364390**

Labelling Information

All labelling complies with the requirements of the European Medical Devices Directive 93/42/EEC and includes CE marking.

	Unit Pack	Shelf Pack	Case Pack
Company name	•	•	
Manufacturer address	•	•	
Product Catalogue Number (PCN)	•	•	
Sterile symbol showing method of sterilisation	•	•	
Colour Coding		•	
CE marking	•	•	
Single use symbols	•	•	
Lot number	•	•	
Expiry date	•	•	
Instructions for Use (pictorials)		•	
Cannula dimensions	•	•	
Storage instructions	•	•	
Quantity in package		•	
Primary barcode (GS1-128) product identification		•	
Secondary barcode (GS1-128) quantity, expiry, lot number		•	
Product name & short description	•	•	

Instructions For Use



Sample Storage & Stability

Samples for pO_2 analysis should not be iced but kept at room temperature and should be analyzed within 15 minutes of collection.1,2,3,4
Samples for Lactate analysis must be maintained on ice slurry and should be analyzed within 15 minutes of collection.[1,2,3,4]
Samples for pH, pCO_2 electrolyte and metabolite analysis can be maintained at room temperature and should be analysed within 30 minutes of collection.[1,2,3,4]
BD has data showing extended stability of pH, electrolytes & Glucose for up to one hour at room temperature (See further reading).

References

1. National Committee Clinical Laboratory Standards. Procedures for the Collection of Arterial Blood Specimens; Approved Standard (Fourth Edition). 2004: NCCLS Document H11-A4.
2. Clinical and Laboratory Standards Institute (CLSI). Blood Gas and pH Analysis and Related Measurements; Approved Guideline (Second Edition). 2009: CLSI Document C46-A2.
3. IFCC Scientific Division Committee on pH, Blood Gases and Electrolytes. "Approved IFCC Recommendations on Whole Blood Sampling, Transport and Storage for Simultaneous Determination of pH, Blood Gases and Electrolytes." European Journal of Clinical Chemistry and Biochemistry. 1995; 33: 247-253.
4. Guder WG, Narayanan S, Wisser H and Zawta B. Samples: From the Patient to the Laboratory: the Impact of Preanalytical Variables on the Quality of Laboratory Results (Fourth Edition). Darmstadt, Germany: Wiley-VCH; 2009.

Further Reading

1. Guder WG, Narayanan S, Wisser H and Zawta B. Samples: From the Patient to the Laboratory: the Impact of Preanalytical Variables on the Quality of Laboratory Results (Fourth Edition). Darmstadt, Germany: Wiley-VCH; 2009.
2. Mahoney JJ et al. "Changes in Oxygen Measurement When Whole Blood is Stored in Iced Plastic or Glass Syringes". Clin Chem. 1991; 37: 1244-1248.
3. Landt M et al. "Interference in Ionised Calcium Measurements by Heparin Salts." Clin Chem. 1994; 40: 677-78.
4. Lyon M et al. "Specific Heparin Preparations Interfere with Simultaneous Measurement of Ionised Magnesium and Ionised Calcium." Clinical Biochemistry. 1995; 28: 79-84.
5. BD White Paper VS5997: Evaluation of the Improved BD Preset™ Syringe For Electrolytes, Glucose, Hemoglobin, and Hematocrit at One Hour After Collection Using the Radiometer ABL® 725 Analyzer, 2008
6. BD White Paper VS7038: "Evaluation of the Improved 3mL BD Preset Syringe For Blood Gases Using the AVL Omni Analyzer". 2003.
7. Stabilis 4.0. Available at: www.Stabilis.org
8. Jagger J, De Carli G, Perry J, Puro V, Ippolito G. "Occupational Exposure to Bloodborne Pathogens: Epidemiology and Prevention". In Wenzel RP, Prevention and Control of Nosocomial Infections (4th Edition). Baltimore, MD: Lippincott Williams & Wilkins, 2003: 430-66.
9. Health Protection Agency. "Eye of the Needle: United Kingdom Surveillance of Significant Occupational Exposures to Bloodborne Viruses in Healthcare Workers". Health Protection Agency, London. Nov 2008.
10. Wicker S et al. "Prevalence and Prevention of Needlestick Injuries Among Healthcare Workers in a German University Hospital". International Archives of Occupational and Environmental Health. 2008; 81: 347-354.
11. Visser L. "Toronto Hospital Reduces Sharps Injuries by 80%, Eliminates Blood Collection Injuries. A Case Study: Toronto East General Hospital Pioneers Healthcare Worker Safety." Healthcare Quarterly. 2006; 9(1): 68-70.
12. Chen LBY, Bailey E, Kogan G, Finkelstein LE and Mendelson MH. "Prevention of NSI in Healthcare Workers: 27-Month Experience with a Resheathable Safety Winged Steel Needle Using CDC Nash database." 4th Decennial International Conference on Nosocomial and Healthcare Associated Infections. Atlanta, Georgia; 5-9 March, 2000.
13. Posters from 14th Journée GERES - Marseille - 23 Mai 2003 a. N. Jobit-Laudette. Incidents involving accidental exposure to blood b. E. Houdain, D. Descamps, A. Wdoviak, C. Ducrond. Notre Démarche de prévention des ABE c. F. Bermon. Prévention des ABE & choix du matériel d. P. Guillain Réduction des ABE : Objectif atteint
14. Glenngård AH & Persson U. Costs associated with sharps injuries in the Swedish health care setting and potential cost savings from needle-stick prevention devices with needle and syringe. Scand J Infect Dis 2009:Feb 19:1-7.
15. BD White Paper VS5940. "Incident of Blood Splatter During Activation of Safety-Engineered Blood Collection Devices." 2001.