TECHNICAL INFORMATION SHEET

BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle With Pre-Attached Holder

Product Catalogue Number: **368835**

TIS368835 FY16/003, English

BD Life Sciences
Preanalytical Systems

Intended Use

Single use blood collection needle with an integrated holder and sterile fluid path, intended to be used by healthcare professionals for the collection of human venous blood for the purpose of in vitro diagnostic testing. The device includes an integrated safety shield designed to be activated with one hand, to reduce the risk of an accidental needlestick injury and a flash chamber to inform the user of successful venous access.

Manufacturing Information

(Legal) Manufacturer	Becton, Dickinson and Company Belliver Industrial Estate Belliver Way Roborough, Plymouth, PL6 7BP, UK
Standards & Certificate Numbers	EN ISO 13485
Country of origin	UK
Certification body	BSI (0086)

Sterilisation

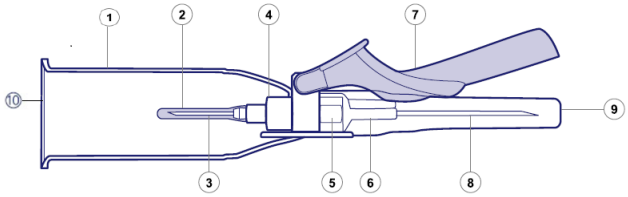
Method:	Gamma Radiation
SAL:	10^{-6}
Standards applied:	EN ISO 11137

Compliance

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

Product Specification

Cannula Dimensions:	
External Dimensions (gauge x inch)	21 G x 1
External Dimensions (mm)	0.8 x 25.4
Internal Diameter (mm)	0.635
Global medical device nomenclature (GMDN)	35209
Material Safety Data Sheet (MSDS)	Not applicable
Shelf-Life	3 years
IV / Shield Colour	Green
Does product contain?	
Latex (NRL):	No
Dry Natural Rubber (DNR):	No
Phthalates:	No
Material of animal origin:	No
Product Storage:	Do not expose to direct sunlight



1. Holder	Polypropylene (PP)
2. NP Sleeve	Synthetic Isoprene
3. NP Cannula	Stainless Steel (304 Grade)
4. Hub	Polystyrene (PS)
5. Blood Droplet Reduction System	Polyethelene (PE) and Stainless Steel (304 Grade)
6. Flash Chamber	Polystyrene (PS)
7. Safety Shield	Polypropylene (PP)
8. IV Cannula	Stainless Steel (304 Grade)
9. IV Shield	Polypropylene (PP)
10. Peel Tab	Contains paper, polyethelene (PE), high density polyethelene (HDPE) and adhesive

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)		•	On Separate Insert
Cannula dimensions	•	•	•
Storage instructions	•	•	•
Quantity in package		•	•
Primary barcode (GS1-128) product identification		•	•
Secondary barcode (GS1-128) qty, expiry, lot number			•
Product name & short description		•	•

Packaging Specifications

50 unit pack weight (kg):	0.37	**50 unit packaging material:**	Cardboard
50 unit pack volume (m^3):	0.0026623	**50 unit packaging weight (kg):**	0.063
50 unit pack dimensions LxHxW (mm):	160 x 129 x 129		
400 unit pack weight (kg):	3.33	**400 unit packaging material:**	Cardboard
400 unit pack volume (m^3):	0.0257507		
400 unit pack dimensions LxHxW (mm):	539 x 273 x 175		

Further Reading

1. BD White Paper VS9237, Evaluation of the BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle for Hemolysis as Measured by Visual Observations and Potassium and Lactate Dehydrogenase

2. BD White Paper VS9222, User Assessment of the BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle for Safety Shield Activation and Flash Visibility

3. BD White Paper VS9221, Evaluation of the BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle for Blood Flow Rate, 2015

4. Tosini W, Ciotti C, Goyer F, Lolom I, L'Heriteau F, Abiteboul D, Pellissier G and Bouvet E. "Needlestick Injury Rates According to Different Types of Safety-Engineered Devices: Results of a French Multicenter Study." Infection Control and Hospital Epidemiology. 2010; 31; 402-7.

5. European Biosafety Workshop. Prevention of sharps injuries in the hospital and healthcare sector. Implementation guidance for the EU Framework Agreement, council directive and associated national legislation. June 2010.

6. Glenngård AH and Persson U. Costs Associated with Sharps Injuries in the Swedish Health Care Setting and Potential Cost Savings From Needle-Stick Prvention Devices with Needle and Syringe." Scandinavian Journal of Infectious Diseases. Feb. 2009; 19: 1-7.

7. Frost and Sullivan. "Safety & Economy: a Survey On the Use of BD Vacutainer® Eclipse™ Blood Collection Needles in UK Hospitals". 2008. Reference available from BD on request.

8. De Carli G et al. "Needlestick-Prevention Devices: We Should Already Be There." Journal of Hospital Infection. 2008, doi:10.1016/j.jhin.2008.10.017

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. Lamontagne F et al. "Role of Safety-Engineered Devices in Preventing Needlestick Injuries in 32 French Hospitals". Infection Control and Hospital Epidemiology. 2007; 28(1): 18-23.

11.Hernandez Navarrete MJ et al. "Occupational Exposures to Blood and Biological Material in Healthcare Workers. EPINETAC Project 1996-2000." Medicina Clínica (Barcelona). 2004; 122: 81-86.

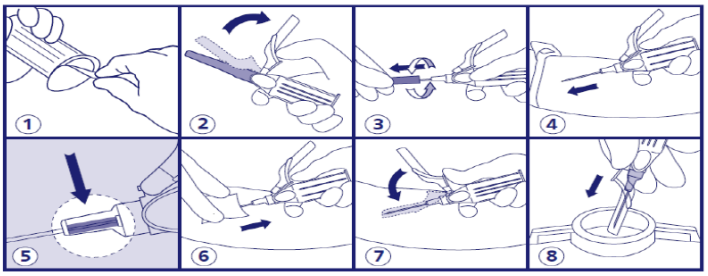
12. Posters from 14th Journée GERES - Marseille - 23 Mai 2003
a. N. Jobit-Laudette. Incidents involving accidental exposure to blood
b. E. Houdain, D. Descamps, A. Wdoviak, C. Ducrond. Notre Démarche de prévention des ABE
c. F. Bermon. Prévention des ABE & choix du matériel
d. P. Guillain Réduction des ABE : Objectif atteint

13. Jagger J and Perry J. "Comparison of EPINet Data for 1993 and 2001 Shows Marked Decline in Needlestick Injury Rates". Advances in Exposure Prevention. 2003; 6(3): 25-27.

14. Jagger J, De Carli G, Perry J, Puro V, Ippolito G. Chapter 31. Occupational exposure to bloodborne pathogens: epidemiology and prevention. In: Wenzel RP; Prevention and Control of Nosocomial Infections. 4th ed. Baltimorek Md: Lippincott, Williams & Wilkins; 2003

15. BD White Paper VS5940. Incident of Blood Splatter During Activation of Safety-Engineered Blood Collection Devices, 2001

Instructions for Use



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