

# TECHNICAL INFORMATION SHEET

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



BD Life Sciences  
Preanalytical Systems

Product Catalogue Number: **368836**

TIS368836 FY16/003, English

### 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

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

### Sterilisation

<b>Method:</b>	Gamma Radiation
<b>SAL:</b>	10 <sup>-6</sup>
<b>Standards applied:</b>	EN ISO 11137

### Compliance

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

### Product Specification

#### Cannula Dimensions:

<b>External Dimensions (gauge x inch)</b>	22 G x 1
<b>External Dimensions (mm)</b>	0.7 x 25.4
<b>Internal Diameter (mm)</b>	0.559

**Global medical device nomenclature (GMDN)** 35209

**Material Safety Data Sheet (MSDS)** Not applicable

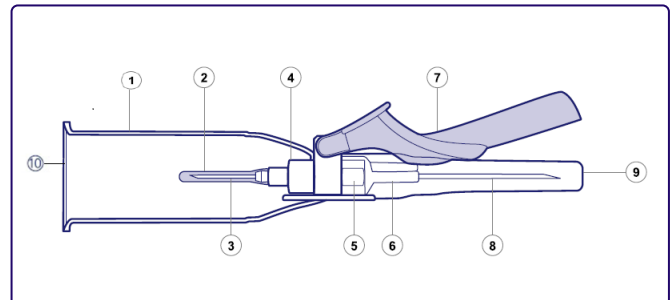
**Shelf-Life** 3 years

**IV / Shield Colour** Black

#### Does product contain?

<b>Latex (NRL):</b>	No
<b>Dry Natural Rubber (DNR):</b>	No
<b>Phthalates:</b>	No
<b>Material of animal origin:</b>	No

**Product Storage:**  Do not expose to direct sunlight



<b>1. Holder</b>	Polypropylene (PP)
<b>2. NP Sleeve</b>	Synthetic Isoprene
<b>3. NP Cannula</b>	Stainless Steel (304 Grade)
<b>4. Hub</b>	Polystyrene (PS)
<b>5. Blood Droplet Reduction System</b>	Polyethelene (PE) and Stainless Steel (304 Grade)
<b>6. Flash Chamber</b>	Polystyrene (PS)
<b>7. Safety Shield</b>	Polypropylene (PP)
<b>8. IV Cannula</b>	Stainless Steel (304 Grade)
<b>9. IV Shield</b>	Polypropylene (PP)
<b>10. Peel Tab</b>	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		•	•

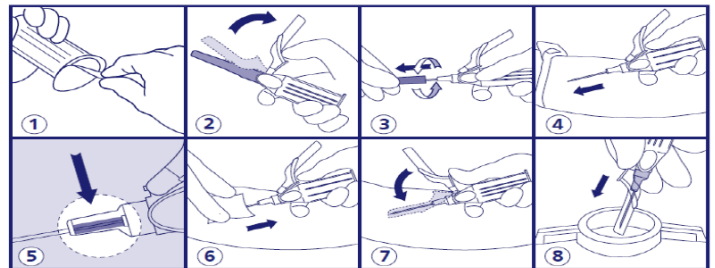
## Packaging Specifications

50 unit pack weight (kg):	0.37	50 unit packaging material:	Cardboard
50 unit pack volume (m <sup>3</sup> ):	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 <sup>3</sup> ):	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. Glengård AH and 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." *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. Ducron. Notre Démarche de prévention des ABE
  - c. F. Bermon. Prévention des ABE & choix du matériel
  - d. P. Guillaïn 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. Baltimore 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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