

TECHNICAL INFORMATION SHEET

BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle with Integrated Holder



Product Catalogue Number: **368836**

Product Description

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 examination. The device includes a user activated safety shield 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, CE0050
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

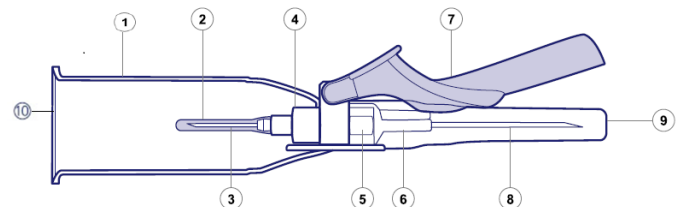
Standards:	EN ISO 11137
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Compliance

Regulation:	European Medical Device Regulation 2017/745
Classification:	Class IIa

Product Specification

Product Storage:	Do not expose to direct sunlight
Shelf-life:	3 years
Global medical device nomenclature (GMDN):	35209
Material Safety Data Sheet (MSDS):	Not applicable
External Dimensions (gauge x inch):	22 G x 1
External Dimensions (mm):	0.7 x 25.4
IV / Shield Colour:	Black
Latex (NRL):	No
Dry Natural Rubber (DNR):	No
Phthalates:	No
Material of animal origin:	No



- Holder** Polypropylene (PP)
- NP Sleeve** Synthetic Isoprene
- NP Cannula** Stainless Steel (304 Grade)
- Hub** Polystyrene (PS)
- Blood Droplet Reduction System** Polyethylene (PE) and Stainless Steel (304 Grade)
- Flash Chamber** Polystyrene (PS)
- Safety Shield** Polypropylene (PP)
- IV Cannula** Stainless Steel (304 Grade)
- IV Shield** Polypropylene (PP)
- Peel Tab** Contains paper, polyethylene (PE), high density polyethylene (HDPE) and adhesive

Packaging Specifications

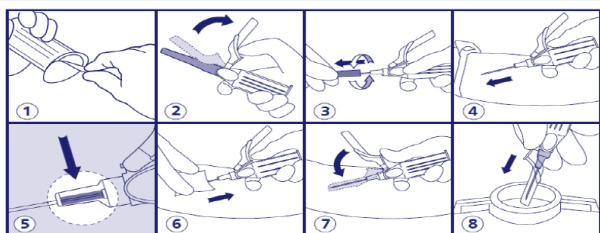
50 unit pack weight (kg):	0.37	50 unit packaging material:	Cardboard
50 unit pack volume (m ³):	0.0026623	50 unit packaging weight (kg):	0.063
50 unit pack dimensions LxHxW (mm):	160 x 129 x 129	400 unit pack weight (kg):	3.33
400 unit packaging material:	Cardboard	400 unit pack volume (m ³):	0.0257507
400 unit packaging weight (kg):	0.302	400 unit pack dimensions LxHxW (mm):	539 x 273 x 175

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) quantity, expiry, lot number			•
Product name & short description		•	•

Instructions For Use



Further Reading

1. BD White Paper VS9221, Evaluation of the BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle for Blood Flow Rate, 2015
2. BD White Paper VS9222, User Assessment of the BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle for Safety Shield Activation and Flash Visibility, 2015
3. 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, 2015
4. Stabilis 4.0. Available at: www.Stabilis.org
5. Stabilis 4.0. Available at: www.Stabilis.org
6. Glengård 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.
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. Wdowiak, C. Ducrond. Notre Démarche de prévention des ABE c. F. Berman. Prévention des ABE & choix du matériel d. P. Guillaïn Réduction des ABE : Objectif atteint
13. 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.
14. BD White Paper VS5940. "Incident of Blood Splatter During Activation of Safety-Engineered Blood Collection Devices." 2001.

Sample Storage & Stability

Not applicable

References

Not applicable