

TECHNICAL INFORMATION SHEET

BD Vacutainer® Eclipse™ Blood Collection Needle



Product Catalogue Number: **368609**

Intended Use

Single use, sterile needle used in combination with a blood collection tube holder to perform venepuncture for the purpose of collecting single or multiple venous blood samples derived from the human body for the purposes of in-vitro diagnostic examination. This device includes a user activated safety shield to reduce the risk of an accidental needle stick injury. These products are intended for use by healthcare professionals.

Manufacturing Information

(Legal) Manufacturer: Becton, Dickinson and Company 1 Becton Drive, Franklin Lakes, NJ 07417, USA
 Standards & Certificate Numbers: EN ISO 13485:2012, MD19.2137, CE 252.191
 Country of origin: USA
 Certification body: NSAI (0050)
 EU Authorised Representative: Becton, Dickinson and Company Belliver Industrial Estate Belliver Way Roborough, Plymouth, PL6 7BP, UK

Sterilisation

Method: Gamma Radiation
 SAL: 10⁻⁶
 Standards applied: EN ISO 11137

Product Standards & Guidelines

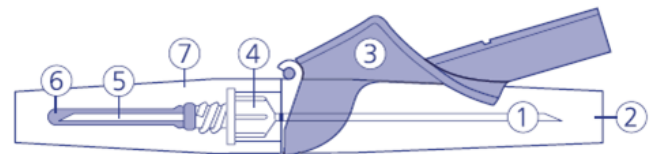
Standards: EN ISO 11137

Compliance

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

Product Specification

Product Storage: Do not expose to direct sunlight
 Shelf-life: 5 years
 Global medical device nomenclature (GMDN): 12745
 Material Safety Data Sheet (MSDS): Not applicable
 External Dimensions (gauge x inch): 21 G x 1 1/4
 External Dimensions (mm): 0.8 x 32
 Internal Diameter (mm): 0.57
 IV / Shield Colour: Green
 Latex (NRL): No
 Dry Natural Rubber (DNR): No
 Phthalates: No
 Material of animal origin: No



1. **IV Cannula** Stainless Steel (304 Grade)
2. **IV Shield** Polypropylene (PP)
3. **Safety Shield** Polypropylene (PP)
4. **Hub** Polystyrene (PS)
5. **NP Cannula** Stainless Steel (304 Grade)
6. **NP Sleeve** Synthetic Isoprene
7. **NP Cannula Shield** Polyethylene (PE)

Packaging Specifications

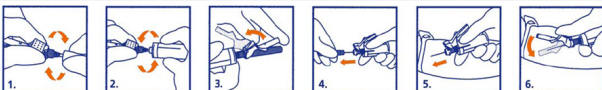
48 unit pack weight (kg):	0.199	48 unit packaging material:	Cardboard
48 unit pack volume (m ³):	0.000797	48 unit packaging weight (kg):	0.025
48 unit pack dimensions LxHxW (mm):	140 x 64 x 89	480 unit pack weight (kg):	1.996
480 unit packaging material:	Cardboard	480 unit pack volume (m ³):	0.010100
480 unit packaging weight (kg):	Not Available	480 unit pack dimensions LxHxW (mm):	279 x 157 x 232

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		•	•
EU Authorised Representative		•	•

Instructions For Use



Further Reading

1. 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.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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
7. 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.
8. Tosini W; Ciotti C; Goyer F; Lolom I; L'Heriteau F; Abiteboul D; Pellissier G; 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
9. 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.
10. 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.
11. 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. Ducron, Notre Démarche de prévention des ABE c. F. Bermon. Prévention des ABE & choix du matériel d. P. Guillaïn Réduction des ABE : Objectif atteint
12. 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.
13. 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.
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