

# TECHNICAL INFORMATION SHEET

## BD Vacutainer® Eclipse™ Blood Collection Needle



BD Diagnostics  
Preanalytical Systems

Product Catalogue Number: **368609**

TIS368609, LS, 10 10 10, 01

### 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

<b>(Legal) Manufacturer</b>	Becton, Dickinson and Company 1 Becton Drive, Franklin Lakes, NJ 07417, USA
<b>Standards &amp; Certificate Numbers</b>	ISO 13485:2003, MD19.2137
<b>Country of origin</b>	USA
<b>Certification body</b>	NSAI (0050)
<b>EU Authorised Representative:</b>	Becton, Dickinson and Company Belliver Industrial Estate, Plymouth, Devon, PL6 7BP, UK

### 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

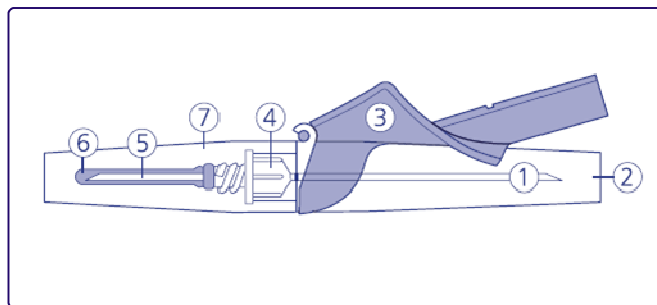
### Product Specification

#### Cannula Dimensions:

<b>External Dimensions (gauge x inch)</b>	21 G x 1 1/4
<b>External Dimensions (mm)</b>	0.8 x 32
<b>Internal Diameter (mm)</b>	0.57

<b>Global medical device nomenclature (GMDN)</b>	12745
<b>Material Safety Data Sheet (MSDS)</b>	Not applicable
<b>Shelf-Life</b>	5 years
<b>IV / Shield Colour</b>	Green
<b>Does product contain?</b>	
<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. IV Cannula</b>	Stainless Steel (304 Grade)
<b>2. IV Shield</b>	Polypropylene (PP)
<b>3. Safety Shield</b>	Polypropylene (PP)
<b>4. Hub</b>	Polystyrene (PS)
<b>5. NP Cannula</b>	Stainless Steel (304 Grade)
<b>6. NP Sleeve</b>	Synthetic Isoprene
<b>7. NP Cannula Shield</b>	Polyethylene (PE)

## 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) qty, expiry, lot number			•
Product name & short description		•	•
EU Authorised Representative:		•	•

## Packaging Specifications

<b>48 unit pack weight (kg):</b>	0.199	<b>48 unit packaging material:</b>	Cardboard
<b>48 unit pack volume (m³):</b>	0.000797	<b>48 unit packaging weight (kg):</b>	0.025
<b>48 unit pack dimensions LxHxW (mm):</b>	140 x 64 x 89		
<b>480 unit pack weight (kg):</b>	1.996	<b>480 unit packaging material:</b>	Cardboard
<b>480 unit pack volume (m³):</b>	0.010100		
<b>480 unit pack dimensions LxHxW (mm):</b>	279 x 157 x 232		

## Further Reading

- Tosini W, Giotti 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
- 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.
- 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.
- Frost & Sullivan. Safety & Economy: a survey on the use of BD Vacutainer® Eclipse™ blood collection needles in UK hospitals. – Available on request.
- De Carli G et al., Needlestick-prevention devices: we should already be there, J Hosp Infect (2008), doi:10.1016/j.jhin.2008.10.017
- Eye of the Needle: United Kingdom Surveillance of Significant Occupational Exposures to Bloodborne Viruses in Healthcare Workers; Health Protection Agency November 2008
- Lamontagne F et al., Role of safety-engineered devices in preventing needlestick injuries in 32 French hospitals. Infect Control Hosp Epidemiology 2007;28(1):18-23.
- A case study: Toronto East General Hospital pioneers healthcare worker safety, 2005 BD Case study available on Request
- 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.
- Posters from 14th Journée GRES - Marseille - 23 Mai 2003
  - N. Jobit-Laudette. Incidents involving accidental exposure to blood
  - E. Houdain, D. Descamps, A. Wdowiak, C. Ducron. Notre Démarche de prévention des ABE
  - F. Bermon. Prévention des ABE & choix du matériel
  - P. Guillaumin Réduction des ABE : Objectif atteint
- Jagger J, Perry J. Comparison of EPINET data for 1993 and 2001 shows Marked Decline in Needlestick Injury Rates. Adv Exposure Prev 2003; 6(3):25-27.
- 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
- BD White Paper VS5940. Incident of Blood Splatter During Activation of Safety-Engineered Blood Collection Devices, 2001
- Mendelson MH et al. Prevention of NSI in healthcare workers: 27 month experience with a resheathable safety winged steel needle using CDC Nash database, 4<sup>th</sup> Decennial International Conference of Nosocomial and Healthcare Associated Infections; Atlanta, Georgia - March 5-9,2000

## Instructions for Use



**BD Diagnostics**  
 Preanalytical Systems  
 The Danby Building  
 Edmund Halley Road  
 Oxford Science Park  
 Oxford, OX4 4DQ, UK  
 Tel: +44 (0)1865 748844  
 Fax: +44 (0)1865 781528  
 www.bd.com  
 bdukvacutainer@europe.com