TECHNICAL INFORMATION SHEET

BD Vacutainer® Safety-Lok™ Blood Collection Set

Product Catalogue Number: 367284

Product Description

Single use, sterile winged set used in combination with a blood collection tube holder or syringe 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, or in combination with an IV infusion line for short term intravenous administration of fluids for up to 2 hours. The device includes a safety shield which locks over the needle when activated by the user 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:	ISO 13485:2003, MD19.2137
Country of origin:	USA or Japan
Certification body:	NSAI (0050)
Notified Body:	NSAI (0050)
EU Authorised Representative:	BD Switzerland Sarl, Terre Bonne Park - A4, Route de Crassier 17, 1262 Eysins, Switzerland

Sterilisation

Method:	Ethylene Oxide (EtO)
SAL:	10^{-6}
Standards applied:	EN ISO 11135

Product Standards & Guidelines

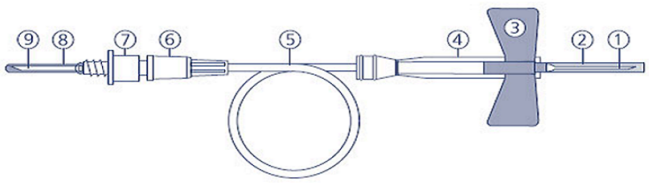
Standards:	EN ISO 11135

Compliance

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

Product Specification

Product Storage:	Do not expose to direct sunlight
Shelf-life:	2 years
Global medical device nomenclature (GMDN):	58490
Material Safety Data Sheet (MSDS):	Not applicable
External Dimensions (gauge x inch):	23 G x 3/4
Internal Diameter (mm):	0.6 x 19
Tubing Length:	178mm - 7 inches
Tubing Volume:	0.225mL
Wing Colour:	Light Blue
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** Polyethylene (PE)
3. **Wing** Polyvinyl chloride (PVC)
4. **Safety Shield** Polypropylene (PP)
5. **Tubing** Polyvinyl Chloride (PVC) Memory-Free
6. **Luer Connection** Acrylonitrile butadiene styrene (ABS)
7. **Luer Adaptor Hub** Polypropylene (PP)
8. **NP Sleeve** Synthetic Isoprene
9. **NP Cannula** Stainless Steel (304 Grade)

Packaging Specifications

50 unit pack weight (kg):	0.450	50 unit packaging material:	Polyvinyl chloride (PVC) and paper
50 unit pack volume (m^3):	0.002550	50 unit packaging weight (kg):	0.005
50 unit pack dimensions LxHxW (mm):	250 x 85 x 120	200 unit pack weight (kg):	1.650
200 unit packaging material:	Cardboard	200 unit pack volume (m^3):	0.016600
200 unit packaging weight (kg):	0.065	200 unit pack dimensions LxHxW (mm):	410 x 150 x 270

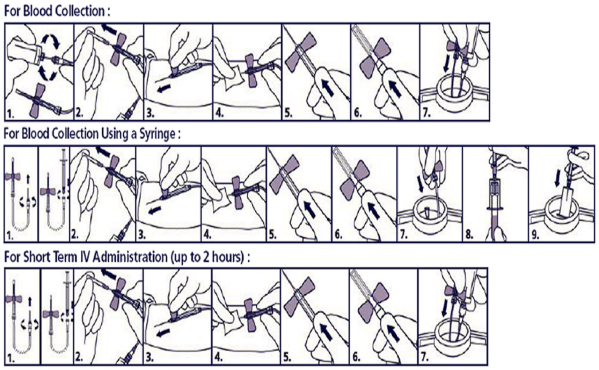
Product Catalogue Number: **367284**

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		•	•
Secondary barcode (GS1-128) quantity, expiry, lot number			•
Product name & short description	•	•	•
Authorised Representative	•	•	•

Instructions For Use



Sample Storage & Stability

Not applicable

References

Not applicable

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. 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.
3. Hernandez Navarrete MJ et al. "Occupational Exposures to Blood and Biological Material in Healthcare Workers. EPINETAC Project 1996-2000." Medicina Clinica (Barcelona). 2004;122:81-86.
4. 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
5. 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.
6. 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
7. Console G, Giudice G, Fabbri P, Gremo F, Meliga F, Miniero M, Nelli M. Esperienza Multicentrica sull'introduzione dei dispositivi medici per la prevenzione della puntura accidentale, Giornale Italiano delle Infezioni Ospedaliere 2003; 10(3):120-125.
8. Rogues A-M, Verdun-Esquer C, Buisson-Valles I, Laville M-F, Agne`s Lasheras A, Sarrat A, Helene Beaudelle H, Brochard P and Gachie J-P. "Impact of Safety Devices for Preventing Percutaneous Injuries related to Phlebotomy Procedures in Health Care Workers." American Journal of Infection Control. 2004; 32: 441-4.
9. 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.

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