TECHNICAL INFORMATION SHEET

BD Vacutainer® Push Button Blood Collection Set

Product Catalogue Number: 367338

Intended Use

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 feature which retracts 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:	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

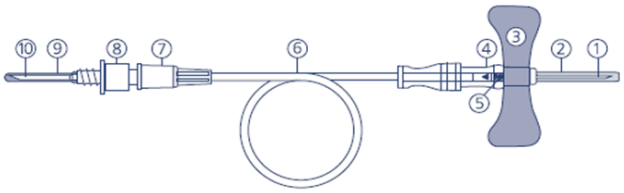
Standards:	EN ISO 11137

Compliance

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

Product Specification

Product Storage:	Do not expose to direct sunlight
Shelf-life:	2 years
Global medical device nomenclature (GMDN):	58490
Material Safety Data Sheet (MSDS):	Not applicable
External Dimensions (gauge x inch):	21 G x 3/4
Internal Diameter (inches):	0.022
External Dimensions (mm):	0.8 x 19
Internal Diameter (mm):	0.5588
Tubing Length:	178mm - 7 inches
Tubing Volume:	0.225mL
Wing 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** Polyethylene (PE)
3. **Wing** Polyolefin
4. **Front Barrel** Polypropylene (PP)
5. **Rear Barrel** Acrylic
6. **Tubing** Polyvinyl Chloride (PVC) Memory-Free
7. **Adaptor Hub** Polypropylene (PP)
8. **Adaptor Connection** Acrylonitrile butadiene styrene (ABS)
9. **NP Sleeve** Synthetic Isoprene
10. **NP Cannula** Stainless Steel (304 Grade)

Packaging Specifications

1 unit pack weight (kg):	0.006	1 unit packaging material:	PETG Copolyester
1 unit pack volume (m^3):	0.000074	1 unit packaging weight (kg):	0.005
1 unit pack dimensions LxHxW (mm):	10 x 106 x 70	50 unit pack weight (kg):	0.419
50 unit packaging material:	Cardboard	50 unit pack volume (m^3):	0.004150
50 unit packaging weight (kg):	0.065	50 unit pack dimensions LxHxW (mm):	276 x 106 x 142
200 unit pack weight (kg):	2.078	200 unit packaging material:	Cardboard
200 unit pack volume (m^3):	0.018000	200 unit packaging weight (kg):	0.300
200 unit pack dimensions LxHxW (mm):	435 x 147 x 282		

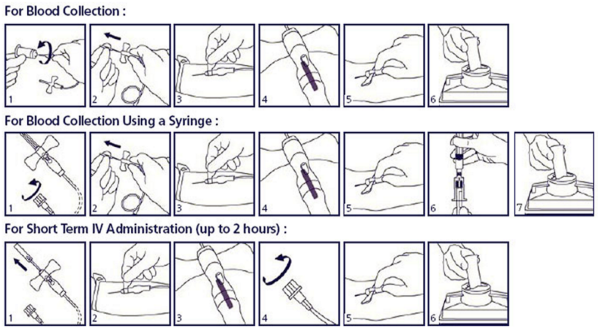
Product Catalogue Number: **367338**

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



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. 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
4. Wicker S et al. "Prevalence and Prevention of Needlestick Injuries Among Healthcare Workers in a German University Hospital". International Archives of Occupational and Environmental Health. 2008; 81: 347-354.
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. Hotaling M. "A Retractable Winged Steel (Butterfly) Needle Performance Improvement Project". Joint Commission Journal on Quality and Patient Safety. 2009; 35(2): 100-105.
8. BD White Paper VS7814-2: "BD Vacutainer Push Button Collection Set: An Impressive Safety Record. Frost & Sullivan Report." 2007.
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.