TECHNICAL INFORMATION SHEET

BD Vacutainer® UltraTouch™ Push Button Blood Collection Set

Product Catalogue Number: 367363

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 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 processionals.

Manufacturing Information

(Legal) Manufacturer:	Becton, Dickinson and Company 1 Becton Drive, Franklin Lakes, NJ 07417, USA
Standards & Certificate Numbers:	EN ISO 13485
Country of origin:	USA
Certification body:	NSAI (0050)
Notified Body:	NSAI (0050)
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

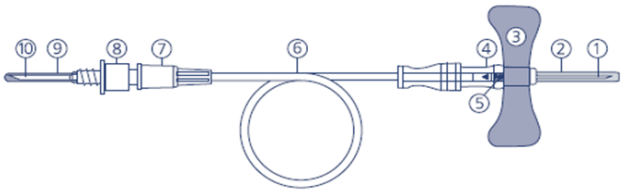
Standards:	EN ISO 11137

Compliance

Regulation:	European Medical Device Regulation 2017/745
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):	25G x 3/4
Internal Diameter (inches):	0.016
External Dimensions (mm):	0.5 x 19
External Dimensions (mm):	0.406
Tubing Length:	305 mm - 12 inches
Priming Volume:	0.350mL
Wing Colour:	Dark 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** Polyolefin
4. **Front Barrel** Polypropylene (PP)
5. **Rear Barrel** Acrylic
6. **Tubing** Polyvinyl Chloride (PVC) Memory-Free
7. **Luer Adaptor Connection** Acrylonitrile butadiene styrene (ABS)
8. **Luer Adaptor Hub** Polypropylene (PP)
9. **NP Sleeve** Synthetic Isoprene
10. **NP Cannula** Stainless Steel (304 Grade)

Packaging Specifications

1 unit pack weight (kg):	0.005	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):	106 x 10 x 70	50 unit pack weight (kg):	0.42
50 unit packaging material:	Cardboard	50 unit pack volume (m^3):	0.00419
50 unit packaging weight (kg):	0.065	50 unit pack dimensions LxHxW (mm):	275 x 105 x 145
200 unit pack weight (kg):	2.0	200 unit packaging material:	Cardboard
200 unit pack volume (m^3):	0.0201	200 unit packaging weight (kg):	Not Available
200 unit pack dimensions LxHxW (mm):	440 x 160 x 285		

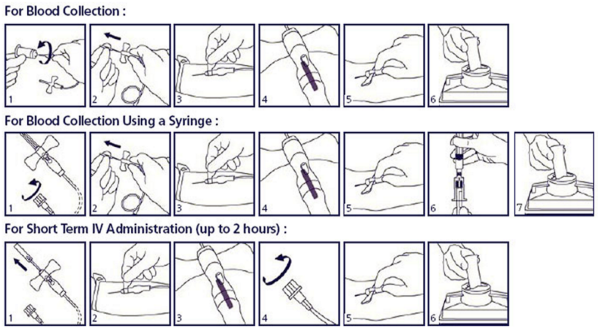
Product Catalogue Number: **367363**

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	•	•	•
Authorised Representative	•	•	•

Instructions For Use



Sample Storage & Stability

Not applicable

References

Not applicable

Further Reading

1. Stabilis 4.0. Available at: www.Stabilis.org
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. Stabilis 4.0. Available at: www.Stabilis.org
5. Hotaling M. "A Retractable Winged Steel (Butterfly) Needle Performance Improvement Project". Joint Commission Journal on Quality and Patient Safety. 2009; 35(2): 100-105.
6. 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.
7. BD White Paper VS9248 , Comparison of Penetration Force for the BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with PentaPoint™ Comfort Bevel and RightGauge™ Cannula to the Current BD Vacutainer® Push Button Blood Collection Set with Thin Wall 3-Bevel Cannula, 2016.
8. BD White Paper VS9249, Evaluation of Tube Fill Time of the BD Vacutainer® UltraTouch™ Push Button Blood Collection Set with PentaPoint™ Comfort Bevel and RightGauge™ Cannula as Compared with the Current BD Vacutainer® Push Button Blood Collection Set with Thin Wall 3-Bevel Cannula, 2016.
9. BD White Paper VS9250, Performance Evaluation of BD Vacutainer® UltraTouch™ Push Button Blood Collection Set and Comparison with the Current BD Vacutainer® Push Button Blood Collection Set for Visual and Analytical Indicators of Hemolysis, 2016.
10. BD White Paper VS9324, A Comparison of the BD Vacutainer® Push Button Blood Collection Set With a Number of Non-Safety or First Generation Safety Engineered Blood Collection Devices for Needlestick Injury Rate and Health Care Worker Assessment of the Functionality and Usability of the Devices, 2016