TECHNICAL INFORMATION SHEET

BD Vacutainer® One Use Holder

Product Catalogue Number: 364815

Product Description

Single use, blood collection tube holder, used in combination with a venous access device for the collection of a single or multiple blood samples into evacuated collection tubes. This product is intended for use by health care professionals.

Manufacturing Information

(Legal) Manufacturer:	Becton, Dickinson and Company Belliver Industrial Estate Belliver Way Roborough, Plymouth, PL6 7BP, UK
Standards & Certificate Numbers:	ISO 14001:2015, EMS 37154 ISO 13485:2016 MD 613320
Country of origin:	Ireland, USA
Certification body:	BSI UK (0086)
Notified Body:	N/A
EU Authorised Representative:	BD Switzerland Sarl, Terre Bonne Park - A4, Route de Crassier 17, 1262 Eysins, Switzerland

Sterilisation

Method:	This product is non-sterile.

Compliance

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

Product Specification

Product Storage:	Do not expose to direct sunlight
Shelf-life:	No specified shelf life
Global medical device nomenclature (GMDN):	37566
Material Safety Data Sheet (MSDS):	Not applicable
Latex (NRL):	No
Dry Natural Rubber (DNR):	No
Phthalates:	No
Material of animal origin:	No



1. **Holder** Polypropylene (PP)

Packaging Specifications

250 unit pack weight (kg):	0.595	250 unit packaging material:	Polyethylene
250 unit pack volume (m^3):	0.011625	250 unit packaging weight (kg):	0.020
250 unit pack dimensions LxHxW (mm):	Bag dimensions (flat) 482.6 x 398.78	1000 unit pack weight (kg):	2.850
1000 unit packaging material:	Cardboard	1000 unit pack volume (m^3):	0.044610
1000 unit packaging weight (kg):	0.460	1000 unit pack dimensions LxHxW (mm):	419.1 x 355.6 x 255.5

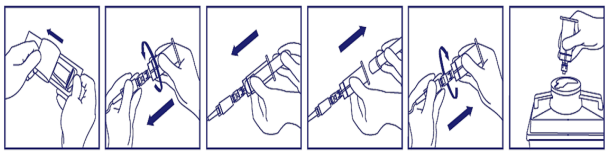
Product Catalogue Number: **364815**

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)		•	•
CE marking		•	•
Single use symbols		•	•
Lot number		•	•
Quantity in package		•	•
Primary barcode (GS1-128) product identification		•	•
Secondary barcode (GS1-128) quantity, expiry, lot number		•	•
Product name & short description		•	•

Instructions For Use



Further Reading

1. Clinical and Laboratory Standards Institute: Procedures for the Collection of Diagnostics Blood Specimens by Venipuncture (7th Edition). Wayne, PA, USA, 2007: Document GP41-A7.
2. Garza D and Becan-McBride K. Phlebotomy Handbook: Blood Collection Essentials (Fourth Edition). Upper Saddle River, N.J: Prentice Hall, 2001.
3. McCall RE and Tankersley CM. Phlebotomy Essentials (Fourth Edition). Philadelphia, USA: Lippincott Williams and Wilkins, 2007.
4. Guder WG, Narayanan S, Wisser H and Zawta B. Samples: From the Patient to the Laboratory: the Impact of Preanalytical Variables on the Quality of Laboratory Results (Fourth Edition). Darmstadt, Germany: Wiley-VCH; 2009.
5. Clinical and Laboratory Standards Institute (CLSI; formerly NCCLS): Protection of Laboratory Workers from Occupationally Accquired Infections (Third Edition). Wayne, PA, USA, 2005: Document M29-A3.
6. BD Publication: Recommendations For The Decontamination Of Reusable Blood Collection Holders, 2006
7. BD White Paper: BD Vacutainer™ Standard Yellow Needle Holder Decontamination Procedure for Presence of Residual Blood, 2001

Sample Storage & Stability

Not applicable

References

Not applicable

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