

TECHNICAL INFORMATION SHEET

BD Microtainer® Contact-Activated Lancet



Product Catalogue Number: **366594**

Intended Use

Single-use, sterile micro-collection lancet used to perform fingerstick punctures for the purpose of collecting capillary blood. The device includes a safety feature which automatically retracts the lancet blade/needle when the device is used 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 Limited, Pottery Road, Dun Laoghaire, CO.Dublin, Ireland
Standards & Certificate Numbers:	ISO 13485:2003, MD19.2137
Country of origin:	Poland
Certification body:	NSAI (0050)
Notified Body:	NSAI (0050)

Sterilisation

Method:	Gamma Radiation
SAL:	10 ⁻⁶
Standards applied:	ISO 11137

Product Standards & Guidelines

Standards:	ISO 11137
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Compliance

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

Product Specification

Product Storage:	Do not expose to direct sunlight
Shelf-life:	5 years
Global medical device nomenclature (GMDN):	61578
Material Safety Data Sheet (MSDS):	Not applicable
Needle / blade:	Stainless Steel (304 Grade)
Tab cap:	Polypropylene (PP)
Main housing:	Polypropylene (PP)
Shield:	Polyethylene (PE)
Needle carrier / protective tab:	Polystyrene (PS)
Rear Cap:	Polypropylene (PP)
External Dimensions (mm):	1.5 x 2.0
Lancet Body Colour:	Blue



Packaging Specifications

200 unit pack weight (kg):	0.790	200 unit packaging material:	Cardboard
200 unit pack volume (m ³):	0.002170	200 unit packaging weight (kg):	0.05535
200 unit pack dimensions LxHxW (mm):	115 x 115 x 164	2000 unit pack weight (kg):	8.400
2000 unit packaging material:	Cardboard	2000 unit pack volume (m ³):	0.027000
2000 unit packaging weight (kg):	0.6216	2000 unit pack dimensions LxHxW (mm):	590 x 245 x 185

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



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. Garza D and Becan-McBride K. Phlebotomy Handbook: Blood Collection Essentials (Fourth Edition). Upper Saddle River, NJ: Prentice Hall, 2001.
3. 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.
4. Reiner CB, et al. "Optimal Sites and Depths for Specimens by Skin Puncture of Infants and Children as Assessed from Anatomical Measurements". Clin Chem. 1990; 36(3): 547-549.
5. Clinical and Laboratory Standards Institute (CLSI; formerly NCCLS): Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture; Approved Standard (Sixth Edition). Wayne, PA, USA, 2008: Document H4-A6.
6. BD White Paper VS7499: A Comparison of BD Microtainer® Contact-Activated Lancet (Low Flow) with BD Microtainer® Genie™, LifeScan OneTouch® SureSoft™ Gentle, and SurgiLance™ One-Step PLUS Safety Lancets for Comfort, Ease of Use, and Blood Volume, 2006

Sample Storage & Stability

Not applicable

References

Not applicable