Becton Dickinson and Company
BD Medical,
Medication and Procedural Solution

BD Switzerland Sàrl
Terre Bonne Park - A4
Route de Crassier 17
1262 Eysins,
Switzerland

bd.com

TECHNICAL DATA SHEET

BD Microlance™ 3 hypodermic needle
Sterile, Single Use, Latex free

1. General Information

1.1 General

Intended use: BD Microlance™ 3 hypodermic needles are single-use medical devices intended for the hypodermic administration of pharmaceuticals.

BD Microlance™ 3 hypodermic needles are manufactured in different sizes, depending on the various exterior diameters and lengths of the cannulas. Each type of needle is recognized by the colour of the hub and by the identification system, both by the International System of Units (measurement in millimetres) and the American system (measurements in inches).

BD conventional needle design, materials and clinical application are based on well-established technologies and procedures. Sterile, single use disposable Microlance needles have been manufactured by BD and used successfully for over 50 years. Microlance needles are designed to operate with other devices. The needle hub has a female luer fitting which mates to male luer fittings, and is compatible with luer slip or luer lock syringes.

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Gauge and Diameter information

GAUGE	DIAMETER (mm)
14 / 2,1 mm	1,950-2,150
16 / 1,6 mm	1,600-1,690
18 / 1,2 mm	1,200-1,300
19 / 1,1 mm	1,030-1,100
20 / 0,9 mm	0,860-0,920
21 / 0,8 mm	0,800-0,830
22 / 0,7 mm	0,698-0,730
23 / 0,6 mm	0,600-0,673
24 / 0,55 mm	0,550-0,580
25 / 0,5 mm	0,500-0,530
26 / 0,45 mm	0,440-0,470
27 / 0,4 mm	0,400-0,420
30 / 0.3 mm	0.298-0.320

SPECIAL NEEDLES

BD Reference	Description Gauge/Inches	Length	Wall	Color code	Box (units)	Case (units)
304000	30G x ½”	13 mm	Regular	Yellow	100	5.000
304434	21G x 5/8”	16 mm	Thin	Green	100	5.000
301700	19G x1”	25 mm	Thin	Ivory	100	5.000
301750	19G x 2”	50 mm	Thin	Ivory	100	4.000
300637	16G x 1½”	40 mm	Regular	White	100	5.000

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REGULAR NEEDLES

BD Reference	Description Gauge/Inches	Length	Wall	Color code	Box (units)	Case (units)
302200	27G x 3/4”	19 mm	Regular	Grey	100	5.000
300635	27G x ½”	13 mm	Regular	Grey	100	5.000
304300	26G x 5/8”	16 mm	Regular	Brown	100	5.000
303800	26G x 1/2”	13 mm	Regular	Brown	100	5.000
300300	26G x 3/8”	10 mm	Regular	Brown	100	5.000
300400	25G x 1”	25 mm	Regular	Orange	100	5.000
300600	25G x 5/8”	16 mm	Regular	Orange	100	5.000
304100	24G x 1”	25 mm	Regular	Violet	100	5.000
300700	23G x 1¼”	30 mm	Thin	Blue	100	5.000
300800	23G x 1”	25 mm	Thin	Blue	100	5.000
301000	22G x 1½”	40 mm	Thin	Black	100	5.000
300900	22G x 1¼”	30 mm	Thin	Black	100	5.000
304727	22G x 1”	25 mm	Thin	Black	100	5.000
304432	21G x 1½”	40 mm	Thin	Green	100	5.000
301156	21G x 1”	25 mm	Thin	Green	100	5.000
301300	20G x 1½”	40 mm	Thin	Yellow	100	5.000
304827	20G x 1”	25 mm	Thin	Yellow	100	5.000
301500	19G x 1½”	40 mm	Thin	Ivory	100	5.000
304622	18G x1½”	40 mm	Thin	Pink	100	5.000
301155	21G x 2”	50 mm	Thin	Green	100	4.000
300094	22G x 2”	50mm	Regular	Black	100	4.000
301900	18G x 2”	50 mm	Regular	Pink	100	4.000

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1.2 Certification

BD REFERENCE	BD MANUFACTURER	ISO CERTIFICATION	CE MARKING	BD MANUFACTURING SITE
300700, 300800, 300900, 301000, 301156, 301300, 301900, 304432, 304434, 304727, 304827	Becton Dickinson S.A. - Crta. Mequinenza, s/n. 22520-Fraga (Huesca) Spain	AENOR - EN ISO 9001:2008 Certificate Nº N° ER-0097/1994 AEMPS NB nº0318 EN ISO 13485:2013 Certificate N° 2015 05 0047EN	AEMPS N°0318 – Certificate n 95 06 0006 CP	Becton Dickinson S.A. - Crta. Mequinenza, s/n. 22520-Fraga (Huesca) Spain EN ISO 13485: 2013 Registration Number: 2015 05 0047 EN
300094, 300300, 300600, 300635, 300637, 301500, 301700, 301900, 301750, 302200, 303800, 300400, 304100, 304300, 304622, 304000, 301155	Becton Dickinson & Company Limited Donore Road Drogheda Co. Louth Ireland	NSAI – N° MD 19.1609 -EN ISO 13485:2012	NSAI 050 – N° Q252.157	Becton Dickinson S.A. - Crta. Mequinenza, s/n. 22520-Fraga (Huesca) Spain EN ISO 13485: 2013 Registration Number: 2015 05 0047 EN

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1.3 Material

COMPONENT	MATERIAL
Needle Hub	COLOR CODED POLYPROPYLENE
Needle Shield	POLYPROPYLENE
Bonding Agent	EPOXY
Needle	STAINLESS STEEL AISI 304 (Chromium 18-20%; Nickel 8-12%; Manganese 2%; Silicon 1%)
Lubricant	MEDICAL GRADE SILICONE OIL, <0.25 mg /cm^2

1.4 Material of concern

Materials of concern are chemicals or substances that have been identified as having the potential to cause long term effects on humans or the environment.

MATERIAL	COMMENT
Phthalates	No phthalates intentionally added. No DEHP, CAS number 117-81-1, EC number 204-211-0, intentionally added
Latex	The products do not contain natural latex.
Bisphenol A	Bisphenol A (CAS number 80-05-7, EC number 201-245-8) might be found in very low amount (at a concentration inferior to 5ppm) as a residue from the epoxy synthesis processing. Epoxy is used as needle bonding agent.
Substances of animal origin BSE/TSE	BD, Microlance devices utilize very small amounts of tallow or tallow derivatives (e.g. stearates in polymers). Per MEDDEV 2.4/1 Rev. 9 June 2010 and MEDDEV 2.11/1 Rev 2 January 2008, such substances are not considered as derivatives of animal tissues for the purpose of this rule which therefore does not apply.
Polyvinyl chloride (PVC)	The products do not contain polyvinyl chloride

1.5 REACH information

BD maintains an active REACH compliance program and works closely with its supply base on an ongoing basis with a view to obtaining information on REACH Substances of Very High Concern ("SVHC") through regular communication and exchange

1.6 Biocompatibility

BD Medical products comply with the requirements of the standard for biocompatibility of medical devices, ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing.

1.7 Sterilization

Ethylene Oxide Sterilization following *EN ISO 11135-1*. ETO residues are within applicable regulations.

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1.8 Shelf life

Shelf life 5 years. No special storage or transportation condition. Recommendations are to store in room temperature, in dry and warm place and not exposed to strong light.

1.9 Standards

HARMONISED STANDARDS	
EN 556-1:2002/ COR 2006	Sterilisation of Medical Devices – requirements for medical devices to be labelled "sterile".
EN 980: 2008	Graphical Symbols for use in the labelling of medical devices.
BS EN 1041+A1: 2013	Terminology, symbols and information provided with medical devices. Information supplied by the manufacturer with medical devices
EN 1707:1996	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings
EN 20594-1:1993/AC:1996	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
EN IS010993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN IS0 10993-3:2009	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO10993-4:2009	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
EN IS0 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-7:2008/AC:2009	Biological Evaluation of Medical Devices Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-11:2009	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO10993-12:2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
EN ISO 10993-13:2010	Biological Evaluation of Medical Devices Part 13:Identification and quantification of degradation products from polymeric medical devices
EN ISO 10993-15:2009	Biological evaluation of medical devices - Part 15: Identification and qualification of degradation products from metals and alloys
EN ISO 10993-17:2009	Biological Evaluation of Medical Devices Part 17:Establishment of allowable limits for leachable substances
EN ISO 10993-18:2009	Biological evaluation of medical devices - Part 18: Chemical characterisation of materials
EN ISO 11135-1:2007	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11138-2:2009	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes

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EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2006/AC:2009	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 13485:2012/AC:2012 and EN ISO 13485:2003	Medical devices – Quality management Systems Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices. Application of risk management to medical devices
EN 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice
NON HARMONISED STANDARD	
IS EN ISO 7884-1: 2016	Sterile hypodermic needles For Single Use– Requirements and Test Methods
ISO 594-1:1993	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
ISO 594-2:1998	Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 2: Lock fittings
ISO 9626: 1995	Stainless steel needle tubing for the manufacture of medical devices
ISO 6009: 2016	Hypodermic Needles for Single Use-Colour Coding for Identification
ISO 14644-1:1999	Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness
ISO 10993-2:2009	Biological Evaluation of Medical Devices Part 2
ISO10993-10:2009	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
ISO 15223-1:2012	Graphical Symbols for use in the labelling of medical devices.
ISO 2859-1:1999	Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

1.10 Classification

Class IIa Medical Device under Rule 6, Annex IX of Medical Devices Directive 93/42/EEC as amended

1.11 GMDN code

GMDN code 59230

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1.12 Good Manufacturing practices

The entire manufacturing and testing processes are following the Good Manufacturing Practices as specified below

- Incoming raw materials are verified via material inspection and testing and our suppliers are approved via our vendor management system.
- In addition to the automatic on-line inspections, in-process inspections are performed in addition to final product testing to ensure compliance with approved specifications.
- The manufacturing and testing details of each batch of product are recorded on a batch record which is retained in accordance with our document control procedures
- BD operates a system of Internal and external audits to maintain compliance
- BD confirms that it will continue to adhere to relevant international standards in designing and manufacturing its products.
- BD reserves the right to use the internal change control procedure to change raw material suppliers and production process

1.13 Others

- (Material) Safety Data Sheets are not required for this product
- Certificate of Food Contact (*COMMISSION REGULATION (EU) No. 10/2011 of January 14th, 2011 concerning materials and plastic objects intended to get in touch with foodstuffs)* is not required as BD products are used for general purpose injection and aspiration of fluids from vials, ampoules and parts of the body below the surface of the skin.
- No separate Instruction for Use is available for these devices.

2. Packaging

2.1 Packaging material

LABELS: according to European Medical Device directive, multilingual

Web packaging	POLYAMIDE
Box	PAPER

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2.2 Example labeling

Example Unit pack label, SKU 300400, legal manufacturer Drogheda, from document DGW 924

Example Unit pack label, SKU 300800, legal manufacturer Fraga, from document DGW 920