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TECHNICAL DATA SHEET
BD Microlance™ 3 Hypodermic needle
Sterile, single use, Latex free

1. General Information

1.1 General

BD Microlance ™ 3 hypodermic needles are latex free, sterile needle, with triple cut bevel, single-use medical devices intended for the injection and/ or aspiration of medical fluids like body fluids (blood, etc) and drugs.

Regular needles

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

Special needles

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

Technical specification needles

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

1.2 Certification

BD PRODUCT CODE	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 – N° ER-0097/1994 – ISO 9001:2008; AEMPS – N° 2015 05 0047EN EN – ISO 13485:2013	AEMPS 0318 – N° 95 06 0006 CP	Becton Dickinson S.A. - Crta. Mequinenza, s/n. 22520-Fraga (Huesca) Spain
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

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
Web packaging	POLYAMIDE
Box	PAPER

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**
DEHP/Phthalates	The products do not contain di(2ethylhexyl) phthalate DEHP as CAS number 117-81-7, EC number 204-211-0
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	These 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 Directive 2003/32/EC, 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

Based on information available and BD's continuous data collection efforts throughout the supply chain, BD have not identified any chemicals in the articles and packaging with the Product Numbers as referenced above, in an individual concentration above 0.1% weight by weight (w/w), which have been listed as SVHC and included in the "Candidate List" published by the European Chemical Agency (ECHA) on 28 October 2008, according to Art. 59 (1, 10) of the Regulation (EC) N° 1907/2006 (REACH). The substances published in such list are candidates for eventual inclusion in the List of Substances Subject to Authorization (Annex XIV of REACH).

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

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

1.8 Shelf life

Shelf life 5 years

Store in dry and warm place and not exposed to strong light and then include any specific storage conditions if special handling is applicable

1.9 Standards

EN 556-1	Sterilization of Medical Devices-requirement for medical devices to be labeled "sterile"
EN ISO 7864:	Sterile hypodermic needles for single use
EN 980	Graphical Symbols for use in the labeling of medical devices
EN 1041	Terminology, symbols and information provided with medical devices. Information supplied by the manufacturer with medical devices
EN ISO 6009	Hypodermic needles for single use – Color coding for identification
EN ISO 9626	Stainless steel needle tubing for the manufacture of medical devices
EN 1707 / ISO 594-2	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Lock fittings (only applies to Luer Lock Syringes)
EN 20594-1	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment-Part 1: General requirements (ISO 594-1:1986)
EN ISO 10993 series	Biological evaluation of medical devices
EN ISO 11135-1	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 11737-1	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN-ISO 11737-2	Sterilization of medical devices- Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 13485	Medical Devices, Quality Management Systems, Requirements for Regulatory purposes
EN ISO 14971	Medical devices- Application of risk management to medical devices
EN ISO 15223-1	Medical devices-Symbols to be used with medical devices labels, labeling and information to be supplied Part.1: General requirements

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

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 Data Safety 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.

2. Packaging

2.1 Labelling Languages

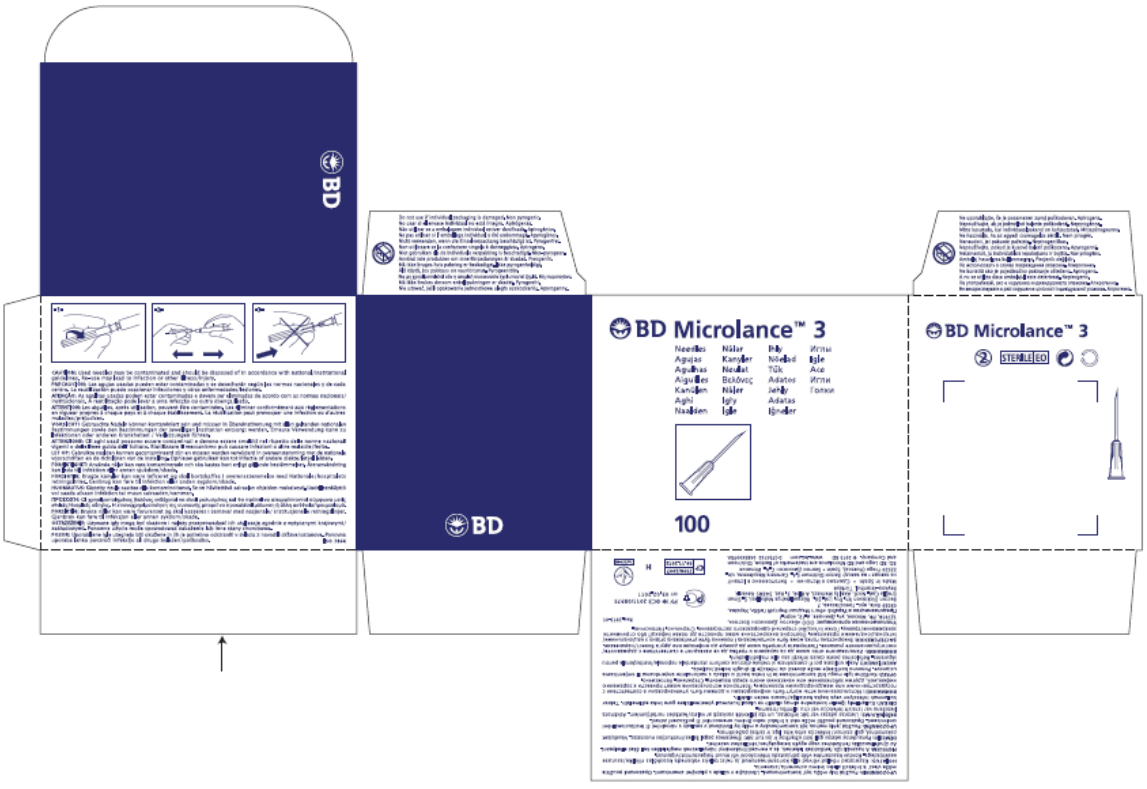
LABELS: according to European Medical Device directive, multilingual

2.2 Example labelling

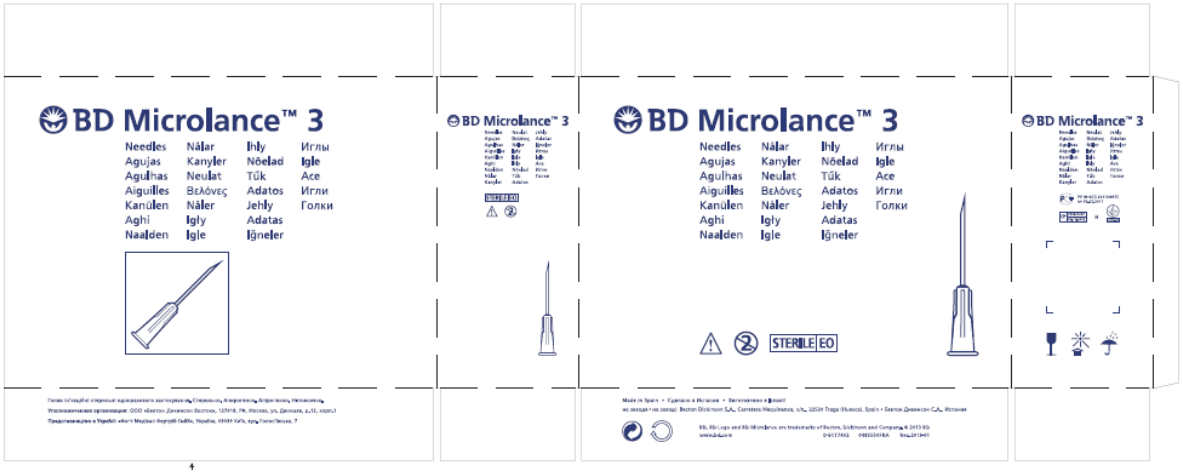
Manufacturer: Drogheda

Unit pack

Shelf carton



Shipping case



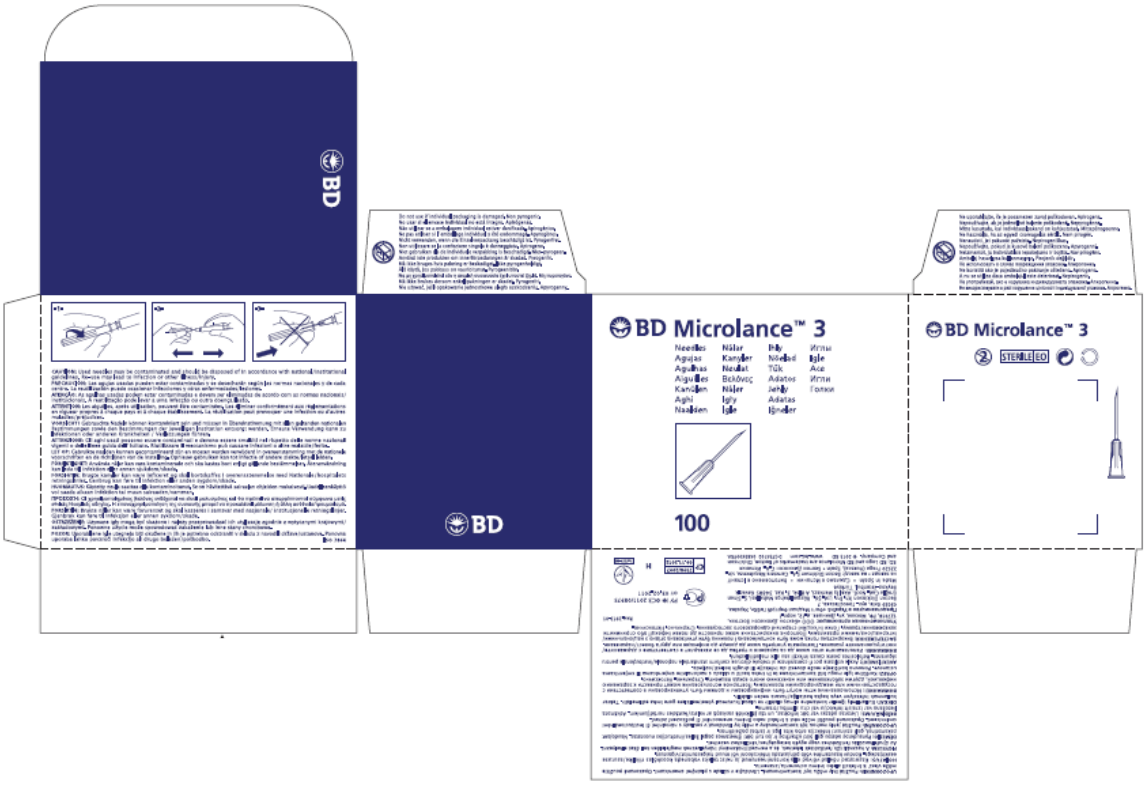
Shelf carton label

Case carton label

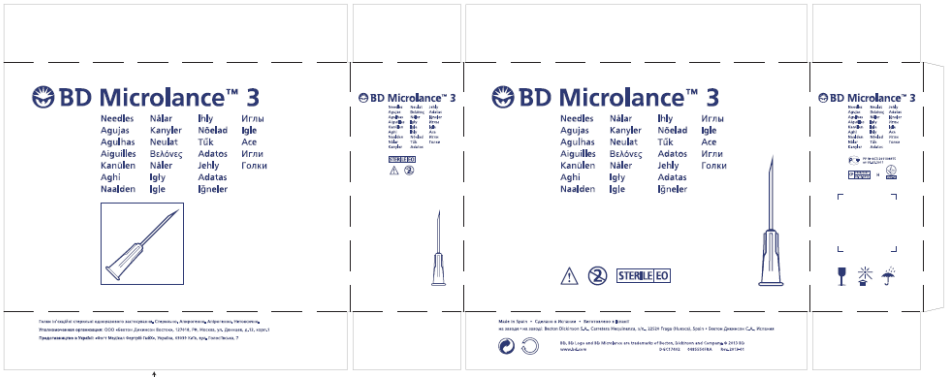
Manufacturer: Fraga

Unit pack

Shelf carton



Shipping case



Shelf carton label

Case carton label