BD Microlance™ 3 needles
Sterile

BD Switzerland Sàrl
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bd.com
TDS number: V201-007 – Rev.03
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1. General Information

1.1 Intended use

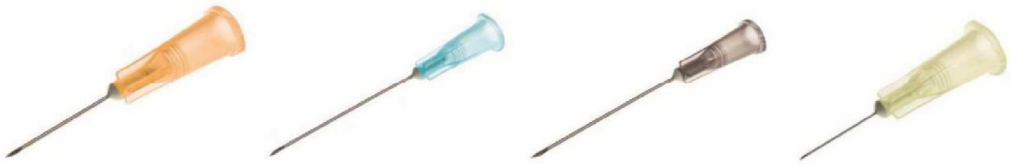
BD Microlance™ 3 hypodermic needles are a single-use medical device intended for injection and/or aspiration of medical fluids, understood as both bodily fluids (blood, etc.) and medicines. The needles are also supplied non-sterile in bulk. This product is sold to other device manufacturers and is packed in bulk and labelled "non-sterile".

1.2 General description

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. The needle hub has a female luer fitting which mates to male luer fittings and is compatible with luer slip or luer lock syringes.

The range of products is as follows:



BD Catalog Number	BD Product Description	Gauge Size	Length (mm)	Length (inch)	Color Code	Wall	Bevel
300637	NEEDLE 16GA 1-1/2IN	16G	40	1 ½"	White	Regular	Regular
301900	NEEDLE 18GA 2IN	18G	50	2"	Pink	Regular	Regular
304622	NEEDLE 18GA 1-1/2IN SB TW	18G	40	1 ½"	Pink	Thin	Short
301500	NEEDLE 19GA 1-1/2IN TW	19G	40	1 ½"	Cream	Thin	Regular
301700	NEEDLE 19GA 1IN	19G	25	1"	Cream	Thin	Regular
301750	NEEDLE 19GA 2IN	19G	50	2"	Cream	Thin	Regular
301300	NEEDLE 20GA 1-1/2IN	20G	40	1 ½"	Yellow	Thin	Regular
304827	NEEDLE 20GA 1IN	20G	25	1"	Yellow	Thin	Regular
301155	NEEDLE 21 GA 2IN	21G	50	2"	Green	Thin	Regular
301156	NEEDLE 21GA 1IN	21G	25	1"	Green	Thin	Regular
304432	NEEDLE 21GA 1-1/2IN	21G	40	1 ½"	Green	Thin	Regular
304434	NEEDLE 21GA 5/8IN	21G	16	5/8"	Green	Thin	Regular
300094	NEEDLE 22GA 2IN	22G	50	2"	Black	Regular	Regular
300900	NEEDLE 22GA 1-1/4IN	22G	30	1 ¼"	Black	Thin	Regular
301000	NEEDLE 22GA 1-1/2IN	22G	40	1 ½"	Black	Thin	Regular
304727	NEEDLE 22GA 1IN	22G	25	1"	Black	Thin	Regular
300700	NEEDLE 23GA 1-1/4IN	23G	30	1 ¼"	Blue	Thin	Regular
300800	NEEDLE 23GA 1IN	23G	25	1"	Blue	Thin	Regular
304100	NEEDLE 24GA 1IN	24G	25	1"	Purple	Regular	Regular
300400	NEEDLE 25GA 1IN	25G	25	1"	Orange	Regular	Regular
300600	NEEDLE 25GA 5/8IN	25G	16	5/8"	Orange	Regular	Regular
300300	NEEDLE 26GA 3/8IN	26G	10	3/8"	Brown	Regular	Regular
303800	NEEDLE 26GA 1/2IN	26G	13	½"	Brown	Regular	Regular
304300	NEEDLE 26GA 5/8IN	26G	16	5/8"	Brown	Regular	Regular
300635	NEEDLE 27GA 1/2IN	27G	13	1 ½"	Grey	Regular	Regular
302200	NEEDLE 27GA 3/4IN	27G	19	¾"	Grey	Regular	Regular
304000	NEEDLE 30GA 1/2IN	30G	13	½"	Yellow	Regular	Regular

Note: Please check BD catalog number availability in your country.
The BD Product Description can slightly differ from the Declaration of Conformity; please always refer to the BD Catalog Number.

Further features: N/A

1.3 Certification

BD Catalog Number	BD Legal Manufacturer and ISO 13485 Certification	CE Certificate Number And Notified Body Brief Name	BD Manufacturing Site (Country of Origin) and ISO 13485 Certification	EC Representative (if applicable)
300094* 300300* 300400* 300600* 300635* 300637* 301155* 301500* 301700* 301750* 301900* 302200* 303800* 304000* 304100* 304300* 304622* 304827 301300 304434 301156 304432 304727 300900 301000 300800 300700	**Address:** Becton Dickinson S.A. Carretera de Mequinenza, s/n 22520 Fraga (Huesca) Spain **ISO 13485** Certificate No.: 2015 05 0047 EN	CE certified with AEMPS (0318) Certificate No.: 95 06 0006 CP	**Address:** Becton Dickinson S.A. Carretera de Mequinenza, s/n 22520 Fraga (Huesca) Spain **ISO 13485** Certificate No.: 2015 05 0047 EN	N/A

* Ongoing project: BD is transferring the legal manufacturer from BD Drogheda (Ireland) to BD Fraga (Spain) and from Notified Body NSAI (Ireland) to AEMPS (Spain), completion date in 2020.

There will be no renewal of CE certificate 252.157 (NSAI 0050) from Drogheda as products are currently transitioning to the CE certificate number 95 06 0006 CP (AEMPS 0318) (as per above table). There is no change to form, fit or function. Changes are limited to legal manufacturer name and address and notified body. Each label will be updated at different times.

The first lot for each SKU with new legal manufacturer and notified body number is:

- 300094 – Transfer ongoing
- 300300 – Transfer ongoing
- 300400 – Transfer ongoing
- 300600 – Transfer ongoing
- 300635 – Transfer ongoing

- 300637 – Transfer ongoing
- 301155 – Transfer ongoing
- 301500 – Transfer ongoing
- 301700 – Transfer ongoing
- 301750 – Transfer ongoing
- 301900 – Transfer ongoing
- 302200 – Transfer ongoing
- 303800 – Transfer ongoing
- 304000 – Transfer ongoing
- 304100 – Transfer ongoing
- 304300 – Transfer ongoing
- 304622 – Transfer ongoing

1.4 Materials

Component	Material
Hub	Polypropylene and colorants
Shield piece	Polypropylene
Cannula	Stainless steel (Chromium 18-20%; Nickel 8-12%; Manganese 2%; Silicon 1%)
Adhesive	Epoxy resin
Lubricant	Medical grade Silicone oil

1.5 Materials 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	Based on our ongoing data collection efforts and/or information received from our suppliers as per 11 May 2020, BD has not identified any • 1,2-Benzendicarboxylic acid, dihexyl ester (branched & linear) (CAS#68515-50-4), • 1,2-Benzendicarboxylic acid, di-C6-8-branched alkyl esters (CAS#71888-89-6), • 1,2-Benzendicarboxylic acid, di-C7-11-branched and linear alkyl esters (CAS#68515-42-4), • 1,2-Benzendicarboxylic acid, di-C6-10 alkyl esters (CAS#68515-51-5), • 1,2-Benzendicarboxylic acid, mixed decyl, hexyl, and octyl diesters (CAS#68648-93-1), • Benzyl butyl phthalate (BBP) (CAS# 85-68-7), • Bis (2-ethylhexyl) phthalate (DEHP) (CAS# 117-81-7), • Bis (2-methoxyethyl) phthalate (DMEP) (CAS# 117-82-8), • Di-n-hexyl phthalate (DnHP) (CAS# 84-75-3), • Dibutyl phthalate (DBP) (CAS# 84-74-2), • Diisobutyl phthalate (DIBP) (CAS# 84-69-5), • Diisopentylphthalate (DIPP) (CAS# 605-50-5), • Dipentyl phthalate (DPP) (CAS# 131-18-0), • N-pentyl-isopentylphthalate (CAS# 776297-69-9), or • Dicyclohexyl phthalate (DCHP) (CAS# 84-61-7) in the articles and packaging with the Product Numbers as referenced above, in an individual concentration above 0.1% weight by weight (w/w).
Latex	Based on our ongoing data collection efforts and/or information received from our suppliers as per 11 May 2020, the articles with the Product Numbers above are not formulated with natural rubber latex.
Bisphenol A	Based on our ongoing data collection efforts and/or information received from our suppliers as per 11 May 2020, BD has not identified any • 4,4'-isopropylidenediphenol (BPA) (CAS# 80-05-7) in the articles and packaging with the Product Numbers as referenced above, in an individual concentration above 0.1% weight by weight (w/w). Bisphenol A (BPA), CAS# 80-05-7, is a component in a raw material in the adhesive. Based on information from our suppliers and BD test results, the BPA level is less than 0.1% w/w (<1000 ppm). These levels are below a de minimis concentration with no demonstrable clinically significant exposure nor toxicity. No labeling for California Prop 65 is needed. No REACH SVHC declaration is required.
Substances of animal origin BSE/TSE	The raw materials used in the manufacture of these devices do not contain any animal tissue but may contain very small amounts of chemicals that are derived from animal-derived raw materials. These products are manufactured using polymer resins which may contain very small amounts of stearic acids and related substances derived from tallow derivatives. Our resin suppliers have confirmed that these chemicals have been produced with multiple cycles of conditions at least as rigorous as those specified in Annex C.5 of EN ISO 22442-1:2015 and Section 6 of EMA 410/01 Rev. 3. Therefore, these raw materials meet or exceed the requirements of EN ISO 22442-1 and EMA 410/01 Rev. 3. Based on this information, these products are considered not to present any risk with respect to TSE/BSE or other animal-borne diseases. Furthermore, as recognized by MEDDEV 2.4/1, such derivative chemicals produced in accordance with the aforementioned standards and guidelines are considered irrelevant

	when determining the classification of a medical device (per MDD 93/42/EEC and EU No 722/2012).
Polyvinyl chloride (PVC)	The medical devices and packaging referenced above have not been designed nor intentionally manufactured with any additives or raw materials that contain PVC. No PVC is intentionally added to these medical devices.

1.6 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 11 May 2020, BD has 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 16 January 2020 according to Art. 59 (1,10) of the Regulation (EC) N° 1907/2006 (REACH).

1.7 Biocompatibility

BD Medical products comply with the requirements of the standard for toxicity, pyrogenicity and biocompatibility of medical devices, ISO 10993 series - Biological Evaluation of Medical Devices.

1.8 Sterilization method

Ethylene Oxide Sterilization following *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)*. ETO residues are within applicable regulations.

1.9 Shelf life and storage conditions

The BD Microlance™ 3 shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
BD Microlance™ 3 have a shelf life of 5 years.

Store in a dry and warm place, not exposed to strong light.

1.10 Standards

As per extract from the Declaration of Conformity linked to the CE certificate number 95 06 0006 CP:

Harmonized Standards	
EN 556-1:2001/ AC:2006	Sterilization of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile" - Part 1: Requirements for Terminally Sterilized Medical Devices
EN ISO 10993 Series	Biological evaluation of medical devices - Part 1 : 2009/ AC :2010 Evaluation and testing within a risk management process - Part 7: 2008 /AC: 2009 Ethylene oxide sterilization residuals
EN ISO 11737-2:2009	Sterilization of medical devices – Microbiological methods - Part 2:2009 Test of sterility performed in the definition, validation and maintenance of a sterilization process.
EN ISO 13485:2016/AC:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices. Application of risk management to medical devices
EN ISO 15223-1:2016	"Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements"
EN 20594-1:1993/AC:1996/A1:1997	Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment - Part 1: General requirements
Non-Harmonized Standards	
EN ISO 6009:2016	Sterile hypodermic needles for single use. Identification color coding
EN ISO 7864:2016	Sterile hypodermic needles for single use
EN ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices
UNE-EN ISO 11135:2015	Sterilization of health-care products -- Ethylene oxide
EN 1041:2008+A1:2013	Information supplied by the manufacturer with medical devices
EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices – Part 1:2017 Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2017	Packaging for terminally sterilized medical devices - Part 2: 2017 Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2018	Sterilization of medical devices – Microbiological methods - Part 1:2018 Determination of a population of microorganisms on products

Note:
The above standards reflect the status at the time of drafting this document. More information or updates are available on request in the Declaration of Conformity.

1.11 Classification

BD Microlance™ Needles are classed as class IIa per Annex IX, Section III, Rule 6 of the Medical Device Directive 93/42/EEC as amended.

1.12 GMDN code

According to ISO/TS 20225 (GMDN nomenclature), BD Microlance™ 3 needles are referenced as follows:
GMDN Code: 59230
GMDN Term: Hypodermic needle, single-use, sterile

1.13 Manufacturing practices

The entire manufacturing and testing processes are following the 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.

1.14 Other information

- (Material) Safety Data Sheets are not required for this product.
- Certificate of Food Contact *(Commission Regulation EU 1183/2012 on "plastic materials and articles intended for contact with food" and Directive 2002/72/CE (as amended) "relating to plastic materials and articles intended to come into contact 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.
- Good Manufacturing Practices as defined by the FDA Pharmaceutical is not applicable for Medical Devices.

2. Packaging

2.1 Packaging configuration

BD Catalog Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
300637	NEEDLE 16GA 1-1/2IN	1	100	5000	No
301900	NEEDLE 18GA 2IN	1	100	4000	No
304622	NEEDLE 18GA 1-1/2IN SB TW	1	100	5000	No
301500	NEEDLE 19GA 1-1/2IN TW	1	100	5000	No
301700	NEEDLE 19GA 1IN	1	100	5000	No
301750	NEEDLE 19GA 2IN	1	100	4000	No
301300	NEEDLE 20GA 1-1/2IN	1	100	5000	No
304827	NEEDLE 20GA 1IN	1	100	5000	No
301155	NEEDLE 21 GA 2IN	1	100	4000	No
301156	NEEDLE 21GA 1IN	1	100	5000	No
304432	NEEDLE 21GA 1-1/2IN	1	100	5000	No
304434	NEEDLE 21GA 5/8IN	1	100	5000	No
300094	NEEDLE 22GA 2IN	1	100	4000	No
300900	NEEDLE 22GA 1-1/4IN	1	100	5000	No
301000	NEEDLE 22GA 1-1/2IN	1	100	5000	No
304727	NEEDLE 22GA 1IN	1	100	5000	No

BD Catalog Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
300700	NEEDLE 23GA 1-1/4IN	1	100	5000	No
300800	NEEDLE 23GA 1IN	1	100	5000	No
304100	NEEDLE 24GA 1IN	1	100	5000	No
300400	NEEDLE 25GA 1IN	1	100	5000	No
300600	NEEDLE 25GA 5/8IN	1	100	5000	No
300300	NEEDLE 26GA 3/8IN	1	100	5000	No
303800	NEEDLE 26GA 1/2IN	1	100	5000	No
304300	NEEDLE 26GA 5/8IN	1	100	5000	No
300635	NEEDLE 27GA 1/2IN	1	100	5000	No
302200	NEEDLE 27GA 3/4IN	1	100	5000	No
304000	NEEDLE 30GA 1/2IN	1	100	5000	No

*"No": IFU may be available but not as an insert.

2.2 Packaging material

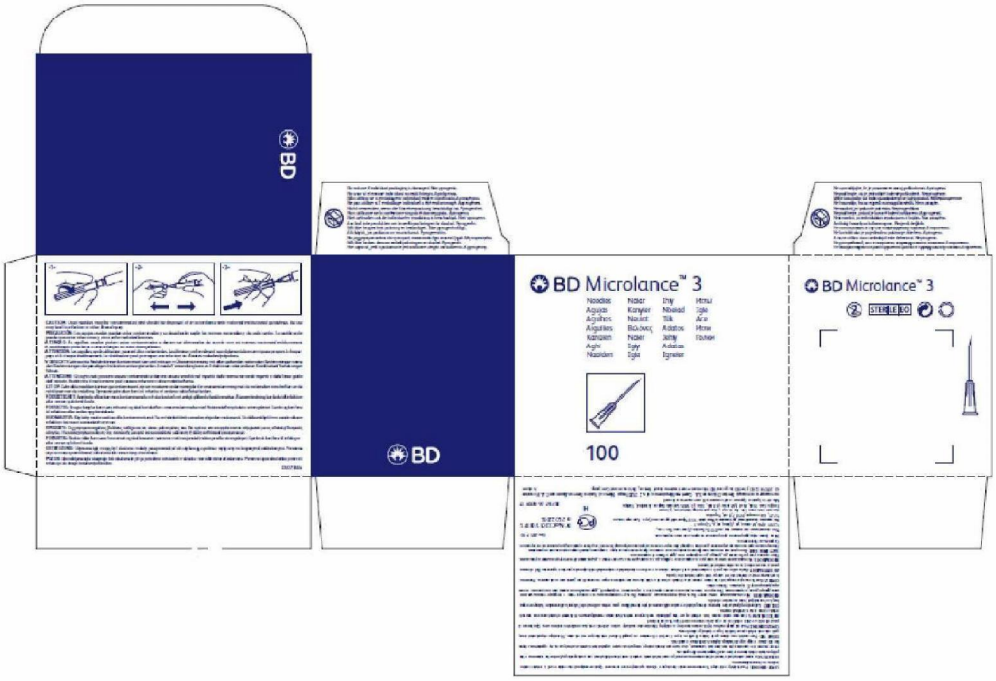
Component	Material
Unit Pack	Paper: medical use paper 60gr/m² Film: Polyamide/Polyethylene
Shelf Box	Cardboard
Shipping Case	Corrugated cardboard

2.3 Examples of labeling

Labels: According to European Medical Device directive, labels are multilingual.

Primary Packaging Label (Top Web) extracted from document DGW911 related to reference 304434:

Shelf Box extracted from document DGF341 related to reference 304434:



REVISION	CHANGE SUMMARY
01	Initial release according to new template
02	Update of 1.1: Intended use Update of 1.3: Certification Update of 1.10: Standards Update of 2.3: Examples of labeling
03	Update of 1.3: Certification