

BD Medical

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TECHNICAL DATA SHEET

BD™ Blunt Fill and Filter needles

Sterile, Single use, Latex free

1. General Information

1.1 General

Single use latex free needles, for medication aspiration and mixing, with “blunt” bevel.



Reference	Description	Filter	Length	Color code	Box (units)	Case (units)
305181	18G 1	No	25 mm	Red	100	1000
305180	18 G 1 ½	No	40 mm	Red	100	1.000
303129	18 G 1 ½	No	40 mm	Red	100	5.000
305211	18 G 1 ½	with 5 micron filter	40 mm	Purple	100	1.000

The BD™ Blunt Fill Needle and BD™ Blunt Filter Needle have been specifically designed for the safe preparation of injections and other fluid transfer to safely bridge medication preparation and administration. The non-coring bevel design will pierce IV bag septum or rubber vial caps, whereas high penetration forces are necessary to injure skin (10 times higher than with a regular fill needle). The integrated filter avoids the risk of injection of particles from glass ampoules or rubber vial stoppers and the clinical consequences of the injection of these particles into the patient. The specific non-coring design of the bevel eliminates the risk of rubber particles being cut from multi-dose vial stoppers and the consequent risk of particle injections and entry of air into the vial (potential contamination of the medication). The BD™ blunt needles combine Healthcare workers' safety (no sharps) with Patients' safety (no particles, no contamination of the medication).



The 18 Gauge needle allows rapid filling, even with viscous solutions. It has been designed to minimize the change in technique. The red color code of the needle hub and the needle shield clearly identify the needle as being a specialty needle, not to be used for skin injections. They are easily identifiable when placed on a sterile field. By replacing a standard needle with the BD™ Blunt Fill Needle, the number of sharps introduced into the medication delivery process is significantly reduced. By avoiding skin injuries during fluid transfer or the preparation of injections, the BD™ Blunt Needles contribute to the safety of healthcare professionals, with injured skin being more vulnerable to the entry of work-related bacteria and viruses.

1.2 Certification

BD PRODUCT CODE	BD MANUFACTURER	ISO CERTIFICATION	CE MARKING	BD MANUFACTURING SITE
305211 305180 305181	Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417, USA	NSAI –NB n° 0050 ISO 9001 :2008 Certificate 19.2305 ISO 13485:2012 Certificate MD19.2305	NSAI NB n° 0050: N° 252.308	BD Medical Surgical, 2153 12 th Ave, Columbus, NE 68601 USA
303129	Becton Dickinson S.A. - Crta. Mequinenza, s/n. 22520-Fraga (Huesca) Spain	AENOR – N° ER-0097/1994 – ISO 9001:2008 AEMPS – N° 2015 05 0047 EN– ISO 13485:2013	AEMPS NB n° 0318 – N° 2015 03 0838 CP	Becton Dickinson S.A. - Crta. Mequinenza, s/n. 22520-Fraga (Huesca) Spain

1.3 Material

Component	Material
Needle Hub (305180, 305081, 303129)	POLYPROPYLENE
Needle Hub (305211).	POLYCARBONATE
Needle Shield	POLYPROPYLENE
Bonding Agent.	EPOXY
Needle	STAINLESS STEEL 304
Filter (305211 only):	PLASTIC MEMBRANE FILTER; Filter size: 5 microns
Lubricant	MEDICAL GRADE SILICONE OIL, <0.25 mg /cm ²
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. Needle hub to Catalogue number 305211 is made of polycarbonate and contains BPA
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

Catalogue number 303129, 305211	Sterilization method: Ethylene Oxide Sterilization (EN ISO 111351 “Sterilization for Healthcare 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.
Catalogue number 305180, 305181	Sterilization method: Radiation (EN ISO 111371 “Sterilization for Healthcare products Radiation –Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices).

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 ISO 15223-1	Medical devices-Symbols to be used with medical devices labels, labeling and information to be supplied Part.1: General requirements
EN 1041	Terminology, symbols and information provided with medical devices. Information supplied by the manufacturer with medical devices
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 11137-1	Sterilization of health care products – Radiation – 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

* except for needle bevel geometry and color coding

1.10 Classification

- Class I Sterile (references: 305181, 305180, 305211) Medical Device under Rule 1, Annex IX of Medical Devices Directive 93/42/EEC as amended.
- Class I Sterile (303129) Medical Device under Rule 2, Annex IX of Medical Devices Directive 93/42/EEC as amended.

1.11 GMDN code

- GMDN code 45316 (references: 305181, 305180, 303129)
- GMDN code 16266 (reference: 305211)

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

- The EU representative for US produced blunt needles catalogue number 305181, 305180 and 305211 is BD Temse, Belgium. Other blunt needles catalog number 303129 are produced by a European manufacturer.
- 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

LABELS: according to European Medical Device directive, multilingual

2.4 Example labelling

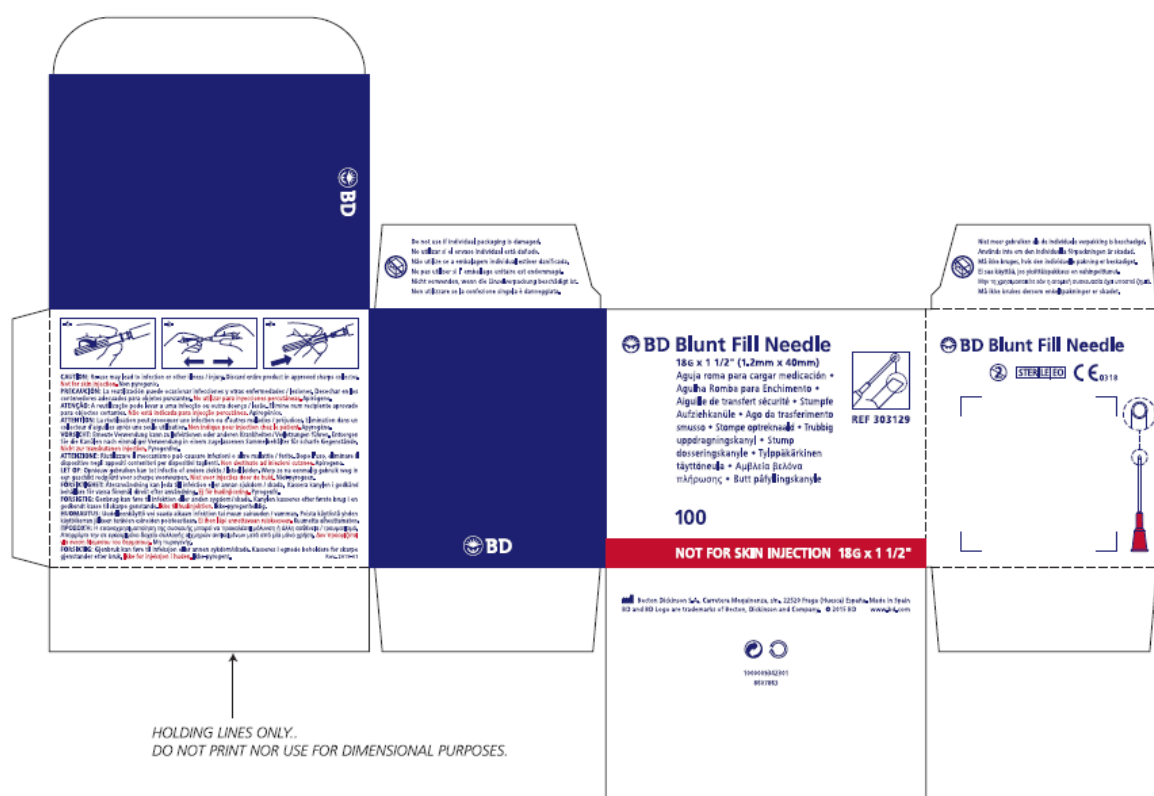
Manufacturer: Fraga

Unit pack





Shelf carton

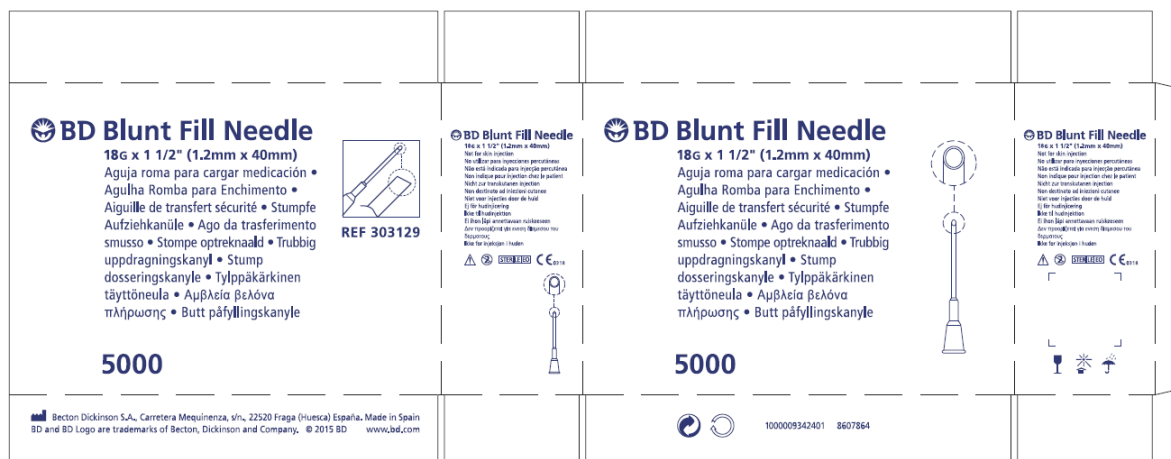


Shelf carton label





Case carton



Case carton label



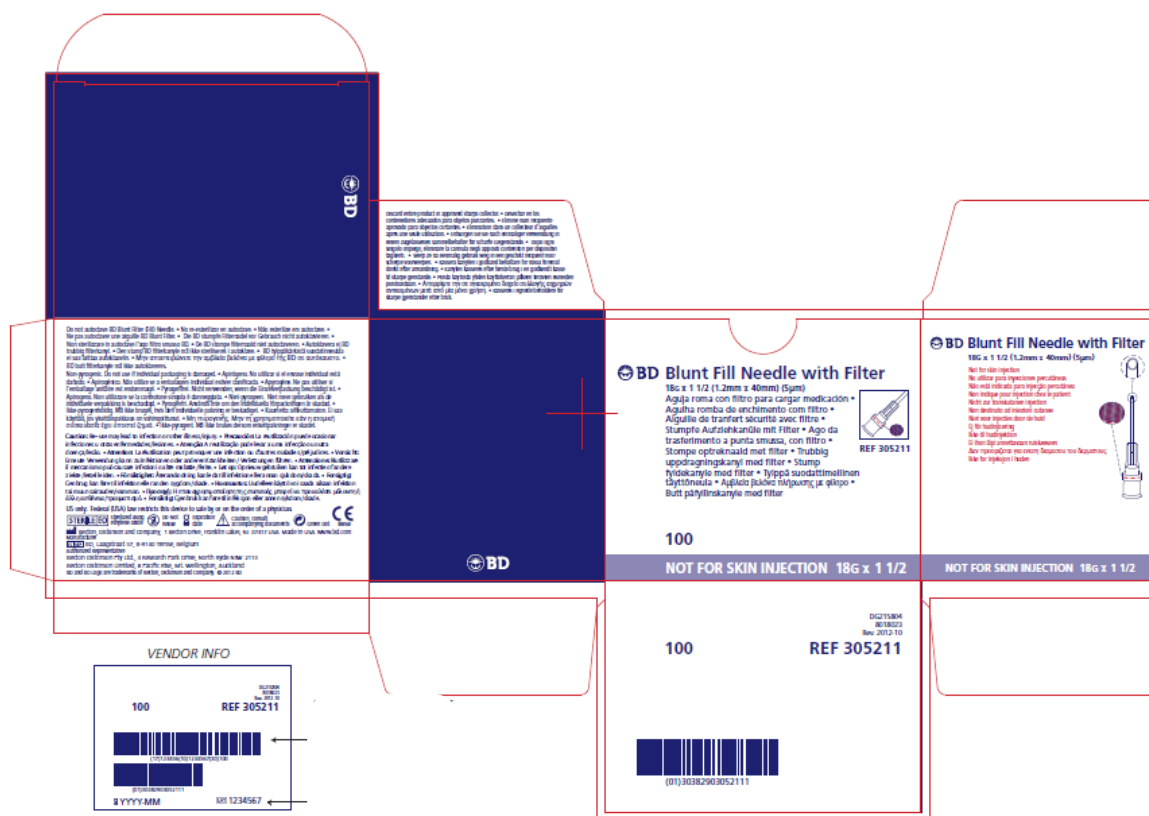


Manufacturer: Franklin Lakes

Unit pack



Shelf carton





Case carton label



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