Becton Dickinson and Company
BD Medical

A-One Business Centre
Z.A. Vers-la-Pièce n. 10
CH-1180 Rolle
Switzerland
bd.com

TECHNICAL DATA SHEET

BD Blunt fill and filter needles
Sterile. Single use, Latex free

1. General Information

1.1 General

The BD Fill and Filter Needles are used for aspiration of fluids from vials and ampoules. The BD Fill and Filter Needles are not for skin injections.

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

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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 nº 0050 ISO 9001 :2008 Certificate 19.2305 ISO 13485:2012 Certificate MD19.2305	NSAI NB nº 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 nº 0318 – N° 2015 03 0838 CP	Becton Dickinson S.A. - Crta. Mequinenza, s/n. 22520-Fraga (Huesca) Spain

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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)	PLASTIC MEMBRANE FILTER, Filter size: 5 µ
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 phthalates and as such 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	The products were assessed for TSE (Transmissible Spongiform Encephalopathy) contamination risk. The raw materials used in the manufacture of this device do not contain any animal tissue but may contain very small amounts of animal derived raw materials. This product is manufactured using polymer resins which may contain very small amounts of surfactants or fatty acids derived from tallow. Our resin suppliers have confirmed that these tallow derived materials have been produced using multiple cycles of conditions at least as rigorous (and normally more rigorous) as those specified in Annex C.5 of EN ISO 22442-1. Therefore, the raw materials meet or exceed the requirements of EN ISO 22442-1. Therefore, the raw materials meet or not to present any risk with respect to TSE or other animal borne disease.
Polyvinyl chloride (PVC)	The products do not contain polyvinyl chloride

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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

Catalogue number 303129	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, 305211	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 / Storage

Shelf life 5 years

No specific storage conditions are required. Store in dry and warm place and not exposed to strong light.

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1.9 Standards

Harmonized Standards	Title
EN 556-1:2001	Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE'
EN 980: 2008	Symbols for use in the labelling of medical devices
EN 1041:2008 + A1: 2013	Information supplied by the manufacturer with medical devices
EN ISO 10993 series	Biological evaluation of medical devices
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 11137-1:2006	Sterilization for Healthcare products Radiation –Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN ISO 11138-2	Sterilization pf health care products – Biological Indicators – Part 2: Biological indicators for ethylene oxide sterilization processes
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	Sterilization of medical devices – Microbial 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 validation of a sterilization process
EN ISO 13485:2012	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 20594-1: 1987 + A1: 1994 + A2: 1998	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements - AMD 8072: February 1994; AMD 9881: March 1998
EN ISO 22442-1:2007	Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management
EN ISO 22442-2: 2007	Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling

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Non-Harmonized Standards	Title
ISO 9626:1991 + A1: 2001	Stainless steel needle tubing for the manufacture of medical devices
EN ISO 11607/ A1: 2014	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2/ A1: 2014	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 15223-1:2012	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements

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 (reference: 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)

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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

- The EU representative for US produced blunt needles catalogue number 305181, 305180 and 305211 is BD Temse, Belgium. Catalog number 303129 is produced by a European manufacturer.
- (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.
- There is no separate Instruction for Use, IFU, relevant information is captured on the shelf box graphics.

2. Packaging

2.1 Labelling

LABELS: according to European Medical Device directive, multilingual

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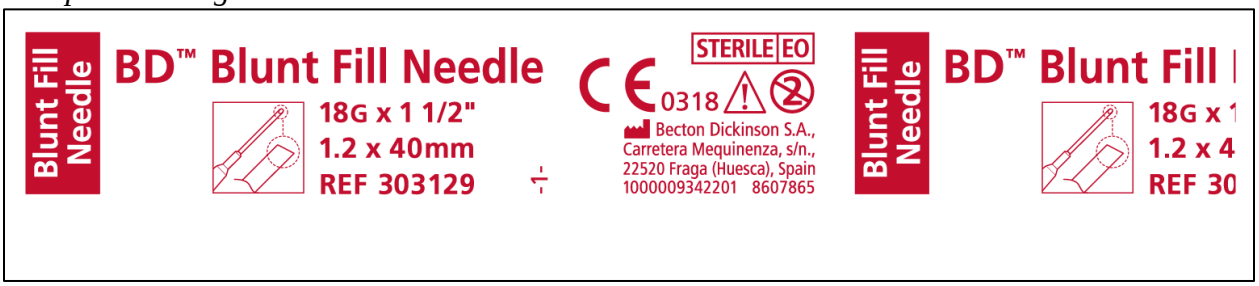
Example labels

Manufacturer: Fraga

Unit pack catalogue number 303129



Extract from shelf carton

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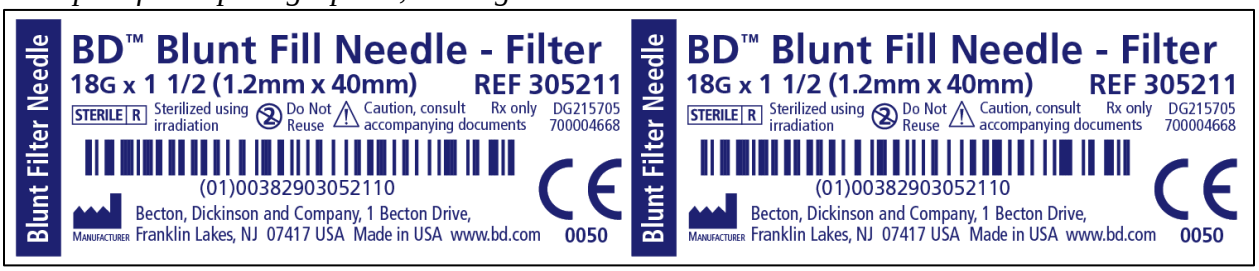
Manufacturer: Franklin Lakes

Example of Unit pack graphics, catalogue number 305211



Extract from Shelf carton, catalogue number 305211