BD Blunt Fill and Filter Needles
Sterile
305211 – 305180 – 305181 – 305183 - 303129

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins, Switzerland
bd.com

TDS number: V201-013 – Rev. 01
2019-June

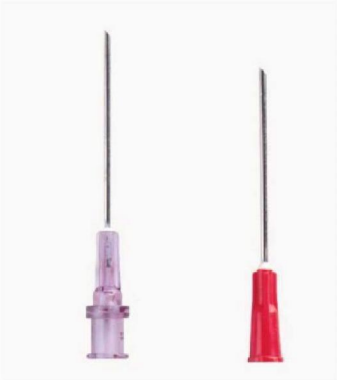
1. General Information

1.1 Intended use

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.

1.2 General description

The BD Filter and Fill Needles are single use medical devices, sold to healthcare professionals, used for aspiration of fluids from vials and ampoules and are not for skin injections.
The BD™ Blunt Fill Needles have female luer fittings, which mate to male luer fittings.



BD Catalog Number	BD Product Description	Gauge Size	Filter	Length (mm)	Length (inch)
305211	NEEDLE FILTER BLUNT FILL 18X1-1/2	18G	5 micron filter	40	1 ½
305180	NEEDLE 18X1-1/2 BLUNT FILL	18G	No	40	1 ½
305181	NEEDLE 18X1 IN BLUNT FILL	18G	No	25	1
305183	NEEDLE 20X1 IN BLUNT FILL	20G	No	25	1
303129	NDLE 18GA 1-1/2 IN BLT FILL NC TW SHLD	18G	No	40	1 ½

Note: Please check BD catalog number availability in your country.
The BD Product Description can slightly differ from the DoC, please always use 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)
305211 305180 305181 305183	**Address:** Becton Dickinson and Company 1 Becton Drive Franklin Lakes New Jersey 07417 United States **ISO 13485** Certificate No.: MD19.2305	CE certified with NSAI (0050) Certificate No.: 252.308	**Address:** BD Medical Surgical 2153 12th Avenue Columbus NE 68601 United States **ISO 13485** Certificate No.: MD19.2143	Becton Dickinson Distribution Center NV Laagstraat 57 B-9140 Temse Belgium
303129	**Address:** Becton Dickinson S.A. Ctra. De Mequinenza. s/n 22520 Fraga (Huesca) Spain **ISO 13485** Certificate No.: 2015 05 0047 EN	CE certified with AEMPS (0318) Certificate No.: 2015 03 0838 CP	**Address:** Becton Dickinson S.A. Ctra. De Mequinenza. s/n 22520 Fraga (Huesca) Spain **ISO 13485** Certificate No.: 2015 05 0047 EN **Address:** BD Medical Surgical 2153 12th Avenue Columbus NE 68601 United States **ISO 13485** Certificate No.: MD19.2143	N/A

1.4 Materials

Component	Material
Needle hub	Polycarbonate (Filter Needles) Polypropylene (Fill Needles) Colorant
Needle/ Cannula	Stainless steel
Needle Shield	Polypropylene Colorant **(For reference 303129 only)**
Lubricant	Silicone
Adhesive	Epoxy
Filter	Plastic membrane filter **(For reference 305211 only)**

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 April 2019, BD has not identified any • Bis (2-ethylhexyl) phthalate (DEHP) (CAS# 117-81-7), • Dibutyl phthalate (DBP) (CAS# 84-74-2), • Diisobutyl phthalate (DIBP) (CAS# 84-69-5), • Benzyl butyl phthalate (BBP) (CAS# 85-68-7), • Bis(2-methoxyethyl) phthalate (DMEP) (CAS# 117-82-8), • Diisopentylphthalate (DIPP) (CAS# 605-50-5), • Dipentyl phthalate (DPP) (CA5# 131-18-0), • di-n-hexyl phthalate (DnHP) (CA5# 84-75-3), • N-pentyl-isopentylphthalate (CA5# 776297-69-9), or • Dicyclohexyl phthalate (DCHP) (CA5# 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 April 2019, the articles with the Product Numbers above are not formulated with natural rubber latex.
Bisphenol A	Bisphenol A (BPA), CA5# 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% wt/wt (<1000 ppm). These levels are below a de minimis concentration with no demonstrable clinically significant exposure nor toxicity. **For Product Number 305211 only**: There is a polycarbonate component in this product. Bisphenol A (BPA), CAS# 80-05-7, is an organic compound that is a chemical building block for polycarbonate. Based on information from our suppliers and BD test results, the BPA level is less than 0.1% wt/wt (<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 acid 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 22442-1 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 T5E/B5E 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 and packaging.

1.6 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per April 2019, BD has not identified any chemicals in the articles and packaging of BD Blunt Fill and Filter Needles, 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 June 2018 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

- **Radiation sterilization** following 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)*. References 305211, 305180, 305181 and 305183 are sterilized with radiation.

- **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)*. Reference 303129 is sterilized with Ethylene Oxyde. ETO residues are within applicable regulations.

1.9 Shelf life and storage conditions

The BD Blunt Fill and filter Needles shelf life have been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
BD Blunt Fill and filter Needles reference 305211, 305180, 305181, 305183 and 303129 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 document number DOC DTF0006 linked to CE certificate number 252.308:

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 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
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

Harmonized Standards	
EN ISO 11137-2:2013	Sterilization of health care products – Radiation - Part 2: Establishing the sterilization dose
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes.
EN ISO 14971:2012	Medical devices. Application of risk management to medical devices.
EN 20594-1:1994	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment.
EN 1707:1996	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Lock fittings
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
EN ISO 15223-1:2016	Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements
Non-Harmonized Standards	
EN ISO 9626:1991/ A1:2001	Stainless steel needle tubing for the manufacture of medical devices

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

1.11 Classification

BD™ Fill and Filter Needles (305211, 305180, 305181 and 305183) are Class I Medical Devices, sterile, as per Annex IX, Section III, Rule 1 of the Medical Device Directive 93/42/EEC.

BD™ Blunt Fill Needle (303129) is class I, sterile medical device as defined in the Medical Devices Directive (93/42/EEC) Annex IX, Section III rule 2.

1.12 GMDN code

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure), BD Blunt Fill and Filter are referenced as follows:

- For BD™ Blunt Filter Needle (305211):

GMDN Code: 16266
GMDN Term: Medication transfer needle, filtering

- For BD Blunt Fill Needles:

GMDN Code: 45316
GMDN Term: Medicine preparation needle/cannula

1.13 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.

1.14 Other information

- (Material) Safety Data Sheets are not required for this product.
- Certificate of Food Contact (*Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food)* 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 Packaging configuration

BD Catalog Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
305211	NEEDLE FILTER BLUNT FILL 18X1-1/2	1	100	1000	No
305180	NEEDLE 18X1-1/2 BLUNT FILL	1	100	1000	No
305181	NEEDLE 18X1 IN BLUNT FILL	1	100	1000	No
305183	NEEDLE 20X1 IN BLUNT FILL	1	100	1000	No
303129	NDLE 18GA 1-1/2 IN BLT FILL NC TW SHLD	1	100	5000	No

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

2.2 Packaging material

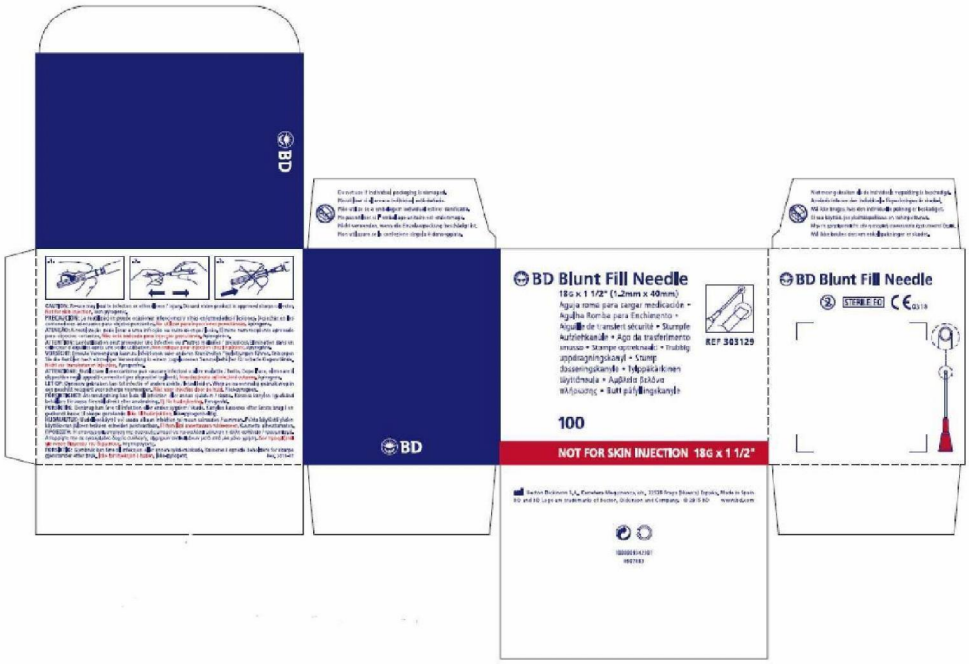
Component	Material
Unit Pack	**For references 305211, 305180, 305181 and 305183:** Top web: Paper Bottom web: Thermoformable plastic **For reference 303129:** Top Web – Polyamide/Polyethylene Bottom Web – Paper
Shelf Box	Corrugated carton
Shipping Case	Corrugated carton

2.3 Examples of labeling

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

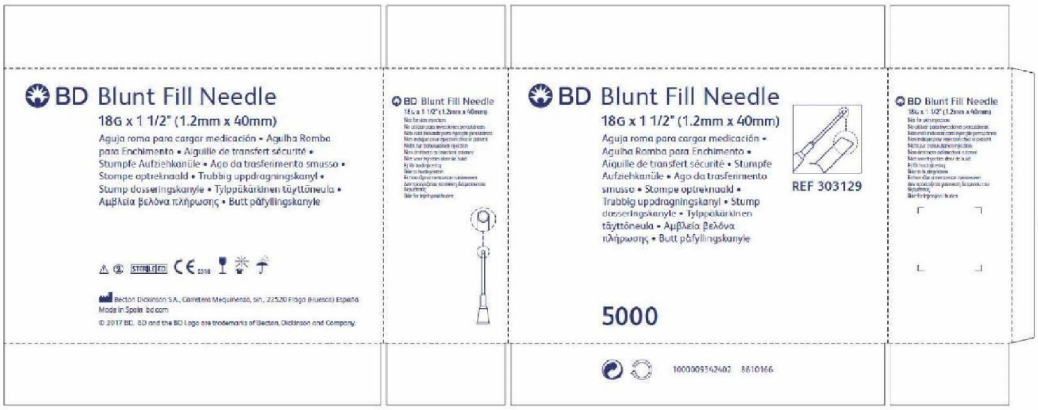
Primary Packaging Label (Top Web) extracted from document 1000093422 related to reference 303129:

Shelf Box extracted from document 10000093423 related to reference 303129:



Shelf Box label extracted from document 10000093426 related to reference 303129:

Shipping Case extracted from document 1000093424 related to reference 303129:



Case Label extracted from document 10000093427 related to reference 303129:

REVISION	CHANGE SUMMARY
01	Initial release according to new template