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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<br>305180<br>305181 | Becton, Dickinson and Company<br>1 Becton Drive<br>Franklin Lakes, NJ 07417, USA | NSAI –NB nº 0050<br>ISO 9001 :2008<br>Certificate 19.2305<br>ISO 13485:2012<br>Certificate<br>MD19.2305 | NSAI NB nº<br>0050:<br>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 –<br>N° ER-0097/1994 – ISO 9001:2008<br><br>AEMPS –<br>N° 2015 05 0047 EN– ISO 13485:2013 | AEMPS NB nº 0318 –<br>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.<br>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

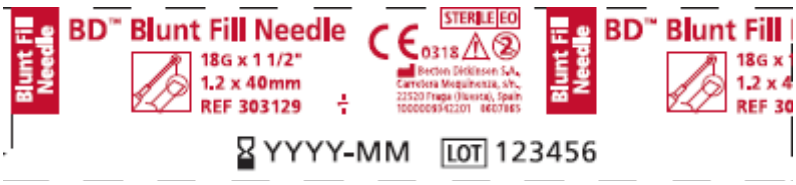
***2.1 Labelling***

LABELS: according to European Medical Device directive, multilingual

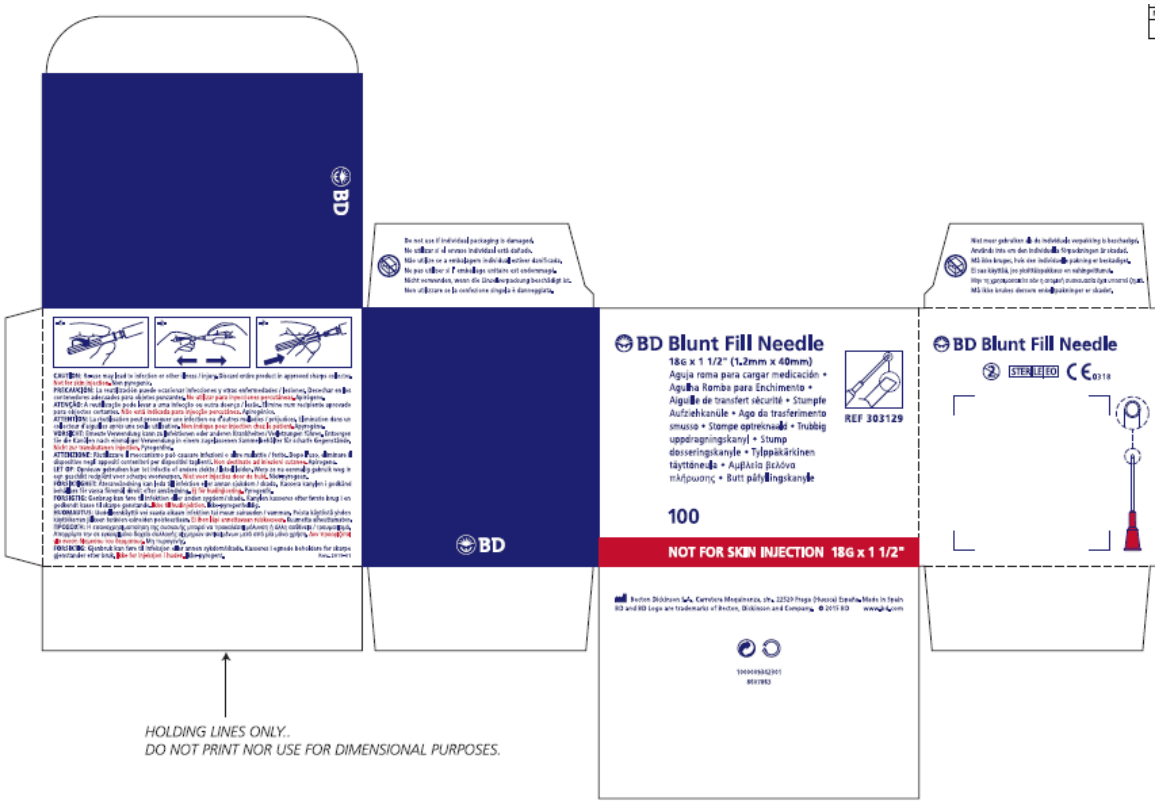
***2.4 Example labelling***

***Manufacturer: Fraga***

***Unit pack***



## *Shelf carton*




## *Shelf carton label*

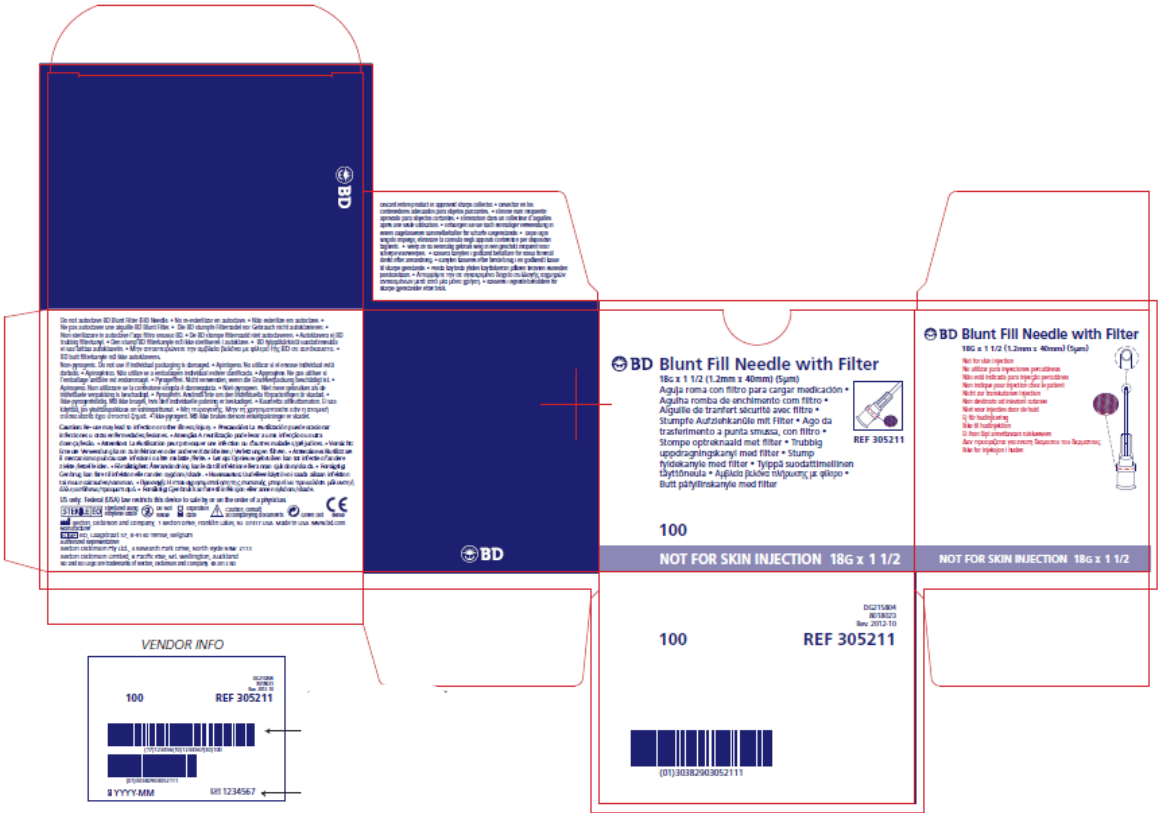
## *Case carton*


## *Case carton label*

## *Manufacturer: Franklin Lakes*

## *Unit pack*


## *Shelf carton*



## *Case carton label*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