BD SafetyGlide™ Needles, Sterile, Single-use

BD Switzerland Sàrl
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bd.com
TDS number: V201-046 – Rev. 02
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1. General Information

1.1 Intended use

The BD SafetyGlide™ Needles Product Family are used for general purpose injection and aspiration of fluids from vials, ampoules and parts of the body below the surface of the skin.

1.2 General description

BD SafetyGlide™ Needle is a device that is composed of a typical hypodermic needle with a hinge arm that is connected to the hub. The hinge arm can be pushed forward manually after use allowing a mechanism to move forward towards the needle point. After the arm movement has been initiated manually, the hinge arm mechanism completes the full engagement. When the cover reaches the needle point it slides over the point and provides a secure encapsulation.

BD SafetyGlide™ Needles are sold sterile, single-use.

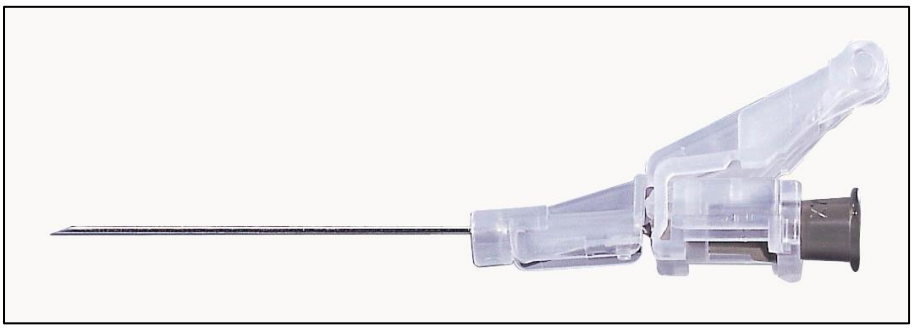


Figure 1: BD SafetyGlide™ Needle

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BD Catalog Number	BD Product Description	Gauge Size	Color code	Length (mm)	Length (inch)	Wall	Bevel
305918[1]	BD SafetyGlide™ Needle 18GA 1-1/2IN	18G	Pink	40	1 ½	Regular wall[1]	Regular bevel
305915	BD SafetyGlide™ Needle 21GA 1IN	21G	Green	25	1	Thin wall	Regular bevel
305917	BD SafetyGlide™ Needle 21GA 1-1/2IN	21G	Green	40	1 ½	Thin wall	Regular bevel
305900[2]	BD SafetyGlide™ Needle 22GA 1-1/2IN	22G	Black	40	1 ½	Regular wall	Regular bevel
305902[1]	BD SafetyGlide™ Needle 23GA 1IN	23G	Blue	25	1	Regular wall[1]	Regular bevel
305901[1]	BD SafetyGlide™ Needle 25GA 5/8IN	25G	Orange	16	5/8	Regular wall[1]	Regular bevel
305916[1]	BD SafetyGlide™ Needle 25GA 1IN	25G	Orange	25	1	Regular wall[1]	Regular bevel
305921	BD SafetyGlide™ Needle 27GA 5/8IN	27G	Gray	16	5/8	Regular wall	Regular bevel

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 use the BD Catalog Number.

[1] BD will standardize the needles between 16 G and 25 G to be thin-wall (TW) needles, while the 27 G and 30 G needles which remain unchanged (regular wall). Therefore, as of the 30th of September 2022, the products SKUs 305901, 305902, 305916 and 305918 will be manufactured with thin walls. There is not impact on the product conformity.

[2] Across BD, we routinely refine our product portfolio to serve our customers and patients more effectively. In our continuing effort to improve customer experience and streamline our broad product offering, we would like to inform you that the product SKU 305900 will be discontinued effective from the 30th of September 2022. For more information on the end date of the sales in your country, please contact your BD sales representative.

The product SKU 305900 will be replaced by an alternative, the product SKU 304387, as described in the table below. This is a direct replacement with the same intended use.

Discontinued code	Product description	Substitute code	Substitute code Description
305900	BD SafetyGlide™ Needle 22GA 1-1/2IN	304387	BD SafetyGlide™ Needle 23GA 1-1/2IN

The alternative product SKU 304387, described in the table below, is a new product configuration. This product is sold sterile, single-use.

BD Catalog Number	BD Product Description	Gauge Size	Color code	Length (mm)	Length (inch)	Wall	Bevel
304387	BD SafetyGlide™ Needle 23GA 1-1/2IN	23G	Blue	40	1 ½	Thin wall	Regular bevel

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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)
304387[3] 305900 305901 305902 305915 305916[4] 305917 305918 305921	**Address:** Becton Dickinson and Company 1 Becton Drive Franklin Lakes New Jersey 07417 USA **ISO 13485** Certificate No.: MD19.2305	CE certified with NSAI (0050) Certificate No.: 252.232	**Address:** Becton Dickinson and Company Route 7 & Grace Way Canaan, CT 06018 USA **ISO 13485** Certificate No.: MD19.2369	Becton Dickinson Distribution Center Laagstraat 57 B-9140 Temse Belgium
305916[4]			**Address:** BD (BARD) Boulevard Montebello No 1 Parque Industrial Colonial Reynosa, Tamaulipas C.P. 88787 **ISO 13485** Certificate No.: FM550148	

[3] As SKU 304387 is a new product configuration that will be implemented as a replacement for SKU 305900, the related declaration of conformity is not yet available.

[4] The product SKU 305916 is manufactured in both Canaan and Reynosa manufacturing sites.

1.4 Materials

Component	Material
Cannula	Stainless Steel
Hub	Polypropylene
Shield	Polypropylene
Lubricant	Medical Grade Silicone
Adhesive	Epoxy
Safety Arm	Polypropylene
Safety Latch	Stainless steel

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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.

For products SKUs 305900, 305901, 305902, 305915, 305916, 305917, 305918 and 305921:

Material	Comment
Phthalates	Based on our ongoing data collection efforts and/or information received from our suppliers as per 24 May 2022, BD has not identified any • 1,2-Benzenedicarboxylic acid, dihexyl ester (branched & linear) (CAS# 68515-50-4), • 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters (CAS# 71888-89-6), • 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (CAS# 68515-42-4), • 1,2-Benzenedicarboxylic acid, di-C6-10 alkyl esters (CAS# 68515-51-5), • 1,2-Benzenedicarboxylic 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), • Diisopentyl phthalate (DIPP) (CAS# 605-50-5), • Dipentyl phthalate (DPP) (CAS# 131-18-0), • N-pentyl-isopentyl phthalate (CAS# 776297-69-9), or • Dicyclohexyl phthalate (DCHP) (CAS# 84-61-7) in the article and packaging with the product numbers as referenced above, in an individual concentration above 0.1% w/w.
Latex	Based on our ongoing data collection efforts and/or information received from our suppliers as per 24 May 2022, natural rubber latex and latex are not part of the material formulation for the articles with the product numbers referenced above.
Bisphenol A	BD has not identified any Bisphenol A (BPA), CAS# 80-05-7, in the article with the product number referenced above. It is not a building block of any of the raw materials utilized and is not intentionally added. BD has not done any testing to evaluate levels of this chemical in these products.
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. This product is 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 ISO 22442-1:2020 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, this product is considered not to present any risk with respect to TSE/BSE or other animal-borne diseases. Furthermore, 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, MDR 2017/745, 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.

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1.6 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 24 May 2022, 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 08 July 2021 according to Art. 59 (1,10) of the Regulation (EC) No 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

BD SafetyGlide™ Needles are sterilized using Radiation. The sterilization method is validated per EN ISO 11137: "Sterilization of health care products – Radiation".

Data to support re-sterilization of these products by the customer may be available through customer quality agreement with BD. The customer is responsible for validation of their own sterilization processes ensuring that the parameters used are not harsher than those defined by BD.

1.9 Shelf life and storage conditions

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

Note:

- Processing by the user, such as re-sterilization, might impact the shelf life of the product(s).
- BD recommends to store in a dry and warm place, not exposed to strong light.

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1.10 Standards

As per extract from the Declaration of Conformity (DTF0004_DoC_041422) linked to CE certificate number 252.232, for SKUs 305900, 305901, 305902, 305915, 305916, 305917, 305918 and 305921:

Standards	
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes.
EN ISO 10993 series	Biological evaluation of medical devices
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
EN 1041:2008	Information supplied by the manufacturer of medical devices
ISO 23908:2011	Sharps injury protection -- Requirements and test methods -- Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
EN 556-1:2001/AC:2006	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE" – Requirements for terminally sterilized medical devices
IEC 62366-1:2015+AMD2020	Medical devices – Part 1: Application of usability engineering to medical devices – Amendment 1
EN ISO 14971:2019	Medical devices – Application of Risk Management to Medical Devices
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 22442-1:2020	Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management
EN ISO 11737-1:2018	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2020	Sterilization of health care products – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 11135:2014/A1:2019	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 11137-1:2015	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2:2015	Sterilization of health care products – Radiation – Establishing the sterilization dose
EN ISO 11138-1:2017	Sterilization of health care products - Biological indicators – Part 1: General requirements
EN ISO 11138-2:2017	Sterilization of health care products - Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects – Good clinical practice
EN 1707:1996	Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Lock Fittings
ISO 7864:1993	Sterile hypodermic needles for single-use – Requirements and test methods
ISO 9626:1991 AMD1 2001	Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods
ISO 6009:2016	Hypodermic needles for single use – Colour coding for identification

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.

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1.11 Classification

BD SafetyGlide™ Needles are Class IIa Medical Devices under Rule 6 of Annex IX of the Medical Device Directive 93\42\EEC.

1.12 GMDN code

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure), BD SafetyGlide™ Needles are referenced as follows:

GMDN Code: 59230
GMDN Term: Hypodermic Needle, Single Use

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.

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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*
305918	BD SafetyGlide™ Needle 18GA 1-1/2IN	1	50	500	Yes
305915	BD SafetyGlide™ Needle 21GA 1IN	1	50	500	Yes
305917	BD SafetyGlide™ Needle 21GA 1-1/2IN	1	50	500	Yes
305900	BD SafetyGlide™ Needle 22GA 1-1/2IN	1	50	500	Yes
305902	BD SafetyGlide™ Needle 23GA 1IN	1	50	500	Yes
304387	BD SafetyGlide™ Needle 23GA 1-1/2IN	1	50	500	Yes
305901	BD SafetyGlide™ Needle 25GA 5/8IN	1	50	500	Yes
305916	BD SafetyGlide™ Needle 25GA 1IN	1	50	500	Yes
305921	BD SafetyGlide™ Needle 27GA 5/8IN	1	50	500	Yes

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

2.2 Packaging material

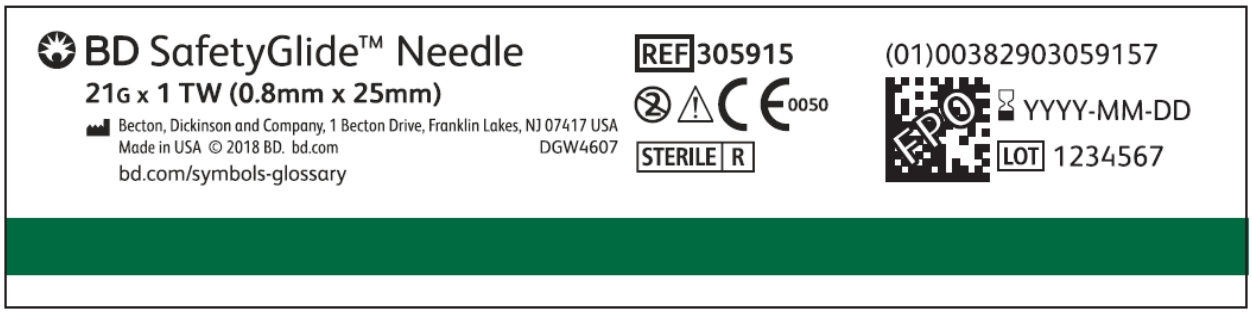
Component	Material
Unit Pack	Top Web: Medical Grade Paper and film Bottom Web: Thermoformable plastic
Shelf Box	Corrugated Carton
Shipping Case	Corrugated Carton

2.3 Examples of labeling

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

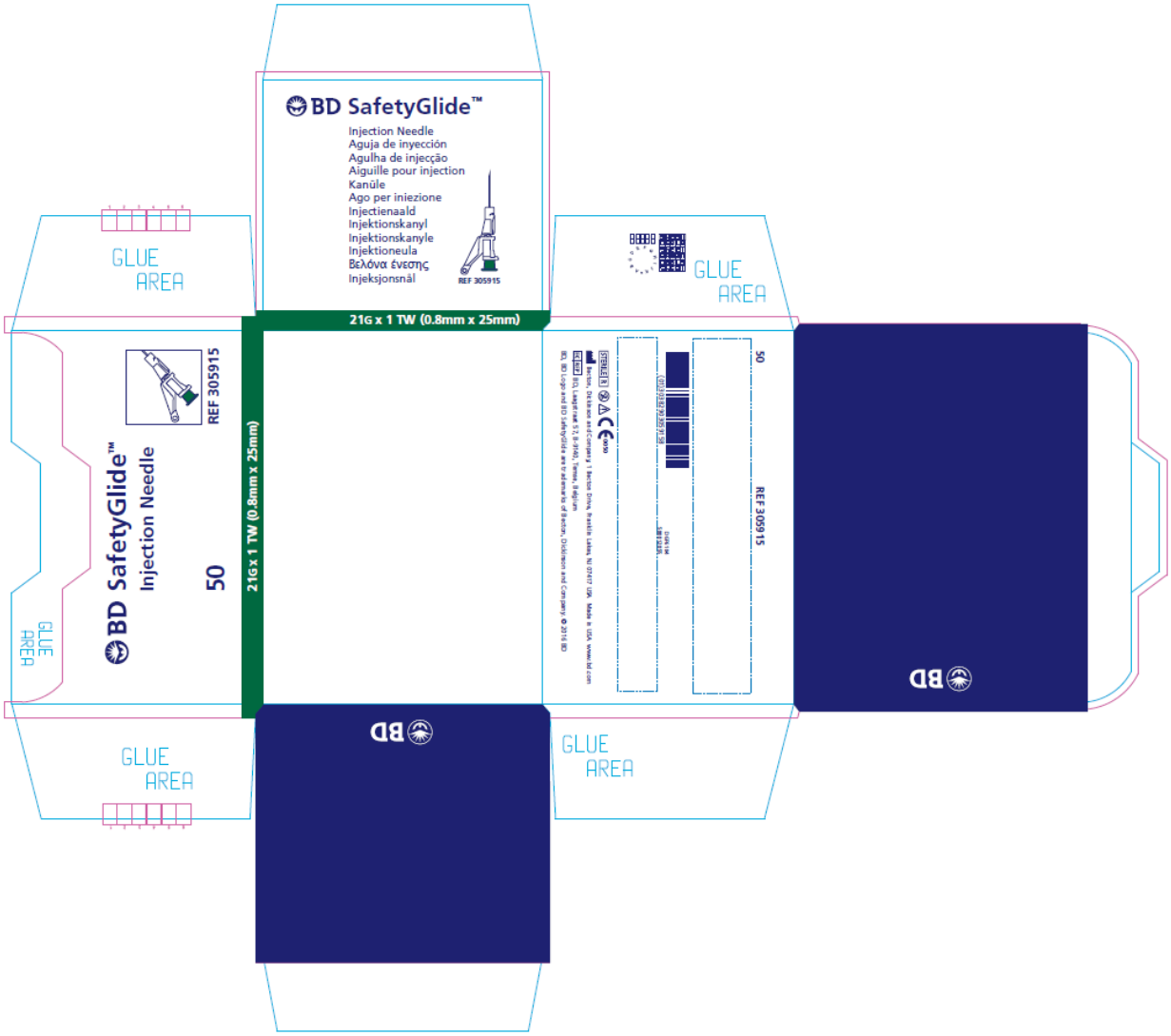
The IFU is translated in English, Spanish, Portuguese, French, German, Italian, Dutch, Swedish, Danish, Finnish, Greek and Norwegian.

Primary Packaging Label (Top Web) extracted from document DGW46 related to reference 305915:



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Shelf Box extracted from document DGF61 related to reference 305915:



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Shipping Case extracted from document DGC17 related to reference 305915:

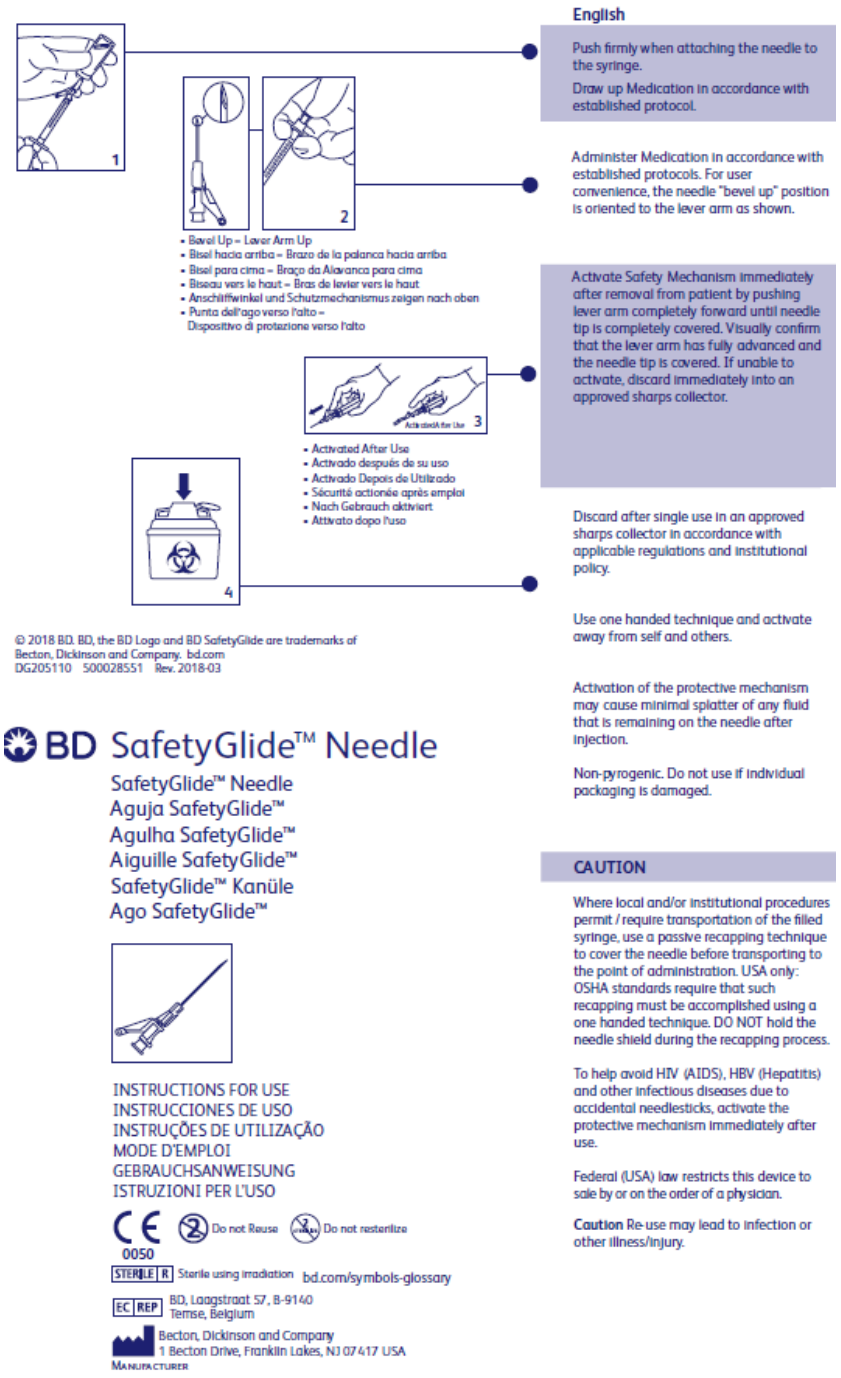


Case Label extracted from document DG1300 related to reference 305915:



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IFU insert (English part) extracted from document DG2051 related to reference 305915:



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REVISION	CHANGE SUMMARY
01	Initial release according to new template
02	Update of: • 1.2 General description • 1.3 Certification • 1.5 Materials of concern • 1.6 REACH information • 1.8 Sterilization method • 1.9 Shelf life and storage conditions • 1.10 Standards • 1.11 Classification • 2.1 Packaging configuration • 2.2 Packaging material • 2.3 Examples of labeling

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