BD SafetyGlide™ Syringes with needle, Sterile, Single-use

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TDS number: V201-047 – Rev. 03
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1. General Information

1.1 Intended use

BD SafetyGlide™ Syringes with Needles are used for general purpose injection and aspiration of fluids from vials, ampoules, and parts of the body below the surface of the skin. The device contains a mechanism which covers the needle point after use. In the activated position the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.

1.2 General description

The BD SafetyGlide™ Syringes assembly consists of a polypropylene barrel imprinted with a graduated scale and polypropylene plunger rod with a natural rubber/synthetic rubber/ thermoplastic elastomers stopper affixed to the end.

BD SafetyGlide™ Syringes are sold with SafetyGlide™ needles. The needle assembly consists of a lubricated stainless-steel cannula attached to the needle hub using epoxy or UV cure adhesive. The needle assembly is protected with a polypropylene shield.

The SafetyGlide™ needles are 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™ Syringes with needles are sold sterile, single use.

Figure 1: BD SafetyGlide™ Syringes with needle

Figure 2: BD SafetyGlide™ Insulin Syringe with needle

BD Catalog Number	BD Product Description	Capa-city	Scale	Gauge	Color code	Length	Wall	Bevel
305935	BD SafetyGlide™ Insulin Syringe 3/10 mL with needle 29G 1/2IN	0.3 mL	30 I.U.	29G	Natural	½ IN 13 mm	Regular wall	Regular bevel
305937	BD SafetyGlide™ Insulin Syringe 3/10 mL with needle 31G 5/16IN	0.3 mL	30 I.U.	31G	Natural	5/16 IN 8 mm	Thin wall	Regular bevel
305932	BD SafetyGlide™ Insulin Syringe ½ mL with needle 29G 1/2IN	0.5 mL	50 I.U.	29G	Natural	½ IN 13 mm	Regular wall	Regular bevel
305934	BD SafetyGlide™ Insulin Syringe ½ mL with needle 30G 5/16IN	0.5 mL	50 I.U.	30G	Natural	5/16 IN 8 mm	Thin wall	Regular bevel
305946[1]	BD SafetyGlide™ Tuberculin Syringe 1 mL with needle 26GA 3/8IN	1 mL	0.01 mL	26G	Brown	3/8 IN 10 mm	Regular wall	Intradermal Bevel
305945	BD SafetyGlide™ Tuberculin Syringe 1 mL with needle 27GA 1/2IN	1 mL	0.01 mL	27G	Grey	½ IN 13 mm	Regular wall	Regular bevel
305930	BD SafetyGlide™ Insulin Syringe 1 mL with needle 29G 1/2IN	1 mL	100 I.U.	29G	Natural	½ IN 13 mm	Regular wall	Regular bevel
305905[2]	BD SafetyGlide™ Syringe 3 mL with needle 23GA 1IN	3 mL	0.1 mL	23G	Blue	1 IN 25 mm	Regular wall[2]	Regular bevel
305904[2]	BD SafetyGlide™ Syringe 3 mL with needle 25GA 5/8IN	3 mL	0.1 mL	25G	Orange	5/8 IN 16 mm	Regular wall[2]	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 the BD Catalog Number.

[1] 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 305946 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 305946 will be replaced by an alternative, the product SKU 303327, 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
305946	BD SafetyGlide™ Tuberculin Syringe 1 mL with needle 26GA 3/8IN	303327	BD SafetyGlide™ Tuberculin Syringe 1 mL with needle 27GA 3/8IN

The alternative product SKU 303327, described in the table below, is a new product configuration. This product is sold sterile, single-use.

BD Catalog Number	BD Product Description	Capa-city	Scale	Gauge	Color code	Length	Wall	Bevel
303327	BD SafetyGlide™ Tuberculin Syringe 1 mL with needle 27GA 3/8IN	1mL	0.01 mL	27G	Grey	3/8 IN 10 mm	Regular wall	Intradermal Bevel

[2] 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 (RW, regular wall). Therefore, as of the 30th of September 2022, the products SKUs 305904 and 305905 will be manufactured with thin walls (TW). There is not impact on the product conformity.

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)
305904 305905	**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.: 252.231	**Address:** Becton, Dickinson and Company Route 7 & Grace Way Canaan, CN 06018 USA **ISO 13485** Certificate No.: MD19.2369	Becton Dickinson Distribution Center Laagstraat 57 B-9140 Temse Belgium
305930 305932 305934 305935 305937 305945 305946 303327[3]			**Address:** BD Medical-Diabetes Care 1329 West Highway 6 Holdrege, NE 68949 USA **ISO 13485** Certificate No.: CM19.1436	

[3] As the product SKU 303327 is a new product configuration, the related declaration of conformity is not yet available.

1.4 Materials

Component		Material
Syringe	Barrel	Polypropylene
	Plunger Rod	Polypropylene
	Stopper	Natural Rubber/ Synthetic Rubber/ Thermoplastic elastomers
	Lubricant	Medical Grade Silicone
Needle	Cannula	Stainless Steel
	Hub	Polypropylene + colorant
	Shield	Polypropylene
	Lubricant	Medical Grade Silicone
	Adhesive	Epoxy, UV cured
	Safety Arm	Polypropylene
	Safety Latch	Stainless Steel

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 SKUs 305904, 305905, 305930, 305932, 305934, 305937, 305945, 305946 and 303327:

Material	Comment
Phthalates	Based on our ongoing data collection efforts and/or information received from our suppliers, 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, natural rubber latex and latex are not part of the material formulation for the articles with the product numbers referenced above.
Bisphenol A	Based on our ongoing data collection efforts and/or information received from our suppliers, BD has not identified any • 4,4'-isopropylidenediphenol (BPA) (CAS# 80-05-7) in the articles and packaging with the Product Numbers as referenced above, in an individual concentration above 0.1% weight by weight (w/w). **For SKUs 305904 and 305905**: 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. **For SKUs 305930, 305932, 305934, 305937, 305945, 305946 and 303327:** 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% w/w (<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. 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.

Material	Comment
Substances of animal origin BSE/TSE	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.

For SKU 305935:

Material	Comment
Phthalates	The products are not made with phthalates.
Latex	The products are not made with natural rubber latex.
Bisphenol A	The products are not made with BPA.
Substances of animal origin BSE/TSE	The products utilize very small amounts of tallow or tallow derivatives (e.g. stearates in polymers). Per MEDDEV 2.4/1 Rev. 9 June 2010, such substances are not considered as derivatives of animal tissues for the purpose of this rule which therefore does not apply.

1.6 REACH information

For SKUs 305904, 305905, 305930, 305932, 305934, 305937, 305945, 305946 and 303327:

Based on our ongoing data collection efforts and/or information received from our suppliers, 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).

For SKU 305935:

In general, we are a downstream user of substances, although BD also incorporate substances into its product formulations. We recognize that while our products, as mixtures, are exempt from REACH obligations, some of the individual substances within these mixtures require Registration. We wish to assure you that we have assessed our product portfolio and will remain in compliance with all relevant obligations pertaining to the REACH Regulation for all non-exempt substances which BD import or manufacture within the European Economic Area (EEA) in total quantities above 1 ton per annum (tpa). Please note that not all the substances within our product portfolio require Registration.
We also wish to inform you that BD have been pro-actively communicating with its upstream suppliers with a view to obtaining information on REACH Substances of Very High Concern ("SVHC").

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™ Syringes with needles are sterilized using Radiation. The sterilization method is validated as per EN ISO 11137: "Sterilization of health care products – Radiation".

1.9 Shelf life and storage conditions

The BD SafetyGlide™ Syringes with needles shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.

BD SafetyGlide™ Syringes with needles have a shelf life of 5 years.

Note:

- BD recommends to 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 (DTF0001DOC_6-22-2022) linked to CE certificate number 252.231, for SKUs 305904, 305905, 305930, 305932, 305934, 305935, 305937, 305945 and 305946:

Standards	
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes.
EN ISO 14971:2019	Medical devices. Application of risk management to 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 ISO 10993 series	Biological evaluation of 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 -- Part 2: 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 11737-1:2018	Sterilization of medical devices – Microbial methods- Part 1: Determination of a population of microorganisms on products
EN 556-1:2001/AC:2006	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE" – Requirements for terminally sterilized medical devices
EN ISO 20594-1:1993	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
ISO 7886-1:1993 COR1 1995*	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
EN 1041:2008	Information supplied by the manufacturer of medical devices
ISO 7886-2:1996*	Sterile hypodermic syringes for single-use – Part 2: Syringes for use with power-driven syringe pumps
EN 8537:2007	Sterile single-use syringes, with or without needle, for insulin
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
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 – Radiation
ISO 11607-1:2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2020	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes

Standards	
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects – Good clinical practice
EN ISO 22442-1:2020	Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management
IEC 62366-1:2015+AMD2020	Medical devices – Part 1: Application of usability engineering to medical devices – Amendment 1
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

Note:
- "*": Some exceptions / exemptions may apply
- 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.

1.11 Classification

BD SafetyGlide™ Syringes with needles are a 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™ Syringes with needles are referenced as follows:

- GMDN Code: 47017
- GMDN Term: General-purpose syringe

- GMDN Code: 35904
- GMDN Term: Metered Delivery Hypodermic Syringe

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

- GMDN Code: 38501
- GMDN Term: Insulin syringe, fixed-needle

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.

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*
305935	BD SafetyGlide™ Insulin Syringe 3/10 mL with needle 29G 1/2IN	1	100	400	Yes
305937	BD SafetyGlide™ Insulin Syringe 3/10 mL with needle 31G 5/16IN	1	100	400	Yes
305932	BD SafetyGlide™ Insulin Syringe ½ mL with needle 29G 1/2IN	1	100	400	Yes
305934	BD SafetyGlide™ Insulin Syringe ½ mL with needle 30G 5/16IN	1	100	400	Yes
305946	BD SafetyGlide™ Tuberculin Syringe 1 mL with needle 26GA 3/8IN	1	100	400	Yes
303327	BD SafetyGlide™ Tuberculin Syringe 1 mL with needle 27GA 3/8IN	1	100	400	Yes
305945	BD SafetyGlide™ Tuberculin Syringe 1 mL with needle 27GA 1/2IN	1	100	400	Yes
305930	BD SafetyGlide™ Insulin Syringe 1 mL with needle 29G 1/2IN	1	100	400	Yes
305905	BD SafetyGlide™ Syringe 3 mL with needle 23GA 1IN	1	50	400	Yes
305904	BD SafetyGlide™ Syringe 3 mL with needle 25GA 5/8IN	1	50	400	Yes

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

2.2 Packaging material

Component	Material
Unit Pack	Top Web: Medical Grade Paper/Plastic Film Bottom Web: Thermoformable Plastic
Shelf Box	Corrugated Carton
Shipping Case	Corrugated Carton/PE shrink film
IFU	Paper

2.3 Examples of labeling

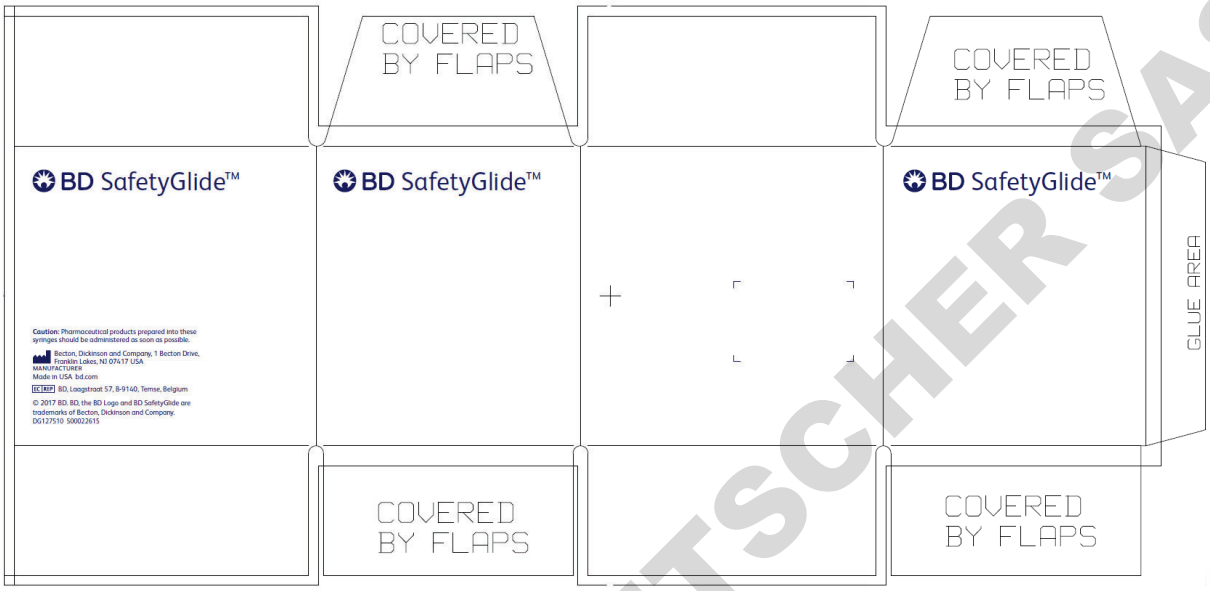
Labels: According to European Medical Device directive, labels are multilingual.

The IFU for SKUs 305904 and 305905 is labeling in English, Spanish, Portuguese, French, German, Italian, Dutch, Swedish, Danish, Finnish, Greek and Norwegian language.

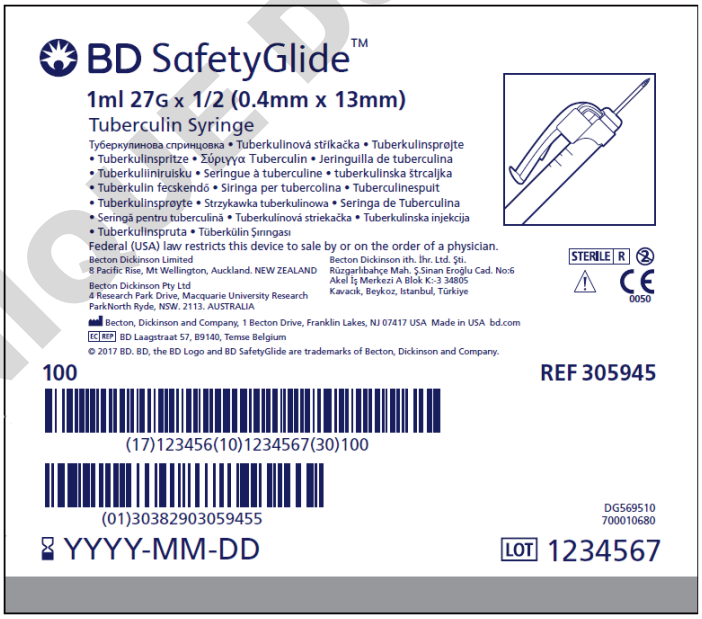
The IFU for SKUs 303327, 305930, 305932, 305934, 305935, 305937, 305945 and 305946 is labeling in English, Bulgarian, Czech, Danish, German, Greek, Spanish, Finnish, French, Croatian, Hungarian, Italian, Dutch, Norwegian, Polish, Portuguese, Romanian, Slovak, Slovenian, Swedish, Turkish language.

Primary Packaging Label (Top Web) extracted from document DG1348 related to reference 305945:

Shelf Box extracted from document DG1275 related to reference 305945:

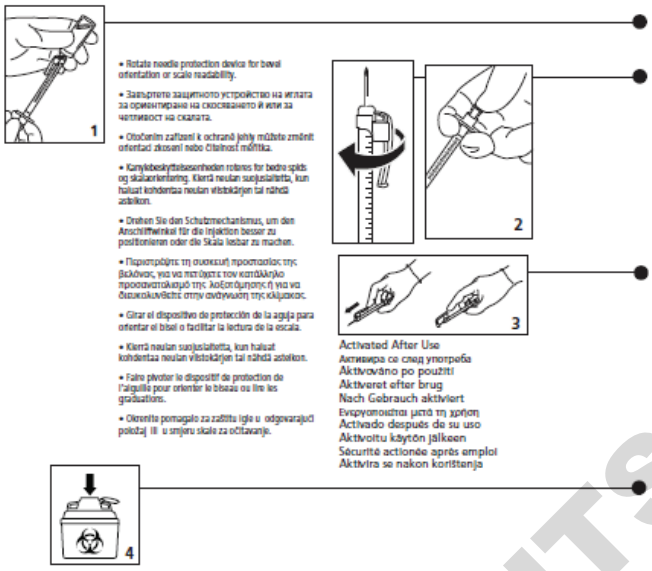


Shelf Box label extracted from document DG5695 related to reference 305945:



Case Label extracted from document DG5705 related to reference 305945:

IFU insert (English part) extracted from document DG2052 related to reference 305945:



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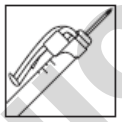
8606725 DG205207 Rev. 2013-12

BD SafetyGlide™ Syringe

SafetyGlide™ Syringe
Спринцовка SafetyGlide™
Stříkačka SafetyGlide™
SafetyGlide™ Sprøjte
SafetyGlide Spritze™
Σύριγγα SafetyGlide™
Jeringuilla SafetyGlide™
SafetyGlide™ -ruisku
Seringue SafetyGlide™
Štrcaljka SafetyGlide™



INSTRUCTIONS FOR USE
ИНСТРУКЦИИ ЗА УПОТРЕБА
NÁVOD K POUŽITÍ
BRUGSANVISNING
GEBRAUCHSANWEISUNG
ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ
INSTRUCCIONES DE USO
KÄYTTÖOHJEET
MODE D'EMPLOI
KORISNIČKE UPUTE

CE 0050

STERILE R – Sterilization Using Radiation
– Attention, See Instruction For Use
– Do Not Reuse
– Used By
– Manufacturer
– Waste Management for Europe
LOT – Batch Code
EC REP – Authorized Representative in the European Community

EC REP BD, Laagstraat 57, B-9140
Temse, Belgium

Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417 USA

Made in USA

English

Draw up Medication in accordance with established protocol.

Administer Medication in accordance with established protocols. For user convenience, the needle protection device can be rotated for ease of injection.

Activate Safety Mechanism immediately after removal from patient by moving the pushrod completely forward until the pushrod is fully extended and the needle tip is covered. Visually confirm that the pushrod has fully advanced and the needle tip is covered. If unable to activate, discard immediately into an approved sharps collector.

Discard after single use in an approved sharps container in accordance with applicable regulations and institutional policy.

Use one handed technique and activate away from self and others.

Non-pyrogenic. Do not use if individual packaging is damaged.

CAUTION

Where local and/or institutional procedures permit / require transportation of the filled syringe, use a passive recapping technique to cover the needle before transporting to the point of administration.

USA only: OSHA standards require that such recapping must be accomplished using a one handed technique. DO NOT hold the needle shield during the recapping process.

To help avoid HIV (AIDS), HBV (Hepatitis) and other infectious diseases due to accidental needlesticks, activate the protective mechanism immediately after use.

Do not autoclave BD SafetyGlide™ Syringes before use.

Re-use may lead to infection or other illness/ injury.

Federal (USA) law restricts this device to sale by or on the order of a physician.

BD

REVISION	CHANGE SUMMARY
01	Initial release according to new template
02	Update of: • 1.1 Intended use • 1.2 General description • 1.3 Certification • 1.4 Materials • 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 • 1.12 GMDN code • 2.1 Packaging configuration • 2.3 Examples of labeling Removal of product SKU 305906 throughout this TDS because there are no sales in EU. Removal of product SKU 305907 throughout this TDS because this product has been discontinued.
03	Update of: • 1.2 General description • 1.3 Certification • 1.5 Materials of concern • 1.6 REACH information • 1.10 Standards • 1.12 GMDN code • 2.1 Packaging configuration • 2.3 Examples of labeling Addition of SKUs 305930, 305932, 305934, 305935 and 305937.