BD Eclipse™ SmartSlip™ Hypodermic Safety Needle, Sterile, Single Use

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1. General Information

1.1 Intended use

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

Single use sterile, with a safety mechanism that covers the needle point after use. In the activated position, the needle cover guards against accidental needlestick during normal handling and disposal of the used needle/syringe.
The SmartSlip™ Technology consists of a plastic clip designed with a mechanism inside the hub luer for connecting to a luer slip and luer lock syringe.

BD Eclipse™ SmartSlip™ safety needle complies with the criteria defined for safety devices:

- The safety mechanism is an integrated part of the device; it is also aligned with needle bevel, facilitating easy orientation of the needle bevel and low-angle injections
- Immediate and intuitive activation, at the earliest point of time with regard to the gesture
- Single-handed activation, irreversible mechanism, with indication that the safety device has been activated

BD Catalog Number	BD Product Description	Gauge Size	Length mm - inch	Wall	Color Code
302436	NEEDLE 27X1-1/2 ECLIPSE	27G	38 - 1 ½	Regular	Medium Grey
302437	NEEDLE 18X1-1/2 ECLIPSE	18G	38 - 1 ½	Thin	Pink
305760	NEEDLE ECLIPSE S/T 25X5/8 RB	25G	16 - 5/8	Regular	Orange
305770	NEEDLE ECLIPSE S/T 27X1/2 RB	27G	13 - 1/2	Regular	Medium Grey
305771	NEEDLE ECLIPSE S/T 30X1/2 RB	30G	13 - 1/2	Regular	Yellow
305886	NEEDLE 23X1-1/4 ECLIPSE SMARTSLIP	23G	32 - 1 ¼	Thin	Deep Blue
305887	NEEDLE ECLIPSE S/T 22X1-1/4 RB	22G	32 - 1 ¼	Thin	Black
305888	NEEDLE ECLIPSE S/T 20X1-1/2 RB	20G	38 - 1 ½	Thin	Yellow
305889	NEEDLE ECLIPSE S/T 27X3/4 RB	27G	19 - 3/4	Regular	Medium Grey
305891	NEEDLE ECLIPSE S/T 25X1 RB	25G	25 - 1	Regular	Orange
305892	NEEDLE ECLIPSE S/T 23X1 RB	23G	25 - 1	Thin	Deep Blue
305894	NEEDLE ECLIPSE S/T 21X1 RB TW	21G	25 - 1	Thin	Deep Green
305895	NEEDLE ECLIPSE S/T 21X1-1/2 RB TW	21G	38 - 1 ½	Thin	Deep Green
305899	NEEDLE ECLIPSE S/T 20X1 RB	20G	25 - 1	Thin	Yellow

Please check BD catalog number availability in your country.

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)
302436 302437 305760 305770 305771 305886 305887 305888 305889 305891 305892 305894 305895 305899	**Address:** Becton Dickinson and Company 1 Becton Drive Franklin Lakes New Jersey 07417-1884 United States **ISO 13485** Certificate No.: MD19.2305	CE certified with NSAI (NB No. 0050) Certificate No.: 252.232	**Address:** Becton Dickinson S.A. Ctra. Mequinenza, s/n 22520 Fraga (Huesca) Spain **ISO 13485** Certificate No.: 2015 05 0047 EN	Becton Dickinson Distribution Center Laagstraat 57 B-9140 Temse Belgium

1.4 Materials

Component	Material
Cannula	Stainless Steel
Hub	Polypropylene
Plastic clip for Eclipse™ Luer Slip application	Polypropylene
Shield	Polypropylene
Lubricant	Medical Grade Silicone
Adhesive	Epoxy
Eclipse Cover	Polypropylene

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	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) • Benzylbutyl phthalate (BBP) (CAS# 85-68-7) • Bis(2-methoxyethyl phthalate) (DMEP) (CAS#117-82-8) • Diisopentylphthalate (DIPP) (CAS#605-50-5) • Dipentyl phthalate (DPP) (CAS#131-18-0) • Di-n-hexyl phthalate (DnHP) (CAS#84-75-3) • N-pentyl-isopentylphthalate (CAS# 776297-69-9) in the BD Eclipse™ SmartSlip™ safety needle and its packaging, in an individual concentration above 0.1% weight by weight (w/w).
Latex	The BD Eclipse™ SmartSlip™ safety needle is not formulated with natural rubber latex.
Bisphenol A	Bisphenol A (BPA), CAS# 80-05-7, is a component in a raw material in the adhesive. Based on information from BD's 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 the BD Eclipse™ SmartSlip™ safety needles do not contain any animal tissue but may contain very small amounts of animal-derived raw materials. These products are manufactured using polymer resins which may contain very small amounts of surfactants or fatty acids derived from tallow. BD's resin suppliers have confirmed that these tallow-derived materials 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 TSE/BSE or other animal-borne diseases. Furthermore, as recognized by MEDDEV 2.4/1, tallow processed in accordance with the aforementioned standards and guidelines is considered irrelevant when determining the classification of a medical device (per MDD 93/42/EEC and EU No 722/2012).
Polyvinyl chloride (PVC)	The BD Eclipse™ SmartSlip™ safety needles 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.

1.6 REACH information

Based on BD's ongoing data collection efforts and/or information received from BD's suppliers, BD has not identified any chemicals in the articles and packaging of the BD Eclipse™ SmartSlip™ safety 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 27 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

Sterilization method is validated per 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

1.9 Shelf life and storage conditions

- Shelf life: 5 years
- No special storage or handling conditions are required. It is recommended to store in a dry and warm place, not exposed to strong light.
- The packaging configuration has been tested to ensure that sterility is maintained during shipment and storage conditions. Shelf life studies have indicated that the product will remain sterile at least until its stated expiration date.

1.10 Standards

As per extract from the Declaration of Conformity:

Harmonized Standards	
EN 20594-1:1994 Amd 1 1998	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
EN 1707:1997	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
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 556-1:2001 COR1 2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
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 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
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice

Harmonized Standards	
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
Non-Harmonized Standards	
EN ISO 7864:1993	Sterile hypodermic needles for single use
EN ISO 6009:1992/COR 1 2008	Hypodermic needles for single use – Colour coding for identification
ISO 9626	Stainless steel tubing for the manufacture 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

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.

1.11 Classification

Class IIa Medical Devices as per Annex IX, Section III, Rule 6 of the Medical Device Directive 93\42\EEC.
Rule 6 reads, "All surgically invasive devices intended for transient use are in Class IIa".
Hypodermic Needles are intended for transient use, i.e., continuous use for less than 60 minutes as per Annex IX, Section I, paragraph 1.1 and are surgically invasive as per Annex IX, Section I, paragraph 1.2. Paragraph 1.2 indicates that for the purposes of the directive, devices other than those which produce penetration through a non-established body orifice, shall be treated as surgically invasive devices.

1.12 GMDN code

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure), BD Eclipse™ SmartSlip™ is referenced as follows:
GMDN Code: 59230
GMDN Term: Hypodermic Needle, Single Use, Sterile

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.

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*
302436	NEEDLE 27X1-1/2 ECLIPSE	1	100	1.200	Yes
302437	NEEDLE 18X1-1/2 ECLIPSE	1	100	1.200	Yes
305760	NEEDLE ECLIPSE S/T 25X5/8 RB	1	100	1.200	Yes
305770	NEEDLE ECLIPSE S/T 27X1/2 RB	1	100	1.200	Yes
305771	NEEDLE ECLIPSE S/T 30X1/2 RB	1	100	1.200	Yes
305886	NEEDLE 23X1-1/4 ECLIPSE SMARTSLIP	1	100	1.200	Yes
305887	NEEDLE ECLIPSE S/T 22X1-1/4 RB	1	100	1.200	Yes
305888	NEEDLE ECLIPSE S/T 20X1-1/2 RB	1	100	1.200	Yes
305889	NEEDLE ECLIPSE S/T 27X3/4 RB	1	100	1.200	Yes
305891	NEEDLE ECLIPSE S/T 25X1 RB	1	100	1.200	Yes
305892	NEEDLE ECLIPSE S/T 23X1 RB	1	100	1.200	Yes
305894	NEEDLE ECLIPSE S/T 21X1 RB TW	1	100	1.200	Yes
305895	NEEDLE ECLIPSE S/T 21X1-1/2 RB TW	1	100	1.200	Yes
305899	NEEDLE ECLIPSE S/T 20X1 RB	1	100	1.200	Yes

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

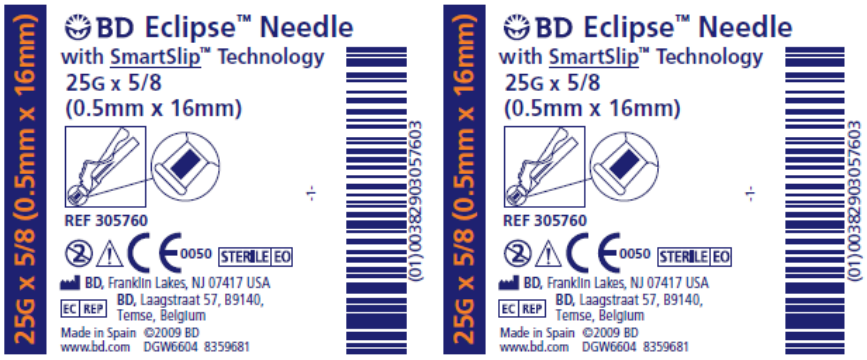
2.2 Packaging material

Component	Material
Top Web	Film
Blister Bottom Web	Thermoformable Plastic
Shelf Carton	Corrugated Carton
Shipping Case	Corrugated Carton

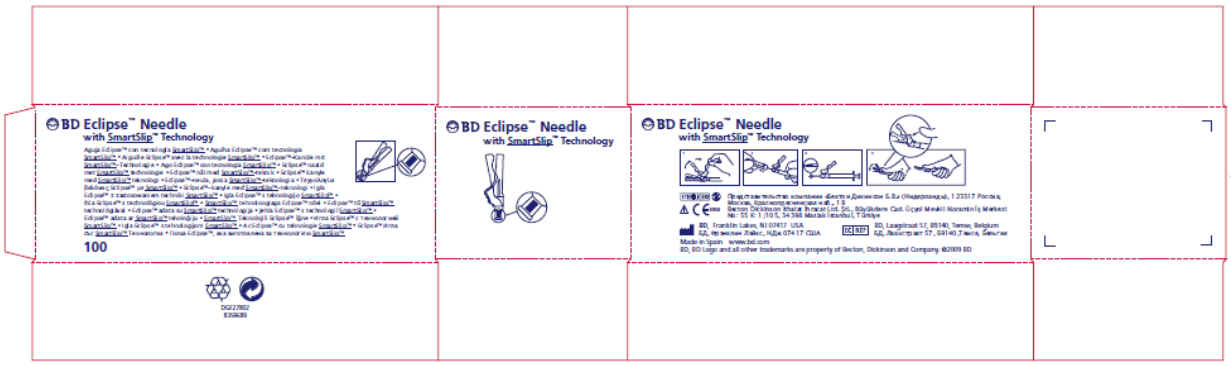
2.3 Examples of labeling

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

Primary packaging label (top web) extracted from document DGW66 related to reference 305760:

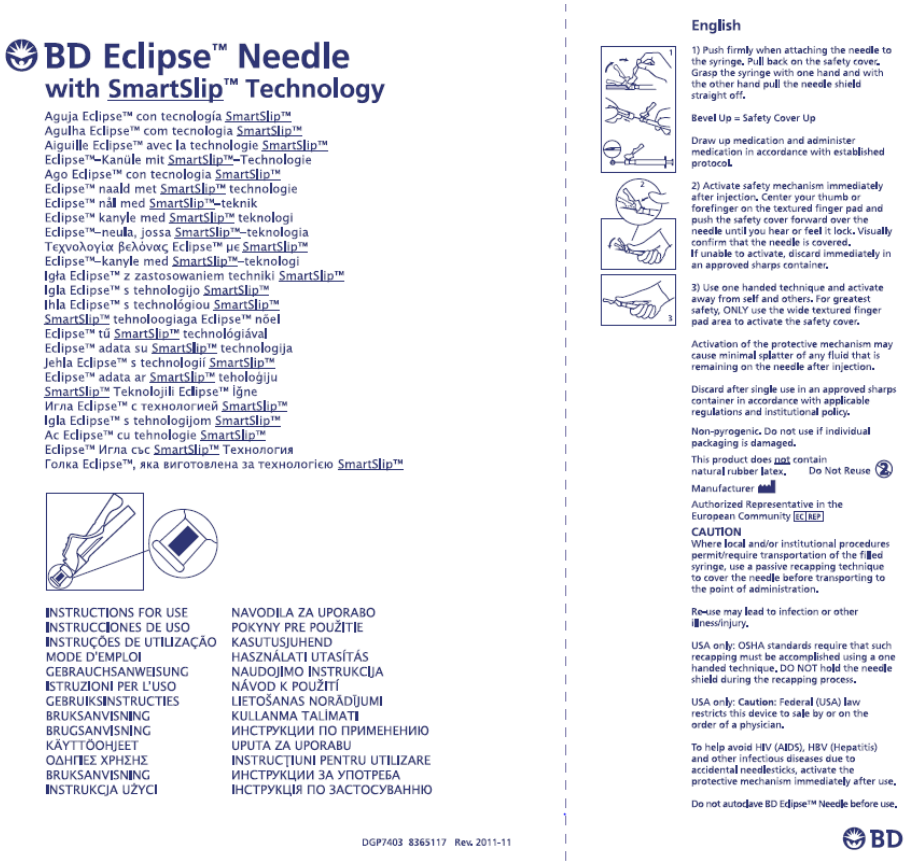


Shelf box labels extracted from documents DGF278 and DGL345 related to reference 305760:



Shipping case label extracted from document DGL346 related to reference 305760:

Extract of IFU insert from document DGP74 related to reference 305760:



REVISION	CHANGE SUMMARY
01	Initial release according to new template