

**BD Eclipse™ SmartSlip™
Hypodermic Safety Needle,
Sterile, Single Use**BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins, Switzerland
bd.comTDS number: V201-017 – Rev. 01
2019-April**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.

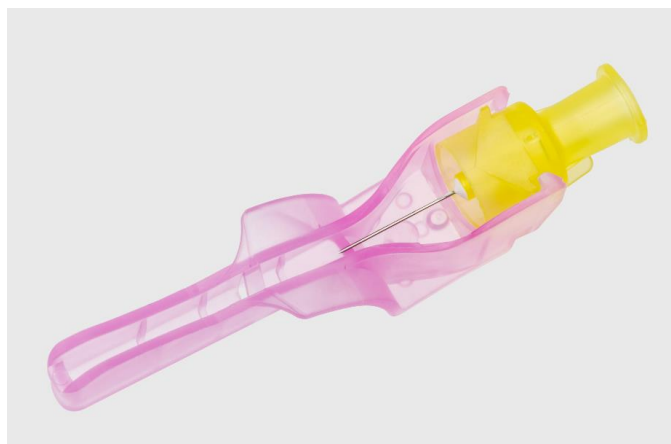
1.2 General description

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 1/2 | Regular | Medium Grey |
| 302437 | NEEDLE 18X1-1/2 ECLIPSE | 18G | 38 - 1 1/2 | 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 1/4 | Thin | Deep Blue |
| 305887 | NEEDLE ECLIPSE S/T 22X1-1/4 RB | 22G | 32 - 1 1/4 | Thin | Black |
| 305888 | NEEDLE ECLIPSE S/T 20X1-1/2 RB | 20G | 38 - 1 1/2 | 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 1/2 | 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 | <p>BD has not identified any:</p> <ul style="list-style-type: none"> • 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) <p>in the BD Eclipse™ SmartSlip™ safety needle and its packaging, in an individual concentration above 0.1% weight by weight (w/w).</p> |
| Latex | The BD Eclipse™ SmartSlip™ safety needle is not formulated with natural rubber latex. |
| Bisphenol A | <p>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).</p> <p>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.</p> |
| Substances of animal origin BSE/TSE | <p>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.</p> <p>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).</p> |
| 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 |

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| 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.

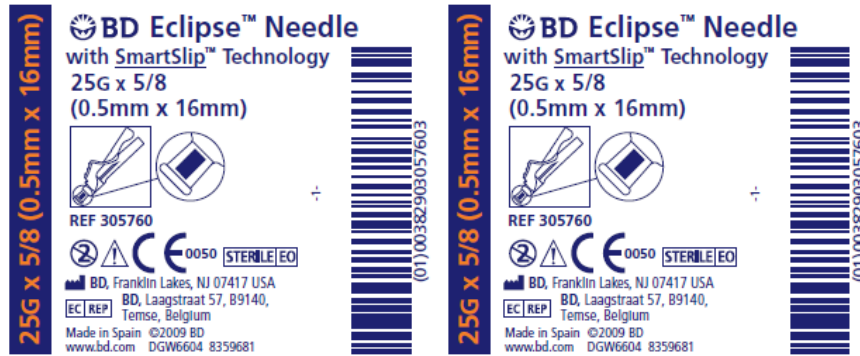
2.2 Packaging material

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

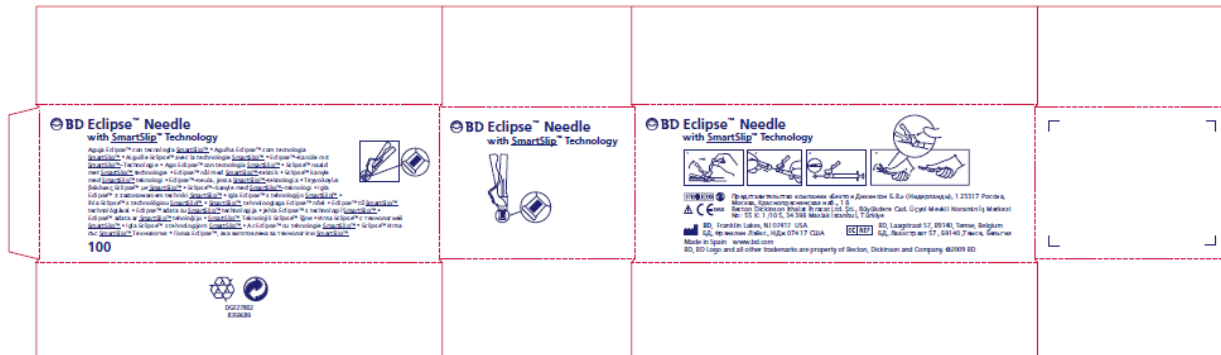
2.3 Examples of labeling

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:



DGL34503
8359690

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

BD Eclipse™ Needle with SmartSlip™ Technology
 25G x 5/8 (0.5mm x 16mm)

Injection Needle • Aguja de inyección • Agulha de injeção • Aiguille pour injection • Injektionskanüle • Ago per iniezione • Injektionsald • Injektionskanül • Injektionskanyle • Injektionsneula • Βελόνες ένεσης • Injektionsnål • Igla iniekcijna • Injekcijska igla • Injekčná ihla • Szűrtű • Injekciós tű • Injektions adata • Injekcijska jehla • Injekcijska adata • Injekcijska igla • Injektions nål • Игла для инъекций • Injekcijska igla • Ac pentru injectii • Ињекционална игла • Голка для инъекций

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1200 (12 x 100) REF 305760

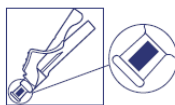
(01)50382903057608

DGL34603 8360349

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

BD Eclipse™ Needle with SmartSlip™ Technology

Aguja Eclipse™ con tecnología SmartSlip™
 Agulha Eclipse™ com tecnologia SmartSlip™
 Aiguille Eclipse™ avec la technologie SmartSlip™
 Eclipse™-kanüle mit SmartSlip™-Technologie
 Ago Eclipse™ con tecnologia SmartSlip™
 Eclipse™ naal met SmartSlip™ technologie
 Eclipse™ kanyle med SmartSlip™-teknik
 Eclipse™ kanyle med SmartSlip™-teknologi
 Eclipse™-neula, jossa SmartSlip™-teknologia
 Τεχνολογία Βελόνος Eclipse™ με SmartSlip™
 Eclipse™-kanyle med SmartSlip™-teknologi
 Igla Eclipse™ z zastosowaniem techniki SmartSlip™
 Igla Eclipse™ s tehnologijom SmartSlip™
 Ihla Eclipse™ s technológiou SmartSlip™
 SmartSlip™ tehnoloogiaga Eclipse™ nõel
 Eclipse™ tő SmartSlip™ technológiával
 Eclipse™ adata su SmartSlip™ tehnologijaa
 Jehla Eclipse™ s tehnologijom SmartSlip™
 Eclipse™ adata ar SmartSlip™ tehnologiju
 SmartSlip™ Teknologiji Eclipse™ Igla
 Игла Eclipse™ с технологией SmartSlip™
 Igla Eclipse™ s tehnologijom SmartSlip™
 Ac Eclipse™ cu tehnologie SmartSlip™
 Eclipse™ Игла със SmartSlip™ Технологија
 Голка Eclipse™, яка виготовлена за технологією SmartSlip™



INSTRUCTIONS FOR USE
 INSTRUCCIONES DE USO
 INSTRUÇÕES DE UTILIZAÇÃO
 MODE D'EMPLOI
 GEBRAUCHSANWEISUNG
 ISTRUZIONI PER L'USO
 GEBRUIKSNSTRUCTIES
 BRUKSANVISNING
 BRUKSANVISNING
 KÄYTTÖOHJEET
 ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ
 BRUKSANVISNING
 INSTRUKCJA UŻYCI

NAVODILA ZA UPORABO
 POKYNY PRE POUŽITIE
 KASUTUSJUHEND
 HASZNÁLATI UTASÍTÁS
 NAUDOJIMO INSTRUKCIJA
 NÁVOD K POUŽITÍ
 LIETOSANAS NORĀDĪJUMI
 KÜLLANMA TALIMATI
 ИНСТРУКЦИИ ПО ПРИМЕНЕНИЮ
 UPUTA ZA UPORABU
 INSTRUCȚIUNI PENTRU UTILIZARE
 ИНСТРУКЦИИ ЗА УПОТРЕБА
 ІНСТРУКЦІЯ ПО ЗАСТОСУВАННЮ

DGP7403 8365117 Rev.2011-11

English

1) Push firmly when attaching the needle to the syringe. Pull back on the safety cover. Grasp the syringe with one hand and with the other hand pull the needle shield straight off.

Bevel Up = Safety Cover Up

Draw up medication and administer medication in accordance with established protocol.

2) Activate safety mechanism immediately after injection. Center your thumb or forefinger on the textured finger pad and push the safety cover forward over the needle until you hear or feel it lock. Visually confirm that the needle is covered. If unable to activate, discard immediately in an approved sharps container.

3) Use one handed technique and activate away from self and others. For greatest safety, ONLY use the wide textured finger pad area to activate the safety cover.

Activation of the protective mechanism may cause minimal splatter of any fluid that is remaining on the needle after injection.

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

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

This product does not contain natural rubber latex. Do Not Reuse

Manufacturer: BD
 Authorized Representative in the European Community CE/EP

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.

Reuse may lead to infection or other injury.

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.

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

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

Do not autoclave BD Eclipse™ Needle before use.

| REVISION | CHANGE SUMMARY |
|-----------------|---|
| 01 | Initial release according to new template |