CERTIFICATE OF COMPLIANCE

Becton Dickinson, S.A.
Crta Mequinenza S/N
Fraga (Huesca) 22 22520 ES

Product Name : NEEDLE ECLIPSE S/T 27X1/2 RB
Catalog Number : 305770 **Manufacture Date** :2022/08/01
Batch Number : 2208007
Expiration Date : 2027/07/31

REGULATORY COMPLIANCE AND QUALITY SYSTEM

BD Products comply with the regulatory requirements of the region in which these are sold and manufactured.

BD Products sold in the US comply with the current FDA Quality System Regulation 21CFR820. Medical devices are listed with FDA per 21CFR807. Manufacturing sites are registered with FDA per 21CFR807. The devices satisfy FDA pre-market notification requirements per 21CFR 807.

BD Products which are CE marked comply with Medical Devices Directive 93/42/EEC and are manufactured within production facilities that comply with the international standard ISO 13485: Quality Systems - Medical Devices - Requirements For regulatory purposes.

STERILITY

All products which are labeled as "sterile" and released for sale by BD are certified to be sterile as long as the package is unopened and undamaged.

This product is primarily sterilized via Ethylene Oxide (EO). Sterilization cycle development/validation is performed to 10-6 SAL in accordance with current ISO 11135 guidelines.

BIOCOMPATABILITY

This product has been evaluated in accordance with ISO 10993 "Biological Evaluation of Medical Devices", and complies with all relevant sections.

PYROGENICITY

All products which are labeled as non-pyrogenic and released for sale by BD have been tested per United States Pharmacopeia (USP) chapter 85 - Bacterial Endotoxins Test and meets limits as specified in chapter 161- Medical Devices-Bacterial Endotoxin and Pyrogen Tests.

QUALITY CONTROL TESTING AND RELEASE

Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and signed off by qualified personnel for product release. The released devices meet applicable BD product specifications.

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PRODUCT SPECIFIC SPECIFICATIONS

This product complies with the following BD Specifications:
SFG31

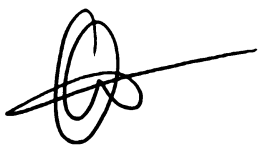
BD MANUFACTURING SITE

BD Manufacturing Site:
Becton Dickinson SA; Ctra. Mequinenza s/n, 22520 Fraga, Spain

Primary Sterilization site:
Becton Dickinson SA; Ctra. Mequinenza s/n, 22520 Fraga, Spain

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

CE Certificate Number: 252.232



Angeles Cerezo
Quality Manager, BD Fraga

BD Eclipse™ Needles with SmartSlip™ Technology
Hypodermic Safety Needle,
Sterile, Single-Use

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins, Switzerland
bd.com

TDS number: V201-017 – Rev. 02
2022-June

1. General Information

1.1 Intended use

The BD Eclipse™ 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.

1.2 General description

BD Eclipse™ Needles with SmartSlip™ Technology contain a mechanism that covers the needle point after use. In the activated position the needle cover guards against accidental needlesticks during normal handling and disposal of the used needle/syringe. The needle assembly is also protected with a polypropylene shield.

BD Eclipse™ Needles with SmartSlip™ Technology have a standard Luer hub that can be used with ISO-compliant Luer-Lok or Luer-Slip syringes.

BD Eclipse™ Needles with SmartSlip™ Technology are sold sterile, single-use.

Figures 1 and 2: BD Eclipse™ Needles with SmartSlip™ Technology

BD Catalog Number	BD Product Description	Gauge Size	Color Code	Length	Wall	Bevel
302437	BD ECLIPSE™ SMARTSLIP™ NEEDLE 18GA 1-1/2IN	18G	Pink	1 ½ IN 40 mm	Thin wall	Regular bevel
305899[1]	BD ECLIPSE™ SMARTSLIP™ NEEDLE 20GA 1IN	20G	Yellow	1 IN 25 mm	Thin wall	Regular bevel
305888[1]	BD ECLIPSE™ SMARTSLIP™ NEEDLE 20GA 1-1/2IN	20G	Yellow	1 ½ IN 40 mm	Thin wall	Regular bevel
305894	BD ECLIPSE™ SMARTSLIP™ NEEDLE 21GA 1IN	21G	Green	1 IN 25 mm	Thin wall	Regular bevel
305895	BD ECLIPSE™ SMARTSLIP™ NEEDLE 21GA 1-1/2IN	21G	Green	1 ½ IN 40 mm	Thin wall	Regular bevel
305887[1]	BD ECLIPSE™ SMARTSLIP™ NEEDLE 22GA 1-1/4IN	22G	Black	1 ¼ IN 30 mm	Thin wall	Regular bevel
305892	BD ECLIPSE™ SMARTSLIP™ NEEDLE 23GA 1IN	23G	Blue	1 IN 25 mm	Thin wall	Regular bevel
305886[1]	BD ECLIPSE™ SMARTSLIP™ NEEDLE 23GA 1-1/4IN	23G	Blue	1 ¼ IN 30 mm	Regular wall	Regular bevel
305760[2]	BD ECLIPSE™ SMARTSLIP™ NEEDLE 25GA 5/8IN	25G	Orange	5/8 IN 16 mm	Regular wall [2]	Regular bevel
305891[2]	BD ECLIPSE™ SMARTSLIP™ NEEDLE 25GA 1IN	25G	Orange	1 IN 25 mm	Regular wall [2]	Regular bevel
305770	BD ECLIPSE™ SMARTSLIP™ NEEDLE 27GA 1/2IN	27G	Gray	½ IN 13 mm	Regular wall	Regular bevel
305889[1]	BD ECLIPSE™ SMARTSLIP™ NEEDLE 27GA 3/4IN	27G	Gray	¾ IN 19 mm	Regular wall	Regular bevel
302436[1]	BD ECLIPSE™ SMARTSLIP™ NEEDLE 27GA 1-1/2IN	27G	Gray	1 ½ IN 40 mm	Regular wall	Regular bevel
305771	BD ECLIPSE™ SMARTSLIP™ NEEDLE 30GA 1/2IN	30G	Yellow	½ IN 13 mm	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 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 products SKUs 302436, 305886, 305887, 305888, 305889 and 305899 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.

These SKUs (except SKU 302436) will be replaced by alternatives, as described in the table below. These are direct replacements with the same intended use. These alternative products are sold sterile, single-use.

Discontinued code	Product description	Substitute code	Substitute code Description
305899	BD ECLIPSE™ SMARTSLIP™ NEEDLE 20GA 1IN	305894	BD ECLIPSE™ SMARTSLIP™ NEEDLE 21GA 1IN
305888	BD ECLIPSE™ SMARTSLIP™ NEEDLE 20GA 1-1/2IN	305895	BD ECLIPSE™ SMARTSLIP™ NEEDLE 21GA 1-1/2IN
305887	BD ECLIPSE™ SMARTSLIP™ NEEDLE 22GA 1-1/4IN	305892	BD ECLIPSE™ SMARTSLIP™ NEEDLE 23GA 1IN
305886	BD ECLIPSE™ SMARTSLIP™ NEEDLE 23GA 1-1/4IN		
305889	BD ECLIPSE™ SMARTSLIP™ NEEDLE 27GA 3/4IN	305760	BD ECLIPSE™ SMARTSLIP™ NEEDLE 25GA 5/8IN
302436	BD ECLIPSE™ SMARTSLIP™ NEEDLE 27GA 1-1/2IN	N/A	N/A

[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 (regular wall). Therefore, as of the 30th of September 2022, the products SKUs 305760 and 305891 will be manufactured with thin walls. 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)
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 USA **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	Based on our ongoing data collection efforts and/or information received from our suppliers as per 16 November 2021, 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 articles 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 16 November 2021, natural rubber latex and latex are not part of the material formulation for the articles with the Product Numbers above.
Bisphenol A	Based on our ongoing data collection efforts and/or information received from our suppliers as per 16 November 2021, 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% (w/w). Bisphenol A (BPA), CAS# 80-05-7, is a component in a raw material used in the adhesive. 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.
RoHS	It is BD's view that the above-referenced products do not meet the definition of electrical and electronic equipment as stated in Art. 3(1) of Directive 2011/65/EU ("EU RoHS") and, therefore, do not fall within the scope of the EU RoHS Directive. Based on our ongoing data collection efforts and/or information received from our suppliers as of 16 November 2021, there is no intentionally added lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, or polybrominated diphenyl ether in the above-listed products. Furthermore, based on our ongoing data collection efforts and/or information received from our suppliers as of 16 November 2021, BD has not identified any bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) or diisobutyl phthalate (DIBP) in an individual concentration above 0.1% w/w in the above-listed 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. These products are 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, these products are 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 devices (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.

1.6 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 16 November 2021, 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 Eclipse™ Needles with SmartSlip™ Technology are sterilized using Ethylene Oxide. The sterilization process is validated as 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. ETO residues are within applicable regulations.

Data to support re-sterilization of these products by the customer may be available through contract arrangement 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 Eclipse™ Needles with SmartSlip™ Technology shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
BD Eclipse™ Needles with SmartSlip™ Technology have a shelf life of 5 years.

Note:

- Shelf life: Processing by the user, such as re-sterilization, might impact the shelf life of the product.
- 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 (DTF0004 DoC 041422) linked to CE certificate number 252.232:

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.

1.11 Classification

BD Eclipse™ Needles with SmartSlip™ Technology 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 Eclipse™ Needles with SmartSlip™ Technology 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.

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*
302437	BD ECLIPSE™ SMARTSLIP™ NEEDLE 18GA 1-1/2IN	1	100	1200	Yes
305899	BD ECLIPSE™ SMARTSLIP™ NEEDLE 20GA 1IN	1	100	1200	Yes
305888	BD ECLIPSE™ SMARTSLIP™ NEEDLE 20GA 1-1/2IN	1	100	1200	Yes
305894	BD ECLIPSE™ SMARTSLIP™ NEEDLE 21GA 1IN	1	100	1200	Yes
305895	BD ECLIPSE™ SMARTSLIP™ NEEDLE 21GA 1-1/2IN	1	100	1200	Yes
305887	BD ECLIPSE™ SMARTSLIP™ NEEDLE 22GA 1-1/4IN	1	100	1200	Yes
305892	BD ECLIPSE™ SMARTSLIP™ NEEDLE 23GA 1IN	1	100	1200	Yes
305886	BD ECLIPSE™ SMARTSLIP™ NEEDLE 23GA 1-1/4IN	1	100	1200	Yes
305760	BD ECLIPSE™ SMARTSLIP™ NEEDLE 25GA 5/8IN	1	100	1200	Yes
305891	BD ECLIPSE™ SMARTSLIP™ NEEDLE 25GA 1IN	1	100	1200	Yes
305770	BD ECLIPSE™ SMARTSLIP™ NEEDLE 27GA 1/2IN	1	100	1200	Yes
305889	BD ECLIPSE™ SMARTSLIP™ NEEDLE 27GA 3/4IN	1	100	1200	Yes
302436	BD ECLIPSE™ SMARTSLIP™ NEEDLE 27GA 1-1/2IN	1	100	1200	Yes
305771	BD ECLIPSE™ SMARTSLIP™ NEEDLE 30GA 1/2IN	1	100	1200	Yes

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

2.2 Packaging material

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

2.3 Examples of labeling

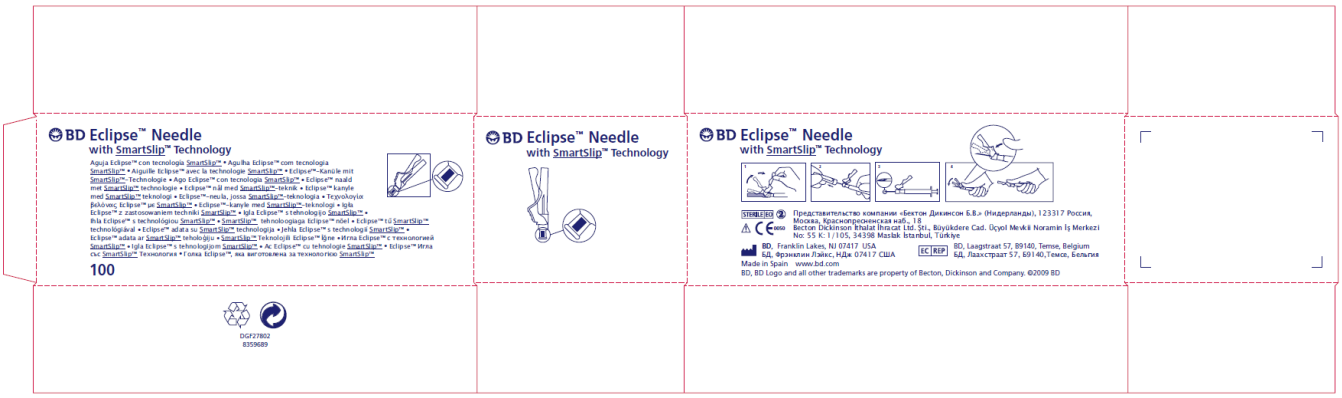
Labels: According to European Medical Device directive, labels are multilingual.

IFU is labeling in English, Spanish, Portuguese, French, German, Italian, Dutch, Swedish, Danish, Finnish, Greek, Norwegian, Polish, Slovenian language.

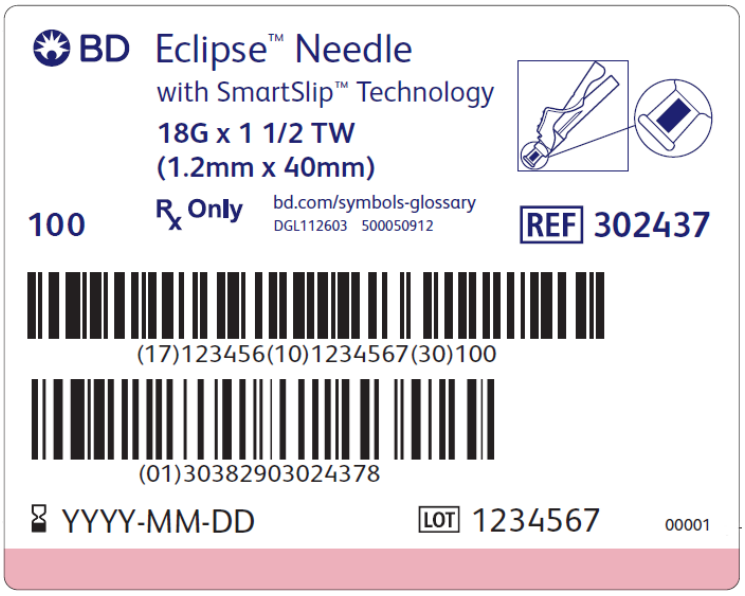
Primary packaging label (top web) extracted from document DGW538 related to reference 302437:

(01)00382903024377
YYYY-MM-DD
LOT 1234567

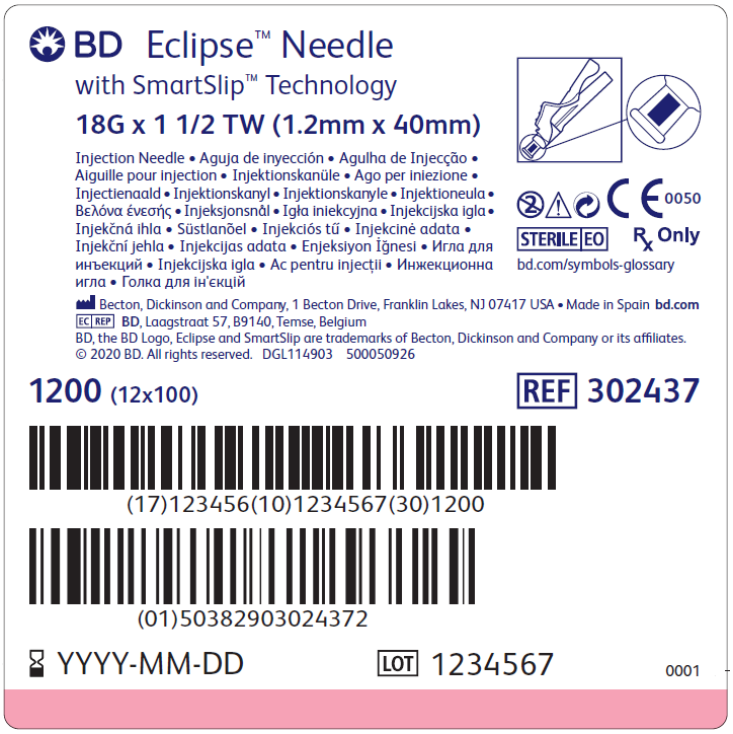
Shelf Box extracted from documents DGF278 related to reference 302437:



Shelf Box label extracted from document DGL1126 related to reference 302437:



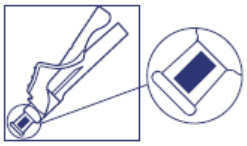
Case Label extracted from document DGL1149 related to reference 302437:



Extract of IFU insert from document DGP74 related to reference 302437:

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™ naald met SmartSlip™ technologie
Eclipse™ nål med SmartSlip™-teknik
Eclipse™ kanyle med SmartSlip™ teknologi
Eclipse™-neula, jossa SmartSlip™-teknologia
Τεχνολογία βελόνας Eclipse™ με SmartSlip™
Eclipse™-kanyle med SmartSlip™-teknologi
Igła Eclipse™ z zastosowaniem techniki SmartSlip™
Igla Eclipse™ s tehnologijo SmartSlip™
Ihla Eclipse™ s technológiou SmartSlip™
SmartSlip™ tehnoloogiaga Eclipse™ nõel
Eclipse™ tű SmartSlip™ technológiával
Eclipse™ adata su SmartSlip™ technologija
Jehla Eclipse™ s technológií SmartSlip™
Eclipse™ adata ar SmartSlip™ tehnoloģiju
SmartSlip™ Teknolojili Eclipse™ İğne
Игла Eclipse™ с технологией SmartSlip™
Igla Eclipse™ s tehnologijom SmartSlip™
Ac Eclipse™ cu tehnologie SmartSlip™
Eclipse™ Игла със SmartSlip™ Технология
Голка Eclipse™, яка виготовлена за технологією SmartSlip™

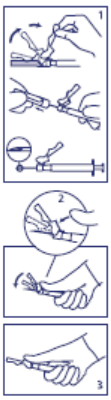


INSTRUCTIONS FOR USE
INSTRUCCIONES DE USO
INSTRUÇÕES DE UTILIZAÇÃO
MODE D'EMPLOI
GEBRAUCHSANWEISUNG
ISTRUZIONI PER L'USO
GEBRUIKSINSTRUCTIES
BRUKSANVISNING
BRUGSANVISNING
KÄYTTÖOHJEET
ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ
BRUKSANVISNING
INSTRUKCJA UŻYCI

NAVODILA ZA UPORABO
POKYNY PRE POUŽITIE
KASUTUSJUHEND
HASZNÁLATI UTASÍTÁS
NAUDOJIMO INSTRUKCIJA
NÁVOD K POUŽITÍ
LIETOŠANAS NORĀDĪJUMI
KULLANMA TALİMATI
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

Authorized Representative in the European Community EC REP

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.

Re-use may lead to infection or other illness/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 needlesticks, 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
02	Update of: • 1.1 Intended use • 1.2 General description • 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 labelling