BD PosiFlush™ SP Syringe, Sterile fluid path, Single use
BD PosiFlush™ XS Syringes, Sterile, Single use

BD Switzerland Sàrl
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TDS number: V201-015 – Rev. 03
2023-March

1. General Information

1.1 Intended use

1.1.1 Intended purpose

BD PosiFlush™ SP Syringes:
BD PosiFlush™ SP Syringes are intended to be used FOR FLUSHING ONLY of in-situ peripheral intravenous catheters (PIVCs), peripherally inserted central catheters (PICCs), central venous catheters (CVCs), and implanted venous access ports.

BD PosiFlush™ SP Syringe is not intended for dry product reconstitution, for medication dilution, or where intravenous therapy with sodium chloride is indicated.

BD PosiFlush™ SP Syringe must not be used on a sterile field.

BD PosiFlush™ XS Syringes:
BD PosiFlush™ XS Syringes are intended to be used FOR FLUSHING ONLY of in-situ peripheral intravenous catheters (PIVCs), peripherally inserted central catheters (PICCs), central venous catheters (CVCs), and implanted venous access ports.

BD PosiFlush™ XS Syringe is not intended for dry product reconstitution, for medication dilution, or where intravenous therapy with sodium chloride is indicated.

Using aseptic technique, **BD PosiFlush™ XS Syringe can be used on a sterile field.**

1.1.2 Intended User

BD PosiFlush™ SP and BD PosiFlush™ XS Syringes are to be used by healthcare professionals experienced in vascular access and the use of these devices. The BD PosiFlush™ SP and BD PosiFlush™ XS syringes are manual devices that may be operated by a large range of people with various human characteristics including hand sizes and strengths.

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1.2 General Medical Devices description

BD PosiFlush™ SP Syringe:
BD PosiFlush™ SP Syringes is ready to use sterile medical devices (according to regulation (eu) 2017/745 of the European Parliament and of the council). It is a polypropylene syringe containing sterile and non-pyrogenic isotonic 0.9% sodium chloride solution. The syringe content is guaranteed to be sterile, non-toxic and non-pyrogenic.

BD PosiFlush™ SP Syringes are individually packaged. Each shelf box contains 30 devices and each case box contains 480 devices. The package includes detailed Instructions for Use in a language appropriate to the destination market.
The devices are sterilized using steam sterilization. The steam sterilization method guarantees a Sterility Assurance Level (SAL) of 10^{-6} for the fluid path and solution.

BD PosiFlush™ XS Syringe:
BD PosiFlush™ XS Syringe is ready to use sterile medical devices (according to regulation (eu) 2017/745 of the European Parliament and of the council). It is a polypropylene syringe containing sterile and non-pyrogenic isotonic 0.9% sodium chloride solution. The contents of our unopened or undamaged blister packages are guaranteed to be sterile, non-toxic, and non-pyrogenic.

BD PosiFlush™ XS Syringes are individually packaged. Each shelf box contains 30 devices, and each case box contains 240 devices. The package includes detailed Instructions for Use in a language appropriate to the destination market.
The devices including blister packaging are sterilized using steam sterilization. The steam sterilization method guarantees a SAL of 10^{-6} for the packaged device, including fluid path and solution.

BD PosiFlush™ SP and BD PosiFlush™ XS Syringes are not to be re-sterilized or re-used.
All sizes of the prefilled syringes (3, 5 and 10mL) share a common barrel diameter. The tip cap is the same for each type of syringe. The plunger stopper is identically assembled on each size of syringes (3, 5 and 10mL).

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Figure 1: BD PosiFlush™ SP and BD PosiFlush™ XS Syringes

Device (Trade Name)	BD Catalog Number	Product Description	Color
BD PosiFlush™ SP	306573	BD PosiFlush™ SP syringe CE 3mL	Orange
	306574	BD PosiFlush™ SP syringe CE 5mL	Orange
	306575	BD PosiFlush™ SP syringe CE 10mL	Orange
	306583	BD PosiFlush™ SP syringe EMA 3mL	Orange
	306584	BD PosiFlush™ SP syringe EMA 5mL	Orange
	306585	BD PosiFlush™ SP syringe EMA 10mL	Orange
BD PosiFlush™ XS	306570	BD PosiFlush™ XS syringe CE 3mL	Blue
	306571	BD PosiFlush™ XS syringe CE 5mL	Blue
	306572	BD PosiFlush™ XS syringe CE 10mL	Blue
	306580	BD PosiFlush™ XS syringe EMA 3mL	Blue
	306581	BD PosiFlush™ XS syringe EMA 5mL	Blue
	306582	BD PosiFlush™ XS syringe EMA 10mL	Blue

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.

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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)
306573 306574 306583 306584	**Address:** Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417 USA **ISO 13485** Certificate No.: MD19.2305	CE certified with NSAI (0050) Certificates No.: 745.008 and 745.008D	**Address:** BD Medical Surgical 2153 12th Avenue Columbus NE 68601 United States **ISO 13485** Certificate No.: MD19.2143 **OR** Becton Dickinson S.A. 12 Av Mequinenza 22520 Fraga, Hesca, Spain **ISO 13485** Certificate No.: 2015 05 0047 EN	Becton Dickinson Ireland Ltd. Donore Road Co. Louth Drogheda, A92 YW26, Ireland
306575 306585	**Address:** Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417 USA **ISO 13485** Certificate No.: MD19.2305	CE certified with NSAI (0050) Certificates No.: 745.008 and 745.008D	**Address:** BD Medical Surgical 2153 12th Avenue Columbus NE 68601 United States **ISO 13485** Certificate No.: MD19.2143 **OR** Becton Dickinson and Company 12 Av Mequinenza 22520 Fraga, Hesca, Spain **ISO 13485** Certificate No.: 2015 05 0047 EN **OR** **Address:** Becton, Dickinson and	Becton Dickinson Ireland Ltd. Donore Road Co. Louth Drogheda, A92 YW26, Ireland

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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)
			Company Limited Donore Road Drogheda Co. Louth Ireland **ISO 13485** Certificate No.: MD19.1609	
306570 306571 306572 306580 306581 306582	**Address:** Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417 USA **ISO 13485** Certificate No.: MD19.2305	CE certified with NSAI (0050) Certificates No.: 745.008 and 745.008D	**Address:** Becton, Dickinson and Company Limited Donore Road Drogheda Co. Louth Ireland **ISO 13485** Certificate No.: MD19.1609	Becton Dickinson Ireland Ltd. Donore Road Co. Louth Drogheda, A92 YW26, Ireland

1.4 Basic UDI-DI

The Basic UDI-DI is 038290WKCQDZQWJK for BD PosiFlush™ SP and BD PosiFlush™ XS Syringes.

1.5 Eudamed Registration

- Manufacturer Single Registration Number (SRN): US-MF-000019182
- EU Authorised Representative Single Registration Number (SRN): IE-AR-000007610

1.6 Person Responsible for Regulatory Compliance

The information about the Person Responsible for Regulatory Compliance (PRRC) can be found on Eudamed website:

https://ec.europa.eu/tools/eudamed/#/screen/home

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1.7 Materials

Component	Material
0.9% Sodium Chloride Solution	Sodium Chloride (NaCl) and Water for Injection
Barrel with Luer-Lok tip	Polypropylene
Tip Cap	Polypropylene + Colorant
Stopper	Elastomer
Plunger Rod	Polypropylene
Lubricant	Silicone

1.8 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, BD has not identified any • 1,2-Benzendicarboxylic acid, dihexyl ester (branched & linear) (CAS#68515-50-4), • 1,2-Benzendicarboxylic acid, di-C6-8-branched alkyl esters (CAS#71888-89-6), • 1,2-Benzendicarboxylic acid, di-C7-11-branched and linear alkyl esters (CAS#68515-42-4), • 1,2-Benzendicarboxylic acid, di-C6-10 alkyl esters (CAS#68515-51-5), • 1,2-Benzendicarboxylic 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), • Diisopentylphthalate (DIPP) (CAS# 605-50-5), • Dipentyl phthalate (DPP) (CAS# 131-18-0), • N-pentyl-isopentylphthalate (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% weight by weight (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 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). 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. These products are manufactured using polymer resins which may contain very small amounts of stearic acids and related substances derived from tallow

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	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 22442-1:2015 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 device (per MDD 93/42/EEC, euMDR 2017/745 Annex VIII, 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 products.

1.9 REACH information

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) according to Art. 59 (1,10) of the Regulation (EC) No. 1907/2006 (REACH).

1.10 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.

1.11 Sterilization method

BD PosiFlush™ SP and BD PosiFlush™ XS Syringes are moist heat sterilized.

- ISO 11737-1:2018: Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
- ISO 11737-2: 2019: Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ISO 17665-1: 2006: Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- EN 556-1: 2001: Sterilization of medical devices - Requirements for medical devices to be designated "STERILE". Part 1: Requirements for terminally sterilized medical devices

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The steam sterilization method guarantees a Sterility Assurance Level of 10^{-6} for the fluid path and solution.

For the BD PosiFlush™ XS product, the packaged device is also sterile to a Sterility Assurance Level of 10^{-6} and it can be used on a sterile field. The validation and controls are performed according to EN ISO 17665-1 requirements and EN 556-1.

1.12 Shelf life and storage conditions

The BD PosiFlush™ SP and BD PosiFlush™ XS shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time. BD PosiFlush™ SP and BD PosiFlush™ XS syringes have a shelf life of 3 years.

The resulting recommendations in terms of transportation and storage of the BD PosiFlush™ SP and BD PosiFlush™ XS syringes are:

- They need to be stored under specific conditions: the temperatures need to be maintained at 15°C - 25°C (59° - 77°F) with excursions permitted to 30°C (86°F).
- They must not freeze.

1.13 Standards

As per extract from Technical Documentation:

Standards	
Quality Standard	
ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes.
Risk Management Standard	
ISO 14971: 2019	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
Biocompatibility Standards	
ISO 10993-1: 2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-2:2006	Biological evaluation of medical devices -Part 2: Animal welfare requirements
ISO 10993-3:2014	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
ISO 10993-5: 2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-6:2016	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
ISO 10993-10: 2010	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
ISO 10993-11: 2017	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO 10993-12: 2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

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ISO 10993-13 :2010	Biological evaluation of medical devices -Part 13: Identification and quantification of degradation products from polymeric medical devices
ISO 10993-15:2019	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys
ISO 10993-17: 2002	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
ISO 10993-18: 2020	Biological evaluation of medical devices - Part 18: Chemical characterization of materials
Labeling Standards	
EN 1041:2008	Information supplied by the manufacturer of medical devices
ISO 15223-1: 2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
Usability Engineering Standards	
IEC 62366-1:2015	Medical Devices – Application of usability engineering to medical devices
Design Specific Standards	
ISO 594-2 :1991	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings
Sterilization Standards	
ISO 11737-1:2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006)
ISO 11737-2: 2019	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009)
ISO 17665-1: 2006	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)
EN 556-1: 2001	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE". Part 1: Requirements for terminally sterilized medical devices
Packaging Standards (apply to BD PosiFlush™ XS syringes only)	
ISO 11607-1:2019	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
Clinical Investigation standards	
BS EN 540 :1993	Clinical investigation of medical devices for human subjects
ISO 14155:2020	Clinical investigation of medical devices for human subjects — Good clinical practice
Clean room Spec Standards	
ISO 14644-1:2015	Clean rooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
ISO 14644-2:2015	Clean rooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
ISO 14644-3:2019	Clean rooms and associated controlled environments - Part 3: Test methods
ISO 14644-4:2001	Clean rooms and associated controlled environments - Part 4: Design, construction and start-up
ISO 14644-5:2004	Clean rooms and associated controlled environments - Part 5: Operations

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ISO 14644-7:2004	Clean rooms and associated controlled environments - Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)
ISO 14644-8: 2013	Clean rooms and associated controlled environments - Part 8: Classification of air cleanliness by chemical concentration (ACC)
Animal tissue and derivatives related standards	
ISO 22442-1:2020*	Medical devices utilizing animal tissues and their derivatives. Application of risk management *Partially applied (Annex C.5)

Note:
The above standards reflect the status at the time of drafting this document.

1.14 Classification

BD PosiFlush™ SP and BD PosiFlush™ XS Syringes are classified as class III medical device as defined in the MDR (EU) 2017/745 Annex VIII.

1.15 Medical Device Nomenclature

EMDN Code: A02010701
EMDN Term: Syringes Prefilled with Sterile Physiologic Solution

According to ISO 15225 (Medical devices - Quality management - Medical device nomenclature data structure), BD PosiFlush™ SP and BD PosiFlush™ XS Syringes are referenced as follows:
GMDN Code: 64786
GMDN Term: Vascular Catheter/cannula flush solution, non-anticoagulant, non-antimicrobial

1.16 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.

1.17 Other information

- (Material) Safety Data Sheets are not required for this product.

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- 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*
306573	BD PosiFlush™ SP syringe CE 3mL	1	30	480	Yes
306574	BD PosiFlush™ SP syringe CE 5mL	1	30	480	Yes
306575	BD PosiFlush™ SP syringe CE 10mL	1	30	480	Yes
306583	BD PosiFlush™ SP syringe EMA 3mL	1	30	480	Yes
306584	BD PosiFlush™ SP syringe EMA 5mL	1	30	480	Yes
306585	BD PosiFlush™ SP syringe EMA 10mL	1	30	480	Yes
306570	BD PosiFlush™ XS syringe CE 3mL	1	30	240	Yes
306571	BD PosiFlush™ XS syringe CE 5mL	1	30	240	Yes
306572	BD PosiFlush™ XS syringe CE 10mL	1	30	240	Yes
306580	BD PosiFlush™ XS syringe EMA 3mL	1	30	240	Yes
306581	BD PosiFlush™ XS syringe EMA 5mL	1	30	240	Yes
306582	BD PosiFlush™ XS syringe EMA 10mL	1	30	240	Yes

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

2.2 Packaging material

Component	Material
Unit Pack (Flow wrap)	Polypropylene

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PosiFlush SP	
Unit Pack (Blister Pack) PosiFlush XS	Top Web: Steam paper Bottom Web: Polypropylene
Shelf Box	Chipboard carton
Shipping Case	Corrugated carton

2.3 Examples of labeling

BD Catalog Number	Languages available on labeling
306573	UK & USA/English France/French Germany/German Spain/Spanish Portugal/Portuguese Italy/Italian Greece/Greek Netherland/Dutch Sweden/Swedish Finland/Finnish Norway/Norwegian Denmark/Danish
306574	
306575	
306570	
306571	
306572	
306583	UK & USA/English Poland/Polis Slovenia/Slovenian Slovakia/Slovak Hungary/Hungarian Czech Republic/Czech Turkey/Turkish Russia/Russian Croatia/Croatian Bulgaria/Bulgarian Romania/Romanian UAE/Arabic
306584	
306585	
306580	
306581	
306582	

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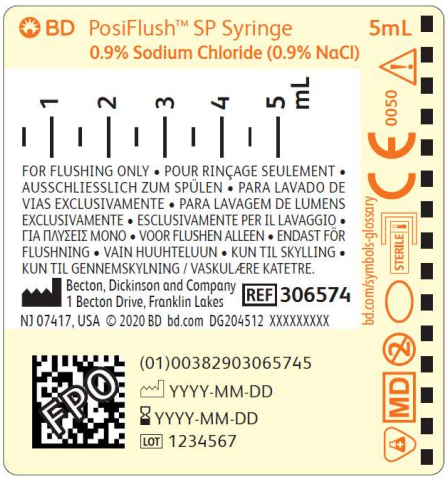
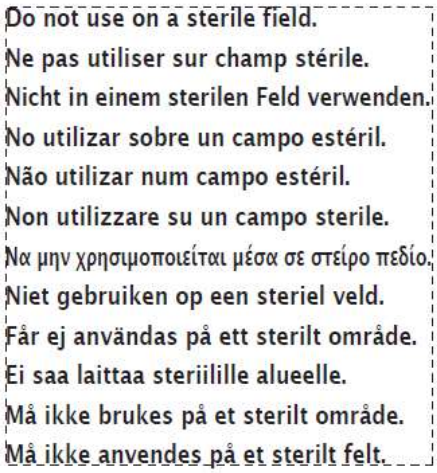
Primary Packaging Label (barrel label) extracted from document DG2045 Rev.12 related to reference 306574:



Unit pack (flow wrap) extracted from document DGW1511 Rev.03 related to reference 306574:



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Shelf Box extracted from document 10000303830 Rev.03 related to reference 306574:

Shelf Box label extracted from document 10000303832 Rev.04 related to reference 306574:

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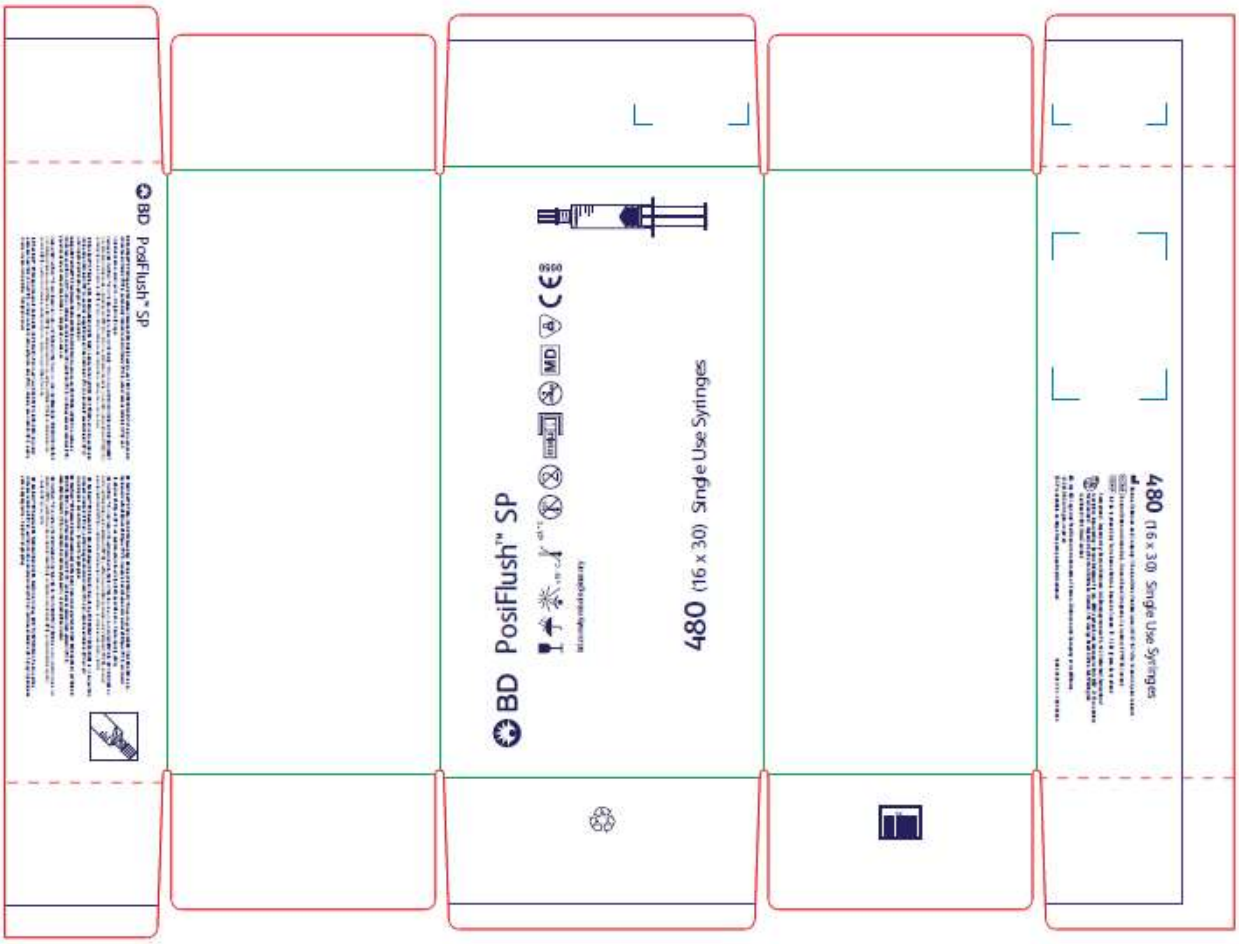
Shipping Case extracted from document 10000303831 Rev.04 related to reference 306574:



Case Label extracted from document 10000303833 Rev.04 related to reference 306574:

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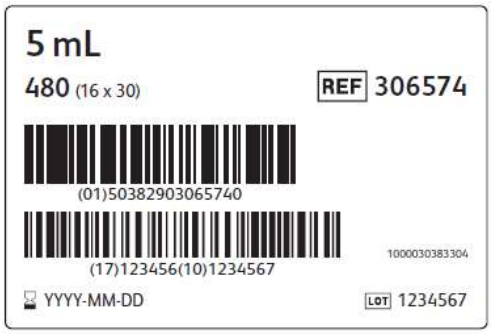

IFU insert (English part only) extracted from document 1000223600 Rev.05 related to reference 306574:

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ENGLISH

INSTRUCTIONS FOR USE

Follow instructions for use, manufacturer guidelines, and institution procedures for flush administration.

DESCRIPTION

BD PosiFlush™ SP Syringe is a ready to use medical device (according to regulation (EU) 2017/745 of the European Parliament and of the Council). It is a polypropylene syringe containing sterile and non-pyrogenic isotonic 0.9% sodium chloride solution. The syringe content is guaranteed to be sterile, non-toxic, and non-pyrogenic.

INTENDED USE/INDICATIONS FOR USE

- BD PosiFlush™ SP Syringes are intended to be used FOR FLUSHING ONLY of in-situ peripheral intravenous catheters (PIVCs), peripherally inserted central catheters (PICCs), central venous catheters (CVCs), and implanted venous access ports.
- BD PosiFlush™ SP Syringe is not intended for dry product reconstitution, for medication dilution, or where intravenous therapy with sodium chloride is indicated.
- **BD PosiFlush™ SP Syringe must not be used on a sterile field.**

INTENDED PATIENT POPULATION

BD PosiFlush™ SP Syringe is to be used with patients with in-situ peripheral intravenous catheters (PIVCs), peripherally inserted central catheters (PICCs), central venous catheters (CVCs), and implanted venous access ports.

INTENDED USER

BD PosiFlush™ SP Syringe is to be used by healthcare professionals experienced in vascular access and the use of these devices. The BD PosiFlush™ SP Syringes are manual devices that may be operated by a large range of people with various human characteristics, including hand sizes and strengths.

CONTRAINDICATIONS

- Use in hypernatremia and fluid retention patients, when the administration of sodium or chloride could be clinically detrimental.
- Do not use BD PosiFlush™ SP Syringe if a patient has a known allergy to any of its components, materials or 0.9% sodium chloride solution, which may lead to an allergic response resulting in anaphylaxis.

PERFORMANCE CHARACTERISTICS

- Interoperability with Vascular Access Devices (VAD).
- All syringe barrels (3 mL, 5 mL and 10 mL) have the same 10 mL diameter syringe barrel and therefore the flush pressure is equivalent for all sizes.

WARNINGS

- Do not use if unit package or content is damaged.
- Do not use if product has been left at freezing temperature.
- Verify the expiration date on the product package or label. Do not use if product has expired.
- Do not use if syringe tip cap or stopper is damaged.
- Do not use if solution is cloudy or colored, contains a precipitate, or has any type of suspended particulate matter.
- Do not re-use. Re-use may lead to infection or other illness/injury.
- Small parts are a potential choking hazard. After use, discard small parts according to your facility protocol.
- Do not re-sterilize.
- Possible complications and/or adverse reactions associated with flushing may include sepsis, infections (localized/systemic), mucocutaneous blood exposure, exposure to bloodborne pathogens, air embolism, particulate embolism, blood clots, phlebitis, leakage that may lead to hazardous drug/fluid exposure, irritation, a transitory taste or odor during flushing. Use of contaminated normal saline product may lead to infection and possibly death.
- Not using aseptic technique and failure to adhere to flushing guidelines may lead to: catheter related bloodstream infection and related injury or death, catheter failure, catheter related complications such as occlusion, infiltration, extravasation, erythema, swelling or pain.

PRECAUTIONS

- Store at controlled temperature (15-25°C). Excursions permitted to 30°C. Do not leave at freezing temperature.
- Check with drug manufacturer instructions for use to ensure compatibility with 0.9% sodium chloride solution prior to use. If 0.9% sodium chloride solution is not compatible, follow the drug manufacturer instructions for flushing practices, or first flush the vascular access device (VAD) with a compatible solution such as 5% dextrose in water to remove traces of the medication in accordance with manufacturer and institution policies.
- Clinicians should consider the patient's specific medical conditions, treatment needs, age, and weight that may require restricted sodium or fluid intake when deciding to flush with 0.9% sodium chloride injection. Saline flushes should be taken into account when prescribing fluids to not exceed fluid intake guidelines.
- There are no known clinical studies of flushing with BD PosiFlush™ SP Syringe in pregnant and lactating women.
- BD PosiFlush™ SP Syringe is designed to be used with ISO luer compliant components for intravenous applications.
- For single use only. Discard any partially used product.
- EU Only: Users should report any serious incident related to the device to the Manufacturer and National Competent Authority.

DIRECTIONS FOR USE

Single use, single patient device. To ensure safe medication preparation and administration, clinicians should practice the "7 rights" of medication administration: right patient, right drug, right dose, right time, right route, right reason and right documentation.

Current practice recommendations are to flush before and after each medication, fluid administration, or blood sampling; and at regular intervals when catheters are not in use. However always consider device manufacturer, medication and institution guidelines.

Follow disinfection protocols as per institution and manufacturer guidelines.

Use aseptic technique throughout the procedure.

1. Open pack and remove syringe.
2. Check that syringe tip cap is in place. Inspect clarity of solution. (Fig. 1a)
3. Depress plunger with tip cap on to release the stopper seal. (Fig. 1b)
4. Unscrew tip cap from the syringe ensuring that there is no touch contamination of the syringe luer connection. (Fig. 2)
5. Push syringe plunger to expel the air. (Fig. 3)
6. Connect BD PosiFlush™ SP syringe to vascular access device, taking care that there is no touch contamination of the connection. (Fig. 4) Ensure secure connection.
7. Push syringe plunger to inject the required volume of saline following institution's policy. (Fig. 5) Inject the solution slowly in order to avoid overpressure. In case of plunger resistance, it is recommended that excessive force is not exerted.
8. After use, dispose of in accordance with recognized procedure in your institution. (Fig. 6)

COMPOSITION PER UNIT

Polypropylene syringe with BD Luer-Lok™ tip.

BD PosiFlush™ SP Syringe is not formulated with Natural Rubber Latex.

Saline solution: sodium chloride 9 g/l (NaCl 0.9%), distilled sterile water to volumes, preservative free and non-pyrogenic.

Flow pack consists of Polypropylene.

CLINICAL BENEFITS

- The BD PosiFlush™ SP syringe is a pre-filled, single use 0.9% sodium chloride syringe that helps to improve clinician efficiency by eliminating steps and time involved in the manual preparation of saline syringes.
- The BD PosiFlush™ SP syringe reduces risk of touch contamination that may occur during manual preparation of saline flush syringes.

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REVISION	CHANGE SUMMARY
01	Initial release according to new template
02	Update of 1.5: Material of concern Added details in 1.9: Shelf life and storage conditions Update of 1.10: Standards Update of 1.12: GMDN code Update of 2.3: Examples of labelling
03	Update according to new template and MDR certification.

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