BD PosiFlush™ SP & XS Syringe pre-filled with a sterile 0.9% Sodium Chloride Solution, Sterile

BD Switzerland Sàrl
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TDS number: V201-015 – Rev. 02
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1. General Information

1.1 Intended use

The BD PosiFlush™ SP and XS syringe are intended for immediate use in maintaining patency of vascular access devices.

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

1.2 General description

The syringe consists of a ready to use syringe, which is pre-filled with an injectable sterile, non-pyrogenic and isotonic 0.9% sodium chloride solution. The syringe is not to be re-sterilized or re-used.

The BD PosiFlush™ XS (externally Sterile) is presented with individual protection for maintaining sterility and can be used on a sterile field. BD PosiFlush™ SP cannot be used on a sterile field.

All sizes of the pre-filled syringes (3, 5 and 10 ml) 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, 10 ml).

	BD Catalog Number	BD Product Description	Color Code
BD PosiFlush™ SP, sterile Fluid Path	306573	3ml BD PosiFlush™ SP	Orange
	306574	5ml BD PosiFlush™ SP	Orange
	306575	10 ml BD PosiFlush™ SP	Orange
	306583	3ml BD PosiFlush™ EMA SP	Orange
	306584	5ml BD PosiFlush™ EMA SP	Orange
	306585	10 ml BD PosiFlush™ EMA SP	Orange
BD PosiFlush™ XS, externally sterile	306570	3ml BD PosiFlush™ XS	Blue
	306571	5ml BD PosiFlush™ XS	Blue
	306572	10 ml BD PosiFlush™ XS	Blue
	306580	3ml BD PosiFlush™ EMA XS	Blue
	306581	5ml BD PosiFlush™ EMA XS	Blue
	306582	10 ml BD PosiFlush™ EMA XS	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.

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 New Jersey 07417 United States **ISO 13485** Certificate No.: MD19.2305	CE certified with NSAI (0050) Certificate No.: 252.780 **AND** CE certified with GMED (0459) Certificate No.: 16730	**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	Becton Dickinson and Company Donore Road Drogheda Co Louth, Ireland

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)
306575 306585	**Address:** Becton Dickinson and Company 1 Becton Drive Franklin Lakes New Jersey 07417 United States **ISO 13485** Certificate No.: MD19.2305	CE certified with NSAI (0050) Certificate No.: 252.780 **AND** CE certified with GMED (0459) Certificate No.: 16730	**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 Company Donore Road Drogheda Co Louth, Ireland **ISO 13485** Certificate No.: MD19.1609	Becton Dickinson and Company Donore Road Drogheda Co Louth, Ireland
306570 306571 306572 306580 306581 306582	**Address:** Becton Dickinson and Company 1 Becton Drive Franklin Lakes New Jersey 07417 United States **ISO 13485** Certificate No.: MD19.2305	CE certified with NSAI (0050) Certificate No.: 252.780 **AND** CE certified with GMED (0459) Certificate No.: 14879	**Address:** Becton Dickinson and Company Donore Road Drogheda Co Louth, Ireland **ISO 13485** Certificate No.: MD19.1609	Becton Dickinson and Company Donore Road Drogheda Co Louth, Ireland

1.4 Materials

Component	Material
Saline Solution	Sodium Chloride 0.9%
Barrel	Polypropylene
Tip Cap	Polypropylene + Colorant
Stopper	Elastomer
Plunger Rod	Polypropylene
Lubricant	Silicon oil

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 10 June 2020, 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 as per 10 June 2020, the articles with the Product Numbers above are not formulated with natural rubber latex.
Bisphenol A	Based on our ongoing data collection efforts and/or information received from our suppliers as per 10 June 2020, 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 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, as recognized by MEDDEV 2.4/1, 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 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 10 June 2020, 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 16 January 2020 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

The steam sterilization method guarantees a Sterility Assurance Level of 10-6 for the finished product, including fluid path, solution and outer surface of the syringe.

For the BD PosiFlush™ SP and XS product, the external syringe is also sterile to a Sterility Assurance Level of 10-6. The validation and controls are performed according to EN ISO 17665-1 requirements and EN 556-1.

1.9 Shelf life and storage conditions

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

The resulting recommendations in terms of transportation and storage of the sodium chloride pre-filled syringes are:

- They need to be shipped in order to maintain the conditions of transportation of 0-40°C (32-104°F) targeting 25°C
- 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

1.10 Standards

As per extract from the Declaration of Conformity DoC PosiFlush SP and XS rev B linked to CE certificate number 252.780:

Harmonized Standards	
EN 556-1:2001	Sterilization of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile" - Part 1: Requirements for Terminally Sterilized Medical Devices
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN 62366:2008	*Medical Devices – Application of usability engineering to medical devices*
EN 22442:2007	*Medical devices utilizing animal tissues and their derivatives*
EN ISO 15223-1:2016	*Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements*
EN ISO 10993-1:2009	*Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
EN ISO 10993-4:2009	*Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood*
EN ISO 10993-5:2009	*Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*
EN ISO 10993-11:2009	*Biological evaluation of medical devices - Part 11: Tests for systemic toxicity*
EN ISO 10993-12:2012	*Biological evaluation of medical devices - Part 12: Sample preparation and reference materials*
EN ISO 10993-17:2009	*Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances*
EN ISO 10993-18:2009	*Biological evaluation of medical devices - Part 18: Chemical characterization of materials*
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 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 ISO 1707:1996	*Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings*
EN 20594-1:1993	*Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements*
EN ISO 11737-1:2006	*Sterilization of medical devices – Microbial methods- Part 1: Determination of a population of microorganisms on products*
EN ISO 11737-2:2009	*Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*
Non-Harmonized Standards	
BS EN 540:1993	Clinical investigation of medical devices for human subjects
ICH Q1A Guidance	Guideline for stability testing of next drug substances and products
ISO 14644:2000	Clean rooms and associated controlled environments
USP<42>	Version 42
ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

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

The device is a pre-filled syringe with a solution, but as it is to be used for a mechanical action, it is a Class III medical device under rule 13 of Annex IX of the Directive 93/42/EEC.

1.12 GMDN code

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

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.
- BD reserves the right to use the internal change control procedure to change raw material suppliers and production process.

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.
- The EC representative is BD Drogheda, Ireland

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*
BD PosiFlush™ SP, sterile Fluid Path	306573	3ml BD PosiFlush™ SP	1	30	480	Yes
	306574	5ml BD PosiFlush™ SP	1	30	480	Yes
	306575	10 ml BD PosiFlush™ SP	1	30	480	Yes
	306583	3ml BD PosiFlush™ EMA SP	1	30	480	Yes
	306584	5ml BD PosiFlush™ EMA SP	1	30	480	Yes
	306585	10 ml BD PosiFlush™ EMA SP	1	30	480	Yes
BD PosiFlush™ XS, externally sterile	306570	3ml BD PosiFlush™ XS	1	30	240	Yes
	306571	5ml BD PosiFlush™ XS	1	30	240	Yes
	306572	10 ml BD PosiFlush™ XS	1	30	240	Yes
	306580	3ml BD PosiFlush™ EMA XS	1	30	240	Yes
	306581	5ml BD PosiFlush™ EMA XS	1	30	240	Yes
	306582	10 ml BD PosiFlush™ EMA XS	1	30	240	Yes

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

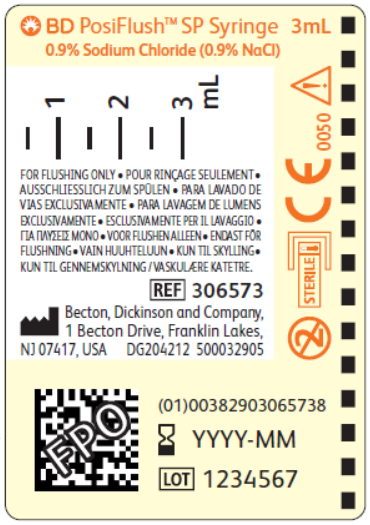
2.2 Packaging material

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

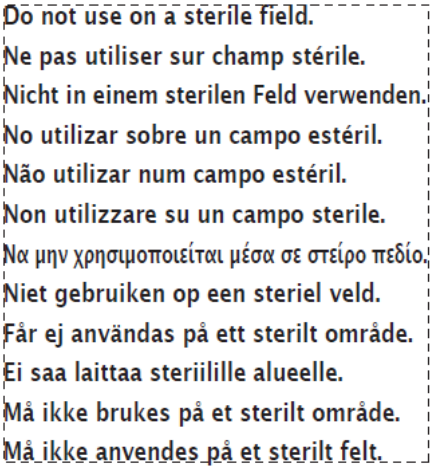
2.3 Examples of labeling

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

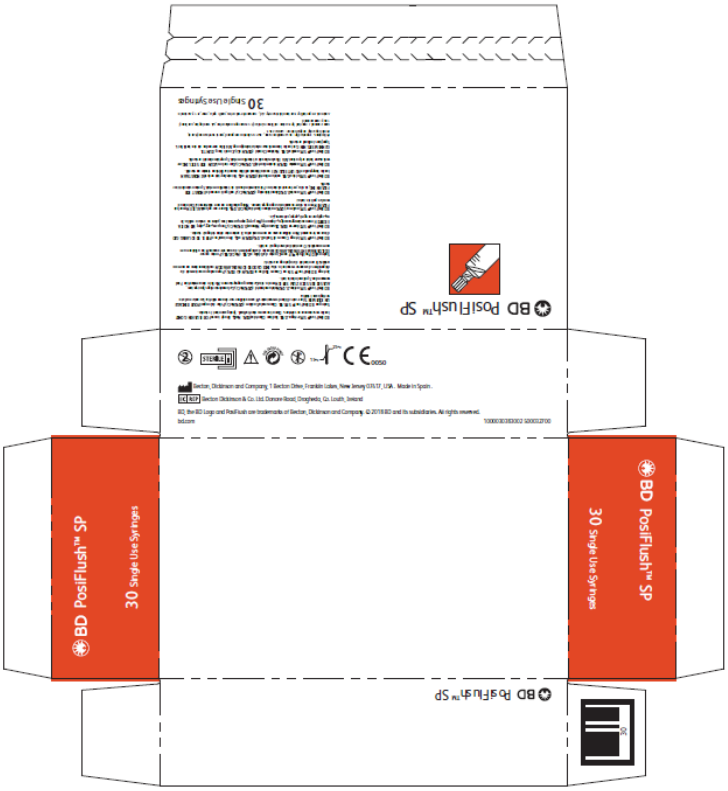
Primary Packaging Label extracted from document DG2042 related to reference 306573 (made in Fraga):



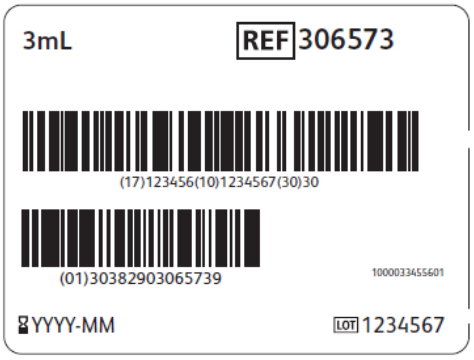
Unit pack (flow wrap) extracted from document DGW1511 related to reference 306573 (made in Fraga):



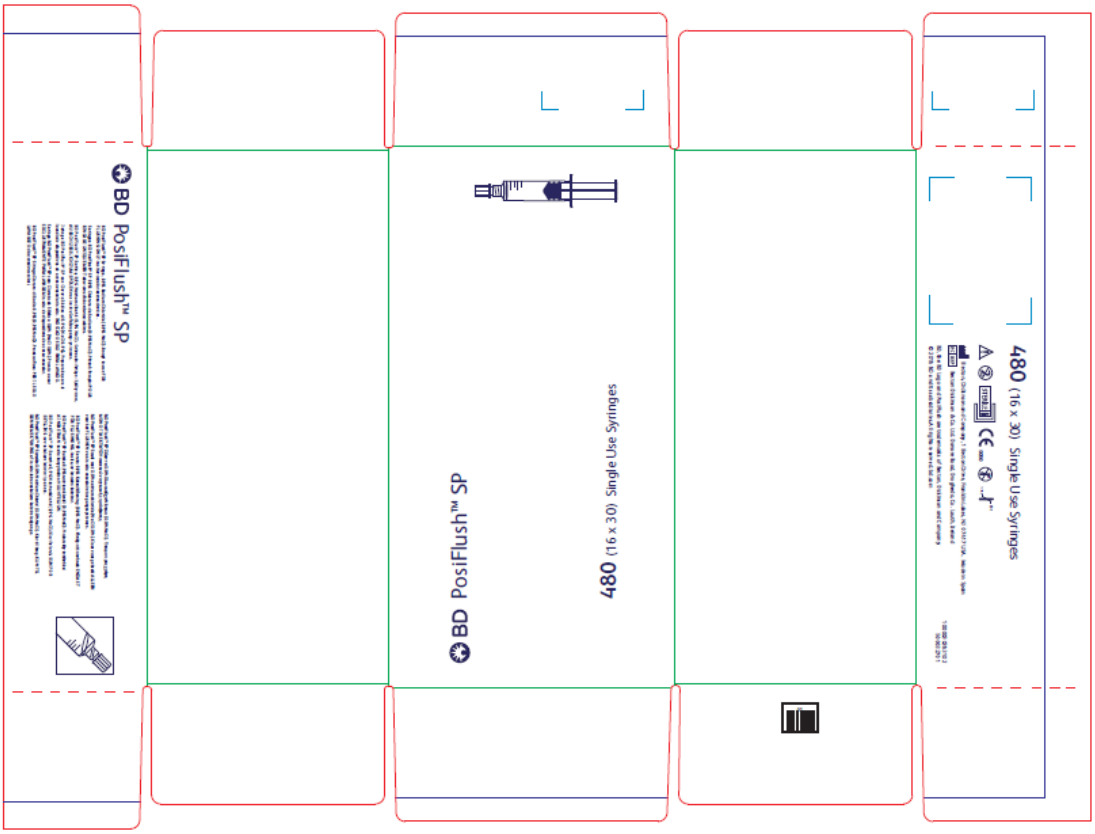
Shelf Box extracted from document 10000303830 related to reference 306573 (made in Fraga):



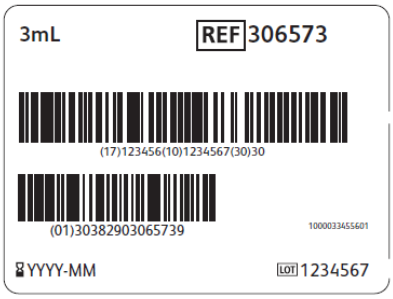
Shelf Box label extracted from document 10000334556 related to reference 306573 (made in Fraga):



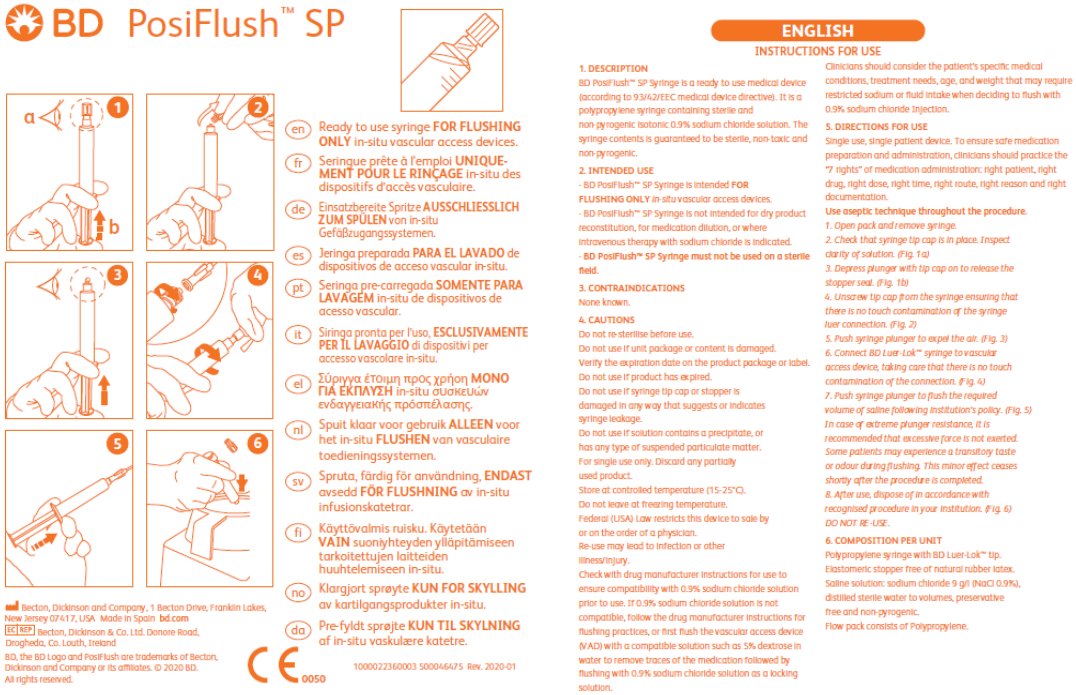
Shipping Case extracted from document 10000303831 related to reference 306573 (made in Fraga):



Case Label extracted from document 10000334557 related to reference 306573 (made in Fraga):



IFU insert (English part only) extracted from document 10000223600 related to reference 306573 (made in Fraga):



BD PosiFlush™ SP

en Ready to use syringe **FOR FLUSHING ONLY** in-situ vascular access devices.

fr Seringue prête à l'emploi **UNIQUEMENT POUR LE RINÇAGE** in-situ des dispositifs d'accès vasculaire.

de Einsatzbereite Spritze **AUSSCHLIESSLICH ZUM SPÜLEN** von in-situ Gefäßzugangssystemen.

es Jeringa preparada **PARA EL LAVADO** de dispositivos de acceso vascular in-situ.

pt Seringa pre-carregada **SOMENTE PARA LAVAGEM** in-situ de dispositivos de acesso vascular.

it Siringa pronta per l'uso, **ESCLUSIVAMENTE PER IL LAVAGGIO** di dispositivi per accesso vascolare in-situ.

el Σύριγγα έτοιμη προς χρήση **ΜΟΝΟ ΓΙΑ ΕΚΠΛΥΣΗ** in-situ συσκευών ενδαγγειακής πρόσπέλασης.

nl Spuit klaar voor gebruik **ALLEEN** voor het in-situ **FLUSHEN** van vasculaire toedieningssystemen.

sv Spruta, färdig för användning, **ENDAST** avsedd **FÖR FLUSHNING** av in-situ infusionskatetrar.

fi Käyttövalmis ruisku. Käytetään **VAIN** suoniyhteyden ylläpitämiseen tarkoitettujen laitteiden huuhtelemiseen in-situ.

no Klargjort sprøyte **KUN FOR SKYLLING** av kartilgangsprodukter in-situ.

da Pre-fyldt sprøjte **KUN TIL SKYLNING** af in-situ vaskulære katetre.

Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, New Jersey 07417, USA Made in Spain bd.com

EC REP Becton, Dickinson & Co. Ltd. Donore Road, Drogheda, Co. Louth, Ireland

CE 0050

10000223600003 500046475 Rev. 2020-01

ENGLISH

INSTRUCTIONS FOR USE

1. DESCRIPTION

BD PosiFlush™ SP Syringe is a ready to use medical device (according to 93/42/EEC medical device directive). It is a polypropylene syringe containing sterile and non-pyrogenic isotonic 0.9% sodium chloride solution. The syringe contents is guaranteed to be sterile, non-toxic and non-pyrogenic.

2. INTENDED USE

- BD PosiFlush™ SP Syringe is intended **FOR FLUSHING ONLY** *in-situ* vascular access devices.
- 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.**

3. CONTRAINDICATIONS

None known.

4. CAUTIONS

Do not re-sterilise before use.
Do not use if unit package or content is damaged.
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 in any way that suggests or indicates syringe leakage.
Do not use if solution contains a precipitate, or has any type of suspended particulate matter.
For single use only. Discard any partially used product.
Store at controlled temperature (15-25°C).
Do not leave at freezing temperature.
Federal (USA) Law restricts this device to sale by or on the order of a physician.
Re-use may lead to infection or other illness/injury.
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 followed by flushing with 0.9% sodium chloride solution as a locking solution.

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.

5. 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.

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 Luer-Lok™ syringe to vascular access device, taking care that there is no touch contamination of the connection. (Fig. 4)
7. Push syringe plunger to flush the required volume of saline following institution's policy. (Fig. 5)
In case of extreme plunger resistance, it is recommended that excessive force is not exerted. Some patients may experience a transitory taste or odour during flushing. This minor effect ceases shortly after the procedure is completed.
8. After use, dispose of in accordance with recognised procedure in your institution. (Fig. 6)
DO NOT RE-USE.

6. COMPOSITION PER UNIT

Polypropylene syringe with BD Luer-Lok™ tip.
Elastomeric stopper free of 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.

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