



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 sodium chloride solution. The syringe content is guaranteed to be sterile, non-toxic, and non-pyrogenic.

INTENDED USE/INDICATIONS FOR USE

- BD PosiFlush™ SP Syringe 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. Saline flushes should be taken into account when deciding to flush with 0.9% sodium chloride injection.

- 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 designed to be used with ISO Iuer 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.

- Do not use in patients suffering from hypotension and fluid retention when the administration of sodium or chloride could be clinically detrimental.

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- Do not use if a patient has a known allergy to any of its components, materials or 0.9% sodium chloride solution.

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.

Use of aseptic technique throughout the procedure.

1. Open pack and remove syringe.

2. Check that syring 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. Squeeze 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 excessive force which may be applied to the stopper seal.

8. Do not use if syringe tip cap or stopper seal is damaged.

9. Do not use if solution is cloudy or colored, contains a precipitate, or has any type of suspended particulate matter.

10. Do not re-use. Re-use may lead to infection or other illness/injury.

11. Small parts are a potential choking hazard. After use, discard small parts according to your facility protocol.

12. Do not sterilize.

13. Possible complications and/or adverse reactions associated with flushing may include sepsis, septicemia, mucocutaneous blood exposure, exposure to bloodborne pathogens, embolism, particulate embolism, blood clots, blebs, leakage that may lead to hazardous or life threatening. Use of contaminated normal saline product may lead to infection and possibly death.

14. Not using aseptic technique and failure to flush or to use the recommended guidelines may lead to catheter related bloodstream infection and related injury or death, catheter failure, complications such as occlusion, infiltration, extravasation, erythema, swelling or pain.

COMPOSITION PER UNIT

Polypropylene syringe with BD Luer-Lok™ tip.

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

Flow pack consisting 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.

15. The BD PosiFlush™ SP syringe reduces risk of touch contamination that may occur during manual preparation of saline flush syringes.

16. The BD PosiFlush™ SP syringe is a sterile, non-toxic, and non-pyrogenic device.

17. 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.

18. After use, dispose of in accordance with institution's policy.

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