BD PosiFlush™ XS Syringe, 0.9% Sodium Chloride (0.9% NaCl)

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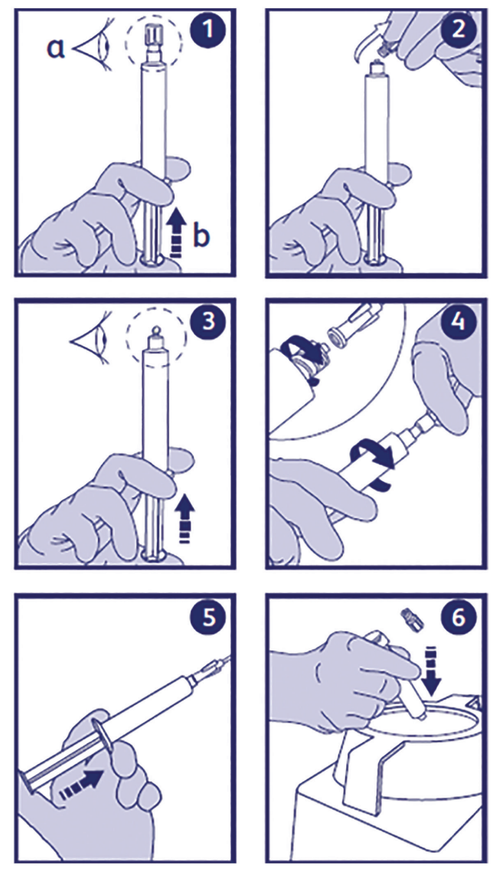

Intended for FLUSHING ONLY of in-situ PIVCs, PICCs, CVCs, and implanted venous access ports.

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

DESCRIPTION

BD PosiFlush™ XS Syringe is a ready to use sterile 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 contents of our unopened or undamaged blister packages are guaranteed to be sterile, non-toxic, and non-pyrogenic.

INTENDED USE/INDICATIONS FOR USE

- 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.**

INTENDED PATIENT POPULATION

BD PosiFlush™ XS 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™ XS Syringe is to be used by healthcare professionals experienced in vascular access and the use of these devices. The 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.

CONTRAINDICATIONS

- Do not use in patients su□ering from hypernatremia and fluid retention when the administration of sodium or chloride could be clinically detrimental. - Do not use BD PosiFlush™ XS 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 syringes (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 blood-borne 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 30ºC. 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™ XS Syringe in pregnant and lactating women. • BD PosiFlush™ XS 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 blister pack and remove syringe. Using sterile technique, place syringe on a sterile field if applicable. 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™ XS 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 over-pressure. 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™ XS Syringe is not formulated with Natural Rubber Latex. Saline solution: sodium chloride 9g/l (NaCl 0.9%), distilled sterile water to volumes, preservative free and non-pyrogenic. Single blister pack consists of paper and Polypropylene – Polyamide film.

CLINICAL BENEFITS

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

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STERILE

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