

SAMSafe® Pre-Filled Normal Saline Flush Syringe,

Used only in flushing compatible intravenous administration sets and indwelling intravenous access devices.

1. DESCRIPTION

AMSafe® Syringe is a ready to use sterile medical device. 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 is guaranteed to be sterile.

2. INDICATIONS FOR USE

AMSafe® Pre-Filled Normal Saline Flush Syringe is a device used in flushing compatible intravenous administration sets and indwelling intravenous access devices.

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 20-25°C (68-77°F). Excursions avoid freezing and excessive heat. 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.

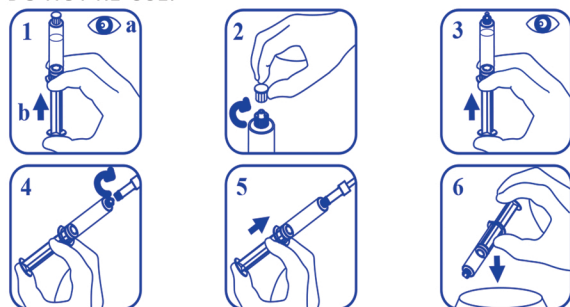
5. DIRECTIONS FOR USE

Single use, single patient device. Use aseptic technique throughout the procedure.

- (1). Open blister pack and remove syringe. 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 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 tip. Elastomeric stopper free of 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 polyethylene and Polypropylene - Polyamide film.

L9931 Rev.E