

DESCRIPTION

The PentaFlush saline 0.9% NaCl pre-filled syringe is a ready-to-use, radiation-sterilised medical device. The syringe is made of polypropylene and contains an isotonic 0.9% sodium chloride solution. The manufacturer guarantees that the contents of the syringes are sterile, non-pyrogenic and non-toxic.

INTENDED USE

The PentaFlush saline 0.9% NaCl pre-filled syringe is intended **ONLY FOR FLUSHING** in-situ vascular access devices.

It may be placed on sterile field. The PentaFlush saline 0.9% NaCl pre-filled syringe is a **SINGLE-USE** medical device intended for use on a **SINGLE PATIENT**.

The PentaFlush saline 0.9% NaCl pre-filled syringe must be used in hospital and/or homecare settings by medical or nursing personnel adequately trained and qualified in the management of vascular accesses.

CONTRAINDICATIONS

The PentaFlush saline 0.9% NaCl pre-filled syringe is **NOT INTENDED** for the reconstitution of dry goods, dilution of medication or for cases where intravenous therapy with 0.9% NaCl saline solution is indicated.

DO NOT USE the PentaFlush saline 0.9% NaCl pre-filled syringe with drugs that are incompatible with sodium chloride

WARNINGS

DO NOT USE the device if the packaging or its contents are damaged. Check the expiry date on the product label or packaging. **DO NOT USE** after the expiry date.

DO NOT USE the device if the syringe cap or rubber ring are damaged to the extent that the syringe leaks.

DO NOT USE the product if the solution appears cloudy and/or contains precipitates and/or any type of suspended particles.

DO NOT USE for direct intravenous injection.

DO NOT ALLOW air to become trapped in the fluid path.

DO NOT RE-STERILISE the syringe.

FOR SINGLE-PATIENT AND SINGLE-USE ONLY. Reusing the device may result in infection or other diseases/injuries. **AFTER USE, REMOVE AND DISCARD UNUSED PORTIONS OF SOLUTION.**

Once the package has been opened, **USE** the syringe **IMMEDIATELY** (to prevent potential contamination).

The end cap on the PentaFlush saline 0.9% NaCl pre-filled syringe poses a choking hazard. Keep out of reach of children.

STORAGE

Store at room temperature (15°-30°C). Do not allow the PentaFlush saline 0.9% NaCl pre-filled syringe to reach freezing temperatures.

DISPOSAL

Dispose of the PentaFlush saline 0.9% NaCl pre-filled syringe and caps in compliance with current regulation

INSTRUCTIONS FOR USE

Use an aseptic technique for the entire procedure.

1. Perform hand washing procedures correctly.
2. Wear PPE (Personal Protective Equipment)
3. Check the expiry date.
4. Check that the packaging is not damaged.
5. Open the package and remove the syringe.
6. Check that the cap on the syringe is correctly positioned and that the solution is transparent. (Fig.1A)
7. Push the plunger rod with the cap in place to release the rubber ring on the syringe. (Fig.1B)
8. Unscrew the cap from the syringe, ensuring that no contact contamination occurs on the Luer connector on the syringe. (Fig.2)
9. Push the syringe plunger to expel the air. (Fig.3) Do not allow air to become trapped in the path of the fluid.
10. Perform scrub disinfection on the hub of the vascular access device for at least 15”.
11. Connect the Luer Lock on the syringe to the vascular access device, taking care to prevent any contamination by contact with the connector. (Fig.4)
12. Push the syringe rod to release the required volume of saline solution in accordance with company procedures and/or protocols and employ the pulsatile “push and pause” technique (Fig. 5).
13. Do not inject a quantity greater than the volume of the catheter; make sure that the volume of the solution being injected is exactly equal to the capacity of the catheter lumen being flushed.
14. **IF ANY RESISTANCE IS ENCOUNTERED DURING THE COMPRESSION STAGE OF THE PLUNGER ROD, DO NOT EXERT FURTHER FORCE** and check for potential obstruction by proceeding as per company procedures and/or protocols.
15. After flushing the catheter lumen, administer the therapy immediately or inject an antimicrobial locking solution to lock the catheter.
16. Dispose of used syringes immediately after use, in accordance with company procedures and/or protocols.

NON-INJECTABLE. DO NOT REUSE.

In the event of severe injury occurring in connection with the “PentaFlush saline 0.9% NaCl pre-filled syringe” device, notify the manufacturer and the competent authority.

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