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Instructions for use – Anoxos Sterile Nitrogen Filled Vials Version 2. Date of Issue: 04 February 2025

This document is designed to provide the best practice information for the use of Sterile Nitrogen Filled Vials to ensure the safety and performance of the product and maintain the integrity of the internal sterility.

Intended use and users:

The temporary storage of customer produced materials for parenteral administration, for use by trained medical professionals.

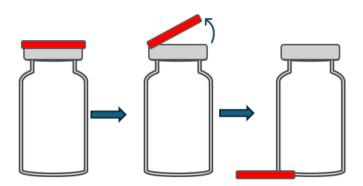
Basic UDI-DI: 50566720VNSYK

Precautions:

- This product is internally sterile, use an aseptic technique for vial access, every time and do not:
- Use if the sterile barrier (stopper and seal) appears to be tampered with or has been removed.
- Reuse needles or syringes for filling and emptying the vial.
- Leave needles or syringes in vials for subsequent medication withdrawal.
- Use if the expiry date has been exceeded

Directions for use

- 1. Gather all required materials (alcohol swab, needle, or syringe and the device).
- 2. Remove the Flip-Off® button from the aluminium seal.



3. Disinfect the vial injection site with an alcohol pad. Caution do not touch the stopper after disinfecting.

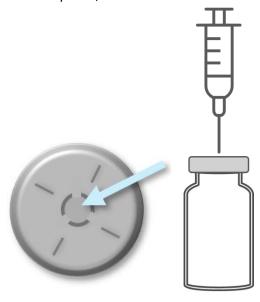


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4. Pierce stopper with needle and fill with product (inset needle within the circle in middle of the stopper as shown perpendicular to the vial) it is recommended that healthcare professionals and end-users follow best practices such as piercing perpendicular to stopper surface and within target ring to avoid hitting the stopper legs, piercing at appropriate speeds, and limit reuse of needles to help reduce stopper coring and fragmentation risks.



- 5. Store vial as per the requirements of your product until content is required.
- 6. To withdraw the product, disinfect the vial injection site with an alcohol pad and pierce the stopper as per the above and draw up product as required per your dosage and procedures.
- 7. Dispose of used vials and needles in accordance to applicable regulations.

Cautions

The product is single use it is not recommended to reprocess the item in any way. Reuse could compromise the performance and safety of the device and may cause contamination due to loss of sterility.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.



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