INSTRUCTION FOR USE

DISPOSAFE Safety IV Cannula with wings and injection port

These instructions contain important information for use of the product. Read the entire contents of these instructions for use, including warnings, cautions and falling to follow instructions could result in death or serious injury to the patient and / or clinician.

1. MATERIALS USED:
PP, PE, POM, HDPE, ABS, Silicon Rubber, Stainless Steel, FEP/PUR/PTFE.

2. COATING MATERIAL: Polydimethylsiloxane

3. DESCRIPTION: Each IV Cannula with safety features is a device that can be used for infusion / administration through peripheral vein. The device is enabled with passive safety feature, to eliminate the needle-stick injuries to the healthcare professionals and waste handlers. Inherently designed transparent flashback chamber enable ease of conformation to venous access. The device is enable with female 6% taper, facilitates integrity of connection with other combination devices.

4. INDICATIONS:

4.1. The device is intended to be used for sample blood or administer fluids intravenously.

4.2. The device may be used on any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.

4.3. Intermittent intravenous drug administration.

4.4. Prophylactic creation of a secure venous access in patients who may require urgent intravenous drug administration, in particular prior to diagnostic or therapeutic procedures.

5. CONTRAINDICATIONS:

5.1. The patient is known or is suspected to be allergic to materials contained in the device.

5.2. Past irradiation of prospective insertion site.

5.3. Previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.

6. INSTRUCTION FOR USE:

6.1. Carefully select and aseptically prepare the site.

6.2. Select suitable size of I.V. Cannula & inspect visually to ascertain that package is intact.

6.3. Remove the protective sheath in straight outward motion and inspect the device. Ensure catheter hub and primary push-off tab are fully enclosed to the needle housing assembly.

6.4. Approach the insertion site slowly at low angle.

6.5. Confirm successful venipuncture by visualizing blood in the flashback chamber.

6.6. Advance the catheter further into the vein, such that catheter is nearly parallel to skin surface, while slightly withdrawing the steel needle.

6.7. Once the insertion is complete, press the vein above from the catheter tip, and pull the needle straight outward. Safety clip will automatically attach to needle tip as needle tip exits catheter hub. Confirm the activation of safety mechanism by hearing an audible click.

6.8. Hold the catheter body and detach the safety cage.

6.9. Connect the infusion line and cover the puncture site with sterile dressing.

6.10. Fix an appropriate sterile lock to avoid the contamination and spillage of blood, while not in use or during the changeover.

6.11. Bolus injection is possible via the integrated injection valve.*

7.CAUTION:

7.1. The device is designed to reduce the risk of accidental needle-sticks; however, care must be taken in order to avoid needle-sticks, in addition to the instruction for use. Universal precautions must be adhered to avoid the exposure to blood borne pathogens. It is recommended that the healthcare professionals follow the recommendations set forth by the Centers for Disease Control and Prevention/Occupational Safety and Health Administration (CDC/OSHA).

7.2. The catheter is soft and fragile; do not use any sharp equipment near to the insertion site or during the insertion or removal.

8. WARNINGS:

8.1. In order to prevent misuse of the device, the use of this product is restricted to a Doctor or qualified medical practitioner.

8.2. The product should be used according to the instructions for use.

8.3. If there is any change in expected performance of the device or in case of any malfunction the device should be immediately removed & sent back to supplier for analysis.

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8.4. Any device that is connected to this product must comply with ISO 80369-7, in order to achieve the intended performance of this product & to avoid leakage in the connection.

8.5. The product should not be reprocessed.

8.6. Visually inspect and carefully check the product and packaging before use. Improper transport and handling may cause structural and/or functional damage to device or packaging.

8.7. The product is guaranteed sterile & non-pyrogenic, if the package has not been opened or damaged.

8.8. Dot not clean or resterilise. For single use only. Discard after use.

8.9. Do not expose to heat or direct sunlight.

8.10. The product should be used immediately after opening the packaging.

8.11. Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reactions or infections.

8.12. Disposal/Discard: Dispose off/Discard the used Device in accordance with your Country's Healthcare and Safety Regulations.

8.13. When using alcohol or alcohol containing antiseptics, care should be taken to avoid prolonged or excessive contact. Solutions should be allowed to completely dry before applying an occlusive dressing.

8.14. Alcohol should not be used to lock, soak, or declot the catheters because alcohol is known to degrade the catheter properties over time with repeated and prolonged exposure.

8.15. (Pediatric) Insertion techniques and placement locations are often modified according to the size and developmental age of the child. Only clinicians experienced in pediatric procedures and placement of venous catheters in pediatric patients should place this catheter in this patient population.

REF Reference No.

LOT Lot No./Batch No.

Manufacturer

Date Of Manufacturing

Use By / Expiry Date

Do Not Reuse

STERILE EO Sterilised By Ethylene Oxide Single Sterile Barrier System

MD Medical Device

Not For General Waste

NON STERILE Do Not Resterilize

Non-Pyrogenic

Do Not Use If Package Is Damage

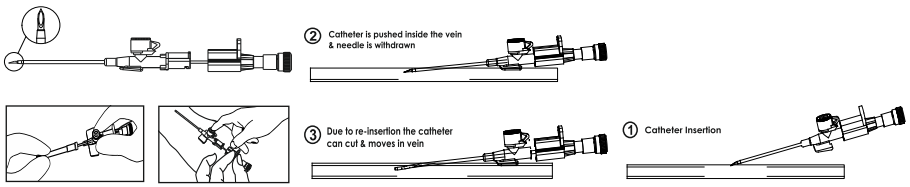
Caution

Consult Instructions For Use

10°C 45°C Temperature Limit

EC REP Authorised Representative In The European Community

Do not expose to heat or direct sunlight.



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