

disposhexa

Safety IV Cannula with wings with 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 failing 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:

1. The device is intended to be used for sample blood or administer fluids intravenously.
2. The device may be used on any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.
3. Intermittent intravenous drug administration.
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. This product is suitable, to be used within CT Scan & MRI Procedures.

5. CONTRAINDICATIONS:

1. The patient is known or is suspected to be allergic to materials contained in the device.
2. Past irradiation of prospective insertion site.
3. Previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.

6. INSTRUCTION FOR USE:

1. Use aseptic technique.
2. Carefully select and aseptically prepare the site.
3. Select suitable size of I.V. Cannula & inspect visually to ascertain that package is intact.
4. 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.
5. Approach the insertion site slowly at low angle.
6. Confirm successful venipuncture by visualizing blood in the flashback chamber.
7. Advance the catheter further into the vein, such that catheter is nearly parallel to skin surface, while slightly withdrawing the steel needle.
8. 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.
9. Hold the catheter body and detach the safety cage.
10. Connect the infusion line and cover the puncture site with sterile dressing.
11. Fix an appropriate sterile lock to avoid the contamination and spillage of blood, while not in use or during the changeover.

INSTRUCTION FOR USE

6.12. Bolus injection is possible via the integrated injection valve.

6.13. Integrated needle free injection port can be used for bolus injection.

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:

1. In order to prevent misuse of the device, the use of this product is restricted to a Doctor or qualified medical practitioner.
2. The product should be used according to the instructions for use.
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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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.
5. The product should not be reprocessed.
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.
7. The product is guaranteed sterile & non-pyrogenic, if the package has not been opened or damaged.
8. Do not clean or resterilise. For single use only. Discard after use.
9. Do not expose to heat or direct sunlight.
10. The product should be used immediately after opening the packaging.
11. Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reactions or infections.
12. Disposal/Discard: Dispose off/Discard the used Device in accordance with your Country's Healthcare and Safety Regulations.
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.
14. Alcohol should not be used to lock, soak, or decontaminate the catheters because alcohol is known to degrade the catheter properties over time with repeated and prolonged exposure.
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.

MAN

Manufacturer

MO

Date Of Manufacturing

USE

Use By / Expiry Date

STERILE

Sterilized By Ethylene Oxide
Single Sterile Barrier System

NO REUSE

Do Not Reuse

NO RSTERILISE

Do Not Resterilize

NON-PYROGENIC

Non-Pyrogenic

CAUTION

Caution

NO USE IF DAMAGE

Do Not Use If Package Is Damage
and Consult Instructions For Use

TEMP LIMIT

Temperature Limit

CONSULT

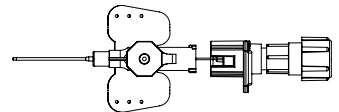
Consult Instructions For Use

MD

Medical Device

EC REP

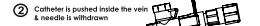
Authorised Representative
In The European Community



① Catheter Insertion



② Catheter is pushed inside the vein & needle is withdrawn



③ Due to re-insertion the catheter can cut & moves in vein



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EC REP

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