

INSTRUCTIONS FOR USE

Cathula®⁺

Safety I.V. Cannula with **tipclip™**
For Sharps Injury Prevention.

DEVICE DESCRIPTION :

- Safety IV cannula is a small, flexible tube designed to deliver IV medications and fluids to the patient through the peripheral vein situated in the arm or leg of the patient and has a built in protection device that encapsulates the tip of the used needle when withdrawn from the catheter.
- This prevents accidental needle stick injury provided the general effective and safe working procedures and precautions are maintained during its use and disposal.

MATERIALS USED

- PP, LDPE, HDPE, PC, Stainless steel, Catheter : Fluorinated Ethylene Propylene (FEP)
Master Batch : Orange, Medium Grey, White, Deep Green, Pink, Deep Blue, Yellow & Violet
- This product does not contain natural rubber latex. This product is DEHP free.

INTENDED USE/INDICATIONS:

- SAFETY I.V. cannula is a conventional device used to provide access to the human circulatory system for infusion of I.V. solution, intermittent intravenous drug administration and to maintain hydration and/or correct dehydration if patient is unable to take sufficient volume of oral fluids.

CONTRAINDICATIONS:

- Product should not be used in patients with known hypersensitivity to any of the materials used.
- For Administration of highly viscous fluids for 26 G, 24 G & 22 G.

INTENDED USER:

- Use is restricted to a qualified doctor or a paramedic.

INTENDED PATIENT POPULATION:

- All patient population irrespective of age and gender.

INSTRUCTIONS FOR USE:

- Carefully select and aseptically prepare the site.
- Select suitable size of I.V. Cannula & inspect visually to ascertain that package is intact.
- Remove cannula from sterile packing.
- Grip the cannula from injection port cap & projection provided on hub (for I.V. Cannula having injection port).
- Grip the cannula so the needle and catheter tip are properly aligned (for I.V. Cannula not having injection port).
- Remove the needle cover.
- Perform venipuncture & check for flash back of blood in flash back Chamber (22 to 14G) or along the catheter length (24 to 26G).
- Advance the catheter into vein and simultaneously withdraw the needle.
- Withdraw the needle completely while pressing the vein just after the tip of the catheter into the vein & discard the needle in appropriate container. Secure the Cannula to the patient with the help of adhesive dressing.
- Connect to the I.V. Infusion set line.
- Cover the puncture site with sterile dressing.
- Drugs can be injected with the help of syringe without needle through integrated injection port after removing the port cap. Close the injection port after use (for I.V. Cannula having injection port).
- Perform routine monitoring & venipuncture site maintenance according to medical norms.

Symbols Glossary



Caution



Batch code



Date of manufacture



Use - by date



Consult Instructions for use



Do not re-use



Do not use if package is damaged



Do not resterilize



Sterilized using ethylene oxide



Medical Device



Single sterile barrier system



Non-pyrogenic



Latex Free

P.T.O.

PRECAUTIONS :

- Open the sterile barrier pack only under aseptic conditions.
- Never try to reinsert the partially or completely withdrawn needle.
- Close the port cap and stoppers when the device is not in use.
- Never rotate the needle or catheter while insertion.
- Select and appropriate size of device before use.
- Insert the needle with the bevel facing up and angle between 10° to 30°.
- Observe the flash back of blood into needle hub and confirm the puncture of the vein

CAUTION :

- The use of this product is restricted to a qualified doctor or a paramedic
- Read instructions before use.
- The product should be used according to the instructions for use (see overleaf).

HMD DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES RESULTING FROM IMPROPER USE.

- Store in clean, dry & insect free place.
- Avoid exposure to Acidic / Corrosive fumes to avoid corrosion / Rust.
- Do not expose to excessive heat or direct sunlight as it can affect packing / sealing integrity.
- Injection from port should be done at slow speed, avoid trying to inject rapidly and suddenly (for I.V. Cannula having injection port).
- The product should be used immediately after opening the packaging.
- Visually inspect and carefully check the product and packaging before use. Improper transport, handling and storage may cause corrosion, structural and/or functional damage to device or packaging.
- Do not attempt to reinsert a partially or completely withdrawn needle, to avoid puncturing of catheter.
- Discard after use in sharps container.
- The product should not be reprocessed.
- For single use only. Do not clean or resterilize. Reuse of device may lead to cross contamination / infection.
- The product is guaranteed non-toxic, sterile & non-pyrogenic if the package has not been opened or damaged.

ADVERSE EFFECTS :

Pain, discomfort, hives, bleeding, blanching, bruising, burning, allergic reaction from hypersensitivity to materials used in the device, local insertion site infection etc.

DISPOSAL :

After use, this product may be a potential biohazard. Handle and dispose off in accordance with accepted medical practice and applicable local, state, and federal law and regulation.

REPORTING OF ADVERSE EVENTS:

In case of any serious adverse event please report the same to E-mail : info@hmdhealthcare.com

Note: For product used in EU also report to the competent authority of the Member State in which the user and/or patient is established

AUG. 2022 / REV.-0



Manufactured By :

**HINDUSTAN SYRINGES
& MEDICAL DEVICES LTD.**

JHARSAINTLY - JAJRU ROAD, SECTOR- 59 PART-II,
BALLABGARH, FARIDABAD (HARYANA) INDIA-121004.
Made In India.



Keep away from Sunlight



Keep dry



Discard in a sharps container