

Instructions For Use (I.F.U)

Cathula[®]

Safety I. V. Cannula with *tipM-clip*[™]

For Sharps Injury Prevention

Device Description:

- Safety I V Cannula is a small, flexible tube designed to deliver I V 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in the arm or leg of the patient and has a built in protection device that encapsulates the tip of the used needle when withdrawn from the catheter.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 (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:

- IV cannula is a conventional device used for intravenous/intravascular access for short-term peripheral cannulation.

Contraindications:

- Product should not be used in patients with known hypersensitivity to any of the materials used.

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 Safety 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 Safety I.V. Cannula having injection port).
- Grip the cannula so the needle and catheter tip are properly aligned (for Safety I.V. Cannula not having injection port).
- Remove the needle cover.
- Perform venipuncture & check for flash back of blood in flashback chamber.
- 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 an appropriate container. Secure the cannula to the patient with the help of adhesive dressing.
- Connect to the I.V. Infusion set line.



Caution



Batch code



Date of manufacture



Use - by date



Consult Instructions
for use



Do not re-use



Do not re-sterilize



Do not use if package
is damaged



Medical Device



Single sterile
barrier system



Sterilized using
ethylene oxide

P.T.O.

- 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 Safety I.V. Cannula having injection port).
- Perform routine monitoring & venipuncture site maintenance according to medical norms.

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 an 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.
- Injections from port should be done at slow speed. Avoid trying to inject rapidly and suddenly (for safety 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 reactions 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 regulations.



Latex Free



Non-pyrogenic



**Keep away
from sunlight**



Keep dry



**Discard in a
sharps container**



Manufacturer



Move Vertically



**Frangible, handle
with care**



Manufacturer & Consumer Complaint Address :

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