

IFU of INTRACURE™

I.V. Cannula/Catheter (with Injection Port & with Wings) Manufactured by Mais India Medical Devices Pvt. Ltd.

General Device Description: I.V. Cannula/ Catheter comprises of a short flexible plastic tube (the Catheter) made up of Polyurethane (P.U.R.) or Polytetrafluoroethylene (PTFE), or Fluorinated Ethylene Propylene (FEP) which is inserted into a vein over a hollow introducer needle, after which the needle is withdrawn and discarded. The I.V. Cannula / Catheter is used in an aseptic environment. The use of the product is restricted to a qualified doctor or a paramedic.

Product Name: I.V. Cannula/ Catheter

Brand Names: INTRACURE™

Variants:

1. I.V. CANNULA WITH INJECTION PORT & WITH WINGS - INTRACURE™

Intended Use:

I.V. Cannula/ Catheter is a device for access to the human circulatory system for introduction of fluids or medicaments and/or withdrawal of blood samples.

Material of construction:

PP, POM, FEP/PUR/PTFE, Silicone, Stainless Steel, LLDPE, HDPE & BaSO₄.

Indications:

- Infusion of I.V. Solutions.
- Intermittent intravenous drugs administration

Contra-indications:

- Product should not be used on patients with known hypersensitivity to any of the materials used.
- Administration of high viscous fluids.
- Large blood transfusions.

Intended Patient Population:

All age groups such as – Neonates, Pediatrics & Adults

24 – 26G – Neonates (0-1 Month)

22G – Pediatrics (1 Month up to 18 years)

14 – 20G – Adults (18 years and older)

Intended User:

Qualified doctor or a paramedic

Use environment:

Proper healthcare setup

Size specifications and color code:

| Size Specification | Color code |
|--------------------|------------|
| Orange | 14G |
| Grey | 16G |
| White | 17G |
| Green | 18G |
| Pink | 20G |
| Blue | 22G |
| Yellow | 24G |
| Violet | 26G |

Instructions for use:

1. Sanities your hands using alcohol cleanser.
2. Position the arm so that it is comfortable for the patient and identify a vein.
3. Apply the tourniquet.
4. Locate an accessible (visible) and suitable peripheral vein and confirm by palpation.
5. Re-check the vein.
6. Put on your gloves, clean the patient's skin with an alcohol wipe and let it dry.
7. Select a suitable size of INTRACURE™ (I.V. Cannula / Catheter) based on patient's age group at the discretion of a Qualified doctor or a paramedic. Visually inspect the packaging. Do not use if damaged.
8. Remove the cannula from its packaging and remove the needle cover ensuring not to touch the needle.
9. Do not touch the catheter.
10. Hold the INTRACURE™ (I.V. Cannula / Catheter) at body and needle hub projection.
11. Insert the needle with the bevel facing upwards at a low angle. Once primary flashback is observed, reduce the angle to nearly parallel with the skin.
12. Advance the cannula slightly, 2 to 3 mm, to ensure the cannula tip is in the vein.
13. Stabilize the cannula.
14. Hold the INTRACURE™ (I.V. Cannula/Catheter) properly/firmly at Catheter Hub with index finger and withdraw the needle back 2 to 3 mm with prompt continuous motion parallel to the skin, ensuring that the catheter hub does not come out from the vein while the needle is being retracted from the catheter hub.

15. Secondary flashback between the needle and cannula will confirm correct placement in the vein.

16. Advance the cannula completely into the vein.

17. Release the tourniquet, apply pressure to the vein at the tip of the cannula and remove the needle fully by pressing the vein at the insertion point with the help of the index finger of the other hand, to stop the blood loss. Remove the cap from the needle and put it at the end of the cannula.

18. Carefully dispose of the needle in a sharps bin.

19. Connect to other infusion devices (as appropriate).

20. Apply a sterile dressing to the cannula to fix it in place.

21. Ensure that the date sticker has been completed and applied.

22. Check the expiry date of the saline solution. If valid, flush the cannula using the saline-filled syringe to verify patency.

23. Dispose of your gloves and equipment in the clinical waste bin. Ensure the patient is comfortable and thank them.

24. Perform routine monitoring & vein puncture site maintenance according to medical norms.

Intended Clinical Benefits to the patients:

·IV cannulation allows delivery of desirable and suitable fluids or medicaments in adequate amounts in patients, who cannot tolerate drugs or fluids by the oral route. Some drugs cannot be absorbed by other routes: for example, a drug with a high molecular weight can only be given intravenously.

·Saves Patients from multiple vein insertions.

·Ease of Movement of IV placement site without the risk of puncture of the vein.

·Biocompatible products.

Clinical Safety:

·Biocompatible products.

·Our device is a single use device.

·Our product is non-toxic, sterile & non-pyrogenic.

Performance characteristics:

·Easy puncture at a wide range of angles due to optimized back cut bevel.

·Sharp back cut bevel for minimal puncture trauma.

·Hygienic administration of medication without an extra needle or risk of needle stick injury.

·Transparent catheter material allows visual confirmation of flashback, aiding successful placement.

·Threaded Stopper with luer lock is used to stop blood spillage after infusion is stopped.