

INSTRUCTIONS FOR USE

MaisSafe™

I.V. CANNULA
with Injection Port & Wings

Intended Use:


The intended use of this product is access to the human circulatory system for introduction of fluids or medicament and/or Withdrawal of blood samples. It provides a closed path system of drug container & patients.


Materials Used:

PTFE/FEP/PUR, PP, PE, POM, Silicon Tube, Stainless Steel & BaSO₄
(BaSO₄: used for radio-opaque lining on catheter)

Indications:


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


 Non-Pyrogenic


 Latex Free

Contra Indication:-

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


 Do Not Reuse

 Medical Device

 Do Not Resterilize

Instructions for use:

- Carefully select and aseptically prepare the site.
- Select suitable size of I.V. Catheter/Cannula & inspect visually to ascertain that package is intact.
- Remove catheter from sterile packing and remove its needle cover.
- Grip the catheter from projection provided on hub.
- Perform venipuncture & check for flashback 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 catheter into the vein & discard the needle in an appropriate container.
- Connect to the I.V. Infusion line.
- Cover the puncture site with sterile dressing.
- Perform routine monitoring & venipuncture site maintenance according to medical norms.

 **Manufactured by:**
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Gurgaon, Haryana-122001 (INDIA)

 **EU REP**
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1030 Brussels, Belgium.

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Medical condition:

- To read "instruction for use" carefully before use of the product.
- The use of the product is restricted to a qualified doctor or a paramedic staff

Warnings:

- The product should not be reprocessed.
- Improper transport and handling may cause structural and/or functional damage to device or packaging.
- The product is non-toxic, sterile & non-pyrogenic.
- Do not Clean or resterilize.
- Do not expose to heat or direct sunlight.
- The product should be used immediately after opening the packaging.
- If the device is reused, then it may cause bacterial infection to the patient.
- **MAIS INDIA disclaims any responsibility for possible consequences resulting from improper use.**

Caution:

- Never try to reinsert a partially or completely withdrawn needle.
- Do not use if package is damaged.
- Discard after single use.


Target Age Group: For All age groups


Duration of Contact of Device : Up to 72 Hours for best performance.


Storage condition: Cool & Dry Place

Device Life: 05 Years


CE 0123

 CE Notified Body No.


 Catalogue Number


 Lot No./ Batch No.


 Manufacturer

 Date of Manufacturing


 Use By / Expiry Date

 Consult Instructions for Use

 Temperature limit
(Upper 40°C and lower 10°C)

 Country of manufacture

 Keep Away From Sunlight

 Humidity limitation
(Upper 60% & Lower 40%)

 Keep Dry


 Caution

 Do Not Use If Package is Damaged

 Sterilized By Ethylene Oxide

 Authorised Representative
In The European Union

 Single Sterile Barrier System

 Unique Device Identifier

 Product Manual (Booklet)