IFU of MAISPEN™

I.V. Cannula/Catheter
(without Injection Port & without Wings)

Manufactured by Mais India Medical Devices Pvt. Ltd.

General Device Description: MAISPEN™ (I.V. Cannula/Catheter) comprises of a short flexible plastic tube (the Catheter) made up of Polyurethane (PUR) or Polytetrafluoroethylene (PTFE), or Fluorinated Ethylene Propylene (FEP) that is inserted into a vein over a hollow introducer needle, after which the needle is withdrawn and discarded.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: MAISPEN™ (I.V. Cannula/Catheter)

Brand Names: MAISPEN™

Variants:
1. I.V. CANNULA WITHOUT INJECTION PORT AND WINGS - MAISPEN™

Intended Use:
MAISPEN™ (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:
Polypropylene (PP), Stainless Steel (SS304), FEP/PUR/PTFE (Fluorinated Ethylene Propylene /Polyurethane / Polytetrafluoroethylene), Polyoxymethylene (POM), Polyethylene (PE), BaSO4.

Indications:
·Infusion of I.V. Solutions.
·Intermittent administration of intravenous drugs.

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
14G	Orange
16G	Grey
17G	White
18G	Green
20G	Pink
22G	Blue
24G	Yellow
26G	Violet

Instructions for use:
1. Sanitize 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 MAISPEN™ (I.V. Cannula/Catheter) based on patient's age group at the discretion of a Qualified doctor or a paramedic.
8. Remove the cannula by removing the needle cover ensuring not to touch the needle.
9. Do not touch the catheter.
10. Hold the MAISPEN™ (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 MAISPEN™ (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.

Accessories which can be used with the device:

MAISPEN™ I.V. Cannula / Catheter can be used along with the connecting accessories such as three-way stopcocks and other infusion devices.

Warnings:

1. The use of this product is restricted to a qualified doctor or a paramedic.
2. Read instructions before use.
3. MAIS INDIA disclaims any responsibility for possible consequences resulting from improper use.
4. The product should not be reprocessed.
5. Visually inspect and carefully check the product and packaging before use.
6. Improper transport and handling may cause structural and/or functional damage to device or its packaging.
7. The product is non-toxic, sterile & non-pyrogenic.
8. Do not clean or re sterilize. For single use only. Discard after use.
9. Re-use of single-use devices creates a potential risk (i.e bloodstream infection) to patient or user.
10. If the device is reused, then it may cause a bacterial infection in patient, and also may lead to contamination and/or impairment of functional capability, which may in turn lead to patient injury.
11. Reinsertion of the needle into the catheter may cause catheter damage or embolism.
12. If there is any change in expected performance of the device or in case of any malfunction, the device should be removed and returned to the manufacturer for investigation.
13. Store in a cool & dry place.
14. Do not expose to heat or direct sunlight.
15. The product should be used immediately after its packaging is opened.

Cautions:

· Never try to reinsert a partially or completely withdrawn needle. Discard the partially or completely withdrawn needle and use a new device.

· In case of non-detection of flashback, if flashback is not observed, suggesting venipuncture failure, remove the cannula and dispose as per hospital norms and re-try with new device instead of the used one.

· Do not use if the packaging is damaged.

· During removal of catheter after its intended purpose, precautions must be taken as

a- Ensure that any sharp edges (Blade and scissors) must not be used to remove the I.V. Fixator.

· Discard after single use.

Potential Side Effects:

·If the **MAISPEN™ (I.V. Cannula/Catheter)** is used for an extended period of time there are chances of ulcer formation, phlebitis and thrombophlebitis.

· Chances of redness or tenderness at the site, where the tip of the catheter is located.

· Improper care or placement of the MAISPEN™ (I.V. Cannula / Catheter) can lead to hematoma.

Disposal Instructions:

The unused device can be safely be disposed of as normal hospital waste in a 'Sharps' container. The used device should be disposed of as 'hospital contaminated waste' – typically incinerated or as per safe hospital practices, as improper disposal can lead to a bio-hazard.

Duration of use:

Short-term duration (Normally intended for continuous use for a duration ranging from 60 minutes to 30 days). [Note: Generally, to be used for up to 72 hours for best performance].

Storage Conditions:

Store in a Cool & Dry Place.
Keep away from sunlight
Temperature: +10°C to +40°C

Shelf life:

5 Years

Lifetime:

Short-term (continuous use for between 60 minutes - 30 days)
(Once inserted, the device shall be used for up to 72 hours, for best performance)

Type of Sterilization:

EO sterilization

Notice to Users and/ or Patients:

Any serious incident that has occurred in relation to the device, should be reported to the Manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

Explanation of symbols used:

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Consult instructions for use (Indicates the need for the user to consult the instructions for use)		Latex free (Indicates a medical device that is Latex free)
	Caution (To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.)		Date of manufacture (Indicates the date when the medical device was manufactured)

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Sterilized using ethylene oxide (Indicates a medical device that has been sterilized using ethylene oxide)		Use-by date (Indicates the date after which the medical device is not to be used)
	Do not re-sterilize (Indicates a medical device that is not to be re-sterilized)		Batch Number (Indicates the manufacturer's batch number so that the batch or lot can be identified)
	Do not re-use (Indicates a medical device that is intended for one single use only)		CE Mark (CE Marking with Notified Body Number)
	Non-pyrogenic (Indicates a medical device that is non- pyrogenic)		Keep away from sunlight (Indicates a medical device that needs protection from light sources)
	Do not use if packaging is damaged and consult instructions for use. (Indicates a medical device that should not be used if its packaging has been damaged or opened, and that the user should consult the instructions for use for additional information)		Authorized representative in the European Union / European Community (Indicates the authorized representative in the European Union / European Community) OBELIS S.A. Boulevard Général Wahis 53, 1030 Brussels, Belgium Contact Number: +32(2)73 25 954 Email ID: regulatory@obelis.net Website: www.obelis.net
	Keep dry (Indicates a medical device that needs to be protected from moisture)		Manufacturer (Indicates the medical device manufacturer) Manufacturing Unit: 525P, Sector-37, Pace City II, Gurgaon, Haryana-122001, India. Contact Details.: +91 8527589990 Fax No.: 0124 404 7533 Email ID: info@maisindia.com Website:www.maisindia.com
	Single sterile barrier system (Indicates a single sterile barrier system)		Country of manufacture (To identify the country of manufacture of products)
	Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information)		Medical device (Indicates the item is a medical device)
	Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified)		Temperature limit (Indicates the temperature limits to which the medical device can be safely exposed.
	This way up		Fragile, handle with care (Indicates a medical device that can be broken or damaged if not handled carefully)

Manufactured by:
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