

INSTRUCTIONS FOR USE

Doc. No.: SPM/TF- CE/ IVC- Safety/ IFU/ 02- Rev. 03. Date: 27/02/2026






INSTRUCTION FOR USE

SAFETY IV CANNULA

Manufacturer: SPM MEDICARE PVT. LTD

Unit-I - B-40, Phase-II, Noida, Gautam Budh Nagar, UP-201305 Unit -III – Industrial Building Plot no. 26, Sector 158, Noida, Gautam buddha, Uttar Pradesh, 201305

 DATE: 27-02-2026	 DATE: 27-02-2026	 DATE: 27-02-2026
Prepared By Executive- QARA	Reviewed By Head-RA	Approved By Managing Director/Auth. Signatory

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Follow manufacturer’s instructions for use and institutional procedures for IV Cannula

PRODUCT NAME: IV Cannula with Safety Feature (with/without wing; with/without injection port)

DESCRIPTION:

The SPM Safety IV Cannula is a sterile, single-use, peripheral intravenous catheter intended to provide short-term vascular access for the administration of fluids, medications, blood products, or for blood sampling.

The device consists of a sharp stainless-steel introducer needle integrated with a flexible catheter manufactured from Polyurethane (PUR) or Fluorinated Ethylene Propylene (FEP), depending on the variant. The catheter is mounted on a hub assembly compatible with standard Luer connectors in accordance with EN ISO 80369-7, ensuring secure connection to intravenous administration sets or infusion systems.

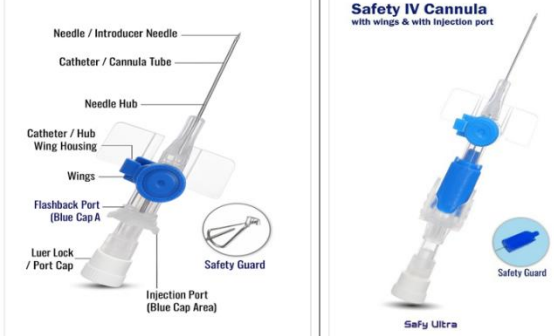
The Safety IV Cannula incorporates a passive or active needle safety mechanism designed to automatically shield or retract the needle immediately after withdrawal from the patient’s vein, thereby reducing the risk of needlestick injury to healthcare professionals. Variants equipped with a flashback chamber include a hydrophobic filter that allows air venting while preventing blood leakage and supports clear visualization of blood flashback during venipuncture to confirm successful vascular access.

The stainless-steel needle features a precision-engineered beveled tip to facilitate smooth and controlled insertion. Once venous access is confirmed by blood flashback, the catheter is advanced into the vein and the needle is withdrawn, activating the safety mechanism.

The device is color-coded according to gauge size for easy identification and selection.



The SPM Safety IV Cannula is sterilized by Ethylene Oxide (EO), supplied in a validated sterile barrier system, and is non-pyrogenic, latex-free, and DEHP-free. It is intended for single use only.

IMAGE OF THE DEVICE:

Sr. No	Device Name	Product Images
1	IV CANNULA WITH INJECTION PORT WITH WINGS WITH SAFETY FEATURE	

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2	IV CANNULA WITHOUT WING WITHOUT INJECTION PORT WITH SAFETY FEATURE	 <p style="font-size: small;">Safety IV Cannula without wings & without injection port</p> <p style="font-size: x-small;">Safety Super</p>	 <p style="font-size: small;">Safety IV Cannula without wings & without injection port</p> <p style="font-size: x-small;">Safety Libre</p>
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DEVICE VARIANTS:

Basic UDI-DI: 89043798IVC78

Device Description	Catheter Type
IV CANNULA WITH INJECTION PORT WITH WINGS WITH SAFETY FEATURE	PUR catheter/ FEP RO catheter
IV CANNULA WITHOUT WING WITHOUT INJECTION PORT WITH SAFETY FEATURE	PUR catheter/ FEP RO catheter

- ✓ Available in different gauge size with identical colour coded body.

INTENDED USE:

The IV Cannula is a sterile, single use medical device intended to provide peripheral vascular access for short term use.

INDICATIONS FOR USE:

- Phlebotomy (blood sampling)
- Infusion of IV solution
- Provide nutritional support
- Maintain hydration and/or correct dehydration
- Administration of intravenous medications.

INTENDED PATIENT POPULATION:

IV Cannula is intended to be used in patients, irrespective of age and gender. Selection of appropriate gauge size and insertion site shall be determined by the trained healthcare professional based on the patient’s age, vein condition, clinical status, and prescribed therapy.

INTENDED USER:

IV Cannula is intended to be used by the trained healthcare professionals like doctors, paramedics, or nursing staff.

INTENDED USE ENVIRONMENT:

IV Cannula is intended to be used in healthcare environments, including hospitals, clinics, and emergency care settings.

CLINICAL BENEFITS:

- Provides reliable short-term peripheral venous access.
- Enables controlled administration of intravenous fluids, medications, blood products,

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and nutritional solutions as prescribed.

- Reduces repeated venipuncture when ongoing therapy is required.
- Supports maintenance of hydration and therapeutic management through secure venous access.
- The clinical benefits are consistent with the intended purpose and established clinical practice for peripheral intravenous catheterization.

PRINCIPLE OF OPERATION:

The IV Cannula provides access to the peripheral venous system. The introducer needle enables insertion into the vein. After venous entry is confirmed by blood flashback, the flexible catheter is advanced into the vein and the needle is withdrawn.

The catheter hub incorporates a Luer connection compatible with standard infusion systems in accordance with EN ISO 80369-7.

PERFORMANCE CHARACTERISTICS:

The IV Cannula is designed and tested in accordance with EN ISO 10555-1 (Intravascular Catheters – Sterile and Single-Use Catheters – General Requirements) and EN ISO 80369-7 (Luer Connectors).

Performance characteristics include:

- Catheter tensile strength and bond strength
- Leak resistance
- Flow rate performance
- Radiopacity (where applicable)
- Needle integrity and sharpness
- Flashback visualization
- Luer connection compatibility

The device complies with applicable mechanical, physical, and functional performance requirements under the above standards.

MATERIAL USED:

Element	Material	Composition / Grade
Threaded Stopper (Luer Lock)	High-Density Polyethylene (HDPE)	Medical Grade HDPE
Flashback Chamber (Hub Cover)	Polypropylene (PP)	Medical Grade PP (110)
Needle Hub	Polypropylene (PP)	Medical Grade PP (110)

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Port Cap (If required)	Polypropylene (PP)	Medical Grade PP (2120)
Silicone Tube	Silicone Rubber	Medical Grade Silicone Elastomer
Wing Housing (Wing Body)	Polypropylene (PP)	Medical Grade PP (2120)
Needle Cover	Polypropylene (PP)	Medical Grade PP
Teflon Holder (Slip Ring)	Poly Acetal (POM)	Medical Grade POM (Polyoxymethylene)
Catheter	Fluorinated Ethylene Propylene (FEP)	Medical Grade FEP
Catheter (Alternative Variant)	Polyurethane (PUR)	Medical Grade PUR
Needle (Cannula)	Stainless Steel (SS)	AISI 304
Metal Clip	Stainless Steel (SS)	AISI 304
Safety Guard	Poly Acetal (POM)	Medical Grade POM (Polyoxymethylene)

- This device does not contain natural rubber latex.
- This device does not contain phthalates, including DEHP.
- The stainless-steel needle may contain trace amounts of nickel. Patients with known hypersensitivity to nickel should be evaluated prior to use.

CONTRAINDICATIONS:

- Hypersensitivity to any material used in the device.
- Not intended for central venous access.
- Avoid insertion in areas of infection, inflammation, oedema, thrombosis, or previously damaged veins.
- Not suitable for administration of highly viscous fluids incompatible with peripheral venous access.

POTENTIAL COMPLICATIONS:

Possible complications associated with peripheral intravenous catheterization may include:

- Local infection or systemic infection
- Phlebitis
- Infiltration or extravasation
- Thrombosis
- Catheter embolism due to catheter damage

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- Air embolism
- Hematoma
- Needlestick injury

The likelihood of these complications can be reduced through adherence to proper aseptic technique and institutional protocols.

RESIDUAL RISKS:

Despite design controls, material selection, verification testing, and compliance with applicable standards, certain residual risks such as phlebitis, infiltration, extravasation, thrombosis, infection, catheter embolism, air embolism, or needlestick injury may remain during clinical use.

These risks are inherent to peripheral intravenous catheterization procedures and can be minimized through proper aseptic technique, correct insertion method, secure fixation, monitoring of the insertion site, and adherence to institutional protocols.

All identified residual risks have been evaluated through the manufacturer's risk management process in accordance with EN ISO 14971. The overall residual risk is considered acceptable when weighed against the clinical benefits of the device.

INSTRUCTIONS FOR USE:

- Inspect the sterile pouch before use. Do not use if the packaging is damaged, opened, or if the device appears defective.
- Open the pouch using aseptic technique.
- Remove the protective needle cover carefully without touching the needle.
- Hold the cannula securely at the injection port and needle hub.
- Insert the cannula into the vein at a low angle in accordance with institutional protocol and standard clinical practice.
- Upon observing blood flashback in the flashback chamber, advance the catheter slightly to ensure proper placement within the vein.
- Stabilize the catheter hub and gently withdraw the needle completely while keeping the catheter in place.
- Confirm that the safety mechanism (safety clip/guard) is fully activated and that the needle tip is completely covered. Do not attempt to reinsert the needle.
- Secure the catheter according to hospital protocol and connect the infusion line or needle-free connector as required.
- Dispose of the used needle immediately in an approved sharps container in accordance with local regulations and institutional policy.

HOW SUPPLIED:

The IV Cannula is supplied sterile, single-use, in a validated single sterile barrier system (blister pack) with protective outer packaging.

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The sterile barrier system has been validated to maintain sterility for the declared shelf life when stored under recommended conditions.

Each package is labelled with the device description, gauge size, batch number, date of manufacture, expiry date, and UDI carrier.

WARNINGS:

- The use of this product is restricted to a trained doctor or a paramedic.
- The product should be used according to the instructions for use. SPM Medicare disclaim any responsibility for possible consequences resulting from improper use.
- Store in dry & cool place. Do not expose to heat or direct sunlight.
- The product should not be reprocessed.
- Visually inspect and carefully check the product and packaging before use because improper transport and handling may cause structural and / or functional damage to device or packaging.
- The product is non-toxic, sterile & non-pyrogenic till the package has not been opened or damaged.
- Do not clean or resterilise the product after opening the packet.
- The product should be used immediately after opening the packaging.
- Perform routine monitoring & venipuncture site maintenance according to medical norms.
- Do not reinsert partially or completely withdrawn needle.
- Dispose off the device as per applicable local, state & country laws and regulations.
- Discard after single use.

PRECAUTIONS:

- Inspect the sterile package and device integrity before use. Do not use if the package is open or damaged.
- Select appropriate gauge size based on patient condition and prescribed therapy.
- Maintain strict aseptic technique during insertion and handling.
- Avoid excessive force, bending, crushing, or crimping of the catheter during use.
- Monitor the insertion site regularly for signs of complications.
- Single use only. Do not re-sterilize.
- Do not use after the expiry date indicated on the packaging.

CAUTIONS:

- Store in a cool and dry place
- Discard after single use
- Do not use if the package is open or damaged
- Do not store at extreme temperature and humidity
- Dispose the blood/medicine contaminated product as per local applicable laws.

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STORAGE:

- Store at a temperature between 10°C and 40°C in a dry environment.
- Keep away from direct sunlight, moisture, and excessive humidity.
- Do not expose to extreme heat or freezing conditions.

STERILITY INFORMATION:

- This device is supplied sterile and is sterilized using Ethylene Oxide (EO).
- The Sterility Assurance Level (SAL) is 10^{-6} .
- The sterile barrier system has been validated in accordance with EN ISO 11607-1 and EN ISO 11607-2 to ensure maintenance of sterility until the stated expiry date when stored under the recommended storage conditions.
- Do not use if the sterile barrier is damaged or compromised.

EXPIRATION PERIOD:

The IV Cannula has a validated shelf life of **5 years from the date of manufacture**, when stored under the recommended storage conditions stated above.

Do not use the device after the expiry date indicated on the packaging.

The expiry date refers to the sterility and performance of the unopened sterile barrier system.

RETURN OF DAMAGED PRODUCT:

Return the product in its original packing identified by the batch number, purchase information, your reference and reason for return. Please contact your local distributor office regarding product return/exchange.

DISPOSAL OF THE USED DEVICE:


- Disposal of the used product should be done according to hospital procedures, State Regulations, National legislation or regional legislation.
- Device should be disposed after use on individual patient during a single procedure.
- Disposal of the packaging material should be done as biomedical waste.
- Any open packaging should be done as biomedical waste.
- Leftover products should be disposed as biomedical waste.

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REPORTING OF SERIOUS INCIDENTS:








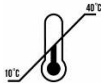
Any serious incident that has occurred in relation to this device must be reported without delay to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established, in accordance with Article 87 of Regulation (EU) 2017/745.

 Manufacturer: SPM Medicare Pvt, Ltd B-40, Phase-II, Noida, Gautam Buddha Nagar, Uttar Prades-201305, India. Manufacturing Site 1- B-40, Phase-II, Noida, Gautam Buddha Nagar, Uttar Prades-201305, India. Manufacturing Site 2- Industrial Building Plot no 26, Sector 158, Noida, Gautam buddha, Nagar, Uttar Pradesh, 201305 India. SRN - IN-MF-000011829 Customer care: No.: +91-840-7070-718 Email: info@spmmedicare.com Web Site: www.spmmedicare.com	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; width: 20px;">EC</td> <td style="text-align: center; width: 20px;">REP</td> <td style="text-align: center;">AUTHORIZED REPRESENTATIVE</td> </tr> <tr> <td colspan="3"> MEDDEVICES LIFESCIENCES B. V. Kraijenhoffstraat, 482, 1017 EG Amsterdam, Netherlands. Customer Care No.: +31202254558 Email: info@meddevices.net </td> </tr> </table>	EC	REP	AUTHORIZED REPRESENTATIVE	MEDDEVICES LIFESCIENCES B. V. Kraijenhoffstraat, 482, 1017 EG Amsterdam, Netherlands. Customer Care No.: +31202254558 Email: info@meddevices.net		
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Revision History:

















Rev. No	Reason for Change	Date	Approval
00	Initial Release	13-04-2024	Managing Director
01	Update in instruction	10/26/2024	Managing Director
02	MDD to MDR Update	26/05/2025	Managing Director
03	Updated Instruction, intended use, Performance Characteristic and Sterility information	27/02/2026	Managing Director

EXPLANATION OF SYMBOLS:

Symbol	Explanation	Symbol	Explanation
	Caution		Catalogue Number
	Manufacturer		Batch code
	Date & Country of manufacturer		Use-by date
	Do not re-sterilize		Temperature Limit

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	Consult instructions for use		Do not use if package is damaged and consult <i>instructions for use</i>
	Keep away from sunlight		Non-Pyrogenic
	Do not re-use		Sterilized using Ethylene Oxide
	Keep dry		Handle with care
	This side up		Maximum stacking
	Do not use hook		Recycling
	Medical Device		Model number
	Unique Device Identifier		Single Sterile Barrier System