INSTRUCTIONS FOR USE

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

INSTRUCTION FOR USE

IV CANNULA

Manufacturer: SPM MEDICARE PVT. LTD
Address: 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/without wing; with/without small wing, with/without injection port; with/without Hydrophobic Filter)

DESCRIPTION:

The SPM IV Cannula is a sterile, single-use, peripheral intravenous catheter intended to provide short-term vascular access.

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

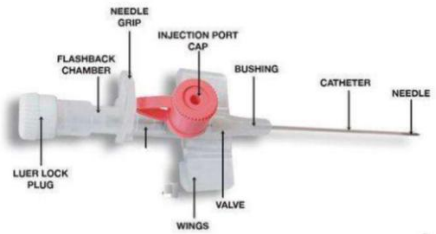
Variants incorporating a flashback chamber include a hydrophobic filter to facilitate air venting and support visualization of blood flashback during venipuncture.

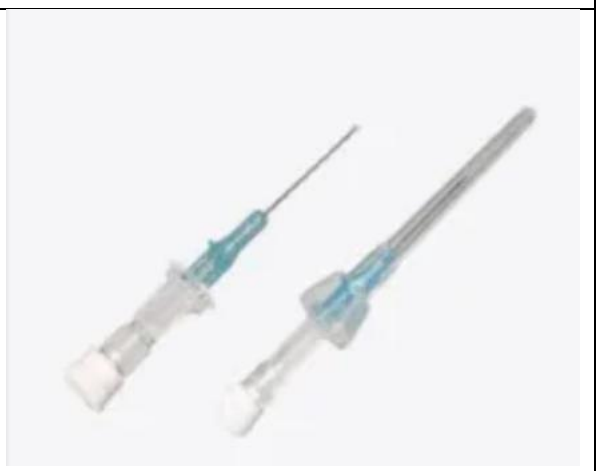
The smooth, bevelled stainless-steel needle is designed to enable controlled insertion into the vein. Upon confirmation of venous access by blood flashback, the catheter is advanced into the vein and the needle is withdrawn and safely discarded.

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

The IV Cannula is sterilized using Ethylene Oxide (EO), supplied in a validated sterile barrier system, and is non-pyrogenic, latex-free, and DEHP-free.

IMAGE OF THE DEVICE:

Sr. No	Device Name	Product Images
1	IV CANNULA WITH WING WITH INJECTION PORT	
2	IV CANNULA WITHOUT INJECTION PORT WITHOUT WINGS & WITH HYDROPHOBIC FILTER	

3	IV CANNULA WITHOUT INJECTION PORT WITH SMALL WINGS	
4	IV CANNULA WITHOUT PORT & WITHOUT WINGS	

DEVICE VARIANTS:

Basic UDI-DI: 89043798IVC78

Device Description	Catheter Type
IV CANNULA WITH WING WITH INJECTION PORT	PUR catheter/ FEP RO catheter
IV CANNULA WITHOUT INJECTION PORT WITHOUT WINGS WITH HYDROPHOBIC FILTER	PUR catheter/ FEP RO catheter
IV CANNULA WITHOUT INJECTION PORT WITH SMALL WINGS	PUR catheter/ FEP RO catheter
IV CANNULA WITHOUT PORT & WITHOUT WINGS	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, 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:

Component	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)
Port Cap (If required)	Polypropylene (PP)	Medical Grade PP (2120)
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
Hydrophobic Filter	PTFE (Polytetrafluoroethylene)	Medical Grade

- 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
- 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 product packaging. Do not use it if the packaging and device is damaged or not intact.
- Open pouch using aseptic technique.
- Remove the needle cover carefully.
- Hold cannula at injection port and needle hub.
- Insert the cannula into the vein at a low angle according to institutional protocol and standard clinical practice.
- Once blood flashback is observed, advance the catheter slightly into the vein.
- Stabilize the catheter and gently withdraw the needle completely. **Do not reinsert the needle once withdrawn**, as this may damage or puncture the catheter.
- Secure catheter and connect infusion line or needle-free connector.
- Dispose of the needle immediately in an approved sharps container.

HOW SUPPLIED:

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

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.

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.

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.

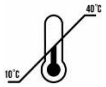
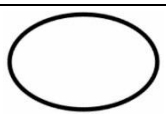
Manufacturer: **SPM Medicare Pvt, Ltd** B-40, Phase-II, Noida, Gautam Buddha Nagar, Uttar Prades-201305, India. **Manufacturing Site 1-** B-40, Phase-II, Noida, Gautam Buddha Nagar, Uttar Prades-201305, India. **Manufacturing Site 2-** Industrial Building Plot no 26, Sector 158, Noida, Gautam buddha, 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	EC REP **AUTHORIZED REPRESENTATIVE** MEDDEVICES LIFESCIENCES B. V. Kraijenhoffstraat, 482, 1017 EG Amsterdam, Netherlands. Customer Care No.: +31202254558 Email: info@meddevices.net

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
	Consult instructions for use		Do not use if package is damaged and consult *instructions for use*
	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