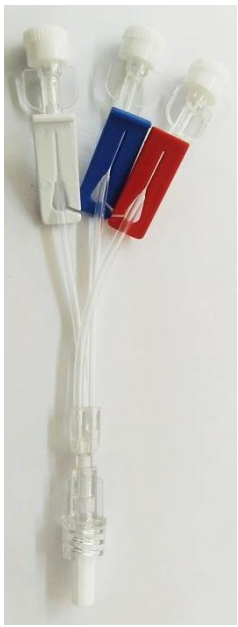
PRODUCT NAME: Extension line with/ without Needle-free Valve

DESCRIPTION:

The SPM's Extension line with/ without Needle-free Valve is a sterile, single-use, Extension line with or without Needle-free Valve. The Extension line is available in single or multi-Way. The multi-way extension line allows the administration of fluids or medications. The extension line with/without needle-free valve is sterilized by ethylene oxide.

IMAGE OF THE DEVICE:

One/Two/ Three-way with Needle-free connector without Needle-free connector



Two/ Three-way

DEVICE VARIANTS:

Product Name	Extension Tubing Length (Available)
Extension line with/ without Needle-free Valve	Two-way without Needle-free connector
Extension line with/ without Needle-free Valve	Three-way without Needle-free connector
Extension line with/ without Needle-free Valve	One-way with Needle-free connector
Extension line with/ without Needle-free Valve	Two-way with Needle-free connector
Extension line with/ without Needle-free Valve	Three-way with Needle-free connector

INTENDED PURPOSE:

Extension line is used to extend the infusion line during administration of IV fluid. It also provides a pressure monitoring aid and also enables multi-drug administration.

INDICATIONS FOR USE:

N. R. Dukare. DATE: 26/05/2025	DATE: 26/05/2025	DATE: 26/05/2025
Prepared By Senior Executive- QA	**Reviewed By QA- MR**	**Approved By Manager- RA/QA**

- SPM's Extension line with/without Needle-free connector is intended use to connection and extension infusion or transfusion sets for administration liquids or medications into the circulation system by using of intravenous catheter and cannula.

INTENDED PATIENT POPULATIONS:

Extension line with/without Needle-free connector is intended to be used in patients irrespective of age and gender.

INTENDED USERS:

Extension line with/without Needle-free connector is intended to be used by the trained healthcare professionals including doctors, registered practitioners, and paramedics or nursing staff.

INTENDED USE ENVIRONMENT:

Extension line with/without Needle-free connector is intended to use in healthcare environments like hospitals and clinics.

CLINICAL BENEFITS:

- The transparent, smooth and kink-resistant PVC tube (latex-free) allows seamless connection
- 6% taper in luer lock allows connection with a variety of medical devices.
- The needle free valve ensures the leak-proof drug administration.

PRINCIPLE OF OPERATION:

The Extension line with/without Needle-free connector allows the extension of the vascular access device like infusion set, cannula, etc. It offers more flexibility and convenience during treatments. The Needle-free/ Luer connector offers leak-proof administration of more than one drug using a standard device like Luer lock/Luer slip syringe.

PERFORMANCE CHARACTERSTICS:

- Interoperability with other vascular access devices like infusion set or IV cannula.
- Extension line with/without Needle-free valve which allows leak proof administration of IV fluid or medications.

MATERIAL USED:

- Tube - PVC
- Luer Connector- Poly Carbonate
- Luer cap- Poly Propylene
- Slide Clamp - LDPP
- Needle free valve – Poly Carbonate

N. R. Dukare.		
DATE: 26/05/2025	DATE: 26/05/2025	DATE: 26/05/2025
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CONTRAINDICATIONS:

Sr. No	Contraindications	Description
1	Allergy to Extension line Materials	Patients with known allergies or sensitivities to materials in the Extension line (e.g., specific plastics) should avoid using the device to prevent allergic reactions.
2	Infection	In patients with active infections or conditions that increase infection risk, using a contaminated or improperly sterile Extension line could exacerbate their condition.
3	Incompatible Medications or Fluids:	Avoid using the Extension line for fluids or medications that are incompatible with the materials of the extension line, as this could lead to chemical reactions or reduced efficacy.
4	Existing Vascular Conditions:	Patients with specific vascular conditions or anatomical abnormalities may be at increased risk of complications or may require different Extension line equipment.
5	Device Misuse:	If the Extension line is damaged or used incorrectly, it could lead to improper dosing or injury. Ensure the device is used according to manufacturer instructions.

POTENTIAL COMPLICATIONS:

Fluid leakage and cross-contamination, Difficulty turning, Incompatibility with medications, Blockage and obstruction, sterility breakdown, misalignment of ports, Material deterioration, and limited durability in high-pressure.

INSTRUCTIONS FOR USE:

- **Step 1.** Insert the syringe tip into the valve.
- **Step 2.** For securing the connection:
  - For Luer Slip syringe: Insert and rotate 1/4 turn
  - For Luer lock syringe: turn syringe clockwise
- **Step 3.** Inject or Aspirate the fluid.
- **Step 4.** To Disconnect, Remove the luer from the valve by turning counter clockwise.

HOW SUPPLIED

The Extension line with/without Needle-free valve is supplied in sterile, single-use Paper pouch packaging, complete with instructions for use and necessary accessories (if any).

WARNINGS

- **For Professional Use Only:** This device must be used only by trained healthcare professionals
- **Sterile Packaging:** Do not use if the packaging is damaged or opened prior to use.
- **Single Use Only:** The device is designed for single use. Do not reuse or re-sterilize.
- **Proper Handling:** Handle with care to avoid damage to the device, which could compromise its sterility and functionality.

- **Allergic Reactions:** Check patient history for allergies to materials in the Extension line.
- **Inspect Before Use:** Ensure all components are present and undamaged before use
- **Follow Instructions:** Carefully follow the included instructions for use to avoid complications
- **Dispose Properly:** Dispose of the device in accordance with local regulations for medical waste.

PRECAUTIONS:

- Check the integrity and functionality of the device before use. Do not use if the package is open or damaged.
- Determine patient's condition and vitals status during device application / Operation.
- When handling the product care should be taken to avoid damage from handling. Avoid crushing and crimping damage to the product due to application of surgical instruments such as forceps, etc.
- Conduct procedure under strict surgical protocol and ensure complete asepsis.
- Do not Re-sterilize. Do not Re-use.
- Single use only.
- Do use after the Expiry Date

⚠ **CAUTIONS:**

- Store in a cool and dry place
- Discard after single uses
- Do not use if the package is open or damage
- Do not store at extreme temperature and humidity
- Do not use if the protective cap is detached.
- Always swab the top of the female connector with a sterile 70% IPA, wipe 1 or 2 second and allow to dry for 30 seconds.
- Do not leave slip luer syringe unattended.

STORAGE:

Stored at controlled temperature (10-40°C). Do not store at freezing temperature.

EXPIRATION PERIOD:

The device has a shelf life of 5 years from the date of manufacturing. The product should not be used after the indicated sterility expiration date.

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.

N. R. Dukare. DATE: 26/05/2025	DATE: 26/05/2025	DATE: 26/05/2025
Prepared By Senior Executive- QA	**Reviewed By QA- MR**	**Approved By Manager- RA/QA**

DISPOSAL OF THE USED DEVICE:

- Disposal of the used product should be done according to hospital procedures, State Regulations, National 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:

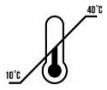
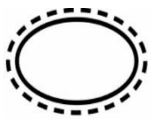
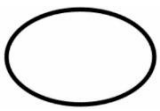
In case of any adverse events and/or potential threat/ complications that may reasonably by regarded as product related and that were not previously expected in nature, severity or occurrence, contact the manufacturer or authorized representative and competent authority of the member state where the user and/or patient is established.

LEGAL MANUFACTURER AND MANUFACTURING FACILITY	
Manufacturer: **SPM Medicare Pvt, Ltd** B-40, Phase-II, Noida, Gautam Buddha Nagar, UP-201305, India. **Manufacturing Site 1-** B-40, Phase-II, Noida, Gautam Buddha Nagar, UP-201305, India. **Manufacturing Site 2-** Industrial Building Plot no 26, Sector 158, Noida, Gautam buddha, Nagar, Uttar Pradesh, 201305. Customer care: No.: +91-840-7070-718 Email: info@spmmedicare.com Web Site: www.spmmedicare.com	**AUTHORIZED REPRESENTATIVE** EC REP MEDDEVICES LIFESCIENCES B. V. Kraijenhoffstraat, 482, 1017 EG Amsterdam, Netherlands. Customer Care No.: +31 202254558 Email: info@meddevices.net

EXPLANATION OF SYMBOLS:

Symbol	Explanation	Symbol	Explanation
	Caution		Catalogue Number
	Manufacturer		Batch code

N. R. Dukare. DATE: 26/05/2025	DATE: 26/05/2025	DATE: 26/05/2025
Prepared By **Senior Executive- QA**	**Reviewed By** **QA- MR**	**Approved By** **Manager- RA/QA**

	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
	The device is latex-free		Single Sterile Barrier System with protective packaging outside
	Medical Device		Model number
	Unique Device Identifier		Single Sterile Barrier System
	Biological risks		

N. R. Dukare.		
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