

**PRODUCT NAME:** Extension/ Pressure Monitoring line (Accu-Line)

**DESCRIPTION:**

The SPM's Accu-Line is a sterile, single-use, Pyrogen-free Extension line. The Extension line is available in different lengths ranging from 10cm to 250cm PVC Tube. The Extension Line consists of male luer on both ends. The device is ethylene oxide sterilized.

**IMAGE OF THE DEVICE:**



**DEVICE VARIANTS:**

Product Name	Extension Tubing Length (Available)
SPM's Accu-Line Extension Line	10cm, 25cm, 50cm, 100cm, 150cm, 200cm and 250cm

**INTENDED PURPOSE:**

Extension Line is used to extend the infusion line during administration of IV fluid. It also provides a pressure monitoring aid.

**INDICATIONS FOR USE:**

- SPM's Extension Line is intended use to connection and extension infusion or transfusion sets for administration liquids or blood into the circulation system by using of intravenous catheter and cannula.
- Allow pressure monitoring.

**INTENDED PATIENT POPULATIONS:**

Accu-Line Extension line is intended to be used in patients irrespective of age and gender.

**INTENDED USERS:**

Accu-Line Extension line is intended to be used by the trained healthcare professionals including doctors, registered practitioners, and paramedics or nursing staff.

**INTENDED USE ENVIRONMENT:**

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Extension line is intended to use in 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.

**PRINCIPLE OF OPERATION:**

The Extension Line allows the extension of the vascular access device like infusion set, cannula or port, etc. It offers more flexibility and convenience during treatments. It also allows pressure monitoring.

**PERFORMANCE CHARACTERSTICS:**

- Interoperability with other vascular access devices like IV cannula or infusion set.
- The extension line allows pressure monitoring.

**MATERIAL USED:**

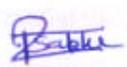
- Extension Tube - PVC
- Female Ports - Poly Propylene
- Luer Connector- HDPE
- Luer protecting cap- Poly Propylene

**CONTRAINDICATIONS:**

S.N	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 set 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.

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**INSTRUCTIONS FOR USE:**

- **Step 1.** Peel Open the pouch.
- **Step 2.** Unscrew the luer cap of three way stop cock female luer.
- **Step 3.** Connect male portion of I.V. Set with female luer of Three Way Stop cock.
- **Step 4.** Remove luer cap of male luer tubing.
- **Step 5.** Hold male luer of tubing upright and open clamp of I.V. Set and allow the solution to displace air entirely from tubing.
- **Step 6.** Close clamp.
- **Step 7.** Connect male luer of tubing to venepuncture device.

**HOW SUPPLIED**

The Extension Line is supplied in sterile, single-use Paper pouch packaging, complete with instructions for use and necessary accessories (if any).

**WARNINGS**

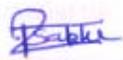
- **For Professional Use Only:** This device must be used only by trained healthcare professionals
- **Sterile Packaging:** Do not use if the packaging is damaged or opened prior to use.
- **Single Use Only:** The Extension line is designed for single use. Do not reuse or re-sterilize.
- **Proper Handling:** 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 Extension Line 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:** 

- Always check for leaks after changing the connection.
- 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

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- Dispose the blood contaminated product as per local applicable laws.

**STORAGE:**

Store at a 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.

**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.

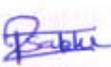
**REPORTING:**

In case of any adverse events and/or potential threat/ complications that may reasonably be 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.

<p><b><u>REGISTERED ADDRESS AND MANUFACTURING FACILITY</u></b></p>  SPM Medicare Pvt. Ltd. B-40, Phase-II, Noida, Gautam Budh Nagar, UP-201305, India. Customer Care No.: +91-840-7070-718 Email: <a href="mailto:info@spmmedicare.com">info@spmmedicare.com</a> Web Site: <a href="http://www.spmmedicare.com">www.spmmedicare.com</a>	<p><b><u>AUTHORIZED REPRESENTATIVE</u></b></p>  MEDDEVICES LIFESCIENCES B. V Kraijenhoffstraat, 482, 1017 EG Amsterdam, Netherlands. Customer Care No.: +31 202254558 Email: <a href="mailto:info@meddevices.net">info@meddevices.net</a>
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**EXPLANATION OF SYMBOLS:**

Symbol	Explanation	Symbol	Explanation
	Caution		Catalogue Number

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	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 <i>instructions for use</i>
	Keep away from sunlight		Non-Pyrogenic
	Do not re-use		Sterilized using EO
	Keep dry		Handle with care
	This side up		Maximum stacking
	Do not use hook		Biological risks
	Medical Device		Model number
	Unique Device Identifier		Single Sterile Barrier System
	Single Sterile Barrier System with protective packaging outside		Authorized representative in the European Community

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