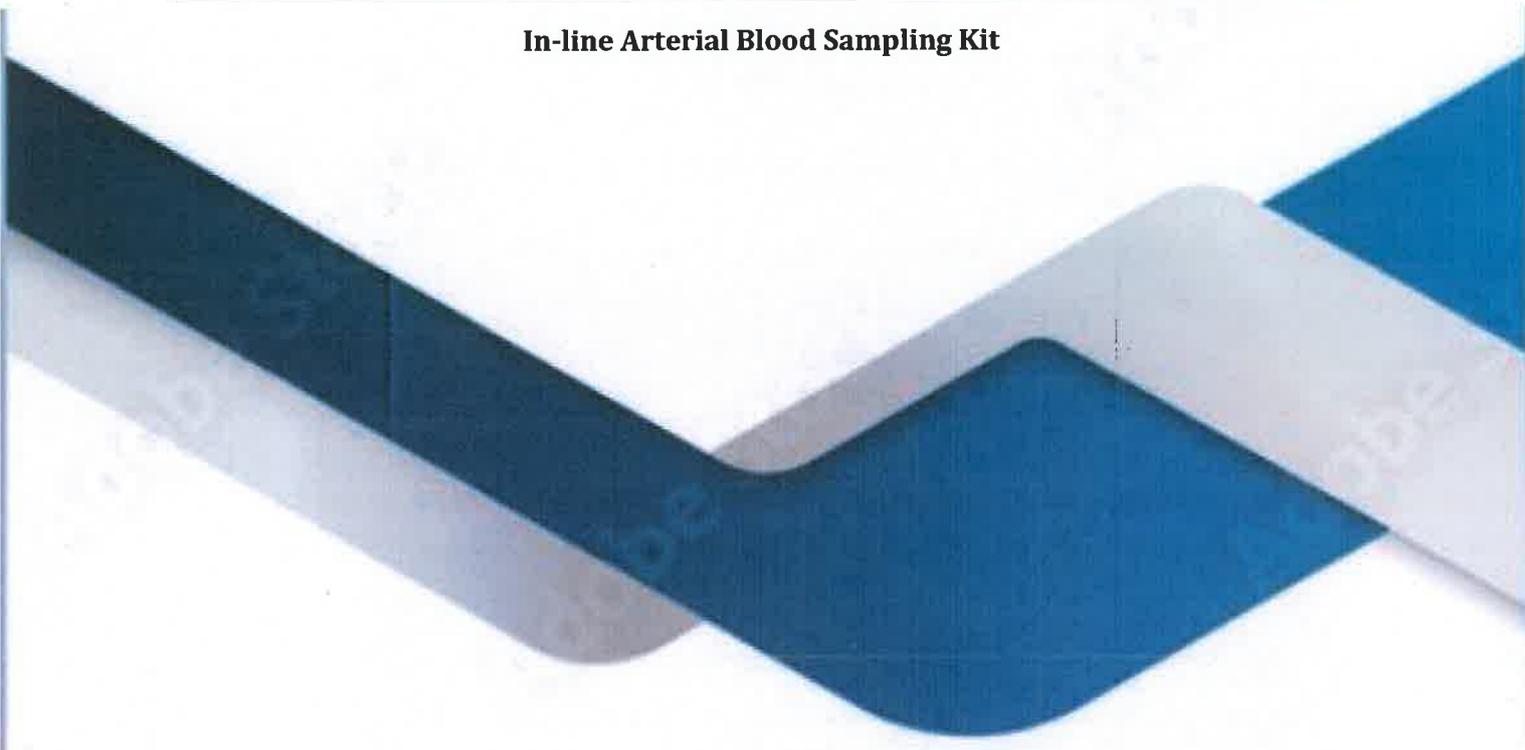




Technical IFU

In-line Arterial Blood Sampling Kit



 DATE: 26/05/2025 Prepared By Asst Manager QA	 DATE: 26/05/2025 Reviewed By RA- Manager	 DATE: 26/05/2025 Approved By Managing Director
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INSTRUCTIONS FOR USE

Doc. No.: SPM/TF- CE/ ABG Syringe- without needle/ 014. - Rev.02 Date: 26-05-2025

Follow manufacturer's instructions for use and institutional procedures for arterial blood sampling:

PRODUCT NAME: In-line arterial Blood sampling Kit (ABG Syringe) –with/ without Bubble filter (without Needle)

DESCRIPTION:

The SPM's In-line arterial Blood sampling Kit range is an In-line Arterial Blood Sampling Kit syringes are used for blood collection by manual aspiration and are supplied without needles. They are designed to be used for arterial blood collection from an arterial line.

Once the sample is obtained, care is taken to eliminate visible gas bubbles, as these bubbles can dissolve into the sample and cause inaccurate results. The sealed syringe is taken to a blood gas analyser. If a plastic blood gas syringe is used, the sample should be transported and kept at room temperature and analysed within 30 min. The SPM's "In-line arterial Blood sampling Kit is Gamma Irradiation sterilized. Sterilized using Gamma Irradiation in accordance with ISO 11137, SAL 10⁻⁶.

IMAGE OF THE DEVICE:



In-Line Arterial Blood Sampling Kit (Without Needle)

DEVICE VARIANTS:

Product Description	Available in
Without Air Bubble Filter	
In-Line Arterial Blood Sampling Kit (Without Needle)	1ml
In-Line Arterial Blood Sampling Kit (Without Needle)	3ml
With Air Bubble Filter	
In-Line Arterial Blood Sampling Kit (Without Needle)	1ml
In-Line Arterial Blood Sampling Kit (Without Needle)	3ml

INTENDED PURPOSE: In-line Arterial Blood Sampling Kit designed to obtain an in-line arterial blood specimen while maintaining a closed system.

INDICATIONS FOR USE:

INSTRUCTIONS FOR USE

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The In-line Arterial Blood Sampling Kit is designed for arterial blood specimen collection for further blood gas analysis.

INTENDED PATIENT POPULATION:

In-line Arterial Blood Sampling Kit is intended to be used in patients irrespective of age and gender.

INTENDED USER:

In-line Arterial Blood Sampling Kit is intended to be used by the trained healthcare professionals like Doctors, paramedics, or nursing staff experienced in blood sampling.

INTENDED USE ENVIRONMENT:

In-line Arterial Blood Sampling Kit is intended to be used in hospital, or a clinical Kitting.

CLINICAL BENEFITS:

- The Sampling Kit contains Heparin lithium which prevents the blood coagulation.
- The Air bubble filter in the In-line arterial Blood sampling Kit variant, facilitate the removal of arterial gas bubble.
- Minimize the chances of error in Blood gas analyser.
- Strong sealing capacity which minimizes the possibility of contamination.

PRINCIPLE OF OPERATION:

The SPM's In-line arterial Blood sampling Kit is a sterile, single-use luer lock syringe without needle is intended to use for arterial blood sampling. The air is removed from the syringe and put the luer cap on. The collected blood sample is further stored and tested using Blood gas analyser. The AirPro variants also contains hydrophobic filter which help to completely remove air bubble filter.

PERFORMANCE CHARACTERISTICS:

- The SPM's In-line Arterial Blood Sampling Kit offers Safe arterial blood sample collection.
- The In-line Arterial Blood Sampling Kit contains fixed units of Heparin Lithium which prevents blood coagulation.
- Comes with luer cap which prevents the blood sample spillage and reduce contamination chances.

MATERIAL USED:

Barrel – Polypropylene
 Plunger – Polypropylene
 Gasket – TPE
 Luer cap – Polypropylene
 Lubricant – Silicone oil
 Anticoagulant coating – Lithium heparin (dry coating)

CONTRAINDICATIONS:

S. No	Contraindications	Description
1	Allergy to Materials used in Syringe	Patients with known allergies or sensitivities to materials in the in-line arterial blood sampling Kit (e.g. specific plastics) should avoid its use to prevent allergic reaction/take the safety measures.

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2	Infection	In patients with active infections or conditions that increase infection risk, using a contaminated or improperly sterile device could exacerbate their condition.
3	Coagulopathy or Bleeding Disorders	Patients with significant coagulopathy or bleeding disorders may have an increased risk of bleeding or hematoma formation at the injection site and may result in sample instability.
4	Device Misuse	If the syringe is damaged or used incorrectly, it could lead to improper sampling, injury or contamination. Ensure the Kit is used according to manufacturer instructions.

POTENTIAL COMPLICATIONS:

Possible complications with Syringe may encounter some challenges like:

- The improper sampling may result in sample contamination.
- Do not inject the aspirated blood back into patient circulation, may leads to blood thinning, internal bleeding, and other complications.
- Inaccurate Blood Gas Measurements.

INSTRUCTIONS FOR USE:

- **Step 1.** Take pre heparinized Arterial Blood Collection Kit 1ml or 3ml as required for blood sample.
- **Step 2.** Collect 1ml or 3ml arterial blood in this heparinized syringe (filling the syringe completely is very important).
- **Step 3.** Remove air bubbles quickly (if any), and place the luer cap. Mix the blood in the syringe gently by rotating the syringe between the palms of the hands to ensure mixing of blood with heparin.
- **Step 4.** Send the sample to the laboratory immediately. If it is not possible to send immediately then keep the syringe in a container having ice-water slurry (not with ice alone) but not for too long because the plastic syringes are partially gas permeable and this permeability increases at a lower temperature.

HOW SUPPLIED:

The SPM's In-line arterial Blood sampling Kit is supplied in sterile, single-use, Blister packaging, complete with instructions for use and accessories (if any).

WARNINGS:

- **For Professional Use Only:** This device must be used by trained healthcare professionals only
- **Sterile Packaging:** Do not use if the packaging is damaged or opened prior to use.
- **Single Use Only:** The Syringe 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 syringe.
- **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.

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PRECAUTIONS:

- Check the integrity and functionality of the sampling Kit 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 not 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
- Dispose the blood/medicine contaminated product as per local applicable laws.

STORAGE:

Store at controlled temperature (10 to 40°C) and humidity (55RH to 75RH).

EXPIRATION PERIOD:

In-line arterial Blood sampling Kit has a shelf life of 2.5 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.

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

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 <i>instructions for use</i>
	Keep away from sunlight		Non-Pyrogenic
	Do not re-use		Sterilized using Gamma Irradiation

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	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
	Single Sterile Barrier System with protective packaging outside		Biological risks