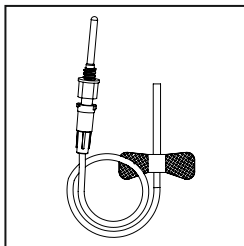




# PLUSCOLLECT® BLOOD COLLECTION SET



SRN. No: **IN-MF-000007279**  
Basic UDI-DI #: **8906025305SVSL**

## INSTRUCTIONS FOR USE

**Product Description:** A Blood Collection Set is a sterile, single-use medical device designed for venipuncture to obtain blood samples and for short-term infusion of fluids. It typically consists of a thin-walled stainless steel needle, flexible transparent tubing, and a connector compatible with standard blood collection tubes/ infusion devices. The winged design allows improved control and patient comfort during insertion • DEHP Free

**Intended Purpose/Use:** The blood collection set is intended for single-use venipuncture to obtain blood samples for diagnostic purposes and for short-term infusion of fluids. The maximum duration of use is up to 2 hours

**Indications:** • Blood needs to be collected from a vein • Fluids need to be given for a short time (not more than 2 hours)

**Patient Population:** • Adults • Pediatrics • Geriatrics • Neonates (select appropriate gauge)

**Intended Users:** Uses is restricted to a qualified Doctor or a Paramedic

**Clinical Benefits:** • Enhanced control and accuracy due to winged grip • Reduced vein trauma and increased patient comfort • Improved access to difficult veins • Lower incidence of needlestick injuries (with safety model)

**Principle of Operation:** The device enables venous access through the insertion of a fine needle. Blood flows through the tubing to a collection container or IV system once venipuncture is achieved

**Materials Used:** Polypropylene, Poly Vinyl Chloride, Isoprene, ABS & Stainless Steel

**Contraindications:** • Do not use on arteries • Not for intramuscular or subcutaneous injection • Avoid in patients with known hypersensitivity to materials used in the product

**Instructions For Use:** • Wash hands and prepare all necessary equipment • Inspect packaging for damage Do not use if package is compromised • Apply tourniquet and identify suitable vein • Disinfect puncture site • Remove protective cap from needle • Grasp the wings between thumb and forefinger • Insert needle into the vein at a shallow angle • Secure the wings to the skin with adhesive tape if needed • Connect to blood collection system or IV line • After use, activate safety mechanism (if applicable) • Dispose of in a sharps container per protocol

**Warnings:** • Single use only – do not reuse • Do not use if the packaging is damaged • Do not attempt to bend or manipulate needle post-use • Dispose of immediately after use to prevent sharps injury

**Precautions / Caution:** • Use proper vein selection techniques • Exercise care during insertion and removal • Monitor patient for any adverse reactions • Ensure correct disposal per facility protocol

**\*Note:** If the above said caution are not followed by the Paramedic Staff, it can lead to halt the intended clinical benefits to patient

**Storage Conditions:** Store in cool & dry place. Do not expose to heat or direct

sunlight

**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 (biomedical waste) should be done according to hospital procedures, State Regulations, national legislation or regional legislation

**Mode of Action:** Mechanically penetrates the vein wall using the hypodermic needle. Blood is drawn through the system via gravity or vacuum (when used with a collection tube)

**Residual Risk:** • Risk of needle stick injury (mitigated by safety features)

• Potential vein damage or hematoma • Risk of infection if aseptic technique is not followed. • Minor patient discomfort

**Clinical Risk:** • Minor bleeding, bruising, or hematoma • Infiltration or phlebitis • Local site infection if not properly disinfected • Allergic reaction to materials (rare)

**Safer Mode of Use:** The maximum duration of use is up to 2 hours

**Incidents Report :** In case of incidence immediately inform to manufacturer (info@mediplusindia.com) and competent authority of country

• **MEDIPLUS (INDIA) LIMITED DISCLAIM ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES RESULTING FROM IMPROPER USE**

**Applicable Standards:**

- ISO 7864 – Sterile hypodermic needles
- ISO 8536-4 – Infusion equipment
- ISO 23908 – Sharps injury protection
- ISO 11135:2014 – Sterilization (ETO)
- EN 1041 – Information supplied by manufacturer
- ISO 15223-1 – Medical device symbols

|        |                                                 |            |                                               |                                                   |                       |
|--------|-------------------------------------------------|------------|-----------------------------------------------|---------------------------------------------------|-----------------------|
| REF    | Catalogue number                                |            | Mfg. date with country of manufacture         |                                                   | Manufacturer          |
|        | Use-by date                                     |            | Do not use if package is damaged              |                                                   | Caution               |
| LOT    | Batch code                                      | STERILE EO | Sterilized using ethylene oxide               |                                                   | Do not re-use         |
|        | Do not resterilize                              |            | Consult instructions for use                  |                                                   | Non-pyrogenic         |
|        | Single sterile barrier system                   |            | Product is not made with natural rubber latex |                                                   | Does not contain DEHP |
| MD     | Medical Device                                  | UDI        | Unique Device Identifier                      |                                                   | Distributor           |
|        | Importer                                        |            | Keep away from sunlight                       |                                                   | Keep dry              |
| EU REP | Authorised Representative in the European Union | CE         | CE mark European Conformity                   | NW/PL/AL_01_Rev. 01,<br>(Issued date: 09/09/2026) |                       |



**MEDIPLUS  
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**CE 1639**

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\*Note: First digit in LOT (1 OR 2) refer to manufacturing unit.

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