

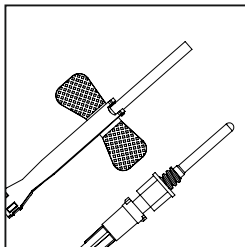


PLUSKICollect®

SAFETY BLOOD COLLECTION SET

Butterfly Wings-Safety Lock

For Short Term IV Administration (up to 2 hours)



SRN. No: **IN-MF-000007279**
Basic UDI-DI #: **8906025305BC5G6**

INSTRUCTIONS FOR USE

Product Description: The Safety Blood Collection Set is a single-use, sterile device designed for venous blood collection and short-term fluid infusion. It features a winged needle with an integrated safety mechanism that automatically shields the needle after use, helping to reduce the risk of needle stick injuries. The material used for safety Blood Collection Set is DEHP Free

Intended Purpose / Use: A Safety Blood Collection Set is intended for venous blood collection and is equipped with an integrated safety mechanism that shields the needle after use, thereby reducing the risk of needlestick injuries and enhancing user safety. The device may also be used 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: • Qualified Doctors • Trained Paramedical Personnel

Clinical Benefits: • Improved control via butterfly wings • Reduced patient discomfort • Better access to difficult veins • Significant reduction in needlestick injuries due to safety mechanism

Principle of Operation: The device enables venous access by inserting a fine needle into the vein. Blood flows through the tubing into a collection system via vacuum or gravity

The **safety mechanism is activated immediately after use**, covering or retracting the needle to prevent accidental injury

Materials Used: Polypropylene, Polyvinyl Chloride (PVC), Isoprene, ABS, Stainless Steel

Contraindications: • Do not use for arterial access • Not intended for intramuscular or subcutaneous injection • Avoid use in patients with known hypersensitivity to device materials

Instructions for Use:

1. Wash hands and prepare all required materials
2. Inspect package; do not use if damaged or opened
3. Apply tourniquet and identify suitable vein
4. Disinfect puncture site
5. Remove needle protective cap
6. Hold wings between thumb and forefinger
7. Insert needle into vein at a shallow angle
8. Secure wings if necessary
9. Connect to blood collection system
10. Complete blood collection
11. Immediately activate the safety mechanism after withdrawal
12. Confirm device is fully covered/locked
13. Dispose of device in sharps container

Warnings: • Single-use device – Do not reuse or resterilize • Do not use if packaging is damaged • Always activate safety mechanism immediately after use • Do not recap needle • Do not attempt to bend or break needle • Improper disposal may lead to sharps injury

Precautions / Caution: • Use proper vein selection technique

- Ensure correct insertion angle • Monitor patient during and after procedure
- Follow institutional infection control practices • Ensure safety feature is fully

engaged before disposal

Storage Conditions: • Store in a cool and dry place • Keep away from direct sunlight and heat

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: • Mechanical penetration of vein using hypodermic needle • Blood withdrawal through tubing system • Post-use activation of safety feature to isolate needle

Residual Risks: • Needle stick injury (minimized by safety feature)
• Hematoma or vein damage • Infection risk if aseptic technique is not followed
• Mild discomfort

Clinical Risks: • Minor bleeding or bruising • Hematoma formation

• Phlebitis or infiltration • Local infection • Rare allergic reactions

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 ltd.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 mark European Conformity	AW/IFUY_06_Rev. 01, (Issued date: 09/09/2026)	



MEDIPLUS
INDIA LIMITED

CE 1639

Mfd. by: Mediplus (India) Limited

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Unit - 2:- 32, Sector - 16, HSIIDC, Bahadurgarh - 124507, Haryana (INDIA). M.L.No.: MFG/MD/2021/000134

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

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