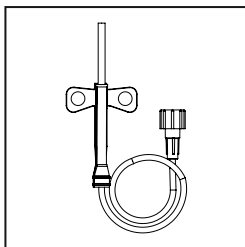




SAFETY SCALP VEIN SET

WINGED INFUSION SET

WITH SHORT, BEVELED SHARP NEEDLE



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

INSTRUCTIONS FOR USE

Product Description: Safety Scalp Vein Set is a sterile, single-use medical device consisting of a stainless-steel needle with flexible wings, extension tubing, connector and an integrated safety mechanism. It is designed to facilitate safe venipuncture for short-term intravenous access while helping reduce the risk of accidental needle-stick injuries after use

Intended Purpose/Use: A Scalp Vein Set with safety mechanism is a sterile, single-use medical device intended for venipuncture to obtain intravenous access for short-term administration of fluids, medications, or blood products, and for blood sampling. The integrated safety mechanism is designed to help reduce the risk of accidental needle-stick injuries after use. The maximum duration of use is up to 6 hours

Indications: • Short-term intravenous administration of fluids, medications, or blood products • Blood sampling or collection through venipuncture • Peripheral intravenous infusion • Blood sample collection • Pediatric or geriatric patients with fragile veins • Emergency venous access

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

Intended Users: Use is restricted to qualified healthcare professionals such as Doctors or Paramedics trained in venipuncture and safe handling of sharps devices

Clinical Benefits: • Minimally invasive with reduced pain • Suitable for small or fragile veins • Enhanced safety for healthcare workers • Reduced risk of needle-stick injuries • Easy to secure and stabilize

Principle of Operation: The device enables direct venous access by inserting the needle into a vein. Fluids or blood are transferred via tubing connected to a collection device or infusion source. After use, the safety mechanism is activated to cover or retract the needle

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

Contraindications: • Do not use in arteries • Not intended for long-term infusion • Avoid use in sclerosed or thrombosed veins • Hypersensitivity to device materials

Instructions for Use: • Wash hands and wear appropriate PPE • Open the sterile package • Select appropriate vein and disinfect the site • Hold wings and insert needle bevel up into the vein • Confirm flashback of blood • Secure the wings with tape • Connect to IV line or syringe as needed • After use, **withdraw the needle and immediately activate the safety mechanism (push/slide shield or retract system as applicable) until a click is felt/heard** • Dispose of the device in an approved sharps container • Do not reuse

Warnings: • Single-use only; reuse may result in infection or device failure

• **Do not attempt to recap the needle. Activate safety mechanism immediately after use** • Do not use if the safety feature is damaged or malfunctioning • Do not use if the package is damaged or expired • Improper disposal may lead to needle-stick injury

Precautions / Caution: • Do not bend the needle prior to insertion • Avoid excessive manipulation after insertion • Ensure full activation of safety

mechanism after use • Use appropriate gauge for patient population • Monitor for signs of infiltration

Storage Conditions: Store in a 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: The needle punctures the vein, creating a controlled pathway for blood withdrawal or fluid administration. The wings allow better control and stabilization during insertion. After withdrawal, the safety feature is activated to prevent exposure to the needle

Residual Risk: • Minimal risk of needle-stick injury if safety mechanism is not activated properly • Risk of phlebitis or local irritation • Potential for air embolism if used improperly • Rare allergic reaction to materials

Clinical Risk: • Local infection at puncture site • Vein damage or infiltration • Hematoma formation • Needle-stick injury (if safety mechanism not used correctly) • Systemic infection (if aseptic technique not followed)

Note: Failure to follow the above instructions may compromise patient safety and intended clinical benefits

Safer Mode of Use: The maximum duration of use is up to 6 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 for single use • ISO 8536-4: Infusion equipment for medical use • ISO 10993: Biological evaluation of medical devices • ISO 23908: Sharps injury protection requirements • EN 1041: Information supplied by the manufacturer

	Catalogue number		Mfg. date with country of manufacture		Manufacturer
	Use-by date		Do not use if package is damaged		Caution
	Batch code		Sterilized using ethylene oxide		Do not re-use
	Do not re-sterilize		Consult instructions for use		Non-pyrogenic
	Single sterile barrier system		Product is not made with natural rubber latex		Does not contain DEHP
	Medical Device		Unique Device Identifier		Distributor
	Importer		Keep away from sunlight		Keep dry
	Authorised Representative in the European Union		CE mark European Conformity		

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

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