nubeno
We Care

INSTRUCTION FOR USE

1. PRODUCT NAME: PERIPHERAL IV CATHETER WITH WINGS & INJECTION PORT. (SAFETY)

1.1 TRADE NAME: Nufix-Safety

1.2 BASIC UDI: 8908017018SIVC01FD

1.3 PRODUCT DESCRIPTION: Safety Peripheral I.V. Catheter uses the sharpness of the needle tip to puncture the skin and enter the vein. After seeing the flashback in FB chamber, the catheter is inserted to the blood vessel, and then the needle is pulled out. When the needle is withdrawn, the Safety clip of needle is automatically activated, which can completely wrap the exposed needle tip. After the puncture is successful, the catheter is left in the vein for infusion treatment, and the tube is sealed after each infusion is completed to reduce the risk of the Peripheral I.V. Catheter being locked.

The Safety Peripheral I.V. Catheter consists of an introducer needle with an integral tip-protector. Key parts are (1) SS Needle, (2) Teflon Holder (3) Catheter (Formed Teflon) (4) Silicon Tube (5) Port Cap (6) Needle Hub (7) Needle Cover (8) Threaded Stopper (9) Hub Cover (10) SS Safety clip.

1.4 MATERIAL OF CONSTRUCTION: Polypropylene, Stainless Steel, Fluorinated ethylene propylene-Teflon (FEP), High density Polyethylene, Silicon Tube, LDPE, Polyoxymethylene (POM) & Master Batch.

1.5 INTENDED USE: Safety Peripheral I.V. Catheters placed inside a vein to provide venous access. The Safety Peripheral I.V. Catheters a medical device, which eliminates the chances of needle stick injuries and blood borne infections to the healthcare providers during needle withdrawal and disposal.

1.6 INDICATION: A properly placed Safety IV Catheter provides access to a vein for infusion of fluids, medications, nutritional support, blood / blood products, for blood sampling, for fluid resuscitation, etc. The tip-protector that locks over the needle tip as the needle is withdrawn helps reduce the risk of accidental needlesticks.

1.7 CONTRAINDICATION: Product should not to be used in patients with known hypersensitivity to any of the materials used. Administration of high viscous fluids, large blood transfusion.

1.8 TARGET POPULATION:

24G-26G for Neonate & infant 22G for Pediatric and 14,16,18,20G for adult.
Neonate: child under 28 days of age.
Infant: 0-1 year
Pediatric: From birth up to the age of 18.
Adult: An adult is anyone who is over 18 or older.

1.9 INSTRUCTION FOR USE:

Due to the risk of bloodborne pathogen exposure, follow Standard Precautions during placement, use and removal of an IV Catheter.

- Select and prepare site as per institutional policy. Apply tourniquet.

- Remove cover in straight outward motion and inspect device.
- Ensure cap is closed and the catheter hub is fully seated and verify the needle bevel is in the upward position.
- Find a stable position to hold Safety IV Catheter by holding the wings with index and middle finger and place the thumb at the flash plug assembly.
- Anchor the blood vessel with gentle skin traction and insert the needle into the skin and blood vessel at an appropriate angle.
- Blood flashback into the flash chamber confirms blood vessel entry.
- Decrease angle and insert device slightly to assure catheter entry into the blood vessel.
- Remove tourniquet.
- Before removing needle, apply pressure to the blood vessel distal to the catheter tip and secure the catheter hub, remove the needle by pulling straight back.
- The Safety clip will automatically engage over the needle tip.

1.10 PRECAUTIONS:

To avoid inadvertently puncturing the posterior wall of the vessel, lower the needle until it is parallel to the skin. Ensure fluid administration/hub connection is secure in order to prevent leaking.

Ensure stabilization of catheter to the patient. Improper stabilization may lead to loss of vascular access.

The use of this product is restricted to a qualified doctor or a paramedic

1.11 STORAGE OF THE DEVICE: - Store in cool and dry place & avoid exposure to direct sunlight

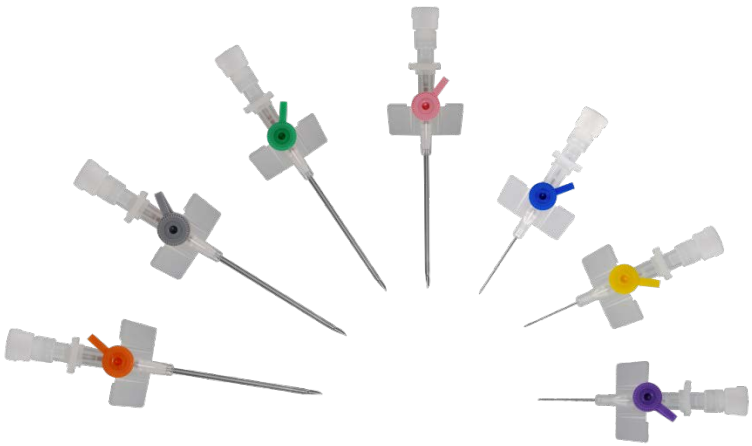
1.12 SHELF LIFE OF THE DEVICE: 05 Years from the manufacturing date.

1.13 DISPOSAL METHOD: - Used medical device is considered as biohazard waste. Dispose-off the used medical device in accordance with hospital, administrative and/or local government policy.

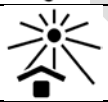
1.14 ADVERSE EVENT: The device is supplied with limited functionality, and there is no foreseeable risk associated with the device usage. Consequences from the improper use may cause or lead to redness, swelling, bruising etc.

1.15 For any feedback or query, customer/user can write or reach to us at:

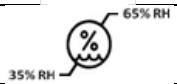
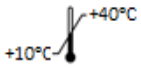
Email- info@nubeno.in **or** Customer Care No: +91-0712-2284001



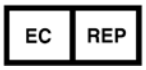
1.16 LABEL INFORMATIONS: -

Symbol	Description
	Device to be sale on order/prescription of a Physician/ Doctor/ Paramedical staff only
	Catalogue Number
	Lot Number: Batch Number
	Expiry date: Device can be used until the end of the month indicated
	Sterilization with ethylene oxide gas
	Single use only
	Manufacturer
	Warnings
	Conformité Européenne. (CE marking is a mandatory conformity marking for certain devices sold within the European Economic Area)
	Do not Re-sterilize.
	Non-Pyrogenic.
	Do not use if package is damaged
	Keep dry.
	Keep away from sunlight.
	Date of manufacturing.
	Consult Instruction for Use.
	Safe disposal.
	Do not use hook.
	Store and stack in upright condition.

INSTRUCTION FOR USE

	Fragile, handle with care
	Unique device identifier
	Single sterile barrier system (For primary package only)
	Medical device
	Country of manufacture
	Moisture limitation
	Temperature limitation

NUBENO HEALTHCARE PRIVATE LIMITED
Plot No. 10A Sector 23, Mihan Nagpur, Maharashtra India (441108)
Mfg. Lic. No. MFG/MD/2021/000002
E-mail: info@nubeno.in, **Customer care: +**91 0712 – 2284001
Regd. Office: Nava Bharat Bhavan Chhatrapati Square, Wardha Road Nagpur, Maharashtra – 440010



MED DEVICES LIFESCIENCES B.V.
Add.: Keizersgracht 482, 1017 EG Amsterdam, The Netherlands
E-mail: info@meddevices.net
Phone: +31-202254558