nubeno
We Care

INSTRUCTION FOR USE

1. PRODUCT NAME: PHERIPHERAL IV CANNULA WITH WINGS & INJECTION PORT.

1.1 TRADE NAME: Nufix

1.2 BASIC UDI: 8908017018IVC015V

1.3 PRODUCT DESCRIPTION: Peripheral IV Cannula consists of a smooth fine tipped tapered Teflon, radio-opaque catheter with sharp triple facetted bevelled needle with dual cutting edges. Ergonomically designed wings for fixation of Catheter to the penetration site. Proximally, Peripheral IV Cannula consists of a flash back chamber for identification of instant penetration of the vein. Provided with size colour coded injection port for intermittent medication / blood sampling.

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: The Peripheral Intravenous Catheters are the most commonly used intravenous device in hospitalized patients. They are primarily used for therapeutic purposes such as administration of medications, fluids and/or blood products as well as blood sampling. The Peripheral Intravenous Catheters are a passive device to provide for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices.

Intended for intermittent / continuous peripheral intra venous infusion. Maximum use period not more than 3 days

1.6 INDICATION: Infusion of I. V. Solutions to maintain hydration and/ or correct dehydration if patient is unable to take sufficient volume of oral fluid. Repeated blood sampling. IV administration- fluid, medications, chemotherapy, nutritional support.

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, Bleeding disorders, Infection at the site, burned extremity, tissue necrosis, etc. Administration of I. V. Catheter is contra-indicated during the process of MRI.

1.8 TARGET POPULATION:

24G-26G for infant & Neonate 22G for Pediatric and 18,20G &,18,20, 14,16 for adult.
Infant: 0-1 year.
Neonate: child under 28 days of age.
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**:

- Check the device for size / color code confirmation. Peel opens the pack and remove the device aseptically. Check the integrity of the I.V. Catheter.
- Position the patient. Identify the landmark for vein puncture.
- Select, prepare & disinfect the vein puncture site appropriately. Open the protective cap on the Catheter.

- Hold the entire Catheter unit securely. Insert the Catheter into the vein. On entering the vein, the flash back indication is visible. Advance the Catheter further into the vein appropriately.
- Gently remove the needle in a controlled & continuous manner & destroy appropriately with needle destroyer & bin to sharps container.
- Immediately apply the luer lock closure cap on Peripheral IV Cannula hub or connect to accessory device appropriately, as per case. Secure the Catheter with a sterile dressing.
- Attach the infusion line-male fitting to the Peripheral IV Cannula hub by removing the closure cap secure connection & run the infusion.
- Flush the Catheter at regular intervals with saline solution to maintain patency or to prevent phlebitis.
- At the time of Peripheral IV Cannula removal, check the catheter tip integrity. Do not apply excessive force or manipulate, during Cannulation.

1.10 WARNING/PRECAUTIONS:

- Check the integrity and functionality of the device before use. Do not use if the Unit Pack is open or damaged.
- Determine patient's condition and vitals status During device application / Operation.
- Conduct procedure under strict surgical protocol and ensure complete asepsis.
- Destroy the device & its accessories after single use as bio-medical waste as per applicable laws.
- Do not put the Device to Use after the Use by Date or Date of Expiry.
- Do not attempt to re-insert partially or completely withdrawn needle.
- Do not Re-sterilize. Do not Re-use. Single use only.

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.

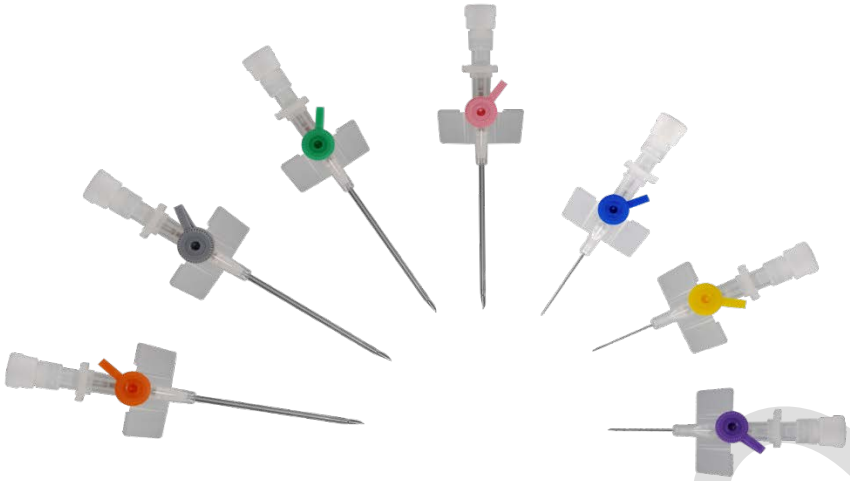
1.13 DISPOSAL METHOD: - Used medical device is considered as biohazard waste. Dispose-off the used medical device in accordance with hospital, administrative and/or local government policy.

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

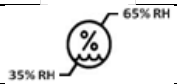
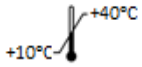
INSTRUCTION FOR USE



1.16 LABEL INFORMATIONS: -

Symbol	Description
℞ Only	Device to be sale on order/prescription of a Physician/ Doctor/ Paramedical staff only
REF	Catalogue Number
LOT	Lot Number: Batch Number
	Expiry date: Device can be used until the end of the month indicated
STERILE EO	Sterilization with ethylene oxide gas
	Single use only
	Manufacturer
	Warnings
CE 0123	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

INSTRUCTION FOR USE

	Date of manufacturing
	Consult Instruction for Use
	Safe disposal
	Do not use hook
	Store and stack in upright condition
	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. India.

EC REP

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