

INSTRUCTION FOR USE

1. PRODUCT NAME: PHERIPHERAL IV CATHETER WITH SMALL WINGS & WITHOUT PORT

1.1 **BASIC UDI:** 8908017018NVC017L

1.2 **PRODUCT DESCRIPTION:** Neo Catheter Ideal for neonates and infants the special IV Catheter has been designed to make cannulation less traumatic for neonates and children. The Nufix Neo IV 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) Needle Hub (5) Needle Cover (6) Threaded Stopper (7) Hub Cover (8) Wing body.

1.3 **MATERIAL OF CONSTRUCTION:** Polypropylene, Stainless Steel, Fluorinated ethylene propylene-Teflon (FEP), LDPE, HDPE, Master Batch.

1.4 **INTENDED USE:** Neo IV Catheter is placed inside a vein to provide venous access. The Neo I.V. Catheter is a medical device, Intended for intermittent / continuous peripheral intra venous infusion. Maximum use period not more than 3 days.

1.5 **INDICATION:** For intermittent or continuous peripheral intravenous infusion of fluids, medications, nutritional support, blood / blood products, for blood sampling, for fluid resuscitation, etc. A properly placed Neo IV Catheter provides access to a vein or artery to sample blood, monitor blood pressure, or administer fluids.

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

1.7 TARGET POPULATION:

Infant: 0-1 year.

Neonate: child under 28 days of age.

Pediatric: From birth up to the age of 18.

1.8 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 IV Catheter.
- Position the patient. Identify the landmark for vein puncture.
- Select, prepare & disinfect the vein puncture site appropriately. Open the protective cap on the Cannula.
- Hold the entire cannula unit securely. Insert the cannula into the vein. On entering the vein, the flash back indication is visible. Advance the cannula 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 IV Catheter hub or connect to accessory device appropriately, as per case. Secure the Cannula with a sterile dressing.

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- Attach the infusion line-male fitting to the IV Catheter hub by removing the closure cap. Secure connection & run the infusion.
- Flush the cannula at regular intervals with isotonic saline solution to maintain patency or to prevent phlebitis.
- At the time of IV Catheter removal, check the catheter tip integrity. Do not apply excessive force or manipulate, during cannulation.

1.9 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.

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

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

1.12 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.

1.13 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.






















1.14 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




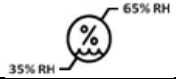
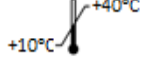


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1.15 LABEL INFORMATIONS: -

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
	Fragile, handle with care
	Unique device identifier

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	Single sterile barrier system (For primary package only)
	Medical device
	Country of manufacture
	Moisture limitation
	Temperature limitation



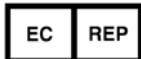
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