

INSTRUCTION FOR USE

1. PRODUCT NAME: PERIPHERAL IV CATHETER WITHOUT WINGS & WITHOUT PORT (WITH SAFETY FEATURES).

1.1 **TRADE NAME:** Nufix-on

1.2 **BASIC UDI:** 89080170181WIVC3N

1.3 **PRODUCT DESCRIPTION:** IV Catheter uses the sharpness of the needle tip to puncture the skin and enter the vein. After seeing the flashback into the FB Chamber catheter is inserted to the blood vessel, and then the needle is pulled out. When the needle is withdrawn, the protective clamp of the I.V. Catheter, which can completely wrap the exposed needle tip.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 needle tip is locked after each infusion is completed to reduce the risk of the needle stick injury.

The Nufix -on 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) Main body (5) Hub Cover (6) Needle Hub (7) Needle Cover (8) Threaded Stopper (9) SS Safety Clip.

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

1.2 **INTENDED USE:** Nufix -on IV Catheter intended to allow the introduction of blood transfusion, administer medications directly into bloodstream. The short flexible and kink-resistant catheter is introduced into a blood vessel over a hollow introducer needle.

1.3 **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 The tip-protector that locks over the needle as the needle is withdrawn helps to reduce the risk of accidental needlesticks.

1.4 **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.

1.5 **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.

1.6 **INSTRUCTION FOR USE:**

- Select and prepare site per institutional policy & apply tourniquet.
- Remove Protective 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 Nufix -on IV Catheter by holding with index and middle finger and place the thumb at the flash plug assembly.

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- 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.
- Note: A slight resistance will occur as the protected needle is removed from the catheter hub.
- Note: Do not reinsert the tip-protector into the hub after it has been removed.
- Connect IV administration line.
- Immediately discard unit into a puncture resistant, leak-proof, disposable sharps container.

1.7 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
- Manufacturer Disclaims Any Responsibility for Possible Consequences Resulting Form

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

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

1.10 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.

1.11 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.






















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




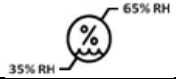
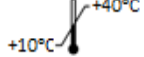


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1.12 LABEL INFORMATIONS: -

Symbols	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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