nubeno
We Care

INSTRUCTION FOR USE

1.1 PRODUCT NAME: BLOOD TRANSFUSION VENTED/NONVENTED

1.2 TRADE NAME: Nubeno

1.3 BASIC UDI: 8908017018BTS015J

1.4 DESCRIPTION OF DEVICE: BLOOD TRANSFUSION is employed for intravascular, gravity-controlled transfusion of blood or blood element. Most commonly transfusion includes red blood cells, platelet, and plasma transfusions. Technical Features: Strong, sleek and sharp spike to puncture blood bag outlets. Transparent & flexible drip chamber.

1.5 INTENDED USE: The BLOOD TRANSFUSION is employed for intravascular, gravity-controlled transfusion/Administer of blood from the patient or into the blood container.

1.1 MATERIAL: DEHP FREE PVC, PP, PE, ABS, Isoprene, & Master Batch.

1.6 INDICATION: Indications for transfusion include symptomatic anemia (causing shortness of breath, dizziness, congestive heart failure, and decreased exercise tolerance), acute sickle cell crisis, and acute blood loss of more than 30 percent of blood volume.

1.7 CONTRAINDICATION: Do not use in patient with a known allergic reaction to any of the product components administration & it is not intended for the delivery of large blood components.

1.8 [i] INSTRUCTION FOR USE:

- Close flow regulator
- Disinfect inlet of container.
- Remove protective cap from closure-piercing device and insert it into the outlet of blood container
- Close the air-vent and roller clamp respectively (For Air vented only)
- Insert the administration set holding the container in an upright position.
- If the device is provided without needle, remove protective cap from male fitting. Gently open flow regulator and allow blood to displace air entirely from the tubing. Close flow regulator and attach to the device.
- Regulate flow by opening flow regulator.
- Suspend containers half fill drip chamber by squeezing and releasing. Don't fill completely.
- Open the snap vent and roller clamp to expel air from tubing. Close clamp.
- Perform venipuncture and regulate flow by opening clamp.
- Designed to deliver 20 drops of distilled water equivalent to 1±0.1ml(1±0.1g).
- This device can be connected with Arterial Cannula, Blood Bags,3 way stop cock and any other device intended to be used in line for blood administration & having a standard 6% connector.

1.9 ⚠ WARNING

- Device is single use only.
- Device must not be reused.

- Reuse of the device may; Cause serious infection, cross contamination, transmission of bacteria, viruses and blood Related transfusion of serious diseases like HIV, Hepatitis.

- The device should be use according to the instruction for use

- Use the device immediately after opening the individual pack.

- Check expiry date prior to use.

- This device should be used by a Doctor/Registered Practitioner or Paramedic.

- Read instruction before use.

- Discard all used sets together with holder in biohazard containers approved for their disposal.

- The device will perform as intended when instructions are followed accordingly.

- Examine individual package for integrity prior to use. If packaging has been damaged, do not use.

- Do not use for subcutaneous infusion or injection.

- Avoid leakage and any air in the tubing during transfusion procedure.

- Please do not use by/on those individuals which are sensitive /allergic.

- The latex may be present in device which needs medical attention to patients/user.

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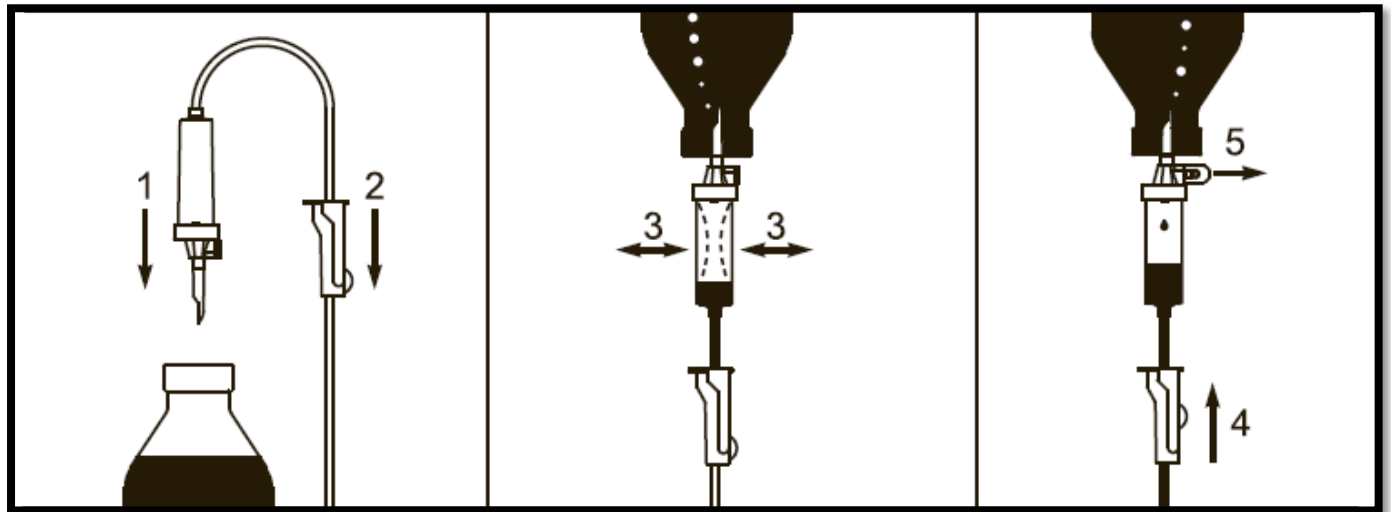
1.13 ADVERSE EVENT: The device is supplied with limited functionality, and there is no foreseeable risk associated with the device usage. Consequences from the improper use may cause or lead to redness, swelling, bruising etc.

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
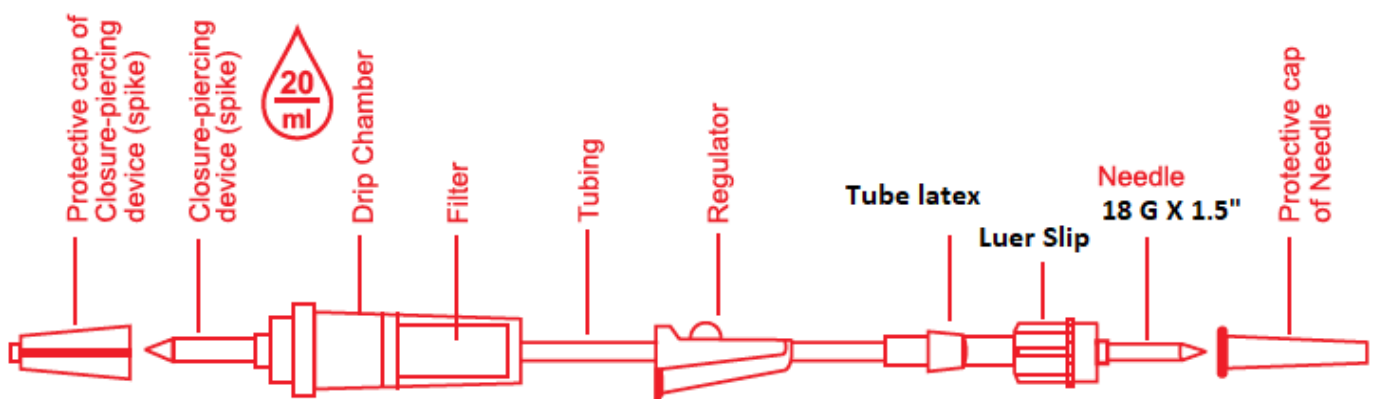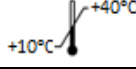
1.14 LABEL INFORMATIONS: -

Symbol	Description
R~X~ Only	Device to be sale on order/prescription of a Physician/ Doctor/ Paramedical staff only
REF	Catalogue Number
LOT	Lot Number: Batch Number
(symbol)	Expiry date: Device can be used until the end of the month indicated
STERILE EO	Sterilization with ethylene oxide gas
STERILE	Sterile Fluid Path
(symbol)	Single use only
(symbol)	Manufacturer
⚠	Warnings
CE 0123	Conformité Européenne (CE marking is a mandatory conformity marking for certain devices sold within the European Economic Area)
(symbol)	Do not Re-sterilize
(symbol)	Non-Pyrogenic
(symbol)	Do not use if package is damaged
(symbol)	Keep dry
(symbol)	Keep away from sunlight

| Symbol	Description
(factory symbol)	Date of manufacturing
(book with i)	Consult Instruction for Use
(safe disposal)	Safe disposal
(crossed hook)	Do not use hook
(up arrows)	Store and stack in upright condition
(fragile glass)	Fragile, handle with care
UDI	Unique device identifier
(oval)	Single sterile barrier system (For primary package only)
MD	Medical device
(factory CC)	Country of manufacture
65% RH / 35% RH (%)	Moisture limitation
+40°C / +10°C	Temperature limitation
(crossed LATEX)	Latex Free
(crossed DEHP)	DEHP Free
200 µm	Filter of liquid with pore size
20 ml	20 Drops/ml
G	Gravity Feed Only

(factory symbol) **NUBENO HEALTHCARE PRIVATE LIMITED**
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EC	REP
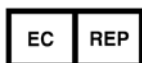
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