nubeno
We Care

INSTRUCTION FOR USE

1. **PRODUCT NAME:** MEASURED VOLUME INFUSION (BURETS SET) VENTED/NON-VENTED.

1.1 TRADE NAME: Nubeno

1.2 BASIC UDI: 8908017018MVS019R

1.3 DESCRIPTION OF DEVICE Burette type measured volume chamber of 100 ml /150 ml with 10 ml overflow limit. Micro drip with drop size of 60 drops per ml. Burette chamber is made of bio-compatible medical grade transparent polymer, suitable for infusion of all types of fluids. Hanger facilitates the hanging of complete device on the I.V. stand. Floating auto shut off valve acts as floating indicator and automatically shut off the drain path to prevent air in line. Roller controller provides accurate flow control. No-kink device prevents the kinking of tube during transportation. Separate plugs for extra medication and continuous change over. Sterile, individually packed.

1.4 INTENDED USE: Measured Volume Infusion Set with Needle intended for use in the administration of fluids from a container into a patient's vascular system through a vascular access device.

1.5 MATERIAL: DEHP FREE PVC, PP, PE, ABS, Isoprene, SS Cannula & Master Batch

1.6 INDICATIONS: For intravenous, infusion of medications or fluid requiring continuous delivery at controlled infusion rates.

1.7 CONTRA-INDICATIONS: It is not intended for the delivery of whole blood, blood components.

1.8 COMPATIBILITY: Measured Volume Infusion Set compatible with medical devices equipped with standard Luer connectors in conformity with standard ISO 80369-7. With plastic infusion bags, plastic or glass bottles.

1.9 WARNING.

- Do Not resterilize and /or reuse the device, as this can compromise the device performance (functionality) and may cause inadequacy, deterioration of the device technical factors, rendering the device non-functional and unfit for intended use and also this may increase the risk of cross contamination due to several aspects including inappropriate reprocessing.
- Re-use of single use device creates a potential risk for patient or user. It may lead to contamination and / or impairment of functional capability.
- Contamination and / or limited functionality of the device may lead to injury, illness of the patient

1.10 INSTRUCTION FOR USE.

- Close clamp and flow regulator.
- Remove spike protective cap and insert piercing spike into bottle through administration port.
- Uncap Air filter shut-off device.
- Open clamp and introduce 20ml of solution into burette.
- Close clamp and half fill the drip chamber by squeezing and releasing, this will float the shut-off valve.
- Remove protective cap from needle and gently open flow regulator to permit solution to expel air from tubing and needle.
- Close flow regulator. Put back protective cap on needle.

- Open clamp and fill burette to required volume.
- Then close the clamp (if required add medication through injection side of burette.)
- Remove needle protective cap and perform venipuncture.
- If the device is provided without needle. Remove protective cap from male fitting. Gently open flow regulator and allow solution to displace air entirely from the tubing.
- Close flow regulator and connect to the catheter/scalp vein set already installed.
- Adjust the flow rate by means of flow regulator, observing number of drops per minute in drip chamber. 60 drops of distilled water delivered by the drip tube are equivalent to 1ml ± 0.1ml (1g ± 0.1g).

Note: The set is provided with shut-off valve in burette chamber to prevent air embolism when burette chamber is empty and should not be used for long term shut-off.

REFILLING:

Leave Air filter shut-off device open and leave flow regulator undisturbed. Open clamp, refill burette to required volume and close clamp. To restart administration, gently squeeze drip chamber to float shut-off valve.

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

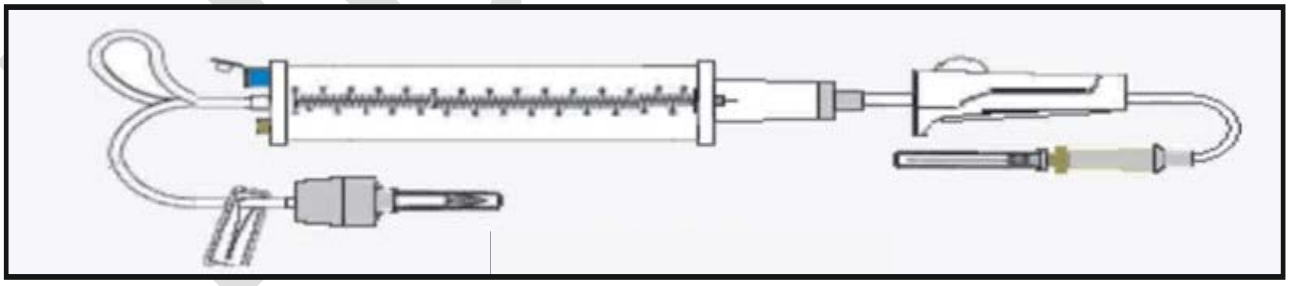
1.12 SHELF LIFE OF THE DEVICE: 05 Years from the manufacturing date.

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.

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



1.15 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
STERILE	Sterile Fluid Path
	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
	Date of manufacturing
	Consult Instruction for Use
	Safe disposal
	Do not use hook
	Store and stack in upright condition
	Fragile, handle with care
UDI	Unique device identifier
	Single sterile barrier system (For primary package only)
MD	Medical device
CC	Country of manufacture
65% RH 35% RH	Moisture limitation
+40°C +10°C	Temperature limitation

INSTRUCTION FOR USE

	Latex Free
	DEHP Free
	Filter of liquid with pore size
	60 Drops/ml
	Gravity Feed Only

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