

INSTRUCTIONS FOR USE

VIGGOFLON™

I.V. Cannula with Catheter & Injection Valve

MATERIAL USED :

- PP, POM, HDPE, LDPE, Silicon Rubber & Stainless Steel
- Catheter: PTFE/FEP/PU/ETFE (see the product ref. code)

COATING MATERIAL :

- Silicone Dispersion

INDICATIONS :

- Infusion of I.V. Solutions (To maintain hydration and/or correct dehydration if patient is unable to take sufficient volume of oral fluid)
- Intermittent intravenous Drugs administration

CONTRAINDICATIONS:

- Product should not be used in patients with known hypersensitivity to any of the material used including coating materials
- Product should not be used for Administration of high viscous fluids
- Product should not be used for Large volume blood transfusion

INSTRUCTIONS FOR USE:

- The device is manufactured & tested in accordance with the international standard "Over needle Peripheral Catheters EN ISO 10555-1 & 5"
- The connecting port of this device is in compliance to EN 20594-1 & ISO 594-2
- Carefully select and aseptically prepare the site
- Select suitable size of I.V. Cannula & inspect visually to ascertain that package is intact
- Remove cannula from sterile packing and remove its needle cover
- Grip the cannula from injection port cap & projection provided on hub
- Perform venipuncture & check for flash back of blood in flash back chamber
- Advance the catheter into vein and simultaneously withdraw the needle
- NEVER TRY TO REINSERT THE PARTIALLY OR COMPLETELY WITHDRAWN NEEDLE
- Withdraw the needle completely while pressing the vein just after the tip of catheter into the vein & discard the needle in an appropriate container
- Connect to the I.V. infusion set line
- Cover the puncture site with sterile dressing
- Drugs can be injected with the help of syringe without needle through integrated injection port after removing the port cap.
 - Close the injection port cap after use
- Perform routine monitoring & venipuncture site maintenance according to medical norms
 - Based on Clinical Evaluation Report (Ref HH-QA-CER-IVC), following recommendations are made for use of the device:
 - Upper limb placements are preferable to lower limbs
 - For blood sampling, it is recommended that larger gauge catheters be used than for infusion
- Use of specialized infusion teams for insertion and monitoring of IV catheters has been shown to lead to better patient outcomes

TERM OF USE :

- Recommended Maximum Duration of Use: 96 hours
- There is no known reactions between the catheter & Magnetic Resonance Imaging (MRI)

WARNINGS:

- The use of this product is restricted to a qualified doctor or a paramedic
- Read instructions before use
- The Product should be used according to the instructions for use
- If there is any change in expected performance of the device or in case of any malfunction the device should be immediately removed & sent back to supplier for analysis
- For Known/reported adverse events associated with use of this device, refer to the Clinical Evaluation Report HH-QA-CER-IVC
- VIGGOFLON DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES RESULTING FROM IMPROPER USE
- Any device that is connected to this product must comply with EN 20594-1 & ISO 594-2 in order to achieve the intended performance of this product & to avoid leakage in the connection
- The product should not be reprocessed
- Visually inspect and carefully check the product and packaging before use. Improper transport and handling may cause structural and/or functional damage to device or packaging
- The product is guaranteed sterile & non-pyrogenic if the package has not been opened or damaged
- Do not clean or resterilise. For single use only. Discard after use
- Store in cool & dry place
- Do not expose to heat or direct sunlight
- The product should be used immediately after opening the packaging.
- Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reactions or infections

Disposal/Discard: Dispose off/Discard the used Device in accordance with your Country's Healthcare and Safety Regulations



Product Ref. No.



Batch Number



Date Of Manufacturing



Use By



Do Not Reuse



Sterilised by Ethylene Oxide Gas



Caution, Consult Accompanying Documents



Consult Instructions for Use



Non-Pyrogenic



Do Not Use if Package is Damage



Do not resterilize



Keep away from sunlight



Keep Dry



Ref. Code: AW/IC_X1e, Rev. 01

Rev. Date :14.12.2015