Size = A3(420X297mm), Black Print

INSTRUCTIONS FOR USE

VIGGOFLON™ - S

SAFETY I.V. CANNULA WITH CATHETER & INJECTION VALVE

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

COATING MATERIAL :
•Silicone Dispersion.

DESCRIPTION
The device VIGGOFLON™ - S IV Catheter consists of major components as in fig. (1), fig. (2) & fig. (3), (A) Stainless steel needle, (B) Locking strip holder cover, (C) Needle hub, (D) Catheter tube, (E) Needle cover, (F) Locking strip holder, (G) Hub cover, (H) Threaded stopper, (I) Catheter Hub, (J) Port cap
Catheter gauge size & length are identified on the product packaging. The color of the flip type port cap also indicates the gauge size of catheter.

GAUGE:	14G	16G	18G	20G	22G	24G
COLOR:	Orange	Grey	Green	Pink	Blue	Yellow

The materials used to manufacture this device do not contain natural rubber latex or PVC derivatives.

Fig. (1)
BEFORE USE

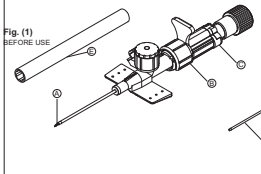
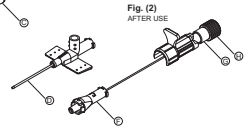


Fig. (2)
AFTER USE



CATHETER ADVANCEMENT (THREADING)
•Decrease angle of insertion further such that catheter is nearly parallel to skin surface.
•Advance entire device prior to threading catheter tip should enter vein.
•Thread catheter into vein using either one-handed or two-handed technique maintaining pressure on skin surface to straighten vein.

NEEDLE RETRACTION:
•Advance the catheter further into the vein, while slightly withdrawing the steel needle.
•Using adhesive tape, fix catheter to the skin. The steel needle still in site minimizes spillage of blood.
•Before removing the steel needle compress the vein at the tip of catheter with the middle finger, to prevent spillage of blood. At the same time stabilize the catheter hub with the index finger to prevent catheter dislodgement during needle removal. Remove needle by pulling needle straight back. Metal safety clip will automatically attach to needle tip as needle tip exits catheter hub. Dispose of needle immediately into sharps container.
•NEVER TRY TO REINSERT THE PARTIALLY OR COMPLETELY WITHDRAWN NEEDLE.

APPLICATIONS:
•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
•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 flip type port cap. Close the flip type 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.

REF	Product Ref. No.		Keep dry
LOT	Batch Number		Fragile, handle with care
	Date Of Manufacturing		This way up
	Use By		Quantity
	Do Not Reuse		Non-pyrogenic
STERILE EO	Sterilised by Ethylene Oxide Gas		

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 viscocity fluids.
•Product should not be used for large volume blood transfusion.

PATIENT PREPARATION:
•Explain cannula insertion procedure to patient.
•Open cannula insertion kit, remove contents onto a clean, preferably sterile, surface.
•Locate an accessible and suitable peripheral vein visually and confirm by palpation.
•Wash hands with antiseptic soap solution and wear gloves.
•Disinfect site of insertion, rubbing for 30 seconds moving from periphery to center of site in circular motion.
•Allow insertion site to dry for approximately 1 minute.
•Apply tourniquet, if needed, proximally to insertion site.

CATHETER INSERTION:
•Carefully select and aseptically prepare the site
•Select suitable size of I.V. Cannula & inspect visually to ascertain that package is intact
•Remove safety IV catheter from individual packing.
•Remove and discard needle cover without touching catheter.
•DO NOT ROTATE CATHETER before insertion.
•Inspect catheter ensuring needle projects beyond tip and bevel points upwards.
•If needed, push/pull skin taut with non-dominant hand.
•Grip the cannula either from flip type port cap or projection provided on hub by holding in dominant hand and approach vein slowly at low angle.
•Puncture the vein with the needle (bevel up).
•Confirm successful venipuncture by visualizing blood in hub cover.

RISK:
•This I.V. catheter is designed to reduce the risk of accidental needlesticks; however, care must be taken to avoid needlesticks. Universal precautions must be adhered to in accordance with Centers for Disease Control and Prevention/Occupational Safety and Health Administration (CDC/OSHA).

TERM OF USE :
•Recommended Maximum Duration of Use: 96 hours.
•There is no known reactions between the catheter & Magnetic Resosnance Imaging (MRI).

WARNINGS:
•The use of this product is restricted to a qualified doctor or a Paramedic.
•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.
•VIGGO MEDICAL DEVICES LTD 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.
•Dot 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.

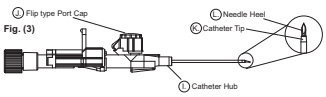


Fig. (3)

	Caution, Consult Accompanying Documents		Manufacturer
	Consult Instructions for Use	EC REP	Authorized EC Representative in the European Community
	Do Not Use if Package is Damage		Recyclable Packaging
	Do not resterilize		Green Dot
	Keep away from sunlight		Recyclable

Rx only

CE 1023

HR - Drugs - 625-L-B(H)
AW/IFU_CB, Rev. 00
Issue Date :12.03.2016