

Size = 158X120 mm, Black Print

Viggo-3-WAY™

INSTRUCTIONS FOR USE

Extension line as an accessory of infusion set

MATERIALS USED:

- SILICON-POLYESTER, POM, PC, PVC, PP, ABS

INDICATIONS:

- Used as a single access device for multiple infusion.
- To separate the injection site from infusion site and prevent mechanical irritation of IV access (in patients at high risk for thrombophlebitis).
- To administer IV contrast agents or fluids in patients undergoing CT/MRI/PET scans, or other procedures that require patient to enter a gantry.
- Small bore high pressure extension lines suitable for high pressure monitoring.

CONTRAINDICATIONS:

- Product should not be used in patients with known hypersensitivity to any of the materials used

INSTRUCTIONS FOR USE:

- Inspect packing of Extension Tube visually to ascertain that package is intact.
- Remove the tube from sterile packing while care must be taken to maintain product hygiene.
- The connecting port of this device is in compliance to EN 20594-1 & ISO 594-2.
- Ensure the secure attachment with other combination device.
- Ensure that venous access (e.g. IV cannula) is patent by flushing with normal saline.
- Connect IV infusion lines to the needle free injection site with universal female port.
- Use the slide clamp to stop and switch the flow of infusion fluid.
- Remove the protective sheath from male luer and connect to venous access device (e.g. IV cannula) and secure the connection by rotating the rotator.

PRIMING:

- Open the slide clamps of IV infusion line and escape air entirely through ENTIRE LENGTH of PVC TUBE. If required the priming can be done with normal saline separately to prevent wastage of infusion fluid.

REMOVAL of EXTENSION TUBE

- Slide the clamp to stop input before removal.
- Unscrew the rotator and remove the extension tube; close IV access (e.g. IV cannula) with suitable stoppers.
- Disconnect the connections from input IV line.

TERM OF USE:

- Recommended Maximum Duration of Use 90hrs as per CDC guideline, while care must be taken depends on type of medication and other factors.

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/manufacturer for analysis.
- For known/reported adverse events associated with use of this device, refer to the Clinical Evaluation Report HH-QA-CER-IV.
- **VIGGO MEDICAL DEVICES DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES RESULTING FROM IMPROPER USE of THE DEVICE**
- Any device that is connected to this product must comply with EN 20594-1 & ISO 594-2. Incorrect connection or lose connection may cause leaking or air getting into blood vessel.
- The device is designed for single use only. Do not re-sterilize and /or reuse.
- 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.
- Single use device dispose the device after use, according to the local legislation.
- Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reactions or infections.
- Contains phthalates, should not be used for the treatment of children, pregnant women or nursing mothers.



Product Ref. No.



Batch Number



Date Of Manufacturing



Use By



Do Not Reuse



Sterilised by Ethylene Oxide Gas



Contains Phthalates



Caution, Consult
Accompanying Documents



Consult Instructions
For Use



Non-Pyrogenic



Do Not Use if
Package is Damage



Do not re-sterilize



Keep away
from sunlight

VIGGO™
MEDICAL DEVICES

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AW/IFU_BS, Rev. 00
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