

Size = 158X120 mm, Black Print

INSTRUCTIONS FOR USE

CONTROFIX™

Infusion set (Micro) with Flow Regulator

MATERIAL USED :

- ABS, PVC, HDPE, PP, POLYCARBONATE (PC) AND POLY ISOPRENE

INDICATIONS :

- Graduated infusion of I.V. Solutions.
- Intravenous drugs administration.
- Total Parenteral Nutrition (TPN).

CONTRAINDICATIONS:

- Product should not be used in patients with known hypersensitivity to any of the materials used.
- Administration of high viscous fluids.
- CANNOT be used for blood transfusion.

INSTRUCTIONS FOR USE:

- The connecting port of this device is in compliance to EN 20594-1 & ISO 594-2
- Open protective cover on the spike (closure piercing device).
- Insert spike into the out let of the solution container.
- Fill the drip chamber up to half by squeezing and releasing. Do not fill completely.
- Make sure that flow regulator is in 'on' position.
- Release clamp on IV set to allow fluid to flow through.
- Prime flow regulator with 10-20 ml.
- Re-clamp proximal (input) tube.
- Connect output tube to IV access.
- Set desired flow rate by rotating graduated marker and also by drop counting in drip chamber of I.V. Set and please note the drop size from the packing of I.V. Set flow rate have a tolerance of $\pm 10\%$.
- Release clamp to allow fluid flow.
- Observe for adequate flow.

TERM OF USE :

- Recommended Maximum Duration of Use: Depends on type of medication and other factors; refer to your facility's guidelines or CDC Guidelines:

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-FR**
- **VIGGO MEDICAL DISCLAIMS ANY RESONSIBILITY 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 this 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
- 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
- **Disposal/Discard:** Dispose off/Discard the used Device in accordance with your Country's Healthcare and Safety Regualtions



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 resterilize



Keep away from sunlight

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