TRIDENT MEDIQUIP LIMITED

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Instruction for Use
(Intravenous Cannula)

➢ **Intended Use:**

- IV Cannula is a sterile & Pyrogen free medical device used to deliver fluids / saline to patients. It is intended for single use. The device is intended to be used for all patients.

➢ **Indication:**

- Intravenous fluid administration.
- Intravenous nutritional support.
- To maintain hydration and/or correct dehydration if patient is unable to take sufficient volume of oral fluids.
- MRI (Magnetic Resonance Imaging) compatible.
- MED (Medial fluid) is applied on catheter as lubricant for smooth insertion into vein.

➢ **Contraindication:**

- Not be used in patient with known hypersensitivity to any of the material used.
- Administration of highly viscous fluids.
- Large blood transfusion.
- Clot obstructed vein, Thrombosis, Phlebitis.
- Stenosis of vein.
- Severe Coagulopathy.

➢ **Undesirable side Effects:**

- Allergy
- Erythema
- Bleeding
- Infection
- Trauma

➢ **Caution:**

- Do not store at extreme temperature. (Storage Condition 5° to 40° C)
- Do not use if package is opened or damaged.
- Store in cool and dry place.
- In case of flushing use a normal saline solution as per standard procedure.
- Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reactions or bacterial infections.

➢ **Direction for use:**

- It is applicable for 14G, 16G, 17G, 18G, 20G, 22G, 24G and 26G.
- Carefully select and aseptically prepare the site.
- Select suitable size of I.V. Cannula & inspect visually to ascertain that package in intact.
- Remove cannula from sterile packing and remove its needle cover.
- Grip the cannula from injection port cap and projection provided on hub.

- The veins of choice for catheterization include the cephalic or basilic veins.
- The smallest gauge of catheter be selected for the prescribed therapy to prevent the risk of phlebitis.
- In an emergency situation or when patients are expected to require large volumes infused over a short period of time, the largest gauge and shortest catheter that is likely to fit the chosen vein should be used.
- Keeping index finger on the catheter hub perform venipuncture and check for flash back of blood in flashback chamber.
- Advance the catheter into the vein and simultaneously withdraw the needle.
- NEVER TRY TO REINSERT THE PARTIALLY OR COMPLETELY WITHDRAWN NEEDLE.
- Withdraw the needle completely while pressing the vein near the cannulation site and discard the needle in an appropriate container.
- Connect the I.V. infusion set line.
- Cover the puncture site with sterile dressing.
- Perform routine monitoring and venipuncture site maintenance according to medical norms. Once placed in situ, the catheter need to be replaced by a new one after every 72 hrs. (Maximum period) or before if the patient feels uneasiness due to formation of phlebitis.
- This device can be connected to all products having a standard 6% connector compliance ISO 80369-7: 2021.

➢ **Material Used:**

- Fluorinated ethylene propylene(FEP) / Polytetrafluoroethylene (PTFE) / Polyurethane (PUR) Catheter, Polypropylene (PP), Polyacetal (POM), High Density Polyethylene (HDPE), Linear Low Density Poly Ethylene (LLDPE), Silicon Rubber & Stainless Steel (SS), Silicone Dispersion

➢ **Target age group:**

- 24G, 26G for Infants & Neonates, 22G for Pediatrics and 14G, 16G, 17G, 18G, 20G for Adult.

➢ **Infants -** 0-1 year
➢ **Neonates** - is a child under 28 days of age
➢ **Pediatrics - F**rom birth up to the age of 18.
➢ **Adults -** an adult is anyone who is 18 or older

➢ **Disposal System:**

- Discard the product and packaging in proper waste container & dispose off the product in accordance with accepted medical practice and applicable local, state and country laws and regulations for handling of bio-medical waste.
- Sharp objects should be disposed of in containers, and other components should be disposed of and handed over to biomedical waste.

➢ **Duration of use:** 72 hrs

➢ **Warning:**

- 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.
- Company disclaim any responsibility for possible consequences resulting from improper use.
- 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 damaged of 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 single use.
- Store in cool & dry place. Do not expose to heat or direct sunlight.
- The product should be used immediately after opening the packaging.

➢ **Reporting of Adverse Events**

A notice to the user or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established,

- In case of any serious incident please report to the below mentioned Mail - ID.
  Mail ID: info@tridentmediquip.com

- **Shelf life:** 5 years

Explanation of symbols as per MDR 2017/745 & EN ISO 15223-1: 2021

	Do not Reuse		Do not Resterilize		Use by Date		Date of Manufacturer
	Catalogue Number		Batch Code		Sterilized by Ethylene Oxide		Do not use if package is damaged
	Keep away from sunlight		Caution		Consult Instructions for Use		Manufacturer
	Temperature Limitation		CE Mark		Non-Pyrogenic		Medical Device
	Unique Device Identifier		European Representative		Keep Dry		Single Sterile Barrier System

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