

Doc. No.:	RGI/IFU-09/3077N
Issue No.:	04
Rev. No.:	03
Date	03.10.2022

Romsons®

STERI FLO WITH NEEDLE

(INFUSION SET FOR SINGLE USE)

REF GS-3077N

Rx
ONLY



INSTRUCTIONS FOR USE

The device is biocompatible, Non-Toxic, Non-Pyrogenic, Phthalate Free, Latex Free, Sterile, Single Use

Caution : Carefully read all instructions prior to use. Observe all warnings & precautions noted throughout these instructions. Failure to do so may result in complications. This device is Sterile & Ready for Use. Sterility is guaranteed - if pack is undamaged. The device is for Single Use Only.

Device Description: Premium Infusion set with Needle and new features for enhanced quality. Sharp piercing spike for easy insertion in I.V container. Specially designed vented infusion set with 1.2 micron air vent filter to ensure entry of air without contamination. DEHP free drip chamber material ensures higher safety standards. Disc type fluid filter prevents entry of any particulate matter in the fluid. DEHP free super smooth kink resistant tubing with efficient roller controller for unrestricted flow. "Y" injection port is provided for additional medication. New advanced rotating luer lock with cap for secure connection to the cannula. Sterile and individually blister packed

Population of use: Adult & Paediatrics.

Intended User : To be administered by an expert qualified medical professional.

Intended Use: Steri Flo I.V. Set intended for intravenous infusion of I.V. Fluids and parenteral drugs. It is used for providing rapid /slowly for infusion of fluid into the patient's from a container to a patient's vascular system through a needle or catheter. Maximum use period not more than 3 days

Preferred Route of Administration: Intravenous

Contents: Sterile, single use Steri Flo IV set packed in a Peel open pouch.

Size: Std , 20 Drops of distilled water equivalent to 1 ml \pm 0.1 ml

Material of Construction: PVC, PP, Master Batch, ABS, Nylon, Polyamide, SS & Isoprene

Storage: Store in a cool & dry place.

Indications: For intravenous, infusion of medications or fluid requiring continuous delivery at controlled infusion rates.

Contraindications Use in patient with a known allergic reaction to any of the product components, Administration of highly viscous fluids, It is not intended for the delivery of whole blood, blood components.

Potential Complications / Risks: Risk from improper fitment due to faulty 6% luer taper, Leakage & blockage, any broken / cracked part / less clear drip chamber and tubing /components, kinking, un-proper tip of piercing spike, faulty air passage in vented piercing spike, uncontrolled flow.

Warnings: This device is intended for Single use only.

DO NOT resterilize and /or reuse the device, as this can compromise the device performance (functionality) and may cause inadequacy, deterioration of the device technical factors, rendering the device non-functional and unfit for intended use and also this may increase the risk of cross contamination due to several aspects including inappropriate reprocessing.

Re-use of single use device creates a potential risk for patient or user. It may lead to contamination and / or impairment of functional capability.

Contamination and / or limited functionality of the device may lead to injury, illness of the patient.

Precautions:

- (i) Check the integrity and functionality of the Infusion sets before use. Do not use if the Unit Pack is open or damaged.
- (ii) Determine patient's condition and vitals status During device application / Operation.
- (iii) Conduct procedure under strict surgical protocol and ensure complete asepsis.
- (iv) Destroy the device & its accessories after single use as bio-medical waste as per applicable laws.
- (v) Do not Re-sterilize. Do not Re-use. Single use only.
- (vi) Do not put the Device to Use after the Use by Date or Date of Expiry.

Adverse Events: Malfunction due to leakage or blockage, Embolism, Allergic reactions, tissue necrosis, Phlebitis, Thrombophlebitis & blistering Phlebitis, Infiltration, Hematoma, Extra Vascular drug administration.

General Instructions:



To be administered by an expert qualified medical professional. Use maximal sterile barrier precautions during administration

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Dispose the device after use as bio-medical waste as per applicable laws.

Use Instructions:

- (1) Check the packing carefully, if packing is found damaged, torn or pierced, discard the piece.
- (2) Wash-up and scrub hands and preferably use pre-sterile protective gloves.
- (3) Peel open the pouch and take out the device aseptically. Close flow regulator.
- (4) Insert the spike at the top of the bottle to its full Length into the top of the solution container.
- (5) Squeeze drip chamber till it is half filled.
- (6) Open flow regulator & allow solution to pass until all air bubbles in the tube are removed. Close the flow regulator.
- (7) Connect the set to intended device and regulate desired flow rate by using flow regulator.

 Mfr.: **Romsons International** (Unit-II), 59J(C) & 9, Noida Special Economic Zone, Noida Dadri Road, Phase-II, Noida-201305 (INDIA)
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Basic UDI DI : 8902120C014RX



 REF	Catalogue Number	 MD	Medical Device		Do not re-use		Consult Instructions for Use
 LOT	Batch Code		Country of Manufacture		Do Not Resterilize		Keep away from sunlight
	Date of Manufacture		Sterilized Using Ethylene oxide		Unique device Identifier		Keep Dry
	Use by date		Non-pyrogenic		Do Not Use if Package is Damaged & consult instructions for use		Caution
	Manufacturer		Authorized Representative in the European Union		Single Sterile barrier system		Temperature Limit
	Gravity Feed		Liquid Filter with Pore Size		Fluid Path		Drops per millilitre