

Doc. No.:	RGI/IFU-09/3314
Issue No.:	04
Rev. No.:	03
Date	03.10.2022

Romsons®

NON VENTED INFUSION SET

(INFUSION SET FOR SINGLE USE)

REF

GS-3314

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: It has a cylindrical collapsible drip chamber to visualize the Drop Rate. The disc type fluid filter to filter any particulate matter in the IV fluid. It has 150 cm long super smooth kink resistant tubing with efficient roller controller for accurate and unrestricted flow. The flash ball type injection port allows for extra medication. The infusion set with drop rate of 20 drops/ml is sterile and individually packed. They come in a standard packing of 25 units per box.

Population of use: Adult & Paediatrics.

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

Intended Use: Non-vented 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 Non Vented IV set packed in a Peel / Tear pouch.

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

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

Storage: Store in a cool & dry place.

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

Contra-indications: 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.

Do not attempt to re-insert a partially or completely withdrawn needle.

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

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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) Tear / 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) Perform vein puncture and regulate flow by opening flow regulator gradually to achieve the desired flow rate.
- 8) Remove needle protector holding needle upright.

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



	Catalogue Number		Medical Device		Do not re-use		Consult Instructions for Use
	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