Doc. No.:	RGI/IFU-09/3097N
Issue No.:	04
Rev. No.:	03
Date	03.10.2022

Romsons®

ROMOTROL

(INFUSION SET FOR SINGLE USE)

REF **GS-3097N**

℞ 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: Device Contains Flow regulator with extension set for precise flow control. Ensures safe application in demanding critical care settings. Reliable Drop Rate accuracy across the full adjustable scale. Ergonomic dial design with ridges for easy grip and adjustment. Precise Drop Rate control of IV fluids with range of 5ml/hr to 250 ml/hr. Double scale for 10% and 40% solution strengths. DEHP Free soft and kink resistant PVC tubing. Male luer connector at one end and female luer connector at other end.Provided with a latex free"Y" type injection port made up of silicone for intermittent medication. Can be used with all standard I.V sets using luer lock connections. Sterile and individually blister packed..

Population of use: Adult & Paediatrics**.**

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

Intended Use: Romotrol 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 Romotrol iv set packed in a Peel open pouch.

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

Material of Construction: PVC, PP, PE, ABS , Polyamide, Isoprene, Acrylic, EVA & 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.

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)Peel / Tear 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) Removing prime stop connector from rotating luer locks connector & 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.

(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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CE 2460

Basic UDI DI : 8902120C014RX

REF	**Catalogue Number**	MD	**Medical Device**		**Do not re-use**		**Consult Instructions for Use**
LOT	**Batch Code**	IN	**Country of Manufacture**		**Do Not Resterilize**		**Keep away from sunlight**
	Date of Manufacture	STERILE EO	**Sterilized Using Ethylene oxide**	UDI	**Unique device Identifier**		**Keep Dry**
	Use by date		**Non-pyrogenic**		**Do Not Use if Package is Damaged & consult instructions for use**		**Caution**
	Manufacturer	EC REP	**Authorized Representative in the European Union**		**Single Sterile barrier system**	40 °C (104 °F) 10 °C (50 °F)	**Temperature Limit**
	Gravity Feed	15 µm	**Liquid Filter with Pore Size**		**Fluid Path**	20 ml	**Drops per millilitre**