Doc. No.:	RGI/IFU-09/3303
Issue No.:	04
Rev. No.:	03
Date	03.10.2022

Romsons®

ROTAFLO

(I.V. EXTENSION LINE WITH ROTATING TYPE PRECISION FLOW CONTROLLER)

REF **GS-3303**

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 undamaged. The device is for Single Use Only.

Device Description: It contain Tubing, Y- Injection site, rotating type Flow Controller, Luer Lock Connector. Clear markings on the dial allow you to easily set a specific flow rate, Precision Controller with Extension. Ensure safe application in demanding critical care settings. Reliable flow rate accuracy across the full adjustable scale. Male luer connector at one end, female luer connector at other end.

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 Rotaflo packed in a Peel open pouch.

Material of Construction: PVC, PP, ABS, Isoprene, & MB

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 and tubing /components, kinking.

Warnings: 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- Peal open package to remove the device & remove protector cap female connector.

2- Check & put to close position the rotating type precision flow controller.

3- Connect female luer lock connector to intended device.

4- Remove the male luer cap.

5-Run infusion & flush tubing and controller of the Air: Flick and tap the rotating type controller during flushing to release any trapped air. Then turn dial to close position & then back to full open position again, to ensure complete removal of air from the controller.

6-When all the air flushed from the controller, upper Tubing and lower Tubing, turn the dial to close position.

7-Connect line to the patient/ intended device.

8-Rotate to rotating type precision flow controller to desired flow rate /hr) confirm by timing drops with watch. Use the flow chart as guide.

9-An adjusted setting made by drop confirmation can vary from the dial marking, however, if there is a large discrepancy from the dial numbers to actual flow (runs too slow), look for blockage in the IV Line.

10-Use 'Y' port only for additional drug administration.

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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

Fluid Path