

Doc. No.:	RGI/IFU-09/3310N
Issue No.:	04
Rev. No.:	03
Date	03.10.2022

Romsons®

STERISET

(INFUSION SET for single use with Needle)

REF GS-3310N

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 and enhanced quality. Manufactured from DEHP free material safe to be used in all kinds of patients without any associated complications. Sharp spike is provided for better penetration in all types of fluid containers. Vented set with 1.2µ air vent filter to ensure entry of contamination free air. DEHP free drip chamber material ensures higher safety standards. Provided with disc type fluid filter to prevent entry of any particulate matter. Equipped with specially designed "Y" injection port made up of silicone, having re-sealing property for additional medication. Smooth kink resistant tube with efficient roller controller for unrestricted flow. New advanced rotating luer lock at distal end 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 Set 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 Inflow set IV set packed in a Peel / Tear pouch.

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

Material of Construction: PVC, PP, ABS, PE, Nylon, Acrylic, SS, Master Batch & 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 / 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) 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)
 **OBELIS S.A.**, Bd. Général Wahis 53, 1030 Brussels, Belgium, Email: mail@obelis.net



Basic UDI DI : 8902120C014RX

 REF	Catalogue Number	 MD	Medical Device	 Do not re-use	 Consult Instructions for Use
 LOT	Batch Code	 3IN	Country of Manufacture	 Do Not Resterilize	 Keep away from sunlight
 W	Date of Manufacture	 STERILE EO	Sterilized Using Ethylene oxide	 UDI	 Keep Dry
 H	Use by date	 XX	Non-pyrogenic	 Do Not Use if Package is Damaged & consult instructions for use	 Caution
 M	Manufacturer	 EC REP	Authorized Representative in the European Union	 Single Sterile barrier system	 40 °C (104 °F) 10 °C (50 °F)
 G	Gravity Feed	 15 µm	Liquid Filter with Pore Size	 Fluid Path	 20 ml