

Doc. No.:	RGI/IFU-09/3223
Issue No.:	04
Rev. No.:	03
Date	03.10.2022

Romsons®

INTRASAFE®

(I.V. Cannula with Injection Port, Wings & Safety Feature)

REF GS-3223



INSTRUCTIONS FOR USE

The device is biocompatible, Non-Toxic, Non-Pyrogenic , 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. To be administered by an expert qualified medical professional.

This device is Sterile & Ready for Use. Sterility is guaranteed – if pack is undamaged. The device is for Single Use Only.

Device Description : Specially designed innovative safety cannula. The cannula protects the healthcare provider from the risks associated with accidental needle stick injuries. It allows caregivers safe and easy I.V. access. Special double tapered and Kink resistant FEP-Teflon catheter. Unique mechanism on the tip which immediately covers the sharp tip of the ,Self-activating safety mechanism prevents the incidences of needle stick injuries and blood splash. Robust needle tip protection. Triple faceted needle tip for improved patient comfort and reduced incidences of complications like phlebitis. Luer lock end allows universal attachment to all standard devices.

Population of Use: Adult & Paediatrics.

Intended Use : Intended for intermittent / continuous peripheral intra venous infusion. Maximum use period not more than 3 days.

Preferred Route of Administration: Cephalic, Basilic, and Median Cubital Veins.

Contents : Sterile, I.V. Cannula with wing, luer lock, injection port & radio-opaque stripes.

Size : G 14,16,18, 20, 22, 24, 26.

Material of Construction : Polypropylene, Polyoxymethylene, Stainless Steel, Fluorinated ethylene propylene-Teflon (FEP), Polyethylene, Silicone , Master Batch..

Storage : Store in a cool & dry place.

Indications : For intermittent or continuous peripheral intravenous infusion of fluids, medications, nutritional support, blood / blood products, for repetitive blood sampling, for fluid resuscitation, etc.

Contra-indications: Administration of high viscous fluids, large blood transfusion, hypersensitivity to device material, Bleeding disorders, Infection at the site, burned extremity, tissue necrosis, etc. Administration of I. V. Cannula is contra-indicated during the process of MRI

Potential Complications / Risks : Pain, failure to access vein, air embolism, catheter mal-positioning, catheter- related infection, phlebitis, thrombophlebitis, catheter occlusion, clotting, catheter damage, catheter kinking, peripheral nerve palsy, skin & soft tissue necrosis, migration of the catheter, etc.

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 factor, 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 WITHDRAWN NEEDLE.

In the event of catheter damage / separation, recovery of any portion should be performed based on physician determination of individual patient condition & appropriate retrieval protocol under fluoroscopy.

On the needle withdrawn after penetration of cannula the needle tip securely gets fixed in a fixture thereby preventing any risk of needle stick injury.

Do not administer I. V. Cannula during the process of MRI & near MRI as this may interfere with the magnetic resonance imaging procedure.

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 after the Date of Expiry.
- (vii) Do not attempt to re-insert partially or completely withdrawn needle.

Adverse Events: Hematoma, Infection, Pain, Swelling, Undue perforation, Phlebitis, Thrombophlebitis, Extravasation, Embolism, etc.

General Instructions : To be used by a qualified / a trained paramedic person. Use maximal sterile barrier precautions during administration. Catheter has radio-opaque stripes for X-ray visualization.

For safe combination/attachment to infusion line accessory: I.V. Cannula hub is rigid with a 6% luer taper.

For proper & secure union with the I.V. Line and to match with rigid 6% luer taper male fitting (with/without luer lock) of infusion accessory.

The attachment to be done by push fitment & clockwise rotation at 90 degree angle to the I.V. Cannula hub.

(These are only the guidelines & hence, user's medical experience / expertise in important).

Doc. No.:	RGI/IFU-09/3223
Issue No.:	04
Rev. No.:	03
Date	03.10.2022

Use Instructions :

- (1) Check the device for size / color code confirmation. Peel open the pack and remove the device aseptically.
- (2) Check the integrity of the I.V. Cannula.
- (3) Position the patient. Identify the landmark for vein puncture. Select, prepare & disinfect the vein puncture site appropriately. Open the protective cap on the Cannula. Hold the entire cannula unit securely. Insert the cannula into the vein. On entering the vein the flash back indication is visible. Advance the cannula further into the vein appropriately. Gently remove the needle in a controlled & continuous manner & discard appropriately to needle destroyer & bin to sharps container.
- (4) Immediately apply the luer lock closure cap on I.V. Cannula hub or connect to accessory device appropriately, as per case. Secure the Cannula with a sterile dressing.
- (5) Attach the infusion line-male fitting to the I.V. Cannula hub by removing the closure cap. Secure connection & run the infusion.
- (6) Flush the cannula at regular intervals with isotonic saline solution to maintain patency or to prevent phlebitis.
- (7) At the time of I.V. Cannula removal, check the catheter tip integrity. Do not apply excessive force or manipulate, during cannula removal.

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

EC REP OBELIS S.A, Bd. Général Wahis 53, 1030 Brussels, Belgium, Email: mail@obelis.net

Basic UDI DI : 8902120C001RN



REF	Catalogue Number	MD	Medical Device	Single Use Only	Instructions for Use
LOT	Batch Code	Country of Manufacture		Do Not Re-sterilize	Keep away from sunlight
Date of Manufacturer		STERILE EO	Sterilized Using EO	UDI	Store in a Dry Place / Keep Dry
Use before expiry date		Non-pyrogenic		Do Not Use if Pack is Damaged	Caution, Consult Documents
Manufacturer		EC REP	Authorized Representative in the European Union	Single Sterile barrier system	Temperature Limit