Doc. No.:	RGI/IFU-09/3227
Issue No.:	04
Rev. No.:	03
Date	03.10.2022

Romsons®

VENICAN®

(Intravenous cannula)

(I.V. Cannula with Injection Port & Wings)

REF GS-3227

℞ ONLY

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 : I.V. Cannula consists of a smooth fine tipped tapered Teflon, radio-opaque cannula with sharp triple facetted beveled needle with dual cutting edges. Ergnomically designed wings for fixation of cannula to the penetration site. Proximally, I.V. Cannula consists of a flash back chamber for identification of instant penetration of the vein. Provided with size color coded injection port for intermittent medication / blood sampling.

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, Ethylene-vinyl acetate ,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 blood sampling, for fluid resuscitation, etc.

Contraindications: 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, needle stick injuries, 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 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.
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.
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 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 administered by an expert qualified medical professional. 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).

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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 & destroy appropriately with 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.

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Basic UDI DI : 8902120C001RN

CE 2460

REF	**Catalogue Number**	MD	**Medical Device**		**Single Use Only**		**Instructions for Use**
LOT	**Batch Code**	IN	**Country of Manufacture**		**Do Not Re-sterilize**		**Keep away from sunlight**
	Date of Manufacturer	STERILE EO	**Sterilized Using EO**	UDI	**Unique device Identifier**		**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**	40 °C (104 °F) 10 °C (50 °F)	**Temperature Limit**