

Doc. No.:	RGI/IFU-09/1020C
Issue No.:	04
Rev. No.:	03
Date	03.10.2022

Romsons®

URINE COLLECTING BAG

(without NRV & without Bottom Outlet - Bag Capacity 2000ml)

REF GS-1020C



INSTRUCTIONS FOR USE

The device is biocompatible, Non-Toxic, Non-Pyrogenic, Phthalate 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. 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 : Single use, Urine Collection Bag for drainage purpose. Closed urine drainage system for short and long term use. Manufactured from soft clinical grade PVC sheeting. Reinforced eyelets allow easy hanging and provide maximum protection against tearing. Kink resistant 90cm tube provided with universal tapered connector. Easy to read scale for quick determination of urine volume. Device comes without Bottom outlet & NRV. Capacity-2000ml

Population of Use: Adult.

Intended User: To be administered by an expert qualified medical professional, Urologist & Trained nurse.

Intended Use : Used for short term urine collection & drainage. Maximum use period not beyond 7 days.

Preferred Route of Administration: Attached to the In-dwelled urethral catheter.

Contents : Urine Collection Bag (2000ml) without NRV & without Bottom Outlet

Size : 2000ml.

Material of Construction : Polyvinyl chloride, Polypropylene, PVC Sheet MB

Storage : Store in a cool & dry place.

Indications : Any medical condition requiring management of collection & drainage of urine.

Contra-indications : Hypersensitivity to device material, Any abnormality associated with using of a urine bag, lower abdominal wounds or scarring overlying cellulitis.

Potential Complications / Risks : Dislodgement of connection from the urethral catheter, Temporary blockage due to folding of tubing,

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 put the Device to Use after the Use by Date or Date of Expiry.

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.

This device contains phthalates, hence the risk benefits must be considered prior to use in children, pregnant mothers & lactating mothers.

While hanging by bedside, keep up the urine bag way up from the floor.

Precautions :

- (i) Check the integrity and functionality of the urine collecting bag 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) Dispose the device & its accessories after single use as bio-medical waste as per applicable laws.
- (iv) Do not Resterilize. Do not Re-use. Discard after single use.
- (v) Do not put the Device to Use after the Use by Date or Date of Expiry.

Adverse Events : CAUTI, Microbial colonization, etc.

General Instructions : To be administered by an expert qualified medical professional. Use maximal sterile barrier precautions during administration. (These are only the guidelines & hence, user's medical experience / expertise is important).

Use Instructions :

- (1) Check the packing carefully, if found damaged, torn or pierced discard the piece. Do not use if pack is damaged.
- (2) Wash up and scrub hands and preferably use pre sterile protective gloves.
- (3) Tear open the pack & drawout the device with care.
- (4) Remove the cap from the Tapered Connector.
- (5) Connect the Tapered Connector to the Urethral Catheter.
- (6) To discard & dispose used Urine Bag.

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 : 8902120A012RD



	Catalogue Number		Medical Device		Do not Re-use		Consult Instructions for Use
	Batch Code		Country of Manufacture		Do Not Resterilize		Keep away from sunlight
	Date of Manufacture		Sterilized Using Ethylene Oxide		Unique device Identifier		Keep Dry
	Use by date		Authorized Representative in the European Union		Do Not Use if Pack is Damaged		Caution

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	Manufacturer		Single Sterile barrier system	 10 °C (50 °F) 40 °C (104 °F)	Temperature Limit
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