

Doc. No.:	RGI/IFU-09/1020R5
Issue No.:	04
Rev. No.:	03
Date	03.10.2022

Romsons®

URINE COLLECTING BAG

REF

(With NRV, T-Type Bottom Outlet & Hanger - Bag Capacity 2000ml)

GS-1020R5



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. Transparent, Urine Drainage Bag with Non Return Valve (NRV), with hanger & kink resistant flexible tube, with stepped tapered connector for grip fixation to the funnel of the foley balloon catheter / urethral catheter. Urine Bag provided with T-Type Bottom Outlet for management of fast, efficient drainage. Scale graduations on the bag are for indicative purpose only are not intended for measurement function.

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) with NRV, T-Tap Bottom Outlet & Hanger.

Size : 2000ml.

Material of Construction : Polyvinyl Chloride, PVC Sheet, Polypropylene, Polyethylene Thermoplastic Rubbers, LDPE, Master Batch.

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, contamination of the bottom outlet.

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.

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 use. 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.

While hanging by bedside, keep up the urine bag way up from the floor so that the bottom outlet is not contaminated.

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) Close the Bottom Outlet 'T - Type' of the Urine Bag.
- (5) Remove the cap from the Tapered Connector.
- (6) Connect the Tapered Connector to the Urethral Catheter.
- (7) For drawing samples use the Sampling Port.
- (8) Non-return valve (NRV) provided on the Urine Bag to enables constant flow of urine into the Urine Bag.
- (9) Hang the Urine Bag to the patient's bed with the Hanger provided on the Bag.
- (10) To discard & dispose used Urine Bag ensure that the 'T - Type' bottom outlet of the Urine Bag is closed.
- (11) Discard the Urine Bag after Use.

Doc. No.:	RGI/IFU-09/1020R5
Issue No.:	04
Rev. No.:	03
Date	03.10.2022

Mfr.: **Romsons International** (Unit-II), 59J(C) & 9, Noida Special Economic Zone, Noida Dadri Road, Phase-II, Noida-201305 (INDIA)
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 Re-sterilize		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
	Manufacturer		Single Sterile barrier system		Temperature Limit		