

Doc. No.:	RGI/IFU-09/1024A/B/C
Issue No.:	04
Rev. No.:	03
Date	03.10.2022

Romsons®

LEG BAG -URINE COLLECTING BAG

(With NRV, T-Type Bottom Outlet - Bag Capacity 750ml)

REF GS-1024A/B/C



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. Manufactured from soft clinical grade PVC sheeting. Suitable for day & night use for incontinence. Non-return valve to prevent the backflow of urine, Convenient for tying on thigh with optional elastic straps' Type bottom outlet Size : 750 ml, Tube Length: 10cm(A), 30cm(B) & 40cm(C) , Individually packed.

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 : Leg Bag (750ml) with NRV, T-Tap Bottom Outlet.

Size : 750ml.

Material of Construction : Polyvinyl Chloride, Polypropylene, Polyethylene Thermoplastic Rubbers, 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.

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.

Precautions :

- (i) Check the integrity and functionality of the leg bag -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 in 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) Non-return valve (NRV) provided on the Urine Bag to enables constant flow of urine into the Urine Bag
- (8) Put and fasten the leg band high on your thigh with the bag label facing patient.
- (9) To discard & dispose used Urine Bag ensure that the 'T - Type' bottom outlet of the Urine Bag is closed.
- (10) Discard the Urine Bag after Use.



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 8902120A0013RF



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

Doc. No.:	RGI/IFU-09/1024A/B/C
Issue No.:	04
Rev. No.:	03
Date	03.10.2022



Manufacturer



Single Sterile barrier system



Temperature Limit