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Romsons®

URINE COLLECTING BAG

(without NRV & without Bottom Outlet - Bag Capacity 1500ml) REF GS-1020E

℞ ONLY

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 kink resistant flexible tube, with stepped tapered connector for grip fixation to the funnel of the foley balloon catheter / urethral catheter. 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-dewelled urethral catheter.

Contents : Urine Collection Bag (1500ml) without NRV & without Bottom Outlet.

Size : 1500ml.

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 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) Remove the cap from the Tapered Connector.
(5) Connect the Tapered Connector to the Uretheral 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)
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CE 2460
Basic UDI DI : 8902120A012RD

REF	**Catalogue Number**	MD	**Medical Device**		**Donot Re-use**		**Consult Instructions for Use**
LOT	**Batch Code**	IN	**Country of Manufacture**		**Do Not Re-sterilize**		**Keep away from sunlight**
	Date of Manufacture	STERILE EO	**Sterilized Using Ethyele Oxide**	UDI	**Unique device Identifier**		**Keep Dry**
	Use by date	EC REP	**Authorized Representative in the European Union**		**Do Not Use if Pack is Damaged**		**Caution**
	Manufacturer		**Single Sterile barrier system**	40 °C 10 °C	**Temperature Limit**		