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Romsons®

PAEDIATRIC URINE COLLECTING BAG

(With Self Adhesive Facility - Bag Capacity 100ml & 200ml)

REF GS-1062-100&200

Rx 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 : The pediatric urine bag is suitable for both male and female infants. Hypoallergic adhesive is used for fixation to minimize the risk of allergy and injury, These urine collection bags are sterile & individually packed. The urine collection bag has an easy to read scale for quick determination of urine volume This urine bag is a perfect pick for short as well as long term use, The capacity of the urine bag is 100 ml

Population of Use: PAEDIATRIC.

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 : Paediatric Urine Collecting Bag. With Self Adhesive Facility.

Size : 100ml, 200 ml

Material of Construction : LDPE Sheet, LDPE, ACRYLIC, 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 bag due to poor adhesion, Temporary blockage due to folding of bag.

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 paediatric 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 & draw out the device with care.
- (4) Remove the adhesive liner from the urine bag and fix appropriately over the paediatric genitalia.
- (5) After use discard & dispose the used Paediatric Urine Collecting Bag as bio-medical waste as per applicable laws.

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Basic UDI DI : 8902120A008RN



REF	Catalogue Number	MD	Medical Device	Do not Re-use	Consult Instructions for Use
LOT	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	