INSTRUCTION FOR USE FOR PAEDIATRIC URINE BAG

Product Name : **Paediatric Urine Bag**

Brand Name : Ultramed Paediatric Urine Collector Bag

Manufacturer's Name : Ultra for medical products (Ultramed) Co (U.M.I.C) S.A.E

Manufacturer's Address : Part No. (304:310) & part no. (312) – Industrial Area, Arab El Awamer – Abnoub - Assiut – Egypt.

Description of the Device:

- Pediatric Urine Bag is a sterile medical device designed from non-toxic, Medical grade Polyethylene sheet for efficient and reliable short-term urine collection. Suitable for use in a variety of clinical settings like hospitals, clinics or home care settings.
- Pediatric urine bag is designed to collect urine from male and female babies and can be used for urine sampling for monitor and diagnostic purpose
- It has Transparent design to allow for easy monitoring of urine output and color.
- It is Provided with **Hypoallergic adhesive** that fits securely around the genital area to prevent leakage and easy removal.
- The Pediatric Urine Bag tailored for children's anatomy and urine output.
- The capacity of urine bag is **100 ml** for pediatric urine bag.
- It has **Graduated marks:** for approximate measurement of urine volume.
- It is Provided with **Sponge mats** to maintain integrity of the bag and prevent leakage.
- the bag is applied to the child's genital area, ensuring a secure fit, and is monitored regularly for filling and potential leakage**.**
- Provides a non-invasive method for urine collection, which is especially beneficial for young patients.
- Product is conventional and fully equivalent with many products in market.
- The product is CE marked.
- The product is approved by the Ministry of Health.
- The product is sterilized using EO (Ethylene Oxide).
- The product is intended for **single-use** and should be removed immediately after urine collection, typically within **1hr**.
- Paediatric urine collection bags are sterile & individually packed in a tear pouch.

Material Used:

- Polyethylene.
- Sponge mats
- Medical Grade Hypoallergenic glue

Intended purpose:

The paediatric urine bag is designed for male and female infants and children for the non-invasive collection of urine samples for diagnostic or monitoring purposes

Variants:

Trade Name	Variant	REF (Product ID Number)
Ultramed Urine Collection Bag	Medical Grade adhesive	3005

Clinical Indications:

- **Monitoring Output:** In healthcare settings, urine bags are used to measure and monitor urine output in critically ill or hospitalized patients, as changes in urine output can indicate fluid balance, kidney function, or hydration status.
- **Diagnostic purposes:** to collect urine sample for testing, Urine bag can help to detect urine color which reflect disease, infection, drug effect

Contraindications: Not known

Patient Target Group: both male and female infants.

Intended User:

To be used by an expert qualified medical professional, Skilled or Trained Personnel (**In-Charge**)

Application site in the body:

Pediatric Urine collection bag is non-invasive device for external use

Replacement Frequency:

- These are designed for one-time use and should be replaced after collecting a sample.
- Discard the bag immediately after use to prevent contamination
- Replace the bag sooner if it leaks, or becomes detached.
- Change the device immediately upon suspected contamination.

Clinical benefits:

- **Non-Invasive Collection**: Urine bags provide a non-invasive method for collecting urine, which can be less stressful for both the child and caregiver compared to catheterization.
- **Ease of Use**: They are typically easy to apply and remove, making them convenient for caregivers to manage.
- **Hygiene**: Urine bags can help maintain hygiene and reduce the risk of contamination compared to other collection methods, especially in young children who may have difficulty using a toilet.
- **Monitoring Output**: They allow for monitoring of urine output, which can be crucial in assessing hydration status or kidney function in pediatric patients.
- **Versatility**: Urine bags can be used in a variety of settings, including hospitals, clinics, and at home, making them a versatile option for managing urinary needs.
- **Reduced Risk of Trauma**: Using a urine bag minimizes the risk of trauma to the urethra and bladder that can occur with catheterization.
- **Facilitates Diagnosis**: They can facilitate the collection of urine samples for diagnostic tests, making it easier to identify infections or other urinary issues.

Use Environment:

- Hospital, Emergency Room, clinics, Home

Life time of device:

- The pediatric urine bag should be removed immediately after urine collection, with a maximum duration of use of 1 hour.

Sterility status and Method of sterilization:

- Pediatric Urine Bag supplied in sterile state and sterilized using ethylene oxide.

Performance Characteristics:

- **Transparent urine bag sheet:** to easily inspect the urine color and volume
- **Sponge mats:** to maintain integrity of the bag and prevent leakage
- **Medical Grade Hypoallergenic glue:** for better grip and easy removal of the bag
- **Graduated marks:** to measure the urine volume approximately

Risks Associated with reuse

- Re-use of the device may create a potential risk to the patient, including contamination and/or impairment of the device function.

Instruction for Use:

Before Use

1. Write the child's name and date of birth on the sample container, if not already labeled in case of sample collection
2. Carefully inspect the packaging; if packing is found damaged, torn or pierced, discard the piece
3. Wash hands thoroughly with soap and water and dry
4. Remove the child's diaper
5. Follow steps in chart below:

During Use

Male



Step1: Lay Infant on his back and wash entire genital area. A gentle bath soap is preferred. Avoid using a lotion soap solution, oils and baby powders as it can leave a residue that may interfere with adhesion. Wash scrotum first, then penis and anus last. Rinse and dry. Cleanse entire area again using the towelette provided. Allow to air-dry



Step2: Remove protective paper from the bottom half of the adhesive patch. It is easier to leave the top half of the adhesive covered until the bottom section has been applied to the skin

Female



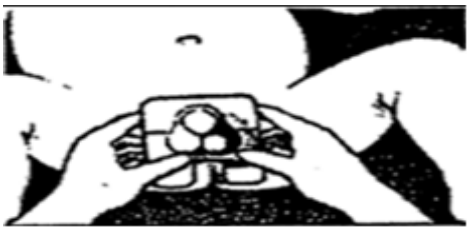
Step1: Lay Infant on his back and wash each skinfold in the genital area. A gentle bath soap is preferred. Avoid using a lotion soap solution, oils and baby powders as it can leave a residue that may interfere with adhesion. Wash anus last. Rinse and dry. Cleanse entire area again using the towelette provided. Allow to air-dry



Step2: Remove protective paper from the bottom half of the adhesive patch. It is easier to leave the top half of the adhesive covered until the bottom section has been applied to the skin. Ensure that the skin surface is dry before applying collection bag

During Use

Male

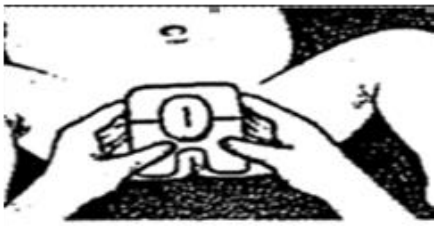


Step3: When pressing adhesive to the skin, be sure to start at the narrow bridge of skin between the anus and the base of the scrotum and work outward from this point. Be sure skin is dry before applying the collection bag. This is important to prevent feces from entering the bag

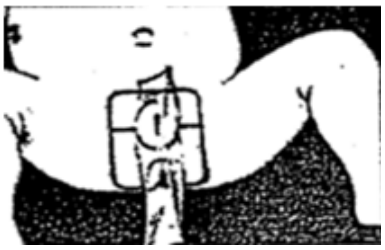


Step4: Press adhesive firmly against the skin, avoiding wrinkles. When the bottom section is in place, remove the protective paper from the upper portion of the adhesive patch. Work upward to complete application

Female



Step3: Stretch perineum to separate skin folds and expose vagina. When applying adhesive to the skin, be sure to start at the narrow bridge of skin that separates the vagina from the anus, and work outward from this point. This is important to prevent feces from entering the bag



Step4: Press adhesive firmly against the skin, avoiding wrinkles. When the bottom section is in place, remove the protective paper from the upper portion of the adhesive patch. Work upward to complete application. Securing adhesive around the vagina

After Use

6 Once the infant voids into the collection bag, the top of the collector is sealed securely by folding and sealing the adhesive area. This will help prevent spillage and maintain the cleanliness of the specimen

7 Carefully transfer specimen to the sterile container and be careful not to contaminate the specimen

8 Make sure the container cover is closed securely

9 Wash your hands with soap and water and dry

Warnings:

- For Single use.
- Discard after single use, Reusing can be associated with Cross infection,
- Do not use if the packaging is damaged or has been previously opened.
- DO NOT re-sterilize and /or reuse the device, as this can compromise the device performance (functionality) and may cause inadequacy, deterioration of the device technical factors, rendering the device non-functional and unfit for intended use.

- 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.
- Do not use if package is open or damaged.
- Check the integrity and functionality of the Pediatric Urine Collection Bag before use.
- The product should be used only by experienced person who have a thorough understanding of the clinical and technical aspects of product.
- Contamination and / or limited functionality of the device may lead to injury, illness of the patient.
- Never use the device after expiry date
- Store up to 32º C, avoid excessive heat, protect from direct sunlight and moisture.
- The device should be disposed as per the safe disposal instructions as described in the instructions for use.
- Ultramed will not assume any responsibility in case of any incidental or consequential damages resulting from reuse of the product.

Precautions:

- Carefully read all instructions prior to use. Observe all warnings & precautions noted throughout these instructions.
- Failure to do so may result in complications. This device is Sterile & Ready for Use. Sterility is guaranteed - if pack is undamaged.
- The device is for Single Use Only.
- Use the product immediately after opening the individual blister packing.
- Do not Re-use the device, as this may lead to infection to the User & Patient
- Avoid using the product if there are signs that it has been contaminated or damaged
- It could be necessary to keep an eye on the bag's size to ensure that it doesn't overfill.
- **Careful Removal of pediatric urine bag** to not cause pain to the children
- Proper hygiene is important to avoid infection
- Proper positioning: be sure to start at the narrow bridge between the anus and the genitalia and work outward from this point. This is important to prevent feces from entering the bag.
- Regular checks: regularly check the bag for leaks or tear
- Once the product has been opened, use it immediately. Never procrastinate using it because if you do, you are allowing its contamination
- Destroy the device after single use as bio-medical waste as per applicable laws.
- Do not Re-sterilize.
- Do not use the device after the Expiry Date.

Potential Complications / Risks:

- **Leakage:** improper sealing or damage to the bag can cause urine to leak leading to skin irritation or infections which can cause discomfort.

General Instructions:

- To be used by an expert qualified medical professional.
- Use sterile barrier precautions during use.
- Dispose the device after use as bio-medical waste as per applicable laws.

Conditions of Handling, Preservation and Storage:

- Not more than 5 cartons on each other.
- Nice Ventilated place.

- Out of Sunlight.
- Suitable temperature up to 30 ℃ ± 2℃.
- Humidity: RH 65% (± 5)

Safe Disposal of single-use medical devices:

- Adopt adequate precautions for the elimination and disposal of the device and comply with the provisions of the laws in force on biologically hazardous waste.
- Single-use devices must be segregated from other reusable devices and, should not be returned to a Decontamination facility for reprocessing. Once discarded (used or unused) medical devices are considered to be special waste and should be managed as healthcare (clinical) waste. All medical devices that are to be disposed of, must in accordance with Health and Safety, Carriage of Dangerous Goods and Waste Regulations.
- Discarded devices should be placed in UN-type approved waste containers suitable for clinical waste (UN 3291); these should be rigid and puncture-proof. In general devices other than sharps should not be placed in sharps boxes as sharps waste is treated and disposed of in a different manner.
- Guidance on the type and color of the container should be sought from the Board Waste Management Officer. rigid water-tight containers are used for waste requiring incineration in a suitably permitted or licensed facility

Method of sterilization

- Sterilized Using Ethylene Oxide

Shelf life

- 5 years (from the date of manufacturing)

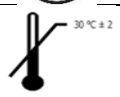
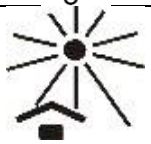
Basic UDI: 622300425UCB3003RX

Reporting of incident to Manufacturer & Competent Authority:

- For providing feedback on this product write to shady@ultramedumic.com
- In case of any serious incident occurred, please report it to the Ultra for medical products (ultramed) Co (U.M.I.C) S.A.E and/or its Authorized Representative and to your national authority. The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website: https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

Details of symbols used in labels:

Symbol	Meaning
EU REP Obelis SA 53 Bd. Général Wahis B-1030 Brussels,Belgium Phone : 32.2.732.59.54 Fax : 32.2..732.60.03 E-mail: mail@obelis.net www.obelis.net	EU REP
CE 2803	CE Mark with notified body number 2803
STERILE EO	Sterilized by Ethylene Oxide
	For Single Use Only

Symbol	Meaning
	Lot No.
	Date of Manufacturing
	Use by / Expiry date
	Catalogue No.
	Non- Pyrogenic
	Medical Device
	Unique device Identifier
	Don't use if package is not intact
	Manufacturer’s address
	Phthalate-Free
	Read Instructions for Use
	Not to be re-sterilized
	storage at room temperature up to 30 °C ± 2°C
	Cautions
	Protect from rain / Keep Dry
	Protect from sunlight / Keep away from Sunlight
	Symbol for „This way Up“
	Symbol for „handle with Care“
	Recycle
	Don’t put more than 5 cartons upon each other

Symbol	Meaning
	Latex Free

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& Fax:002-088-4964222**& Mob:** 002-01001558853, 002-01068832355
Cairo Head Office: 64, Nakhla El Motaiy Triumph Square Heliopolis **Tel:** 022/4171621-4143794 **& Fax**: 022/4171613 **& Mob**: 01223988200
Assuit Office: 23, July Str. Tel: 088/2364111 – 2364222 **& Fax:** 088/2334964 & Mob. : 01223988202
Alexandria Office: 212Abd El salaam Airef Str, Luran **Tel:** 03/5856202– 5856458 **& Fax:** 03/5828988& **Mob:** 01223948666
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