# INSTRUCTION FOR USE FOR ADULT URINE COLLECTION BAG

***Product Name*** : **Urine collection bag**

***Brand Name*** : Ultramed Urine Collection Bag with Non-Return valve
Ultramed Urine Collection Bag with Non-Return valve with T-Connector
Ultramed Urine Collection Bag with Non-Return valve [Screw Valve]
Ultramed Urine Collection Bag with Non-Return valve with Sampling port
Ultramed Urine Collection Bag with Non-Return valve [Leg bag]
Ultramed Urine Collection Bag [ empty 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:***

- A urine bag, also known as a urinary drainage bag or catheter bag, is a medical device designed According to **ISO 8669-2:1996** for efficient and reliable short-term urine collection. Suitable for use in a variety of clinical settings like hospitals, clinics or home healthcare settings, often in conjunction with a urinary catheter, this bag features advanced design elements that enhance usability and patient comfort**.** It used to collect urine from a patient who is unable to empty their bladder. It consists of a plastic bag usually attached to a catheter that is inserted into the bladder through the urethra
- A urine bag is typically made of transparent or translucent, biocompatible high-quality, medical grade DEHP-free PVC material, allowing healthcare providers to monitor urine output easily.
- The urine bag consists of:
  - **a main bag compartment** where urine is collected
  - **a drainage tube** with tapered inlet connector that connects the bag to Urinary Catheter which makes urine flow from the bladder through the catheter into the bag.
  - it may have **graduated markings** on its surface to approximate measure urine output.
  - **A drainage valve or tap or outlet** is usually at the bottom of the bag to facilitate emptying without spillage.
  - The drainage valve may be **push-pull connector** or **t-shaped connector or screw valve** for emptying of the bag
  - The **screw valve** has the feature of gradually controlled drainage
  - The urine bag may be also connected **sampling port** for easily taking a sample of urine from the bag.
  - It is equipped with a **non-return valve** (anti reflux mechanism) to prevent backflow of urine into the bladder thereby reducing the risk of contamination and helping to maintain patient hygiene

❖ **The urine bag has some types;**

- **Urine bag without outlet (empty bag) is known also as closed-ended urine collection bag:** Flexible container for collecting urine, without an opening for drainage of the contents.
- **Leg Bag:** is Smaller, portable urine bags attached to your leg and allows you to move around more easily. Because the bag is hidden under your clothes, it may also make you feel more comfortable about the catheter

- The capacity of urine bag is **2000** ml for drainage bag, **350 ml or 500 ml or 750 ml** for leg bag.
- The drainage bag should be replaced if there is clouding, odor, or discoloration of urine in the bag. Depending upon your activity level
- The urine collection bag & the leg bag is designed for short-term and should be replaced every 7 days or earlier if signs of contamination occur
- Product is conventional Product and fully equivalence with many products in market.
- The product is approved by the Ministry of Health.
- This product is CE marked from 2008.
- The product is sterilized using EO (Ethylene Oxide)
- This product is for single use.
- Individually packed in a tear pouch

**Material Used:**

- High Density Polyethylene [H.D.P.E.]
- Master Batch
- Polypropylene [ P.P.]
- Poly Vinyl Chloride [P.V.C.] non phthalate and DEHP free.
- Stainless Steel
- Elastic String

**Intended purpose:**

- The urine bag is intended to collect and temporarily store urine from adult patients who are unable to urinate normally due to medical conditions or circumstances, via connection to a urinary catheter.
- Overall, their primary purpose is to enable safe and hygienic urine collection, support patient comfort and convenience, and assist healthcare professionals in patient care and urine output monitoring

**Variants:**

| Trade Name | Variant | REF (Product ID Number) |
|---|---|---|
| Ultramed Urine Collection Bag | with Non-Return valve | 3003 |
| Ultramed Urine Collection Bag | Leg Bag | 3004 |
| Ultramed Urine Collection Bag | With T-Connector | 3008 |
| Ultramed Urine Collection Bag | (Empty Bag ) | 3009 |
| Ultramed Urine Collection Bag | With Sampling Port | 3010 |
| Ultramed Urine Collection Bag | With Screw Valve | 3012 |

**Clinical Indications:**

- **Catheterized patients:** Urine bags are used by individuals with catheters to manage continuous or intermittent urinary drainage.
- **Post-surgery:** After certain surgical procedures as: bladder, prostate, urological procedures, or other major surgeries patients may have difficulty urinating, either due to anesthesia effects or temporary bladder dysfunction. Urine bags are used to collect urine until normal bladder function resumes.

- **Urinary Retention:** Some medical conditions, such as neurological disorders or, can lead to urinary retention, where the bladder cannot empty fully. In such cases, a catheter connected to a urine bag may be inserted into the bladder to drain urine continuously or periodically.
- **Incontinence:** For patients who have urinary incontinence and are unable to control their bladder function, urine bags provide a means of collecting urine and preventing leakage.
- **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.
- **Bedridden Patients:** Patients who are bedridden or immobile may use urine bags as a convenient method for managing urinary elimination without having to constantly access a toilet.
- **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:**

- ❖ No specific requirements or restrictions on use for patient population
- ❖ Adults
- ❖ It used for male and female patients.
- ❖ Hospitalized patients, patients in intensive care units or in-house under special care

**Intended User:**

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

**Application site in the body:**

- The medical device Urine collection bag is a Non-Invasive Device so no contact with skin, it is for External Use**.**

**Replacement Frequency:**

- The drainage bag should be replaced if there is clouding, odor, or discoloration of urine in the bag. Depending upon your activity level
- Change the device immediately upon suspected contamination, leakage, or malfunction occurs, or according to hospital protocol.

**Clinical benefits:**

- The clinical benefits derived from the device are achieved, which facilitates urinary management in patient who are immobile, bedridden, or have limited mobility or Post-Surgical which manage urine drainage and provide time for healing while avoiding complications like urinary retention or leakage and improve mobility with secure attachment with adjustable straps in case leg bag, also allow for the measurement and monitoring of urinary output, which is critical for evaluating kidney function, hydration status, and treatment efficacy.

**Use Environment:**

- The urine collection bag is intended for use in hospital, clinical, and homecare settings for the collection and temporary storage of urine. The device is designed for use in sterile or controlled environments, such as operating rooms, ICUs, or other clinical areas where aseptic conditions must be maintained. Always select the appropriate version according to the use environment and follow standard hygiene and infection-control procedures.

**Life time of device:**

- Maximum duration of use: it should be up to 7 days

**Sterility status and Method of sterilization:**

- Urine collection bag Supplied in sterile state and sterilized using Ethylene oxide**.**

**Information on medical device intended to be used with other devices:**

- Urine bags are designed to be compatible with various types of urinary catheters, including Foley latex catheters, Foley Silicone catheters, Nelaton catheters through universal connector which designed according to ISO 80369-1, ISO 80369-20.

**Performance Characteristics:**

- Clear, transparent & flexible and kink-resistant Tube.
- Available with hanger for easy handling through Reinforced eyelets allow easy hanging and provide maximum protection against tearing.
- Urine collection bag graduated in ml with measured volume
- capacity: 2000 ml for normal urine collection bag & 500 ml for Leg collection bag
- Available with sampling port for quick & safe collection of urine sample.
- T-Connector distinct from Push/Pull as indicated Visually when connector is fully seated and locked in place while Push/pull characteristic soft click sound heard when the valve is closed correctly.
- It is also available with T-connector and screw valve

**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 | Choose the suitable type of Urine Collection Bag for the patient |
| 2 | Carefully inspect the packaging; if packing is found damaged, torn or pierced, discard the piece |
| 3 | Wash-up and scrub hands and preferably use sterile protective gloves |
| 4 | Peel / Tear open the pouch and take out the device aseptically |
| 5 | Visually inspect the Urine Collection Bag to ensure no visible damage or defects |
| 6 | Ensure the drainage valve/outlet is fully closed before use |
| | **During Use** |
| 7 | **Adults-Attaching the Urine Collection Bag**:<br>- Make sure the drainage tube is properly attached to the catheter.<br>- Position the Urine Collection Bag below the level of the bladder to facilitate gravity drainage, prevent potential reflux/potential infection & Monitor urine flow into the bag |
| 8 | **Attaching a Leg Bag**:<br>- Fasten the leg bag straps securely to the thigh. Secure the catheter itself to the leg with tape.<br>- Be sure to leave some slack in the catheter and don't put too much pressure on the bladder, urethra, and other parts of the body.<br>- Don't fasten the straps on the leg bag too tightly to the leg, as that may interfere with the circulation |
| | **After Use** |
| 9 | **Emptying the Urine Collection Bag**:<br>- Wash hands thoroughly. Keep the bag below hip or bladder level.<br>- Hold the bag over the toilet, or the special container.<br>- Open the outlet at the bottom of the bag, and empty it into the toilet or container.<br>- Do not let the bag touch the rim of the toilet or container.<br>- Clean the outlet with rubbing alcohol and gauze. Close the outlet securely. |

- Wash the hands again

**Emptying a Leg Bag**:

- Wash hands thoroughly.
- Unfasten the bottom leg strap only.
- To drain the bag, open the outlet at the bottom of the leg bag.
- Drain bag contents into the toilet or other receptacle.
- Once the urine has been drained, Close the outlet to reseal the bag.
- Re-fasten the bottom leg strap

Please note that because a leg bag is smaller than a usual urine drainage bag, it will have to be emptied more frequently at least two or three times a day or when it is a third to half full

**Changing Your Bag**:

-Wash the hands well.

- Open the packet of your new bag ready to be connected
- Empty the existing urine bag into a toilet or a designated container
- Disconnect the end of the catheter from the drainage tube gently (try not to pull too hard) while pinching the end of the catheter with your fingers so that no urine can drain out, and put the bag aside

-Do not let the end of the catheter or bag touch anything

-Clean/ Disinfect the end of the catheter with rubbing alcohol and a cotton ball or gauze.

-Place a towel under the connection between the catheter and the bag.

-Attach the catheter to the connector of the new urine bag securely.

Always take the bag to the catheter not the catheter to the bag

- Dispose of old Bag Properly

-Wash the hands again thoroughly

**Warnings*:***

- For Single use.
- Discard after single use, Reusing can be associated with Cross infection, Device Malfunction and Reactions to endotoxins as sterilization will not inactivate toxins produced by the breakdown of Gram-negative bacteria even if the bacteria themselves are killed.
- 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 and also this may increase the risk of cross contamination due to several aspects including inappropriate reprocessing.
- The product should be used only by a qualified doctor or paramedic who are experienced and have a thorough understanding of the clinical and technical aspects of product.
- Re-use of single use device creates a potential risk for patient. 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.
- 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.
- Do not use if package is open or damaged.
- Check the integrity and functionality of the Urine Collection Bag before use.

- ❖ Never use the device if it expired, the expire date is printed on the packaging.
- ❖ Store in temperature up to 32º C, avoid excessive heat, protect from direct sunlight and moisture

**Precautions:**

- ❖ Before using, carefully read all instructions. Observe all cautions and warnings included in these instructions.
- ❖ Avoid using the product if there are signs that it has been contaminated or damaged
- ❖ Regular monitoring of urine color and verification of unobstructed urine flow into the collection bag are required to detect possible health issues and avoid tube occlusion
- ❖ Inspect the bag for any leaks and the tubing's connection points for leaks.
- ❖ **Attention**: close the outlet valve before use
- ❖ Urine bags should be emptied regularly when the urine bag is about two thirds full to prevent overfilling and discomfort.
- ❖ Proper hygiene is important to avoid infection, and the bags and tubes should be cleaned or replaced as directed by healthcare professionals.
- ❖ Proper positioning: ensure the urine bag is positioned below the level of the bladder to prevent backflow
- ❖ Secure the bag: use strap to secure the tube of the bag to prevent it from failing or being dislodged
- ❖ The **leg bag straps** shouldn't be tightly attached, for the comfort of the patient.
- ❖ Regular checks: regularly check the bag for leaks, tear or obstruction
- ❖ It is important that If your leg bag becomes full and you do not wake up, there is a chance that your bladder will become full and the urine may reflux (flow) back to your kidneys. This may cause infection which can make you very unwell
- ❖ Once the product has been opened, use it immediately. Never procrastinate using it because if you do, you are allowing its contamination
- ❖ If the package is damaged or opened, do not use it.
- ❖ The device is for Single Use Only.
- ❖ Do not re-sterilize.
- ❖ After a single usage, discard it

**Potential Complications / Risks:**

- **Accidental removal:** The urine bag may be accidentally removed if it is handled improperly or is not fastened securely.
- **Leakage:** improper sealing or damage to the bag can cause urine to leak leading to skin irritation or infections which can cause discomfort, embarrassment,
- **Blockage or obstruction:** The flow of urine may be impeded if the catheter or urine bag kinks, twists, or becomes blocked. In order to clear the blockage, this could hurt and need medical attention.

**General Instructions**:

1. to be used by a trained and qualified healthcare provider and medical professional.
2. During operation, take all necessary sterile barrier precautions. After usage, dispose of the device as biomedical waste in accordance with the applicable laws
3. Check that (urine flows normally, the overfill of the bag and no leakage)

**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 |
| 2 | 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 ℃ ± 2℃ |
|  | Cautions |
|   | Latex Free |
|  | Protect from rain / Keep Dry |
|  | Protect from sunlight / Keep away from Sunlight |
|  | Symbol for „This way Up“ |
|  | Symbol for „handle with Care“ |
|   | Don’t put more than 5 cartons upon each other |

# INSTRUCTION FOR USE FOR PAEDIATRIC URINE BAG

***Product Name*** : **Paediatric Urine Collector**

***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 Paediatric Urine Collector | 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**



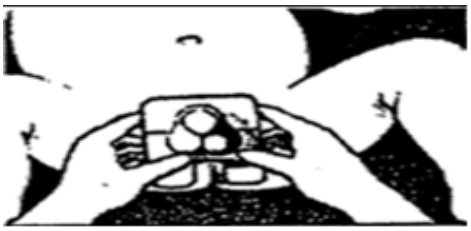
**Step1**: Lay Infant on his back and wash each skinfold in the genital area. A gentle bath soap is preferred. Avoid using a lotion soap solution, oils and baby powders as it can leave a residue that may interfere with adhesion. Wash anus last. Rinse and dry. Cleanse entire area again using the towelette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

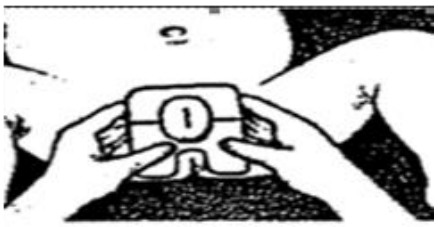


**Step3**: When pressing adhesive to the skin, be sure to start at the narrow bridge of skin between the anus and the base of the scrotum and work outward from this point. Be sure skin is dry before applying the collection bag. This is important to prevent feces from entering the bag

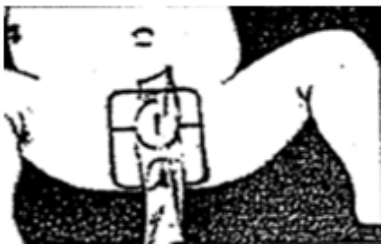


**Step4**: Press adhesive firmly against the skin, avoiding wrinkles. When the bottom section is in place, remove the protective paper from the upper portion of the adhesive patch. Work upward to complete application

**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)

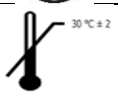
**Basic UDI:** 622300425UCB3003RX

**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 |
| 2 | 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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**Assiut Factory:** Part No. (304:310) & part no. (312) – Industrial Area, Arab El Awamer – Abnoub - Assiut – Egypt. T**el**: 002-088-4964333 (500), 002-088-4964666 (600), 002-088-4964777 (700), 002-088-4964888 (800), 002-088-4964999 (900)
**& 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
**E-mail:** info@ultramedumic.com, **shady@elaggargroup.com** **Website:** **www.ultramedumic.com**