Doc. No.:	RGI/IFU-09/257
Issue No.:	04
Rev. No.:	03
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UNIVERSAL

MID STREAM URINE COLLECTION SET

(With Funnel & Closure Cap)

REF UN- 257

℞ ONLY

INSTRUCTIONS FOR USE

The device is biocompatible, Non-Toxic, Non-Pyrogenic , 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.
This device is Sterile & Ready for Use. Sterility is guaranteed - if pack is undamaged. The device is for Single Use Only.

Device Description : MID Stream Urine Collection Set consists of a transparent, cylindrical chamber. The chamber has screw thread on the top for effective closure with Cap. Chamber's bottom has a conical base to allow instant visibility of any sediments drained out with the urine. Chamber bears an identification label which also consists of graduation markings for indicative purpose only. A funnel is attached to the top of the chamber to enable quick, hassle free collection of urine sample. A screw cap is provided separately. User removes the funnel after urine collection & securely caps the urine chamber. User writes the identification particulars on the label.

Population of Use: Adult & Paediatrics**.**
Intended User : To be used by the Patient or by the nursing attendant.
Intended Use : Intended for effective & easy collection of urine specimens from hospital and home based patients. Midstream or clean-catch urine collected midway through the urination process is necessary for culture, so that any bacteria present around the urethra and on the hands do not contaminate the specimen. Device used once for Immediate use.
Preferred Route of Administration: Direct Midstream Urine Specimen Collection

Contents : Sterile, MID Stream Urine Collection Set is packed in soft peel open unit pack.

Size : Capacity-20ml.

Material of Construction : GPPS(General Purpose Polystyrene), LLDPE(Linear low-density polyethylene), EVA, HDPE, MB.

Storage : Store in a cool & dry place.

Indications : Urine collection for pathological / routine examination as a result of urinary tract infections, diabetes, evaluation of metabolic status, collection of mid-stream urine sample for routine / microbiological examination, etc.

Potential Complications / Risks : Non-adherence by user to follow proper urine sample collection. Possible risks, (a) Unknowingly, contamination of the collected urine sample. (b) Non-disposable (unsafe disposal) of the used funnel. (c) Un-proper screw capping of the urine collection container leading to urine spillage & resulting in loss of urine sample & scope for cause of infection / contamination.
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.
Re-use of single use device creates a potential risk for patient or user. Do not put the Device to Use after the Use by Date or Date of Expiry.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 mid stream urine collection set 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) Destroy / 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 : Contamination of the collected urine sample & false pathological results. Inadvertent spillage of urine & scope for contamination due to negligent handling / loose capping of the chamber.

General Instructions : To be used by the Patient or by the nursing attendant.

Potential Complications / Risks : Non-adherence by user to follow proper urine sample collection. Possible risks, (a) Unknowingly, contamination of the collected urine sample. (b) Non-disposable (unsafe disposal) of the used funnel. (c) Un-proper screw capping of the urine collection container leading to urine spillage & resulting in loss of urine sample & scope for cause of infection / contamination.
Use Instructions :
(1) Read the instructions carefully, and follow each of the steps to ensure you collect the correct specimen for the test.
(2) Check the packing carefully, if found damaged, torn or pierced discard the piece. Do not use if pack is damaged.
(3) Wash up and scrub hands before use.
(4) Peel open the pack & drawout the device with care.
(5) Take the funnelled urine container & keep handy. Take precaution not to touch inner surface of the funnel.
(6) For women, keep the legs apart and hold the skin folds apart while voiding. For men, retract the foreskin (if uncircumcised) while voiding.
(7) Pass a small amount of urine into the urinal.
(8) Midway through urination, fill the container to half full.
(9) You may finish voiding into the urinal until the bladder is empty.
(10) Remove the funnel carefully without spilling the collected urine. Replace the funnel with cap & screw down to close urine container.
(11) Wash your hands thoroughly.
(12) Write required identification particulars on the label of the urine collection container.
(13) Deliver the container to the laboratory as soon as possible after completion of the collection.

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(14)Urine Specimen containers should not be reused.

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CE 2460
Basic UDI DI : 8902120A007RL

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 Ethylene 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 Consult Instructions for Use**		**Caution**
	Manufacturer		**Single Sterile barrier system**	10 °C 40 °C	**Temperature Limit**		