

Product description

Sippi Disposable Unit™ is a urinary output system intended to be used by medical personnel on catheterized patients.

Intended purpose

Sippi Disposable Unit™ is a medical device comprised of a sterile single use set of tube, measuring chamber and bag. Sippi Disposable Unit™, together with Sippi Base Unit™, is intended to allow for continuous automated measurement of urine output to monitor a patient's diuresis. Sippi Disposable Unit™ is intended to collect urine during at most 7 days from a catheterized patient.

The measurement chamber contains a water/urine soluble capsule with silicone oil that reduces biofilm formation and growth of bacteria.

The device is intended to be used in hospitals and health care facilities by health care professionals experienced in managing medical equipment.

Contraindications

The device is not intended to be used on patients with pronounced bleeding (haematuria), markedly concentrated urine, or any other cases where the properties of the urine may cause a blockage of flow in the self-emptying measuring chamber.

Warnings

- Do not use the product if the sterile packaging is broken or damaged.
- Replace the product after 7 days or if biofilm formation is indicated, as the Sippi Disposable Unit™ will eventually be affected by urinary biological activity in the system. Buildup of biological activity will also negatively affect the automated measuring feature when Sippi Disposable Unit™ is used together with Sippi Base Unit™.
- Do not reuse the product, neither by cleaning nor resterilizing the product. Reusing the product induces higher risk of catheter associated urinary tract infections.
- Do not use the product after its expiration date.

- Do not combine Sippi Disposable Unit™ with other devices than Sippi Base Unit™ for automated measurements of urine output.
- Do not use the product in wet environments, for example when showering the patient.

Precautions

- Use an aseptic technique when handling the patient connection and the Sippi Disposable Unit™.
- The urine collection bag should be placed below the patient to aid urine flow.
- Clamp the tube when transporting a catheterized patient or when removing the Sippi Disposable Unit™ from a catheterized patient to avoid backflow or leakage of urine.
- Urine in the tubing set is not measured until it reaches the measurement chamber. Therefore, use caution when treating patients especially with low urine output (e.g. small children) to ensure change of volume in the tube does not affect the interpretation of measurement.

Instructions for use

Connecting the Sippi Disposable Unit™ to catheterized patient

1. Open the sterile package that contains the Sippi Disposable Unit™. Ensure that all parts are intact and that the drainage tap at the bottom of the urine collection bag is closed to avoid leakage.
2. Attach the Sippi Disposable Unit™ to an appropriate hanger by first inserting the left side of the measurement chamber into the recess and then pressing the right side until it snaps in. Thereafter secure the bag by hanging it by the buttonholes on the pegs of the hanger.
3. The hanger should position the Sippi Disposable Unit™ below the patient but without having the bag touch the floor.
4. Remove the protective cover of the connector and connect to the patient's indwelling urinary catheter using an aseptic technique.
5. Ensure that the slide clamp is open so that the urine can flow through the closed system to the urine collection bag. Check that the urine

drainage works and that the measuring unit empties at maximum level of the measuring chamber.

Replacing the Sippi Disposable Unit™

The Sippi Disposable Unit™ is replaced by closing the slide clamp so that no urine can flow through the system. Thereafter, the Sippi Disposable Unit™ is disconnected from the patient's indwelling urinary catheter, and a new Sippi Disposable Unit™ is connected following the steps above.

Extracting a urine sample from the Sippi Disposable Unit™

A urine sample may be extracted from the Sippi Disposable Unit™ by inserting a plastic syringe through the needle free sample port on the connector. Use an aseptic technique when extracting urine from the needle free sample port to avoid catheter associated urinary tract infections.

Assessing produced urine volume

For automated measurement of produced urine volume, the Sippi Disposable Unit™ shall be used together with Sippi Base Unit™. Without the Sippi Base Unit™ the scale on the urine collection bag allows for an approximate and indicative assessment of the urine volume produced by the patient.

Emptying the urine collection bag

The urine collection bag is emptied by opening the drainage tap. The urine collection bag enables a maximum urine volume of 2000 ml, however it should be emptied when the urine level reaches 1500 ml. After emptying is complete, close the drainage tap.

No action is needed on the Sippi Base Unit™ when emptying the urine collection bag.

Other information

- Disposal of the product should be handled according to accepted medical practice and applicable local laws and regulations for potential biohazards.
- The product should be stored in room temperature.

- The shelf life of Sippi Disposable Unit™ is 5 years.
- Sippi Disposable Unit™ is DEHP free.

Any serious incident occurring in relation to the Sippi Disposable Unit™ should be reported to Observe Medical AB using the contact information stated below, and the competent authority of the Member State in which the user and/or patient is established.

customersupport@observemedical.com

www.observemedical.com

+46 (0)10 – 641 02 02



Observe Medical AB
Krokslätts Parkgata 4
431 68 Mölndal, Sweden

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