



DRAINAGE BAGS

INSTRUCTION FOR USE

APPLICATION :

The drainage bag is used to collect urine/waste fluids from a patient and measure approximately the amount of drained fluids..

PERFORMANCE CHARACTERISTICS:

The "Drainage Bag" is characterized by :

- Its high and continuous drainage capacity through the smooth internal walls of the tubes.
- Its ability to visualize the amount of urine/liquid through the transparent color of the bag superimposed on a white background.
- Its ability to protect against retrograde contamination and infections thanks to the presence of non-return valves and the sampling point.
- High drain capacity (speed and flow) due to the efficiency of the drain valve.
- Its ability to attach to the patient's bed and support the weight of the bag filled to its maximum capacity through the presence of a mounting system

OPERATING INSTRUCTIONS :

1. Wash your hands thoroughly and open the packaging.
2. Attach the bag to the D or G side of the bed, stiff from the handle or, if present, use the strip. The attachment of the bag should be at a height not exceeding the patient's bladder.
3. Put on a pair of disposable gloves (not supplied).
4. Remove the protective cap from the conical end of the catheter and connect it to the urological catheter (not provided) already introduced into the patient, being careful not to contaminate the patient.
5. Remove disposable gloves and discard them.
6. Make sure that the probe, once positioned, allows a regular flow of urine/liquid and for this you must use the sheet clamp if available.
7. To read the quantity of liquid collected, use the approximate scale on the bag as a reference.
8. If bag models are used that have closure devices on the drainage tube (eg: clamp, tube clamp plate, roller). It is possible to perform vesical gymnastics.

HOW TO PERFORM URINE COLLECTION :

Model with sampling point :

1. Inform the patient, clamp the drainage tube above the sampling point.
2. Wash hands thoroughly.
3. Put on a pair of disposable gloves (not supplied).
4. Disinfect the sampling point, insert the syringe into the Needle-less connector Fig.1-A or the needle of the syringe Fig.1-B (not supplied) into the sampling point of the conical end of the catheter.
5. Aspirate the required amount of urine, open the catheter again to restore drainage to the bag.

Model without sampling point :

1. Inform the patient.
2. Wash hands thoroughly and put on a pair of disposable gloves (not supplied).
3. Take the sample for analysis, using the drain valve and drain the urine into a clean container (not supplied) being careful not to touch the edges of the container.
4. After the operation close the tap, disinfect it and put it back in its reserve pocket, if present..

HOW TO EMPTY THE BAG :

Model with drain valve :

1. Put on a pair of disposable gloves (not supplied).
2. Open the drain valve and wait for the liquid inside the bag to flow completely into the collection system adopted (container not supplied).
3. At the end of the operation, close the tap, disinfect it and put it back in the tap/cast support, if available.

Model with piston drain valve :

1. Put on a pair of disposable gloves (not supplied).
2. Open the piston drain valve by firmly holding the fixed part of the valve with your index finger and thumb.
3. With the second hand slowly pull down the moving piston at the same time until the end of the stroke.
4. Wait until the liquid, inside the bag, flows completely into the collection system adopted (container not provided).
5. After the operation close the tap by firmly holding the fixed part and with the second hand push slowly upwards, then at the same time turn the mobile piston until the end of its run. Disinfect it.

Model without drain valve :

1. Put on a pair of disposable gloves (not supplied).
2. Detach the bag and, if necessary, replace it as indicated in the following point
3. Drain the bag into a container (not supplied) or into the appropriate draining devices by tearing the bag on the pre-cut portion on the device.

HOW TO REPLACE THE BAG :

1. Put on a pair of disposable gloves (not supplied).
2. Very carefully detach the urological catheter from the patient, then place the protective cap back on the conical end of the catheter and discard the device.
3. To apply a new bag to the patient, repeat the operations previously indicated in the OPERATING INSTRUCTIONS.

WARNINGS :

- Use restricted to qualified physicians. BioService Tunisia declines all responsibility for damage caused to the patient in the event of improper use of the device, misuse or in the event of employment by persons who do not have the required qualifications.
- Visual verification of the integrity of the packaging is necessary before opening.
- When handling the device, always use a sterile procedure to reduce the risk of infection.
- Never fix the bag, during use, at a height higher than the bladder of the patient because if this happened, there would be a reflux of urine into the bladder.
- Do not stretch the catheter as this will certainly cause internal damage to the urethra.
- Do not use the bag for infusions.
- Do not fill the bag beyond the maximum capacity.
- The scale on the bag is expressed in millimeters (ml) and is approximate and not accurate.
- Make sure that the catheter, once positioned, allows a regular flow of urine so as to avoid a reflux of urine towards the bladder.
- Do not put the bag on the ground when it is connected to the catheter because this is certainly a risk of infection and its malfunction.
- Maximum duration of use :15 jours. Depending on the patient's clinical setting. In any case, the need for more frequent replacement of the device must be decided by the medical/nursing staff.
- Sterilized with EtO ; Sterility is guaranteed provided the packaging is intact - Do not resterilize.
- Single-use medical device, single patient, reuse can cause infections both for the patient and for the user of the device.
- Non-pyrogenic
- Expiry date : 5 years with the packaging in good condition and kept under normal storage conditions (Keep in its packaging in a cool, dry place.).
- Avoid exposure to light and high temperatures. The temperature should be between 5°C and 40°C.
- For staff safety, when required by hospital regulations or by the department, it may be necessary to use sterile gloves, masks and protective goggles (Caution: these accessories are not supplied with the device).
- Urological catheter, single-use gloves and syringe are not included in the product.
- Any serious incident occurring in connection with the device should be notified to the manufacturer and to the competent authority of the Member State in which the user and/or the patient is established.
- Dispose of after use in accordance with the regulations in force.
- Do not use this device for premature infants, infants, newborns and children weighing less than 10 kg.

MANUFACTURER INFORMATION :

- First market launch : 2014
- Code and revision date : 8450570000 rev 04 of 10/2022
- Number of EC certifying body : 0459

Fig. 1-A



Fig. 1-B

