Fourie Safety System Instructions for Use

Description

The Fourie Safety System is designed for the collection of urine and irrigation fluid from the bladder whenever irrigation of the bladder, intermittent or continuous, is used. The system is equipped with a proprietary device aimed at eliminating the risk of inadvertent bladder distention. Once the pressure in the urine bag reaches a value of 20-25cm H20, the safety mechanism is automatically activated. This allows for a large amount of irrigation fluid to drain, preventing harmful and painful bladder distention.

Indications

For use with urological procedures requiring subsequent bladder irrigation.

Contraindications

None

Potential Complications

Any urine collecting system may cause or be associated with following adverse events:

- Disconnection, resulting in a loss of sterility.
- Blockage and distension.
- Spillage

Caution

The Fourie Safety System should only be connected and used by physicians and other qualified medical personnel who are trained and experienced in the technique, and with the equipment normally used during and after urological procedures.

Preparation for Use

Inspect the package for any mechanical damage.



Do not use if package is damaged

Caution

All necessary manipulation during the preparation and during the intervention must be carried out under sterile conditions.

Intended Use and Disposal: The Fourie Safety System is intended to be used on an individual patient during a single procedure, and then disposed of according to the hospital medical waste management procedure. It is not intended to be reprocessed and used again.

Instructions for Use

- 1. Remove the product from the sterile packaging, using the aseptic technique.
- Remove the protective cap from the Step-Down Connector.
 Ensure that the Drainage Tap is closed, and Sliding Clamps are open.
 Attach the Step-Down Connector to the urinary catheter.
- 5. Hang the bag below the level of the patient.
- To avoid inadvertent deployment of the expandable pouch during transportation, remove the protective 6. Paper Clip only after the patient has arrived in the ward. Should the expandable pouch be deployed, it can be replaced with a new one.
- 7. When removing the expandable pouch, after it has been activated, avoid lifting the pouch up from the floor. Roll the pouch into a bucket and dispose of it according to the hospital medical waste management procedure.
- Relevant for Fourie Safety System with Agitator only: Prior to use of the Agitator it is advisable to 8 temporarily close the Distal Slide Clamp to prevent deployment of the expandable pouch. The Clamp should be re-opened immediately after the agitation is complete.

| REF | DESCRIPTION | QUANTITY |
|---------|------------------------------------|----------|
| URO 039 | Fourie Safety System with Agitator | 10 |
| URO 040 | Fourie Safety System | 10 |



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