Instructions for Use (IFU)

Product name: Disposable Sterile Urine Collection Bags

Product Model/Specification: type Ⅰ and type Ⅱ

Indications for use:

The Disposable Urine Collection Bags are used as an auxiliary medical devices combined with a disposable urethral catheter for the collection of urine during the treatment of patients.

Contraindications:

None.

Potential complications:

None.

Structure:

The Disposable Urine Collection Bags consists of inlet tube, pressure maintaining valve (optional), lanyard, urine storage bag, cross valve, pagoda joint, protective joint, protective cap, one-way valve and hanging ring.

Instructions

Clinicians and nurses should perform the following operations in an aseptic manner:

- Check whether the packaging is complete before using the product.
- Remove the packaging and check the components of the product are damaged or not, whether there is fracture at the joint.
- Close the cross valve, pull out the protective cap, and connect the pagoda joint with the inlet tube or drainage urine catheter.
- Proper use bed hooks, hanging loops or lanyards to fixed inlet tube and urine storage bag.
- Observe the urine volume in the urine storage bag at the right time. When the liquid reaches the specified value, open the cross valve switch to eliminate the urine in the bag.
- If the pressure maintaining valve fails, replace the product in time when using type Ⅱ product.
- Disposal of the product should be carried out according to the regulations of medical waste.

- The Disposable Urine Collection Bag is single use only, destroyed after use.
- The product is provided after sterilization, it is forbidden to use if the packaging is broken.
- The recommended product usage time is no more than 7 days.
- This product is to be operated by trained or experienced medical staff.
- The product is sterilized by ethylene oxide and valid for 2 years. Do not use if the product has expired.

Symbols: refer to device label or package

 Date of manufacture	 Manufacturer
 Batch code	 Use-by date

REF Catelogue number	STERILE EO Sterilized using ethylene oxide
Do not re-use	Do not use if package is damaged
Caution	Consult instruction for use
Do not resterilize	EC REP Authorized representative in the European Community
35℃ Upper limit of temperature:35℃	80% 10% humidity limitation :10%-80%

Date of Production:
See label of the package.
Expire Date:
Two years after the date of sterilization.
Date of Sterilization:
See label of the outer box.
Storage:
This product should be stored in a room with a relative humidity of no more than 80%, storage temperature no higher than 35℃,no corrosive gas and good ventilation.

: SHANDONG GRED MEDIC CO., LTD.

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CE 2797: The medical device is complied with MDD 93/42/EEC.

2797 is the code of Notified Body BSI.

EC REP: SUNGO Europe B.V.

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