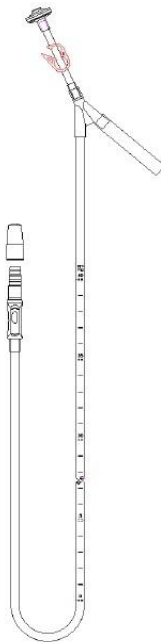




TECHNICAL DATA

“UROPOCKET” component for Urology Set, with graduated tube, clamp and 1,2 µ air filter
Uno Meter™ - Abdo Pressure®
REF. FP0000001
LATEX FREE

- **CE Certification (Encl. V) as per CEE Directive 93/42/CEE issued by the Notified Body n°0373. Certificate n.° QPZ-1924-19 issued on 20.12.2019 with extension to 12/31/2028 per EU Regulation 2023/607. Class II A CND A03010202.**
- The material used for production of the transfusion sets is made of high polymers to which have been added the stabilisers and plastifiers allowed by the law (DEHP-FREE and DOTE-FREE).
- They are chemically stable, transparent, flexible and resistant to traction.
- Non-toxic inks are used to highlight the indices for measuring or reading printed on the parts in direct contact with the product. This is assessed according to the providers of polyethylene medical envelope printed externally.
- That the materials used are compatible with the pharmaceutical products with which they may come into contact during normal use. They are also biocompatible and non-toxic as required by the following standards: UNI EN ISO 10993 – 1: “current ed.”; UNI EN ISO 10993 – 4: “current ed.”; UNI EN ISO 10993 – 5: “current ed.”; UNI EN ISO 10993 – 10: “current ed.”. Tests performed: Allergic sensitization, Intracutaneous irritation or reactivity, Cytotoxicity; Hemolysis, Chemical validation, LAL test.
- The device is disposable. Reuse carries serious risks of biological contamination.
- Method of sterilisation : ETO (ethylene oxide) - disposable (non re-sterilisable). Residual ETO: less than 4 mg/unit
- Recommended storage conditions: at room temperature (5-30°C) in a clean, dry place (humidity between 40/65%) in the original packaging.
- Shelf life : the packaging, in polyethylene envelopes, guarantees the stability and the preservation of the product for at least 5 years.
- Disposal through special hospital procedures.



Components:

1. Cap for spike
2. Conical connector
3. Tube cm. 105 Ø 4,8 x 6,8 mm Sha74 with printed scale
4. Y connector
5. Tube cm. 1,5 Ø 6,4x8,9 mm Sha74
6. Tube cm. 5 Ø 3,5x5,5 mm Sha74
7. Clamp for tube Ø 5,5 mm
8. Air filter 1,2 µ
9. Envelope cm. 25x40

Material:

POLYETHYLENE
ABS
PVC DEHP-FREE
PVC DEHP-FREE
PVC DEHP-FREE
PVC DEHP-FREE
PP RED
PVC DEHP-FREE +
VERSAPOR-1200R - 1.2µm
PE + MEDICAL PAPER

The set components undergo a dimensional and qualitative control by our QC department; physical tests on eluates, biocompatibility, apyrogenicity and sterility tests as well as bacterial endotoxin controls are performed on the finished product based on validated internal protocols.

Standard packaging:

- 20 units each Carton Box cm 40,5x29,5x17h
- 480 units each Carton Box cm 84x62x105h