Suprapubic Set (Puncture / Drainage)

Description:
- UltraDrain Suprapubic Puncture & Drainage Set
- Spear Suprapubic Metal Tip Puncture & Drainage Set

Configuration:
See brochure

Intended use:
Used for percutaneous Bladder drainage

Indication:
- Urethral obstruction.
- Urethral trauma.
- Post-operative bladder drainage as requested, by physician.
- Chronic retention

Contraindications:
- Lower abdominal scars.
- Bladder tumors

Caution:
Federal (USA) law restricts this device to sale by or on the order of a physician.

Warning/ Precaution:
- Ensure that patient has full bladder.
- Determine bladder limits by palpation.
- Place patient in dorsal position.
- Do not exert excessing pressure while introduction of trocar.
- For single use only.
- Attempt to resterilize a single use device may compromise its structural integrity and/or lead to device failure which may result in patient injury or illness.
- Do not use if package is opened or damaged.
- Dispose in accordance with recognized medical practice and under observance of applicable law and regulation.
- Only experienced surgeons should use this device.
- Storage temperature between 5ºC to 30ºC.

Instruction for Use:
Connect appropriate size catheter to urine drainage bag. Prepare skin with antiseptic solution. Administer local anesthesia 3cm above symphysis pubis. Make small incision with scalpel. With slight twisting action and steady gentle pressure, insert the trocar and sleeve assembly into the bladder midline, until urine is seen rising along trocar. Remove the trocar from the sleeve. Simultaneously occluding the sleeve outlet with thumb, insert the catheter down the sleeve. Once the catheter position is secured into bladder, slide the sleeve external to the abdomen. Pull off the perforated section of the sleeve, careful not to dislodge the catheter.

Removal Instructions:
1. Deflate balloon completely and withdraw catheter.
2. a) If catheterization is discontinued, apply a dry dressing to punctuate site or
   b) If recatheterisation is necessary, follow normal procedure.

Storage:
The device should be stored in a clean, dry area. Do not expose to organic solvents, ionizing radiation or ultraviolet light. The devices must be used prior to the sterilization expiration date on package.

Do not reuse, reprocess & resterilize:
Reuse, Reprocessing & resterilization may compromise the structural integrity, can also create risk of contamination & may not give desired result or create complications, infections which may result in injury, illness or death.

Limited Express Warranty:
The limited express warranty as set forth herein is exclusive and in lieu of all warranties of merchantability and fitness for use, remedies, obligations and liabilities for consequential damages.
The products are being sold only for the purpose described herein and such limited express warranty runs only to the original user. In no event shall ALLWIN be liable for any breach of warranty in any amount exceeding the purchase price of the product. ALLWIN reserves the right to make design changes to products without liability to incorporate said changes in ALLWIN products previously designed or sold.

REF Catalogue Number | LOT Batch Code | Date of Manufacture | Use By | Do not re-use | Do not Re-Sterilize | Rx only — Caution: Federal Law restricts this device to sale by or on the order of a physician or a practitioner trained in its use.

Consult Instruction for use | Do not use if Packing is damaged | Caution | Keep out of sunlight | Keep Dry | STERILE EO — Sterilized using ethylene oxide

EC REP
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Temperature Limit

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