PRESCRIPTIVE INFORMATION

PRESCRIPTIVE INFORMATION FOR FOLEY CATHETERS, DRAINAGE BAGS AND URINE METERS

INDICATIONS FOR USE: For urological use only.

CAUTIONS

- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Do not aspirate urine through drainage funnel wall.
- Some Foley catheters may contain Natural Rubber Latex which may cause allergic reactions. Please check package.
- Contains or Presence of Phthalates: Di(2-ethylhexyl)phthalate (DEHP) is a plasticizer used in some polyvinyl chloride medical devices. DEHP has been shown to produce a range of adverse effects in experimental animals, notably liver toxicity and testicular atrophy. Although the toxic and carcinogenic effects of DEHP have been well established in experimental animals, the ability of this compound to produce adverse effects in humans is controversial. There is no evidence that neonates, infants, pregnant and breast feeding women exposed to DEHP experience any related adverse effects. However, a lack of evidence of causation between DEHP-PVC and any disease or adverse effect does not mean that there are no risks.
- With Temperature-Sensing Probes, in the presence of RF energy sources, local heating, temperature errors, and probe damage may occur. In medical use, unplug the temperature-sensing catheter at the temperature monitor before activating electrosurgical or other types of direct coupled RF energy sources. Do Not Stretch Catheter. This will cause repositioning of the probe. Do not use Stylet. This will cause stretching of catheter.

WARNINGS

- On catheter, do not use ointments or lubricants having a petrolatum base. They will damage latex and may cause balloon to burst.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.
- Visually inspect the product for any imperfections or surface deterioration prior to use. Use Luer tip syringe to inflate with stated mL of sterile water OR for pre-filled products, remove clip and squeeze reservoir to inflate with stated mL of sterile water.
- Store catheters at room temperature away from direct exposure to light, preferably in the original box.

ADDITIONAL INFORMATION

- This is a single use device. Do not resterilize any portion of this device. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of a patient.
- Aggressive traction, particularly in the presence of suturing is not recommended for 100% silicone catheters.
- Should balloon rupture occur, care should be taken to assure that all balloon fragments have been removed from the patient.
- Do not exceed recommended balloon capacities.
- Sterile unless package is opened or damaged.

Catheters should be replaced in accordance with the CDC guideline, "Guideline for Prevention of Catheter-Associated Urinary Tract Infection." At the onset or first signs of a urinary tract infection, catheter encrustation, or any other catheter-related adverse effect, the catheter should be replaced.

STATLOCK® FOLEY STABILIZATION DEVICES

TRAINING AND EDUCATION

For additional training and education on a number of topics, visit our Training Center

read more

CONTACT US

read more

INDICATIONS FOR USE: The STATLOCK® Stabilization Device is used with compatible catheters.

CONTRAINDICATIONS: Known tape or adhesive allergies.

WARNINGS AND PRECAUTIONS

- Do not use the STATLOCK® stabilization device where loss of adherence could occur, such as with a confused patient, unattended access device, diaphoretic or nonadherent skin.
- Observe universal blood and body fluid precautions and infection control procedures, during the STATLOCK® stabilization device application and removal.
- Minimize catheter manipulation during STATLOCK® stabilization device application and removal.

DAILY MAINTENANCE

- The STATLOCK® stabilization device should be assessed daily and changed when clinically indicated, at least every seven days. If pad becomes soiled, wash with soap/water, saline or hydrogen peroxide.
- Do not use alcohol or prepackaged bathing systems, which could lead to early lifting. If showering/bathing, cover with plastic wrap or waterproof dressing.
- Conduct skin assessment prior to application and repeat daily per facility protocol.
- Use clinical judgment on the removal of the STATLOCK® stabilization device if the patient experiences any fluid shifts that may interfere with skin integrity.
- Sterile unless package is opened or damaged.

For the latest information, always check the “Instructions for Use” that comes packaged with the product.