

All Silicone Foley Balloon Catheter



CE 0197

Sterilized using ethylene oxide / Do not reuse / Consult instructions for use / Do not re-sterilize
/ Do not use if package is damaged / Keep away from sunlight / Keep dry

REF: 1001-06~10, 1002-12~26, 1004-14~26, 1005-14~26, 1006-14~26, 1006S-18, 1001-06BL, 1011-10~24, 1011UB-10~24, 1011B-10~24, 1014-14~26, 1001UB-08~10, 1002UB-12~26, 1002UBS-12~26, 1002UBF-12~26, 1003UB-10~26, 1007UB-08~26, 1007UBS-08~26, 1007UBF-08~26, 1001F-08~10, 1002F-12~26, 1007UB-08OT~26OT, 1007UBS-08OT~26OT, 1007UBF-08OT~26OT, 1007-06OT, 1007F-06OT(Transparent Catheter) / 1001UB-08B~10B, 1002UB-12B~26B, 1003UB-12B~26B, 1011-10B~24B, 1001F-08B~10B, 1002F-12B~26B (All Blue Catheter) / * The additional product number "-1" is given next to the end of above product numbers for the products which have catheter funnel made from liquid silicone rubber (LSR).

Intended use

Foley Balloon Catheters are used for routine drainage or routine post-operative drainage and irrigation of the bladder.

Intended User

All Foley balloon catheter should be used by physicians, trained medical staffs and suitably trained personnel.

Instructions for Use

Preparation

- Remove catheter from sterile pouch using aseptic technique. / - Fill sterile water into balloon with syringe and check the leakage on the balloon and check valve. / - Deflate the balloon completely with syringe after leakage test.

Insertion

- Connect catheter funnel with urine bag connector. / - Lubricate the catheter using a water soluble jelly. / Insert catheter until catheter balloon is properly positioned into bladder. / - Fill sterile water into balloon with syringe according to volume indication on the catheter funnel. Do not over inflate. / - Check the urine flow from the drainage funnel to ensure the function of catheter. / - If bladder irrigation is needed, connect irrigation solution with connector of irrigation funnel.

Removal

- Deflate the balloon completely by releasing syringe plunger. Use only gentle aspiration. / - Remove the catheter from the patient.

Warning

- Do not use device if package has been damaged or opened. / - The balloon should be re-inflated at least every two weeks with the stated nominal fill volume. / - If the balloon cannot be deflated with syringe, use scissors to cut side arm below the valve. / - Use water soluble lubricants on catheter shaft. Do not use petroleum based lubricant. / - Never clamp the catheter. Catheter can be damaged by clamp. / - Do not use syringe with needle. / - Do not collect urine sample through directly from catheter shaft. / - If the balloon cannot be deflated with syringe, gently infuse some warm water into balloon and try to deflated balloon. If this method is failed, cut side arm below the valve with scissor to deflate the balloon. / - Disposal of the device shall be made in accordance with applicable national regulations for biologically hazardous waste. / - Do not expose the product to high temperature, humid air and ultraviolet ray during storage. / - Do not re-sterilize and reuse this device to avoid any potential risk of infection. / - Silicone tube can be cut off or balloon can be burst by excessive external force or scratches so be careful when handling it. / - For long term patient, catheter should be replaced to new one within 30days.

Contraindication

- Foley catheters are contraindicated in the presence of urethral trauma.

Side Effect

- Bladder spasms / - Irritation of the urethral mucosa / - Incorrectly positioned catheter can cause of urethral damage if the balloon was inflated within the urethra. / - Urinary tract infection

Inflation Volume of Balloon

Balloon Capacity	Minimum Volume	Maximum Volume
1.5ml	1.5ml	1.5ml
3ml	3ml	3ml
5ml	5ml	5ml
5-10ml	5ml	10ml
30ml	30ml	30ml

Note

To reduce diffusion of silicone balloon, filling at least 5% glycerin solution into balloon is recommended.

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



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