

ULTRA FOR MEDICAL PRODUCTS CO.

Silicone Foley Catheter

Code No.: 3007

1- Description:

- For bladder catheterization (2 way).
- For bladder irrigation and drainage (3-way).

2- Advantages & Features:

- Soft, frosted and kink resistant all transparent silicone.
- Atraumatic, soft, rounded, closed tip with two lateral eyes for efficient drainage.
- Color coded plain connector for easy identification.
- Made of 100% silicone.

3- Indications:

- To drain the bladder in case of acute urinary retention.
- For post operative drainage and irrigation of bladder.

4- Contraindications:

- Long term complication; Stricture of the urethra.
- Standard Medical text books and scientific literature should be consulted for specific adverse reaction information.
- The catheter cannot be retained in human body for over 29 days, and 14 days is strongly recommended.

5- The purpose:

- For bladder catheterization (2 way).
- For blood irrigation and drainage (3-way).

6- Instruction for Use:

(In all instances aseptic technique must be used)

Inflation Procedure



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• Insert the luer tip of the syringe with a firm push/twist motion into the catheter valve housing to assure activation of the valve.

Inflate with the prescribed volume (i.e. 1.5 ml/cc balloon: maximum 1.5 ml/cc sterile water; 3/5 ml/cc balloon: maximum 5 ml/cc sterile water; 5/10 ml/cc balloon: maximum 10 ml/cc sterile water; 30 ml/cc balloon: maximum 30 ml/cc sterile water; 50 ml/cc balloon: maximum 50 ml/cc sterile water).

- While holding syringe plunger check for any evidence of leaking or deflation.
- Release syringe plunger and allow balloon to deflate and observe for any difficulty with the deflation. Use only gentle aspiration, if necessary, to deflate balloon.
- Carefully insert the catheter shaft into the urethral meatus until its tip and balloon are suitably located in the bladder, normally indicated by urine flow. Then slowly inflate the balloon with the prescribed volume of sterile water and gently pull the catheter shaft backwards ensuring that the balloon is correctly "seated" at the neck of the bladder.
- Deflation Procedure
- Insert the syringe luer tip into the valve housing with a firm push/twist motion.
- Release syringe plunger and allow balloon to deflate.
- Use only gentle aspiration, if necessary, to deflate balloon.
- The balloon should spontaneously deflate.
- If deflation does not occur, proceed to the alternative methods listed below.
- STEP 1: Aspirate by slowly pulling back on syringe plunger handle to force deflation. If this does not work, proceed to Step 2.
- STEP 2: Remove syringe and fill syringe with 2-3 ml/cc of sterile water; reinsert syringe tip into valve; inject water into balloon and aspirate. If this does not work, proceed to Step 3.
- STEP 3: Use scissors to sever the side arm below the valve or cut the catheter shaft at some safe distance from the meatus and catheter should drain spontaneously. It this does not work, proceed to Step 4.
- STEP 4: Inject 100-200 ml/cc of suitable irrigating fluid into bladder. Then slowly inject 10-15 ml/cc of mild mineral oil/water mixture into the balloon by syringe/needle and wait for deflation followed by a volume of a suitable irrigation fluid to avoid any chance of chemical cystitis. If this does not work, proceed to Step 5.
- STEP 5: Scope around the catheter and use a suitable device to puncture the balloon.



7- Care instructions:

- Do not clamp or kink catheter shaft. Clamping may damage catheter, preventing deflation. Use of sterile catheter spigot is recommended to stop urine flow.
- Do not use needle to inflate balloon.
- Do not aspirate urine through the drainage funnel wall.
- Use water soluble lubricants only. Do not use ointments or lubricants having a petrolatum base. They will damage catheter's material and may burst balloon.
- Fill catheter balloon with sterile water only.
- Do not expose silicone catheter to radiation as it will change the properties of the silicone rubber to those caused by heat ageing.
- Do not use if package is open or damaged.
- Discard after single use.

8- Storage conditions:

- Not more than 5 cartoons on each other.
- Nice Ventilated place.
- Out of Sun light.
- UV lights and high dosage of radiation should be avoided during storage.
- The storage environment should not contain any equipment that generates ozone, such as mercury vapour lamps, high voltage electrical appliances or others that give rise to electric sparks or silent electrical discharges.
- Room temperature.



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9- Product code with size and measures:

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Sizes: 6 FG to 24 FG.

Size	Type	Code	Color
6	2-Way	3007-6/2	Light Green
8	2-Way	3007-8/2	Blue
10	2-Way	3007-10/2	Black
12	2-Way	3007-12/2	White
14	2-Way	3007-14/2	Green
16	2-Way	3007-16/2	Orange
	3-Way	3007-16/3	
18	2-Way	3007-18/2	Red
	3-Way	3007-18/3	
20	2-Way	3007-20/2	Yellow
	3-Way	3007-20/3	
22	2-Way	3007-22/2	- Vi <mark>ole</mark> t
	3-Way	3007-22/3	
24	2-Way	3007-24/2	Light Blue
	3-Way	3007-24/3	

10- List of product components:

• 100% Silicone Foley catheter.

11- Sterility:

• Sterilized by Ethylene oxide Gas (20% ETO +80 % Carbone dioxide).

12-Shelf life: 5 Years.

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Technical File

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