



太平洋醫材股份有限公司  
Pacific Hospital Supply Co., Ltd.  
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## Product Specifications

**Product Family:** Pre-connected urinary drainage system

**Product variants:**

Cat. Code	Specification		
	Catheter OD (Fr)	Catheter effective length (cm)	Balloon volume (mL)
M06059	12	34	5~15
M06061	14	34	5~15
M06062	16	34	5~15
M06063	18	34	5~15
M06064	20	34	5~15
M06065	22	34	5~15

**Descriptions:**

Pre-connected urinary drainage system is mainly a combination of one urinary drainage bag and one 2-way silicone foley catheter by foiling them at the connection. The tear drop shape bag is intended for urine collection; and 2-way foley catheter is to be inserted into the bladder through urethra to perform indwelling catheterization. The application procedures simplified as insert 2-way foley catheter into the bladder, inflate the balloon by injection nominal volume of sterile water or normal saline from side port to fix the location of catheter. Properly hang the urinary drainage bag at bedside by attached hook or string and bed sheet clip. While the evacuation of bag is required, uninstall the outlet tube from holder and release clamp so the urine will drain out, then reinstall the outlet tube back. Sampling of fresh urine could be achieved via the sampling port on the inlet connector, and retained urine could be done through the outlet tube as evacuation process. Air vents on bag and drip chamber help the fluent drainage of urine, and one-way valve in the drip chamber prevent reflux of collected urine.

**Construction:**

Refer to engineering drawings for illustration.



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**Material List:**

Part	Material
2-Way foley	Silicone
Sampling connector	ABS
Bed sheet clip	ABS
Slide clamp	HDPE
Hanger hook	PP
S-hook	POM
Outlet tube	silicone
Outlet clamp	PP
Outlet connector	PVC (DOTP)
Inlet tube	PVC (DINP)
White sheet	PVC (DINP)
Transparent sheet	PVC (DINP)

**Sterility:**

The product is supplied in sterile status using ethylene oxide sterilization method pursuant to ISO 11135:2014 with sterility assurance level  $10^{-6}$  pursuant to EN 556-1: 2001.

**Packaging specifications:**

Each product is packed in a coated paper-film peel pouch. 20 pcs are packed per carton with PE bag.

Materials of packaging system are:

Parts	Material
Pouch	Water-based coated paper PET+LLDPE
Bag	LDPE
Carton	5-layer corrugated board

**Shelf life:**

3 years for shelf life and it was verified in accordance with ISO 11607-1: 2019.



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**Storage conditions:**

Product shall be stored in room environment, within temperature of 10~40°C, and 30~90% relative humidity.