

Product Descriptions Urine Drainage Bag			Prepared by	Chen Jufang
			Checked by	Miao Jinfeng
Doc. No.	MDK/CE 06-06		Approved by	Gao Qing
Effective date	2018.05.20	Ver. A/0	Page No.	Page 1 of 5

Product Descriptions

1. Description of the product

Product name: Urine Drainage Bag

Brief introduction:

The product was tested the biocompatibility showed no toxicity, sterile, physical and chemical performances are complying with standard requirements. The product is composed with connector, connector cap, drainage in tube, flow stopcock, flow returning stopcock valve, urine storage bag, drainage out tube, drainage out tube switch, in which flow stopcock, connector cap, drainage out tube switch are manufactured with PE and PP by injection molding; connector is manufactured by PVC by injection molding; drainage in tube, drainage out tube are manufactured with PVC by extrusion molding; flow returning stopcock valve, urine storage bag are manufactured with PVC by injection molding.

Intended use: Intended for clinical patient urine collection use.

Contraindications: This product contains DEHP; clinical medical staff should pay attention to the high-risk groups (neonatal and prepubertal male, pregnant and lactating women), try to choose alternative products

Materials: PVC

Validity: 5 years.

Model and specification:

Adult pull-push valve: 2000ml;1500ml;1000ml;

Adult T type valve: 2000ml;1500ml;1000ml

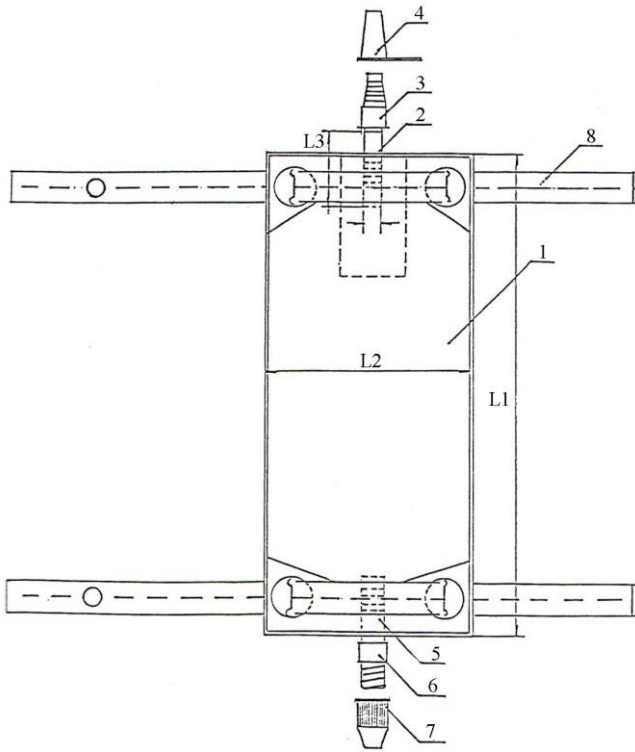
Adult Without valve: 2000ml;1500ml;1000ml

Pediatric: 200ml;100ml

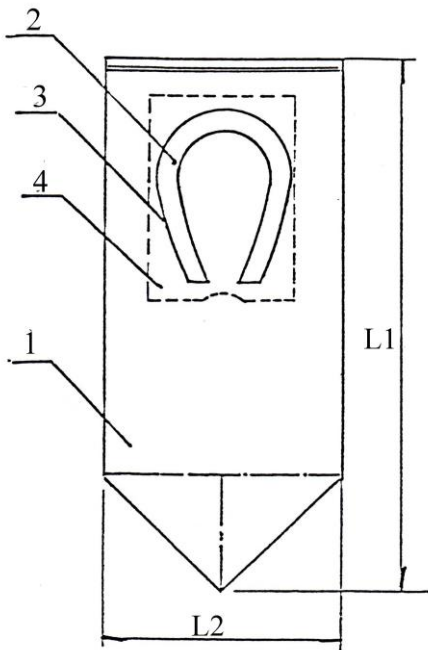
2. Structure and parameters

2.1 Structure

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For 1000ml 1500ml 2000ml Urine Drainage Bag:
 1-bag body
 2-Inlet tube
 3-Inlet connector
 4-Dust cap
 5-Outlet tube
 6-outlet connector
 7-Drainage tap



For 100ml,200ml, Urine Drainage Bag
 1-Bag body
 2-Sponge gasket
 3- Double Sides Adhesive Tape
 4-Protecting paper

2.2 Configuration of the Device

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Size (Rated volume)	Bag Body			Inlet	
	L1	L2	Thickness (double layers)	L3	D
2000ml	248±5	175±5	≥0.22	900± 20	6±0.5
1500ml	297±5	130±5		42±5	11±0.5
1000ml	265±5	110±5		35±5	10±0.5

2.3 Device Technical Parameters

Our company conducted sampling inspection batch by batch according to ISO8669-1/2:1988, ISO8669-3/4: 1990 and ISO2859-1, the test results showed physical performance, chemical performance and biological performance are all passed and compliance with standard requirements. For detail see below:

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Test item		Standard
Physical performance	Tolerance of volume	Tolerance of volume of bag body shall $\pm 10\%$
	Airproof	Assembled converse flow-proof device
		The line ioned around bag body shall be well sealed, shall no leakage
	Connection intensity	Connection between each parts shall endure 40N static pull force for 15S no breaking of falling
	Tube	Tube shall have good tenacity
	Appearance	bag body shall be soft, clear, no contamination, no obvious mechanic foreign substrate Diameter of tube shall be equal, no bubble, crack, no bad injected defect Sub-scale of bag body shall be clear, correct, not easily to fall
	Size of bag body	Shall be comply with the requirment in Clauze 2.2
Size of tube	Length of tube shall not less than 600mm	
	Internal diameter of tube shall not less than 3.5mm	
Chemical performance	Deoxidation substrate	Comparing with control sample, KMnO ₄ consumable shall not more than [c(KMnO ₄ =0.002mol/L)] 2.0ml
	pH	Comparing with control sample, the difference of pH of sample shall not more than 1.5
	UV absorption	Shall not more than 0.1
	EO residual	Each device shall 0.1mg
Biological performance	Sterility	Shall be sterile.
	Pyrogen	Shall be no pyrogen.
	Hemolysis	Hemolysis rate shall not more than 5%
	Acute general toxicity	Shall be no acute general toxicity

3 Critical materials supplier

Materials	Supplier information
PVC	Jiangsu Dahai Plastic Incorporated Company