公司名称（英文）：**Sanhill Medical Instrument Co., Ltd.**

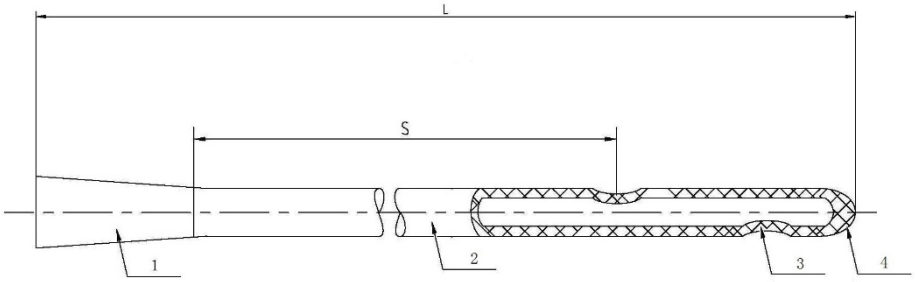
公司名称（中文）：上海震海医用设备有限公司

Technical File	Version: A/4
	Chapter: 5
Product Description (including product specification, drawings) 产品描述,规格及图纸	Pages: 1-4

Product description

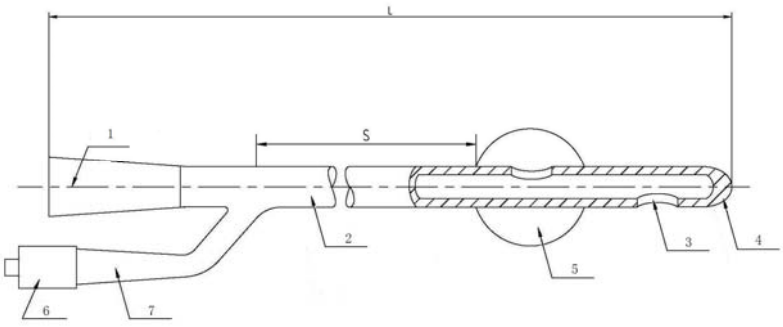
The product is composed of shaft and connector, and the materials of shaft and connector are consist of latex. The device was sterilized by EO. The valid period of sterilization was 5 years.

本产品主要采用天然橡胶制成。产品由排泄锥形接口、管身、球囊、阀、充起锥形接口、冲洗锥形接口等组成.采用环氧乙烷灭菌.有效期为五年



Sterile urethral catheter for single uses (1-funnel without balloon)

(1. Drainage funnel 2. Shaft 3. eyelet 4. tip)



Sterile urethral catheter for single uses (2-funnel with balloon)

(1. Drainage funnel 2. Shaft 3. eyelet 4. tip 5. Latex Balloon 6. Valve 7. Inflation funnel)

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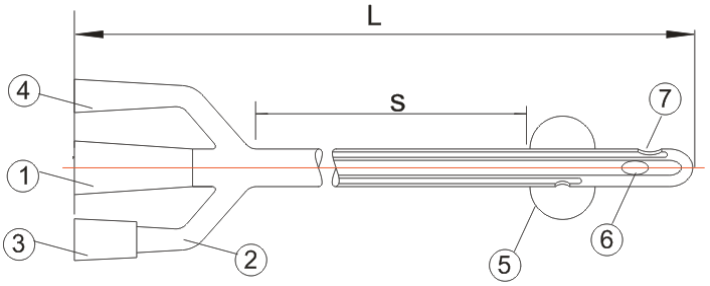

Sterile urethral catheter for single uses (3-funnel with balloon)

(1. Drainage funnel 2. Inflation funnel 3. Valve 4. Irrigation funnel 5. Latex Balloon 6. Drainage Eyelet 7. Irrigation Eyelet)

Intended use

Sterile urethral catheter is used for catheterization in clinical patients. The device intended for being introduced into the vesical cavity through the urethra in order to provide drainage and/or flushing of the bladder. 1-way catheter is used for temporary urinary catheterization. 2-ways catheter is used for indwelling catheterization. The 3-ways can be used for bladder irrigation.

适用范围：用于医疗机构临床对患者泌尿系统引流、一次性使用无菌导尿管用于临床病人的导尿。用于通过尿道引入膀胱腔的装置，以提供膀胱的引流和/或冲洗。单腔用于临时导尿。双腔用于留置导尿。三腔可用于膀胱冲洗。

Contraindication and Caution

- Please read the IFU carefully before use.
  使用前应仔细阅读使用说明
- This product has ethylene oxide sterilization, sterile products, valid for 5 years.
  本品已经环氧乙烷灭菌，产品无菌，有效期五年
- Single packing damage, it is prohibited to use, only for the use of disposable, destroyed after use;
  单包装破损，禁止使用，仅供一次性使用，用后销毁；
- Read the instructions carefully before use, in the period of validity is used;
  使用前应仔细阅读说明书，在有效期内使用
- According to the patient's body to choose the appropriate specifications, for children or suspected urinary tract stenosis, catheters should be fine;
  应根据病人的体型选择合适的规格，对小儿或疑有尿路狭窄者，导尿管宜细；
- This product use should be in accordance with the requirements of the hospital or the environmental protection department after the disposal of waste;
  本品用后应按医院或环保部门要求处置废弃物
- Suggested that the single use shall not be more than 7 days;
  建议使用一次不得超过 7 天
- Insert the urine tube movements should be gentle, for avoiding damage on urinary mucosa, don't insert too deep or too shallow and repeatedly twitch catheter;
  插入尿管动作应轻柔，以免损伤尿路粘膜，勿插入过深或过浅，尤忌反复抽动导尿管
- Excessive filling of the bladder, and patients with extremely weak, micturition slowly, and for the first time put urine amount shall not exceed 1000 ml, in order to prevent bladder decompression

cause bleeding or syncope;
对膀胱过度充盈，而患者又极度虚弱，排尿宜缓慢，且第一次放尿量应不超过1000ml，以免膀胱减压引起出血或晕厥；

- And urethral catheter if there is resistance, does not pull outside too hard, so as not to damage the urethra;
  尿道插管如有阻力，不要用力拉太远，以免损伤尿道
- Indwelling catheter, often should check the catheter fixed, observation ever emerge;
  留置导尿时，应经常检查导尿管固定情况，观察有否脱出
- Allergic to latex with caution;
  对乳胶过敏者慎用
- With severe urethral inflammation, urethral stricture, severe acute prostatitis, suspected to be connected with blunt and penetrating trauma of urethral rupture were banned.
  对有严重尿道炎症、尿道严重狭窄、急性前列腺炎、怀疑与钝性或穿透性外伤有关的尿道断裂者禁用
-

Type/models 型号规格如下

Types: Fr6, Fr8, Fr10, Fr12, Fr14, Fr16, Fr18, Fr20, Fr22, Fr24 for different tube diameter.

Model: 1-funnel without balloon, 2-funnel and 3-funnel with balloon

Product specification

To ensure the performance and safety of the device during clinical use, the technical specification has been established to ensure fulfillment of essential requirements. Key performance is listed as bellows. 1-way(without balloon), 2-way(with balloon), 3-way(with balloon).

The minimum overall length is given in table 1 (see also figures above), and the minimum flow rates is given in table 2.

Table 1. Shaft dimensions

Catheter type	L（min.）	S(min.)
Pediatric without balloon	150mm	NA
Pediatric with balloon	220mm	150mm
Female without balloon	150mm	NA
Female with balloon	220mm	130mm
Male without balloon	360mm	NA
Male with balloon	360mm	275mm
NA=not applicable.		

Table 2. Average flow rates

Outside diameter（mm）	Specification Fr	Drainage lumen mL/min
2.0	6	≥10
2.7	8	≥15
3.3	10	≥30
4.0	12	≥50
4.7	14	≥70
5.3	16	≥100
6.0	18	≥100

6.7	20	≥100
7.3	22	≥100
8.0	24	≥100

性能指标 Specifications:

1 外观 **Surface finish**

当用正常视力或矫正视力在 2.5 倍放大条件下检验时，管身、尖部、球囊和孔眼应无外来物质，且不应有加工缺陷和表面缺陷。

When examined by normal or corrected to normal vision, the external surface of the effective length of the catheter shall appear free from extraneous matte, andprocess and surface defects that may present an unacceptable risk of patient harm.

2 尺寸 **Size designation**

2.1 导尿管应用其公称外径（mm）表示，精确到 0.1mm，其公差应为±0.33mm。

The outer diameter shall be expressed as the nominal dimension in millimetres, rounded upwards to the nearest 0,1 mm. Tolerances on this stated size shall be ±0,33 mm.

2.2 长度 **Length**

最小全长（L）和最小管身长度（S）应按表 1 规定。The minimum overall lengths (*L*) and the minimum shaft lengths(S) shall be as given in Table 1

3 强度 **Strength**

当按 ISO 20696-2018《一次性使用无菌导尿管》附录 A 所给方法试验时，尖部和锥形接口应与管身连为一体，管身应无断裂。

When tested the tip/shaft union and lateral drainage holes shall not show any sign of breaking and neither the tip nor the funnel shall become detached from the shaft. Compliance shall be checked by the test method in ISO 20696-2018 Annex A.

4 连接器分离力 **Connector security**

当按 ISO 20696-2018《一次性使用无菌导尿管》附录 B 所给方法试验时，排泄锥形接口应不与试验连接器分离。When tested the drainage funnel shall not part from the test connector. Compliance shall be checked by the test method in ISO 20696-2018 Annex B.

5 球囊可靠性 **Balloon safety**

5.1 当按 ISO 20696-2018《一次性使用无菌导尿管》附录 C 所给方法试验时，球囊应无泄漏，并且不应影响排泄孔。

注：未充起球囊，其两端外形应与管身平滑地连为一体，在其周围环境温度下，球囊充入水至规定的容积后，应呈现基本对称地鼓起。

If present, the balloon shall not leak and shall not occlude the lateral drainage holes.
Compliance shall be checked by the test method in ISO 20696-2018 Annex C.
The change in profile at each end of the uninflated balloon should have a smooth transition to the shaft.
The balloon should be capable of approximately symmetrical expansion when filled with water at ambient temperature to its specified balloon capacity.

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5.2 当按 ISO 20696-2018《一次性使用无菌导尿管》附录 D 所给方法试验时，水的回收率应不低于 ISO 20696-2018《一次性使用无菌导尿管》附录 D 表 D.2 规定值。
When deflating the balloon, the percentage of water recovered shall not be lower than the value given In ISO 20696-2018 Table 2. Compliance shall be checked by using the test method in ISO 20696-2018 Annex D.

6 流量 **Flow rate**

当按 ISO 20696-2018《一次性使用无菌导尿管》附录 E 所给方法试验时，流量应符合表 1 规定。The minimum average flow rates shall be as given in ISO 20696-2018 Table 3. Compliance shall be checked using the flow rate test method in ISO 20696-2018 Annex E.

平均流量 Everage flow rate

标称规格 **Designated size**		平均流量（最小值）**Average flow rate (minimum)**	
Outer diameter 外径, mm	**Charrière equivalent**[a] 法国规格 (FG/Ch/Fr)	**Drainage lumen** 排泄腔 mL/min	**Irrigation lumen** 冲洗腔 mL /min
2.0	6	10	不适用 n.a.
2.7	8	15	不适用 n.a.
3.3	10	30	不适用 n.a.
4.0	12	50	不适用 n.a.
4.7	14	70	25
5.3	16	100	25
6.0	18	100	25
6.7	20	100	25
7.3	22	100	30
8.0	24	100	30
8.7	26	100	30
9.3	28	100	不适用 n.a.
10.0	30	100	不适用 n.a.

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7 耐弯曲性 **Kink stability**

弯曲导尿管各腔的液体流量应不低于平直导尿管液体流量的 50%。

The flow rate of each cavity of the bent catheter should not be less than 50% of the flow rate of the straight catheter.

8 无菌 Sterile

导尿管应经过确认过的灭菌过程，使产品达到无菌。

The urinary catheter should go through a confirmed sterilization process to make the product sterile.

9 环氧乙烷残留量 Ethylene oxide residue

环氧乙烷残留量应不大于 10μg/g。

The residue of ethylene oxide should not be greater than 10 ug/g.

10 化学指标 Chemical index

10.1 酸碱度 PH value

导尿管浸出液和空白对照液，pH 值之差≤1.The urethral catheter extraction solution compares with blank control solution, the difference of PH value is less than 1.5

10.2 重金属总含量 Total heavy metal content

导尿管浸出重金属总重量应不超过 1μg/mL。

The total weight of heavy metals extracted from the catheter shall not exceed 1 μg/mL.

10.3 易氧化物 Readily oxidation substance

导尿管浸出液与同体积的同批空白对照液相比，0.002mol/L 的高锰酸钾溶液消耗量之差应≤ 2.0mL。The difference between the consumption of 0.002mol/L potassium permanganate solution and the same volume of the same batch of blank control solution should be ≤ 2.0mL.