

ICS 11.040.20

CCS C40

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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0872-2013

Test methods for ureteral stents

输尿管支架试验方法

Issued on: May 18, 2022

Implemented on: October 1, 2014

Issued by: National Medical Products Administration

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Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules. This revised standard adopts ASTM F1828-1997 "ureteral stent norms." Content include.

--- According to GB/T

1.1 provisions of editorial changes;

--- On the test apparatus made appropriate improvements, but there is no difference in technology. This standard by the National Standardization Technical Committee medical infusion apparatus (SAC/TC106) proposed. This standard by the State Food and Drug Administration Jinan Medical Device Quality Supervision and Inspection Center. This standard was drafted. Shandong Hengxin detection technology development center. Drafters of this standard. Song Jinzai, Zhang Limei, Xu Hui.

This standard is intended to give an implanted ureteral stent used to evaluate the safety and effectiveness of the test method. These kidney stent Dirty side and bladder ends with retainer, through the ureter draining urine from the kidneys to the bladder. This standard gives the evaluation of ureteral stent characteristics arbitration test methods. Note that these test methods should not be used in the production of the manufacturer Quality control and batch release. Ureteral stent Test Method

1 Scope

YY/T 0872 specifies the test methods for ureteral stents, the double-J tubes placed between kidney and bladder to keep urine draining past a stone, a stricture or a surgical repair. It covers how the properties that decide clinical performance are measured: the radial strength that keeps the lumen open, the flexibility and coil retention that hold the ends in place, the tensile strength for removal, the surface behaviour and the radiopacity that lets the stent be seen on a plain film. A stent that migrates or fractures has to be retrieved endoscopically, and one that encrusts becomes impossible to remove at all. Ureteral stenting is high-volume urology in China. The standard carries Amendment 1 of 2022, and this is the method a Chinese registration expects the performance data to follow.

Disposable ureteral stent test method for evaluating the characteristics of arbitration ends

with fixing device according to the standards, and these stents Short-term urine drainage from the kidney to the bladder. The diameter of these stents have generally 3.7Fr ~ 14.0Fr, a length of 8cm ~ 30cm, the Silicone rubber, polyurethane and other polymers, and in the form of non-sterile and sterile disposable form of supply. The product will have a long-term retention (more than 30d) situation, but not common, so this standard does not cover this situation. Also, the standard Nor does it include non-ureteral applications (such as kidney colostomy and ileostomy) ureteral stents. Because the hospital's sterilization equipment, sterilization processes Presence and stent characteristics produce differences, so this standard does not apply to non-sterile ureteral stent.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

GB/T 528 Determination of vulcanized rubber or thermoplastic rubber tensile stress-strain properties Biological evaluation of

GB/T 16886 (all parts) Medical Devices

YY/T 0586 Medical Polymer Co. X-ray opaque Test Method

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Artificial urine artificialurine An organic and inorganic compound solution, its physical and chemical properties close to normal human urine. Artificial urine instead of human urine to Effects of simulated human urine ureteral stent.

3.2 Bladder fixtures bladderretentionmeans Prevent the physical structure of the stent from the bladder off the end of the stent bladder.

3.3 Breaking strength breakstrength The stent required to break the maximum tensile load.

3.4 Cross section crosssection Vertical section view of the bracket in the longitudinal direction of the stent.

3.5 The distal end of distal End remote from the starting point, the distal end of the stent is indwelling in the bladder, also known as bladder end.