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**Tube and catheter for nephrostomy
and cystostomy**

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Foreword

This translation has been made based on the original Japanese Industrial Standard established by Minister of Health, Labour and Welfare through deliberations at the Japanese Industrial Standards Committee according to the proposal of establishing a Japanese Industrial Standard from Japan Medical Devices Manufacturers Association (JMED)/Japanese Standards Association (JSA), with a draft of Industrial Standard based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

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Tube and catheter for nephrostomy and cystostomy

1 Scope This Japanese Industrial Standard specifies the requirements for catheters used for urethral catheterization, contrast or chemical feeding, which are detained in renal, ureter or bladder after nephrostomy or cystostomy through the skin (hereafter referred to as “catheters”).

2 Normative references The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

JIS T 0307 *Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied*

JIS T 0993-1 *Biological evaluation of medical devices—Part 1: Evaluation and testing*

JIS T 3214 *Urethral Catheters*

JIS T 3215 *Drainage catheters and accessory devices*

ISO 594-1 *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment—Part 1 : General requirements*

3 Requirements

3.1 Stress at breakage

3.1.1 Connecting part When connecting parts are tested according to annex A, the force applied to them at breakage shall be not less than the value of the minimum force shown in table 1. However, as for the funnel-shaped connecting part, the minimum force at breakage shall be the standard value of **5.5** (Safety of funnel for urination) in **JIS T 3214**.

Table 1 Minimum force of connecting parts at breakage

Nominal outside diameter (mm)	Minimum force at breakage (N)
2 >	5
2 to 4	5
> 4	15

Remarks : The numerical values of this table are derived from that of table 1 of **JIS T 3215**.

3.1.2 Catheter When catheters are tested according to annex B, the minimum force applied to them at breakage shall be as specified in table 2. However, as for catheters with balloon, the minimum force shall be the standard value of **5.4** (Strength) in **JIS T 3214**.

Table 2 Minimum force of catheters at breakage

Nominal outside diameter (mm)	Minimum force at breakage (N)
2 >	5
2 to 4	10
> 4	20

Remarks : The numerical values of this table are derived from that of table 2 in **JIS T 3215**.

3.2 Biological safety The catheters shall be assessed for biological safety according to **JIS T 0993-1**.

3.3 Assurance of sterility As for catheters marked as “Sterilized”, the sterility shall be ensured based on Criteria for Validation of Sterilization or the criteria equivalent or better to this.

Information : Criteria for Validation of Sterilization is as specified in “Notification No.1” issued by Inspection and Guidance Division, Pharmaceutical and Medical Safety Bureau, Ministry of Health, Labour and Welfare, dated July 1, 1997 and entitled “Criteria for Validation of Sterilization”.

3.4 Test for corrosion For the metal part of catheters detained inside a body, there shall be no signs of corrosion in the tested specimen when the test is carried out according to annex C.

3.5 Safety of balloon

3.5.1 The front and rear edges of a balloon, when it is not expanded, shall be so shaped as to be capable of smooth connection with shaft parts. The balloon shall be expanded symmetrically (the maximum rate of the distance to the center part of the shaft of balloon is less than 4) when expanded (when filled with water up to specified capacity at normal temperature).

3.5.2 The balloon shall be tested according to annex D, and be almost drained of water.

3.6 Blockage of rumen for urination When water is poured into the rumen for urination after the catheter is immersed in artificial urine for 14 days, water shall flow smoothly without any blockage.

As for catheters with the rumen for cleaning, check it also for any blockage.

4 Packaging

4.1 Primary packaging The tube and catheter shall be individually packed primarily so that they remain sterile and are not damaged during regular handling, transportation and storage. The tube and catheter shall be sealed in a tamper-evident manner.