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Urethral catheters

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Foreword

This Japanese Industrial Standard has been revised by the Minister of Health, Labour and Welfare through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by Medical Technology Association of Japan (MTJAPAN)/Japanese Standards Association (JSA) with a draft being attached, based on the provision of Article 12, paragraph (1) of the Industrial Standardization Act applied mutatis mutandis pursuant to the provision of Article 16 of the said Act. This edition replaces the previous edition (**JIS T 3214** : 2011), which has been technically revised.

However, **JIS T 3214** : 2011 remains valid for three years from the date of public notice of the revision of this Standard.

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Urethral catheters

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 20696** : 2018, Edition 1, with some modifications of the technical contents in order to reflect the actual situation in Japan.

The dotted underlines indicate changes from the corresponding International Standard. A list of modifications with the explanations is given in Annex JA.

1 Scope

This Standard specifies requirements for urethral catheters, with or without a balloon, which are used for urethral catheterization, pressure hemostasis, cleaning of bladder, etc. (hereafter referred to as catheters). This Standard does not apply to nephrostomy catheters and cystostomy catheters to be placed through a stoma covered by **ISO 20697**.

NOTE 1 Requirements for ureteral stents are specified in **JIS T 3270**.

NOTE 2 The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows.

ISO 20696 : 2018 *Sterile urethral catheters for single use* (MOD)

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standards and **JIS** are IDT (identical), MOD (modified), and NEQ (not equivalent) according to **ISO/IEC Guide 21-1**.

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 within a risk management process*

NOTE Corresponding International Standard : ISO 10993-1 *Biological evaluation of medical devices — Part 1 : Evaluation and testing within a risk management process*

3 Terms and definitions

For the purpose of this Standard, the following terms and definitions apply.

3.1

urethral catheter

tubular device which is placed in bladder by way of urethra for the purpose of urethral catheterization, pressure hemostasis and/or cleaning of bladder

3.2**balloon capacity**

quantity of liquid which is injected into a balloon lumen and a balloon to expand a balloon appropriately

3.3**shaft**

portion other than the tip of a catheter, balloon, funnel and/or valve

3.4**outer diameter**

diameter of shaft which is measured at the position 2.5 cm from the edge of funnel side of a balloon

When the section of a shaft is oval, the major axis is considered as the outer diameter.

3.5**syringe with sterile water for expansion of balloon**

injection cylinder which is filled with sterile water beforehand to expand a balloon

3.6**effective length**

length (L_1) of the catheter that can be inserted into the body

3.7**effective shaft length**

length of non-perforated portion of the catheter excluding the tip, balloon(s), funnel(s), protective sleeves and/or access port(s)

3.8**funnel**

proximal portion of the catheter, which may be connected to a drainage system

3.9**intermittent**

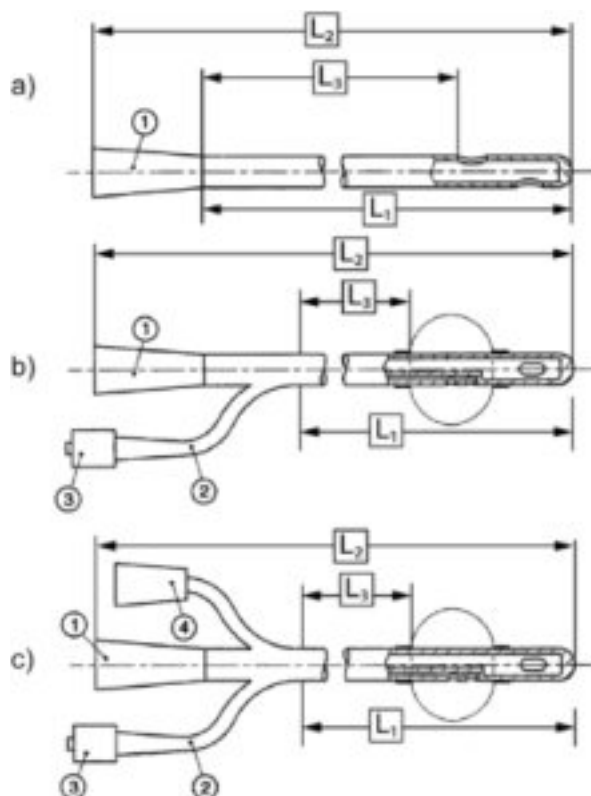
intended to be removed immediately after emptying the bladder

3.10**overall length**

total length from the tip of the catheter to the end of the funnel (L_2)

4 Configuration and names of parts

The typical configuration and names of parts of catheters with or without a balloon are illustrated in Figure 1. Figure 1 is an example of configuration and name of parts of catheters with or without a balloon.



- | | |
|--------------------------|------------------------------|
| 1 drainage funnel | L_1 effective length |
| 2 inflation access port | L_2 overall length |
| 3 valve | L_3 effective shaft length |
| 4 irrigation access port | |

NOTE Urethral catheters may contain accessories such as stilet, temperature sensor, syringe with sterile water for expansion of a balloon, lubricant, disinfectant, gloves, cotton ball, gauze, forceps, urine bag, tube for collecting urine to be tested, wrapping sheet, tray, storage vessel, and protective cap.

Figure 1 Example of urethral catheters with or without balloon

5 Requirements

5.1 Appearance and cleanliness

When examined by normal or corrected to normal vision, the external surface of the effective length of the catheter shall appear free from extraneous matter or process de-

fects (flaws, burrs, etc.). If deemed necessary, inspection shall be conducted under a minimum $2.5 \times$ magnification.

5.2 Dimensions

5.2.1 Outer diameter

The outer diameter of catheters shall be expressed as the nominal outer diameter in millimetres rounded to the nearest 0.1 mm.

Tolerances shall be ± 0.33 mm (± 1 Fr). However, French (Charriere) or English type gauge may also be indicated in addition to the indication of outer diameter diameter in millimetres.

NOTE French (Charriere) may be expressed in, e.g. Fr (Ch). English type gauge may be expressed in, e.g. EG.

Example 1 When the outer diameter is 2 mm,
2.0 mm, 6 Fr (Ch) or 2 EG

Example 2 When the outer diameter is $2 \frac{2}{3}$ mm,
2.7 mm, 8 Fr (Ch)

5.2.2 Designation of balloon capacity

The balloon capacity shows the capacity of a balloon. The balloon injection rate shows the volume of water (distilled or deionized) to be injected to expand the balloon appropriately. Both of them shall be expressed in millilitre.

5.2.3 Length

The minimum effective shaft lengths (L_3) shall be as given in Table 1. The nominal effective shaft length (L_3) shall be expressed in millimetres, rounded to the nearest 0.1 mm.

Table 1 Effective shaft length

Catheter type	L_3 (minimum) mm
Paediatric male	150
Paediatric female	45
Female	60
Male	275
NOTE Effective shaft length : Shorter sizes can be produced using appropriate risk based clinical justification.	

5.3 Strength

When tested according to Annex A, the drainage funnel shall not come off from the shaft,

and the shaft shall not be damaged.

5.4 Safety of drainage funnel

When tested according to Annex B, the connector for test shall not come off from the drainage funnel.

5.5 Balloon safety

When tested according to Annex C, the balloon shall not leak and shall not occlude the lateral drainage holes.

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 (the maximum ratio of the distance to the central part of shaft of balloon is less than 4) when filled with water at ambient temperature to its specified balloon capacity.

When the test is performed according to Annex D, the percentage of water recovered shall not be lower than the value given in Table 2.

Table 2 Balloon test volume percentage recovery

Balloon capacity ml	Minimum percentage of volume recovered %	
	Silicone	Other than silicone
1.5 or under	30	55
3.0	50	55
5.0	55	55
10.0	75	75
20.0	80	80
30.0 or over	80	80
Intermediate cases are recommended to comply with the next higher value.		

5.6 Blockage of drainage lumen and irrigation lumen

After immersing a catheter in simulated urine for 14 days, pass water through the drainage lumen and irrigation lumen. At that time, there shall be no blockage in the lumen, and water shall flow without any troubles.

5.7 Detectability

The catheter or at least its effective length shall be detectable by X-ray or by other means (ultra-sound, etc.).

5.8 Corrosion resistance

If the catheter and its components use metallic materials which directly or indirectly come into contact with chemical or body fluid, the test shall be performed according to Annex E. If the metallic parts show signs of corrosion, the extent of corrosion shall be evaluated in use and risk assessment to confirm the absence of effect on the performance and safety of products.

5.9 Kink stability

Catheter kink stability shall be assessed and confirmed in accordance with Annex F.

NOTE Test methods other than that in Annex F may be used.

5.10 Peak tensile force

When tested according to Annex G, the minimum peak tensile force of the urethral catheter tubular portion, each junction between catheter component and tubing, and each junction between tubular portions shall be as given in Table 3. This Standard does not specify requirements for peak tensile force for tubing of less than 2 mm outer diameter. These values shall be determined by the manufacturer/supplier based on risk assessment.

Table 3 Peak tensile force of catheters

Smallest outer diameter of tubular portion of test piece mm	Minimum peak tensile force N
≥ 2 and ≤ 4	10
> 4	20

5.11 Inflated balloon resistance to traction

The test shall be performed in accordance with Annex H. For 4.66 mm to 8.66 mm (14 French to 26 French) urethral catheters, the balloon shall not pass into or through a funnel-like apparatus, with a size 9.24 mm (28 French) lumen, representing the bladder outlet and urethra. This Standard does not specify requirements for catheter sizes less than 4.66 mm (14 French). These values shall be determined by the manufacturer/supplier based on risk assessment.

6 Biological safety

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

7 Sterility assurance

For the catheters to be marked as STERILE, the sterility shall be assured based on the Criteria for Validation of Sterilization or the equivalent or stricter criteria.

NOTE For the validation of sterilization, the Criteria for Validation of Sterilization specified by the Ministry of Health, Labour and Welfare apply.

8 Packaging

8.1 Primary packaging

The primary packaging shall be capable of preventing the ingress of microorganisms and of appropriately protecting the products inside from damage during normal handling, transportation and storage. Once opened, the primary packaging shall not be easily resealed, and it shall be obvious that the container has been unsealed.

8.2 Secondary packaging

The secondary packaging shall have sufficient strength to protect products inside during normal handling, transportation and storage.

9 Marking

9.1 Primary packaging

The primary packaging shall be labelled with the following information.

- a) Outer diameter (mm) and length (mm or cm) of the catheter. However, French (Charriere) may also be indicated for information in addition to the indication of outer diameter in millimetres (mm).

NOTE French (Charriere) should be expressed in, e.g. Fr (Ch).

- b) Balloon capacity indicated in millilitres (ml)
- c) Indication of “STERILE”, if sterilized
- d) Lot number or manufacturing symbol

9.2 Secondary packaging

The secondary packaging shall be labelled with the following information. However, when the primary packaging is the minimum sales unit without the secondary packaging being used, the following information shall be indicated on the primary packaging.

If the lot number or manufacturing symbol indicates the year and month of sterilization, a separate indication of the year and month of sterilization is not required. A use-by date may be indicated instead of the year and month of sterilization.

- a) Name or trade name, and address of manufacturer/supplier
- b) Certification number of medical equipment
- c) Product's trade name
- d) Outer diameter (mm) and length (mm or cm) of catheter. However, French (Charriere) may also be indicated for information in addition to the indication of outer diameter in millimetres (mm).

NOTE French (Charriere) should be expressed in, e.g. Fr (Ch).

- e) Quantity (number per package)
- f) Indication of “STERILE”, if sterilized
- g) Indication of “DO NOT RE-USE” (The term “disposable” shall not be used.)
- h) Indication of the use of natural rubber, if applicable
- i) Lot number or manufacturing symbol
- j) Year and month of sterilization, if sterilized
- k) Use-by date