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Drainage catheters and accessory
devices

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Contents

	Page
Introduction	1
1 Scope	1
2 Normative references	2
3 Terms and definitions	2
4 Configuration and names of parts	3
5 Requirements	4
5.1 General requirements	4
5.2 Specific requirements	5
6 Packaging	6
6.1 Primary packaging	6
6.2 Secondary packaging	7
7 Marking	7
7.1 Primary packaging	7
7.2 Secondary packaging	7
7.3 Use of symbols	8
Annex A (informative) Test method for determining kink stability	9
Annex B (normative) Test method for corrosion resistance	11
Annex C (normative) Test method for resistance to deformation by suction	12
Annex D (normative) Test method for determining peak tensile force of connections	13
Annex E (normative) Test method for determining peak tensile force of drainage catheter	14
Annex F (normative) Test method for impact resistance of collection device	16
Annex G (normative) Test method for resistance to leakage when negative pressure is applied	18
Annex JA (informative) Comparison table between JIS and corresponding International Standard	19

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 3215** : 2011), which has been technically revised.

However, **JIS T 3215** : 2011 remains valid for three years from the date of public notice of the revision of this Standard.

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Drainage catheters and accessory devices

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 20697** : 2018, Edition 1, with some modifications of the technical contents in order to reflect the actual situation in Japan.

The vertical lines on both sides and 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 drainage catheters and their accessory devices, where the catheter is placed in a body cavity or wound, surgically or percutaneously, for drainage of accumulated fluid or air to the exterior. This Standard is not applicable to those with a special shape at the tip (pigtail, balloon, etc.) to maintain placement in the body, or to the following :

- suction catheters used by airway;
- tracheal catheters (tracheal tube);
- urethral catheter;
- ureteral stents, biliary stents, and other stents;
- drainage catheters placed in digestive tracts percutaneously with gastrostomy technique;
- neuraxial catheters used for removal of cerebrospinal fluid;
- enteral catheters used for removal of solutions or substances from the gastrointestinal tract;
- catheters for nephrostomy or cystostomy;
- catheters and tubes designed for the biliary tract.

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

ISO 20697 : 2018 *Sterile drainage catheters and accessory devices 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

accessory device

device that is used with drainage catheters (3.5) in the drainage system (3.6) for access and/or drainage [e.g. collection device(s) (3.3)] and, where applicable, other accessories such as suction source(s) (3.10), connecting tube(s) (3.4), connector(s), trocar(s) (3.11), split needle(s)/ cannula(s), or introducer(s)

3.2

catheter component

part which is integral with the drainage catheter (3.5)

3.3

collection device

bag, bellows or other portable container designed for collecting drained liquid, or containers designed to collect fluid or air

3.4

connecting tube

tube designed for connecting the drainage catheter (3.5) and collection device (3.3), or collection device and suction source (3.10)

3.5

drainage catheter

tube designed for draining fluid or air from a body cavity or a surgical wound

3.6

drainage system

functional assembly of instruments necessary for drainage or evacuation, and placement of drainage catheters, which consists of drainage catheters (3.5) and accessory devices (3.1)

NOTE 1 A drainage system may be supplied either in the ready-for-use state or in a state requiring the assembly of some components by the user.

NOTE 2 Drainage or evacuation may be achieved either by gravity, by negative pressure generated by an external power source, by manipulation by the user, or by the pre-evacuation of the collection device.

3.7

effective length

length of the drainage catheter (3.5) that can be inserted into the body

3.8

overall length

total length from the tip of the drainage catheter (3.5) to the end of the funnel (3.9)

3.9

funnel

proximal portion of the drainage catheter (3.5) as viewed from an operator, which may be connected to a drainage system (3.6)

A funnel may be a connector joined to the proximal end of a drainage catheter

3.10

suction source

self-contained device capable of exerting a negative pressure on a drainage catheter (3.5) or drainage system (3.6)

NOTE The suction source may be the collection device (3.3).

3.11

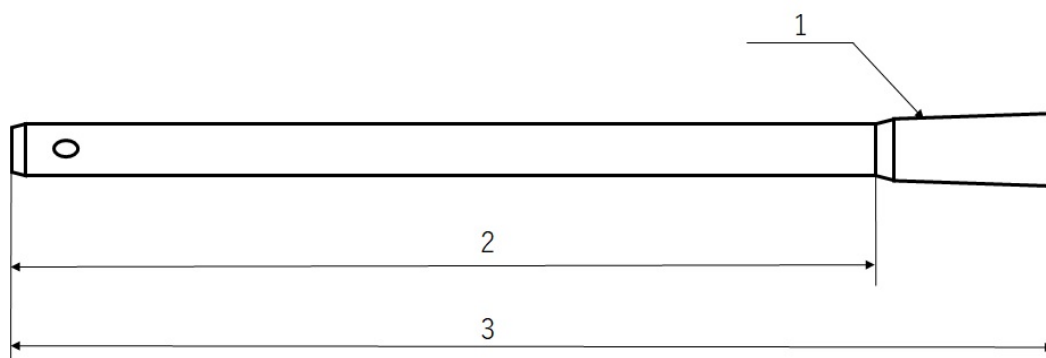
trocar

needle, pointed rod sleeve or any combination thereof which assists in passing the drainage catheter (3.5), when placed in the body cavity or wound, through the body wall

4 Configuration and names of parts

An example of the configuration and names of each part of common drainage catheters is shown in Figure 1.

There may be other types and shapes of products.



- 1 funnel
- 2 effective length
- 3 overall length

Figure 1 Example of drainage catheter

5 Requirements

5.1 General requirements

5.1.1 Biological safety

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

5.1.2 Detectability

The drainage catheter or at least its effective length shall be detectable by X-ray or by other means.

5.1.3 Appearance and cleanliness

When examined visually, the external surface of the effective length of the drainage catheter shall appear free from extraneous matter and defects that may present an unacceptable risk of patient harm.

5.1.4 Dimensions

5.1.4.1 General

The nominal size of the drainage catheter shall be designated as specified in **5.1.4.2** and **5.1.4.3**.

5.1.4.2 Outer diameter

The outer diameter shall be expressed as the nominal dimension of outer diameter of effective length of the drainage catheter in millimetres, rounded to the nearest 0.1 mm.

Tolerances on this stated size shall be ± 0.3 mm (± 1 French).

NOTE French size (F) is a nominal dimensional identification of the outer size of drainage catheters; calculated as three times the outer diameter (in millimetres) : $F = 3 \times \text{outer diameter (mm)}$. Fr or Ch (Charriere) may be used as a symbol of unit.

5.1.4.3 Effective length and overall length

The nominal effective length shall be expressed as an integer in millimetres for effective lengths of less than 100 mm, or either in millimetres or centimetres for effective lengths of 100 mm or more.

5.1.5 Connection of drainage catheter and drainage system

A risk assessment shall be performed on funnel misconnections.

5.1.6 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.

5.2 Specific requirements

5.2.1 Kink stability

The drainage catheter shall not kink in such a way as to affect drainage when operated and placed by the method specified by the manufacturer/supplier.

NOTE A kink stability test method (informative) is shown in Annex A.

5.2.2 Corrosion resistance

For the drainage catheters with metal parts in contact with body fluids, when tested by the method specified in Annex B, the metal parts shall be free from corrosion.

5.2.3 Resistance to deformation

The drainage catheter, accessory devices, or any component(s) designed to form a drainage system, intended to perform drainage or evacuation under negative pressure shall not show deformation (collapse) sufficient to impair the drainage function of the device at the maximum negative pressure as defined by the manufacturer/supplier when tested by the method specified in Annex C.

5.2.4 Peak tensile force

5.2.4.1 Connections

When the test is performed by the method specified in Annex D on each junction of drainage system (each junction between drainage catheter and connecting tube, each junction between connecting tube and collection device, etc.) assembled according to the package insert, the minimum peak tensile force when the junction separates shall be as given in Table 1.

Table 1 Minimum peak tensile force when the junction separates

Smallest outer diameter of tubular portion of connected devices mm	Minimum peak tensile force N
2 ≥	5
2 to 4	5
> 4	15

5.2.4.2 Drainage catheter, and connection of drainage catheter and catheter component

When the test is performed by the method specified in Annex E on each tubular portion of drainage catheter, each junction between drainage catheter tubing and catheter component and each junction between tubular portions (e.g. when the distal tip is connected to the tubular portion of the drainage catheter), the minimum peak tensile force when the tubing breaks or the junction separates shall be as given in Table 2.

Table 2 Minimum peak tensile force at break or separation of drainage catheter and catheter component

Smallest outer diameter of tubular portion of test piece mm	Minimum peak tensile force N
2 ≥	5
2 to 4	10
> 4	20

5.2.5 Impact resistance

When tested according to Annex F, the collection device shall not leak. When tested by the method specified in Annex F, the suction source shall not show any loss of vacuum that impairs the function of the drainage system under normal operating suction pressure.

5.2.6 Airtightness

The drainage system, intended to perform drainage or evacuation under negative pressure shall not leak air at the maximum negative pressure as defined by the manufacturer/supplier when tested by the method specified in Annex G.

6 Packaging

6.1 Primary packaging

The primary packaging shall be capable of preventing the ingress of microorganisms and of 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.