

# JIS

JAPANESE  
INDUSTRIAL  
STANDARD

Translated and Published by  
Japanese Standards Association

---

---

**JIS T 3268** : 2018

(MTJAPAN/JSA)

**Sterile, single-use intravascular  
catheters**

---

ICS 11.040.25

Reference number : **JIS T 3268 : 2018 (E)**

T 3268 : 2018

Date of Establishment: 2012-03-01

Date of Revision: 2018-02-01

Date of Public Notice in Official Gazette: 2018-02-01

Investigated by: Japanese Industrial Standards Committee  
Standards Board for ISO area  
Technical Committee on Medical Equipment

---

JIS T 3268:2018, First English edition published in 2018-09

Translated and published by: Japanese Standards Association  
Mita MT Building, 3-13-12, Mita, Minato-ku, Tokyo, 108-0073 JAPAN

---

In the event of any doubts arising as to the contents,  
the original JIS is to be the final authority.

© JSA 2018

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

Printed in Japan

IN/AT

PROTECTED BY COPYRIGHT

## Contents

	Page
Introduction .....	1
1 Scope .....	1
2 Normative references .....	1
3 Terms and definitions .....	2
4 Configuration and names of parts .....	4
5 Requirements .....	6
5.1 Appearance and cleanliness .....	6
5.2 X-ray detectability .....	6
5.3 Hubs .....	6
5.4 Peak tensile force .....	6
5.5 Distal end and side hole of catheter .....	7
5.6 Corrosion resistance .....	7
5.7 Airtightness .....	7
5.8 Pressure resistance .....	7
5.9 Continuous infusion catheter .....	7
5.10 Balloon catheter .....	8
5.11 Snare catheter .....	8
5.12 Components .....	8
6 Biological safety .....	9
7 Sterility assurance .....	9
8 Packaging .....	9
8.1 Primary packaging .....	9
8.2 Secondary packaging .....	9
9 Marking .....	9
9.1 Primary packaging .....	9
9.2 Secondary packaging .....	10
9.3 Use of symbols .....	11
Annex A (normative) Determination of peak tensile force .....	12
Annex B (normative) Test method for corrosion resistance .....	14
Annex C (normative) Airtightness of catheter .....	15
Annex D (normative) Pressure resistance of general catheter .....	16
Annex E (normative) Power injection test (only for products indicated for power injection) .....	18

Annex F (normative)	Flowrate through catheter .....	20
Annex G (normative)	Determination of rated burst pressure (RBP) .....	22
Annex H (normative)	Balloon fatigue test for damage and leakage on inflation ....	23
Annex I (normative)	Test for balloon deflation time .....	25
Annex J (normative)	Determination of balloon diameter to inflation pressure .....	27
Bibliography	.....	29
Annex JA (informative)	Comparison table between JIS and corresponding International Standards .....	31

## 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 the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14. Consequently **JIS T 3268:2012** is replaced with this Standard.

This **JIS** document is protected by the Copyright Law.

Attention is drawn to the possibility that some parts of this Standard may conflict with patent rights, applications for a patent after opening to the public or utility model rights. The relevant Minister and the Japanese Industrial Standards Committee are not responsible for identifying any of such patent rights, applications for a patent after opening to the public or utility model rights.

# Sterile, single-use intravascular catheters

## Introduction

This Japanese Industrial Standard has been prepared based on **ISO 10555-1:2013**, Edition 2 (including the corrected version published in 2014), **ISO 10555-3** and **ISO 10555-4** with some modifications of the technical contents, reflecting the circumstances in Japan.

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

## 1 Scope

This Standard specifies sterile, single-use intravascular catheters (hereafter referred to as catheters) which are designed to be inserted or implanted into vessels (including AV shunts and vascular grafts) for diagnostic or therapeutic purposes, or to deliver medical devices to the chosen location. However, this Standard does not apply to catheters with anti-thrombogenic property, coated with biological materials such as heparin and urokinase, catheters with antibacterial effect, coated with antimicrobial agents, and hydratable catheters.

NOTE 1 **JIS T 3268:2012** may be applied until January 31, 2021.

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

ISO 10555-1:2013 *Intravascular catheters—Sterile and single-use catheters—Part 1: General requirements* and the corrected version:2014

ISO 10555-3:2013 *Intravascular catheters—Sterile and single-use catheters—Part 3: Central venous catheters*

ISO 10555-4:2013 *Intravascular catheters—Sterile and single-use catheters—Part 4: Balloon dilatation catheters*

(Overall evaluation: 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. For standards indicated below, only the editions of the indicated year shall be applied and any revisions (including amendments) made thereafter shall not be applied.

JIS T 0307:2004 *Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied*

JIS T 0993-1:2012 *Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process*