

JAPANESE INDUSTRIAL STANDARD

Translated and Published by Japanese Standards Association

 $JIS\ T\ 3228^{\,:\,2018}$

(MTJAPAN/JSA)

Biopsy needles for single use

 $\pmb{\text{ICS}} \ 11.040.25$

Reference number: JIS T 3228: 2018 (E)

T 3228: 2018

Date of Establishment: 2005-03-25

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 3228: 2018, First English edition published in 2018-07

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/HN

Contents

	Page
Introduction ····································	
1	Scope
2	Normative references · · · · · 1
3	Terms and definitions ······2
4	Configuration and names of parts ······· 3
5	Requirements ······ 4
5.1	Combination of needle tube ······ 4
5.2	Materials for needle tube · · · · · 4
5. 3	Tolerance on dimensions · · · · · 5
5.4	Appearance and cleanliness · · · · · 5
5.5	Needle point · · · · · 5
5.6	Performance 5
5.7	Tensile strength ·······6
5.8	Elasticity 6
5.9	Bending strength · · · · · · · · · · · · · · · · · · ·
5.10	Fitting with taper of needle hub ···································
5.11	Sterility assurance8
5.12	Biological safety ·····8
6	Packaging ·····8
6.1	Primary container ·····8
6.2	Secondary container ·····8
7	Labelling ·····8
7.1	Primary container ·····8
7.2	Secondary container ·····8
7.3	Use of graphic symbols ·····9
Annex	x A (informative) Guidelines for concept of needle rigidity10

T 3228: 2018

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 3228:2011 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.

Biopsy needles for single use

JIS T 3228: 2018

Introduction

This Japanese Industrial Standard was established in 2005 and has gone through the revision made in 2011 up to the present. Since ISO 80369-6 and ISO 80369-7 have been established in relation to standards for connectors, ISO 594-1: 1986 and ISO 594-2: 1998, which are cited in this Standard, this Standard has been revised to add these standards to normative references.

1 Scope

This Standard specifies biopsy needles for single use to obtain a biopsy specimen (hereafter referred to as biopsy needles). This Standard is also applicable to the needles capable of injecting drug solutions, except for the case where the use of the needles intended to administer medications could be hazardous depending on its usage.

NOTE: JIS T 3228: 2011 is applicable until January 31, 2021.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. For standards with the indication of the year, only editions of the year indicated shall be applied, and the revisions (including amendments) made thereafter shall not be applied. For those without the indication of the year, the most recent editions (including amendments) shall be applied.

- JIS G 4305 Cold-rolled stainless steel plate, sheet and strip
- JIS H 4650 Titanium and titanium alloys Bars
- 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
- ISO 594-1: 1986 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment Part 1: General requirements
- ISO 594-2:1998 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment Part 2: Lock fittings
- ISO 9626: 2016 Stainless steel needle tubing for the manufacture of medical devices Requirements and test methods
- ISO 80369-6: 2016 Small bore connectors for liquids and gases in healthcare applications Part 6: Connectors for neuraxial applications