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Biopsy needles for single use

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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 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.

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Biopsy needles for single use

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*