

JIS

JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS T 9301 : 2005

(JIPT/JSA)

Acupuncture needle for single use

ICS 11.040.60

Reference number : JIS T 9301 : 2005 (E)

PROTECTED BY COPYRIGHT

 **Documents**
Document Sharing Hub

85

Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of Health, Labour and Welfare through deliberations at the Japanese Industrial Standards Committee according to the proposal of establishing a Japanese Industrial Standard from Japan Industries Association of Physical Therapy Device (JIPT)/Japanese Standards Association (JSA), with a draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

Attention is drawn to the possibility that some parts of this Standard may conflict with a patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have technical properties. The relevant Minister and the Japanese Industrial Standards Committee are not responsible for identifying the patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have the said technical properties.

Date of Establishment: 2005-03-25

Date of Public Notice in Official Gazette: 2005-03-25

Investigated by: Japanese Industrial Standards Committee

Standards Board

Technical Committee on Medical Equipment

JIS T 9301 : 2005, First English edition published in 2005-12

Translated and published by: Japanese Standards Association
4-1-24, Akasaka, Minato-ku, Tokyo, 107-8440 JAPAN

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

© JSA 2005

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

PROTECTED BY COPYRIGHT

MT

 **Documents**
Document Sharing Hub

Contents

	Page
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Physical requirements	2
4.1 Materials	2
4.2 Appearance and cleanliness	2
5 Chemical requirements	2
5.1 Limit of acidity and alkalinity of extracts	2
5.2 Limitation of dissolved metals	2
6 Assurance of sterility	3
7 Endotoxin test	3
8 Tolerance of dimensions	3
8.1 Appearance	3
8.2 Tolerance of diameter of wire	3
8.3 Tolerance of length of needle	3
9 Configuration	3
9.1 Appearance	3
9.2 Amount of lubricant	3
10 Needle tip	4
11 Performance	4
12 Packaging	4
12.1 Primary packaging	4
12.2 Secondary packaging	4
13 Labelling	4
13.1 Primary packaging	4
13.2 Secondary packaging	4
Annex 1 (normative) Materials of gold acupuncture needle	6
Annex 2 (normative) Materials of silver acupuncture needle	8

Acupuncture needle for single use

1 Scope This Japanese Industrial Standard specifies requirements for acupuncture needles for single use (hereafter referred to as “acupuncture needles”) used for acupuncture treatment, which are disposed after single use. However, the acupuncture needle has two types: a sterile needle, ready to use, with indication that it has been sterilized in the manufacturing process, and an unsterilized needle.

2 Normative references The following standards contain provisions which, through reference in the text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

JIS C 2502 *Materials for permanent magnet*

JIS G 3521 *Hard drawn steel wires*

JIS G 4308 *Stainless steel wire rods*

JIS G 4309 *Stainless steel wires*

JIS G 4314 *Stainless steel wires for springs*

JIS H 3270 *Copper beryllium alloy, Phosphor bronze and nickel silver rods, bars and wires*

JIS H 8620 *Electroplated coatings of gold and gold alloy for engineering purposes*

JIS H 8622 *Electroplated coatings of gold and gold alloy for decorative purposes*

JIS T 6101 *Nickel-chromium alloy wires for dental use*

JIS T 6104 *Cobalt-chromium alloy wires for dental use*

3 Terms and definitions For the purposes of this Standard, the following definitions apply.

- a) **nominal diameter of wire** dimension of diameter of wire of the needle body marked on the encapsulation or the container of acupuncture needle
- b) **nominal length** dimension of length of the needle body marked on the encapsulation or the container of acupuncture needle
- c) **needle body** part of acupuncture needle to be inserted into the human body
- d) **water** “purified water” specified in Japanese Pharmacopoeia, Part II, Official Monographs, or water with the equivalent or higher property
- e) **water for endotoxin test** “water for injection” specified in Japanese Pharmacopoeia, Part II, Official Monographs or water prepared by the other method not responsive to the detection limit of Lysate (LAL) reagent used for endotoxin test
- f) **sterilized needle** acupuncture needle with indication that it has been sterilized in the manufacturing process, which is ready to use
- g) **unsterilized needle** acupuncture needle which is not sterilized in the manufacturing process and not allowed to indicate as sterilized