INTERNATIONAL STANDARD

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Sterile acupuncture needles for single use

Aiguilles d'acupuncture stériles à usage unique

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Contents

Page

Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 249, *Traditional Chinese medicine.*

Introduction

This International Standard applies to sterile acupuncture needles for single use (specialized for filiform needles) used by professional acupuncturists for acupuncture treatment. Sterile acupuncture needles for single use are sterilized by the manufacturer, and the healthcare professional can open the sealed package and use the needle immediately.

In order to encourage innovation, this International Standard does not enforce the combination of the needle diameter and length. However, considering the clinical usage requirements, the standard provides the specifications for the needle diameter and length.

The sharpness and puncture performance of the needle tip are of very important clinical significance. Annex A states the guidelines and the evaluation methods for the intensity and the sharpness of the needle tip, while Annex B provides two qualitative and quantitative evaluation methods to determine the puncture performance of the needle tip.

The qualitative methods to evaluate the puncture performance of needle tip are described in Annex B. The methods are simple, direct and practical. It makes them especially suitable for routine inspection and for cross-comparison of the acupuncture needles' clinical applications. They also play a very important role in the enhancement of the quality of the needle tip. The methods to evaluate the puncture performance of the needle tip can be used to further evaluate the puncture and puncture performance of the acupuncture needle. Currently, the more appropriate method is to use the needle tip to pierce through polyurethane material; however, this method has not yet been implemented internationally.

Considering the consistency of standards in the future, this standard provides the methods to evaluate the puncture performance of the needle tip and ranks 5.3.5.2 as recommended. The standard does not provide the sharpness index of the piercing through polyurethane material by the needle tip. This index will be added to the standard when it becomes appropriate. To improve product quality, all inspection reports should include the inspection information as well as the results of the performance evaluation.

Since every manufacturer's design, production, and sterilization methods are different, no regulations exist for the materials of the acupuncture needle handle. Still, the needle body and the needle handle of acupuncture needle should have good biocompatibility.

In order to ensure product safety and efficacy, the manufacturer should perform risk analysis and enforce risk management in addition to adhering to the requirements of local rules and regulations, the relevant background data of the medical devices and clinical practice throughout the entire duration of the product's life cycle. ISO 14971 has provided manufacturers a framework for the effective management of hazards associated with the use of medical devices.

In some countries, the requirements proposed here are subject to legal sanctions. Such rules and regulations should take precedence over the standards set forth in this document.

Sterile acupuncture needles for single use

1 Scope

This International Standard specifies the requirements for the sterile acupuncture needles for single use (specialized for filiform needles).

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 6507-1:2005, *Metallic materials — Vickers hardness test — Part 1: Test method*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
body of the needle
part of the acupuncture needle that is inserted into the human body

Note 1 to entry: See Figure 1.

3.2
handle of the needle
part of the acupuncture needle that is not inserted into the human body

Note 1 to entry: See Figure 1.

3.3
tip of the needle
sharp apex at the end of the acupuncture needle body that is inserted into the human body

Note 1 to entry: See Figure 1.

3.4
root of the needle
part of the acupuncture needle that connects the needle body to the needle handle

Note 1 to entry: See Figure 1.

3.5
tail of the needle
end part of the needle handle at the opposite side of the tip of the needle

Note 1 to entry: See Figure 1.

3.6
sterile acupuncture needle
acupuncture needle that has been sterilized

3.7
guide tube
assistant tool in the shape of a slender, long tube into which the needle is placed and used for easy insertion

3.8
hardness of the needle body
measure of resistance of the acupuncture needle body to permanent deformation

3.9
primary package
sealed or closed packaging system that forms a microbial barrier, directly enclosing the acupuncture needle

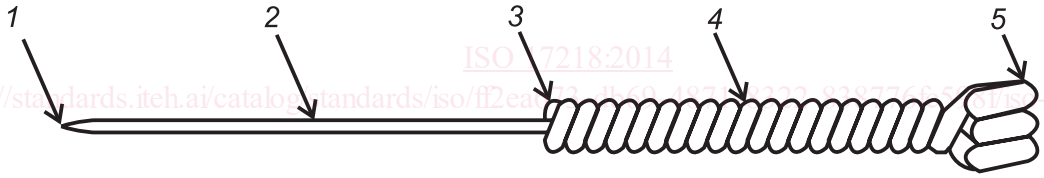
Note 1 to entry: The primary package is usually the smallest unit package of use and the package that is in direct contact with one or more acupuncture needles.

3.10
secondary package
package containing one or more primary packages for distribution and storage

4 Configuration

4.1 Acupuncture needle configuration

The configuration of the acupuncture needle and the name of each of its parts are shown in Figure 1.



Key
1 tip of the needle
2 body of the needle
3 root of the needle
4 handle of the needle
5 tail of the needle

Figure 1 — Example of typical structure of acupuncture needle

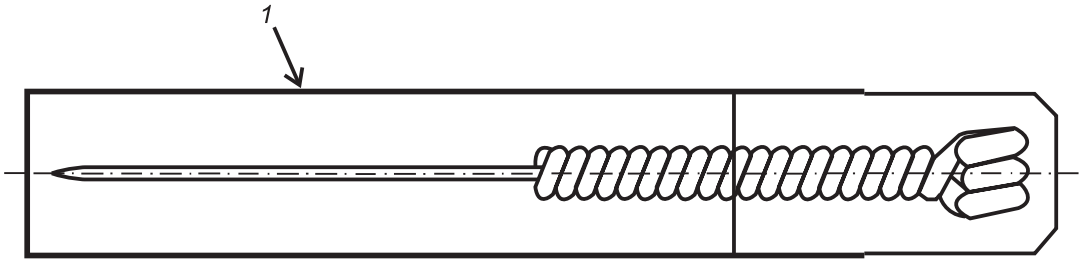
4.2 Acupuncture needle types

The acupuncture needle includes two types:

— acupuncture needle with a guide tube; and

— acupuncture needle without a guide tube.

The acupuncture needle with guide tube is shown in Figure 2. However, no uniform requirement is provided for the fixing method of the needle tube.

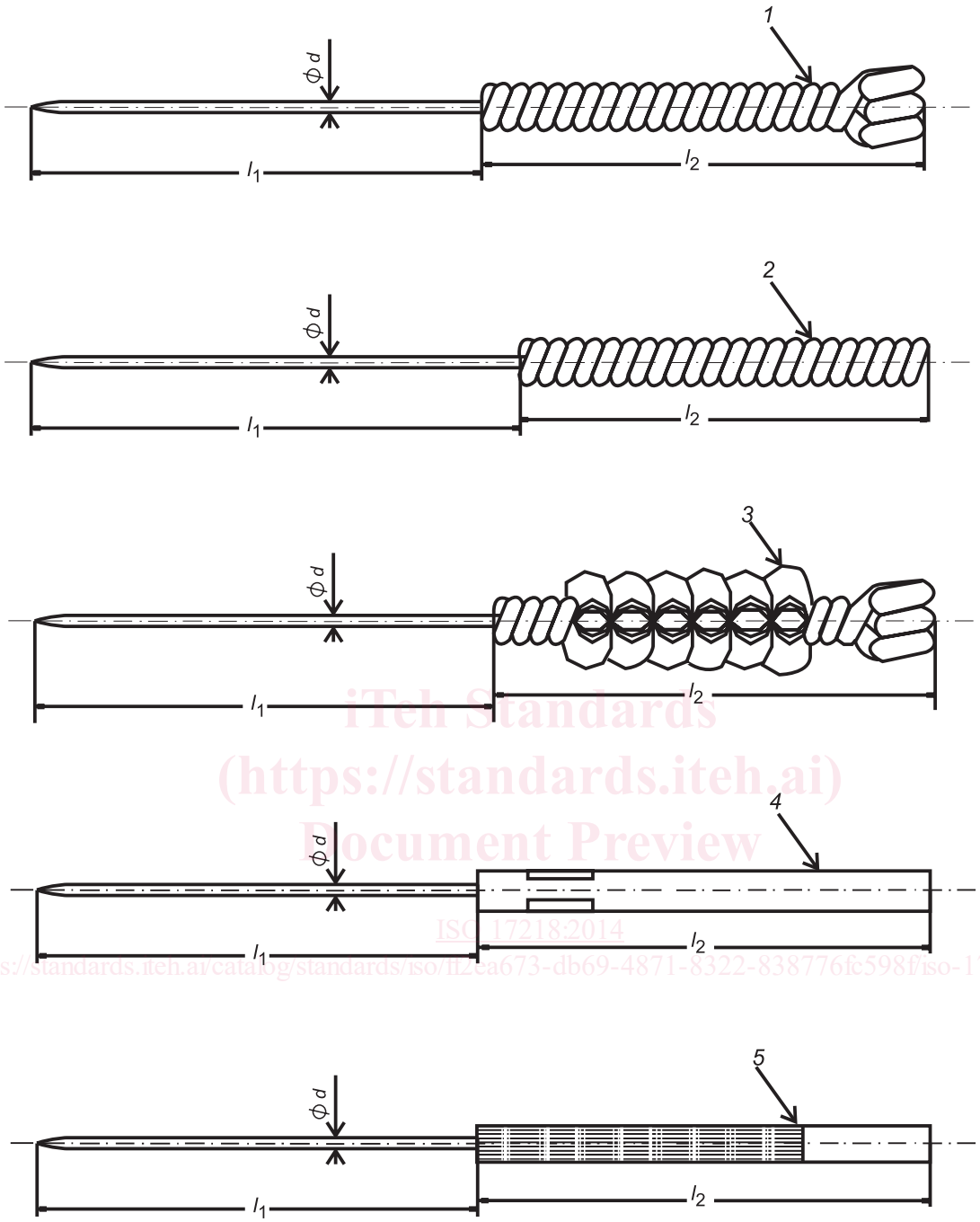


Key
1 guide tube

Figure 2 — The acupuncture needle with a guide tube

4.3 Types of needle handles

The types of needle handles include the ring handle, the plain handle, the flower handle, the metal tube handle, and the plastic handle, etc. The types of needle handles are not limited to those shown in the Figure 3.



Key

1 ring handle
2 plain handle
3 flower handle
4 metal tube handle
5 plastic handle

l_1 length of the needle body
l_2 length of the needle handle
$\varnothing d$ diameter of the needle body

Figure 3 — Example of types of handles of acupuncture needles

5 Requirements

5.1 Materials

The biocompatibility of the body of the needle shall be assessed and documented according to the guidance and principles given in ISO 10993-1.

Compliance is demonstrated by:

a) analogy with published data; or

b) the selection of materials already shown to be biocompatible by proven clinical use in a similar application; or

c) experience with similar devices already on the market together with evidence of traceability to the materials used in the acupuncture needle; or

d) compliance with published procedures for biological evaluation of:

   1) Cytotoxicity;

   2) Sensitization;

   3) Intracutaneous reactivity;

   4) Ethylene oxide sterilization residuals (if using EO. to sterilize).

If the material of the body of the needle is changed and/or if there is a new coating on the surface of the needle body, and if there is risk indicating that these may cause side-effects to the human body, then testing should be in accordance with ISO 10993 series.

NOTE There is no uniform regulation regarding materials of the needle handle and body. Currently, the popularly used material of the needle body is made of X5CrNil8–9, X7CrNil8–9 Austenite Stainless Steel, etc. which are given in ISO 15510:2010.

5.2 Dimensions

5.2.1 Size designation

The size of the acupuncture needle shall be designated by the following:

a) the nominal diameter of the body of acupuncture needle, expressed in millimetres; and

b) the nominal length of the body of acupuncture needle, expressed in millimetres.

The size of acupuncture needle shall be referred to as “the designated metric size” and specified as the diameter of the needle body × the length of the needle body.

EXAMPLE Ø 0,30 × 40 mm

5.2.2 Tolerance of dimensions

5.2.2.1 Diameter of the needle body

When measured by a micrometer or similar equipment, the nominal diameter of the body of acupuncture needle shall comply with Table 1.