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Traditional Chinese Medicine — Intradermal acupuncture needles

La médecine traditionnelle chinoise — Aiguilles d'acupuncture intradermiques

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Foreword

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

Introduction

As one of several different needling approaches, intradermal acupuncture needles are recognized as an effective treatment for various disorders. Intradermal acupuncture needles are easy to use, and especially effective when relatively long-lasting stimulation to a needling site is needed. Therefore, safety, sanitation consideration of intradermal acupuncture needles should be more carefully reviewed as well as their compatibility to human body.

As a biomaterial, acupuncture needles can be corrosive and have potential to lose some of their mechanic characteristics. Furthermore, leachable substances can affect human tissue in any unintended, yet potentially harmful way. To address this problem, biomaterials should have no toxicity or produce any adverse effects and should have appropriate mechanical characteristics such as tensile strength, elasticity, durability of abrasion and fatigue strength. In addition, the material should have a strong corrosion-resistantability.

This standard establishes an international standard for intradermal acupuncture needles. The characteristics of intradermal acupuncture needles include size, material, quality, tests, packing, and identification through regulating marking methods. The standardization of the characteristics of intradermal acupuncture needles has potential to enhance the efficacy and improve the quality and safety of acupuncture treatments using intradermal acupuncture needles especially in regards to the biocompatibility for human body.

Traditional Chinese Medicine — Intradermal acupuncture needles

1 Scope

This International standard specifies the requirements of sterile intradermal acupuncture needle for single use as a medical device, including the following factors:

a) size;

b) material;

c) quality;

d) testing methods;

e) packing; and

f) Identification.

2 Normative references

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

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

ISO 10993-7, Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals

ISO 17218, *Sterile acupuncture needles for single use*

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
intradermal acupuncture needles
a small needling instrument for embedding in the skin.

There are two types of intradermal acupuncture needles. One is termed an intradermal thumbtack type needle and the other is intradermal granule type needle.

[SOURCE: WHO International Standard terminologies on traditional medicine in the Western Pacific region, 5.1.29, modified – 2nd sentence has been added.]

3.2
intradermal granule type needle
an intradermal needle inserted obliquely or horizontally into subcutaneous tissue often across various sites on the human body

3.3
intradermal thumbtack type needle
an intradermal needle resembling a thumbtack

Inserted perpendicularly into subcutaneous tissue, often into the auricular region

[SOURCE: WHO International Standard terminologies on traditional medicine in the Western Pacific region, 5.1.28, modified – 2nd sentence has been added.]

3.4
body of the needle
part of the intradermal acupuncture needle that is inserted into the human body

[SOURCE: ISO 17218:2014, 3.1]

3.5
handle of the needle
part of the intradermal acupuncture needle that is not inserted into the human body and is often used to manipulate the needle during insertion

[SOURCE: ISO 17218:2014, 3.2]

3.6
tip of the needle
sharp apex at the end of the acupuncture needle body that is inserted into the human body

[SOURCE: ISO 17218:2014, 3.3]

3.7
primary package
sealed or closed packaging system that forms a microbial barrier, directly enclosing the acupuncture needle

[SOURCE: ISO 17218:2014, 3.9]

3.8
secondary package
package containing one or more primary packages for transportation and storage

[SOURCE: ISO 17218:2014, 3.10]

4 Structure and dimension of intradermal acupuncture needles

4.1 Size designation

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

a) the nominal diameter of the body of the needle (or when no body of the needle, the maximum diameter of the tip of the needle), expressed in millimetres; and

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

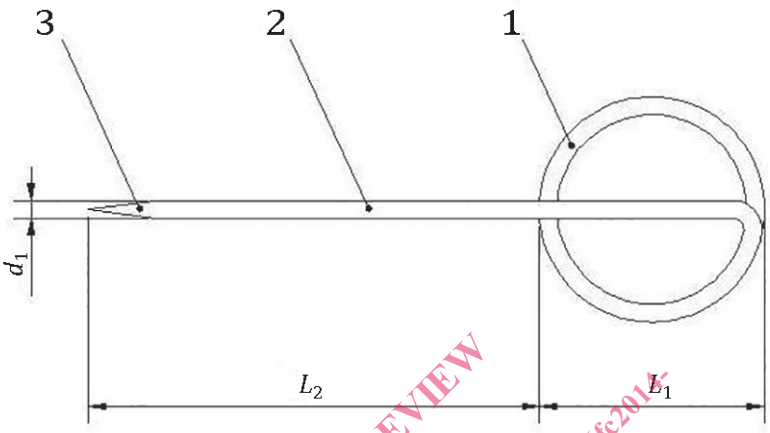
The size shall be referred to as “the designated metric size” and specified as a) × b)

EXAMPLE Ø 0,16 × 10 mm

4.2 Structure and dimension of intradermal granule type needle

4.2.1 Structure of intradermal granule type needle

The intradermal granule type needle shall have the structure as shown in Figure 1 and be composed of the body of the needle, the handle of the needle, and the tape (in some cases). The type of needle handles are not limited to those shown in Figure 1.



Key

1 Handle of the needle
2 Body of the needle
3 Tip of the needle
d_1 Diameter of body of the needle
L_1 Length of handle of the needle
L_2 Length of body of the needle

Figure 1 — Example of typical structure of intradermal granule type needle

4.2.2 Dimension of intradermal granule type needle

The nominal diameter of body of the needle and the length of body and handle of the needle shall be measured using a gauge specified in Table 1 (see Figure 1).

Table 1 — - Nominal dimension of intradermal granule type needle

Dimensions in millimetres

Part		Dimensions	Tolerance
The body of the needle	**Diameter** d_1	d < 0,40	±10 %
	Length L_2	L_2 < 5	±0,5
		5 ≤ L_2 < 10	±0,8
		10 ≤ L_2 ≤ 30	±1,0
The handle of the needle	**Length** L_1	1,6 ≤ L_1	