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Traditional Chinese medicine — Sterile intradermal acupuncture needles for single use

Médecine traditionnelle chinoise — Aiguilles d'acupuncture intradermiques stériles à usage unique

Reference number
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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 and sanitation considerations 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 mechanical 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 International 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 regard to the biocompatibility for human body.

Traditional Chinese medicine — Sterile intradermal acupuncture needles for single use

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;

f) identification.

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

ISO 17218:2014, *Sterile acupuncture needles for single use*

3 Terms and definitions

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

3.1
intradermal acupuncture needles
small needling instrument for embedding in the skin

Note 1 to entry: 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 — Note 1 to entry has been added.]

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

3.3
intradermal thumbtack type needle
intradermal acupuncture needle resembling a thumbtack

[SOURCE: WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region, 5.1.28]

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, modified]

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, modified]

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, modified]

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;

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

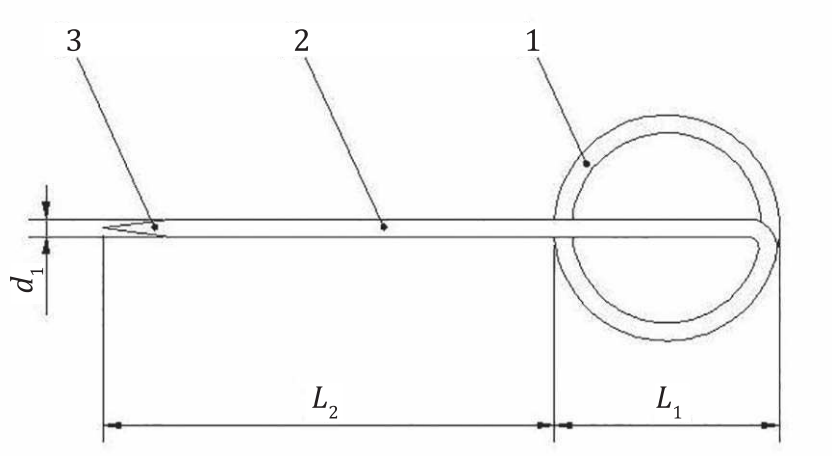
The size shall be referred to as “the designated metric size” and specified as a) × b).

EXAMPLE Ø 0,16 mm × 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	d_1	diameter of body of the needle
2	body of the needle	L_1	length of handle of the needle
3	tip 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).

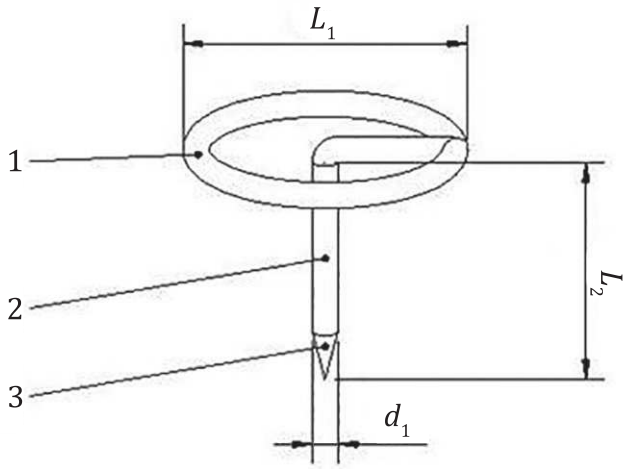
Table 1 — Nominal dimension of intradermal granule type needle

Part		Nominal dimensions mm	Tolerance
The body of the needle	Nominal diameter d_1	$d < 0{,}40$	±10 %
	Nominal length L_2	$L_2 < 5$	±0,5
		$5 \leq L_2 < 10$	±0,8
		$10 \leq L_2 \leq 30$	±1,0
The handle of the needle	Nominal length L_1	$1{,}6 \leq L_1$	

4.3 Structure and dimension of intradermal thumbtack type needle

4.3.1 Structure of intradermal thumbtack type needle

The intradermal thumbtack type needle shall have the structure as shown in Figure 2 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 2.



Key

1	handle of the needle	d_1	diameter of body of the needle
2	body of the needle	L_1	length of handle of the needle
3	tip of the needle	L_2	length of body of the needle

Figure 2 — Example of typical structure of intradermal thumbtack type needle

4.3.2 Dimension of intradermal thumbtack type needle

The nominal diameter and the length of the body of the needle, and the nominal length and the diameter of the handle of the needle shall be measured using a gauge specified in Table 2 (see Figure 2).

Table 2 — Nominal dimension of intradermal thumbtack type needle

Part		Nominal dimensions mm	Tolerance
The body of the needle	Nominal diameter d_1	$d_1 < 0{,}40$	±10 %
	Nominal length L_2	$L_2 < 3$	±0,5
		$3 \le L_2 < 5$	±0,8
		$5 \le L_2 \le 30$	±1,0
The handle of the needle	Nominal length L_1	$2 \le L_1$	

5 Materials

5.1 General

The biocompatibility of the body of the needle, the tape and the coating 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,

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

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 medical devices.

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

5.2 Body of intradermal acupuncture needle

There is no uniform regulation regarding materials of the needle handle and body. Currently, the most popular material for the needle body consists of X5CrNi18–9, X7CrNi18–9 Austenite Stainless Steel, etc., which are listed in ISO 15510.

6 Performance requirements

6.1 Appearance and cleanliness

When observed under a microscope of low magnifications (×10), the intradermal acupuncture needle shall not have roughness, grooves, rust, twist and/or bending. When observed under a microscope of medium or high magnifications (×20 or higher), the tip of the needle shall not have scars, foreign matters, broken or stumpy parts, bending, peeling surface coat and residual substances such as various solvents as used, fine metal particles which may be created in the process of cutting and grinding.

6.2 Drawing strength

The body of the needle shall be solidly joined to the handle of the needle.

When the minimum static force given in Table 3 is applied in the direction of the centre axis of the body of the needle depending on the length of the body of the needle, it shall not be drawn out of the handle of the needle.

Table 3 — Force to test drawing strength

Nomnial length of needle body, L_2 mm	**Force** N
$L_2 < 2$	1,5
$2 \leq L_2 < 5$	3
$5 \leq L_2 \leq 30$	5

6.3 Hardness of the needle body

Apply ISO 17218:2014, 5.3.3.

6.4 Intensity and puncture performance of the needle tip

Apply ISO 17218:2014, 5.3.5.

6.5 Sterility

The sterile intradermal acupuncture needle shall be sterilized through a validated sterilization process in order to ensure that the products are sterile.

In case of using ethylene oxide gas, testing for the residues of ethylene oxide shall comply with ISO 10993-7.

Appropriate sterilization methods can be found in the Bibliography. Requirements for validation and routine control of a sterilization process for medical devices can be found in ISO 11135, ISO 11137-1 and ISO 17665-1.

7 Packing and identification

7.1 Primary packaging

Sterile intradermal acupuncture needle shall be sealed in a primary package. There shall be no foreign matter within the primary package under visual inspection.

7.1.1 Packing method

Primary packaging of intradermal acupuncture needle shall be sealed so as to prevent opening due to pressure or light shock. Primary packaging shall, once opened, be unable to be sealed again. Primary packaging shall be sealed so as to prevent intradermal acupuncture needles from opening due to mishandling. Primary package should be ensured with adequate protection of the contents during normal handling, transit and storage. Primary packaging may be transparent on one or more sides to confirm the contents.

7.1.2 Identification

The symbols to be used with device labels, labelling and information to be supplied on the package shall comply with ISO 15223-1.

The primary package shall be marked with at least the following information:

a) the name or trademark or logo of the manufacturer and/or supplier;

b) a description of the contents, including the designated metric size in accordance with 5.2;

c) the lot number, prefixed by the word “LOT”, and/or date of manufacture;

d) expiry date;

e) method of sterilization, the word “STERILE” or symbol;

f) the words “For single use” or “Do not reuse” or symbol.

NOTE See ISO 17218:2014, 7.2

7.2 Secondary packaging

7.2.1 Packing method

Secondary packaging of intradermal acupuncture needle shall be made to prevent the contents from being damaged during transportation and storage. Secondary package shall be sufficiently robust to protect the contents during handling, transit and storage.

7.2.2 Identification

The symbols to be used with device labels, labelling and information to be supplied on the package shall comply with ISO 15223-1.

The secondary package shall be marked with at least the following information:

a) the name, address and trademark of the manufacturer and/or supplier;

b) a description of the contents, including the designated metric size in accordance with 5.2, the quantity and the type;

c) the lot number, prefixed by the word “LOT”, and/or date of manufacture;

d) expiry date;

e) method of sterilization, the word “STERILE” or symbol;

f) the words “For single use” or “Do not reuse” or symbol;

g) information for handling, storage and transportation;

h) a warning to check the integrity of each primary package before use, such as “Do not use if package is damaged” or symbol;

i) if used, the names or composition of additives (such as lubricant) used as a coating on the surface of needle body;

j) if appropriate, those who are allergic to the material of the needle body should use with caution or follow the instruction of an acupuncture physician.

NOTE See ISO 17218:2014, 7.3

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