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Traditional Chinese medicine — Dermal needles for single use —

Part 1: Tapping-type

Médecine traditionnelle chinoise — Aiguilles dermiques à usage unique —

Partie 1: Type marteau

Reference number
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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

A list of all parts in the ISO 23958 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

A dermal needle is a traditional Chinese medicine device for stimulating acupuncture points, meridians or skin by tapping or rolling. It is composed of a group of needles which stimulate a wide area of skin effectively. The stimulating strength of dermal needles depends on the density of the needles, the sharpness of the needle tips and the length of the needle body, among other things.

Dermal needles are widely used in East and Southeast Asia, the Americas, Europe and Oceania.

According to different operation modes, dermal needles for single use may be divided into two types: tapping-type and roller-type.

This document deals with tapping-type dermal needles for single use, while ISO 23958-2 deals with roller-type dermal needles.

Traditional Chinese medicine — Dermal needles for single use —

Part 1: Tapping-type

1 Scope

This document specifies the particular requirements for the basic safety and essential performance of tapping-type dermal needles for single use. It applies to tapping-type dermal needles that have the capacity to penetrate the skin.

It specifies structure and dimension, materials, and performance requirements for appearance and cleanliness, corrosion resistance, sterility, packaging and identification, transit and storage of tapping-type dermal needles.

It does not apply to roller-type dermal needles, reusable tapping-type dermal needles or devices incorporating a detachable tapping head.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 6507-1, *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 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
dermal needle
device composed of several short needles used for stimulating the meridian or skin

3.2
tapping-type dermal needle
dermal needle with a tapping head

Note 1 to entry: The tapping head is used to tap the skin.

Note 2 to entry: Plum-blossom needles and seven-star needles are typical tapping-type dermal needles.

3.3
roller-type dermal needle
dermal needle composed of a handle and a roller, which has evenly spaced micro needles

3.4
needle body
part of the needle from the tip to the tapping head

Note 1 to entry: See Figure 1.

3.5
needle tip
sharp apex at the end of the dermal needle body intended to penetrate the skin

[SOURCE: ISO 17218: 2014, 3.3, modified]

3.6
handle
part that connects to the tapping head and can be held and used for tapping by the operator

Note 1 to entry: See Figure 1.

3.7
tapping head
multi-cluster needle installed at the head of the tapping-type dermal needle for skin tapping

Note 1 to entry: The tapping head has one or two sides where needles are placed. These two types are referred to as single-headed and double-headed tapping-type dermal needles.

3.8
outer circle
circle connecting the outermost needles installed on the tapping head

3.9
extensive stimulation head
side of the tapping head where needles are evenly spaced along concentric circles

Note 1 to entry: See Figure 1.

3.10
intensive stimulation head
side of the tapping head with a cluster of short needles

Note 1 to entry: This type of needle cluster is located at the opposite side of the tapping head to the extensive stimulation head.

Note 2 to entry: See Figure 1.

3.11
primary package
sealed or closed packaging system that forms a microbial barrier, directly enclosing the tapping-type dermal needle

[SOURCE: ISO 17218:2014, 3.9, modified — definition revised and Note 1 to entry removed.]

3.12
secondary package
package containing one or more primary packages for distribution and storage

[SOURCE: ISO 17218:2014, 3.10]

4 Structure and dimensions of tapping-type dermal needles

4.1 Size designation

The size of the needle body shall be designated by:

a) the nominal diameter of the needle body (or the maximum diameter of the needle tip), expressed in millimetres;

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

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

EXAMPLE ⌀ 0,16 mm × 1,0 mm.

4.2 Structure and dimensions of tapping-type dermal needle

4.2.1 Structure of tapping-type dermal needle

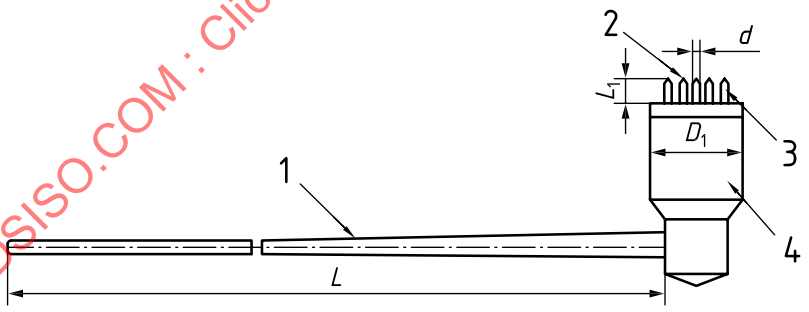
a) A tapping-type dermal needle consists of three parts: a needle body, a tapping head and a handle.

b) The tapping-type dermal needle can be divided into a single-headed needle and a double-headed needle based on whether it has an intensive stimulation head.

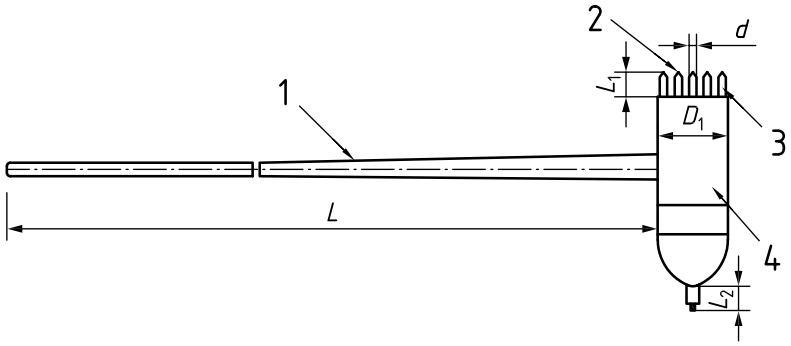
c) In single-headed tapping-type dermal needles, one side of the tapping head is formed with evenly arranged needles along concentric circles.

d) In double-headed tapping-type dermal needles, one side of the tapping head is formed with evenly spaced needles along concentric circles and the other side is formed with a certain number of short needles clustered.

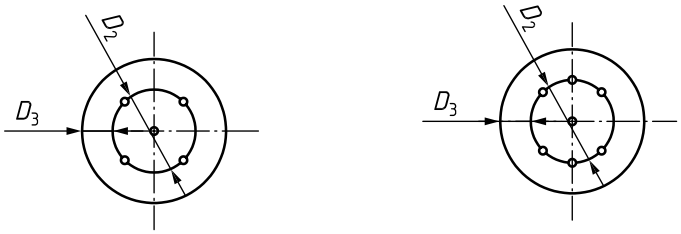
e) A typical structure of a tapping-type dermal needle is shown in Figure 1.



a) Single-headed tapping-type dermal needle



b) Double-headed tapping-type dermal needle



c) Typical structures of an extensive stimulation head (top view)

Key

1 handle
2 needle tip
3 needle body
4 tapping head
L length of the handle
L_1 length of the needles on the extensive stimulation head
L_2 length of the needles on the intensive stimulation head
d diameter of the needle body
D_1 diameter of the tapping head
D_2 diameter of the extensive stimulation head
D_3 distance of the outer circle from the margin of the extensive stimulation head

Figure 1 — Typical structure of a tapping-type dermal needle

4.2.2 Dimensions of tapping-type dermal needle

The nominal diameter of the needle body and the length of the needle body and handle should be measured using a gauge as specified in Table 1.

Table 1 — Nominal dimensions of tapping-type dermal needle

Part	Nominal dimensions mm	Tolerance
Length of the handle (L)	$120 \le L \le 250$	±5,0
Length of the needles on the extensive stimulation head (L_1)	$3{,}0 \le L_1 \le 5{,}0$	±0,50
Length of the needles on the intensive stimulation head (L_2)	$3{,}0 \le L_2 \le 4{,}0$	±0,50
Diameter of the needle body (d)	$0{,}35 \le d \le 0{,}80$	±0,02
Diameter of the tapping head (D_1)	$8 \le D_1 \le 15$	±0,50
Diameter of the extensive stimulation head (D_2)	$6 \le D_2 \le 13$	±0,50
Distance of the outer circle from the margin of extensive stimulation head (D_3)	$D_3 < 10$	±0,50

5 Materials

5.1 General

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

Conformity is demonstrated by one of the following:

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 a similar device already on the market together with evidence of traceability to the materials used in the tapping-type dermal needle;

d) conformity with published procedures for the biological evaluation of:

   1) cytotoxicity;

   2) sensitization;

   3) intracutaneous reactivity;

   4) ethylene oxide sterilization residuals (if using ethylene oxide to sterilize)

If the material of needle body 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 might cause adverse side effects to human tissue, then testing shall be conducted in accordance with the ISO 10993 series.

5.2 Needle body

There is no uniform regulation regarding materials for the needle body. Currently, the most commonly used material consists of X5CrNi18–9 or X7CrNi18–9 austenite stainless steel, which are listed in ISO 15510.

5.3 Handle and tapping head

The handle and tapping head shall be made of polycarbonate (PC), acrylonitrile-butadiene-styrene copolymer (ABS) or other materials with similar elasticity, strength and biological stability.

6 Performance requirements

6.1 Appearance and cleanliness

6.1.1 Needle body and needle tip

When inspected with normal or corrected-to-normal vision:

a) the surface of the needle body shall be clean, bright and free of foreign matter, with no scars or cracks;

b) the needle body shall not be of different lengths, bent, askew, twisted, loosened or retracted.

When examined under 10× magnification the needle tip shall be smoothly pointed, straight and free from burrs, hooks and flat-points.

6.1.2 Handle

a) When inspected with normal or corrected-to-normal vision, the handle shall have no scratches or cracks.

b) The handle shall be straight and flexible.

6.2 Firmness of needle tips

Place a piece of soft rubber on a hard surface, hold the handle so that the needle tip of the extensive stimulation head is facing downward and tap the needle 10 times downward with a distance of 10 cm to 15 cm from the soft rubber, with the result that the needle tip is neither loosened nor retracted.

6.3 Fastness of connection between tapping head and handle of the dermal needle

Fix the handle of the dermal needle to face upward and suspend a 2 kg weight from its tapping head. The connection between the tapping head and the handle should be stabilized and not loose.

6.4 Hardness of the needle body

The hardness test shall be conducted according to the requirements of ISO 6507-1 or other equivalent methods. The needle body shall have a Vickers hardness rating of no less than 350 $HV_{0,2}$.

6.5 Resistance to corrosion

When tested under 10× magnification, there shall be no viable rust on the needle body.

6.6 Sterility

The tapping-type dermal needle shall be sterile. 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.

If using ethylene oxide gas, testing for the residues of ethylene oxide shall conform with ISO 10993-7.

7 Packaging and identification

7.1 Primary packaging

7.1.1 General

The tapping-type dermal needle shall be sealed in a primary package. When inspected with normal or corrected-to-normal vision, there shall be no foreign matter in the primary package with the tapping-type dermal needle.

7.1.2 Packing method

The material of the package shall not have a detrimental effect on the contents. The material and design of this primary package shall be such as to ensure:

a) the maintenance of sterility of the contents under dry, clean and ventilated storage conditions;

b) the minimum risk of contamination of the contents during the removal from the package;

c) appropriate protection of the contents during normal handling, transit and storage;

d) that once opened, the package cannot be easily resealed and it shall be obvious that the package has been opened;

The primary package shall be transparent on one or more sides to confirm the content.

7.1.3 Identification

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

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

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

b) the name of the product;

c) type (e.g. number of the needles, single-headed dermal needle or double-headed dermal needle, dimensions of extensive stimulation head);

d) lot number, prefixed with “LOT”, and/or date of manufacture;

e) expiry date;

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

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

7.2 Secondary package

7.2.1 Packing method

a) One or more primary packages shall be packaged in a secondary package.

b) The secondary package shall be sufficiently robust to protect the contents during handling, transit and storage.

c) One or more secondary packages may be packed in a storage or transport packaging to prevent heavy pressure, direct sunlight, rain or snow damage.

7.2.2 Identification

The symbols to be used with medical device labels, labelling and information to be supplied on the package shall conform 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 supplier;

b) the name of the product;

c) description of the contents, including the length and diameter of the needle body in millimetres;

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

e) expiry date;

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

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

h) information for handling, storage and transportation;

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

j) a warning to not use on open wounds, ulcers, abscesses or tumours, tuberculosis and other lesions;

k) instructions to destroy after use or dispose of according to local medical waste regulations;

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

Those who are allergic to the material of the needle body shall use with caution or follow the instructions of a practitioner.

8 Transit and storage

8.1 Transit

The dermal needles shall be protected from heavy pressure, direct sunlight, rain and snow.

8.2 Storage

After packing, the dermal needle shall be stored at room temperature with a relative humidity of not more than 80 %. The storage place shall be clean and well-ventilated, with no corrosive gas.