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Traditional Chinese medicine — Dermal needles for single use —

Part 2: Roller-type

Médecine traditionnelle chinoise — Aiguilles dermiques à usage unique —

Partie 2: Type rouleau

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 applies to roller-type dermal needles for single use.

Traditional Chinese medicine — Dermal needles for single use —

Part 2: Roller-type

1 Scope

This document specifies the particular requirements for the basic safety and essential performance of roller-type dermal needles for single use. It applies to roller-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 roller-type dermal needles.

It does not apply to tapping-type dermal needles or reusable roller-type dermal needles.

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*

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.

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 roller

Note 1 to entry: See Figure 1.

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

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

3.6
handle
part that connects to the roller, which can be gripped by the operator

Note 1 to entry: See Figure 1.

3.7
roller head
rotating cylindrical part used to hold the needle bodies

Note 1 to entry: See Figure 1.

3.8
needle density
number of needles in the square connecting the outermost needles of the cylinder surface divided by the area

3.9
primary package
sealed or closed packaging system that forms a microbial barrier, directly enclosing the roller-type dermal needle

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

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

[SOURCE: ISO 17218:2014, 3.10]

4 Structure and dimension of roller-type dermal needle

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.

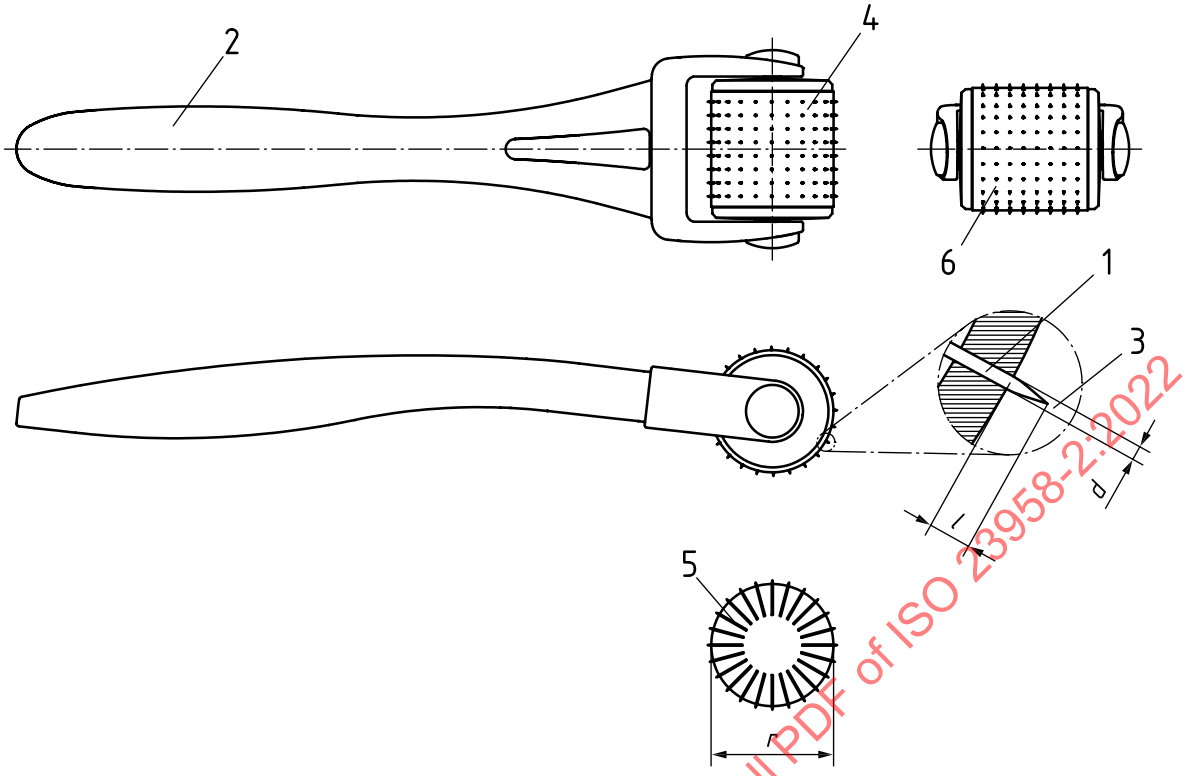
The size shall be referred to as “the designated metric size” and specified as a) × b).

EXAMPLE ⌀ 0,16 mm × 1,0 mm.

4.2 Structure and dimension of roller-type dermal needle

4.2.1 Structure of roller-type dermal needle

A typical configuration of the roller-type dermal needle and the name of each of its parts is shown in Figure 1. This configuration is informative only because there may be other acceptable configurations.



Key

1 needle body
2 handle
3 needle tip
4 roller head (top view)
5 roller head (side view)
6 roller head (front view)
l external exposure length of needle inserted into the roller
d diameter of the needle body
r diameter of the roller

Figure 1 — Example of typical structure of dermal needle, roller-type

4.2.2 Dimensions of roller-type dermal needle

4.2.2.1 Length of the needle body

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

Table 1 — Nominal length of needle body

Nominal length of needle body mm	Tolerance
$0,1 \leq l < 0,5$	±0,10
$0,5 \leq l < 1,0$	±0,15
$1,0 \leq l < 1,5$	±0,20
$1,5 \leq l < 2,0$	±0,25

4.2.2.2 Diameter of the needle body

The nominal diameter of the needle body should be measured using a gauge as specified in Table 2.

Table 2 — Nominal diameter of needle body

Nominal diameter of needle body mm	Tolerance
$0{,}15 \leq d < 0{,}20$	±0,008
$0{,}20 \leq d < 0{,}25$	±0,010
$0{,}25 \leq d < 0{,}30$	±0,015

4.2.2.3 Needle density on roller surface

Indicative spatial density of the needle in the roller should be not less than 6 pcs/cm^2 but not more than 20 pcs/cm^2.

4.2.2.4 Diameter of the roller

The diameter of the roller should be not less than 10 mm but not more than 50 mm.

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 dermal needle;

d) conformity with published procedures for 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 roller head

The handle and roller should be made of polycarbonate (PC) or other materials with similar mouldability, 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

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

6.1.3 Roller

When operating the device, the roller shall rotate smoothly.

6.2 Surface treatment of needle body

When examined at 10× magnification, the surface of the dermal needle shall remain free from various solvents and coating materials used in the manufacturing process, and fine metal particles that can be produced in cutting and grinding.

6.3 Puncture performance of needle tip

Apply ISO 17218:2014, 5.3.5.3.

6.4 Hardness of 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 roller-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.