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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

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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).

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

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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.

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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

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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.

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